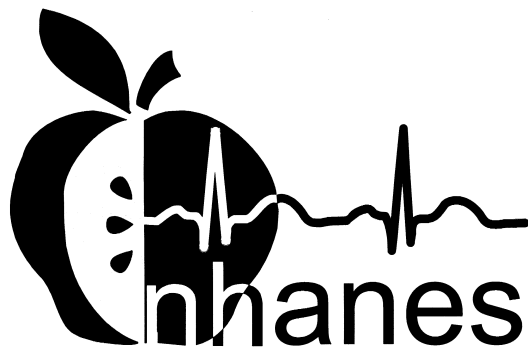

National Health
and Nutrition
Examination Survey

LABORATORY/
MEDICAL
TECHNOLOGISTS
PROCEDURES
MANUAL



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ACRONYMS AND ABBREVIATIONS

AOM	Assistant Office Manager
BIA	Bioelectrical Impedance Analysis
CBC	Complete Blood Counts
LED	Lower Extremity Disease
CAPI	Computer-Assisted Personal Interviewing
CIDI	Composite International Diagnostic Interview
DEXA	Dual Energy X-ray Absorptiometry
DHHS	Department of Health and Human Services
DISC	Diagnostic Interview Schedule for Children
DM	Data Manager
DU	Dwelling Unit
OM	Office Manager
FM	Field Manager
HIV	Human Immunodeficiency Virus
HHANES	Hispanic Health and Nutrition Examination Survey
ISIS	Integrated Survey Information System
MEC	Mobile Examination Center
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
NHANES I	National Health and Nutrition Examination Survey I
NHANES II	National Health and Nutrition Examination Survey II
NHANES III	National Health and Nutrition Examination Survey III
NHES I	National Health Examination Survey I
NHES II	National Health Examination Survey II
NHES III	National Health Examination Survey III
SP	Sample Person
STD	Sexually Transmitted Disease

1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

This chapter provides you with a general description of the health examination surveys conducted by the National Center for Health Statistics (NCHS) and the current National Health and Nutrition Examination Survey (NHANES). It also provides an overview of the tasks that staff will be expected to perform during the survey.

1.1 History of the National Health and Nutrition Examination Programs

This NHANES is the eighth in a series of national examination studies conducted in the United States since 1960.

The National Health Survey Act, passed in 1956, gave the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. In order to fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) the people themselves by direct interview; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, between 1960 and 1984, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data.

The first three national health examination surveys were conducted in the 1960s:

1. 1960-62—National Health Examination Survey I (NHES I);
2. 1963-65—National Health Examination Survey II (NHES II); and
3. 1966-70—National Health Examination Survey III (NHES III).

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11,

while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.

Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status had become increasingly important as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and monitor nutritional changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Four surveys of this type have been conducted since 1970:

1. 1971-75—National Health and Nutrition Examination Survey I (NHANES I);
2. 1976-80—National Health and Nutrition Examination Survey II (NHANES II);
3. 1982-84—Hispanic Health and Nutrition Examination Survey (HHANES); and
4. 1988-94—National Health and Nutrition Examination Survey (NHANES III).

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months to 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many of the ethnic groups within the United States. HHANES, conducted from 1982 to 1984, produced estimates

of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, minority groups often have different health status and characteristics, so black Americans and Mexican Americans were selected in large proportions for NHANES III. Each group comprised 30 percent of the sample. NHANES III was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. To obtain reliable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure levels of pesticide exposure, presence of certain trace elements in the blood, and amounts of carbon monoxide present in the blood. A home examination was incorporated for those persons who were unable or unwilling to come to the exam center but would agree to an abbreviated examination in their homes.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiologic Follow-up Survey, a multiphase survey conducting follow-up interviews with the NHANES I population in order to provide longitudinal data on the health of the U.S. population.

1.2 Overview of the Current NHANES

This NHANES will follow in the tradition of past NHANES surveys, continuing to be a keystone in providing critical information on the health and nutritional status of the U.S. population.

The major difference between the current NHANES and previous surveys is that NHANES is intended to become a **continuous annual survey**. NHANES will also be linked to the National Health Interview Survey following the Survey Integration Plan proposed by DHHS. NHANES will collect data from a representative sample of the U.S. population every year. This new design will allow annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the

questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing will result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period will be about the same as in previous NHANES, about 5,000 a year from 15 different locations. The data from the NHANES are used by government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

1.2.1 NHANES Pilot and Dress Rehearsal

During 1998 and 1999 two comprehensive tests were conducted in the Washington, DC area in preparation for the main study – a pretest and a dress rehearsal. In both tests, respondents were interviewed in their home and then asked to participate in a physical examination in the MEC. Data collected during the pretest and dress rehearsal are not included in the main survey database and no analyses are performed.

The pretest evaluated household interviewing procedures and MEC procedures, including the physical exams, the examination center interviews, the field office and exam center, and the Integrated Survey Information System (ISIS). The dress rehearsal was the final trial run for all survey procedures.

1.2.2 Data Collection for NHANES Main Survey

Data collection on the NHANES main survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. Each year approximately 7,000 individuals of all ages, in households across the United States, will be randomly selected to participate in the main survey. The study respondents include whites as well as an oversample of blacks and Mexican Americans. The study design also includes a representative sample of these groups by age, sex, and

income level. Adolescents and older persons will also be oversampled. The overall goals of data collection are to:

- Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factor;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposure;
- Analyze risk factors for selected diseases;
- Study the relationships between diet, nutrition, and health; and
- Explore emerging public health issues and new technologies.

Randomly selected persons are invited to take part in the survey by first being interviewed in their homes. Household interview data are collected via computer-assisted personal interviewing (CAPI) and include demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents are asked to participate in a physical examination. The examination is conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses all of the state-of-the-art equipment for the exam and is divided into rooms to assure the privacy of each study participant during the exams and interviews. The examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, a variety of physical measurements, and other health interviews conducted by highly trained medical personnel.

Participants who are 50 years and older or less than 1 year old and are unable to travel to the MEC will be offered a home examination administered by an examiner from the MEC. The household interviews and MEC exam combined will collect data in the following important health-related areas:

- Cardiovascular and respiratory disease;
- Vision;
- Hearing;
- Mental illness;
- Growth;
- Infectious diseases and immunization status in children;

- Obesity;
- Dietary intake and behavior;
- Nutritional status;
- Disability;
- Skin diseases;
- Environmental exposures;
- Physical fitness; and
- Other health-related topics.

1.3 Sample Selection

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the U.S. for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians must calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, sex, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the MEC examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for

the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent Form. An additional consent form is required for consent to future general research for both adults (ages 18+) and parents of children under 18 years. This consent form gives permission to store a small sample of blood for future specimen testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

1.4 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat**—Project staff from Westat are responsible for overseeing the field teams and field work.
- **Field Staff**—The field staff consists of three groups of employees: Stand office staff, the interviewers, and the MEC staff.
 - **Stand Office Staff**—For the main survey, an office will be opened in every stand. Each stand office will include a stand coordinator, an office manager (OM), a field manager (FM), two assistant office managers (AOMs), and a data manager (DM).

The stand coordinator is responsible for the overall management of operations at a stand.

The office manager is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. S/he will supervise one or more local office clerks hired to assist with office activities.

The field manager has primary responsibility for the supervision of the household interviewers (health representatives).

The assistant office managers are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. They report to the office manager.

The data manager assists in the setup and testing of computer systems and telecommunications hookups in the field. S/he also coordinates the

maintenance and repair of all field computer systems with the home office and external vendors and acts as the field "help desk" person.

- Interviewers—This staff is primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, interviewers visit the stand office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- MEC Staff—This staff of health professionals conducts the health exams. The main study includes two exam teams traveling from stand to stand.

There are 19 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technicians, 2 MEC interviewers, 2 dietary interviewers, 1 phlebotomist, 1 home examiner, and 2 TB readers. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff.

The following section describes the steps that are always completed prior to the opening of a stand and an overview of the tasks that interviewers are expected to perform. Highlighted items are basic concepts critical to the conduct of the study.

Steps completed prior to interviewing include:

- Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
- Twelve weeks before data collection begins, NHANES staff list the segments. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
- A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
- Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter will briefly describe the study and inform the household that an interviewer will be contacting them in the near future.

The tasks interviewers perform when they arrive at a stand include:

1. After the successful completion of training, interviewers will be given an assignment of sampled dwelling units to contact. Each assignment will consist of pre-labeled Household Folders, pre-labeled Neighbor Information Forms, and the appropriate Segment Folder.
2. Using addresses on the Household Folders and listing/mapping materials in the Segment Folder, interviewers will locate these dwelling units.
3. If a selected address is not a dwelling unit or is not occupied, interviewers will complete the "Vacant/Not a DU Section" on the Screener Non-Interview Form.
4. In an occupied residential dwelling unit, interviewers will contact an adult who lives in the selected household and administer the Screener on a laptop computer.

The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.

All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.

5. If all persons in a household are ineligible, no further work will be done with the case. When eligible household members are identified, interviewers will continue to conduct all the necessary tasks associated with the case.
6. In eligible households, the interviewer will obtain a signed interview consent form prior to completing the medical history and/or the family questionnaire.
7. Next, the appropriate medical history CAPI interview will be administered to eligible respondents. The questions asked will depend on the age of the SP.
8. In each household containing children aged 1-5, floor and window sill dust samples will be obtained. These samples will provide information on lead levels in the household environment.
9. A Family questionnaire will also be administered to one adult family member from each eligible family in the household.
10. Next, an appointment will be scheduled for each SP, coordinating the MEC schedule and the SP schedule. The interviewers also discuss the need to return to the field office 48 hours after the MEC exam to obtain TB results.
11. Interviewers will then obtain signed consent form(s) for each SP for the examination, call the field office to confirm the examination appointment(s), and give each SP an appointment slip.

12. If there is more than one eligible family in a household, this process is repeated with each additional family.
13. Interviewers will record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.
14. Interviewers will also support the survey by conducting field reminders prior to MEC appointments and will reschedule broken, cancelled, or no-show MEC appointments.
15. If an interviewer is unable to complete any of the questionnaires or procedures for any SP, an SP Card will be completed. This card documents the problems encountered in completing one or more tasks.
16. Interviewers will check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures will be implemented and appropriate forms will be completed.
17. When an interview has been completed, interviewers will edit their work, carefully reviewing all forms for completeness and legibility.
18. Interviewers will report in person to the FM at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers will discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.
19. To insure the accuracy and completeness of the survey, all interviewer work will be edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors will provide interviewers with feedback concerning the quality of the work.
20. At the end of each stand field period, interviewers will return all interviewing materials to the supervisor.

1.5 Exams and Interviews in the Mobile Examination Center (MEC)

Examinations and interviews are conducted in Mobile Examination Centers (MEC) composed of four specially equipped trailers. Each trailer is approximately 45 feet long and 10 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including

an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows what exams are performed in the various areas of the MEC.

Exhibit 1-1. Floor plan of the MEC

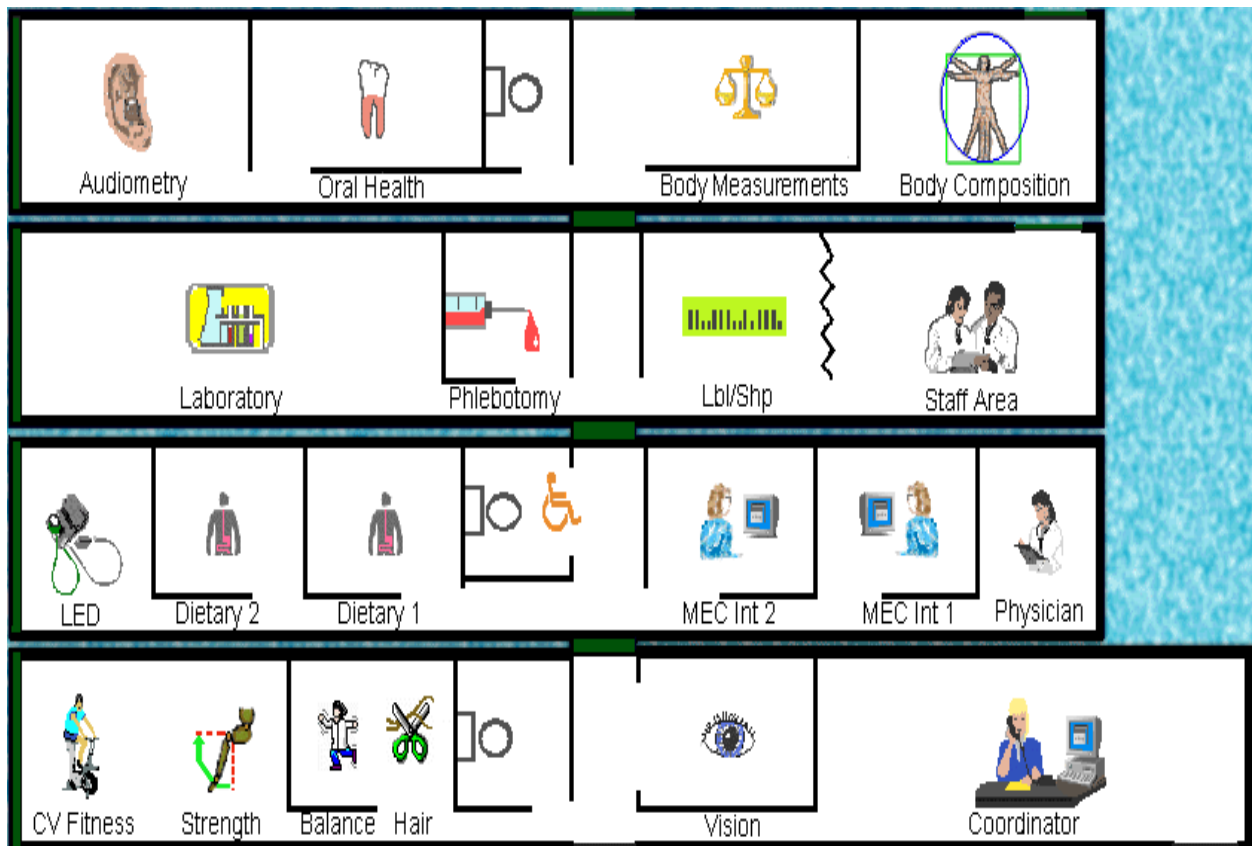


Exhibit 1-2. MEC exams and rooms

<u>Trailer</u>	<u>Room</u>	<u>Room Use</u>
Trailer 1	Reception area Vision room Balance/Hair Fitness	Welcoming and waiting area for SPs Vision tests and hair collection Balance test and hair collection Cardiovascular fitness and muscle strength
Trailer 2	Physician MEC Interview MEC Interview Dietary Interview Dietary Interview Lower Extremity Disease	Physical examination by a physician Health interview Health interview Dietary interview Dietary interview Testing for lower extremity pulses and sensitivity
Trailer 3	Venipuncture Laboratory Label/shipping area Staff lounge	Drawing of blood samples, TB testing Processing of urine and blood samples Lab area for labeling and shipping specimens Staff area that houses main computer system
Trailer 4	Total Body Composition Body measures Dental Audiometry/Tympanometry	Total body composition scans and bioimpedance Body measurements Dental exam by a dentist Hearing tests

Exam Sessions. The MEC operates 5 days a week including weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10 SPs per session. During a stand, work weeks will rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exam Team Responsibilities. There are 19 individuals on the exam team including two TB readers who work in the field office. In addition, a local assistant will be hired to assist the staff in managing examinee flow. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, manages the facility, and supports exam operations.

- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood test and pregnancy test, and serves as the safety officer for the MEC.
- One dentist conducts the dental exam and calls the results to a health technician who records the findings.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours.
- Four certified radiologic technicians take and record body measurements, balance tests, vision tests, hair collection, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA), and administer hearing tests. In addition, the technicians record findings for the dental examiner.
- Three medical technologists conduct clinical laboratory tests on blood and urine specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist administers the phlebotomy questionnaire and draws blood from SPs.
- One home examiner performs home exams for SPs aged 50 years and older or under 1 year old who are unable or unwilling to travel to the MEC. The home exam lasts approximately 1 hour and includes the following:
 - Height;
 - Weight;
 - Skinfold measures;
 - Blood pressure;
 - Vision;

- Blood samples;
- TB antigen placement.

The home examiner assists the MEC laboratory and phlebotomy staff when not performing home exams.

- Two tuberculosis test readers also work in the field office reading the TB tests applied at the MEC. All SPs except those selected for volatile toxicant testing will return to the field office for TB readings. Because the tests must be read 48-72 hours after application, the readers work a different schedule than the MEC staff.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

Examination Components. The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP's age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3:

- **Anthropometry**

The purpose of the anthropometry component is to provide: (1) nationally representative data on selected body measures; (2) estimates of the prevalence of overweight and obesity; (3) data to study the association between body measures and such health conditions and risk factors as cardiovascular disease, diabetes, hypertension, and activity and dietary patterns; and (4) data to monitor growth and development in children. A total of 11 body measurements are collected, but the number and type of measures varies with the age groups.

Exhibit 1-3. Examination components

Component	Ages
Anthropometry	All
Audiometry/Tympanometry	20-69
Balance	40-69 (half-sample with audiometry)
BIA	8-49
Cardiovascular Fitness	12-49
Dietary Interview	All
Hair Collection	1-5 years, females 16-49
Muscle Strength	50+
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years, 20-59 years (half-sample with audiometry)
Oral Health	2+
Physician Exam	All
TB	1+
Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
VOC	20-59

■ **Balance**

Balance disorders, disequilibrium, and dizziness from vestibular disorders constitute a major public health problem. Primary disorders may be hidden by their consequences, such as falls, while subtle dysfunction may underlie difficulties in learning, writing, reading, and in everyday activities. The main objectives of the balance test are to obtain prevalence data, examine the relationship between balance disorders and other factors, and to characterize normal and disordered balance and spatial orientation. The standard Romberg test will be used to measure postural sway.

■ **Bioelectrical Impedance Analysis (BIA)**

The purpose of the BIA exam will be to monitor secular trends in overweight prevalence, describe the prevalence of obesity, and examine the relationship between overweight and obesity and other examination measures. BIA measures the electrical

impedance of body tissues and will be used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

- **Cardiovascular Fitness and Muscular Strength**

Evaluation of physical fitness will provide nationally representative data on measures of physical fitness, estimate the prevalence of persons at risk due to sedentary habit and poor physical fitness, and provide data to study the relationship between leg strength, lower extremity function, and activity limitations. Cardiovascular fitness will be assessed with a submaximal treadmill test on examinees aged 12 through 49 years. Lower body strength will be assessed using a timed measured walk and isokinetic strength testing of the knee extensors and flexors in examinees aged 50 and older.

- **Dietary interview**

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data will be obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

- **Hair collection**

The purpose of the hair component is to obtain a suitable biological sample that can be used for the determination of total mercury levels in hair. Approximately 100 strands will be collected from SPs aged 1-5 years and women aged 16-49 years.

- **Hearing**

The goals of the hearing exam are to obtain normative data on the hearing status of the adult U.S. population, and to evaluate certain covariates that may be related to hearing loss, such as occupational exposure. The hearing component will test adults by performing pure tone audiometry and tympanometry. Because pure tone screening by itself may not be sensitive enough to detect middle ear disease, tympanometry will be conducted to provide an estimate of tympanic membrane compliance.

- **Laboratory**

The laboratory component includes the collection and processing of blood for subjects 1 year and older, urine for subjects 6 years and older, and testing for tuberculosis. On-site pregnancy testing will exclude pregnant women from other examination components such as DEXA, BIA, and cardiovascular fitness testing. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

- **Lower Extremity Disease (LED)**

The purpose of this component is to determine the prevalence of LED and its risk factors. Simple and reproducible measures of lower extremity arterial disease will be obtained. Peripheral neuropathy will be evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities will permit the estimation of prevalence of those at high risk for the late-stage complications of LED.

- **MEC Interview**

The MEC Interview consists of questionnaire sections designed to obtain information on health behaviors, specific conditions, medical history, and risk factors. The information collected in the interview is intended to assist researchers in analyzing the data collected in the other examination components. The interview is administered to all subjects, or a suitable proxy, using computer-assisted interviewing software.

- **Mental Health**

The mental health assessment will be used to estimate the prevalence of selected disorders in the U.S. and to describe the degree of comorbidity between mental health disorders and other medical conditions and biological risk factors. Assessments will be made during the MEC Interview using relevant portions of the Diagnostic Interview Schedule for Children (DISC) and the Composite International Diagnostic Interview (CIDI) for adults.

- **Oral Health**

This component monitors oral health status, risk factors for disease, and access to preventive and treatment services. The exam consists of a series of subcomponents which assess dentition and periodontal disease. In addition, a saliva collection will be obtained on SPs aged 40 and older.

- **Physicians Exam**

Blood pressure assessment and discussion of testing for sexually transmitted disease are the primary elements of the physician's exam. The purpose of assessment of blood pressure is to monitor prevalence and trends in major cardiovascular conditions and risk factors and to evaluate prevention and treatment programs targeting cardiovascular disease. The physician will discuss the purpose of STD testing and arrange for SPs to select a unique password with which to phone NCHS and obtain test results.

- **Total Body Composition**

This component is composed of the BIA and Dual Energy X-ray Absorptiometry (DEXA). The purpose of the DEXA scan is to gain insights into age, sex, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity. A total body scan using dual energy X-rays will be performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.

- **Vision**

The vision component will be used to measure the prevalence of visual acuity impairment in the U.S. population, measure the distribution of refractive error in the U.S. population, evaluate screening strategies for visual impairment and eye disease, and evaluate functional impairment related to vision. The examination consists of a near vision acuity test, a distance vision acuity test, and eyeglass prescription determination (when appropriate), and an automated refraction measurement.

- **Volatile Toxicants**

Information on levels of exposure to a selected group of volatile organic compounds will be collected on a subsample of the survey population to assist in determining whether regulatory mechanisms are needed to reduce the levels of hazardous air pollutants to which the general population is exposed. Participants will receive sampling badges to wear for 48 hours and will return to the MEC with the badge for a second blood draw in 48-72 hours, usually when they are scheduled to return for their TB test. An additional remuneration will be paid for this test.

Second Exams

Approximately 5 percent of SPs aged 12-69 who are examined in each stand will be asked to return for a second MEC exam. Data from the second exam will be used to obtain quality control data of survey procedures. The second exam components are similar, but modified versions of the original MEC exams. Not all components will be repeated. Exams will be conducted by the same examiner who conducted the first exam.

An additional 5 percent of SPs aged 2 and older will be invited to repeat only the dietary interview, either in the MEC or by telephone.

SPs who return for second exams will receive remuneration for their visit and transportation.

Sample Person Remuneration. All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and includes an extra incentive if the SP fasts prior to the exam. Additional, remuneration is offered for tuberculosis skin testing, the volatile toxicant component, the home exam, and the second MEC exam.

Report of Exam Findings. Examinees will receive the results of many of the tests and exams conducted in the MEC, though some results will be used only for research and will not be reported.

One report, a Preliminary Report of Findings, will be produced for the SP on the day of their examination and includes results that are immediately available and require no further evaluation or interpretation. Just prior to the examinee's departure from the MEC, the coordinator prints a report that includes height, weight, and body mass index, complete blood count, blood pressure, and results from the audiometry, cardiovascular fitness, lower extremity disease, vision, and dental exams. The MEC physician reviews the blood pressure and complete blood test results for abnormalities and discusses any problems with the SP (or their parent). The dentist also discusses the dental recommendations with the SP. Approximately 12-16 weeks after the exam, NCHS will mail the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed out.

Certain tests, such as those for sexually transmitted diseases (chlamydia, gonorrhea, and Herpes simplex 1 and 2) and human immunodeficiency virus (HIV) will be released only to the sample person using a specially devised procedure requiring a unique password.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician will offer to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad will be summoned or the SP will be advised to seek immediate medical treatment.

Dry Run Day. At the beginning of the examination period, one-half day will be devoted to calibrating instruments, and practicing MEC procedures. A dry run day is scheduled immediately prior to the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. Any problems must be corrected quickly before the "real" examinations begin. All procedures in the dry run will be completed as though the actual exam session was being conducted. The only difference is that the examinees will be actual volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

1.6 Confidentiality and Professional Ethics

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey so that we can have continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently you must be discreet in speech and action. Your personal appearance and behavior must be governed by these same considerations. Please be aware of your audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

You will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that you are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that you agree to abide by the contractor's Assurance of Confidentiality.

2. OVERVIEW AND LABORATORY TEAM RESPONSIBILITIES

2.1 Overview

The laboratory component of NHANES includes the collection, processing, storage, and shipping of blood, urine, and other biological and environmental specimens. Collectively, these specimens provide data about the health status of the U.S. population.

The blood collection procedure consists of administering a questionnaire to screen for conditions that excludes the participants from the blood draw and determines fasting status, a blood draw, administering TB antigens, and collecting specimens for special studies.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 6 and older to be able to: (1) perform a pregnancy test on selected females 8 to 17 and all females aged 18 to 59 years to exclude pregnant participants from other components that could put the participant at risk; (2) allocate urine into vessels for storage and eventual transport to approximately seven laboratories for analysis; (3) allocate urine into vessels for future studies; and (4) hold and process urine as a back up for blood tests where the amount of blood collected was insufficient.

The purpose of blood collection and processing is to collect sufficient blood from participants aged 1 and older to be able to: (1) perform a complete blood count; (2) allocate blood into vessels for storage and transport to approximately 15 laboratories across the United States for analysis; (3) allocate plasma and serum into vessels for future studies; and (4) process blood and clots for genetic testing.

The purpose of collecting and processing lead dust wipes, hair, and saliva samples is to be able to: (1) store and transport these samples to three laboratories across the country for analysis.

The Coulter® MAXM performs a complete blood count on blood specimens to provide a study of blood cells and coagulation.

2.2 The Laboratory Team

Each laboratory team includes four certified medical technologists who have experience in all aspects of laboratory practice and a certified phlebotomist who has experience in venipuncture and TB antigen administration.

The chief medical technologist is the most senior member of the team. The chief medical technologist is responsible for overseeing all the activities of the medical technologists and phlebotomist in the MEC, quality control, equipment calibration, and maintenance. On a routine basis, the chief medical technologist performs the same duties as the other medical technologists.

The home examiner is a medical technologist who serves as back up in phlebotomy and the laboratory. The home examiner conducts a modified MEC exam including venipuncture in the SPs home, processes home examination specimens in the MEC laboratory, and assists the field office and MEC staff as requested.

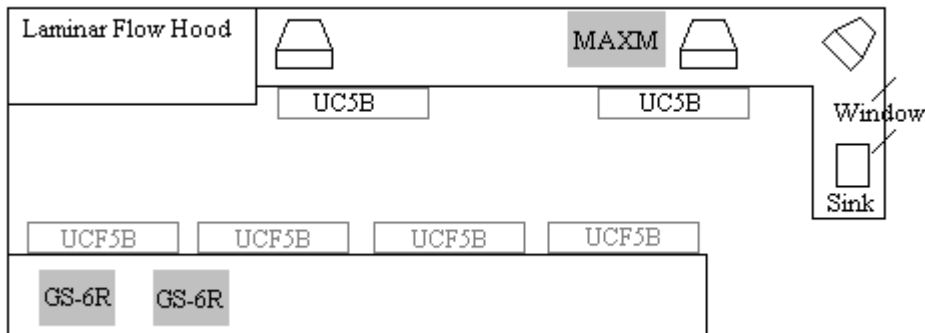
2.3 Tasks

The responsibilities of the phlebotomist include venipuncture, TB testing, conducting special studies, and assisting the medical technologists as needed.

The tasks of the medical technologists include recording MEC equipment QC activities and readings, blood specimen processing, hematology, pregnancy testing, urine processing, lead dust, hair and saliva processing, processing lead dust QC specimens, specimen shipping, labeling vessels, and assisting the phlebotomist as needed.

2.4 Organization of the Laboratory

The laboratory consists of three rooms—the phlebotomy room, the blood and urine processing/hematology room, and the label/shipping room. Blood is collected and TB skin tests are administered and read in the phlebotomy room. Participants are recruited for the special studies.



Laboratory Floor Plan

The laboratory room contains two workstations designated workstation 1 and workstation 2. Blood processing and storage, and HIV urine processing occur at workstation 1. Urine collection, urine processing and storage, pregnancy tests, complete blood counts, dental, lead dust, and hair specimen processing and routine quality control activities occur at workstation 2.

Printing labels, labeling blood-processing racks and shipping occur at workstation 3, which is located in the label/ship area in the other side of the laboratory trailer.

2.5 Tasks – Phlebotomy Room

- Set up supplies and check expiration dates of Vacutainer® tubes;
- For each SP, administer the Venipuncture Questionnaire, perform the venipuncture, administer the TB antigens, and recruit SPs for special studies;
- Enter results of blood collection and administration of the TB antigens;
- Label and transfer all blood specimens to the main laboratory;
- Disinfect all counters at the beginning and end of each day;
- Record QC readings;
- Maintain appearance of the venipuncture area, the equipment, and the daily inventory of supplies; and

- Assist in labeling and assembling blood-processing racks, centrifuging specimens, shipping specimens, set up, tear down and cleaning laboratory at the beginning and end of stand, completing the beginning and end of stand inventories of phlebotomy materials, and clerical activities as time allows.

2.6 Tasks – Workstation 1

- Stock blood processing and storage supplies;
- Receive blood specimens;
- Select correct pre-labeled rack and age appropriate template;
- Set red top blood tubes aside to clot;
- Pipette whole blood for vessel 1(lead/cadmium), vessel 2 (erythrocyte protoporphyrin), vessel 3 (RBC Folate), and vessel 5 (mercury) on all SPs from 3-mL or 5-mL EDTA lavender tube;
- Transfer 3-mL or 5-mL EDTA tube to workstation 2 technologist for hematology;
- Prepare ascorbic acid and make dilutions for RBC Folate;
- Pipette whole blood for vessel 4 (glycohemoglobin) and vessel 6 (CD4) from the 5-mL EDTA tube;
- Centrifuge the 5-mL EDTA tube in refrigerated centrifuge;
- Centrifuge 3-mL gray and 3-mL light blue tubes;
- Check label and store the ACD tubes at room temperature;
- Centrifuge red top tubes;
- Pool serum from all 15-mL red tubes and mix well;
- Aliquot plasma and serum into appropriate storage vessels;
- Pour clots into appropriate storage vessel;
- Enter blood processing results;
- Refrigerate or freeze designated tubes and vessels;
- Access HIV urine processing module and process urine;

- Check contents of blood and HIV urine storage boxes using box maps at the end of each session;
- Disinfect all counters and laminar flow hood at the beginning and end of each session;
- Maintain appearance of the blood processing area, the equipment, and the daily inventory of supplies;
- Assist phlebotomist with venipuncture; and
- Assist in labeling and assembling blood processing racks, shipping specimens, set up, tear down and cleaning laboratory at the beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

2.7 Tasks – Workstation 2

- Perform start of stand, start of session, end of session, weekly, and end of stand quality control checks on laboratory equipment and record results;
- Stock supplies for urine processing, hematology, and pregnancy test;
- Enter urine collection results;
- Run pregnancy test controls;
- Conduct pregnancy test and enter results;
- Perform start-up procedures and run quality control materials on Coulter® MAXM;
- Run SP specimens on the Coulter® MAXM;
- Label and aliquot urine into storage vessels;
- Enter urine processing results;
- Freeze urine vessels;
- Process lead dust, saliva, and hair specimens;
- Check contents of urine, saliva, lead dust, and hair storage boxes and bags using box maps at the end of each session;
- Disinfect all counters at the beginning and end of each session;
- Maintain appearance of the urine processing/hematology area, the equipment, and the daily inventory of supplies;
- Assist phlebotomist with venipuncture; and

- Assist in labeling and assembling blood processing racks, centrifuging specimens, shipping specimens, set up, tear down, and cleaning laboratory at the beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

2.8

Tasks – Workstation 3

- Print hair, pregnancy, urine, blood, and saliva labels and pre-label blood processing racks;
- Generate container IDs at the start of stand;
- Close open containers, create airbills, assign containers to shippers;
- Prepare shipping manifests and send electronic files;
- Prepare blood (whole blood, serum, and plasma), urine, hair, dental, special study samples, and lead dust specimens for shipping;
- Pack, weigh, label, and ship shippers;
- Open all new containers after shipping;
- Run FedEx tracking daily;
- Assist phlebotomist with venipuncture; and
- Assist in centrifuging specimens, set up, tear down, and cleaning laboratory at beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

3. BIOSAFETY

3.1 OSHA (Occupational Safety and Health Administration) Bloodborne Pathogens Regulations

The Occupational Safety and Health Administration has established the Bloodborne Pathogens Regulations. The Bloodborne Pathogens Regulation applies to all persons who may reasonably anticipate contact with blood or other potentially infectious materials in the course of their employment. The focus of this regulation is the creation of a written Exposure Control Plan that describes how the employer will protect employees from exposure. The exposure control plan contains the following components: exposure determination, procedures for evaluating the circumstances surrounding an exposure incident, schedule and methods for implementing sections of the standard covering the methods of compliance, hepatitis B vaccination and postexposure followup, communication of hazards to employees, and recordkeeping. The plan is updated at least annually and kept accessible.

3.2 Exposure Categories

The exposure determination is based on a review of job classifications within the work environment. Employees with occupational exposure are identified and hazards are communicated to these employees.

MEC staff are classified as Category 1 when it is determined they may be routinely exposed to bloodborne pathogens. This category includes the dentist, phlebotomist, and medical technologists. Staff are classified as Category 2 exposure when it is determined they are not usually exposed to blood, but may be exposed under certain circumstances. This category includes the physician and MEC manager.

3.3 Preventive Measures

The employer must make the hepatitis B vaccine and vaccine series available to all employees who have occupational exposure and followup to all employees who experience an exposure incident.

Hepatitis B vaccine is available at no cost to the employee. If previously vaccinated, the employee must provide evidence of antibody testing or completion of vaccine series. If the employee refuses the vaccine, they must complete a Declination Form. Notify the MEC manager immediately if an exposure incident occurs.

3.3.1 Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections

"Universal precautions," (UP) as defined by CDC, are a set of precautions intended to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care. Universal precautions consider blood and some body fluids from all participants potentially infectious for HIV, HBV, and other bloodborne pathogens.

Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infective materials. In addition, universal precautions recommend that all health care workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices.

Pregnant health care workers are not at greater risk of contracting HIV infection than are health care workers who are not pregnant. However, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with, and strictly adhere to, precautions to minimize the risk of HIV transmission.

3.4 Methods of Control

Engineering and work practice controls are the primary methods used to prevent occupational transmission of HBV and HIV. Personal protective clothing and equipment are also necessary when occupational exposure to bloodborne pathogens remains even after instituting these controls.

Engineering controls reduce employee exposure by removing or isolating the hazard or worker from exposure. One example is the provision and mandated use of puncture resistant disposal containers for contaminated sharp instruments. Work practice controls alter the manner in which a task is performed. Comply with the following work practice controls:

- Restrict eating, drinking, applying cosmetics or lip balm, and handling contact lenses to the staff area of the MEC.
- Mouth pipetting is prohibited.
- Storage of food and/or drink in refrigerators or other locations where blood and other potentially infectious materials reside is prohibited.
- Use the laminar flow safety cabinet for blood processing.
- Use hand-washing facilities in the laboratory and phlebotomy rooms.
- Use the eyewash station in case of a splash.
- Routinely check and decontaminate equipment and counters.

3.4.1 Engineering Control - Needle Precautions

All health care workers should take precautions to prevent injuries caused by needles and other sharp instruments or devices during procedures, when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures.

- When discarding contaminated sharps, place them in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- Never recap used needles, or otherwise manipulate them using both hands, or use any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed "scoop" technique or a mechanical device designed for holding the needle sheath.
- Never shear or break contaminated needles.
- Do not remove used needles from disposable syringes.

- Keep puncture-resistant sharps containers upright throughout use, replace routinely, close when moved, and do not overfill.
- Never manually open, empty, or clean contaminated sharps disposable containers.

3.4.2 Work Practice Controls - Personal Protective Equipment

Use personal protective equipment if occupational exposure remains after instituting engineering and work practice controls or if those controls are not feasible. All category 1 MEC staff should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure during contact with any SP's blood or body fluids that require universal precautions. These barrier precautions include gloves, gowns, and other protective apparel and masks.

Hand Washing

Wearing gloves does not replace the need for hand washing, because gloves may have small defects or may tear during use, and hands can become contaminated during removal of gloves. Hand washing is the vigorous, brief rubbing together of all surfaces of lathered hands, followed by rinsing under a stream of water. Hand washing with plain soaps or detergents (in bar, granule, leaflet, or liquid form) suspends microorganisms and rinses them off. In addition, hand washing with antimicrobial containing products kills or inhibits the growth of microorganisms. Hand washing is an important component of the personal hygiene of all MEC personnel. Perform hand washing whenever you are in doubt about the necessity for doing so.

- For most activities, vigorously but briefly (at least 10 seconds) rub together all surfaces of lathered hands and rinse under a stream of water. Times of 15 seconds or less are effective in removing most transient contaminants from the skin. If soil on the hands is visible, increase time for hand washing.
- Use plain soap for hand washing unless otherwise indicated.
- Wash hands when reporting to the MEC at the beginning of the session, at the completion of each session, immediately after removing gloves, and when leaving the laboratory or phlebotomy to go to other parts of the MEC.

- Wash hands and other skin surfaces immediately or when SP safety permits if contaminated with blood or body fluids requiring universal precautions.
- Wash hands before eating, before, between, and after SP contact, after blowing or wiping of nose, and after personal use of the toilet.

Gloves

Gloves play an important role in reducing the risk of transmission of microorganisms. Wear gloves for three important reasons. First, gloves provide a protective barrier to prevent gross contamination of the hands when touching blood, body fluids, secretions, excretions, mucous membranes, and nonintact skin. OSHA mandates the wearing of gloves in specified circumstances to reduce the risk of exposures to bloodborne pathogens. Specifically, OSHA requires wearing gloves when it is reasonably possible that an employee will have contact with blood, or other potentially infectious materials; when performing vascular access procedures; and when touching contaminated items or surfaces. Second, gloves reduce the likelihood that microorganisms present on the hands of personnel will transfer to SPs during invasive or other SP-care procedures that involve touching an SP's mucous membranes and nonintact skin. Third, gloves reduce the likelihood that hands of personnel contaminated with microorganisms from a SP or an inanimate object can transmit these microorganisms to another SP.

Failure to change gloves between SP contacts is an infection control hazard. Wear gloves when touching blood and body fluids requiring universal precautions, mucous membranes, or nonintact skin of all SPs, and for handling items or surfaces soiled with blood or body fluids to which universal precautions apply.

- Wear appropriate gloves when there is the possibility of contact with blood, other potentially infective materials, when performing vascular access procedures, and when handling or touching contaminated items or surfaces.
- It is mandatory to wear gloves when performing phlebotomy, processing blood specimens, processing urine, and performing hematology testing.
- Never wash or decontaminate disposable gloves for reuse.
- Change gloves before and after contact with each SP.

- Gloves should reduce the incidence of blood contamination of hands during phlebotomy, but they cannot prevent penetrating injuries caused by needles or other sharp instruments.
- Remove gloves before leaving the laboratory or phlebotomy room.

Gowns

Various types of gowns and protective apparel provide barrier protection and reduce opportunities for transmission of microorganisms in health care settings. Gowns prevent contamination of clothing and protect the skin of personnel from blood and body fluid exposures. OSHA mandates wearing gowns and protective apparel under specified circumstances to reduce the risk of exposures to bloodborne pathogens. Specifically, OSHA requires the use of such equipment only if it does not permit blood and other potentially infectious materials to pass through or reach employees' work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal use.

- Wear a disposable lab jacket when performing phlebotomy or working in the laboratory.
- Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- Place used protective equipment in appropriately designated areas or containers when being stored or discarded.
- Hang outside street clothing in a designated separate clean area.

Masks

In addition to the laminar flow biological safety cabinet, various types of masks, goggles, and face shields are available alone or in combination to provide barrier protection. Wear a mask that covers both the nose and the mouth, and goggles or a face shield during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions to provide protection of the mucous membranes of the eyes, nose, and mouth from contact transmission of pathogens. The OSHA bloodborne pathogens final rule mandates wearing masks, eye protection, and a face shield in specified circumstances to reduce the risk of exposure. Perform all blood processing tasks in the LSBSC. Use aerosolve containers when centrifuging blood tubes. Wear appropriate face and eye protection such as a mask with glasses with solid

side shields or a chin-length face shield when splashes, sprays, spatters, or droplets of blood or other potentially infectious materials pose a hazard to the eye, nose, or mouth.

3.5 Housekeeping

Under the OSHA standard, each place of employment must keep work areas clean and sanitary. The employer must develop and implement a cleaning schedule that includes appropriate methods of decontamination and the tasks or procedures to be performed. The employer also must ensure that employees follow these procedures:

- Routinely check equipment and decontaminate it before servicing and shipping.
- Clean and decontaminate all equipment and work surfaces contaminated with blood or other potentially infectious materials including keyboard covers.
- Decontaminate work surfaces with a 1% (1:100) bleach solution after completion of routine procedures, at the end of the work shift, and when surfaces have become contaminated since the last cleaning.
- Decontaminate work surfaces with a 10% (1:10) bleach solution or with a 10% Hype Wipe immediately when surfaces become overtly contaminated and after any spill of blood or other potentially infectious material.
- On a regular basis inspect and decontaminate reusable receptacles such as bins, pails, and cans that have likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.
- Always use mechanical means such as forceps or a brush and dust pan to pick up contaminated broken glass; never pick up broken glass with hands even if wearing gloves.
- If using liquid soap for hand washing, replace or clean the dispenser and fill with fresh product when empty. Do not add liquids to a partially full dispenser.
- When discarding glass blood tubes, place them in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- To clean a blood spill perform the following procedure:
 - Wear gloves;
 - Cover spill with disposable paper towels;

- Soak paper towels with 10% bleach solution;
- Let soak for at least 30 seconds;
- Dispose of blood/bleach soaked paper towels in biohazard container;
- Allow area to dry and then remove gloves;
- Wash hands; and
- If spill contains broken glass use dust pan and broom to collect glass pieces. Dispose of broken glass and contaminated paper towels in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom. Disinfect dust pan and broom with bleach solution.

3.6 Identification of Infectious Waste

Consider laboratory wastes, blood and blood products, and sharp items (especially needles) as potentially infectious. Handle and dispose of waste using with special precautions.

3.6.1 Waste Management

A precise definition of infectious waste that is based on the quantity and type of etiologic agents present is virtually impossible to develop. The most practical approach to infective waste management is to identify those wastes that represent a sufficient potential risk of causing infection during handling and disposal and for which some special precautions appear prudent. MEC wastes for which special precautions appear prudent include blood and blood products. Moreover, consider the risk of either injury or infection from certain sharp items (for example, needles) contaminated with blood when disposing of such items. Besides the above guidelines, local and state environmental regulations may also exist.

3.6.2 Infectious Waste Labels

The OSHA Bloodborne Pathogens standard requires that fluorescent orange or orange-red warning labels be attached to containers of regulated waste, to refrigerators and freezers containing blood and other potentially infectious materials, and to other containers used to store, transport, or ship blood or

other potentially infectious materials. These labels are not necessary when (1) using red bags or red containers; (2) labels designate the contents of containers of blood, blood components, or blood products; and (3) individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, or disposal. The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word BIOHAZARD, in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

3.6.3 Handling, Transport, and Storage of Infectious Waste

It is often necessary to transport or store infectious waste within the health care setting before terminal treatment. Do this safely by using proper and common sense procedures. Inform personnel involved in the handling and disposal of infectious waste of the potential health and safety hazards and train in the appropriate handling and disposal methods.

- Place solid waste from the laboratory in biohazard bags and transport to an area designated to hold these bags. A single bag is adequate if the bag is sturdy (not easily penetrated) and if the waste can be put in the bag without contaminating the outside of the bag; otherwise, double-bagging is indicated.
- To minimize the potential risk for accidental transmission of disease or injury, store infective waste waiting terminal processing in a pre-incineration storage area in the MEC accessible only to personnel involved in the disposal process.
- Place regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- Transport closed sharps containers and biohazard bags destined for incineration or steam sterilization to the designated pre-incineration storage.
- Discard all regulated waste according to Federal, state, and local regulations.

3.7 Recordkeeping

Employers must preserve and maintain an accurate record of occupational exposure for each employee. Medical records are kept confidential and maintained for at least the duration of employment plus 30 years.

Exposure Management

An “exposure” that may put a health care worker at risk for HIV infection and therefore requires consideration of postexposure prophylaxis is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object); contact of mucous membrane or nonintact skin (e.g., when exposed skin is chapped, abraded, or afflicted with dermatitis); contact with intact skin when the duration of contact is prolonged (i.e., several minutes or more); or involves an extensive area, with blood, tissue, or other body fluids.

In the event of an exposure follow the steps listed below:

- Notify training supervisor, Director of MEC Operations, and/or MEC physician immediately because postexposure prophylaxis is most likely to be effective if implemented as soon after exposure as possible.
- Treat exposure site by washing wounds and skin sites with soap and water and flushing mucous membranes with water.
- The circumstances and postexposure management is recorded in the health care worker’s confidential medical record. Relevant information includes date and time of exposure, details of the procedure being performed, details of the exposure, details about the exposure source, and details about counseling, postexposure management and follow-up. Document route of exposure and how the exposure occurred on a MEC Incident/Emergency Report form.
- The source-person and the exposed health care worker are evaluated to determine the need for HIV postexposure prophylaxis and followup for hepatitis B virus and hepatitis C virus is also conducted. Assessment of infection risk is conducted by evaluating exposure and testing exposure source.
 - Evaluation of exposure – The exposure is evaluated for potential to transmit HIV based on type of body substance involved and the route and severity of the exposure.
 - Evaluation and testing of an exposed source – The person whose blood or body fluids are the source of an occupational exposure is evaluated for HIV infection. If the HIV serostatus is unknown, the source person should be informed of the incident and, if consent is obtained, tested as soon as possible for serologic evidence of HIV infection.
 - Clinical evaluation and baseline testing of exposed health care workers – Exposed health care workers will be evaluated for susceptibility to bloodborne pathogen infections. Baseline testing for HIV and HBV is performed.
- HIV postexposure prophylaxis – When a health care worker has had an exposure to a source person with HIV or where information suggests that there is a likelihood that the

source person is HIV-infected, recommendations for chemoprophylaxis is explained to the health care worker.

- Followup of health care worker exposed to HIV – Health care workers with occupational exposure to HIV will receive follow-up counseling, postexposure testing, and medical evaluation. HIV-antibody testing is performed for at least 6 months post-exposure (e.g., at 6 weeks, 12 weeks, and 6 months).
- Evaluating physician provides written opinion to employer that includes whether vaccine for HBV is necessary, and documentation of administration and statement that employee was informed of results of evaluation and further treatment, if any.

Training Records

The employer must maintain training records for 3 years. This record must include training dates, content or a summary of training, names and qualifications of trainer(s), and names and job titles of trainees.

3.8 References

1. Occupational Exposure to Bloodborne Pathogens, U.S. Department of Labor, Occupational Safety and Health Administration. *OSHA 3127*, 1996 (Revised)
2. Title 29 Code of Federal Regulations, Part 1910.1030
3. CDC. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987;36(suppl no. 2S).
4. CDC. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988;37:377-388.
5. CDC. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR* 1989,38(S-6):1-36.
6. The tentative final monograph for OTC topical antimicrobial products. *Federal Register* 1978 Jan 6;43 FR 1210:1211-49 T.
7. Price PB. New studies in surgical bacteriology and surgical technique. *JAMA* 1938;111:1993-6.
8. Ulrich JA. Techniques of skin sampling for microbial contaminants. *Hosp Topics* 1965;43:121-3.

9. Lowbury EJJ, Lilly HA, Bull JP. Disinfection of hands removal of transient organisms. *Br Med J* 1964;2:230-3.
10. Sprunt K, Redman W, Leidy G. Antibacterial effectiveness of routine handwashing. *Pediatrics* 1973;52:264-71.
11. Ojajarvi J. The importance of soap selection for routine hygiene in hospital. *J Hyg (Camb)* 1981;86:275-83.
12. Larson E. Current handwashing issues. *Infect Control* 1984;5:15-7.
13. Albert RK, Condie F. Handwashing patterns in medical intensive-care units. *N Engl J Med* 1981;304:1465-6
14. Larson E. Compliance with isolation techniques. *Am J Infect Control* 1983;11:221-5.
15. Garner JS, Simmons BP. Guideline for isolation precautions in hospitals. *Infect Control* 1983;4:245-325.
16. Rutala WA, Stiegel MM, Sarubbi FA. Decontamination of laboratory microbiological waste by steam sterilization. *Appl Environ Microbiol* 1982;43:1311-6.
17. Lauer JL, Battles DR, Vesley D. Decontaminating infectious laboratory waste by autoclaving. *Appl Environ Microbiol* 1982;44:690-4.
18. Rutala WA, Sarubbi FA. Management of infectious waste from hospitals. *Infect Control* 1983;4:198-203.
19. Favero MS. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, sterilization and preservation*. 3rd ed. Philadelphia: Lea and Febiger, 1983;469-92.
20. CDC. Public Health Service Guidelines for the Management of Health-Care Workers Exposed to HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 1988;37(RR-7).

4. VENIPUNCTURE

4.1 Introduction

The phlebotomist conducts an interview to screen SPs for conditions that will exclude them from the blood draw. The phlebotomist also administers a fasting questionnaire to determine fasting compliance. The venipuncture protocol is dependent on the SPs age, person type, and session time. Exhibits 4-1 through 4-4 illustrate the various venipuncture protocols. These protocols indicate the types and numbers of tubes in priority order for each age group and person type. A chart located on the wall in the phlebotomy room also illustrates this information. It is extremely important to perform the venipuncture protocol as described for each SP. Use comments to describe differences between the actual tubes drawn and the established protocol. After entering the results of the blood draw, labels automatically print for the blood tubes. The phlebotomist immediately labels collected tubes and places them through the pass-through window to the laboratory. The phlebotomist completes the TB component and escorts the SP to the coordinator area after offering refreshments.

Exhibit 4-1. Venipuncture protocol – primary

Age in Years	1-2	3-5	6-11	12+
Tube Type – Priority				
3-mL Lavender	1	1	1	1
5-mL Lavender		1	1	2
3-mL Gray (Morning sessions only)				1
3-mL Blue (40+)				1
3-mL Red	2			
7-mL Red		2		
15-mL Red			2	4
10-mL Red				1
8-mL ACD (20+)				2

Exhibit 4-2. Venipuncture protocol – second exam

Age in Years	12-19	20-59	60-69
Tube Type – Priority			
5-mL Lavender	2	2	2
3-mL Gray	1	1	1
(Morning sessions only)			
3-mL Blue (40+)		1	1
15-mL Red	2	2	2
7-mL Gray		2	

Exhibit 4-3. Venipuncture protocol – VIP guest

Age in Years	1-11	12+
Tube Type – Priority		
3-mL Lavender	1	1
3-mL Red	1	1

Exhibit 4-4. Venipuncture protocol – guest and surplus

Age in Years	1+
Tube Type – Priority	
3-mL Lavender	1
3-mL Red	1

If the veins of a SP appear too fragile to accommodate the size of the large red top tubes, substitute smaller red top tubes as an alternative protocol. Exhibit 4-5, alternative venipuncture protocol – primary, illustrates the alternative size and number of tubes in bold with the original tube protocol in parenthesis. When the alternative protocol is substituted for the original protocol, a comment must be recorded. This protocol constitutes a deviation from the established standard and should only be used in rare circumstances.

Exhibit 4-5. Alternative venipuncture protocol - primary

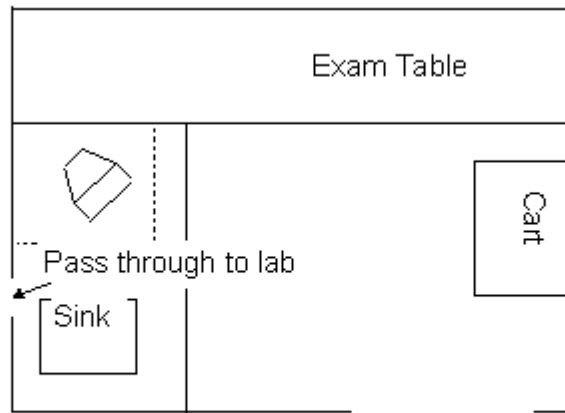
Age in Years	3-5	6-11	12+
3-mL Red	4		
7-mL Red	(2)	4	9
15-mL Red		(2)	(4)
10-mL Red		3	

(#) Represents the standard protocol

4.2 Equipment and Supplies

The phlebotomy room contains an exam table, a sink, data terminal, label printer, refrigerator, supply cart, and cabinets. Figure 4-1 illustrates the floor plan for the phlebotomy room.

Figure 4-1. Floor plan for phlebotomy room



The equipment and supplies used in venipuncture are listed in Exhibit 4-6.

Exhibit 4-6. Equipment and supplies - phlebotomy

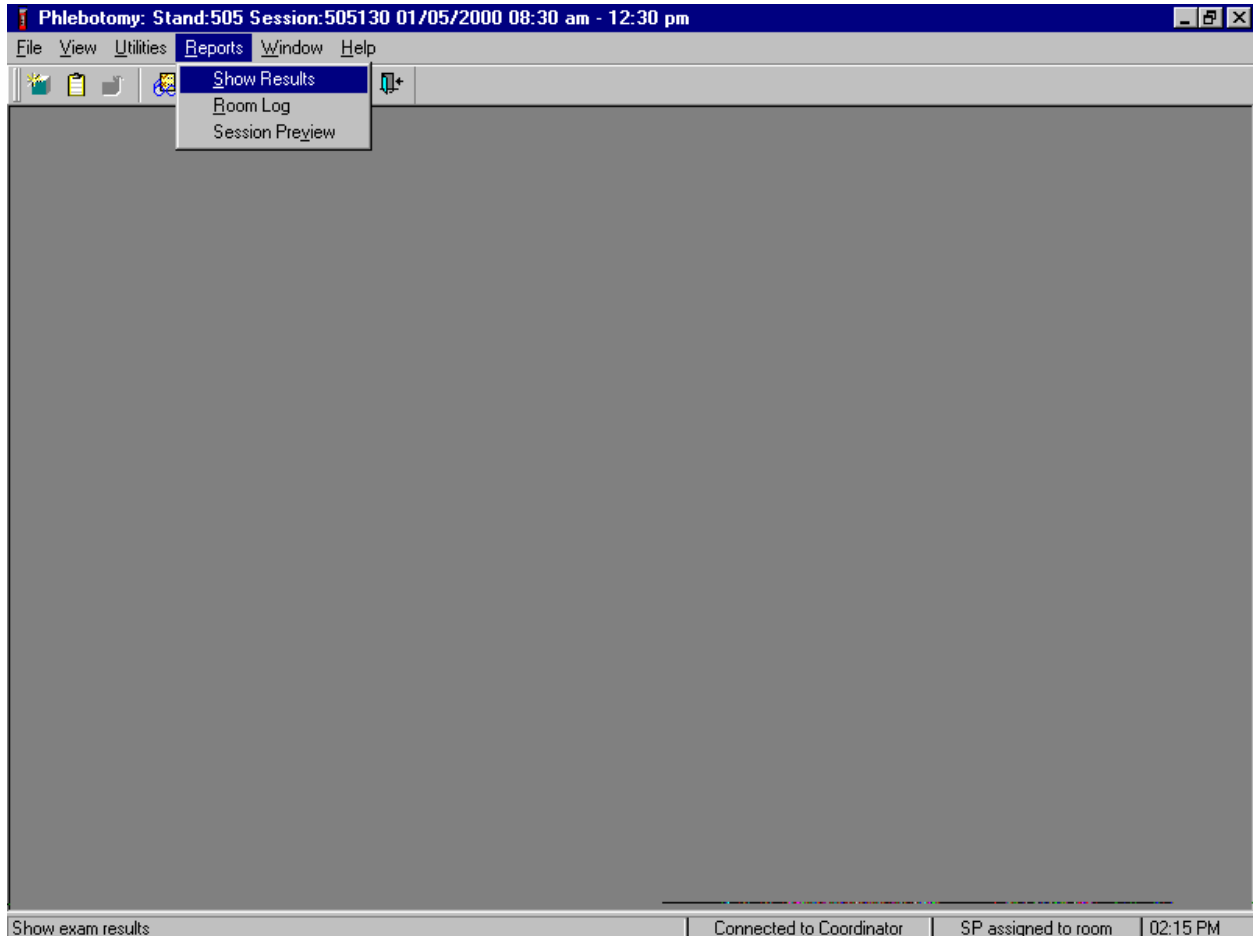
BD Hemogard Vacutainer® 3-mL EDTA	Stretch disposable tourniquet
BD Hemogard Vacutainer® 3-mL Red	Latex tourniquet
BD Hemogard Vacutainer® 5-mL EDTA	Alcohol wipes
BD Hemogard Vacutainer® 3-mL Gray	Iodine prep pads
BD Hemogard Vacutainer® 7-mL Red	2 x 2 Gauze squares
BD Vacutainer® 15-mL Red	Adhesive bandages
BD Vacutainer® 8-mL ACD	Adhesive bandages – children
BD-Vacutainer® 10-mL Red	Transpore tape
BD-Vacutainer® 3-mL Blue	Surgical paper tape
Butterfly blood collection set 21 gauge with adapter	Cartoon stickers
Butterfly blood collection set 23 gauge with adapter	Kleenex
Butterfly blood collection set 25 gauge with adapter	Antibacterial hand soap
BD Vacutainer® multiple sample 21 gauge needle	Hand cream
BD Vacutainer® needle holder – single use	Ammonia inhalant packets
Air sickness bags	Sharps containers, 5 quart and 8 gallon
Heel warmers	Pillow and disposable pillow cover
Labels for Intermec printer	Phlebotomy cart
Nonsterile, powder-free, latex (non-latex for use by latex allergic staff) gloves -- small, medium, large	Hype-Wipe 10% bleach solution

For each SP, the phlebotomist requires the following materials:

- Alcohol wipes,
- 2"x 2" gauze squares,
- Vacutainer® tubes of the appropriate size and type,
- Disposable tourniquet,
- Needle assembly, and
- Adhesive bandage.

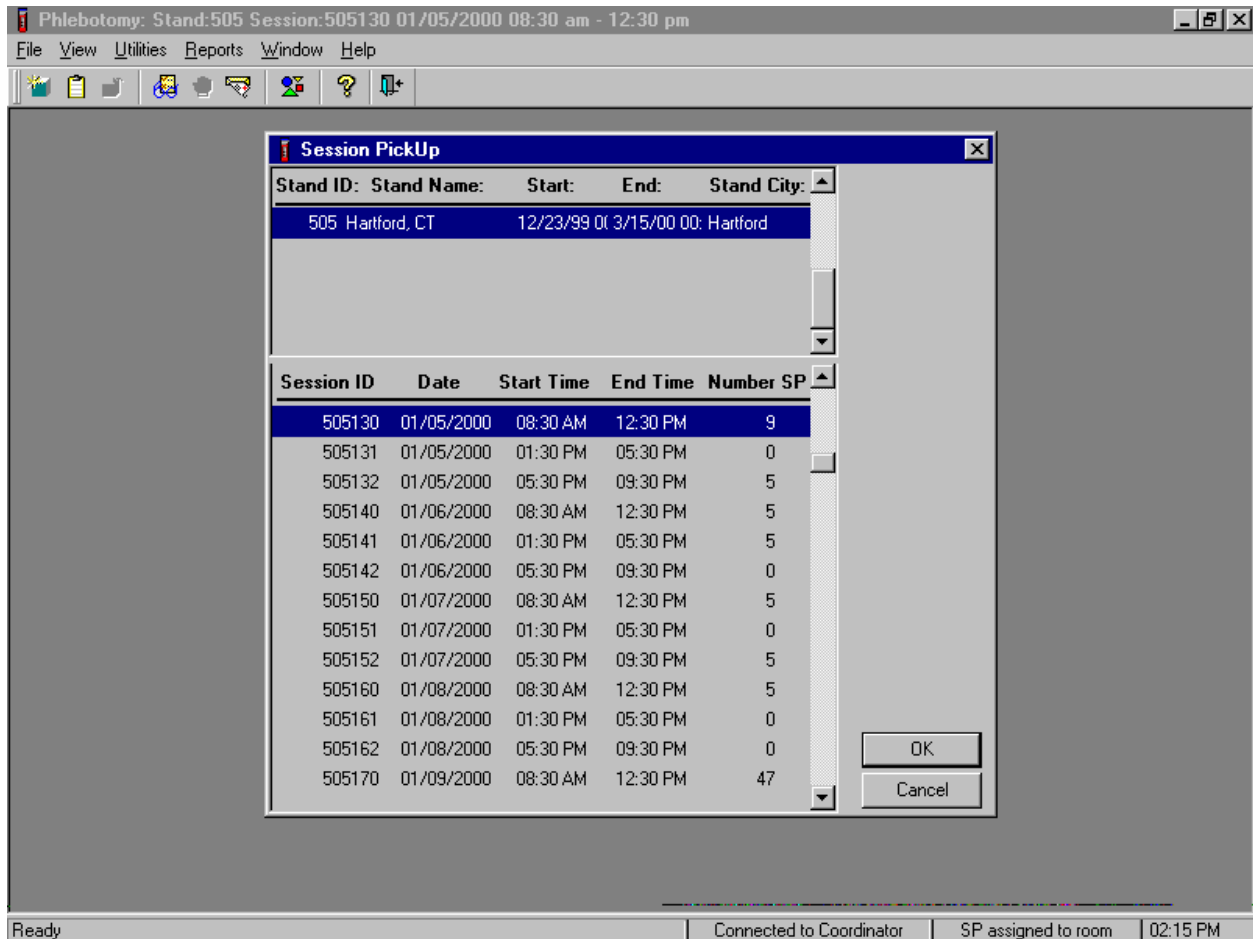
4.3 Session Preview, Show Results, and Room Log Reports

Access the Session Preview report to view all SPs scheduled into any session including the current session.



To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Session Preview} and left click, or type [Alt] [R], [V].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to drag the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The Session Preview Report displays.

Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy Subsystem Stand:505 Session:505130

Session Preview Report 01/28/00 14:47
Stand: 505

Session: 505130 01/05/2000 08:30 AM - 12:30 PM

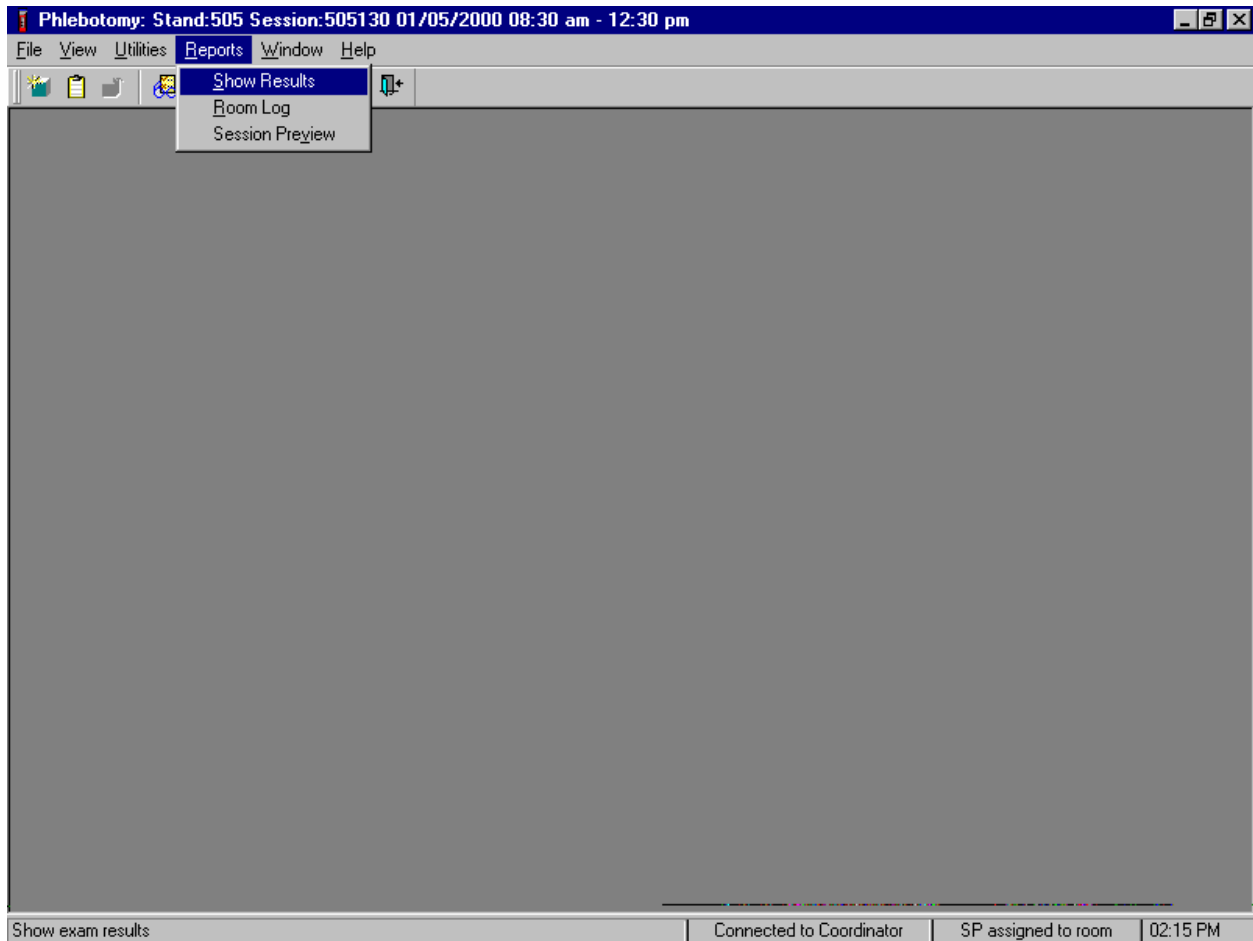
SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
213096	Primary	DRAKE EPCOT	89 years	Male		
306541	Primary	GERTA HOFF	59 years	Female		
735768	Primary	FIG RESPOT	14 years	Female		
878700	Primary	EDNA EPCOT	80 years	Female		
905688	Primary	ROLAND REPOT	78 years	Male		
184340	2nd Exam	*ED FELLOWS	29 years	Male		

Page 1 of 3

Ready | Connected to Coordinator | SP assigned to room | 02:15 PM

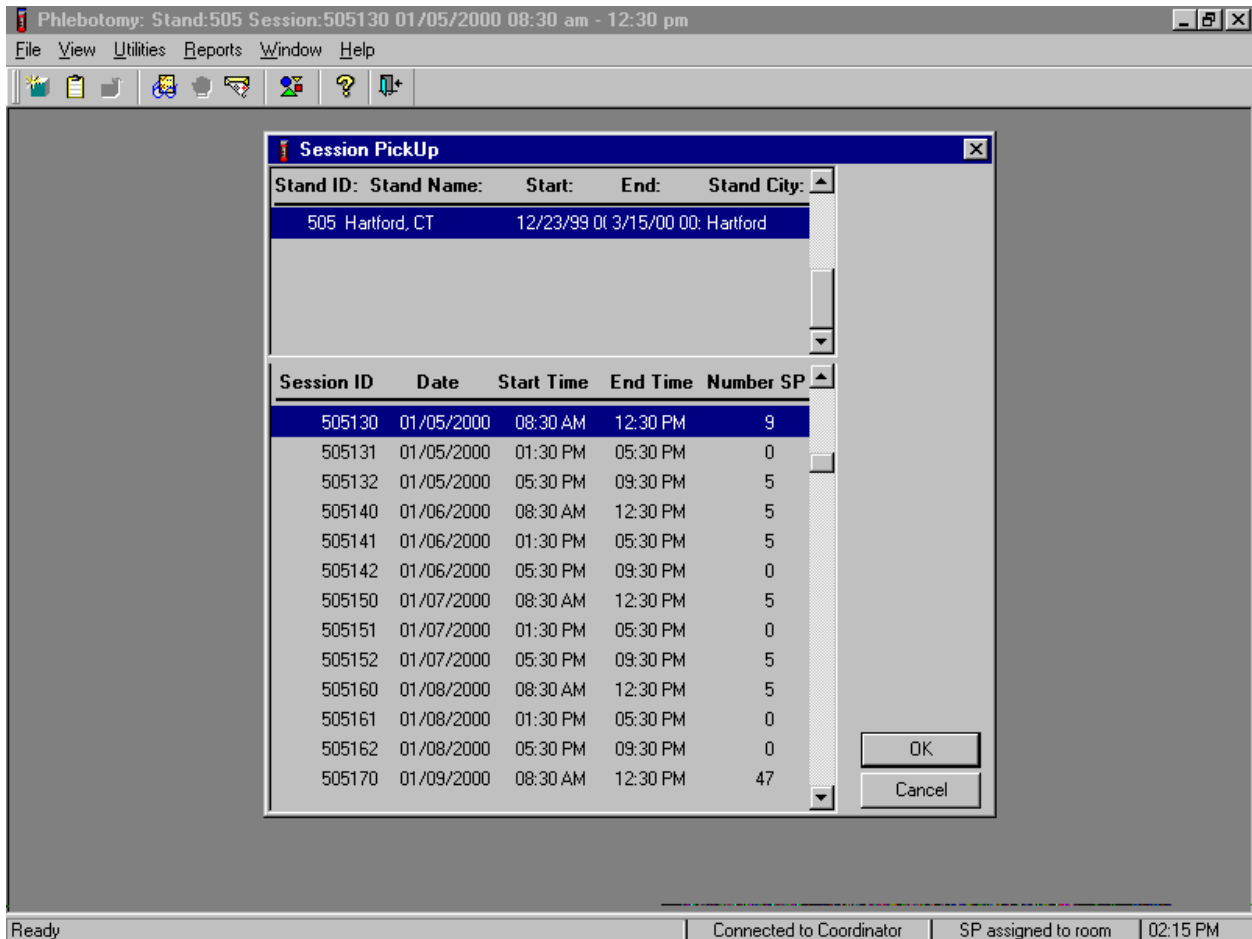
The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any Special Considerations or Consent Comments. A blue asterisk in front of a name indicates that the SP is eligible for the VOC component. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

Access the Show Results report to obtain detailed information about a SP.



To access the Show Results report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Show Results} and left click, or type [Alt] [R], [S].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The Show Results Report displays.

The screenshot shows a software window titled "Phlebotomy Subsystem" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area displays a "Phlebotomy Result Report" for Stand 505, Session 505130, dated 01/05/00, 08:30 - 12:30. The report includes patient information for Stacy Fellows (SP ID: 745137, Appt ID: 5051804) and a list of phlebotomy items with their results. At the bottom, a status bar shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:15 PM".

Phlebotomy Result Report 01/28/00 14:46

Stand: 505
 Session: 505130 01/05/00 08:30 - 12:30

Sp Id: 745137 SP Name: STACY . FELLOWS Person Gender: 2 Age At Interview Yrs: 22
 Appt Id: 5051804 Appt Status: 2 Exam Status: 1 Exam Comment:

Section Id: Section Name: Section Status: Section Comment Code: Section Comment Other:

1	Venipuncture	1		
---	--------------	---	--	--

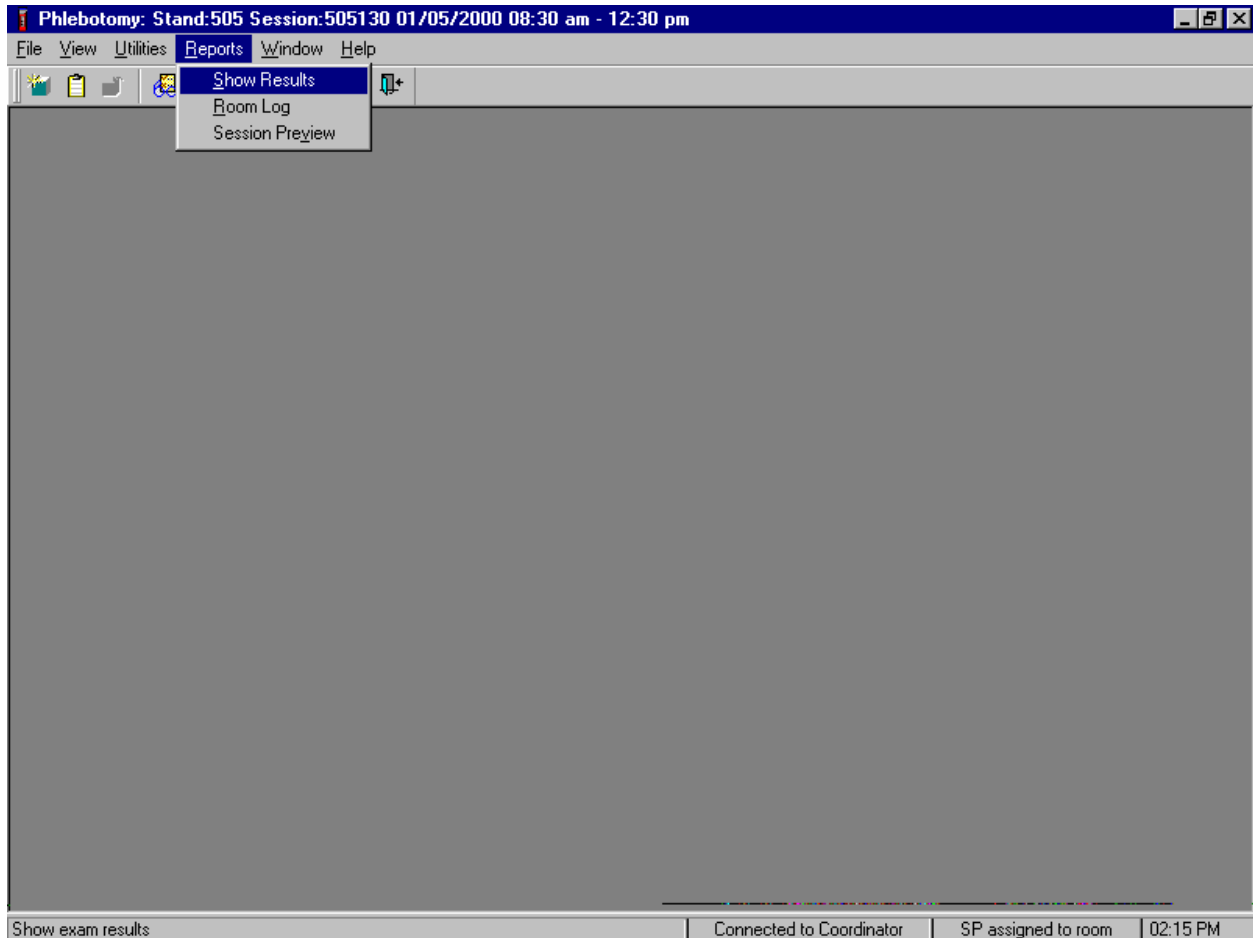
Item Id:	Item Text:	Item Type:	Result Num:	Result String:
PHAFSTHR	Total length of "food fast," hours	2	5.0000	
PHAFSTMN	Total length of "food fast," minutes	2	30.0000	
PHQ010	When was the last time you ate or drank anything other than plain water?	3		1/14/00 09:00:00
PHQ020	Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]	4	2.0000	
PHQ030	Alcohol, such as beer, wine, or liquor?	4	2.0000	
PHQ040	Gum, breath mints, lozenges or cough drops, or other cough or cold rem	4	2.0000	
PHQ050	Antacids, laxatives, or anti-diartheals?	4	2.0000	
PHQ060	Dietary supplements such as vitamins and minerals? [Include multivita	4	2.0000	

Item Name	Num Collecte
5 ml EDTA	2.000

Ready | Connected to Coordinator | SP assigned to room | 02:15 PM

The Show Results Report includes detailed information about a SP's phlebotomy exam. The report includes, Stand number, Session number, Session date and time, SP ID number, SP's name (first, last), Appt ID number, Appt status number, gender, SP's age at interview, and a complete list of all associated item IDs and the item ID results. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Show Results Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Show Results Report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Show Results Report (minimize window button) and left click.

The Room Log report provides detailed information about all SPs who have been through the phlebotomy exam and their exam status.



To access the Room Log report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Room Log} and left click, or type [Alt] [R], [R].

The Phlebotomy Room Log displays the SPs in the current session and their component status. The status is listed as Complete, Partial, or Not Done. Use this report to assess the session status.

Phlebotomy Room Log 01/28/2000 02:46 PM
Stand: 505

Session: 5051578 01/05/2000 08:30 AM - 12:30 PM Total: 2 SPs

SP ID	SP Name	Gender	Age	Component Status
878700	Edna Epcot	Female	80	partial
745137	Stacy Fellows	Female	22	complete

Page 1 of 1

Ready | Connected to Coordinator | SP assigned to room | 02:15 PM

The Phlebotomy Room Log lists the stand number, session number, session date and time, current date and time, SP's ID, first and last name, gender, age, SP status, and component status. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Room Log report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Room Log report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Room Log report (minimize window button) and left click.

4.4 Overview

The coordinator tracks each SP through the MEC using the coordinator system. This system tracks the SP throughout the exam, including arrival, location during the session, and exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC and to determine if all the appropriate examinations are complete. The MEC coordinator monitors exam component status using responses from examination stations.

Each SP receives a bar coded ID bracelet when they arrive at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP's ID number in bar code and eye-readable format. The phlebotomist "wands" the bracelet bar code with a bar code scanner (wand) to log the SP into the phlebotomy component. If necessary, the ID number can be entered manually by reading it from the bracelet.

The phlebotomist is responsible for completing entries for the following procedures:

- Venipuncture;
- TB skin test; and
- VOC special study.

Set up the appropriate blood collection cart in advance making sure there are sufficient supplies for all SPs in the session. Open the phlebotomy exam. Log the SP into phlebotomy by scanning the bar code on the SP ID bracelet or manually typing the SP ID when the SP arrives in phlebotomy.

Conduct the phlebotomy interview and administer the fasting questionnaire. The phlebotomy protocol screen will display. Draw the appropriate tubes, and enter the number of tubes collected next to the expected values. Labels generate automatically. Enter the appropriate comment(s) for any tube that was not collected. Label the blood tubes. Verify that the phlebotomy completion status is correct. The phlebotomy section status is "Complete" if all blood tubes are collected, "Partial" if some, but not all blood tubes are collected, and "Not Done" if no blood tubes are collected.

4.5 Gaining Cooperation

The coordinator will introduce the SP to the examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture. However, the phlebotomist must be prepared to answer all the questions the SP poses about the venipuncture procedure. In addition, the phlebotomist must convince the SP of the importance of cooperation in the venipuncture component of the examination.

Prepare to answer questions about the rationale for the venipuncture, the discomfort involved, the amount of blood being drawn, and the possibility of contracting an infectious disease from the process. To address SPs concerns effectively, know the following information about the procedures used for the study:

- Rationale

Although the SP has provided much useful information in the household and individual interviews, the successful completion of the venipuncture component of NHANES is critical to the success of the study. Using the various specimens, researchers and laboratories are able to perform over 239 different biochemical tests (SPs 12+) which provide detailed information about the SP's health and nutritional status. NHANES data produces descriptive statistics that measure and monitor the health of the U.S. population. Much of this information would not be available in any other way. The laboratories that conduct the analysis are considered the "gold standard" for their particular analyte(s).

- Discomfort

Venipuncture causes only minimal discomfort. A certified, experienced, phlebotomist performs venipunctures. There is a variety of blood collection needles available so that the most appropriate size can be selected for each SP.

- Amount

Phlebotomists draw the following amount of blood:

1-2 years primary SP, 9-mL (0.3 ounces), 0.6 tablespoons

3-5 years primary SP, 22-mL (0.7 ounces), 1.5 tablespoons

6-11 years primary SP, 38-mL (1.3 ounces), 2.5 tablespoons

12+ years primary SP, 102-mL (3.4 ounces), 6.8 tablespoons

12-19 years second exam, 60-mL (2.0 ounces), 4.0 tablespoons

20-59 years second exam, 74-mL (2.5 ounces), 5.0 tablespoons

60-69 years second exam, 60-mL (2.0 ounces), 4.0 tablespoons

1-2 years VIP guest, 6-mL (0.2 ounces), 0.4 tablespoons

3-5 years VIP guest, 10-mL (0.4 ounces), 0.7 tablespoons

6-11 years VIP guest, 18-mL (0.6 ounces), 1.0 tablespoons

12+ years VIP guest, 23-mL (0.8 ounces), 1.5 tablespoons

1-11 years guest, 3-mL (0.1 ounces), 0.2 tablespoons

12+ years guest, 6-mL (0.2 ounces), 0.4 tablespoons

1+ years surplus, 3-mL (0.1 ounces), 0.2 tablespoons

An average adult male has 12 pints of blood and an average female has 9 pints. The Red Cross routinely draws 450-mL (or one pint) during a routine donation. Their requirements limit donation to every 8 weeks. The Red Cross does allow autologous donations where an individual can donate their own blood before their surgery. This consists of one unit per week for up to six consecutive weeks. The maximum volume drawn during a MEC exam amounts to less than 25 percent (102-mL) of the amount drawn from regular donors by the Red Cross. The body manufactures blood daily and replaces this volume of blood within 24 hours.

- Infection control

The supplies used for venipuncture are completely sterile, and are used only once. There is absolutely no possibility of the SPs being infected by any blood-borne disease, such as hepatitis or AIDS, because of participating in the venipuncture component of the NHANES exam.

Gaining the cooperation of a SP is easier if the atmosphere in the phlebotomy room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the phlebotomy room.

- Maintain a clean and uncluttered work area. This is especially important because of today's concern with blood-borne infectious diseases, such as hepatitis and AIDS.
- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.

- Speak face-to-face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he/she is not important. It also implies disinterest.
- Avoid nervous behaviors, such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

4.5.1 Refusal Conversion

The coordinator should notify the phlebotomist of all venipuncture refusals so that the phlebotomist can attempt a refusal conversion.

The phlebotomist should discuss the condition of the SP's refusal with the coordinator before he/she attempts a conversion. If the coordinator indicates that the SP is an adamant refusal, the phlebotomist should not attempt to approach the SP or conduct the phlebotomy interview. If, however, the coordinator and the phlebotomist decide that the SP is a good candidate for a refusal conversion attempt, the phlebotomist may conduct the phlebotomy interview as part of the conversion attempt. If appropriate, the phlebotomist should enlist the help of the coordinator, the health technician, and/or the MEC physician to help convert refusals.

4.6 Performing the Venipuncture on SPs Who Do Not Speak English

When the phlebotomist must administer the venipuncture procedure to a SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the venipuncture.

Convert the phlebotomy interview and fasting questionnaire text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window title is "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:26 PM". The section is titled "Fasting Questionnaire".

¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua pura? 06:00 AM 01/28/2000
[No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o]

Ha tomado o comido algo de lo siguiente ¿desde hoy a las 6:00 de la mañana?

¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.] No : //

¿Alcohol, tal como cerveza, vino o licor? No : //

¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado? Yes 06:30 AM 01/28/2000

¿Antiácidos, laxantes, o antidiarreicos? No : //

¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.] No : //

Fasting Time: 8 Hours 17 Minutes

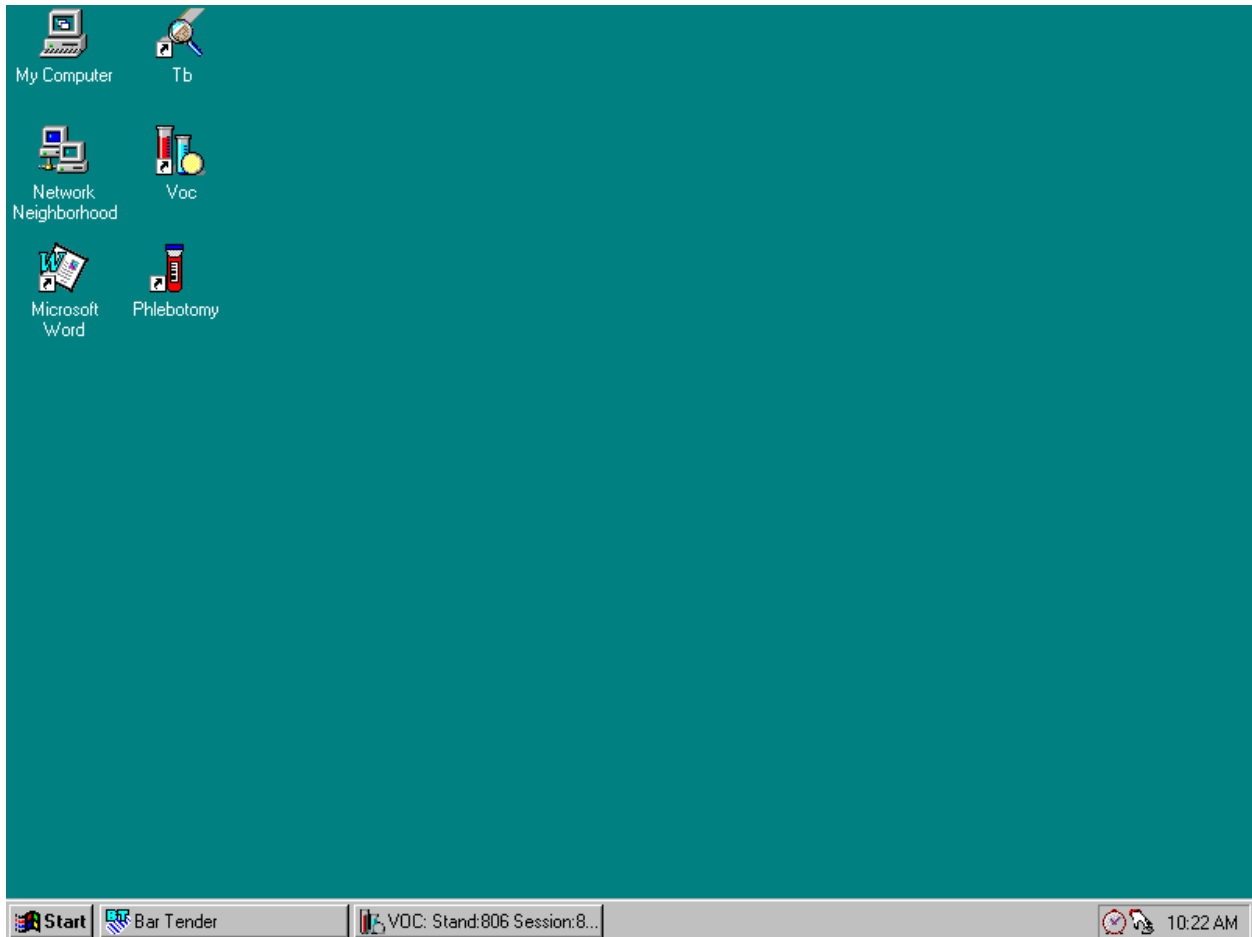
Navigation: 2 of 4. Buttons: End of Section, Close Exam, Finish. A blue arrow icon is on the right.

System tray: Ready | Connected to Coordinator | SP assigned to room | 02:15 PM

To view the phlebotomy interview and fasting questions in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S]. To return the phlebotomy interview and fasting questions to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E].

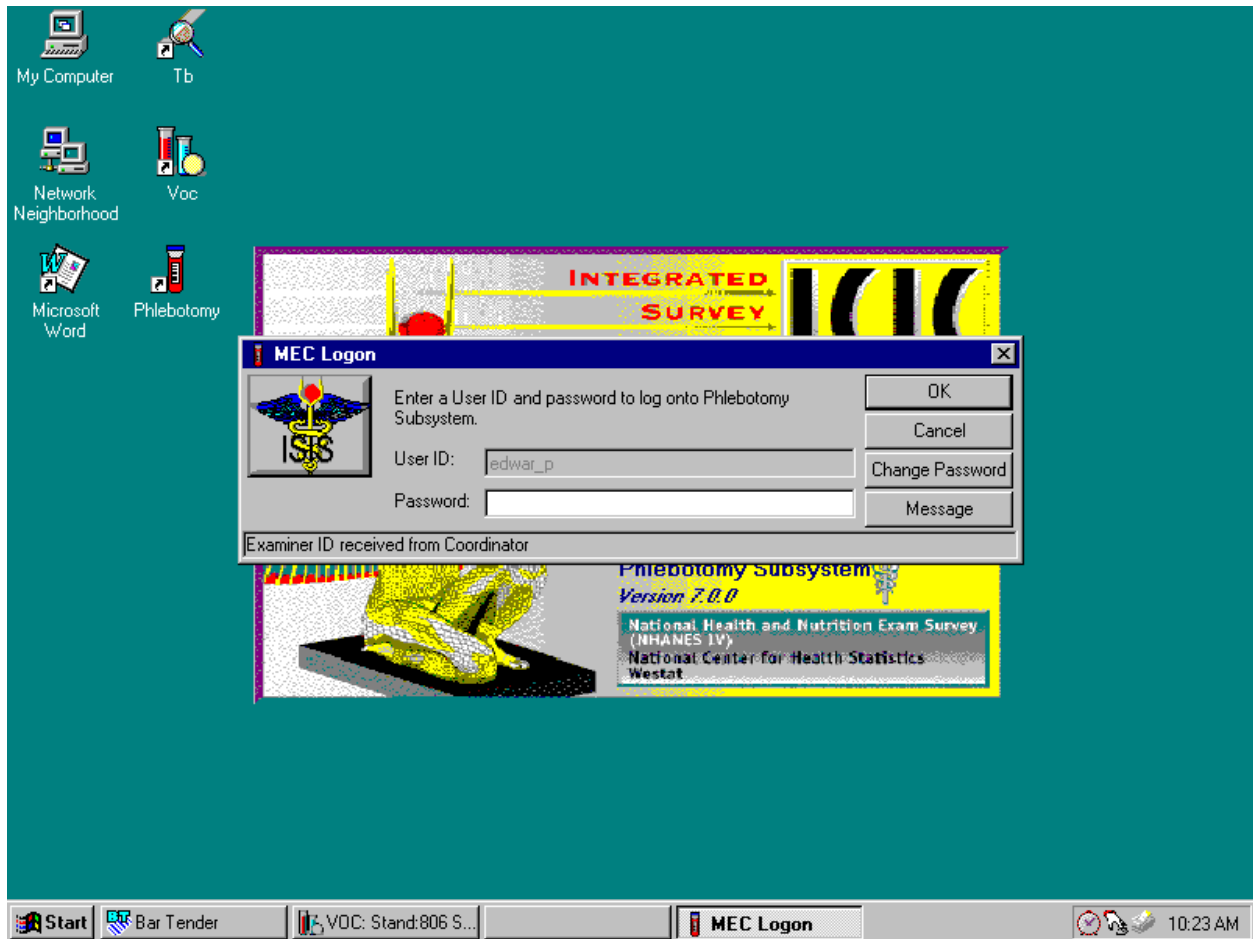
4.7 Begin the Exam and Logon

Open the phlebotomy application.



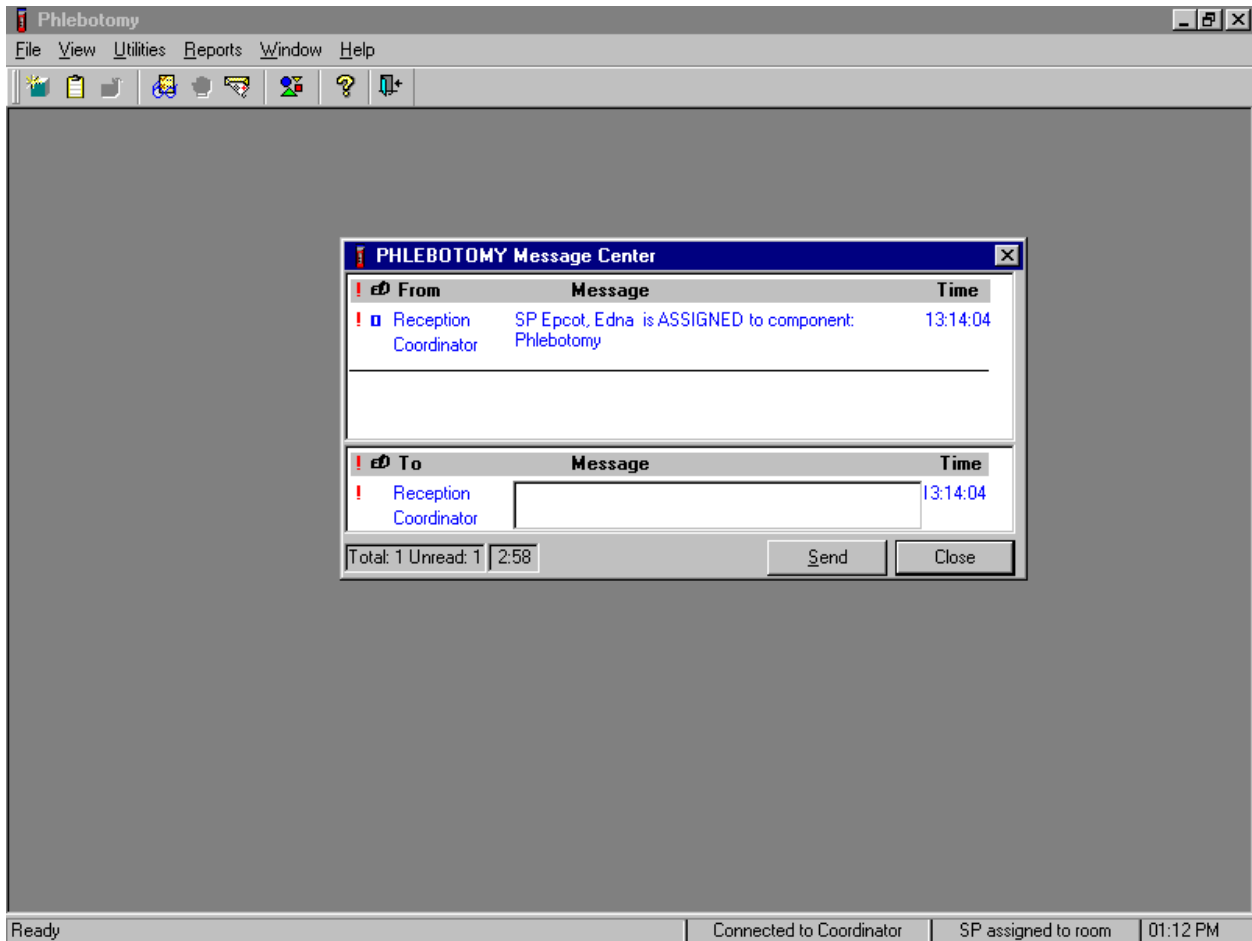
To access the phlebotomy application, use the mouse to direct the mouse arrow to the Phlebotomy icon on the desktop and double left click.

Log onto the phlebotomy application.



The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the **Message** button and left click.

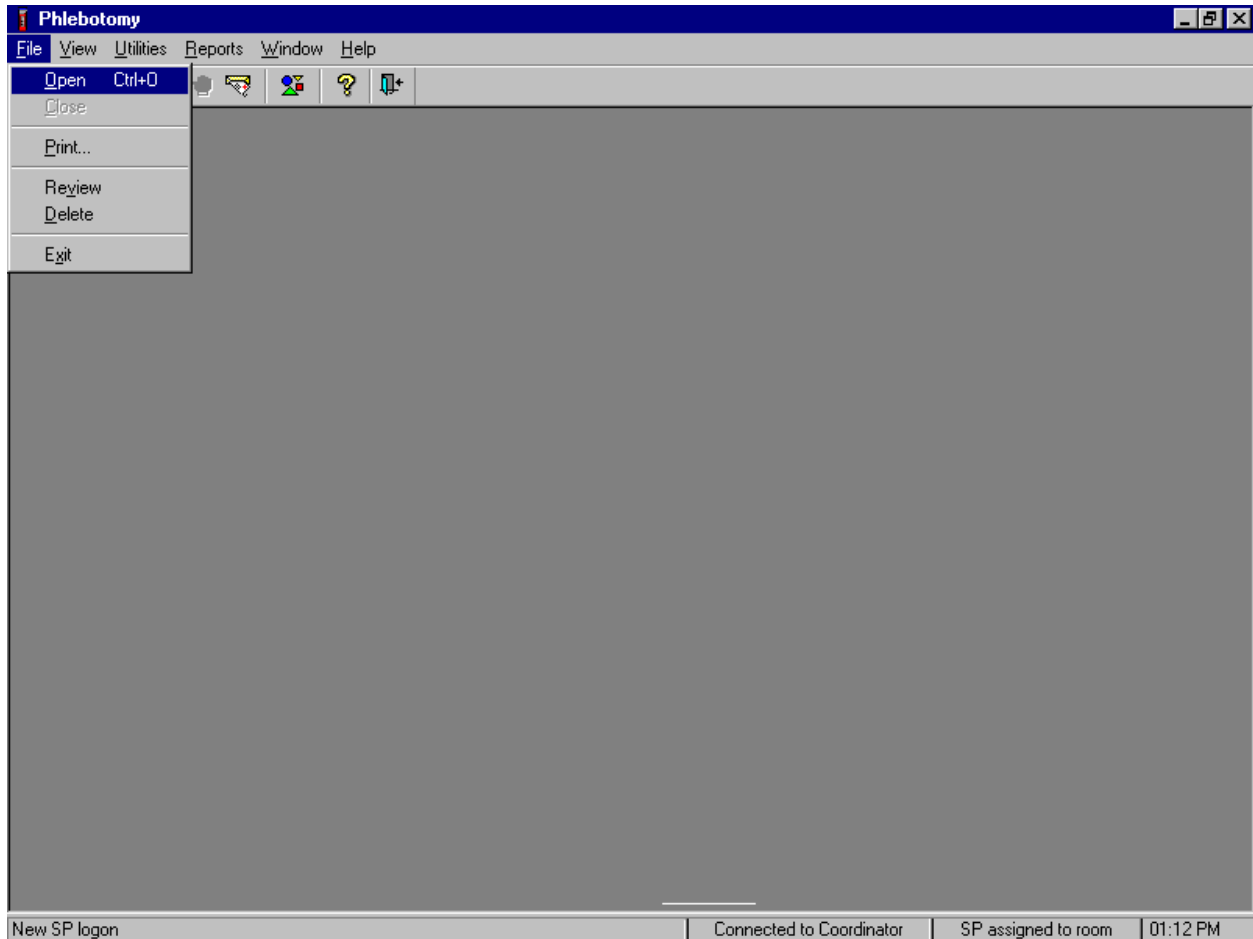
The message center window identifies the SP assigned to phlebotomy.



A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component displays. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the **Send button** and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the **Close button** and left click, or select [Enter].

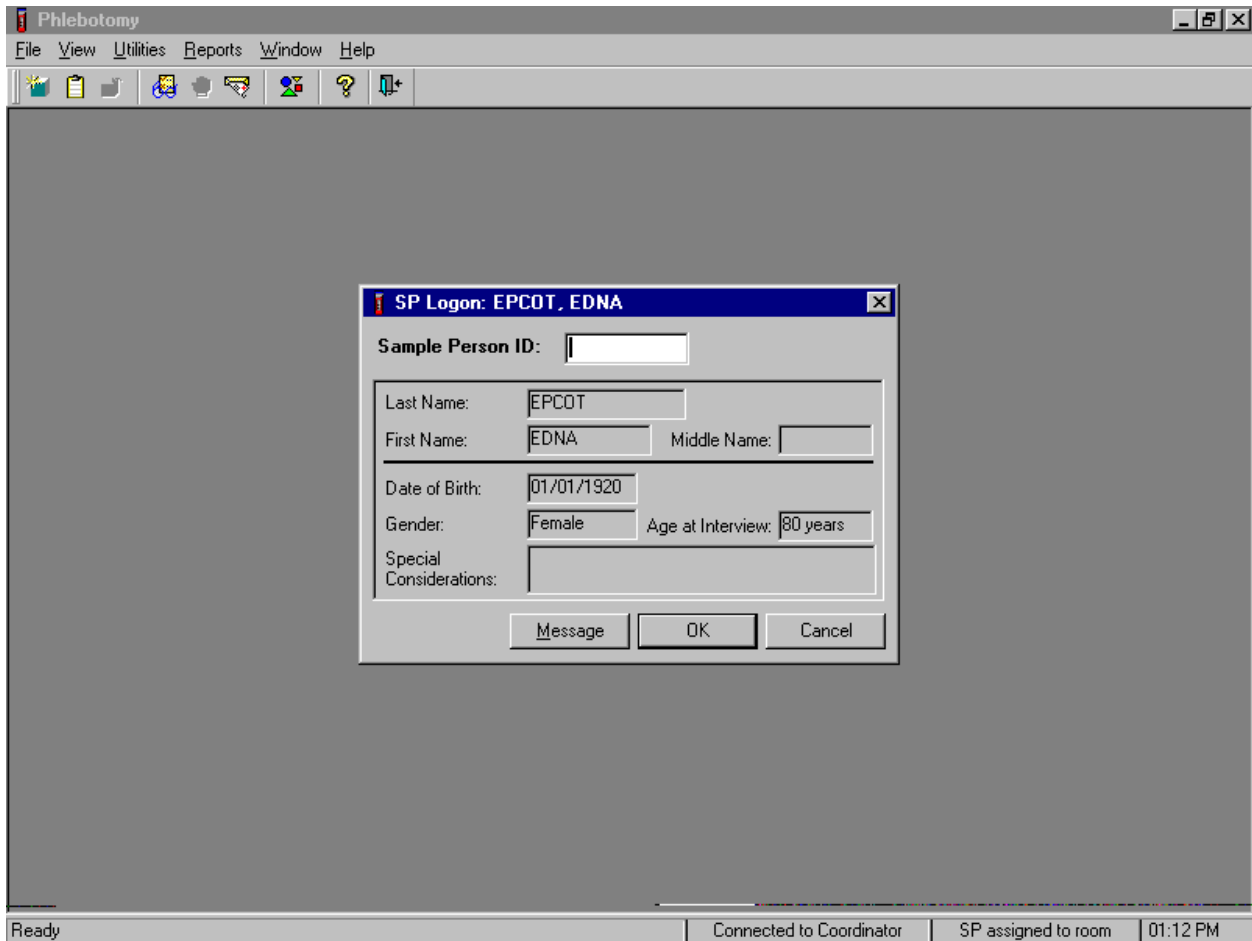
4.8 Open the Exam and Log the SP into the Exam

Open the phlebotomy exam.



To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F], [O], or [Ctrl] [O].

The SP Logon window displays.



The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Verify the information.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. A dialog box titled "SP Logon: EPCOT, EDNA" is open, displaying the following information:

Sample Person ID:	878700		
Last Name:	EPCOT		
First Name:	EDNA	Middle Name:	
Date of Birth:	01/01/1920		
Gender:	Female	Age at Interview:	80 years
Special Considerations:			

Buttons: Message, OK, Cancel

At the bottom of the main window, a status bar displays: "Apply changes and close window", "Connected to Coordinator", "SP assigned to room", and "01:12 PM".

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

4.9 The Phlebotomy Interview

The phlebotomy interview screens the SP for safety exclusions. There are only two reasons to exclude a SP from venipuncture—hemophilia, and having received chemotherapy within the past 4 weeks. Administer the interview (and fasting questionnaire) directly to SPs over the age of 18 or administer the interview questions (and fasting questionnaire) to the SP's parent or guardian for SPs under age 18.

Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly and record the responses.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar is a header bar with the text "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Below the header bar is a status bar with the text "SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:18 PM". The main area is titled "Phlebotomy Interview" and contains two questions with dropdown menus: "Do you have hemophilia?" and "Have you received cancer chemotherapy in the past four weeks?". At the bottom of the main area is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", and a blue arrow button. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:12 PM".

Conduct the phlebotomy interview by asking the question displayed on the screen, "Do you have hemophilia?"

Q1: Do you have hemophilia?

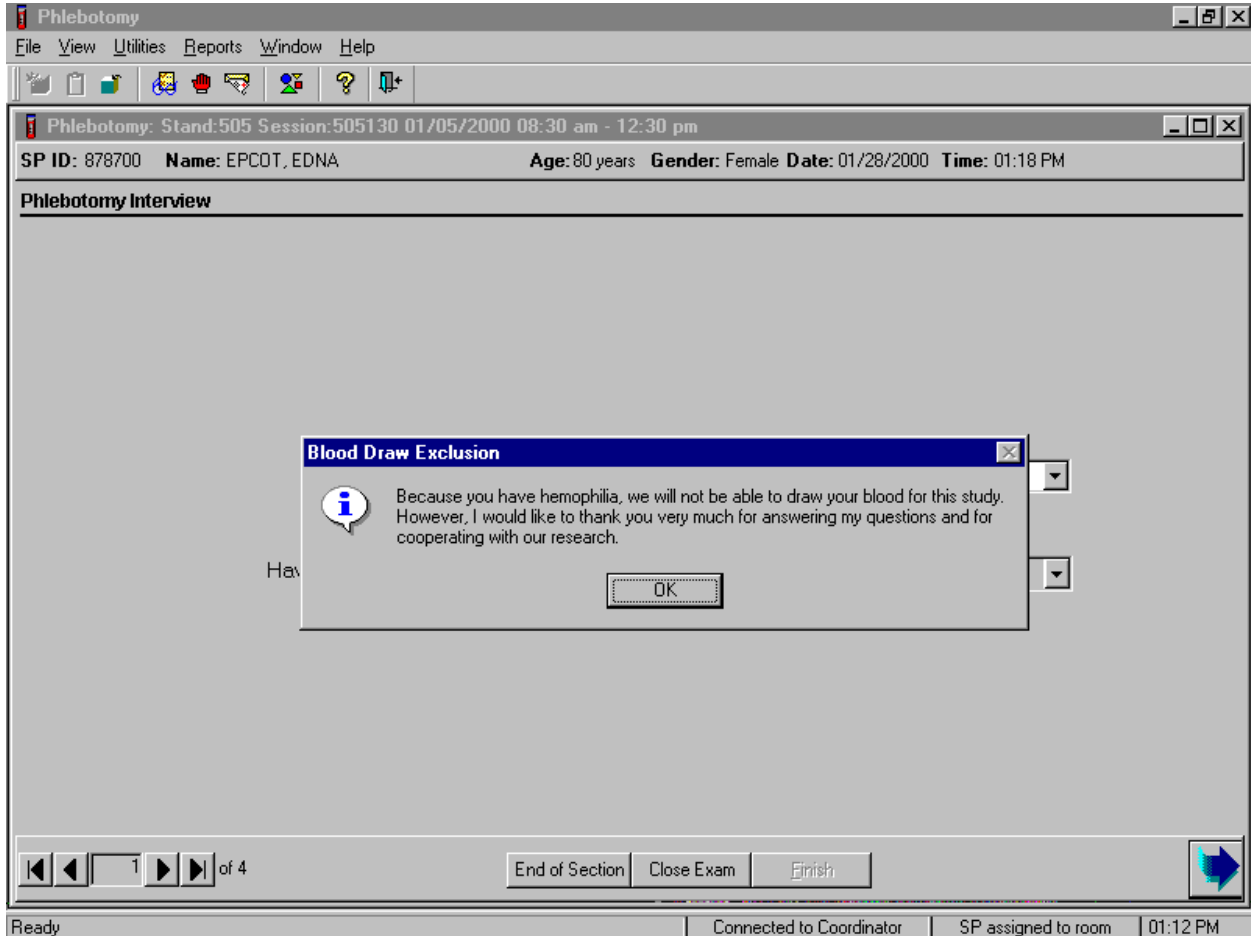
<p>Q1: This question asks whether the SP has hemophilia, which is an exclusion criterion for this procedure.</p>	<p>Explain that we cannot perform phlebotomy on participants who have hemophilia. Hemophilia is a rare disease where an individual's blood does not clot. If a SP's relative has hemophilia but the SP does not, the SP is not excluded. If the SP is excluded the Blood Draw Exclusion box displays. Read the text in the box to the SP and escort them back to the coordinator station.</p>
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Record the exact response.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar is a header bar with the text "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Underneath this is a patient information bar: "SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:18 PM". The main area is titled "Phlebotomy Interview" and contains two questions: "Do you have hemophilia?" and "Have you received cancer chemotherapy in the past four weeks?". A dropdown menu is open over the first question, showing options: "Yes", "No", "Refused", and "Don't Know". At the bottom of the main area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:12 PM".

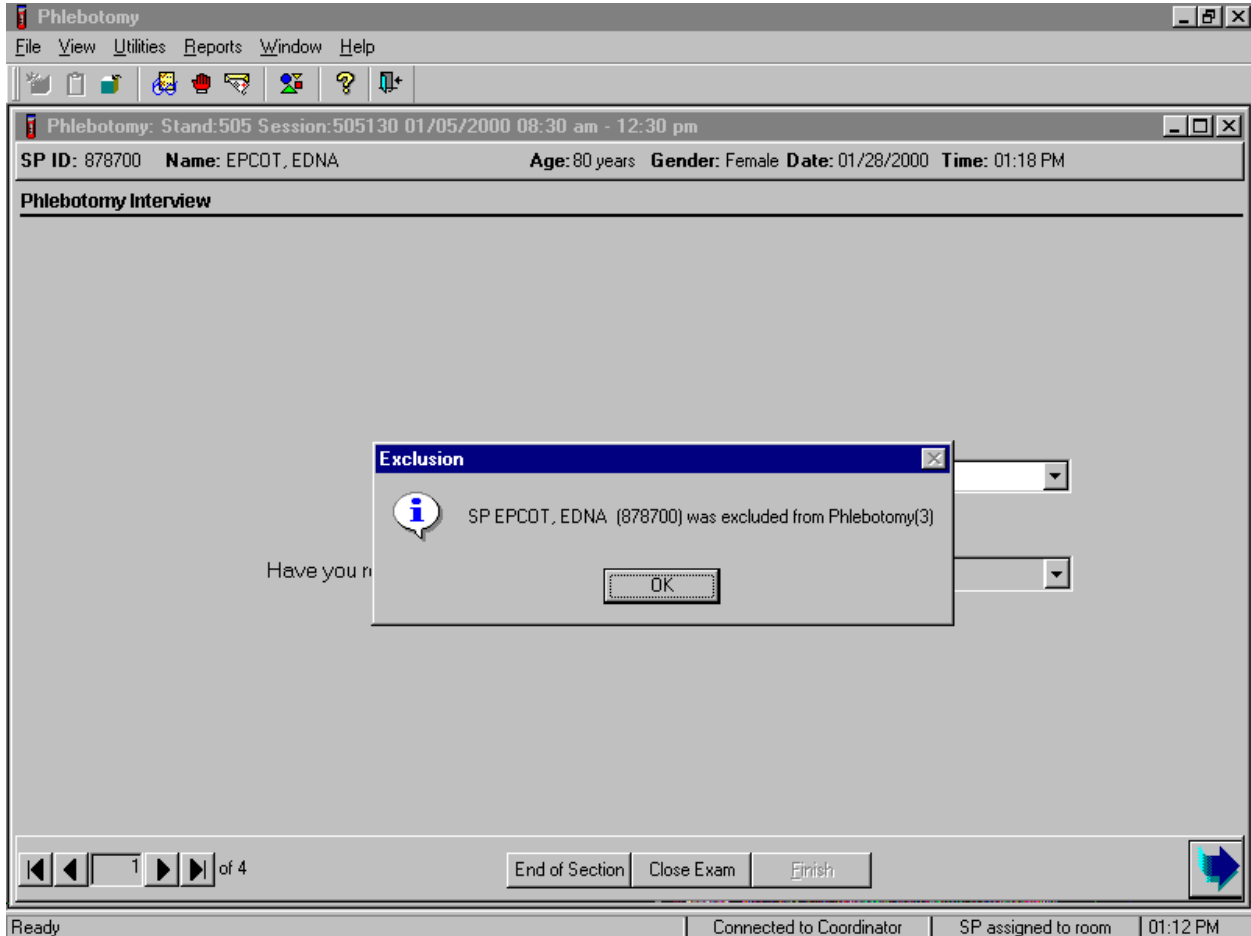
Record the response by typing [Y/y] for "Yes," [N/n] for "No," [R/r] if they refuse, or [D/d] for "Don't know." Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to "Yes," "No," "Refused," or "Don't Know" and left click. If the response is "Yes," "Refused," or "Don't Know," use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

If the SP is excluded from the phlebotomy exam due to hemophilia, the Blood Draw Exclusion informational message text box displays.



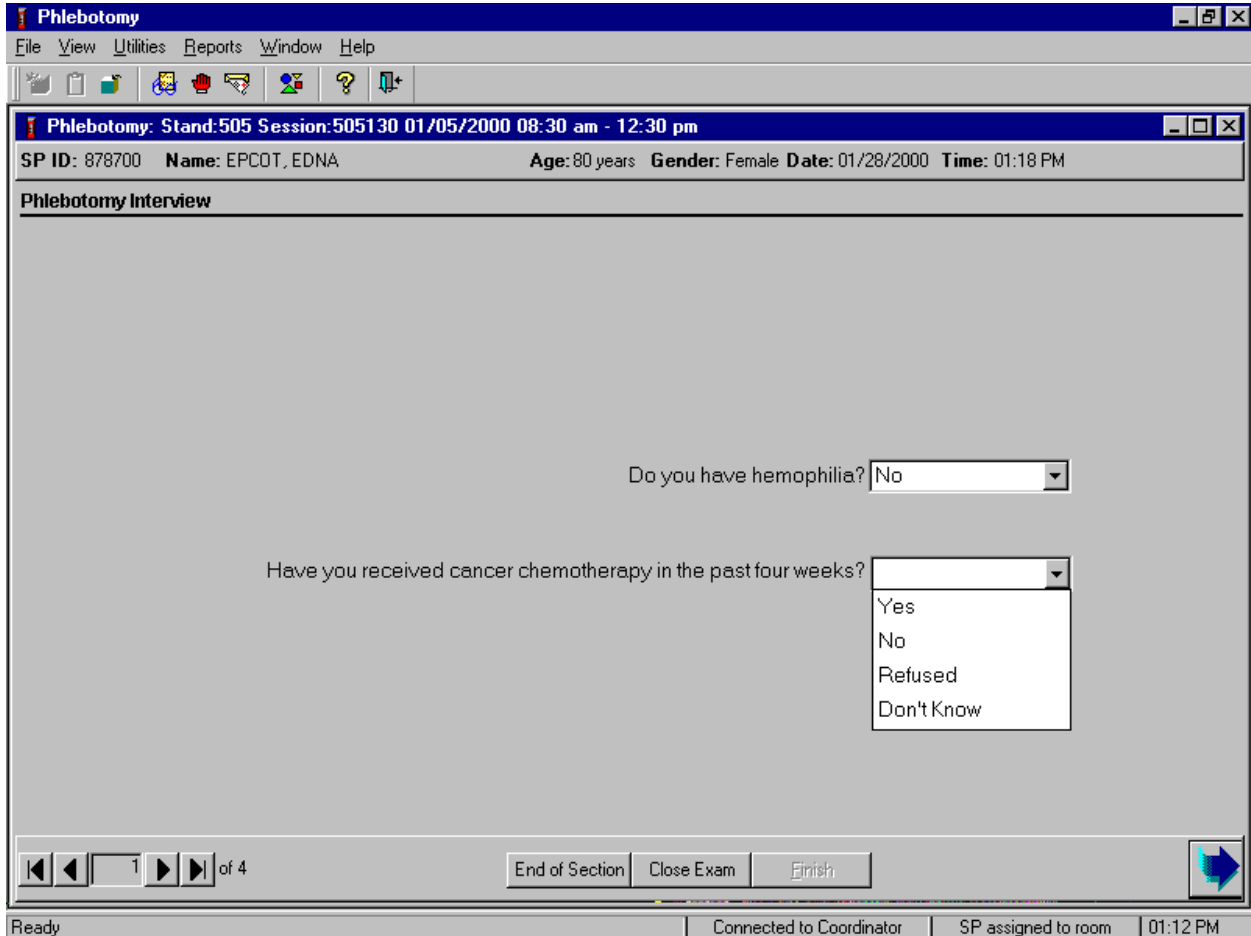
Read the script to the SP. To remove the Blood Draw Exclusion message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

If the SP is excluded from the phlebotomy component due to hemophilia, an Exclusion message text box displays.



To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

Continue the phlebotomy interview by asking the second question displayed on the screen, "Have you received cancer chemotherapy in the past four weeks?"



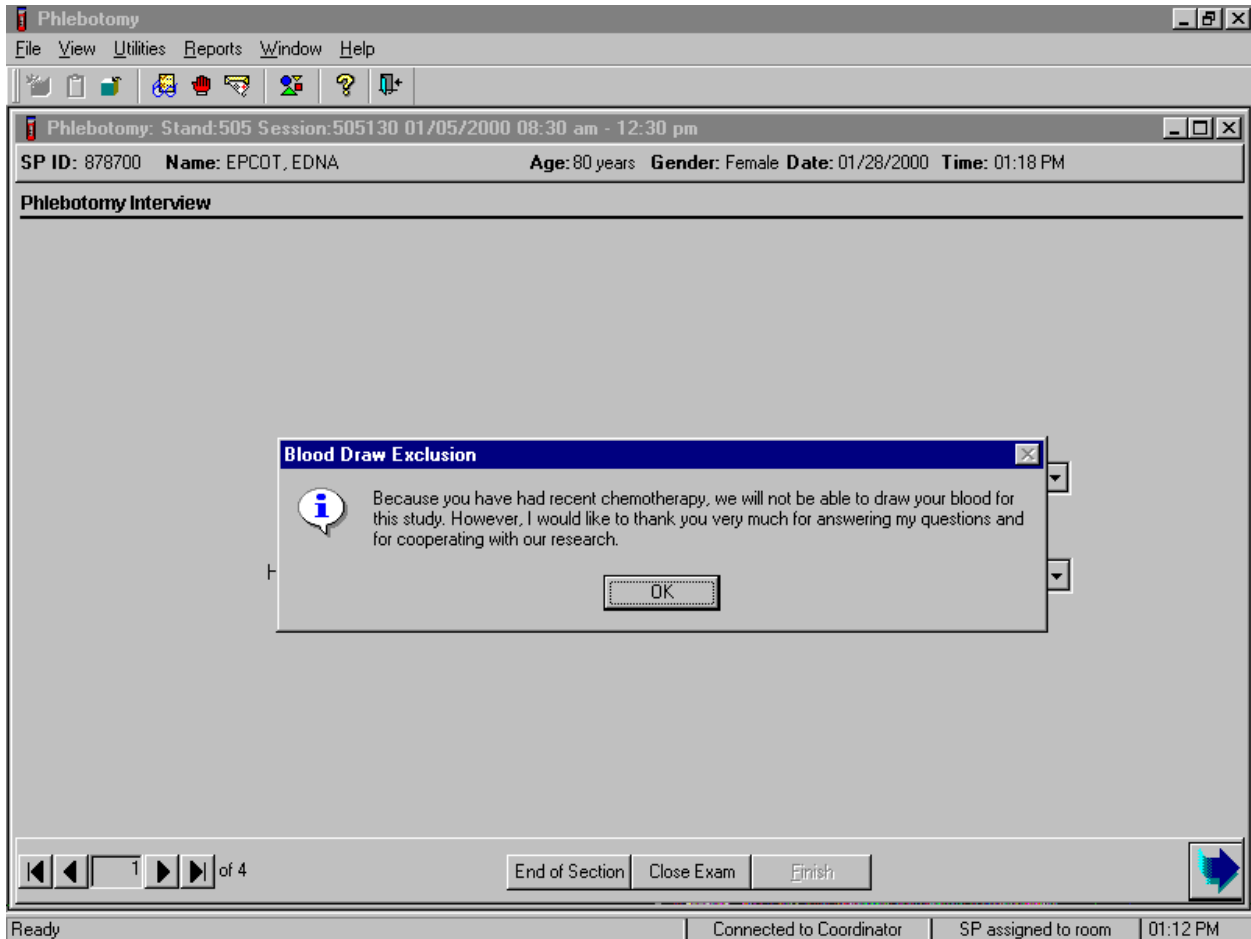
Q2: Have you received cancer chemotherapy in the past four weeks?

<p>Q2: This question asks whether the SP has received chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.</p>	<p>Explain that we cannot perform phlebotomy on participants who have received cancer chemotherapy within the past 4 weeks. If the SP is excluded, the Blood Draw Exclusion box is displayed. Read the text in the box to the SP and escort them back to the coordinator station.</p>
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Record the response by typing [Y/y] for "Yes," [N/n] for "No," [R/r] if they refuse, or [D/d] for "Don't know." Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the

drop-down list, left click to display the responses, and drag the mouse arrow to "Yes," "No," "Refused," or "Don't Know" and left click. If the response is "Yes," "Refused," or "Don't Know," use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

If the SP is excluded from the phlebotomy exam due to cancer chemotherapy, the Blood Draw Exclusion informational message text box displays.



Read the script to the SP. To remove the Blood Draw Exclusion message box use the mouse to direct the mouse arrow to the **OK** button and left click. To progress to the component status screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter]. Review the status and default comment code. Escort the SP back to the coordinator.

4.10 Administering the Fasting Questionnaire

Fasting is critical to many of the laboratory analytes and fasting data is required for correct interpretation of laboratory results. No primary SP age 1-11 or diabetics taking insulin by injection are required to fast. All other primary SPs age 12+ have required fasting times based on the examination session to which they are appointed. SPs appointed to a morning session are asked to fast for 9 hours while SPs appointed to an afternoon or evening session are asked to fast for 6 hours. The phlebotomist administers the fasting questionnaire to all SPs and ISIS calculates and displays the fasting time in number of hours and minutes. The phlebotomist performs the venipuncture if the SP meets the fasting requirement. If the SP has not met the fasting requirement but will meet the required fast within 30 minutes of the end of the session, the SP is asked to continue with other examination components and return to phlebotomy once the fast has been met. The coordinator reassigns the SP to phlebotomy.

The overall objective is to perform phlebotomy on SPs who have met their fast but SPs can be reassigned to phlebotomy at any time, whether they have met the fasting requirement or not. Base the decision to reassign a SP to phlebotomy on the greater goal of completing as many components as possible within the time constraints of the session with phlebotomy as the highest priority component. Sometimes a SP insists on leaving the MEC and it is preferable to get blood from a SP who has not met their fast than not to obtain any blood on the SP. The coordinator and MEC manager are able to provide the best overall assessment of the status of a particular SP and the coordinator and/or the MEC manager should make the decision to reassign an SP to phlebotomy before the fasting period ends. The coordinator and/or the MEC manager should include the phlebotomist in their discussion whenever possible so everyone understands the situation.

Guest and surplus participants do not have a required fast.

If the SP does not meet their fast, but will meet their fast within 30 minutes before the end of the session, the Return for blood draw informational text box displays.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window displays patient information: "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm", "SP ID: 878700", "Name: EPCOT, EDNA", "Age: 80 years", "Gender: Female", "Date: 01/28/2000", and "Time: 01:26 PM". Below this is a "Fasting Questionnaire" section with several questions and input fields, including "When was the last time you ate or drank anything other than plain water?", "Have you had any of the following since today at 9:00 AM?", "Coffee or tea with cream or sugar?", "Gum, breath mint", "Antacids, laxatives, or anti-diarrheals?", and "Dietary supplements such as vitamins and minerals?". A dialog box titled "Return for blood draw" is overlaid on the questionnaire, containing an information icon and the text: "I will need to have you wait until approximately 03:00 PM before I can collect your blood. I will have the Coordinator bring you back here at the right time." with an "OK" button. At the bottom of the window, there are navigation buttons (back, forward, 2 of 4), "End of Section", "Close Exam", and "Finish" buttons. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:12 PM".

Read the text to the SP. To remove the Return for blood draw text box, use the mouse to direct the mouse arrow to direct the mouse arrow to the **OK** button and left click or select [Enter].

When s/he returns to phlebotomy, open the exam, wand the SPs ID bracelet and proceed with the interview questions. If the fasting requirement will not be met by the end of the session, proceed with the venipuncture. Continue to administer the questionnaire.

Read the text exactly and record the time.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:26 PM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

Q2. Have you had any of the following

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]

Alcohol, such as beer, wine, or liquor?

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting Time: Hours Minutes

2 of 4

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 01:12 PM

Q1: When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

<p>Q1: This question elicits the last time the SP ate or drank anything and determines fasting time.</p>	<p>SPs are allowed to consume diet soda, black coffee or tea with saccharine or Equal since these have no affect on study analytes. Do not include flavored waters.</p>
--	---

Enter the response.

The screenshot shows the Phlebotomy software interface. The main window is titled "Phlebotomy" and contains a "Fasting Questionnaire" section. The questionnaire includes fields for "When was the last time you include...", "Coffee or tea with...", "Gum, breath mints, lozeng...", and "Dietary supplements such as vitamins and minerals?". A "Phlebotomy Subsystem" calendar pop-up is open, displaying "January 28, 2000 01:27:06 PM". The calendar shows the days of the week (Sun to Sat) and the dates (1 to 31). Below the calendar, there are "OK" and "Cancel" buttons. The main window also has a "Fasting Time" section with "Hours" and "Minutes" fields. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish".

Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to "AM," or "PM" and left click.

Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse

arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue administering the questionnaire. Verify the initial time response by asking the remaining questions.

Phlebotomy
 File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm
 SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:26 PM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

Q2: Have you had any of the following

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]

Alcohol, such as beer, wine, or liquor?

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting Time: Hours Minutes

2 of 4

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 01:12 PM

Q2: Have you had any of the following since (time from question 1 inserted here)?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]	Black coffee is acceptable but coffee with any additives other than saccharine or Equal are unacceptable. Include all milk products such as half and half, light cream, nonfat milk, and all other non-dairy creamers like Creamora or Coffee-Mate.
--	---

Alcohol, such as beer, wine, or liquor?	Alcohol includes all types of spirits including light beer and wine. If the answer is "Yes" clarify the response. Ask the SP to describe the activity, item consumed and the correct time.
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?	Include sugar-free gum and mints in this category. Give the SP the laminated card that lists common over-the-counter cough drops and cough and cold remedies to refresh their memory if they appear unsure about these items. If the answer is "Yes" clarify the response. Ask the SP to describe the activity, item consumed and the correct time.
Antacids, laxatives, or anti-diarrheals?	Antacids neutralize stomach acids. Laxatives stimulate evacuation of the bowels. Anti-diarrheals relieve diarrhea and cramping. Include all over-the-counter antacids, laxatives, and anti-diarrheals. Give the SP the laminated card that lists all over-the-counter antacids, laxatives, and anti-diarrheals to refresh their memory if they appear unsure about these items. If the answer is "Yes" clarify the response. Ask the SP to describe the activity, item consumed and the correct time.
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]	Vitamins refer to various relatively complex organic substances occurring naturally in plant and animal tissue. They are essential in small amounts for the control of metabolic processes. Many are available over-the-counter as multivitamin-multimineral or single-nutrient supplements like Vitamin C. Include all of these when clarifying the response to this question. Give the SP the laminated card that lists all over-the-counter vitamins, antioxidants, multivitamins, multivitamins with minerals, and therapeutics to refresh their memory if they appear unsure about these items. If the answer is "Yes" clarify the response. Ask the SP to describe the activity, item consumed and the correct time.

To enter a "Yes" or "No" response, type [Y/y] for "Yes" and [N/n] for "No." Use the up and down arrow keys to toggle between the two choices. Alternatively, use the mouse to direct the mouse arrow to the drop down arrow on the response text box, select "Yes" or "No" and left click. If "No" is entered, the next response box is highlighted. If "Yes" is entered, the time and date text boxes are highlighted. Type

in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to "AM," or "PM" and left click.

Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the button and left click.

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter].

4.11 Venipuncture Procedures

The Vacutainer® system of blood collection consists of glass or plastic tubes with color-coded stoppers containing a premeasured vacuum that provides a controlled draw. Some tubes may contain additives to prohibit coagulation or inhibit glycolysis of blood cells. Draw the tubes in the order designated by the venipuncture protocol.

The exact quantity of blood drawn into each tube varies slightly with altitude, ambient temperature, and venous pressure. Fill tubes with additives completely to ensure proper ratio of blood to additive and then mix well to distribute the additive.

Use Vacutainer® tubes at room temperature. Protect tubes from extreme temperatures and store in a cool place. It is important to note the expiration date printed on Vacutainer® tubes. Do not use expired tubes unless they are the only tubes available. Use expired tubes if they still contain a vacuum.

Indicate if using expired tubes by using the "Other, specify" comment option on the venipuncture status screen.

Document the use of each Vacutainer® type in the Supply Use Control Log. Keep a separate line in the log for each type of Vacutainer®. When opening a new box, record the date, the lot number of the box, date in use, the expiration date, and tech ID number.

4.11.1 Preparation of the Puncture Site

It is extremely important that the anticipated puncture site be thoroughly cleaned and all necessary equipment, including needles, and tubes, are kept sterile and free from contamination.

Follow the steps outlined below to prepare the puncture site.

- Place venipuncture equipment where it is readily available but not in danger of being upset. Keep extra equipment within easy reach.
- Thoroughly wash hands.
- Put on gloves.
- Place appropriate blood collection tubes in a test tube rack in the order dictated by the venipuncture protocol. If a SP exhibits nervousness, keep the tubes covered.
- Instruct the SP to sit on the exam table. **Never** attempt a venipuncture on a standing subject. Having the subject sit helps guard against any injury that might result if the subject faints. Place SPs in a supine position if it is impossible to perform the procedure sitting upright. Instruct the SP to extend the arm palm up and straight at the elbow. If the SP is a child or infant, have a medical technologist hold the SP in the proper position.
- Position the arm on the armrest or a pillow so that the veins are readily accessible and the phlebotomist is able to work in a comfortable position. Be sure that the arm is in a downward position with the elbow lower than the heart to prevent backflow.
- Inspect the arm. Use the left arm unless unsuitable. The veins of choice are those located in the antecubital area. Do not draw blood from any arm with an arterial access, such as a fistula or shunt. Also, do not draw blood from a swollen or edematous arm or an arm that has a rash or open sore.
- If the veins in the antecubital space are not suitable, look for suitable veins on the forearm.

- Apply the tourniquet several inches above the selected site.
- Select a vein that is palpable and well fixed to surrounding tissue. Palpate even when the vein is visible. Use the following technique if the veins do not distend quickly:
 1. Massage the arm from wrist to elbow to force blood into the veins;
 2. Tap the area sharply with the index and second finger two or three times to cause the veins to dilate;
 3. Allow the arm to hang at the SP's side without a tourniquet to allow the veins to fill to their capacity; and
 4. Examine the SP's other arm; sometimes the veins in one arm are larger than in the other.
 5. Check carefully for scar tissue or tendons near the vein.

Apply the tourniquet for no more than 1 minute while searching for a vein and then release the tourniquet for 2 to 3 minutes. Avoid prolonged obstruction of blood flow by the tourniquet because it is uncomfortable for the SP and may alter certain results (e.g., cholesterol).

- Reapply the tourniquet when ready to perform the venipuncture.
- Cleanse the area with an alcohol wipe. Do not touch the side of the alcohol wipe that is in contact with the puncture site. Cleanse the area using a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed.
- Repeat with a second alcohol wipe. Dry the cleansed area using a 2x2-gauze pad. The area should be completely dry before performing the venipuncture to reduce the burning sensation caused by alcohol penetrating the skin.
- Determine the correct needle size. Use a 21g, 23g or 25g butterfly or a 21g multisample needle depending on the condition of the SP's veins. The 21g butterfly should be suitable for most SPs. If the SP's veins appear fragile or small, use a 23g or 25g butterfly. If the SP is obese, use a 21g multisample needle.

4.11.2 Venipuncture Technique for the Vacutainer® System With a Safety-Lok Blood Collection Set

1. Prepare the blood collection set. Open the package and attach the needle holder.
2. Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.

3. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of the phlebotomist's less dominant hand.
4. Approach the vein in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
5. Push the needle firmly and deliberately into the vein. If the needle is in the vein, a small amount of blood will appear in the butterfly tubing. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the butterfly tubing. If no blood enters the tube and no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for three minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again if using the same arm for a second try.
6. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
7. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the dominant hand free to pick up and change the tubes. If left-handed, do the reverse.
8. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
9. Immediately invert the lavender, gray, blue, and ACD tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender, gray, and light blue top tubes on the rocker. Gently invert the ACD tubes 5-6 times and place in rack. Do not invert or agitate the red top tubes.
10. Insert the next tube and push it down gently onto the adapter.
11. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
12. Fill tubes in the proper order, according to the protocol.
13. When the last tube has filled, remove the needle in a smooth quick motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. Withdraw the blood collection set by grasping the translucent yellow safety shield grip area with the thumb and index finger. With the opposite hand, grasp tubing between thumb and index finger. Push the yellow shield forward until the safety shield is locked in place.

14. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

4.11.3 Venipuncture Technique for the Eclipse Multisample Needle

1. Prepare the needle. Holding both colored shields, twist and remove the white shield. Screw the needle onto the holder. Rotate safety shield back. Twist and pull needle shield straight off.
2. Place the first tube into the holder, securing it slightly, but not penetrating the stopper.
3. Ask the SP to make a fist. Do not have the SP pump his/her fist since this may alter certain results.
4. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of the phlebotomist's less dominant hand.
5. Approach the veins in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
6. Push the needle firmly and deliberately into the vein. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the Vacutainer® tube. If no blood enters the tube but no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again, if using the same arm for a second try.
7. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
8. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the right (dominant) hand free to pick up and change the tubes. If left-handed, do the reverse.
9. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
10. Immediately invert the lavender, gray, blue, and ACD tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender, gray, and light blue top tubes on the rocker. Gently invert the ACD tube 5-6 times and place in rack. Do not invert or agitate the red top tubes.
11. Insert the next tube and push it down gently onto the adapter.

12. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
13. Fill tubes in the proper order, according to the protocol.
14. When the last tube has filled, remove the needle in a quick, smooth motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. Firmly push forward on the safety shield, lock into place and inspect. After withdrawing the needle, immediately press clean gauze squares over the venipuncture site.
15. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

4.11.4 Concluding the Venipuncture

1. Have the SP place two fingers on the gauze to hold it in place, then ask the SP to raise the arm straight up, elevating the arm above the level of the heart, **without** bending the elbow. The SP should remain in this position for 2 to 3 minutes to help prevent hematomas.
2. Label each tube collected with the computer generated bar code labels. The time prints on the label.
3. Dispose of all visibly contaminated waste in a biohazard bag.
4. Check the venipuncture site for clotting. Apply an adhesive bandage over the gauze pad. Instruct the SP to remove it in no less than 45 minutes if the bleeding has stopped. Also, suggest that the SP sit quietly for a few minutes. If bleeding continues, keep direct pressure on the site for 5 minutes or more.
5. Report any adverse reaction to the venipuncture to the physician immediately and document it by entering an explanation in the Comments section of the Venipuncture Data Entry Screen and by recording the event in the Unusual Occurrence Log.
6. If the SP has been fasting, offer them a snack and juice. Escort them back to the coordinator.
7. Allow two venipuncture attempts with the SP's verbal consent or with the parent's consent if a SP is a child or an infant.
8. If a SP faints or becomes ill causing the termination of procedure without collecting all of the blood, repeat the procedure with the SP's consent after the SP has recovered.

4.12 Pediatric Venipuncture

Pediatric venipuncture requires special techniques. Because the phlebotomist will be dealing with children of different age ranges and levels of understanding, it is important to be able to recognize at what stage a child is in early in the venipuncture process.

Infants and toddlers, aged 1 to 2 years, experience the world through their senses and do not have much of a language base. Therefore, verbal explanations are virtually meaningless. Expect crying and resistance from the start, even at the first touch. Restrain children of this age by enlisting the assistance of a medical technologist. The best techniques to use with these children are to maintain a reassuring tone, to reinforce that the child is a good boy or girl, and to draw the blood quickly. Be sure to reassure the child after the procedure and to use cartoon adhesive bandages and stickers when finished.

Preschoolers, aged 2 to 6 years, think concretely and in absolute terms; things are good or bad, right or wrong, painful or not painful. For these children, use simple, concrete terms when describing the procedure and its consequences. Always be honest. Try to avoid the words "take" which implies remove, "test" that implies pass or fail, and "fix" which implies broken. With children of this age, it is still important to emphasize that the child is a good boy or girl and to use colorful adhesive bandages and stickers. Try using distractions, such as holding something, counting things in the room, and breathing deeply. These techniques may work with the older children in this age group. The phlebotomist may have a medical technologist assist with most of these children.

School-aged children, 7 to 12 years, have a better grasp of language and view the world more realistically. They understand past and future, that is, "this will be over soon," and relative terms, such as "this will hurt a little or a lot." Detailed explanations of the procedure are extremely effective. Again, always be honest. Include demonstrations, that is with a doll, whenever possible. Having the child help during the procedure distracts the child as well as letting him or her have some control. Be sure to reinforce how big a help he/she was after the draw. Give the child realistic choices, such as which arm to choose. The phlebotomist may need to consider having a medical technologist assist with some children even at this stage. Adhesive bandages continue to be important.

Although adolescents, ages 12 to 18 years old are beginning to think abstractly they often regress when placed in stressful situations. It is best to assume that they will act younger than their chronological age. However, it is still very important to address the adolescent as an adult and not as a

child. Provide detailed explanations and inform the adolescent that the best technique is being used. It is very important that the adolescent maintains control of the situation; therefore, give the child some choices as well as allow him or her to help if offered. Be very clear about rules, such as remaining motionless, but do not restrain the child.

Pediatric venipunctures are most successful when children are immobile, the veins are maximally distended, and all supplies are handy. Many children prefer a cloth or gauze under the tourniquet to prevent pinching of skin.

The usual site for pediatric venipunctures is the antecubital fossa. Most venipunctures in children are successful using a 23 or 25-gauge butterfly needle. Follow the general guidelines in Section 4.11 for performing venipunctures.

4.13 Recording the Results of the Venipuncture Procedure

Immediately after completing the venipuncture, enter the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.

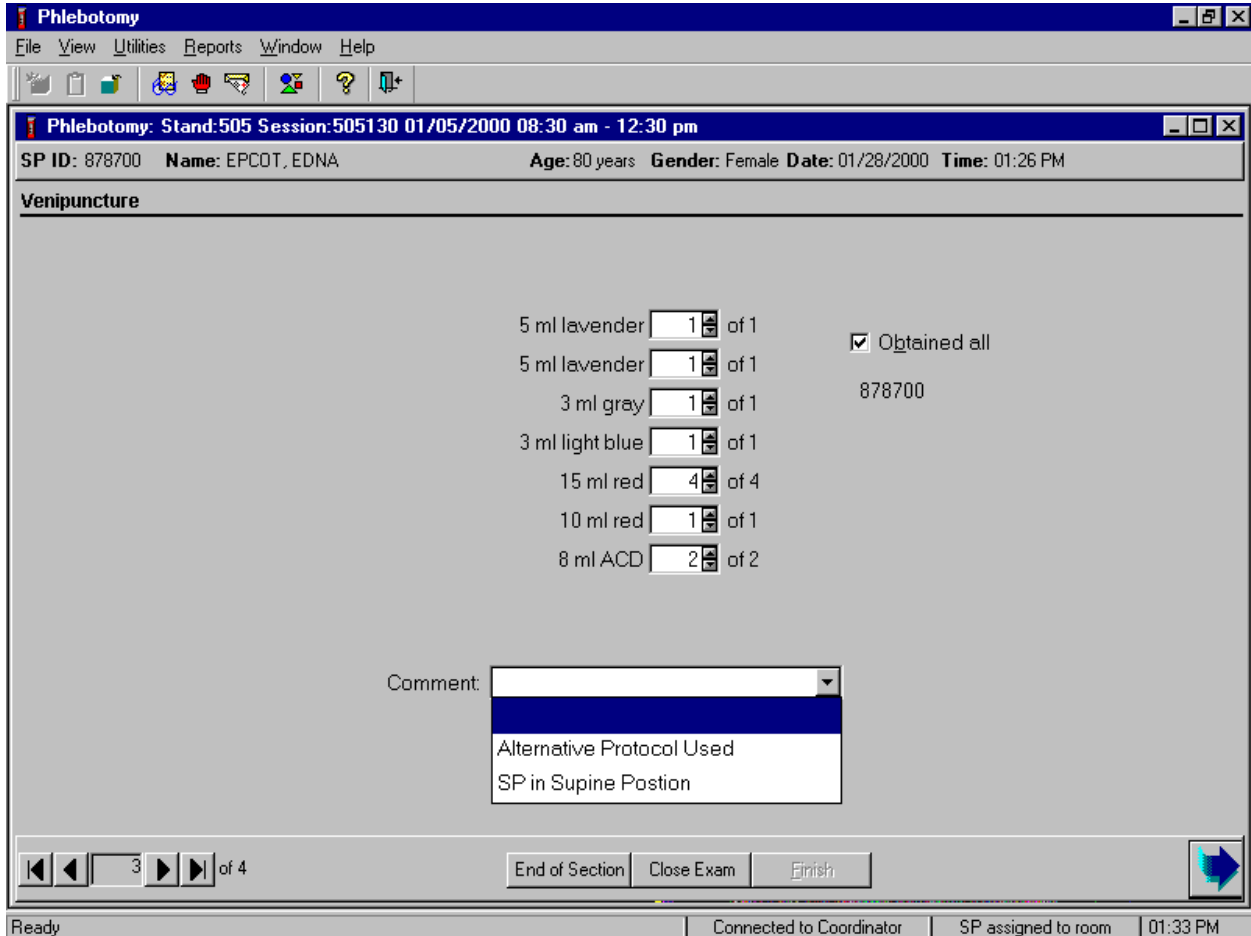
The screenshot shows the Phlebotomy software interface. The title bar reads "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Window, and Help. The toolbar contains various icons for file operations and navigation. The main window displays patient information: SP ID: 878700, Name: EPCOT, EDNA, Age: 80 years, Gender: Female, Date: 01/28/2000, Time: 01:26 PM. Below this is a section titled "Venipuncture" with a list of tubes and their status:

Tube Type	Quantity	Status
5 ml lavender	1 of 1	<input checked="" type="checkbox"/> Obtained all
5 ml lavender	1 of 1	<input type="checkbox"/>
3 ml gray	1 of 1	<input type="checkbox"/>
3 ml light blue	1 of 1	<input type="checkbox"/>
15 ml red	4 of 4	<input type="checkbox"/>
10 ml red	1 of 1	<input type="checkbox"/>
8 ml ACD	2 of 2	<input type="checkbox"/>

Below the list is a "Comment:" field with a dropdown arrow. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:33 PM".

To record all tubes as filled or obtained, use the mouse to direct the mouse arrow to the "Obtained all" check box and left click, or type [ALT] [B]. This records a check mark in the box and marks all tubes as obtained. To mark individual tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number of each tube up or down or type the correct number using the numeric keys.

Document circumstances where the alternative protocol was used or the SP was in the supine position.



To record either "Alternative Protocol Used" or "SP in Supine Position" comments in the Comment text box, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type [A/a] for "Alternative Protocol Used" or [S/s] for "SP in Supine Position" and [Enter], or use the up and down arrows to toggle between the two choices and [Tab.]

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

4.14 Final Venipuncture Procedures

Corresponding labels automatically print for the tubes drawn. Label the ACD tubes with the label containing the Vessel ID. Label all other tubes with bar coded labels with the bar code vertical on the tube.

Place the rack containing the blood collection tubes in the pass through window located over the sink. Alternatively, deliver the rack to the laboratory, and distribute as described below:

- Place the lavender, gray, and blue tubes on the rocker located next to the centrifuge.
- Place the red top and ACD tubes upright in the test tube rack located next to the centrifuges in the laboratory.

Place all used needles in a sharps container and all soiled supplies in a biohazard bag. If blood has spilled on the table or the arm board, wash the area with a Hype-Wipe (10% solution of bleach and water) then prepare the workstation for the next SP. Routinely disinfect the table or arm board with 1% bleach solution. Wash hands and change gloves before approaching the next SP.

4.15 Venipuncture Status

Verify the venipuncture status.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar is a header bar with the text "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Below the header bar is a patient information bar with the text "SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:26 PM". Below the patient information bar is the "Venipuncture Status" section. This section contains a "Status" label, three radio buttons labeled "Complete", "Partial", and "Not Done", a "Comments" label with a dropdown menu, and an "Other text" label with a text input field. At the bottom of the window is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", and a blue arrow button. Below the navigation bar is a status bar with the text "Go to the Section Status Screen", "Connected to Coordinator", "SP assigned to room", and "01:33 PM".

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

SP ID: 878700 Name: EPCOT, EDNA Age: 80 years Gender: Female Date: 01/28/2000 Time: 01:26 PM

Venipuncture Status

Status

Complete
 Partial
 Not Done

Comments [dropdown menu]

Other text [text input field]

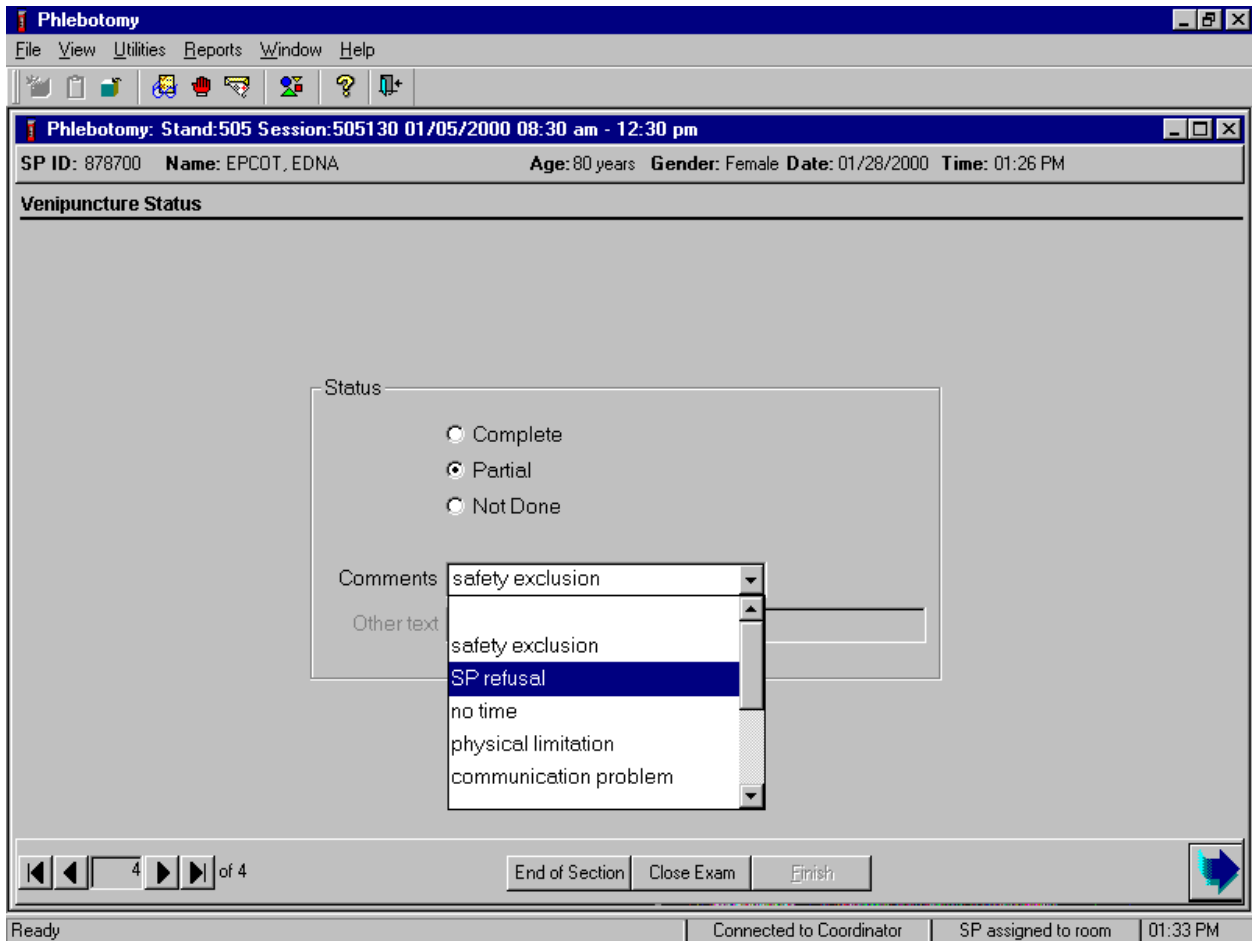
4 of 4

End of Section Close Exam Finish

Go to the Section Status Screen Connected to Coordinator SP assigned to room 01:33 PM

The venipuncture status is complete if all tubes were collected.

Comment codes are used to explain Partial and Not Done status codes.



Choose and enter the appropriate comment code when the venipuncture section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

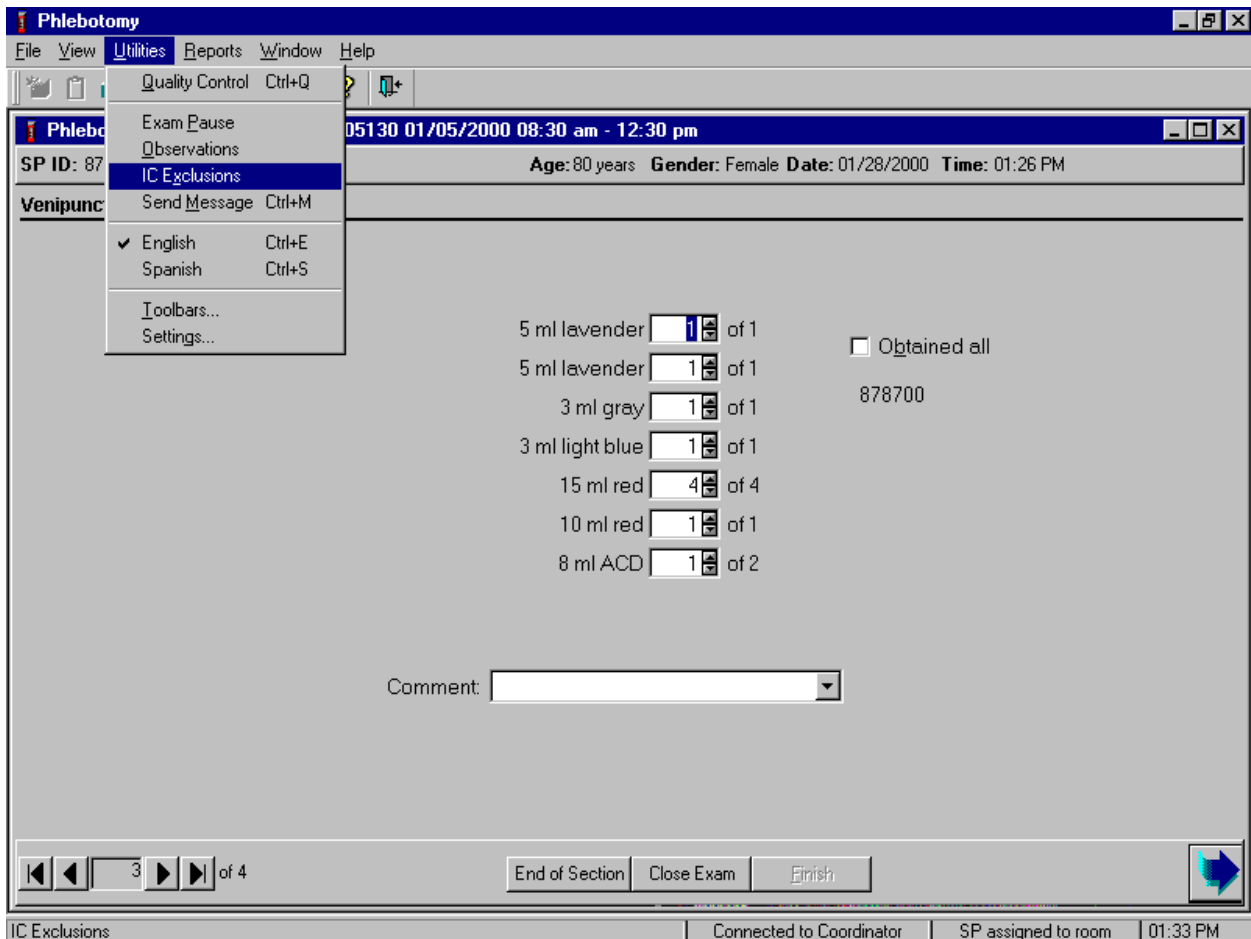
Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	The SP refuses to have his/her blood collected. This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator will code the exam. If the SP refuses after starting the exam, the examiner will code the exam.
no time	Not applicable
physical limitation	SP is unable to have the test due to a physical problem or the veins collapsed after the venipuncture was begun.
Communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable.
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
Interrupted	The exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.
SP did not meet fast	The SP did not meet the required fasting time prior to 30 minutes before the end of the session.
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to progress to the next section (TB) or select [Enter] when this blue arrow is highlighted.

4.16 Informed Consent Exclusions

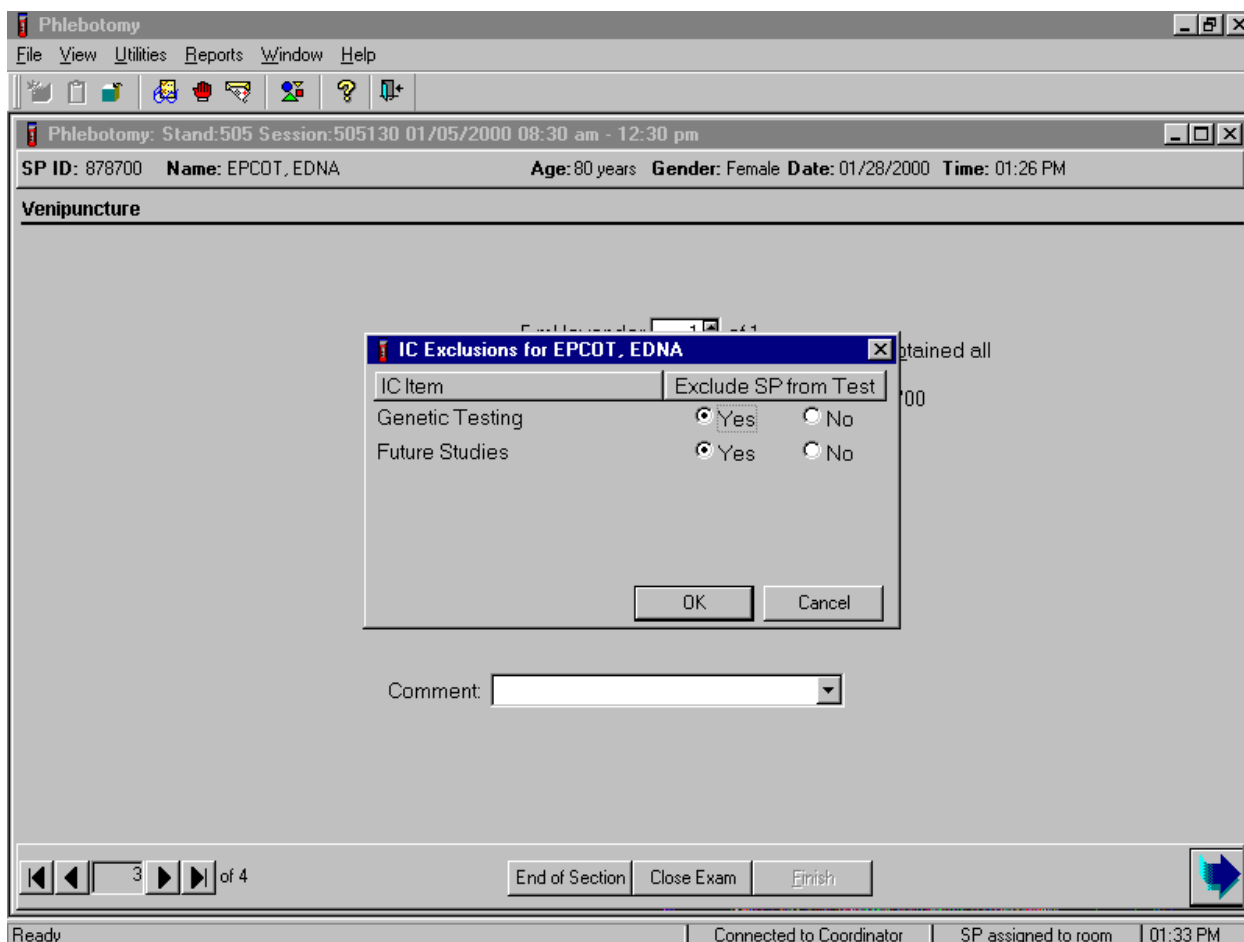
If at any time during the venipuncture procedure the SP indicates he/she does not want his/her blood tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, gonorrhea, and herpes), genetics testing, or future studies, enter this information using the Exclusions screen.

Access the IC Exclusions module.



To access the IC (informed consent) Exclusions module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {IC Exclusions}, and left click, or type [Alt] [U], [X].

The IC Exclusions window displays.

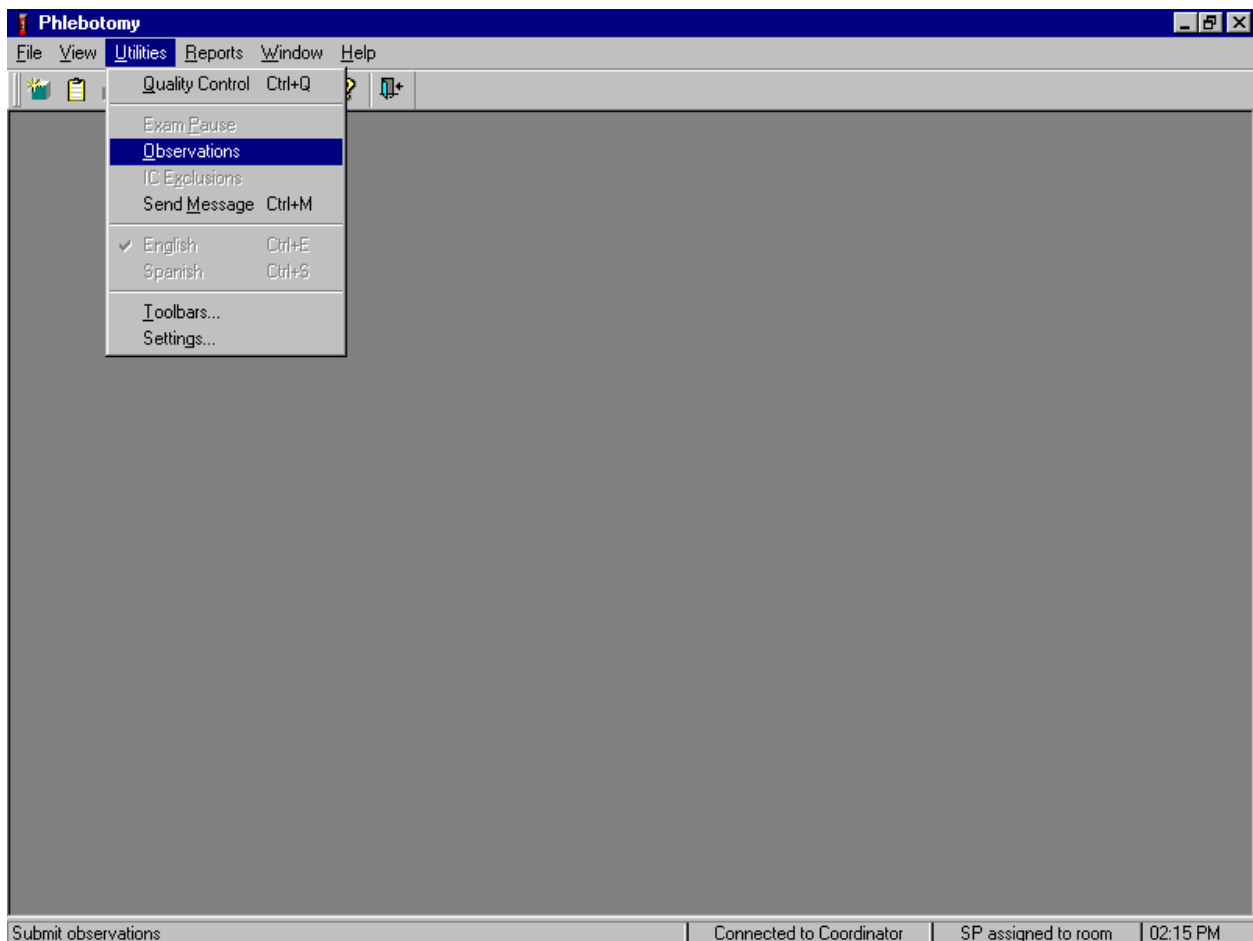


Record each item as directed by the SP. To mark each item, use the mouse to direct the mouse arrow to the "Yes" or "No" radio button and left click. To record these actions and save them to the database, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To cancel these actions without saving the data to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

4.17 Observations

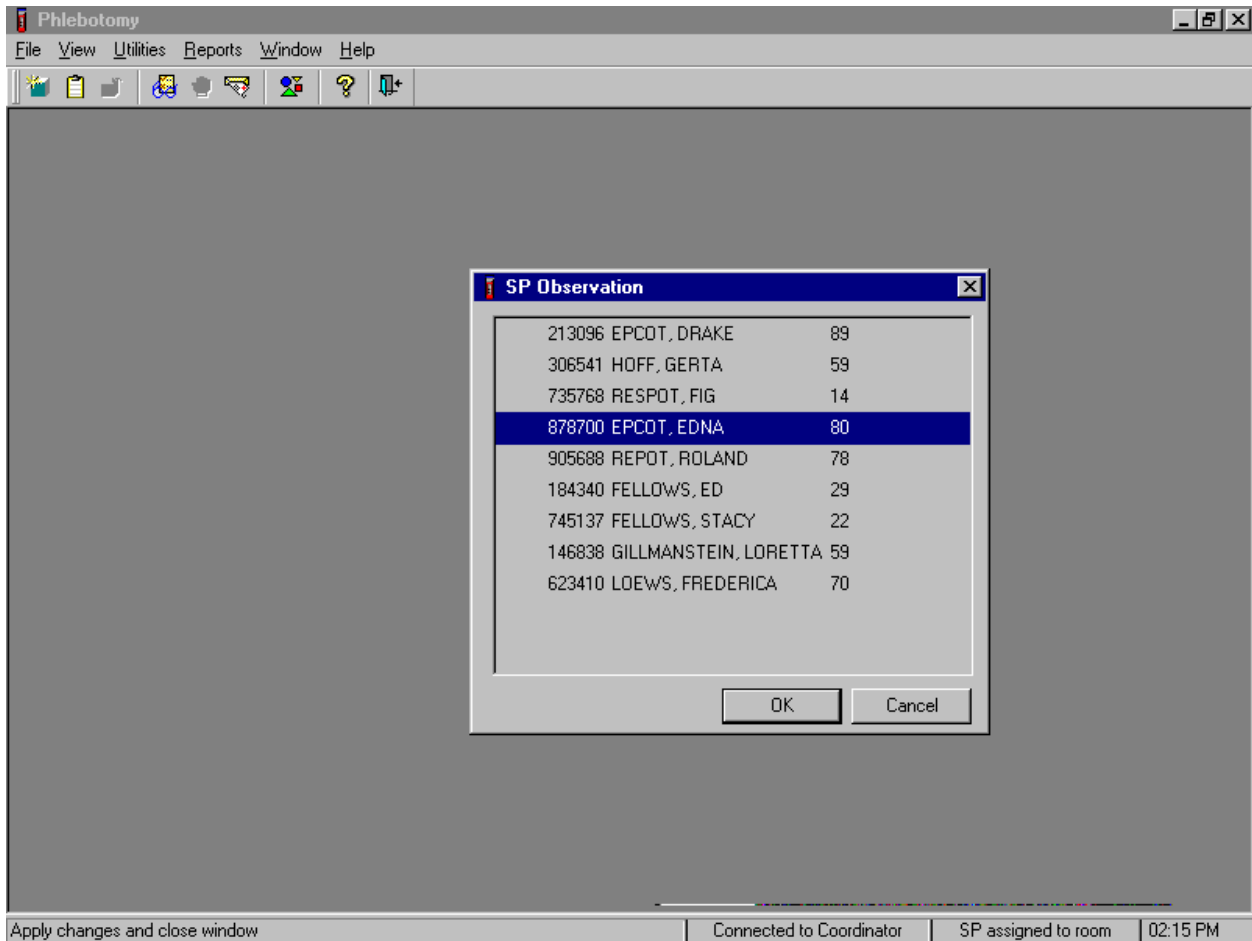
Send confidential observations to the MEC physician. Send an observation on any SP scheduled into the MEC session or the SP currently assigned to the component.

Send an observation on any SP scheduled into the MEC session. Access the observation function.



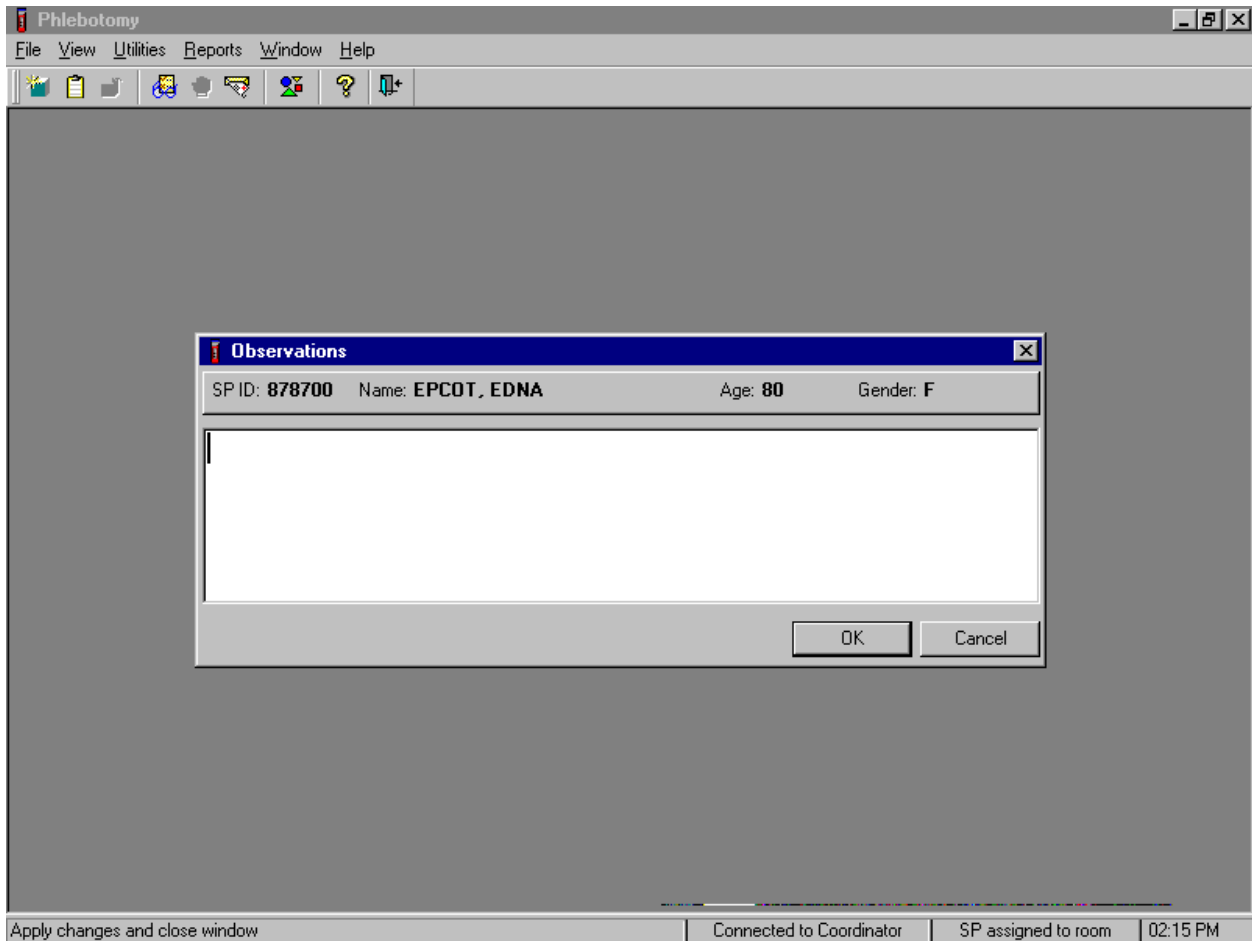
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U], [O].

Select or highlight the correct SP.



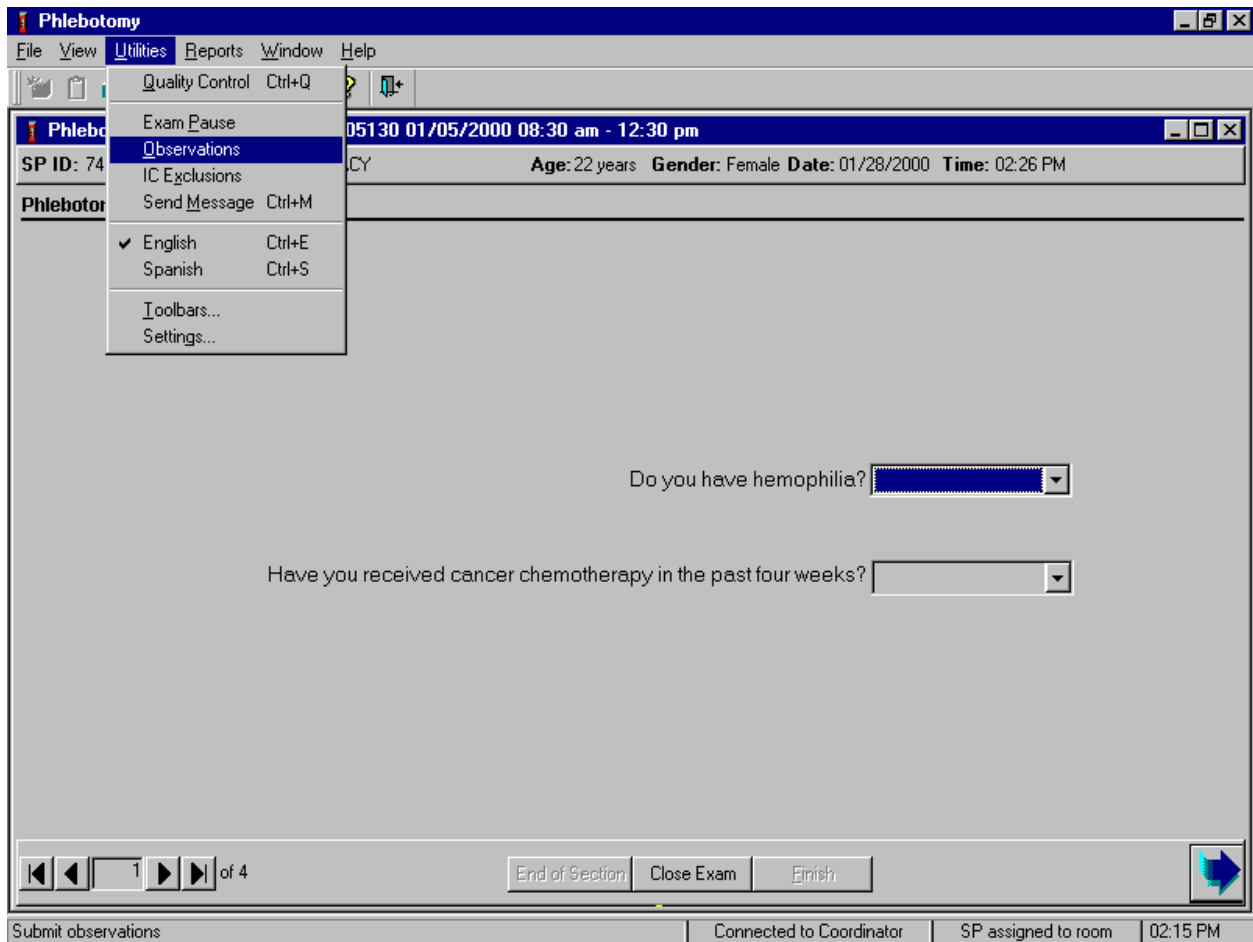
To select or highlight a SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The observation window displays.



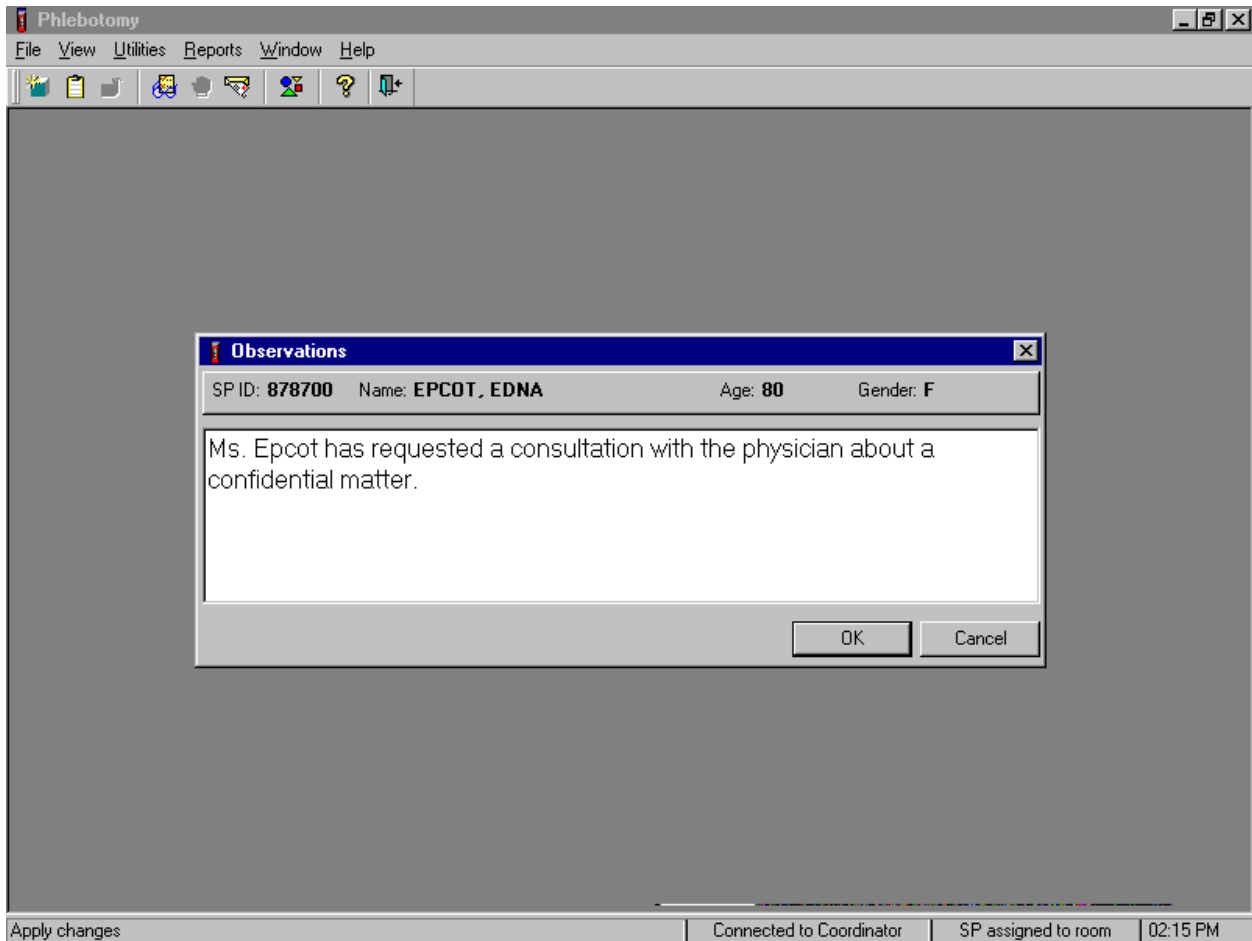
The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Enter an observation on the SP currently assigned to the component.



To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations} and left click, or type [Alt] [U], [O].

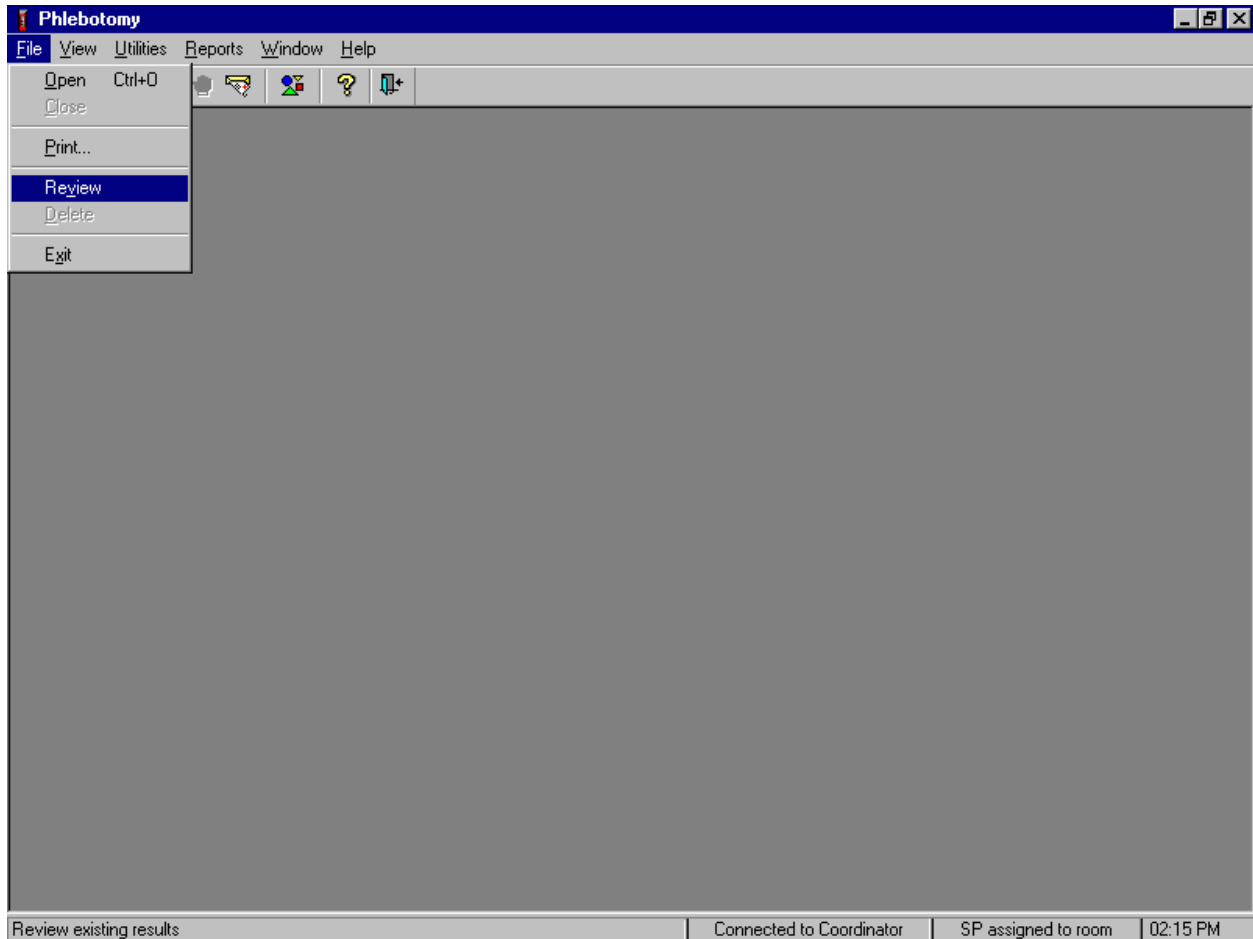
The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

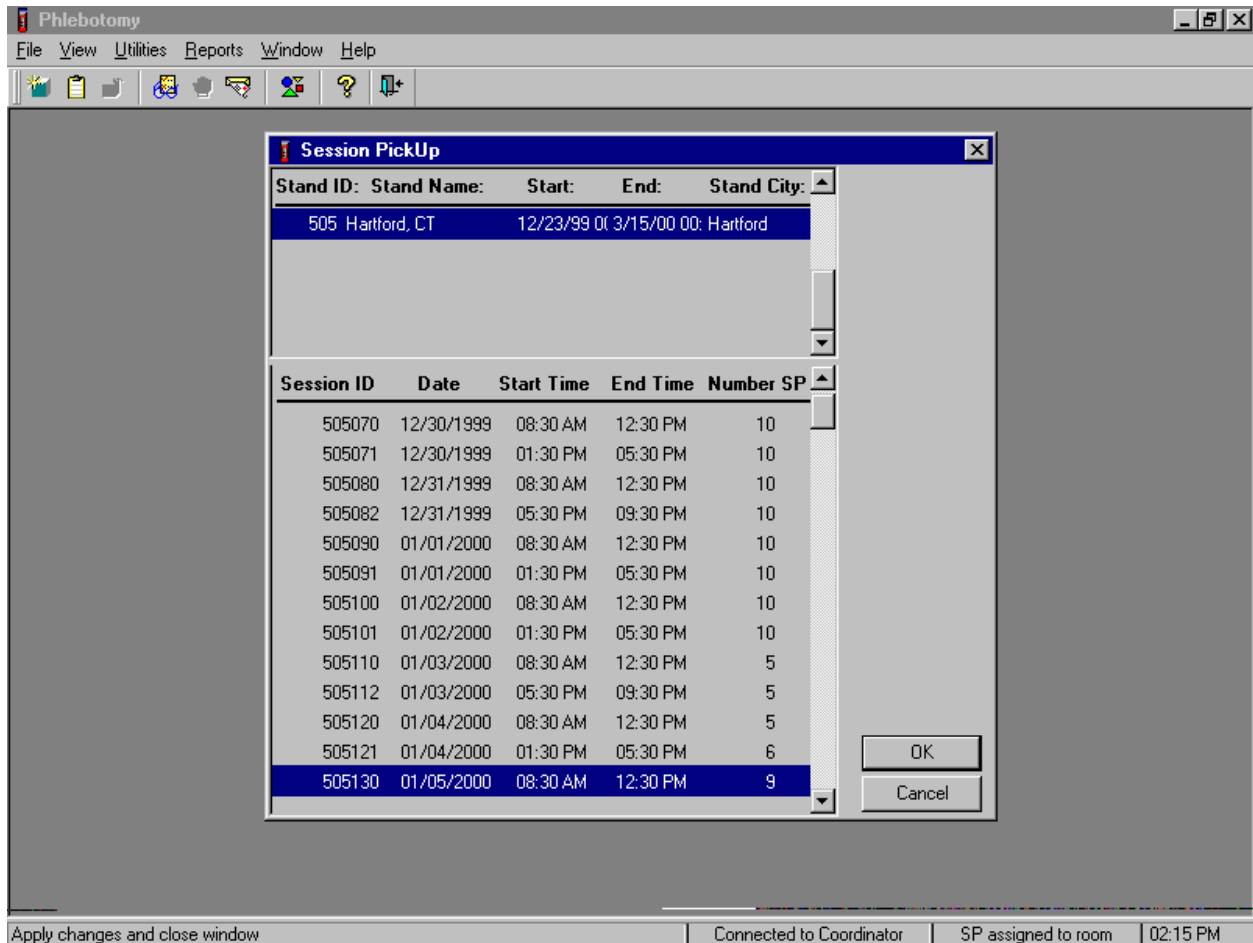
4.18 Review an Exam

Review a completed exam. Access the Review module.



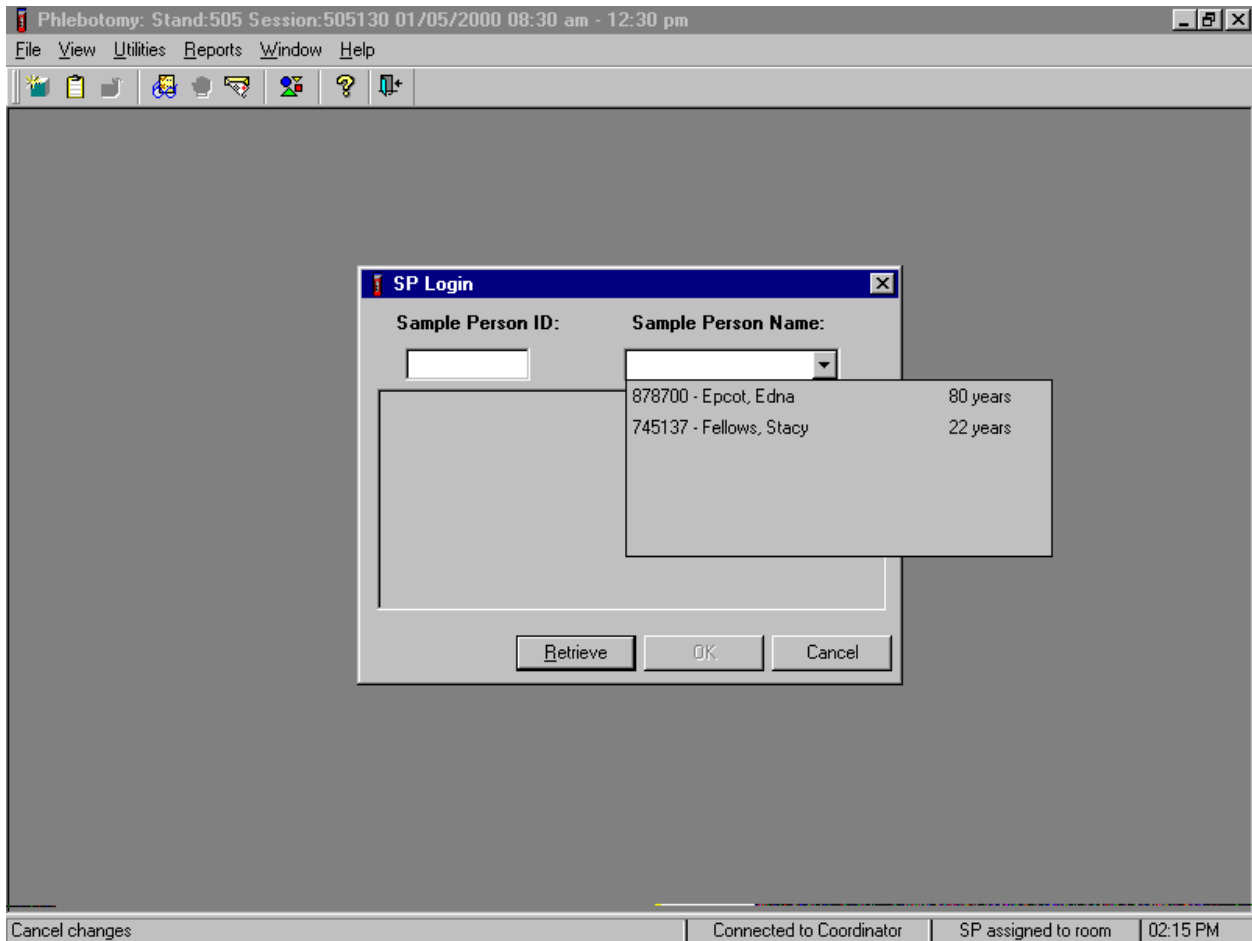
To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F], [V]. The Session PickUp list displays.

Select the session.



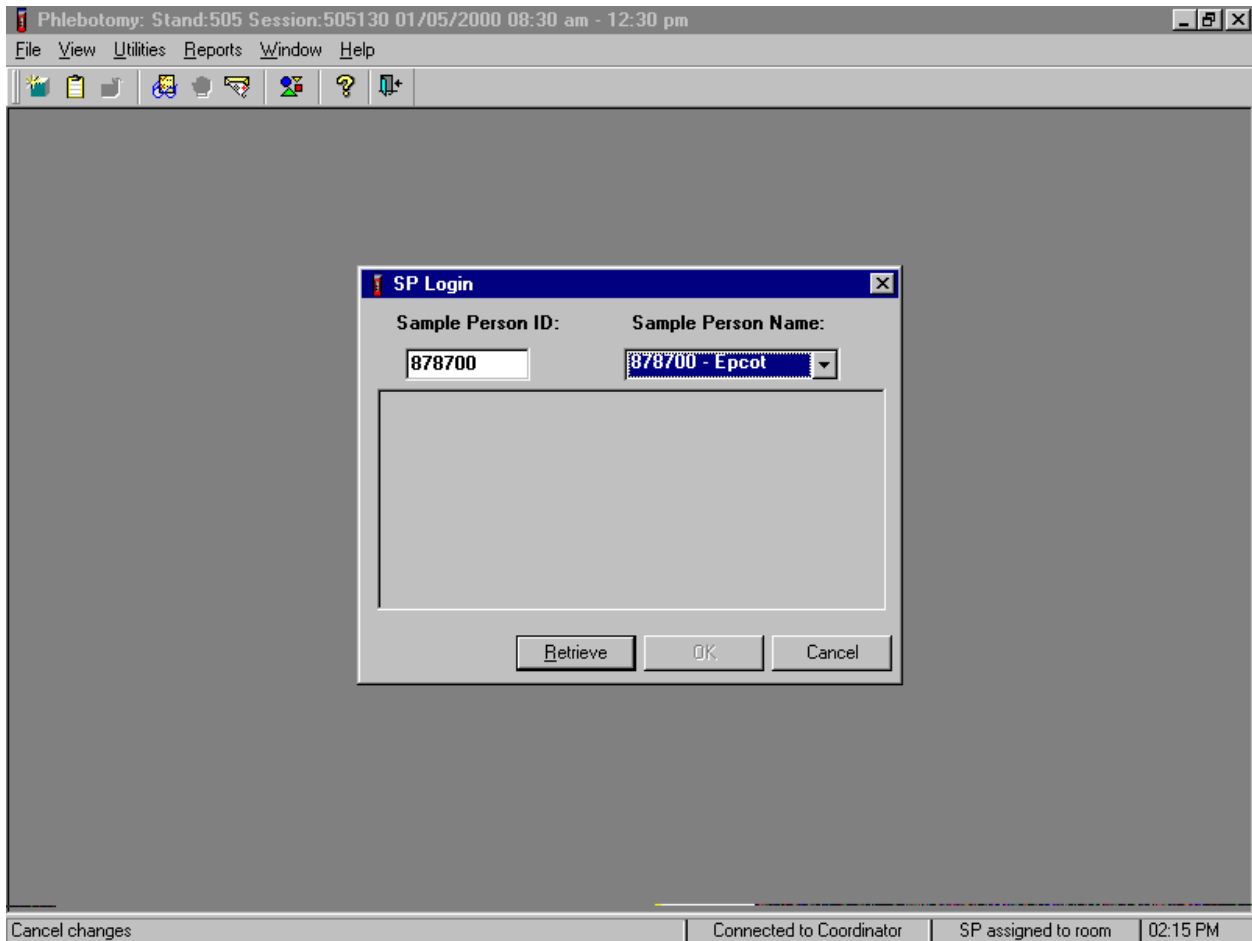
The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Select the SP.



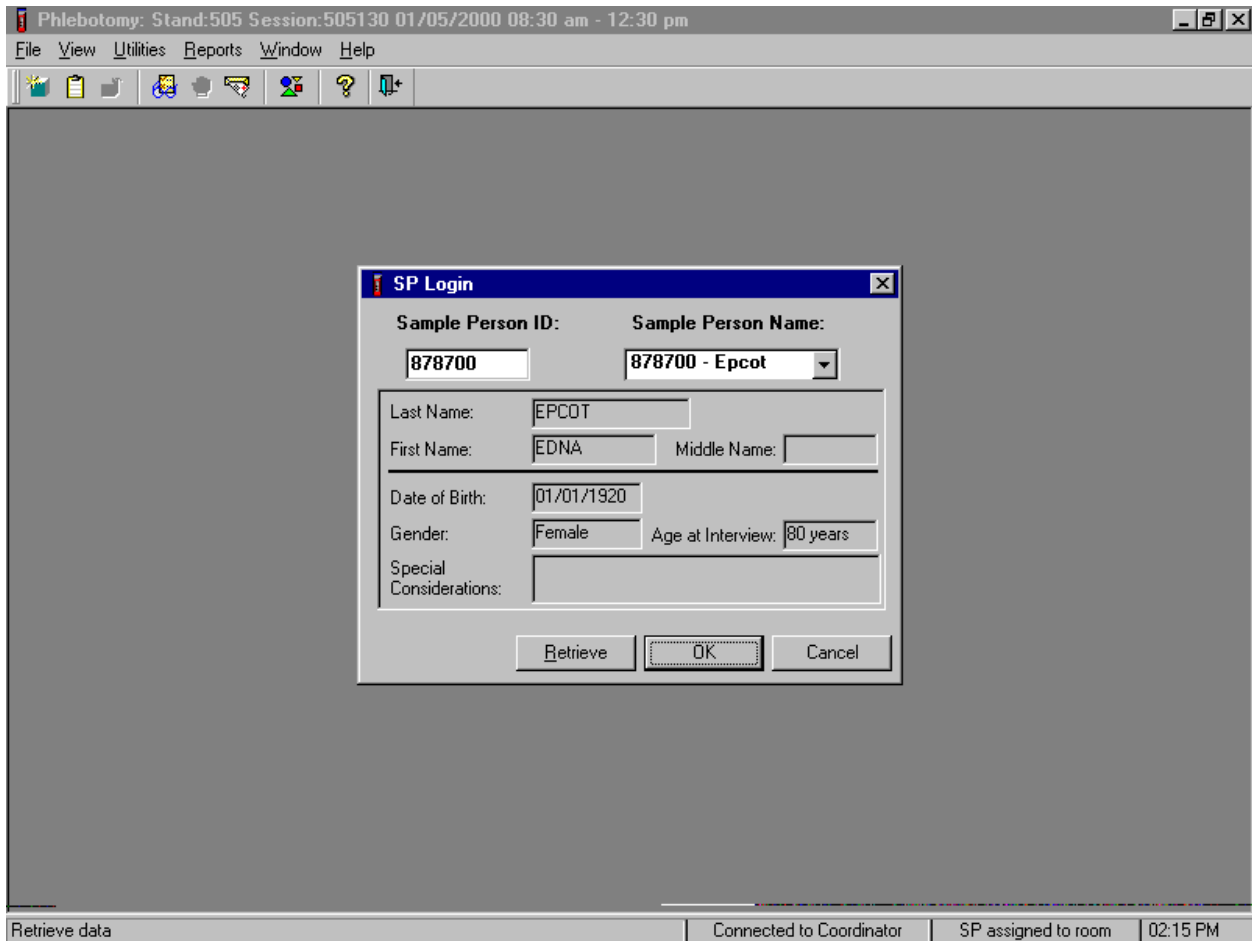
The SP Login window displays. To view a list of previously examined SPs, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.



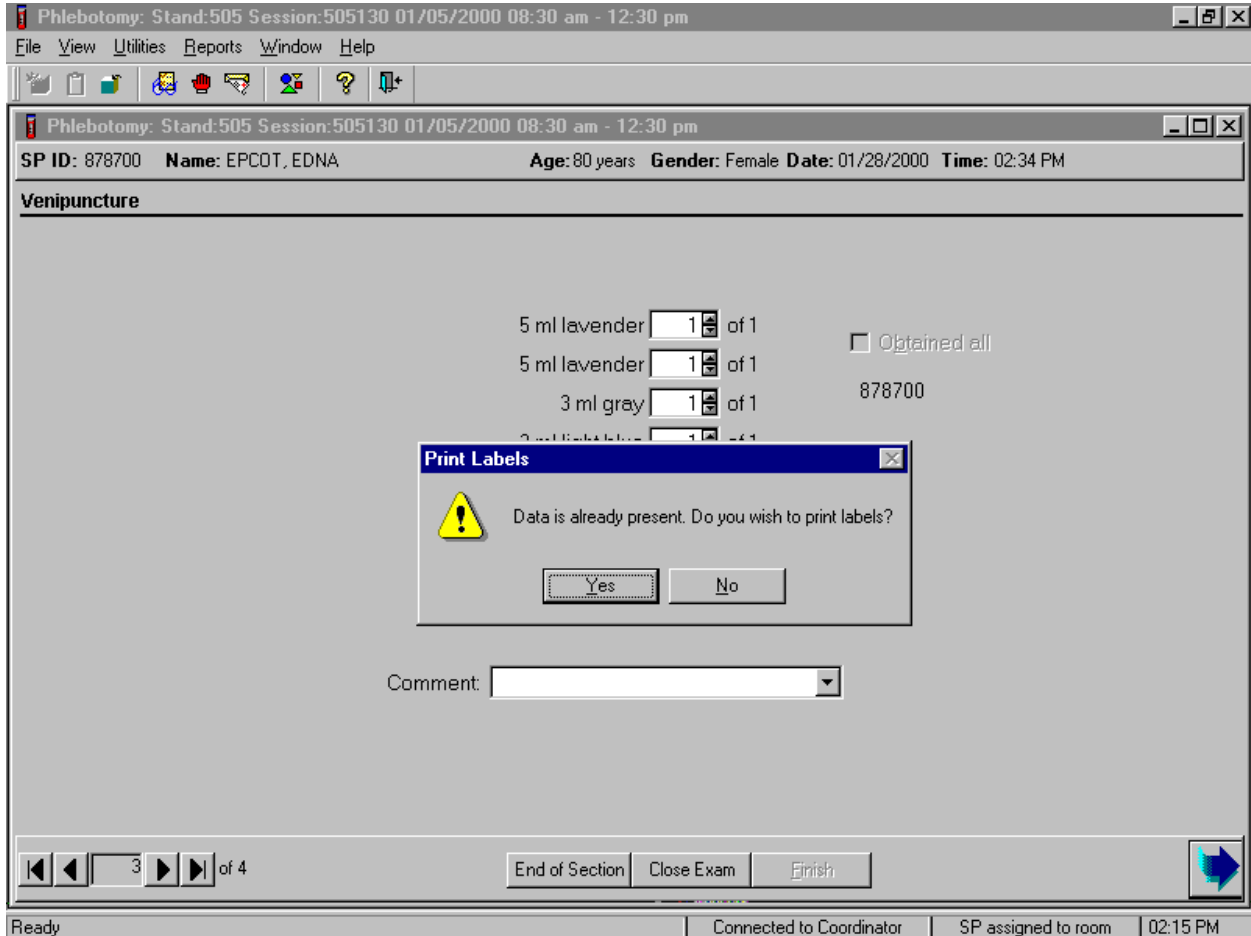
The Sample Person ID and Sample Person Name text boxes fill in with the SP ID and the SP ID and last name. To continue, use the mouse to direct the mouse arrow to the **Retrieve** button and left click, or select [Enter]. To exit, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue to select the SP.



Once the **Retrieve** button is selected, the remaining data in the SP Login box fills in. To move forward and to review the exam, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. The phlebotomy exam screens with results are displayed. To progress through the screens, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

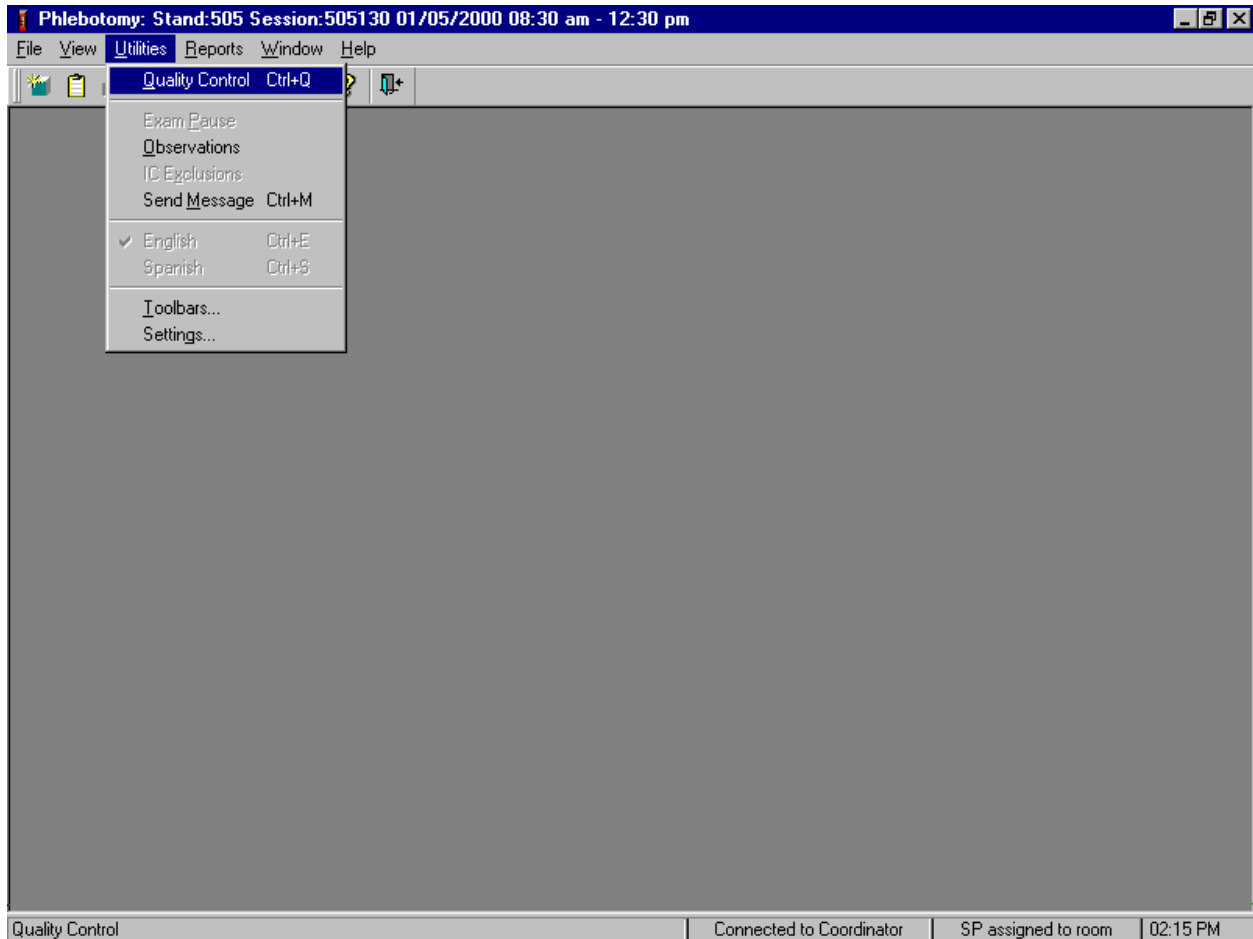
After the venipuncture protocol screen is displayed and the bright blue arrow in the bottom right hand corner is selected, a Print Labels message text box displays.



The Print Labels informational message text box displays the following message; "Data is already present. Do you wish to print labels?" To reprint the labels, use the mouse to direct the mouse arrow to the **Yes** button and left click, or select [Enter]. To decline the opportunity to reprint labels, use the mouse to direct the mouse arrow to the **No** button and left click. The venipuncture status window displays. To finish, select [Enter] or use the mouse to direct the mouse arrow to the **End of Section** button and left click.

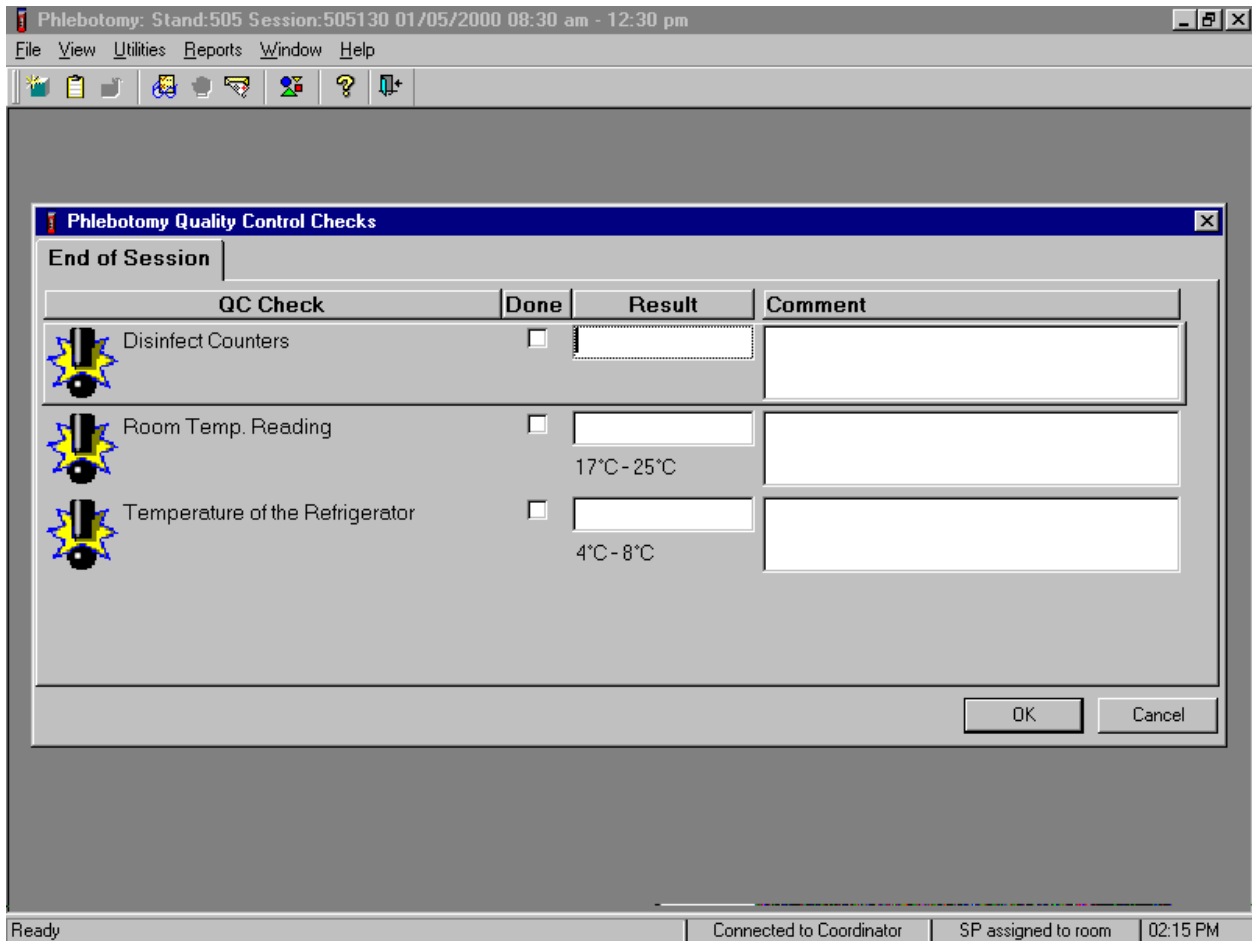
4.19 Phlebotomy Quality Control

Perform phlebotomy quality control at the end of each session.






To access the phlebotomy QC module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U], [Q] or [Ctrl] [Q].

Record the quality control activities. Mark each Done check box with a check mark.






The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Inside, there is a sub-dialog box titled "Phlebotomy Quality Control Checks" with a tab labeled "End of Session". The dialog contains a table with the following structure:

QC Check	Done	Result	Comment
 Disinfect Counters	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
 Room Temp. Reading	<input type="checkbox"/>	<input type="text"/> 17°C - 25°C	<input type="text"/>
 Temperature of the Refrigerator	<input type="checkbox"/>	<input type="text"/> 4°C - 8°C	<input type="text"/>

At the bottom right of the dialog are "OK" and "Cancel" buttons. The main window's status bar at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:15 PM".

To record a check mark in the Disinfect Counters check box, use the mouse to direct the mouse arrow to the check box and left click, then select [Tab] to move to the Result box. Type "Yes" or "Not Done" in the Disinfect Counters Comment text box and then [Tab] to add free form text explaining why the counters were not disinfected for any "Not done" response.

Continue entering the QC.

QC Check	Done	Result	Comment
 Disinfect Counters	<input checked="" type="checkbox"/>		
 Room Temp. Reading	<input checked="" type="checkbox"/>	22 17°C - 25°C	
 Temperature of the Refrigerator	<input checked="" type="checkbox"/>	12 4°C - 8°C	Notified MEC manager, moved supplies to laboratory.

To record a check mark in the Room Temp Reading check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result text box. Enter the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (17-25°C), document the actions taken to resolve the situation in the Comment text box. Select [Tab] to move to the next QC item. To record a check mark in Temperature of the Refrigerator check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result box. Enter the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (4-8°C), document the actions taken to resolve the situation in the Comment text box. To save these actions in the database, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the QC module without

saving these actions in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

4.20 Red Cross Procedures for Handling Vasovagal Reactions

"Fainting" is a partial or complete loss of consciousness. This is due to a reduced supply of blood to the brain for a short time. Occasionally, a person collapses without warning. Recovery of consciousness usually occurs when the victim falls. Injury may occur from the fall. To prevent a fainting attack, a person who feels weak and dizzy should lie down or bend over with his head at the level of his knees.

- Signs and symptoms include:
 1. Extreme paleness;
 2. Sweating;
 3. Coldness of the skin;
 4. Dizziness;
 5. Numbness and tingling of the hands and feet;
 6. Nausea; or
 7. Possible disturbance of vision.

If at any time during the venipuncture procedure the SP exhibits any of the manifestations listed above, conclude the venipuncture immediately, and perform the first aid procedures listed below.

- Place the SP in a supine position.
- Loosen any tight clothing and keep crowds away.

If the SP vomits roll him/her onto his/her side or turn his/her head to the side and, if necessary, wipe out his/her mouth with your fingers, preferably wrapped in cloth.

- Maintain an open airway.

- **Do not** pour water over the SP's face because of the danger of aspiration; instead, bathe his/her face gently with cool water.
- **Do not** give any liquid unless the SP has revived.
- Examine the SP to determine if he/she has suffered injury from falling.
- Seek medical assistance. Do not leave the SP unattended. Call for assistance or use the intercom to speak to the coordinator. Observe the SP carefully afterward because fainting might be a brief episode in the development of a serious underlying illness¹.

4.21 How to Deal With System Failure

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibit 4-7). Complete a Phlebotomy worksheet for each SP while conducting the exam. Enter the results after the system is operational.

¹ From *Standard First Aid and Personal Safety*, Second Edition, the American Red Cross, New York: Doubleday and Company, Inc., 1981, pp. 173-174.

Exhibit 4-7. Phlebotomy worksheet - English

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

SP ID _____



Phlebotomy Interview		Responses <u>Yes, No, Refused, Don't Know</u>	
Do you have hemophilia?			
Have you received cancer chemotherapy in the past four weeks?			
Fasting Questionnaire		Record time and date	
Q1. When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal]			
Confirmation Question: Q2. Have you had any of the following since {insert time from Q1 here}?		Responses <u>Yes, No</u>	If Yes, record time and date
Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]			
Alcohol, such as beer, wine, or liquor?			
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?			
Antacids, laxatives, or anti-diarrheals?			
Dietary supplements such as vitamins and minerals? [Include multi-vitamins and single nutrient supplements.]			
Primary SP Protocol	Second Exam SP Protocol	# Filled	Not Filled 
3 mL lavender (1 age 1-11)			
5 mL lavender (1 age 3-11, 2 age 12+)	5 mL lavender (2 age 12-69)		
3 mL gray (morning only 1 age 12+)	3 mL gray (morning only 1 age 12-69)		
3 mL light blue (1 age 40+)	3 mL light blue (1 age 40-69)		
3 mL red (2 age 1-2)			
7 mL red (2 age 3-5)			
15 mL red (4 age 6-11)	15 mL red (2 age 12-69)		
10 mL red (1 age 12+)			
8 ml ACD (2 age 20+)			
	7-mL gray (2 age 20-59)		
Comments:			

Exhibit 4-8. Phlebotomy worksheet - Spanish

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

SP ID _____

Phlebotomy Interview		Responses <u>Yes, No, Refused, Don't Know</u>	
¿Tiene hemofilia?			
¿Ha recibido algún tratamiento para el cáncer en las cuatro semanas pasadas??			
Fasting Questionnaire		Record time and date	
Q1. ¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua sola? [No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o "Equal".]			
Confirmation Question: Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}?		Responses <u>Yes, No</u>	If Yes, record time and date
¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.]			
¿Alcohol, tal como cerveza, vino o licor?			
¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado?			
¿Antiácidos, laxantes, o antidiarréicos?			
¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.]			
Primary SP Protocol	Second Exam SP Protocol	# Filled	Not Filled 
3 mL lavender (1 age 1-11)			
5 mL lavender (1 age 3-11, 2 age 12+)	5 mL lavender (2 age 12-69)		
3 mL gray (morning only 1 age 12+)	3 mL gray (morning only 1 age 12-69)		
3 mL light blue (1 age 40+)	3 mL light blue (1 age 40-69)		
3 mL red (2 age 1-2)			
7 mL red (2 age 3-5)			
15 mL red (4 age 6-11)	15 mL red (2 age 12-69)		
10 mL red (1 age 12+)			
8 ml ACD (2 age 20+)			
	7-mL gray (2 age 20-59)		
Comments:			

5. URINE SPECIMEN COLLECTION AND URINE, DENTAL SALIVA, AND HAIR PROCESSING AND STORAGE

5.1 Introduction

The purposes of urine collection and processing are to collect sufficient urine from primary SPs age 6 years and older to be able to: (1) perform a pregnancy test for selected females aged 8-11 and all females aged 12 to 59 years; (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis; and (3) process urine on SPs aged 18-49 years for HIV if the phlebotomist is not performing the blood draw or the quantity of serum is insufficient for serum HIV. Collect sufficient urine on VIP guest, guest, surplus, and second exam person types to be able to (1) perform a pregnancy test on all females aged 12 to 59 years and (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis.

The purpose of dental saliva and hair processing is to document collection of various specimens and store these specimens in the laboratory until they are shipped. These specimens are collected in the dental and hair collection rooms on SPs who are primary person types only and transported to the MEC laboratory. Specimens are shipped to laboratories that conduct analysis on them or store the specimens for future research.

Urine specimens are collected from all SPs 6 years of age and older. At least 38-mL of urine is required for primary SPs aged 6-13 and 51-mL from most SP aged 14+ years and older. These volumes include an additional 0.5-mL for the pregnancy test. Document urine collection, perform pregnancy test if indicated, process urine, saliva, and hair samples and store the vessels. At least 5-mL of urine is required on VIP guest, guest, surplus, and second exam person types. Document urine collection, perform pregnancy test if indicated, process urine, and store the vessels.

The MEC coordinator instructs each SP aged 6 years and older to provide a urine sample at the same time the SP changes clothes. If the SP cannot provide a urine sample at that time, the coordinator asks the SP to provide the sample as soon as possible. After collection, the coordinator or assistant coordinator transports the urine specimen to the laboratory.

The coordinator will explain the following instructions to the subject before urine collection:

- Wash hands with soap and water;
- It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces; and
- Close container to minimize exposure to air.

5.2 Supplies

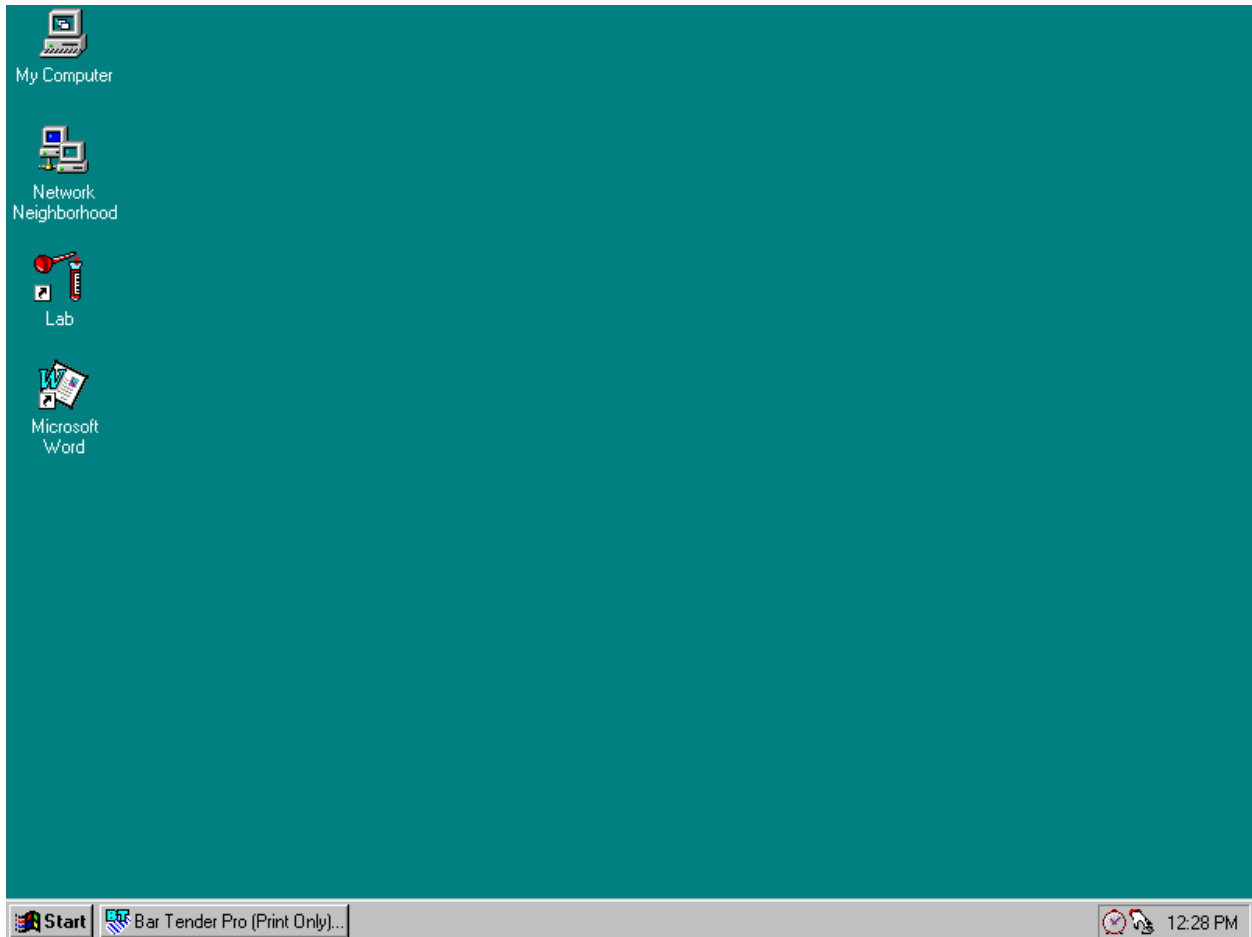
The supplies needed for urine collection and urine, dental saliva, and hair processing and storage are listed in Exhibit 5.1

Exhibit 5-1. Equipment and supplies

5-mL cryovial (urine and dental)	14-mL snap cap test tube (urine)
14-mL snap cap vial with colored dot (Urn Merc)	2-mL cryovial (urine)
Bench cover	Transfer pipette (urine)
5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid (urine)	5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid (urine and dental)
5.25 x 5.25 x 3.0 inch cardboard box with 5 x 5 cardboard grid (urine)	12 x 12 plastic bags (hair)

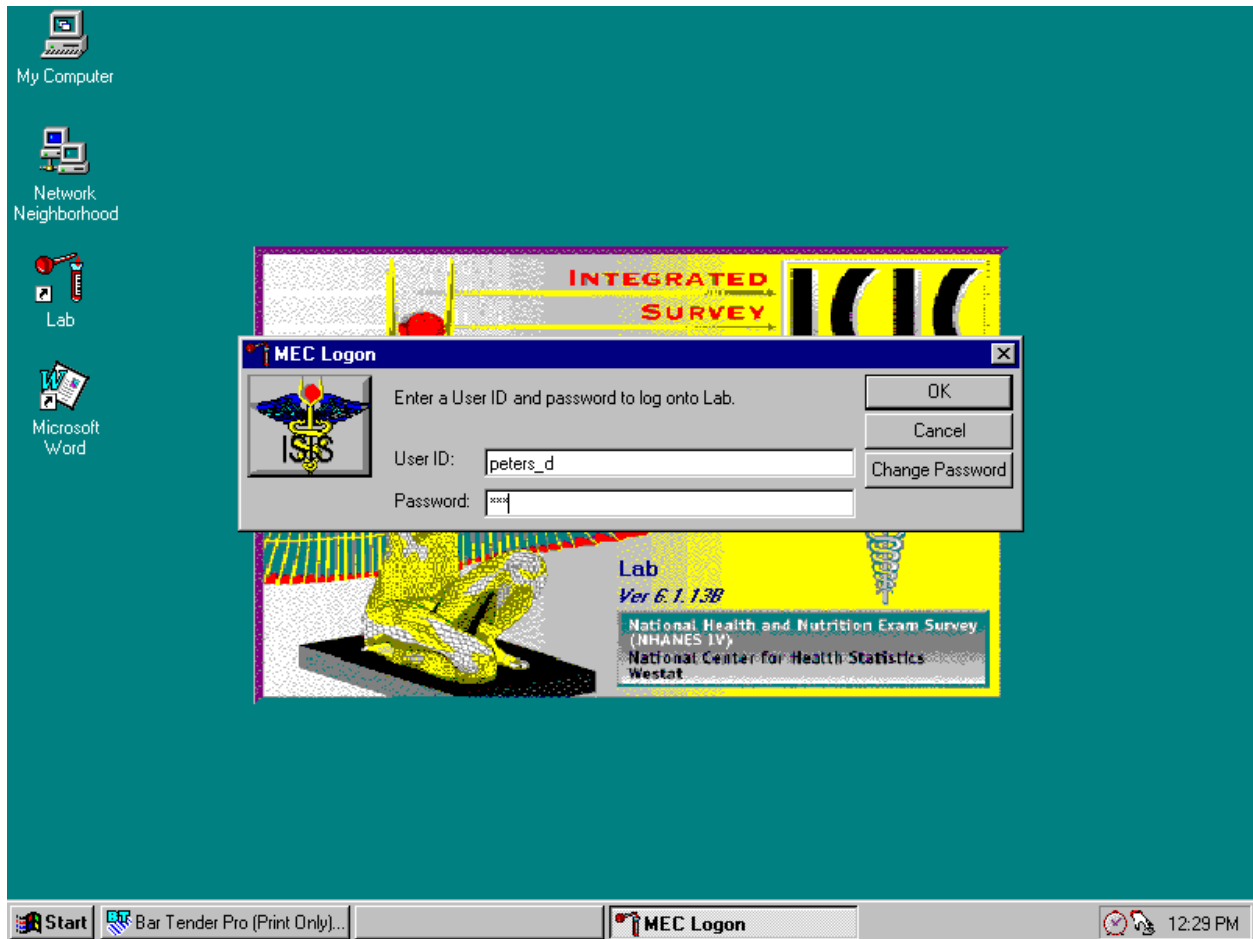
5.3 Document Urine Collection

Open the Laboratory application.



To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Log onto the laboratory application.



The MEC Logon window displays. Type last name, underscore first initial in the User ID space, and [Tab] or [Enter]. Enter password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the **Cancel** button and left click.

Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Message
Appointments for Session: 505210

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status										
								UC	B	CB	U	P	hiv	D	H	V		
108148	108148	CI	VIP	N	M	14	MARINO, WILLIAM	●	○	○	○	○	○	○	○	○	○	○
194149	194149	SC	P	M	F	50	SPARKS, GERTRUDE	○	○	○	○	○	○	○	○	○	○	○
206449	206449	EX	P	M	F	14	RITTER, MARY	○	○	○	○	○	○	○	○	○	○	○
230355	230355	SC	P	M	M	40	TORRES, JORGE	○	○	○	○	○	○	○	○	○	○	○
236673	236673	CI	VIP	N	F	7	SANCHEZ, WENDY	○	○	○	○	○	○	○	○	○	○	○
338454	338454	CI	P	N	M	2	SPARKS, JOHN	○	○	○	○	○	○	○	○	○	○	○
455209	455209	CI	VIP	N	M	4	GRAVELY, ANDY	○	○	○	○	○	○	○	○	○	○	○
502868	502868	CI	G	N	M	15	SWANSON, TRISTAN	○	○	○	○	○	○	○	○	○	○	○
687219	687219	CI	XD2	M	M	30	SPARKS, TODD	○	○	○	○	○	○	○	○	○	○	○
755942	755942	BE	G	N	F	5	JONES, SHARON	○	○	○	○	○	○	○	○	○	○	○
757644	757644	EX	P	M	M	35	RITTER, JIM	○	○	○	○	○	○	○	○	○	○	○
855085	855085	CI	P	N	F	9	SPARKS, SARAH	○	○	○	○	○	○	○	○	○	○	○

Send a Message to Coordinator | Connected to Coordinator | 10:59 AM

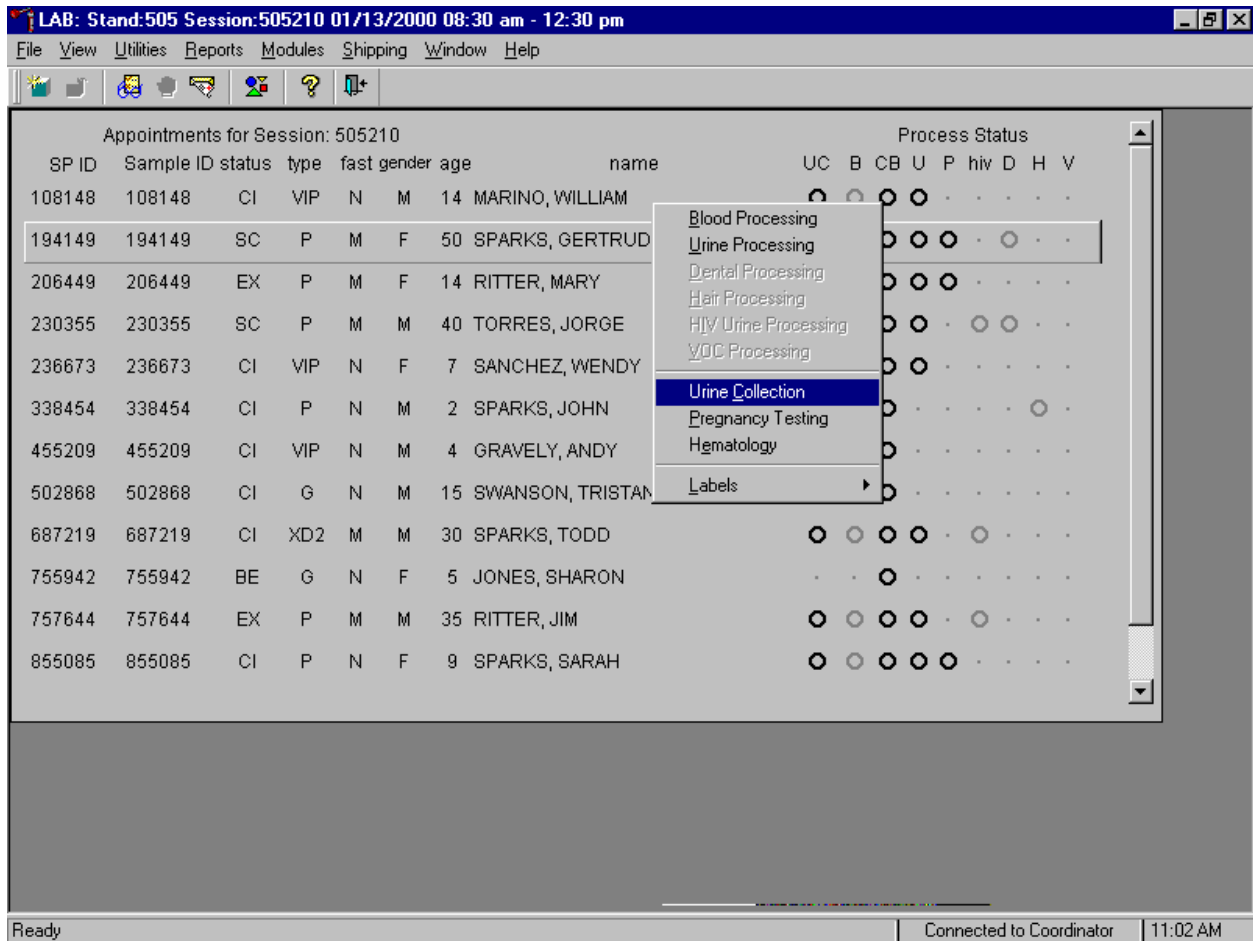
The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run), fast (M=morning, A=afternoon, E=evening, N=none), Gender, Age, and Name (first and last.)

The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), hiv (HIV urine processing), D (dental saliva), H (hair), and V (VOC). The SP is ineligible for a module when the process status is ○. The SP is eligible for a module but no results have been recorded when the process status is ●. The SP is eligible for a module and some results have been recorded when the process

status is **⊙**. The SP is eligible for a module and all results have been recorded and the module is complete when the process status is **●**. The SP is eligible for a module but the process status is O until the SP's blood, dental saliva, and hair samples are recorded as collected. Once the sample is collected, the process status changes from O to **●**. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from O to **●**. The process status updates and changes after each result is saved.

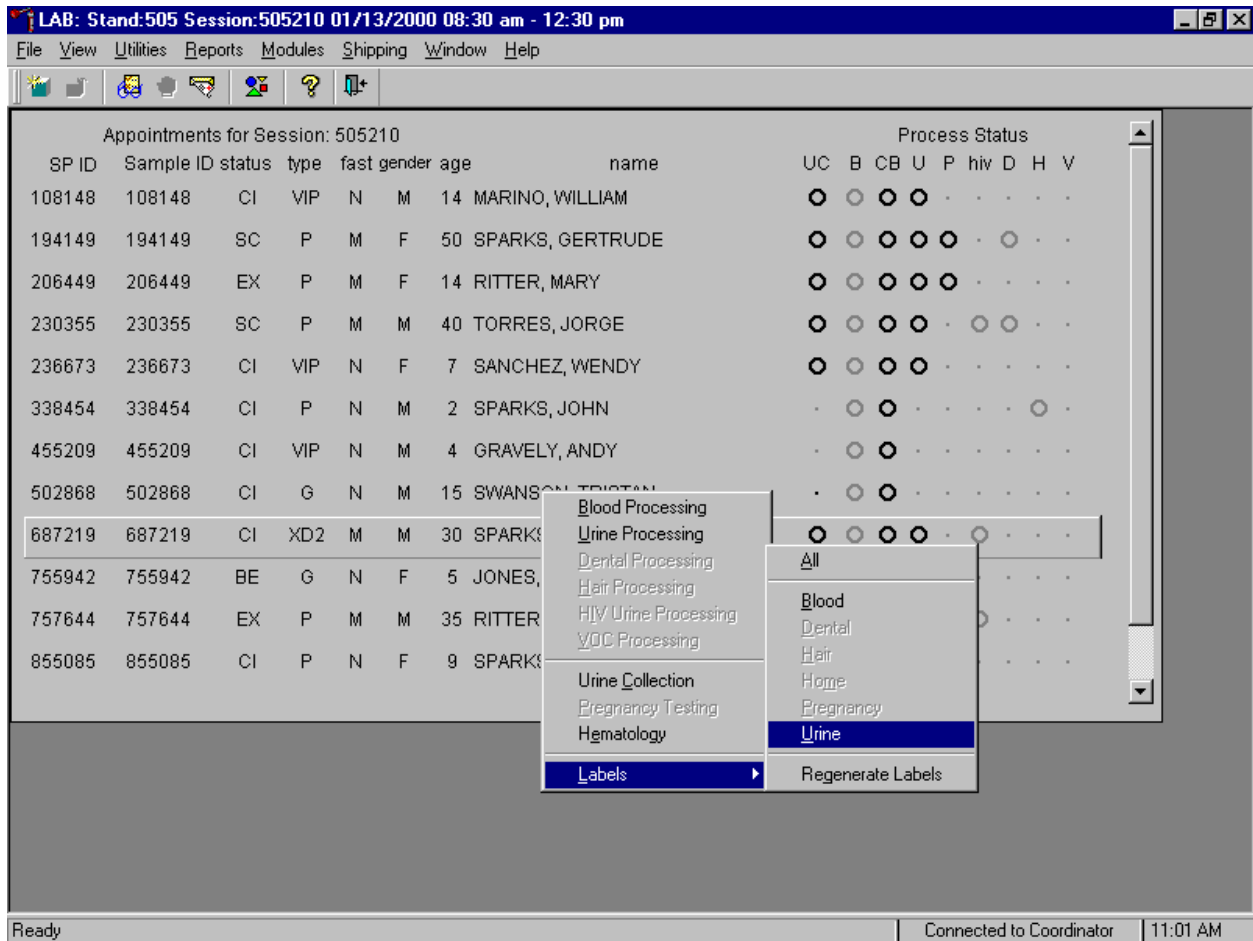
The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP for urine collection. Select a different SP if active SP is not the SP of choice.

Select the correct SP and access the Urine Collection module.



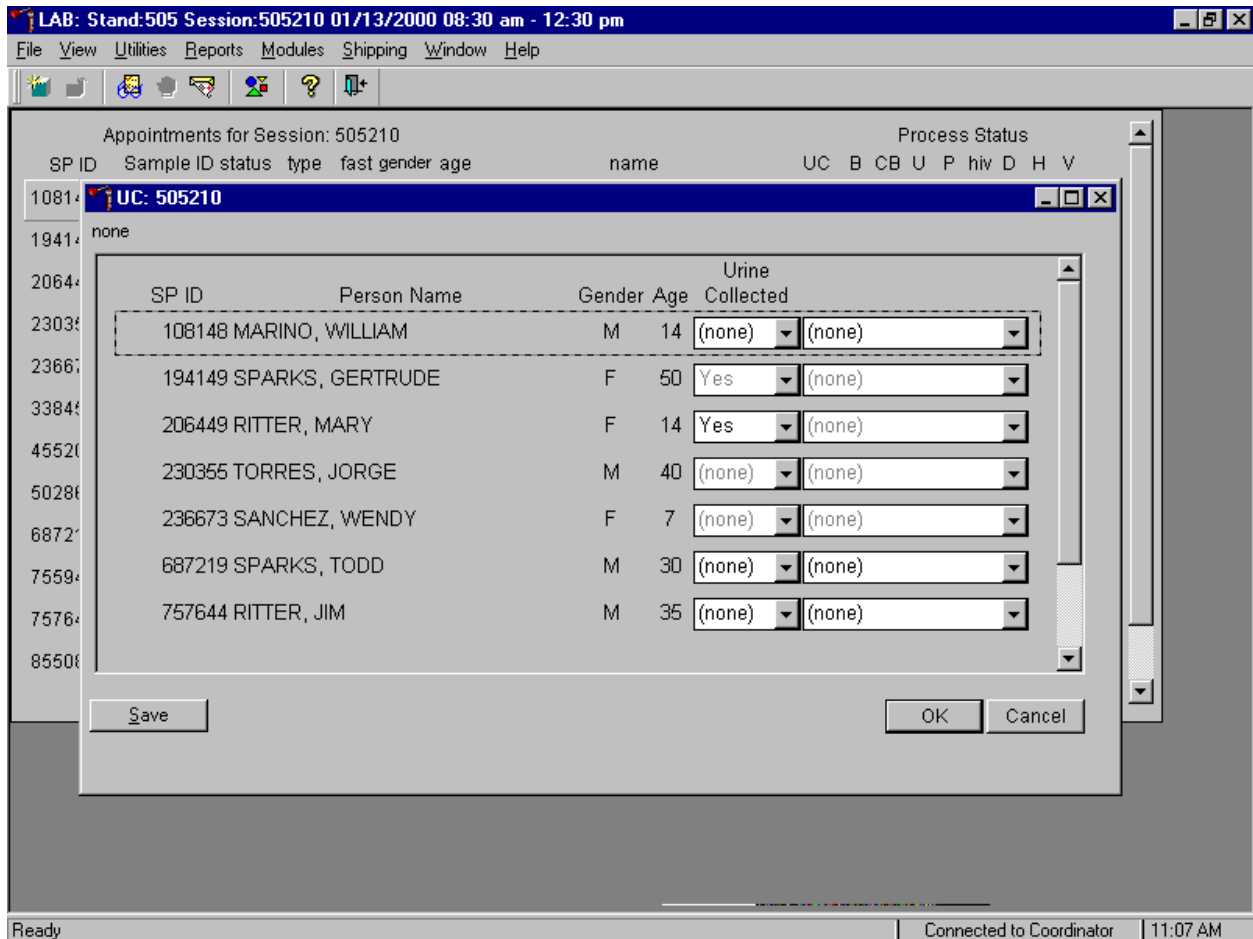
To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Urine Collection module, drag the mouse arrow to {Urine Collection} and left click or type [C/c].

Print additional labels for a particular SP using the heads-up display.



To print additional labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {Urine} and right click or right click on the correct SP, and type [L][U]. Urine processing labels print for the SP in the Label/Ship area.

The urine collection window displays.

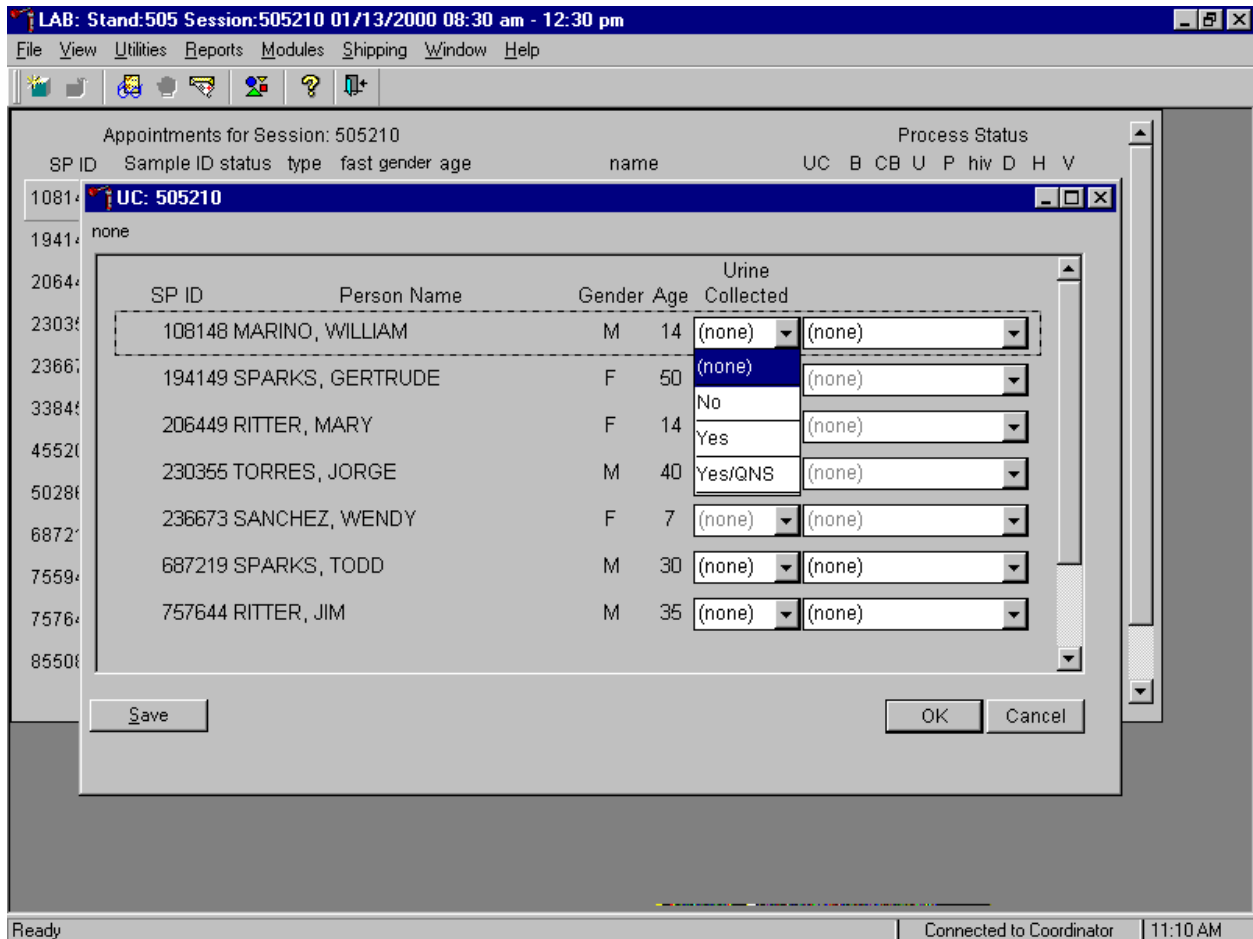


The urine collection window contains columns for the SP ID, Person Name (last, first), Gender, Age, and Urine Collection and Comment result fields. Only SPs who have checked into the MEC session are available for processing. This result field for checked-in SPs is indicated in black while the result field for SPs who have not checked into the MEC session are gray. Use the scroll bar to view all SPs scheduled into the session.

Evaluate the sufficiency of the quantity of urine received in the laboratory. Use the gradations on the urine collection cup to estimate the amount of urine.

Spin all grossly bloody urines for 5 minutes at 2,900 rpms. Pipette from the clear supernatant and add the "blood present" comment code.

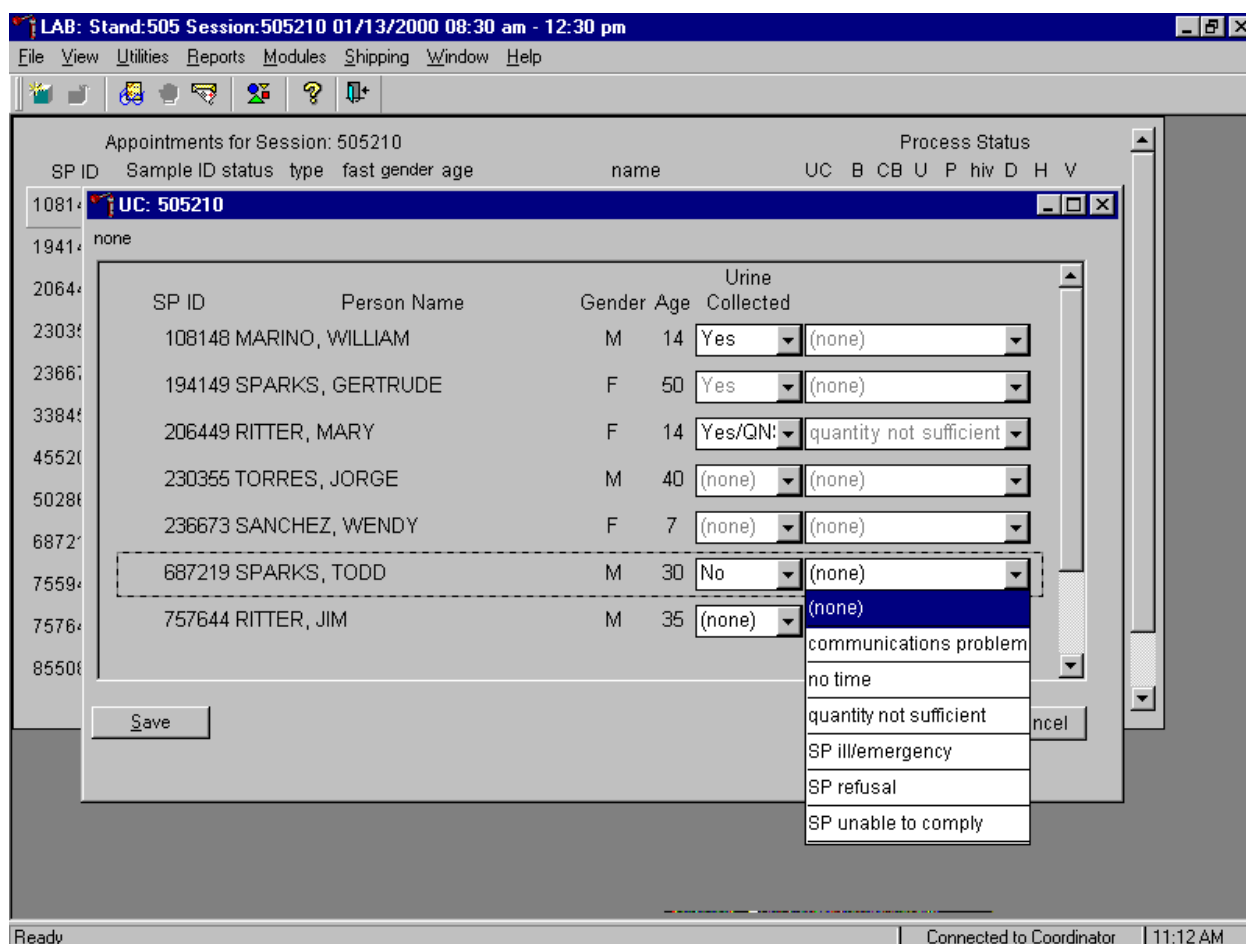
Record urine collection results for each SP as urine is delivered to the laboratory.



Record the urine collection result for each SP by typing [Y/y] for "Yes," [N/n] for "No," or [Q/q] for "Yes/QNS." Alternatively, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes," "No," or "Yes/QNS" and left click. A "Yes/QNS" result notifies the coordinator, who then asks the SP to provide an additional urine specimen. Refrigerate all insufficient urine samples. If and when additional urine is obtained, pool the urine and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each SP. Enter "No" in the result field for all SPs who have not produced a urine sample. Record a result other than "(none)" for all SPs.

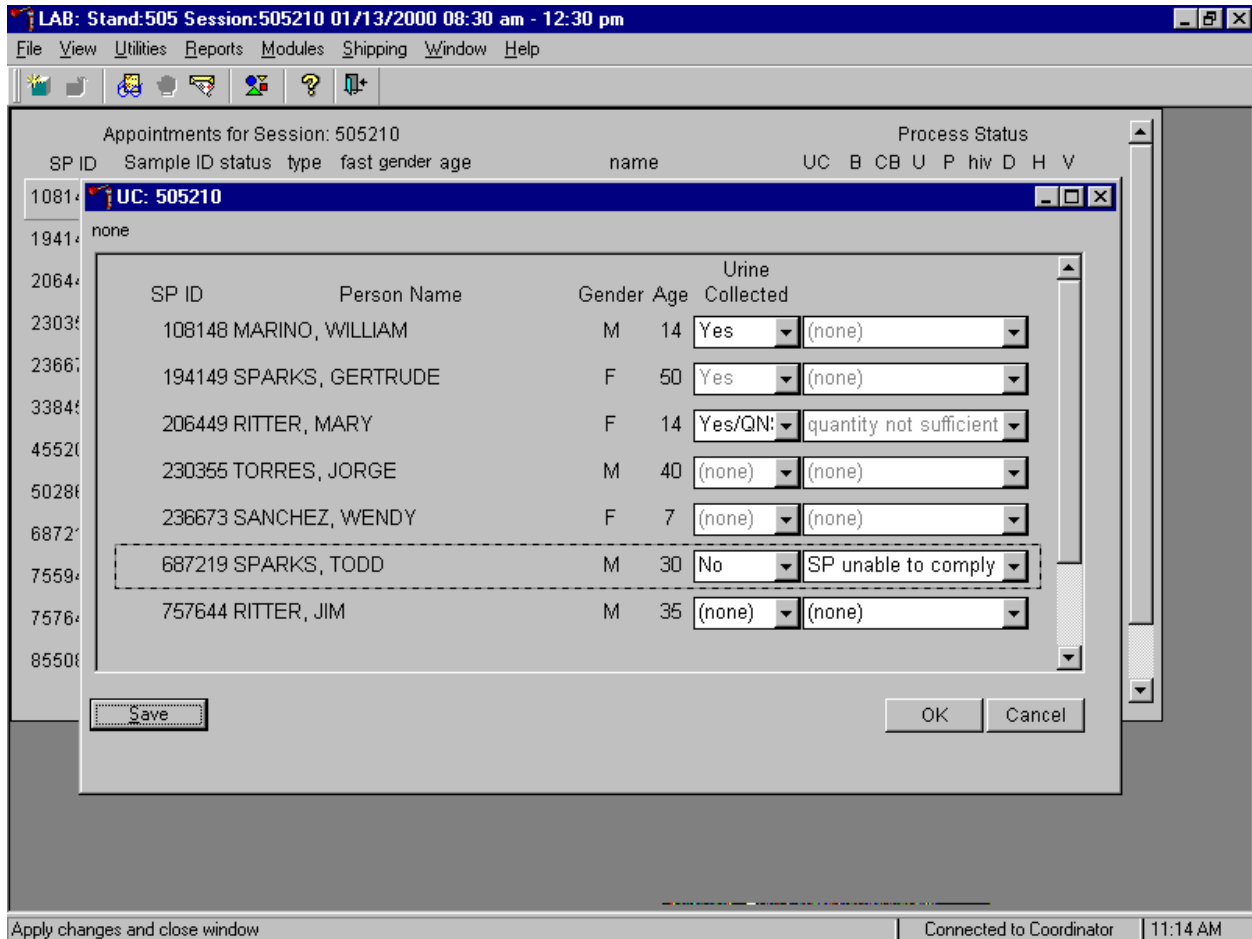
Record a comment for all insufficient urine collections.



To record a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, and select the most appropriate choice. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click.

Comment Code	Use when:
communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
no time	Not applicable
SP ill/emergency	Not applicable
SP refusal	SP refuses to provide urine during the session.
SP unable to comply	SP has a physical limitation that prohibits them from producing a urine specimen or the SP is unable to produce urine during the session.

Continue recording and updating urine collection results as specimens are delivered to the laboratory.



Make sure to use the scroll bar to view all SPs. Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the **S**ave button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the **O**K button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to **C**ancel button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the **X** Close Window button and left click.

5.4 Urine Specimen Assays

Process urine specimens for the following tests.

- Pregnancy test for selected females aged 8-11 and all females aged 12 to 59 years;
- Albumin/Creatinine (Alb/Creat) on all SPs 6+ years old,
- Chlamydia/Gonorrhea (Chlam/GC) on SPs 14-39 years old,
- NTX on SPs 8+ years old,
- Urinary Iodine (Urn Iodine) on selected SPs 6+ years old,
- Priority pesticide (Prior Pest) on selected SPs 6+ years old,
- Organophosphates (Organophos) on selected SPs 6+ years old,
- Urine Mercury (Urn Merc) on female SPs 16-49 years old,
- Heavy Metal on selected SPs age 6+ years old,
- Phytoestrogens (Urn Phytoes) on selected SPs age 6+ years old,
- Polyaeromatic hydrocarbons (PAH) on selected SPs age 6+ years old,
- Phthalates on selected SPs age 6+ years old,
- Extra urine (Xtra Urine) on SPs age 6+ years old; and
- HIV Urine for SPs 18-49 years old if no blood is collected or the quantity of serum is insufficient for serum HIV and the SP has not refused HIV.

5.5 Urine Specimen Protocols

Table 5-1 summarizes the urine processing protocol for primary SPs. Process urine in priority order with vessel 45 filled first, 46 second, etc.

Table 5-1. NHANES urine processing protocol – primary

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial
46	Chlam/GC	14-39	4	5-mL Cryovial
47	NTX	8+	1	2-mL Cryovial
69	Urn Iodine	6+	3	5-mL Cryovial
48	Prior Pest	6+	10	14 mL snap cap tube
49	Organophos	6+	10	14-mL snap cap tube
62	Urn Merc	16-49 Females	5	14-mL snap cap tube with colored dot
50	Heavy Metal	6+	10	14-mL snap cap tube
65	Urn Phytoes	6+	3	5-mL Cryovial
66	PAH	6+	3	5-mL Cryovial
67	Phthalates	6+	3	5-mL Cryovial
51	Xtra Urine	6+	5	5 mL Cryovial
52	Xtra Urine	6+	5	5 mL Cryovial
53	HIV	18-49	3	5 mL Cryovial

Table 5-2 summarizes the urine processing protocol for the VIP guest person type.

Table 5-2. NHANES urine processing protocol – VIP guest

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial

Table 5-3 summarizes the urine processing protocol for the second exam person type.

Table 5-3. NHANES urine processing protocol – second exam

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial
47	NTX	8+	1	2-mL Cryovial

5.6 Labeling Urine Processing Vessels

The appropriate bar code labels automatically print for each SP based on the SP's age, sex, person type, and subsample selection. The label/ship technologist at workstation 3 prints the labels at least one session in advance. The printing procedure is described in Chapter 9. Place labels at workstation 2.

Set up each urine processing rack using the preprinted labels. Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally making sure the label wraps onto itself. Place the label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

5.7 Urine Specimen Processing

- Perform pregnancy test and record results before aliquoting the urine specimen.
- Label all urine aliquot vessels for the SP and place in priority order in the rack.

Allocate the urine sample for each of these tests using the following procedure.

45. Pour 3-mL of the specimen for Alb/Creat into a 5-mL vessel;
46. Pour (or carefully pipette) 4-mL of the specimen for Chlam/GC into 5-mL vessel;
47. Pour 1-mL of the specimen for NTX into 2-mL vessel;
69. Pour 3-mL of the specimen for Urn Iodine into a 5-mL vessel;
48. Pour 10-mL of specimen for Prior Pest into 14-mL vessel;
49. Pour 10-mL of specimen for Organophos into 14-mL vessel;
62. Keep vessel 62 upright at all times; do not invert the tube because the preservative could drain into the caps and spill when opened. If the vessel does become inverted, stand it upright for at least several hours or overnight, then open the cap, and pipette the urine into the 14-mL vessel. Tap the bottom of the capped vessel against a hard surface before opening. Use a plastic transfer pipette to transfer exactly 5-mL of urine into the 14-mL snap cap vessel, snap the cap closed, and mix gently. Do not discard the prepared tubes even if the preservative crystalizes. If the preservative crystalizes, add 5-ml of urine with the transfer pipette and mix extremely well. Do not use these tubes for any other purpose since they contain a preservative.

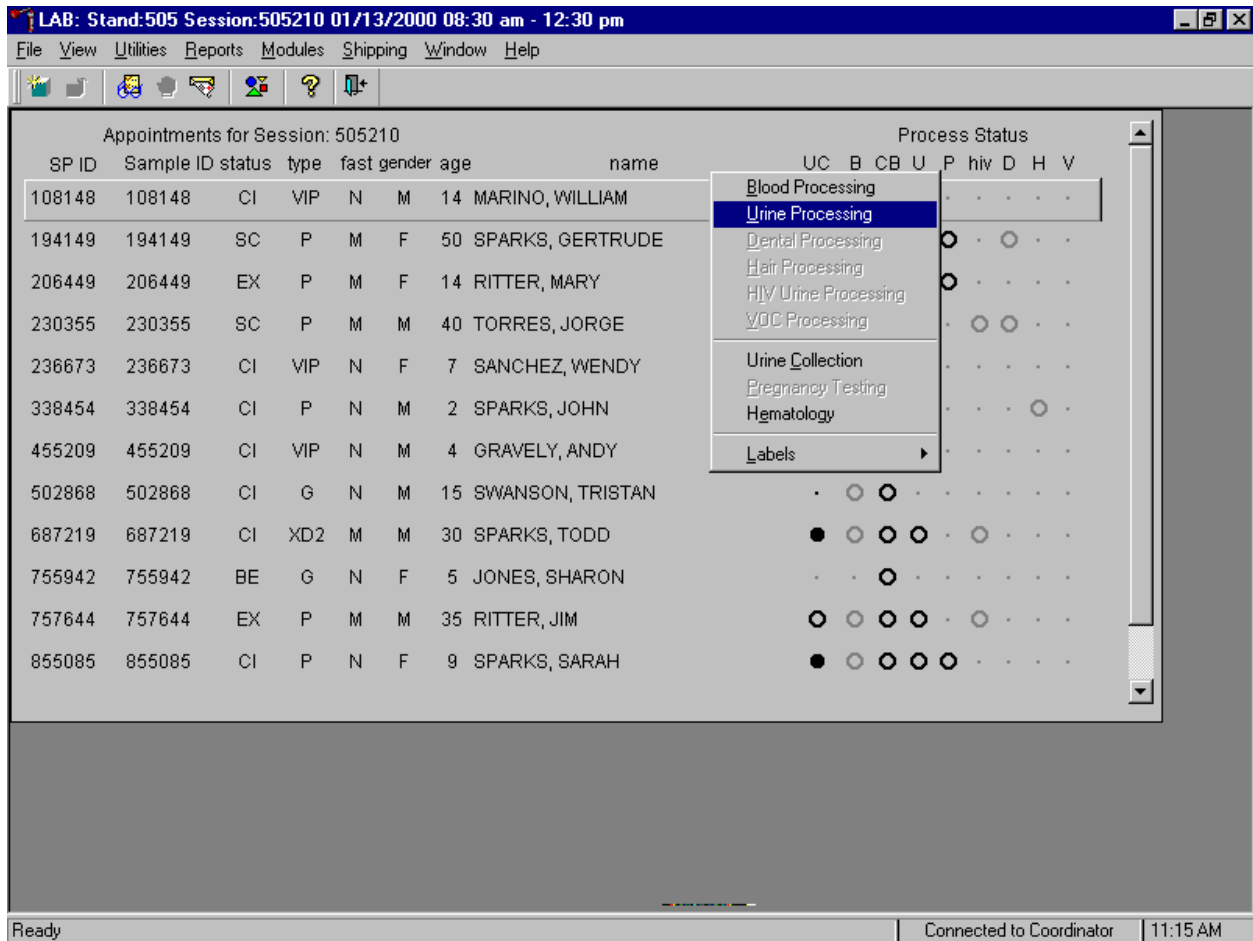
50. Pour 10-mL of the specimen for Heavy Metal into a 14-mL vessel.
65. Pour 3-mL of the specimen for Urn Phytoes into a 5-mL vessel;
66. Pour 3-mL of the specimen for PAH into a 5-mL vessel;
67. Pour 3-mL of the specimen for Phthalates into a 5-mL vessel;
51. Pour 5-mL of the specimen for Xtra Urine into a 5-mL vessel;
52. Pour 5-mL of the specimen for second Xtra Urine into second 5-mL vessel; and
53. Pour 3-mL of specimen for HIV Urine into 5-mL vessel (give this tube to the blood processing technologist).

Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

5.7.1 Record the Results of Urine Specimen Processing

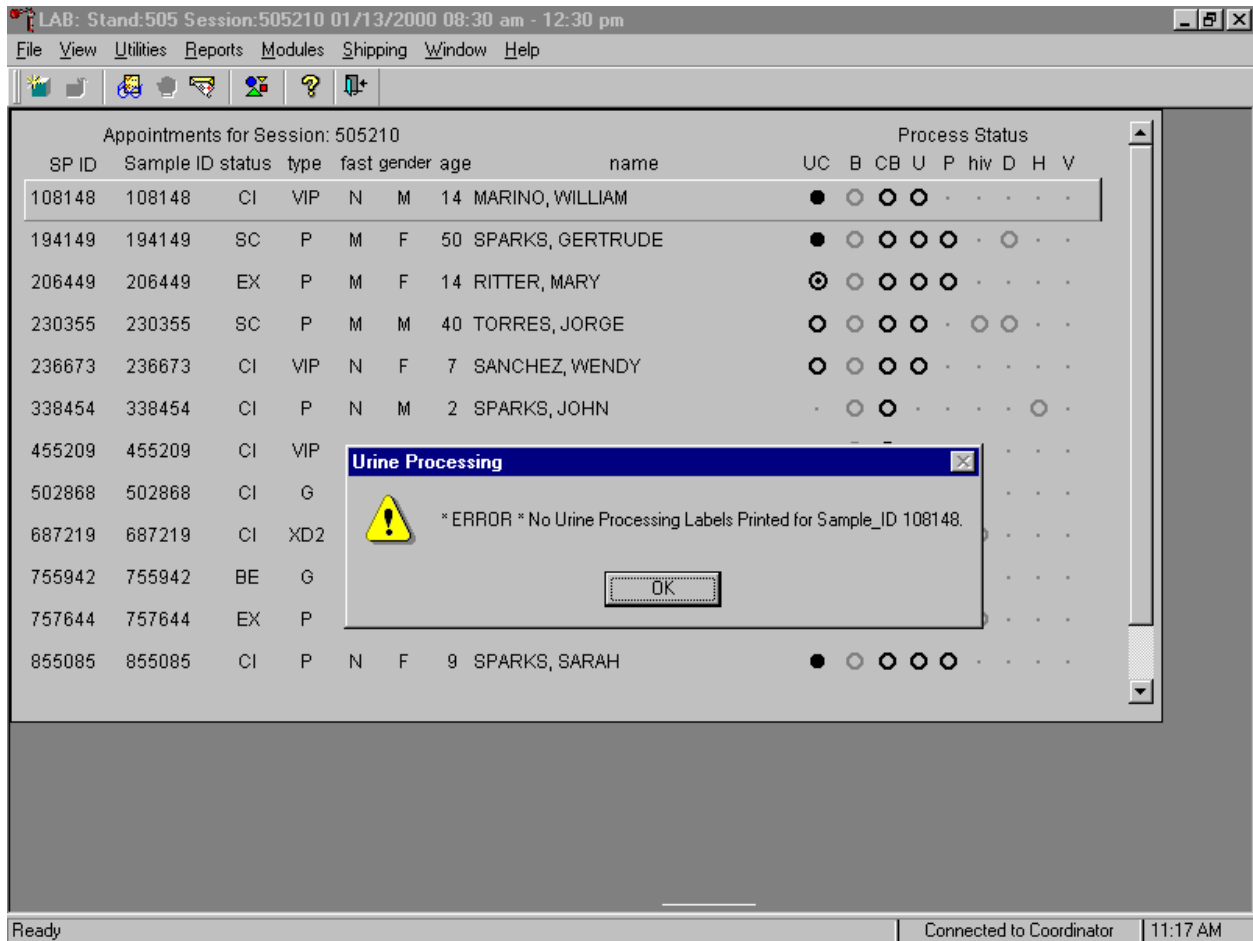
After filling the urine specimen vessels for each SP, use the Urine Processing module to enter the results of urine processing.

Access the Urine Processing module.



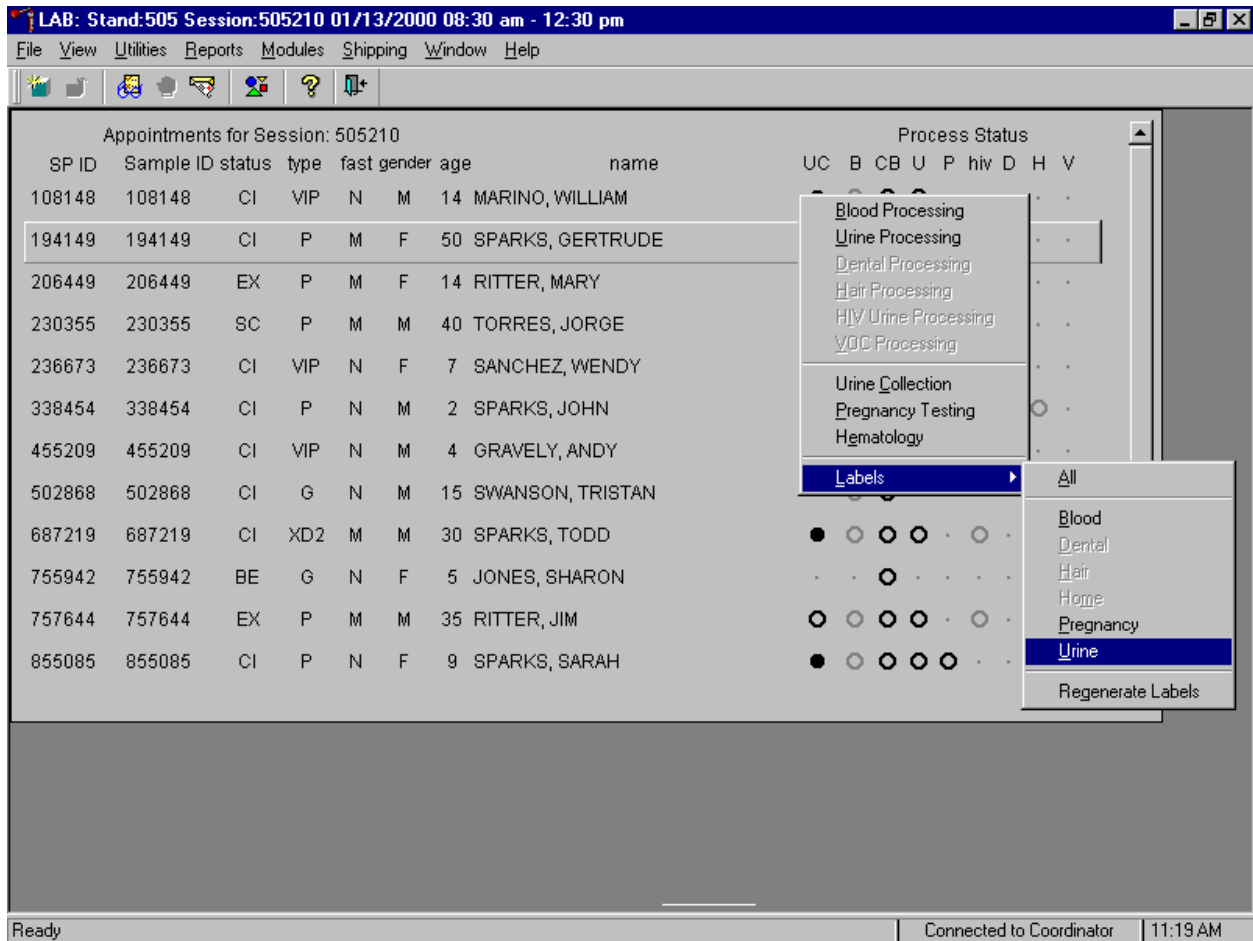
To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Urine Processing} and right click or type [U]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Urine Processing} and right click or type [U].

If labels have not been printed in advance, a Urine Processing message box displays.



Urine processing cannot occur unless labels have been printed in advance. To remove the Urine Processing message box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

Print labels for an individual SP using the heads-up display.



To print labels for a SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {Urine} and left click or type [L] [U]. Label print in the label/ship area. Continue processing urine on this SP.

The SP's urine processing window displays.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505210 Process Status

UR: 230355

none

Tech ID: 1115 Sample ID: 230355 Name: TORRES, JORGE Gender: M Age: 40
 SP ID: 230355 SubSample: 1 Fasting_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
47	NTX	1	U	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
65	Urn Phytoes	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
66	PAH	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
67	Phthalates	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

Cancel changes Connected to Coordinator 11:23 AM

The urine processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Name, Container ID/Slot #, and Filled and Comments buttons.

Individually mark each vessel as Filled - "Yes."

The screenshot shows a software window titled 'UR: 230355' with a 'Process Status' indicator. The window contains a form with the following fields:

Tech ID: 1226 Sample ID: 230355 Name: TORRES, JORGE Gender: M Age: 40
 SP ID: 230355 SubSample: 1 Fasting_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305388	15
47	NTX	1	U	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305389	15
65	Urn Phytoes	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
66	PAH	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
67	Phthalates	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Buttons: Save, OK, Cancel

System tray: Ready | Connected to Coordinator | 11:24 AM

To mark an individual urine vessel as collected or Filled – "Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As each vessel is marked as Filled – "Yes," it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled - "No."

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505210 Process Status

UR: 230355

10 none

19 Tech ID:1226 Sample ID: 230355 Name: TORRES, JORGE Gender: M Age: 40

20 SP ID: 230355 SubSample:1 Fasting_Req: 1

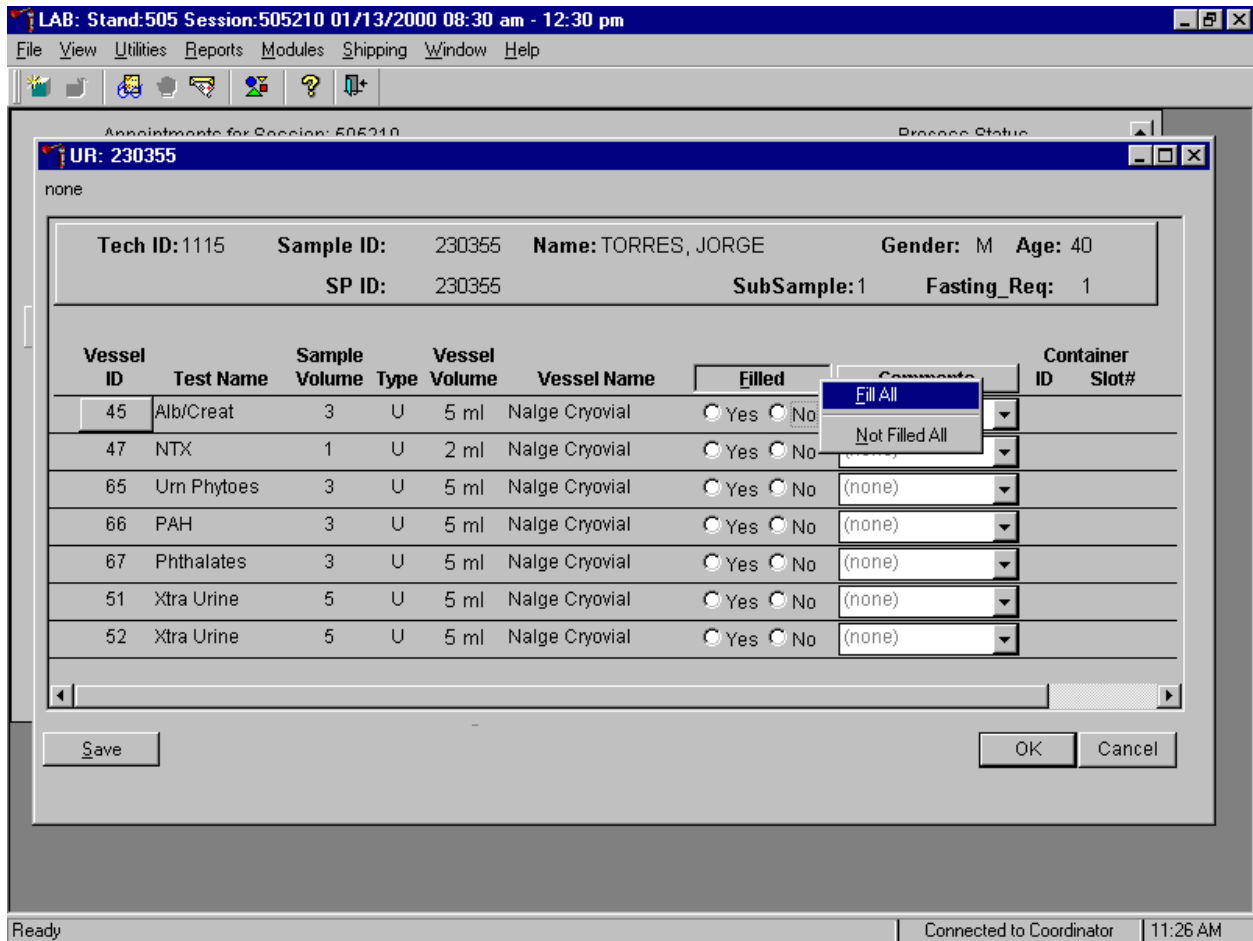
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305388	15
47	NTX	1	U	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305389	15
65	Urn Phytoes	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		
66	PAH	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
67	Phthalates	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
51	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
52	Xtra Urine	5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

Ready Connected to Coordinator 11:25 AM

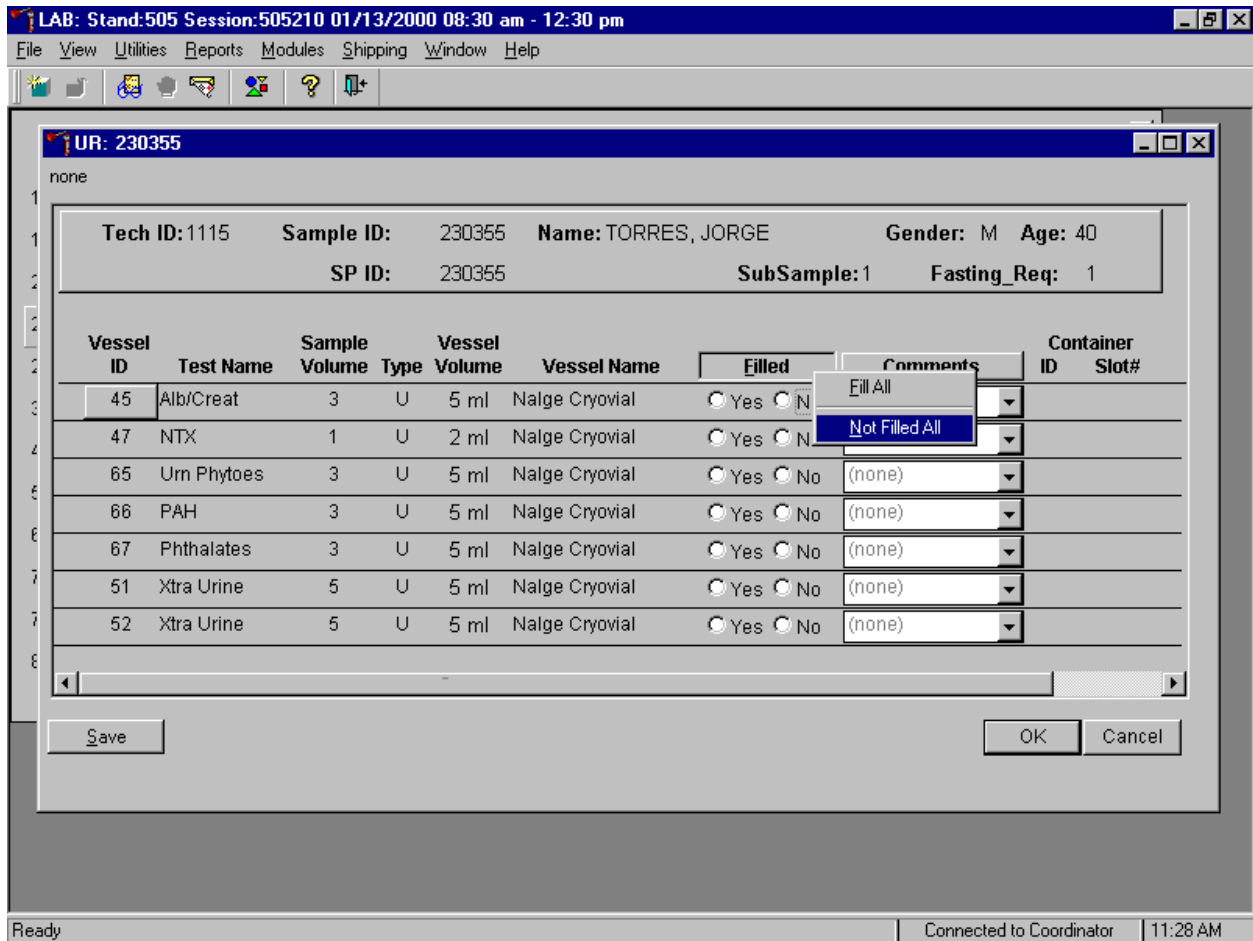
To mark an individual urine vessel as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click. As each vessel is marked as Filled "No," the comment, "quantity not sufficient" is automatically entered in the Comments column.

Collectively mark all vessels as Filled - "Yes."



To collectively mark all vessels as Filled - "Yes", use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [F/f].

Collectively mark all vessels as Filled - "No."



To mark all vessels as Filled - "No", use the mouse to direct the mouse arrow to the **Filled** box, left click, drag the mouse arrow to {Not Filled All} and left click or type [N/n].

Use the quality comment code to indicate if blood is present.

LAB: Stand:805 Session:805170 18-Nov-98 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Heads-Up for Session: 805170

UR: 970468

none

Tech ID:1117 Sample ID: 970468 Name: Magill, Linda Gender: F Age: 16
 SP ID: 970468 SubSample:1 Fasting_Req: 1

Vessel ID	Test Name	Vessel Type	Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	U	3.0	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0001033	4
46	Chlam/GC	U	4.0	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0001034	2
47	NTX	U	1.0	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
48	Prior Pest	U	10.0	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	blood present		
49	Organophos	U	10.0	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		
62	Urin Merc	U	5.0	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
50	Env Urine	U	10.0	17 x 100	<input type="radio"/> Yes <input type="radio"/> No	(none)		

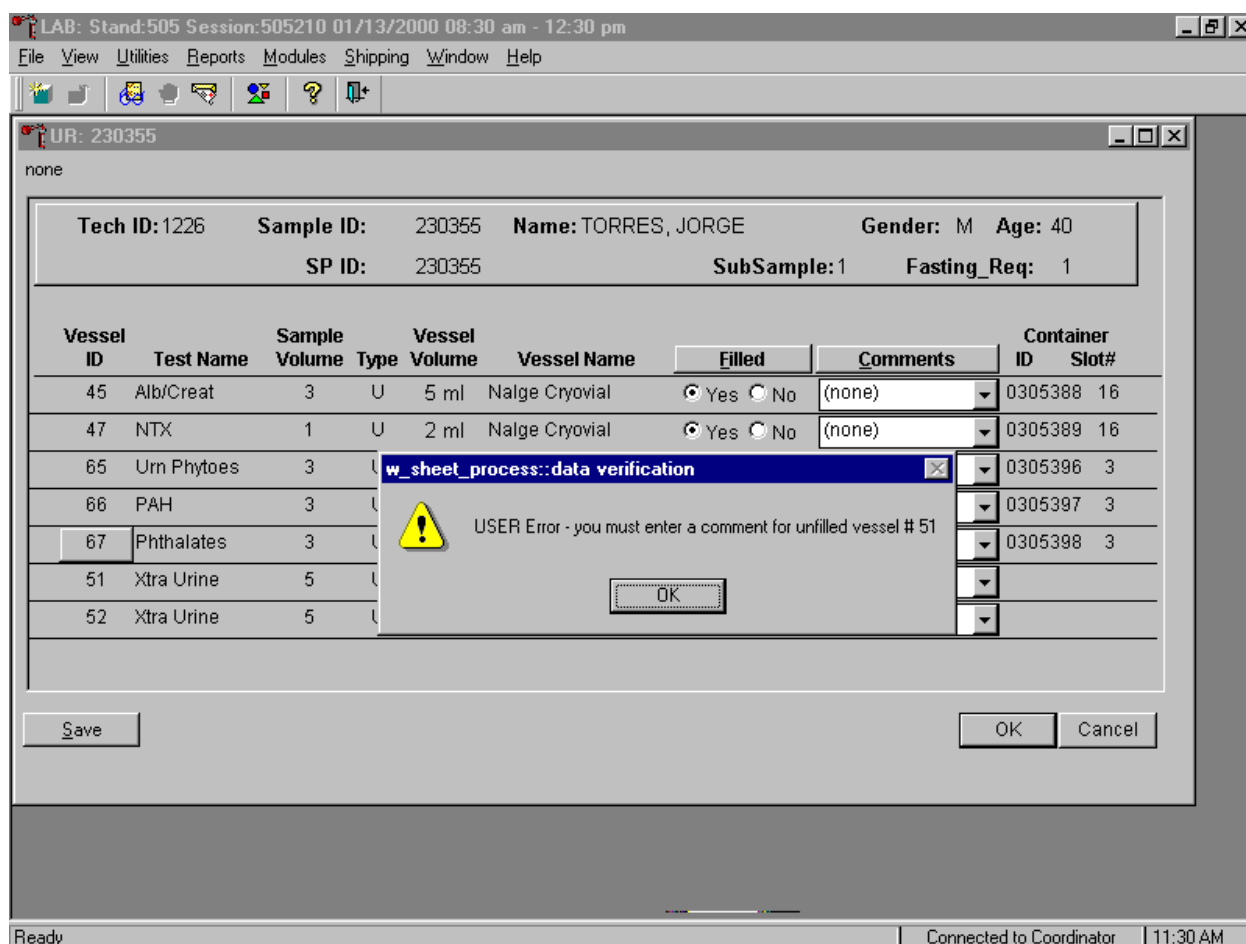
Save OK Cancel

Ready

To enter the quality control comment "blood present" for a filled vessel, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present} and left click.

Comment Code	Use when:
Blood present	Blood is visible in the specimen.

Review the information in the urine-processing window and save the data to the database.

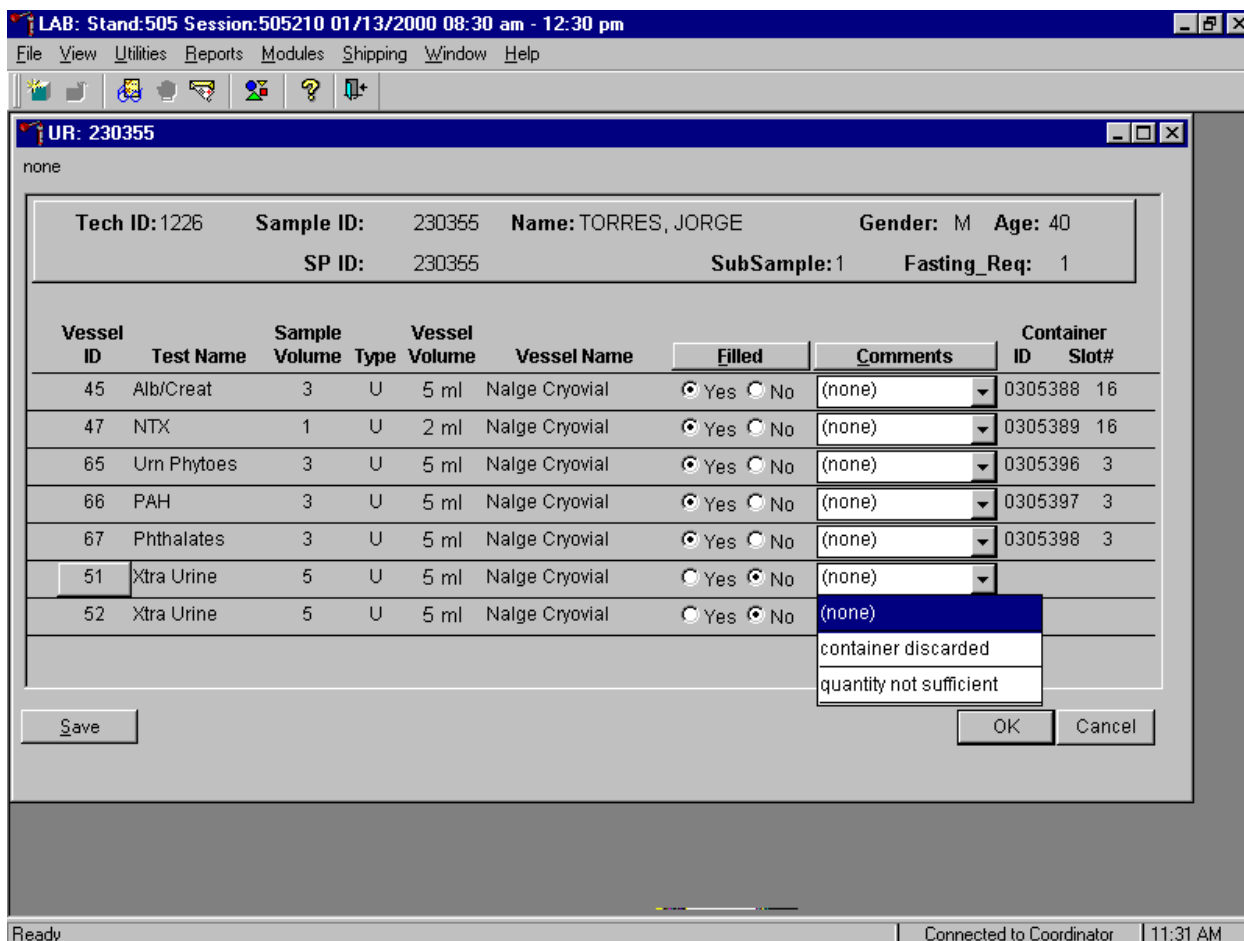


Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

If the **Save** or the **OK** button is selected and all vessels are not marked as either Filled - "Yes" or Filled - "No," a warning message box displays requesting a comment for each unfilled vessel. To remove the warning message box, use the mouse to direct the mouse arrow to the **OK** button and left click.

Process and record results for only one SP at a time.

Do not use the comment, "container discarded" for Filled - "No" vessels.



The drop-down comment list for Filled-"No" contains {container discarded}. Do not use this comment.

5.8 Second Urine Samples

If the initial urine sample does not meet the minimum volume requirement, refrigerate the initial urine until enough additional urine is received to meet the minimum requirements to complete the protocol or the session ends. If a subsequent second sample fulfills this requirement, pool the initial and subsequent urine samples, update the Urine Collection module, access the Urine Processing module, fill the vessels, and record the results. If the session ends and no addition urine has been collected, access the

Urine Processing module, fill as many vessels as possible (in priority order), mark the remaining vessels as filled "No," and save the results.

5.9 Dental Saliva and Hair Processing

Process dental saliva and hair specimens in the lab. Process these specimens using the Dental Processing or Hair Processing modules and store specimens for shipment.

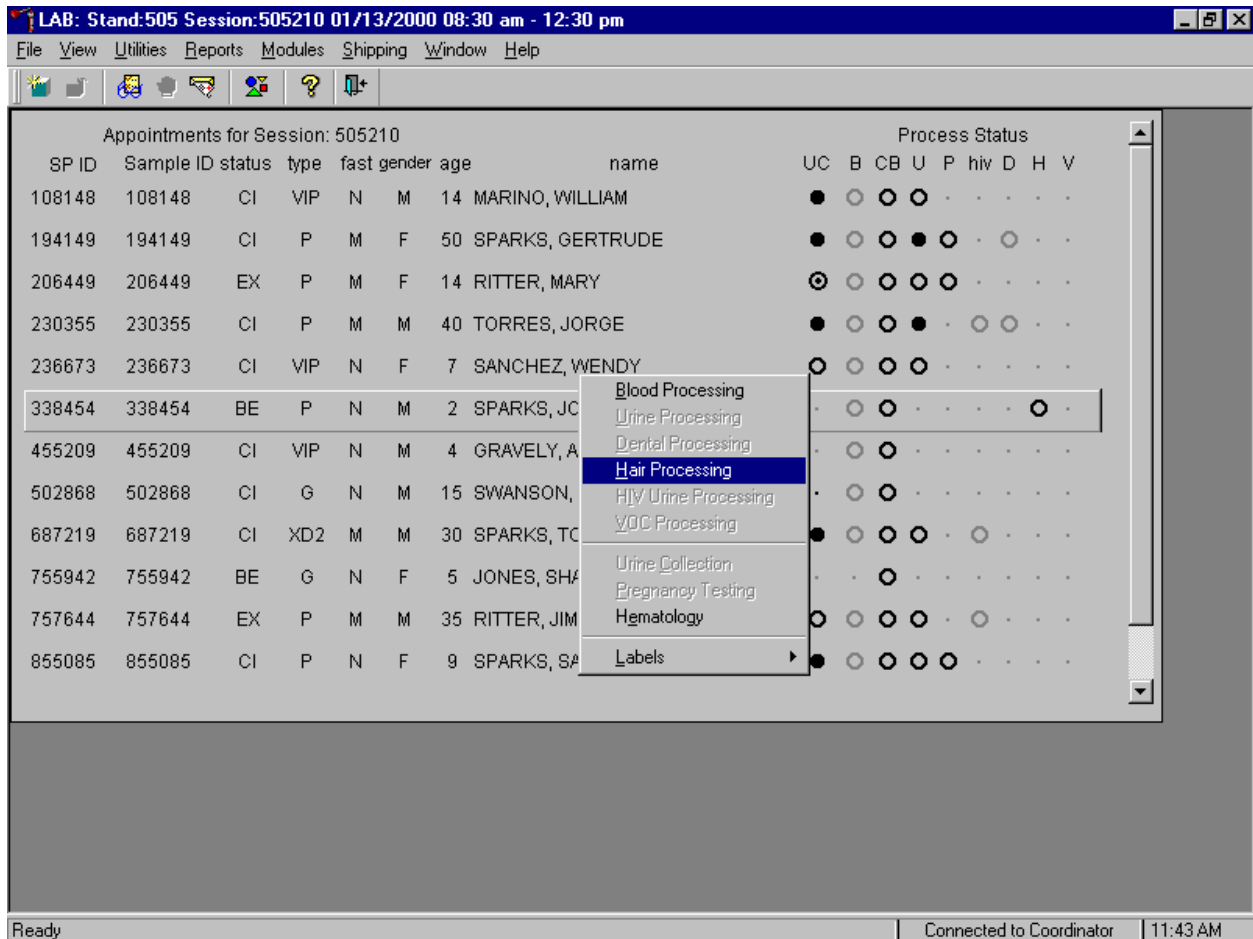
The dentist collects saliva in the dentist's room and transports it to the laboratory in a 30-mL plastic jar. Label one 5-mL cryovial with the SP's preprinted label, transfer the specimen from the 30-mL plastic jar into the 5-mL cryovial using a plastic transfer pipette, record the collection in the Dental Processing module, and store the specimen. Process dental specimens as soon as possible after collection. Do not let the specimens remain at room temperature.

The health technicians collect hair samples in the designated room in trailer 1 and transport the samples to the laboratory in 6 x 6 plastic bags. The health technicians attach a SP ID bar coded label to the outside of the plastic bag after collecting the sample. Record the collection in the Hair Processing module, and store the specimen.

Exhibit 5.2. Dental saliva and hair processing protocol

ID	Test Name	Ages	Sample	Sample Type	Collection Type	Vessel Type
58	Saliva	40+	5.0-mL	Saliva	Saliva	5-mL Cryovial
59	Methylmerc	1-5 both sexes 16-49 women	100 mg	Hair	Hair	6 x 6 plastic bag

Access the Dental or Hair Processing module.



To access the Dental or Hair Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Dental Processing} or {Hair Processing} and right click or type [D] or [H]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Dental Processing} or {Hair Processing}, right click, or type [D] or [H].

The SP's dental or hair processing window displays.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505210

Hair: 338454

none

Tech ID: 1115	Sample ID: 338454	Name: SPARKS, JOHN	Gender: M	Age: 2
	SP ID: 338454	SubSample: 1	Fasting_Req: 4	

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
59	Methylmerc	100	H	100 mg	plastic bag	<input type="radio"/> Yes <input type="radio"/> No		

Save OK Cancel

Ready Connected to Coordinator 11:49 AM

The dental or hair processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Sample Volume, Type (D=dental, H=hair), Vessel Volume, Container ID/Slot #, and Filled and Comments buttons.

Mark each vessel as Filled "Yes" or "No."

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505210

Hair: 338454

none

Tech ID: 1226 Sample ID: 338454 Name: SPARKS, JOHN Gender: M Age: 2
SP ID: 338454 SubSample: 1 Fasting_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
59	Methylmerc	100	H	100 mg	plastic bag	<input checked="" type="radio"/> Yes <input type="radio"/> No	0305442	1

Save OK Cancel

Apply changes and close window Connected to Coordinator 11:50 AM

To mark an individual dental or hair vessel as collected or "filled," use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As each vessel is marked as Filled – "Yes," it is automatically assigned to a slot in an existing (open) container. To mark an individual dental or hair vessel as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click.

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

5.10 Specimen Storage

Fill the urine vessels, enter the urine, dental saliva, and hair processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 5-4.

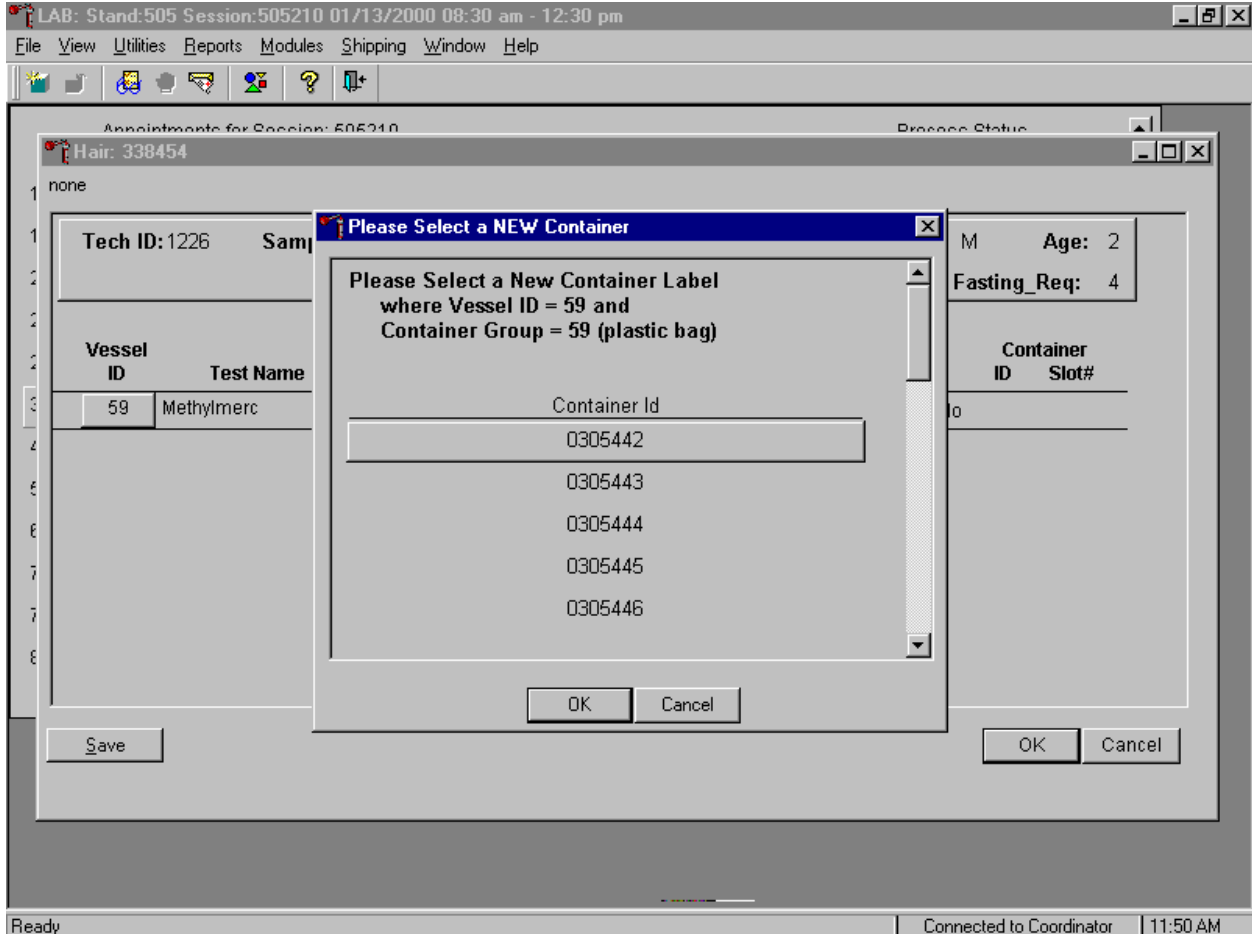
At the beginning of each stand, generate and print a series of bar coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process "opens" a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 5-4. Storage protocol for urine, dental saliva, and hair

Shipping Location	Vessels	Conditions	Vessel Storage
University of Minnesota	45 Alb/Creat	Frozen	9 x 9 three inch box
CDC,NCID NCHSTD	46 Chlam/GC	Frozen	9 x 9 three inch box
University of Washington	47 NTX	Frozen	9 x 9 two inch box
CASPIR	69 Urn Iodine	Frozen	9 x 9 three inch box
CDC/Dr. Dana Barr	48 Prior Pest	Frozen	5 x 5 three inch box
CDC/Dr. Dana Barr	49 Organophos	Frozen	5 x 5 three inch box
CASPIR	62 Urn Merc	Frozen	5 x 5 three inch box
CASPIR	50 Heavy Metal	Frozen	5 x 5 three inch box
CDC/Dr. Dana Barr	65 Urn Phytoes	Frozen	9 x 9 three inch box
CASPIR/Dr. James Grainger	66 PAH	Frozen	9 x 9 three inch box
CDC/Dr. John Brock	67 Phthalates	Frozen	9 x 9 three inch box
CASPIR	51 & 52 Xtra Urine	Frozen	9 x 9 three inch box
CASPIR	58 Saliva	Frozen	9 x 9 three inch box
Research Triangle Institute	59 Methylmerc	Room Temperature	12 x 12 plastic bag

5.10.1 Opening New Containers

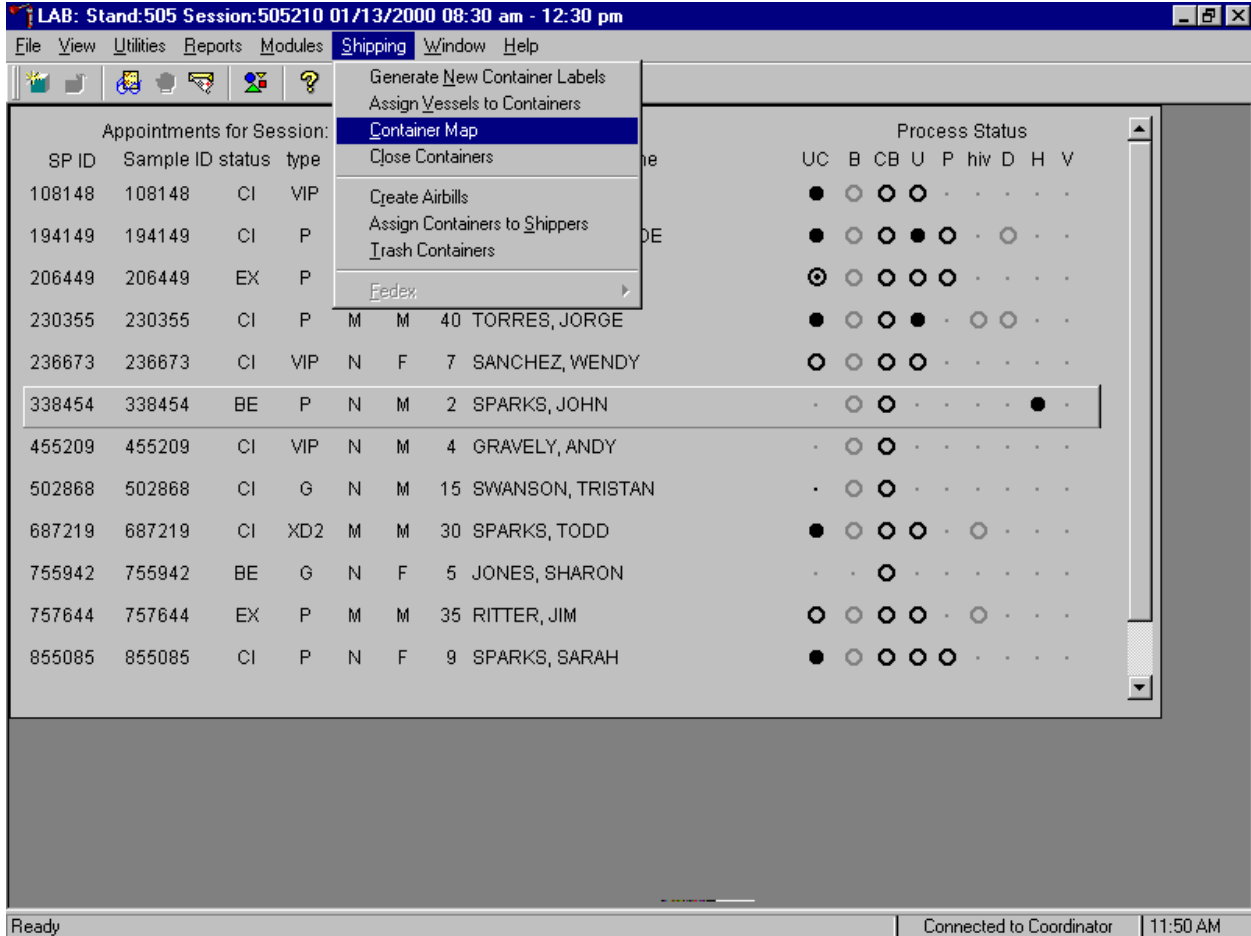
When a container is full, the container will automatically "close." Open a new container when prompted.



When a container is full, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter]. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

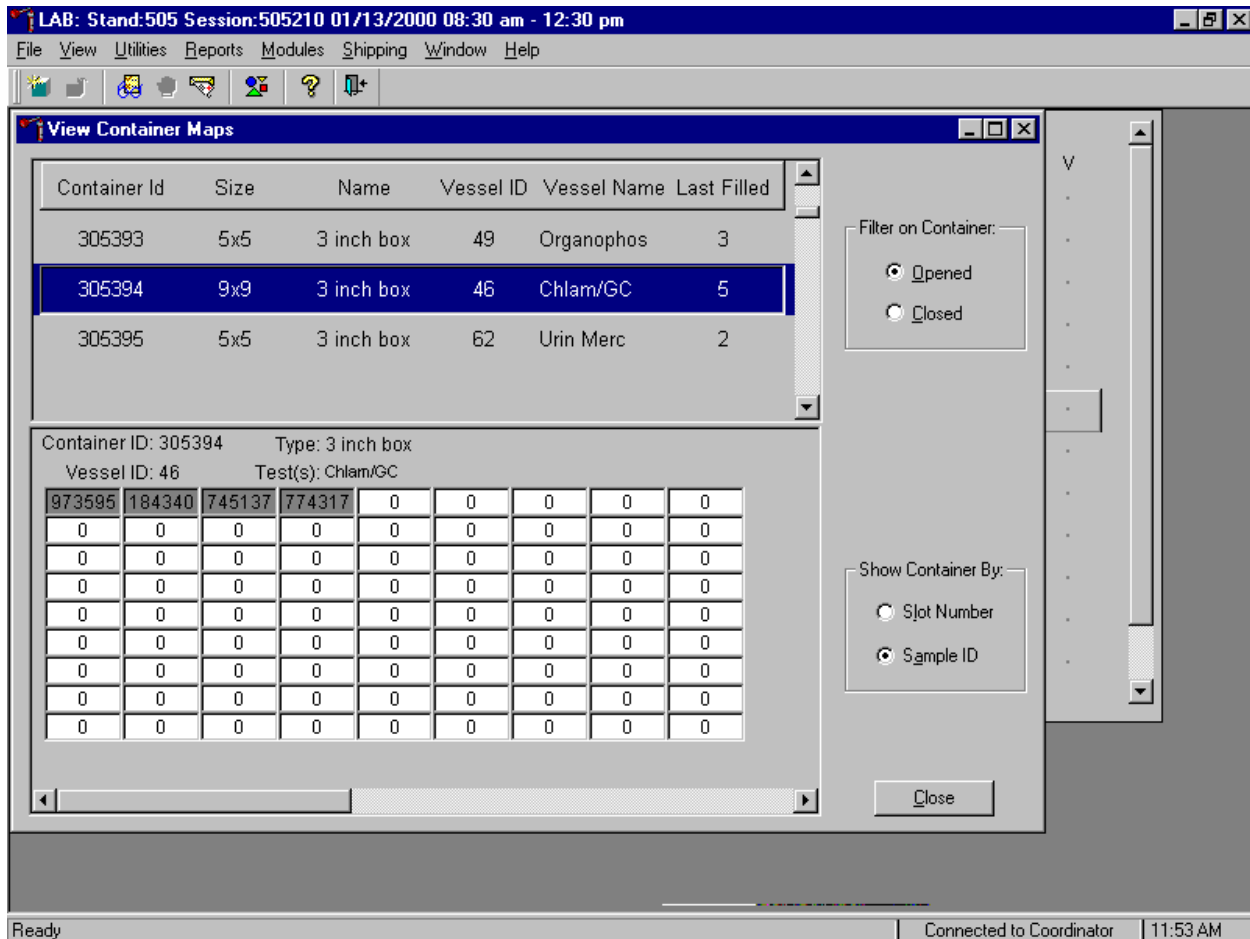
5.10.2 Check Storage Containers

Check the slot assignment of containers associated with vessels 45-51, 58, 59, 62, 65-67, and 69 at the end of each session. Access the Container Map report.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping} in the menu bar, drag the arrow to {Container Map}, and left click or type [Alt] [R] or [Alt] [S], [C].

Verify the contents of each container against the container map.

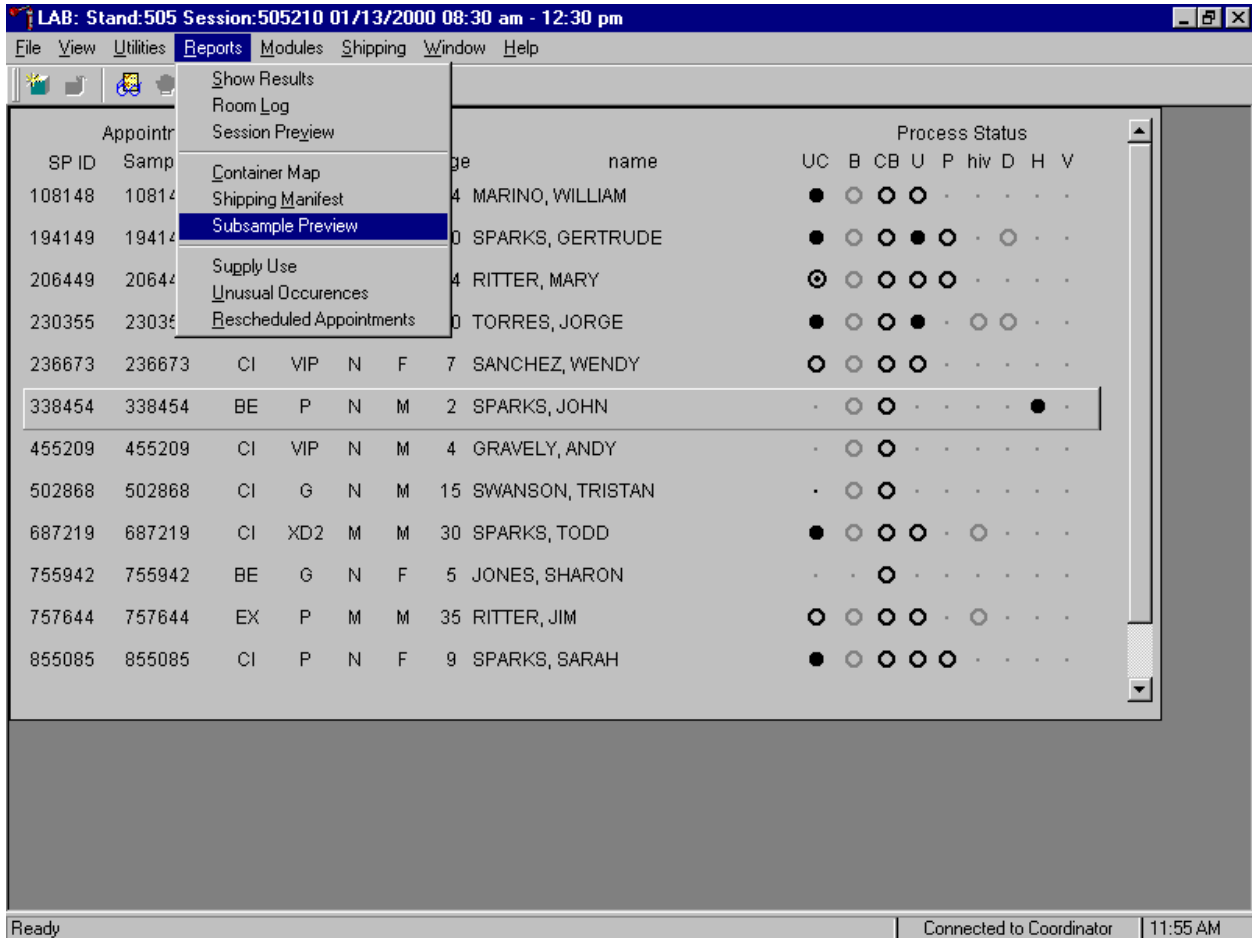


- Set the Filter on Container to "Opened" by using the mouse to direct the mouse arrow to "Opened" and left click.
- Set the Show Container By to "Sample ID" by using the mouse to direct the mouse arrow to "Sample ID" and left click.
- Highlight or select the first container ID for vessel 45 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 45.
- To sort on Container ID, Size, Name, Vessel ID, Vessel Name, or Last Filled, use the mouse to direct the mouse arrow to any column title and right click. To reverse the order, use the mouse to direct the mouse arrow to the column title and right click.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.

- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining urine, dental saliva and hair containers.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

5.11 Subsample and Session Previews

Access the Subsample Preview report to view all SPs in the current session and the selected subsamples for which they are eligible.



To access the Subsample Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Subsample Preview}, and left click.

Review the Subsample Preview report.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505210 Process Status

Subsample Report for Session 505210

SPs Selected for Subsamples in Session 505210

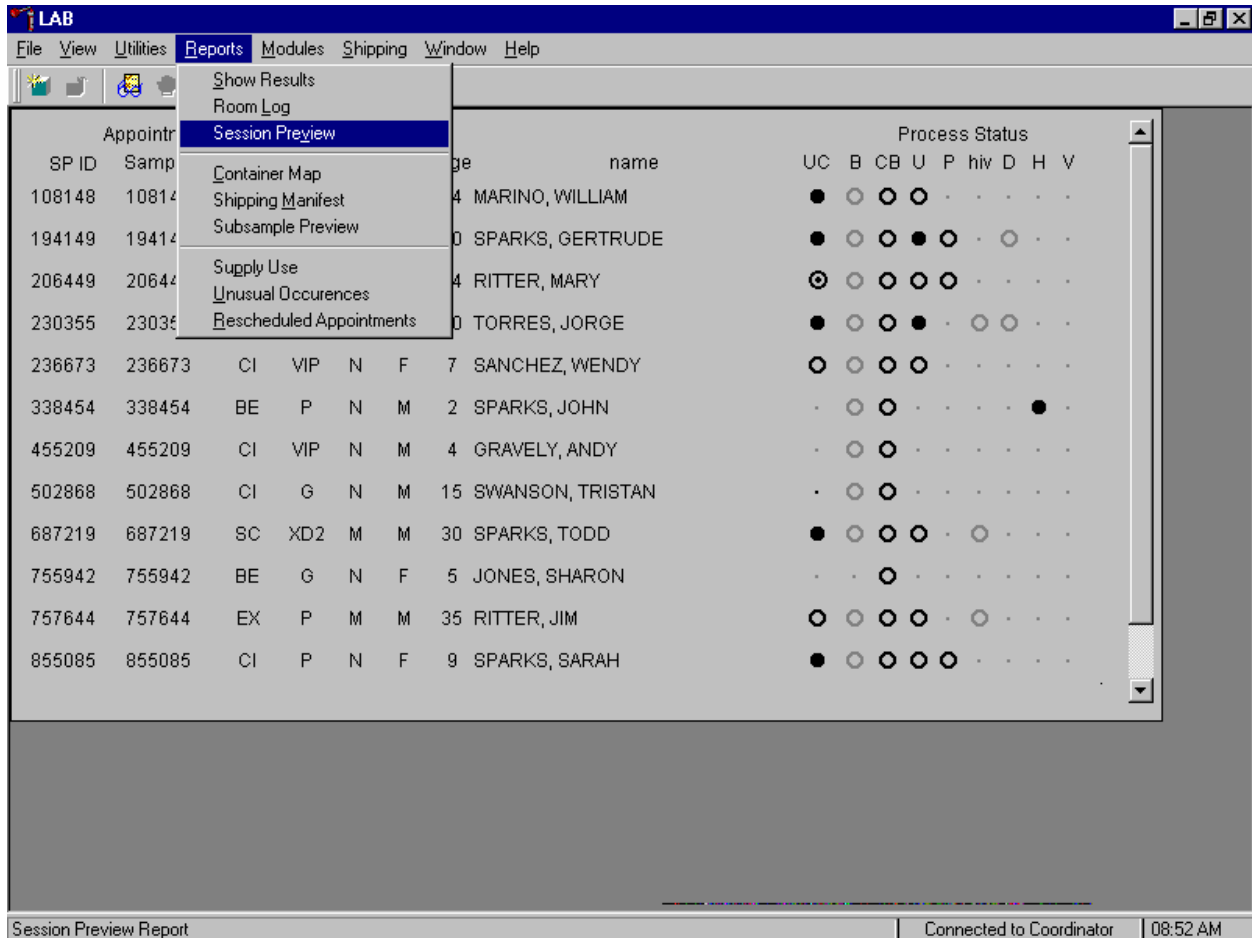
Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
5051808	194149	SPARKS, GERTRUDE	F	50	1	Balance 1 Dioxins 1 Heavy Metals
5051809	230355	TORRES, JORGE	M	40	1	Balance 1 DIMES-In person 1 Serum Phytoestrogens 1 Urine Phytoestrogens 1 PAH 1 Phthalates
5051811	338454	SPARKS, JOHN	M	2	1	DIMES-Telephone
5051816	855085	SPARKS, SARAH	F	9	1	EPA Priority Pesticide 1 Organophosphate Pesticide 1 DIMES-In person 1 Heavy Metals

1/19/00 Page 1 of 3

Ready Connected to Coordinator 11:55 AM

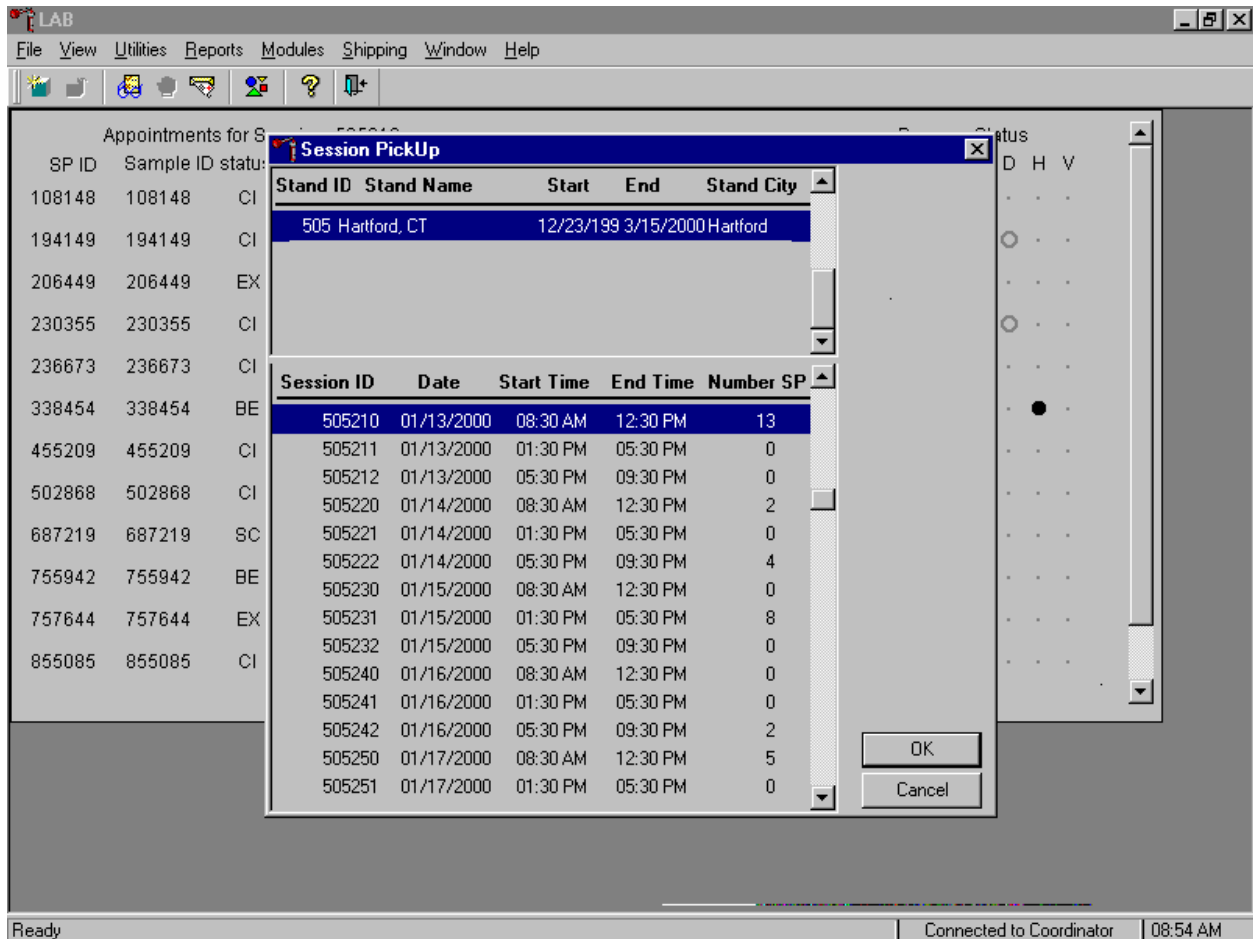
The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible to have the related vessel filled. To view the entire report, use the mouse to direct the mouse arrow to the right scroll bar, and drag the arrow up or down. To print a copy of the report, use the mouse to direct the mouse arrow to the **Print** button and left click. To exit and close the report, use the mouse to direct the mouse arrow to the **Close** button and left click.

Access the Session Preview report to view all SPs scheduled into any session including the current session.



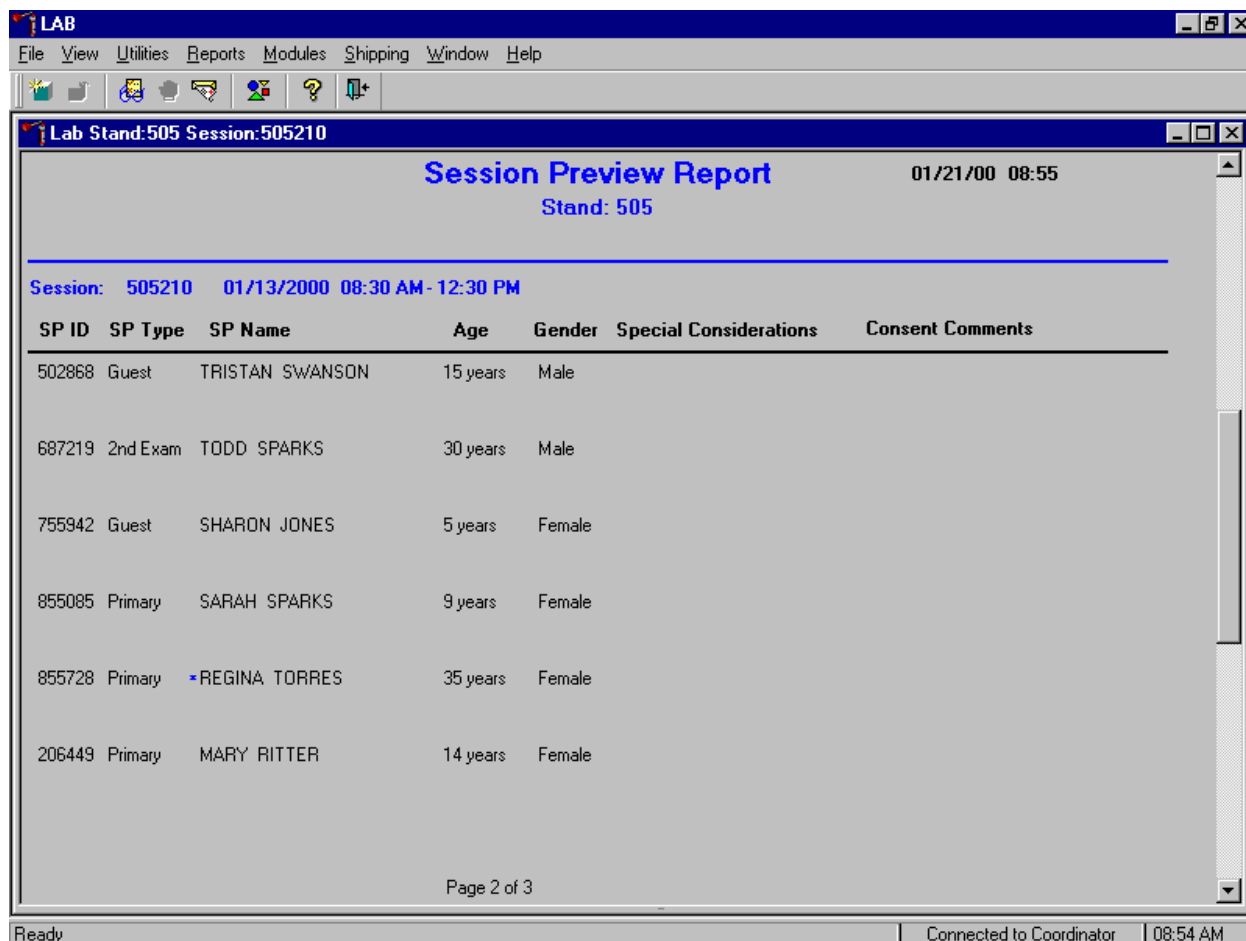
To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Session Preview} and left click or type [Alt] [R], [V].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The Session Preview Report displays.



The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last) Age, Gender and any special considerations or consent comments. A blue asterisk in front of their name indicates SPs eligible for the VOC component.

5.12 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 2 Processing Worksheet (Exhibit 5-3). Complete a Workstation 2 worksheet for each SP after performing the pregnancy test, and while processing the urine, dental saliva, and/or hair specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 5-3. Workstation 2 worksheet

URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING, DENTAL SALIVA, AND HAIR PROCESSING

SP ID _____

	Urine Collected Age 6+	Yes ✓	Yes/QNS ✓	No ✓	Comments: communication problem no time SP ill/emergency SP refusal SP unable to comply		
Result							
	Pregnancy Test Age 8-17	Negative ✓	Invalid ✓	Positive ✓	Serum Confirmation Result (Send observation to physician)		
Result							
	Pregnancy Test Age 18-59	Negative ✓	Invalid ✓	Positive ✓			
Result							
ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Comments <i><u>ONS</u></i> <i>Blood Present</i>	Slot #
45	Alb/Creat	6+	3	Urine			
46	Chlam/GC	14-39	4	Urine			
47	NTX	8+	1	Urine			
69	Urn Iodine	6+	3	Urine			
48	Prior Pest	6+	10	Urine			
49	Organophos	6+	10	Urine			
62	Urn Merc	16-49	5	Urine			
50	Heavy Metal	6+	10	Urine			
65	Urn Phytoes	6+	3	Urine			
66	PAH	6+	3	Urine			
67	Phthalates	6+	3	Urine			
51	Xtra Urine	6+	5	Urine			
52	Xtra Urine	6+	5	Urine			
53	HIV	18-49	3	Urine			
58	Saliva	40+	5.0	Saliva			
59	Methylmerc	1-5 16-49	100 mg	Hair			

**National Health and Nutrition Examination Survey
National Center for Health Statistics
United States Public Health Service
Procedure: Pregnancy Testing**

Prepared by _____

Date Adopted _____

Approved by _____

Director

Signed _____

Director

Dated _____

Director

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

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Date Reviewed _____

Reviewed by _____

Date Reviewed _____

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6. URINE PREGNANCY TEST

I. Purpose and Principle of the Test

Perform a pregnancy test on females of all person types except home exam, ages 12-59, and girls 8-11 who report that they are menstruating when asked during the home interview. This test excludes pregnant women ages 8-59 from participating in the dual-energy x-ray absorptiometry (DXA), bioelectrical impedance analysis (BIA), and cardiovascular fitness (CV Fitness) components of the MEC exam. Report test results immediately since these components are not assigned until the results of the pregnancy test are documented. If a urine pregnancy test is positive on any female SPs ages 8-17, the result is confirmed using a serum test. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

Tests for confirming pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone that the placenta begins to produce in increasing amounts about 10 days after fertilization. The Nimbus® Plus SU test kit for hCG is an immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine/serum for the early detection of pregnancy. It is intended for professional use as an aid in the diagnosis of pregnancy.

The Nimbus® Plus SU Test Device consists of a chromatographic absorbent membrane strip and a unique combination of monoclonal and polyclonal antibodies that selectively identify hCG test samples with a high degree of sensitivity. Within 5 minutes, the test detects levels of hCG as low as 25 mIU/mL (corresponding to 7 to 10 days after conception).

In the test procedure, urine or serum is added to the sample well with the aid of a dropper, and allowed to migrate through the absorbent device. The labeled antibody-dye conjugate then binds to the hCG in the specimen forming an antibody-antigen complex. The complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink/rose color band when hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no formation of a pink-rose color band in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive

reaction zone and control zone. Unbound conjugate binds to the reagents in the control zone, producing a pink/rose color band, demonstrating that the reagents and Test Devise are functioning correctly.

II. Special Safety Precautions

Nimbus®Plus SU Pregnancy Test (Serum or Urine) test kits

- Nimbus®Plus SU is for *in vitro* diagnostic use only.
- Observe standard guidelines for handling biological hazards.
- Wear gloves while handling specimens. After use, dispose of gloves and other contaminated materials appropriately and wash hands.
- Do not use the kit beyond the expiration date printed on the outside of the box.

Hybritech® ICON II HCG Control Set (Urine)

- ICON II HCG Control Set (Urine) material is intended for *in vitro* diagnostic use only.
- The controls of this kit contain material of human origin which has been tested using FDA approved methods and has been found negative for antibody to human immunodeficiency virus (HIV-I and HIV-II), antibody to Hepatitis C virus, and for Hepatitis B surface antigen (HBsAG). No known test method can offer total assurance that HIV-I, HIV-II, Hepatitis B virus, Hepatitis C virus, or other known infectious agents are absent. Handle these reagents as if they were potentially infectious. Information on handling human serum is provided in the USA CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories* (HHS publication NO NIH 88-6395).

Hybritech® ICON II HCG Control Set (Serum)

- ICON II HCG Control Set (Serum) material is intended for *in vitro* diagnostic use only.
- Some components in this kit contain material of human origin which has been tested using FDA approved methods and has been found negative for antibody to human immunodeficiency virus (HIV-I and HIV-II), antibody to Hepatitis C virus, and for Hepatitis B surface antigen (HBsAG). No known test method can offer total assurance that HIV-I, HIV-II, Hepatitis B virus, Hepatitis C virus, or other known infectious agents are absent. Handle these reagents as if they were potentially infectious. Information on handling human serum is provided in the USA CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories* (HHS publication NO NIH 88-6395).

- Reagents in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash immediately with plenty of water.

III. Computerization: Integrated Survey and Information System (ISIS)

The MEC automated ISIS system captures all data and stores it electronically at Westat's home office in Rockville, Maryland. Access the Pregnancy QC module to enter the quality control results. The session number, technologist ID, and run number are automatically captured; enter the kit lot number and expiration date, and the urine and serum control lot and expiration dates. Record control results and save them to the database. All pregnancy quality control results are immediately available electronically at the home office. All data is backed up and stored at Westat's home office.

IV. Specimen Collection and Preparation

Collect a urine specimen on all SPs 6 years and older into a clean plastic container and document the collection in the urine collection module as described in Chapter 5. Perform a urine pregnancy test on females of all person types except home exam, ages 12-59 and girls 8-11 who report that they are menstruating when asked during the home interview. If a urine pregnancy test is positive on any female SPs ages 8-17 confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function. Assay all specimens immediately and record results in the Pregnancy Testing module.

V. Procedure for Microscopic Examination

Not applicable.

VI. Reagents and Supplies

A. Reagents

Nimbus®Plus SU Pregnancy Test (Serum or Urine) test kits

Product Number 1044 (25 or bulk)

Biomerica

1533 Monrovia Avenue

Newport Beach, CA 92663

949-645-2111

1-800-854-3002

■ Components

- One Test Device. (25 or bulk) – Contains a goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG-dye conjugate in a protein matrix with 0.1% sodium azide.
- Transfer dropper - Plastic pipettes for measuring and dispensing patient samples. (Packaged together with the Test Device in a foil pouch.)
- Product instructions

■ Storage and Stability

- Store the Nimbus® Plus SU Pregnancy Test kit at room temperature (15°C - 28°C, 59°F -83°F). Kits are stable up to the expiration date printed on the Test Device package. Date and initial the kit when putting it into use.

Pregnancy Control Sets – Urine and Serum

ICON II HCG Control Set (Urine)

Product Number 9115 (50 test)

Hybritech INC.

San Diego, CA 92121

1-800-854-1957

■ Components

- Hybritech® ICON II HCG Control Set (Urine) is a stable human urine-based material for use as a quality control material. Use controls in the same manner as

SP specimens in accordance with the protocol provided in the Nimbus® Plus SU directional insert.

- Positive Control: Human urine containing approximately 50 mIU hCG/mL and 0.05% Dowicil 200 as a preservative. (3 x 5 mL)
- Negative Control: Human urine containing no detectable concentration of hCG and 0.05% Dowicil 200 as a preservative. (3 x 5 mL)

■ Storage and Stability

- Store the ICON II HCG Control Set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the box label.
- Quantitative hCG values referenced in the package insert were calibrated according to World Health Organization Third International Standard for Chorionic Gonadotrophin (WHO 3rd IS #75/537).

ICON II HCG Control Set (Serum)

Product Number 9107 (50 test)

Hybritech INC.

San Diego, CA 92121

1-800-854-1957

■ Components

- Hybritech® ICON II HCG Control Set (Serum) is a stable human serum-based material for use as a quality control material. Use controls in the same manner as SP specimens in accordance with the protocol provided in the Nimbus® Plus SU directional insert.
- Positive Control: Human serum containing approximately 25 mIU hCG/mL and a preservative. (2 x 10 mL)
- Negative Control: Human serum containing no detectable concentration of hCG and a preservative. (2 x 10 mL)

■ Storage and Stability

- Store the ICON II HCG Control Set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the box label.
- Quantitative hCG values referenced in the package insert were calibrated according to World Health Organization Third International Standard for Chorionic Gonadotrophin (WHO 3rd IS #75/537).

B. Supplies

- Timer

VII. Calibration

Not applicable

VIII. Assay Procedure

Reagent and Material Preparation

- Label each Test Device with the preprinted label or write the SP ID using a felt tip pen.
- Use a new transfer dropper for each specimen or control.

Urine or Serum Testing Procedure

Perform the test procedure for Nimbus® Plus SU Pregnancy Test at room temperature (15°C - 30°C, 59°F -86°F). Before proceeding, carefully read the section entitled *Procedural Notes*.

1. Remove the Test Device from the foil wrapper by tearing along the “splice”, and place it on a clean level surface.
2. Fill the transfer dropper with urine or serum and hold the dropper vertically and dispense drops above the sample well.
3. Add precisely 4 drops (avoid air bubbles) of urine or serum into the sample well (“S”).
4. Read the results at 5 minutes.

IX. Reportable Range of Results

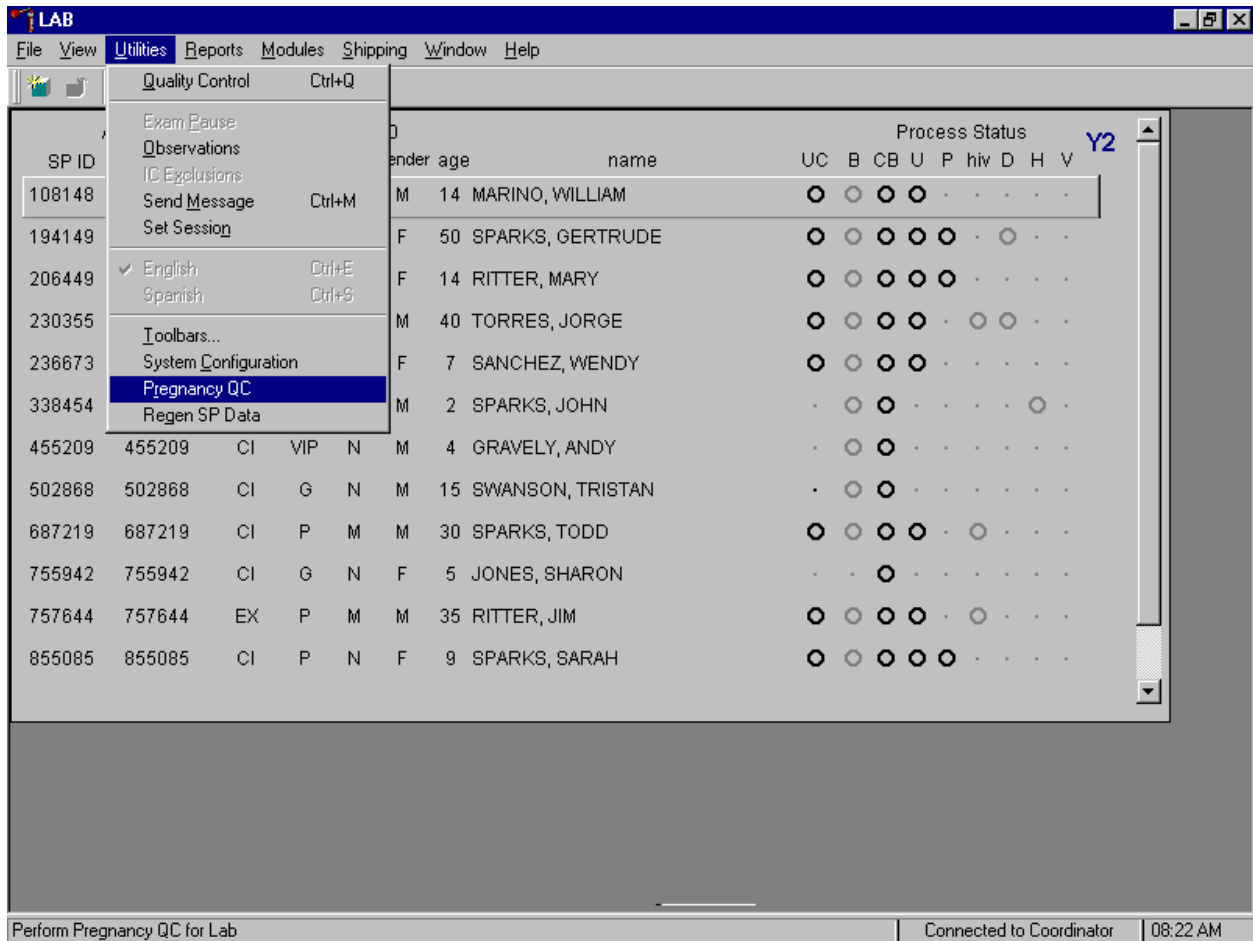
Report results as Positive, Negative, or Invalid.

X. Quality Control

Run negative and positive urine controls containing hCG at concentrations of 0 and 50 mIU/mL respectively, just prior to or concurrently with the first examinee pregnancy test each day and when putting a new kit into use. Run positive and negative serum controls with each serum pregnancy test. The pregnancy QC module contains the following information:

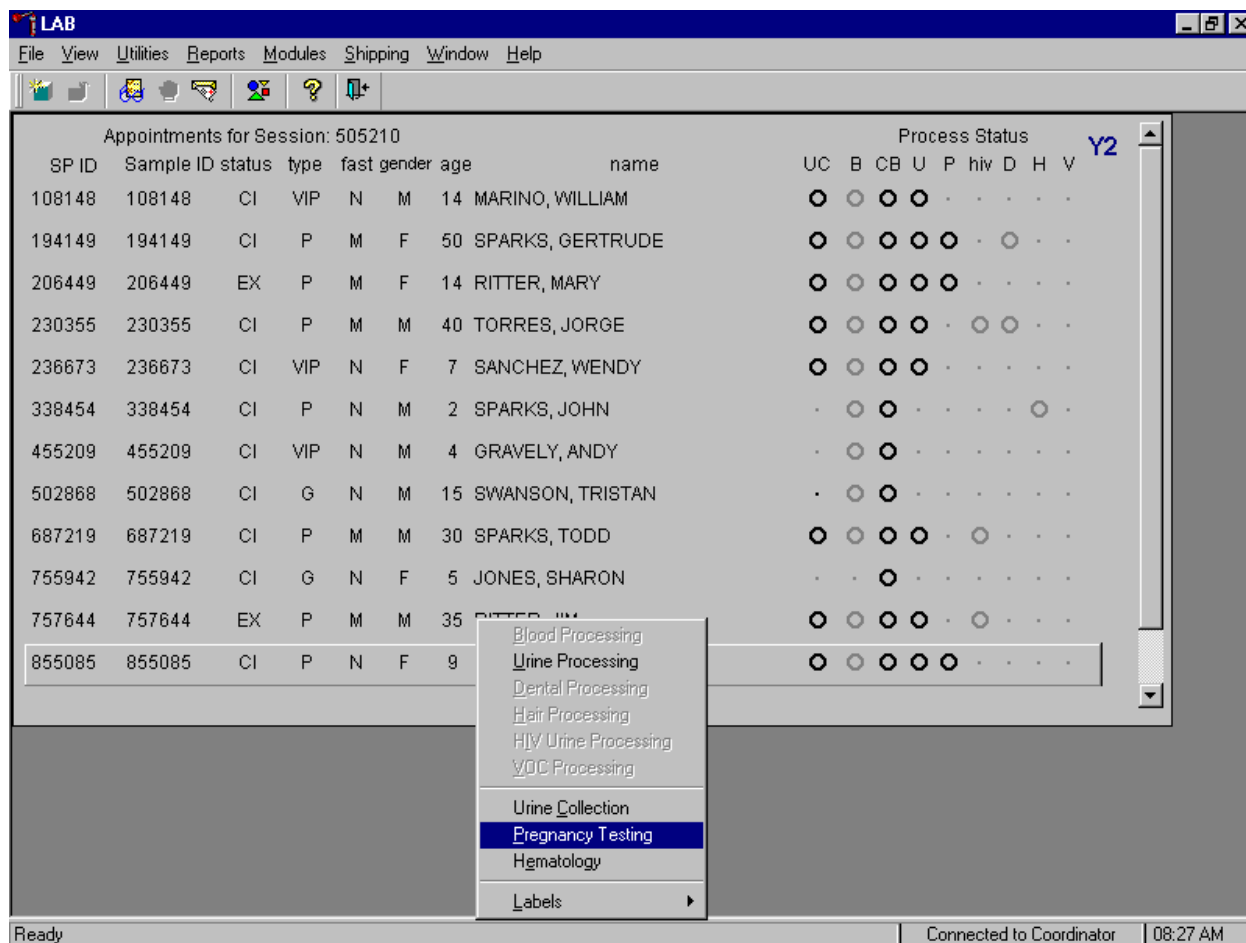
- The session ID number links to the stand number, stand location, date, including day, month, and year. The technologist ID is automatically captured.
- Kit lot number and expiration date fill in automatically from the prior QC report. Update or manually enter this information if necessary.
- The control lot number and expiration date for both the urine and serum control fills in automatically from the prior QC report. Update or manually enter this information if necessary.
- The Control QC Type is either urine or serum. The default type is set as urine.
- Negative Control result
- Positive Control result

Open the Pregnancy QC module.



To open the pregnancy QC module, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the arrow to {Pregnancy QC} and left click or type [Alt] [U], [R].

Alternatively, open the Pregnancy QC module from the heads-up screen.



To access the Pregnancy QC module from the heads-up screen, use the up and down keys to move up and down the list until the correct SP is highlighted or use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing} and left click or type [P].

The pregnancy QC window displays.

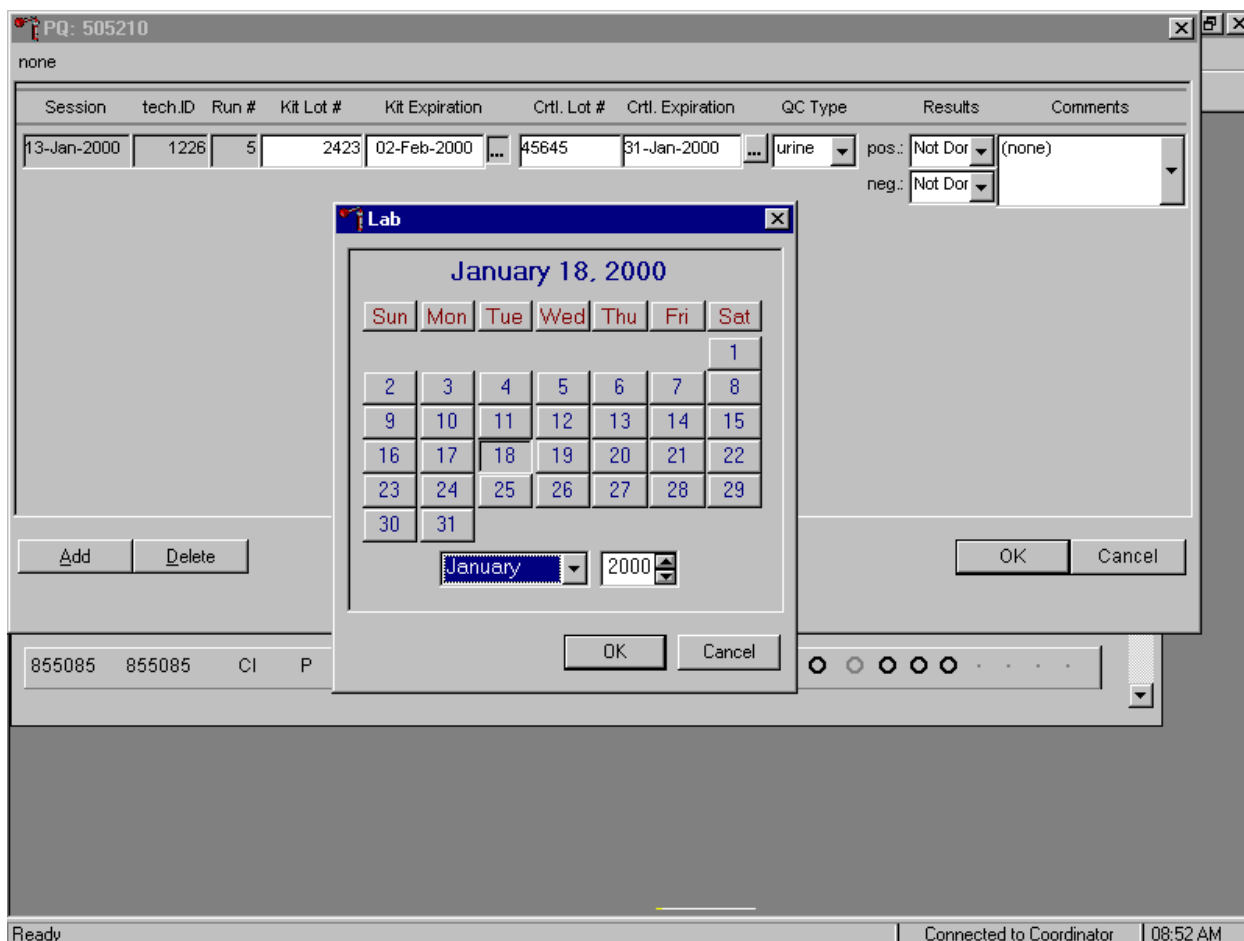
The screenshot shows a software window titled "PQ: 505210" with a "none" label. It contains a data entry form with the following fields and values:

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	02-Feb-2000	45645	31-Jan-2000	urine	pos.: Not Dor neg.: Not Dor	(none)

Below the table are buttons for "Add", "Delete", "OK", and "Cancel". At the bottom of the window, there is a status bar showing "Ready", "Connected to Coordinator", and "08:48 AM".

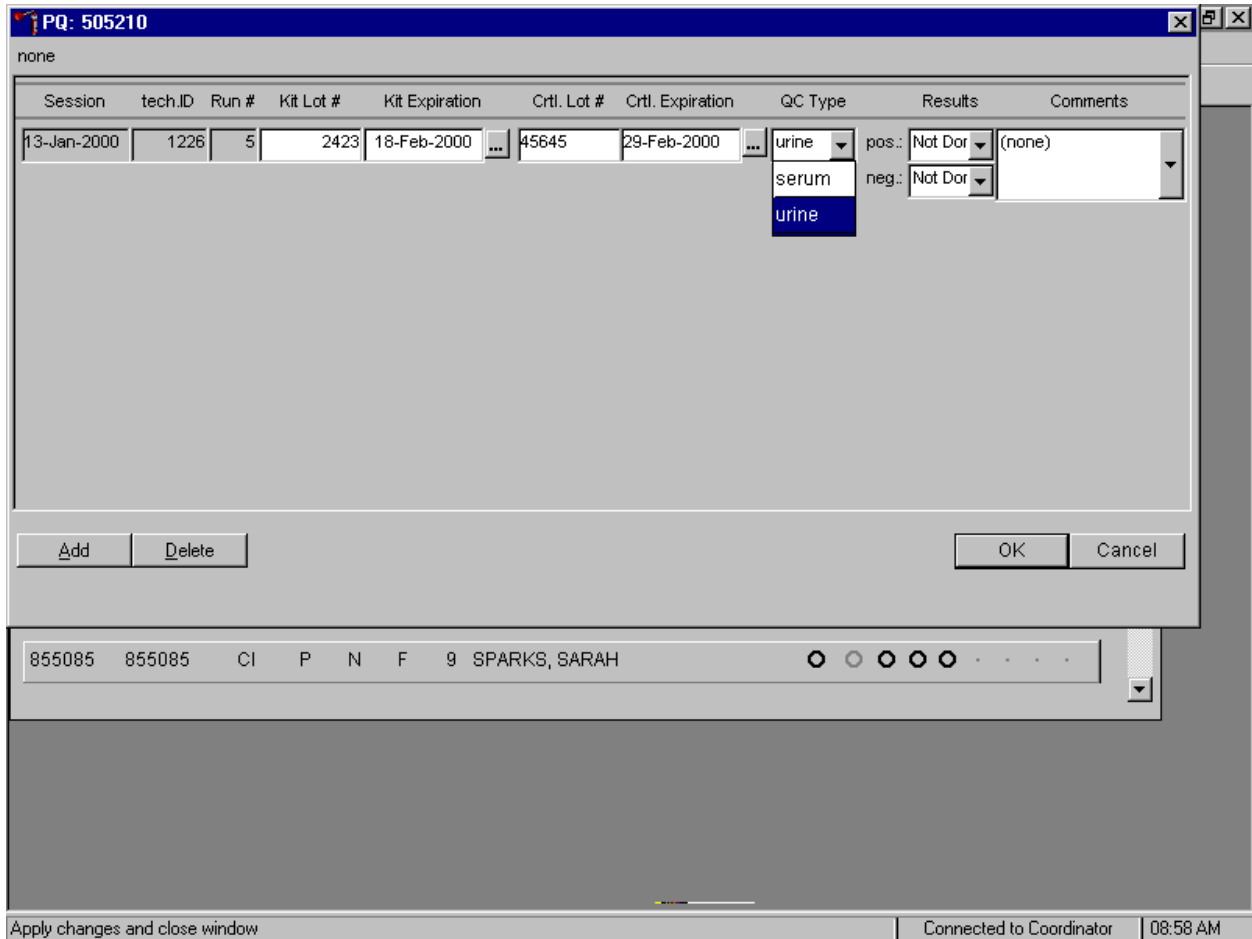
The pregnancy QC module automatically captures the session date and technologist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type - urine. If the window defaults to the current kit, verify the existing lot number and expiration date. If the lot number is incorrect, type in the new kit lot number using the keyboard's numeric keys and select [Tab] to progress to the Kit Expiration blank. Use the calendar to correct the Kit Expiration date. If the screen defaults to the current Ctrl lot number, verify the existing lot number and expiration date. If the lot number is incorrect, type in the new control lot number using the keyboard numeric keys and select [Tab] to progress to the Ctrl Expiration blank. Use the calendar to correct either the Kit or Ctrl Expiration date.

Update the Kit or Ctrl Expiration date using the calendar function.



Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and select [Tab] or use the calendar to enter the date. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis and left click. Alternatively, use the keyboard and press [Shift] then [C/c] to display the calendar. To select the correct month, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to up down controls on the spin box and toggle the year up and down. To transfer this date into the text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or to exit the calendar function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Select the control QC Type.



The QC control type default is “Urine.” To change the QC type to serum or to select urine, use the mouse to direct the mouse arrow to the drop down list, drag the mouse arrow to either serum or urine and left click.

Record the positive and negative control results.

The screenshot shows a software window titled "PQ: 505210" with a "none" subtitle. The main area contains a table with the following columns: Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Ctrl. Lot #, Ctrl. Expiration, QC Type, Results, and Comments. The first row of data is: 13-Jan-2000, 1226, 5, 2423, 18-Feb-2000, 45645, 29-Feb-2000, urine, pos.: Not Done (none), neg.: Not Done. Below the table are "Add" and "Delete" buttons. At the bottom right are "OK" and "Cancel" buttons. A status bar at the bottom shows "Apply changes and close window", "Connected to Coordinator", and "08:59 AM".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	18-Feb-2000	45645	29-Feb-2000	urine	pos.: Not Done (none) neg.: Not Done	

To enter a result in the positive result field, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices; Positive, Negative, and Invalid and select [Tab]. Alternatively, use the mouse to direct the mouse arrow to the drop down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid” and left click. If “Positive” is entered, the Negative response box is highlighted. Type [Tab] to move to the negative result field.

Enter a result in the negative result field.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	18-Feb-2000	45645	29-Feb-2000	urine	pos.: Positive neg.: Not Done	(none)

Buttons: Add, Delete, OK, Cancel

Status Bar: Apply changes and close window | Connected to Coordinator | 09:02 AM

To enter a result in the negative result field, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices; Positive, Negative, and Invalid and [Tab]. Alternatively, use the mouse to direct the mouse arrow to drop down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid,” and left click.

Save results when positive and negative controls demonstrate the expected result.

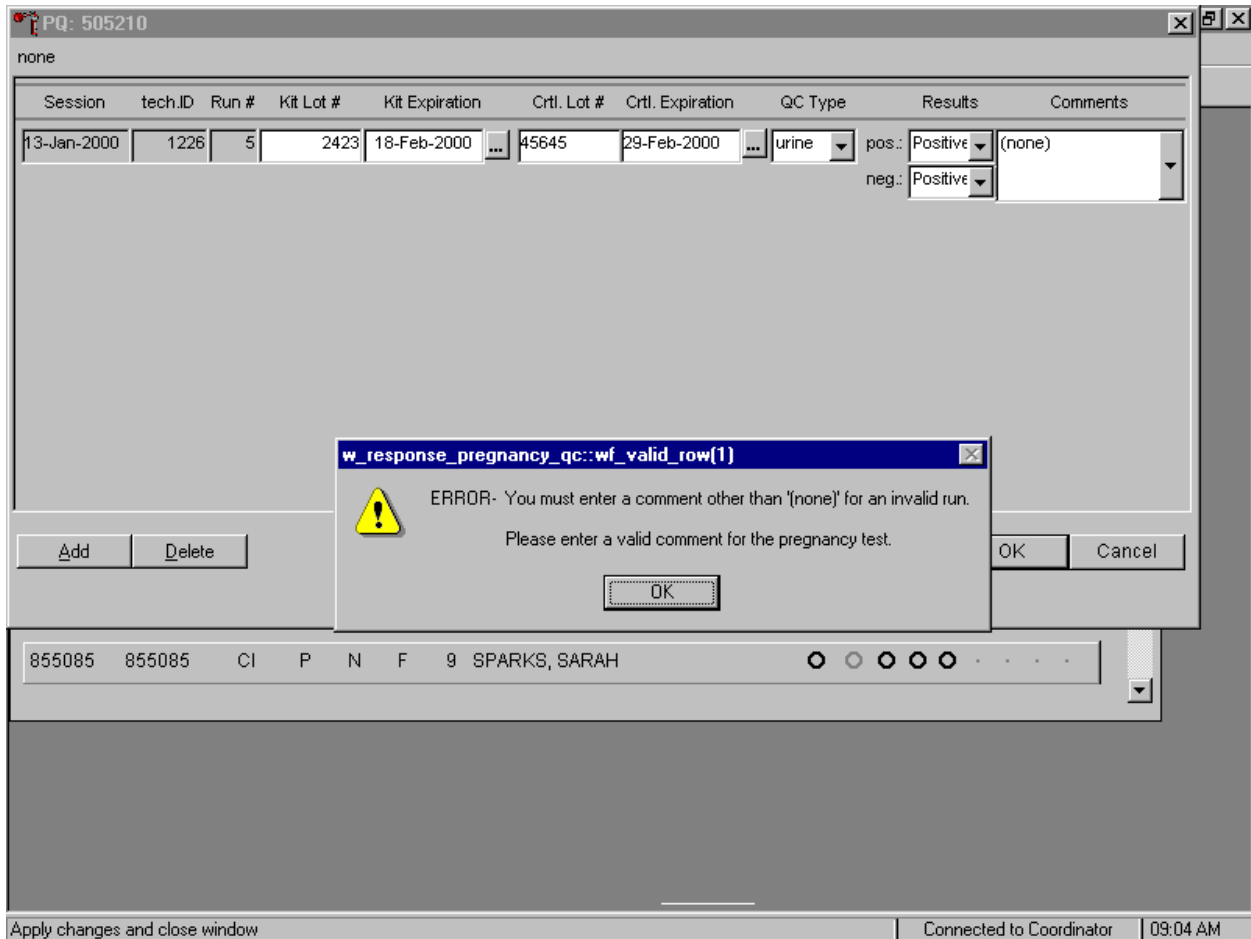
Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	18-Feb-2000	45645	29-Feb-2000	urine	pos.: Positive neg.: Negative	(none)

Buttons: Add, Delete, OK, Cancel

Status bar: Apply changes and close window | Connected to Coordinator | 09:03 AM

If the positive and negative controls demonstrate the expected result, use the mouse to direct the mouse arrow to the **OK** button and left click to save these results and to proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To delete the information in the window and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the **Delete** button and left click or type [D].

Enter a comment for any result that is inconsistent with expected results. If the **OK** button is selected before a comment is entered, the ERROR informational message box displays. Review the text in this box.



To close the box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

Enter a comment for any result that is inconsistent with expected results.

The screenshot shows a software window titled "PQ: 505210" with a table of data. The table has the following columns: Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Crtl. Lot #, Crtl. Expiration, QC Type, Results, and Comments. The first row of data is: 13-Jan-2000, 1226, 5, 2423, 18-Feb-2000, 45645, 29-Feb-2000, urine, pos.: Positive, (none). A dropdown menu is open for the "Results" column, showing the following options: (none), no additional test kit, opened new test kit s, repeat negative contro, and repeat positive contro. The window also has "Add" and "Delete" buttons on the left, and "OK" and "Cancel" buttons on the right. At the bottom of the window, there is a status bar with the text "Apply changes and close window", "Connected to Coordinator", and "09:04 AM".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	18-Feb-2000	45645	29-Feb-2000	urine	pos.: Positive neg.: Positive	(none)

Enter the appropriate comment in the “Comments” column by using the mouse to direct the mouse arrow to the drop down list, left click to display the choices, drag the mouse arrow to the most appropriate choice, and left click when the correct choice is highlighted. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

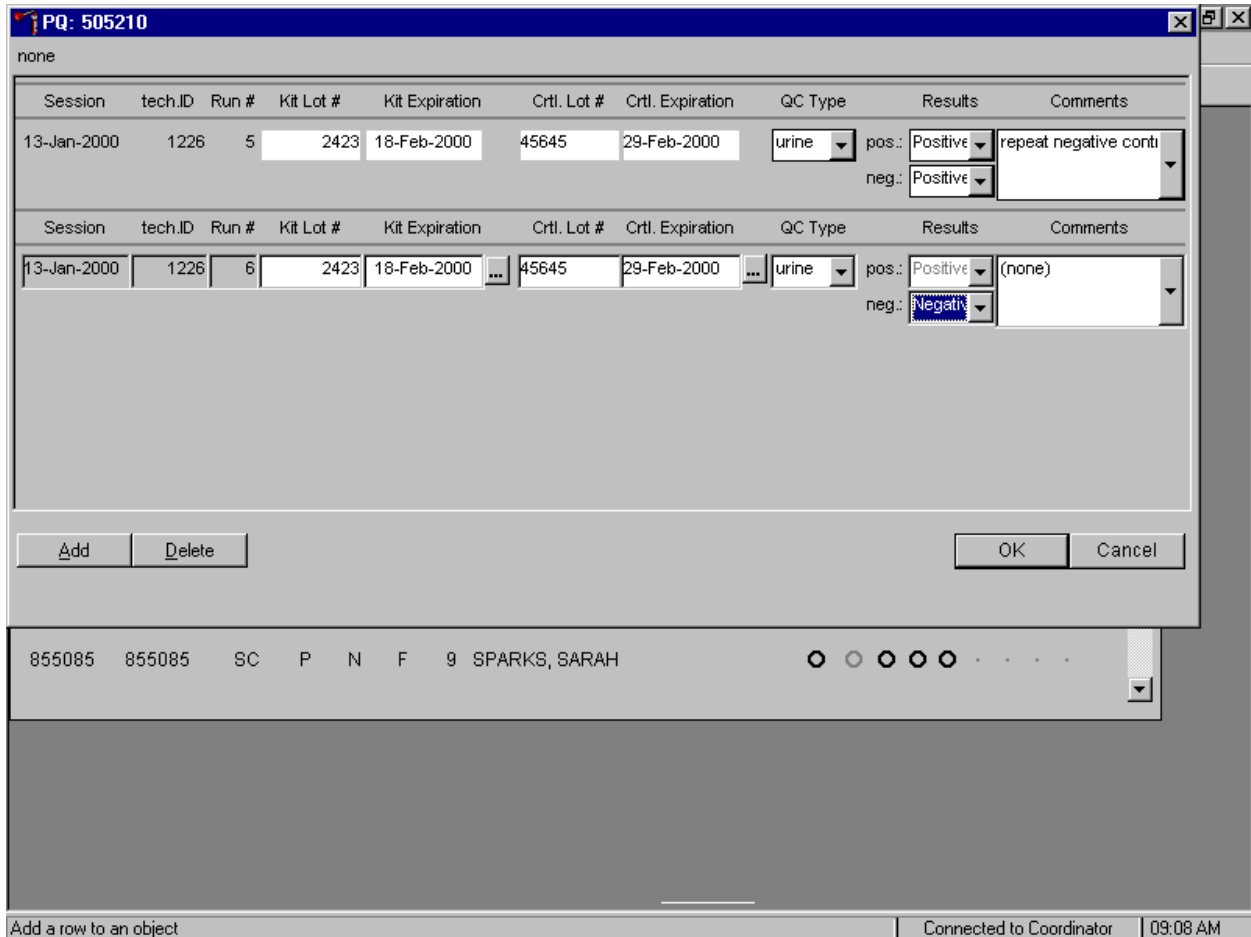
Review the comment.

The screenshot shows a software window titled "PQ: 505210" with a "none" label. It contains a table with the following columns: Session, tech.ID, Run #, Kit Lot #, Kit Expiration, Crtl. Lot #, Crtl. Expiration, QC Type, Results, and Comments. The first row of data is: 13-Jan-2000, 1226, 5, 2423, 18-Feb-2000, 45645, 29-Feb-2000, urine, pos.: Positive, neg.: Positive, and repeat negative control. A dropdown menu is open over the "Results" column, showing options: (none), no additional test kit, opened new test kit s, repeat negative contro (highlighted), and repeat positive contro. Below the table are "Add" and "Delete" buttons. At the bottom right are "OK" and "Cancel" buttons. A status bar at the bottom shows "Apply changes and close window", "Connected to Coordinator", and "09:06 AM".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	18-Feb-2000	45645	29-Feb-2000	urine	pos.: Positive neg.: Positive	repeat negative control

Review all the information in the QC window to verify its accuracy.

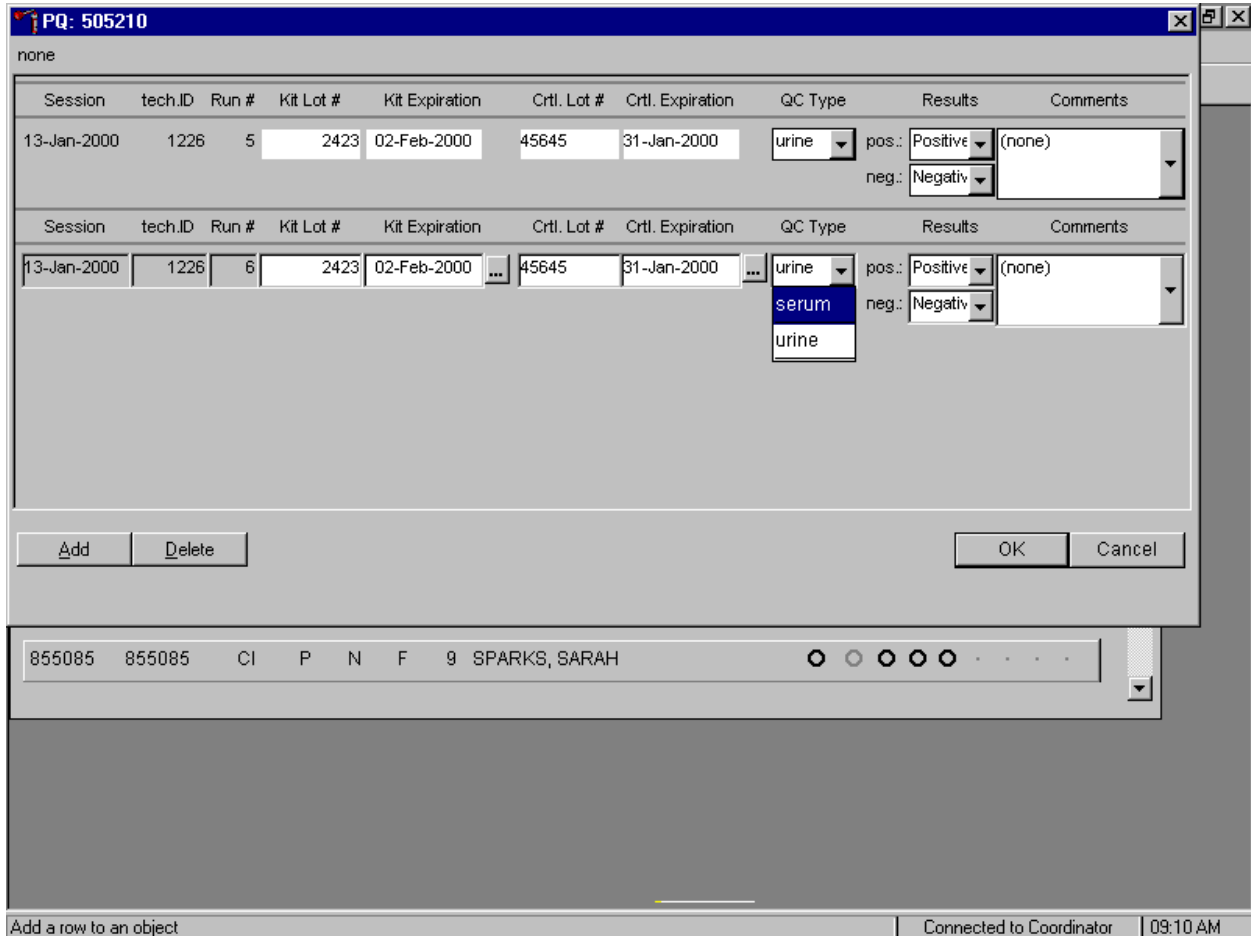
Add a new QC record and repeat the control for invalid or unexpected results.



Rerun or repeat the control that demonstrated the unexpected result. Add a new test line to record the new control results. To add a new QC test line, use the mouse to direct the mouse arrow to the **Add** button and left click or type [A]. Record the new results. If this resolves the inconsistency, use the mouse to direct the mouse arrow to the **OK** button and left click to save these results and to proceed with pregnancy testing.

If this does not resolve the situation, repeat the procedure with a different lot of controls. If this fails to resolve the problem, discard the entire lot of pregnancy test kits and test a new lot.

Add a new test line each time a control is run and remember to record the serum QC each time it is performed.



To add a new QC test line, use the mouse to direct the mouse arrow to the **Add** button and left click or type [A]. The QC Type defaults to “Urine.” Correct the control lot number and expiration date. To change the QC type to serum, use the mouse to direct the mouse arrow to the drop down list, drag the mouse arrow to serum and left click.

Record the serum control results.

none

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Crtl. Lot #	Crtl. Expiration	QC Type	Results	Comments
13-Jan-2000	1226	5	2423	02-Feb-2000	45645	31-Jan-2000	urine	pos.: Positive (none) neg.: Negative	
13-Jan-2000	1226	6	2423	02-Feb-2000	55115	25-Feb-2000	Serum	pos.: Positive (none) neg.: Negative	

Add Delete OK Cancel

855085 855085 CI P N F 9 SPARKS, SARAH

Apply changes and close window Connected to Coordinator 09:12 AM

If the positive and negative serum controls demonstrate the expected result, use the mouse to direct the mouse arrow to the **OK** button and left click to save these results and to proceed with pregnancy testing. If the positive and/or the negative serum controls fail to demonstrate the expected result(s), add a new QC record, and repeat the control.

XI. Interpretation of Results and Remedial Action

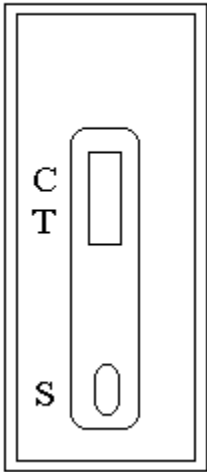


Figure 1
Nimbus Test Device

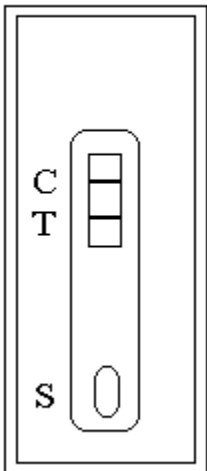


Figure 2
Positive Result
If there is a pink/rose color band in the control region (marked with a “C”) and a pink/rose color band in the test region (marked with a “T”), conclude that there is hCG in the specimen.

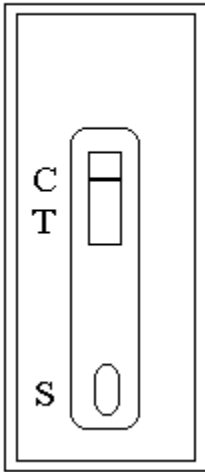


Figure 3
Negative Result
The absence of a color band in the test area next to the letter "T" indicates the absence of any detectable hCG.

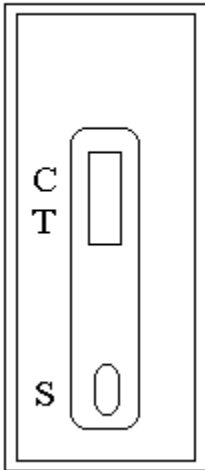


Figure 4
Invalid Result
If the color band does not appear in the control zone "C", the test results are invalid. The urine or serum may have been added to the wrong window or the Test Device may have deteriorated. Repeat the test using a new Test Device.

Positive Result

A specimen that produces a pink/rose color band in the control region and a pink/rose color band in the test region is positive for the presence of hCG.

Negative Result:

A specimen that does produce a pink/rose color band in the control region and does not produce a pink/rose color band in the test region is negative for the presence of hCG.

Invalid Result (any of the following)

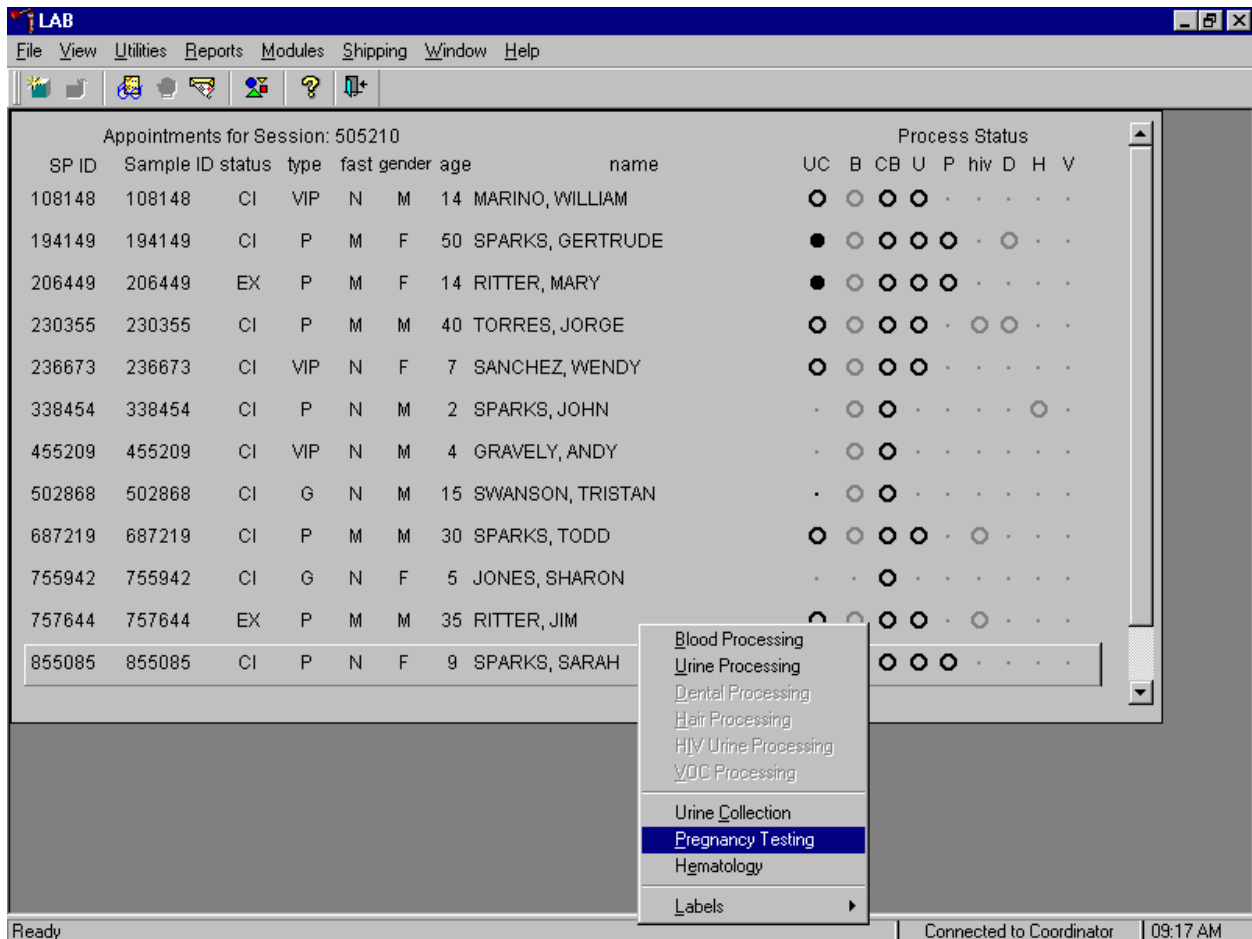
For the test to be valid, the pink/rose color band must appear in the control region. The urine or serum may have been added to the wrong window or the Test Device may have deteriorated. Retest the specimen with a new Test Device.

If an invalid test result occurs repeatedly, or for technical assistance contact the Technical Support Department, 1-800-854-3002.

A. Recording Results

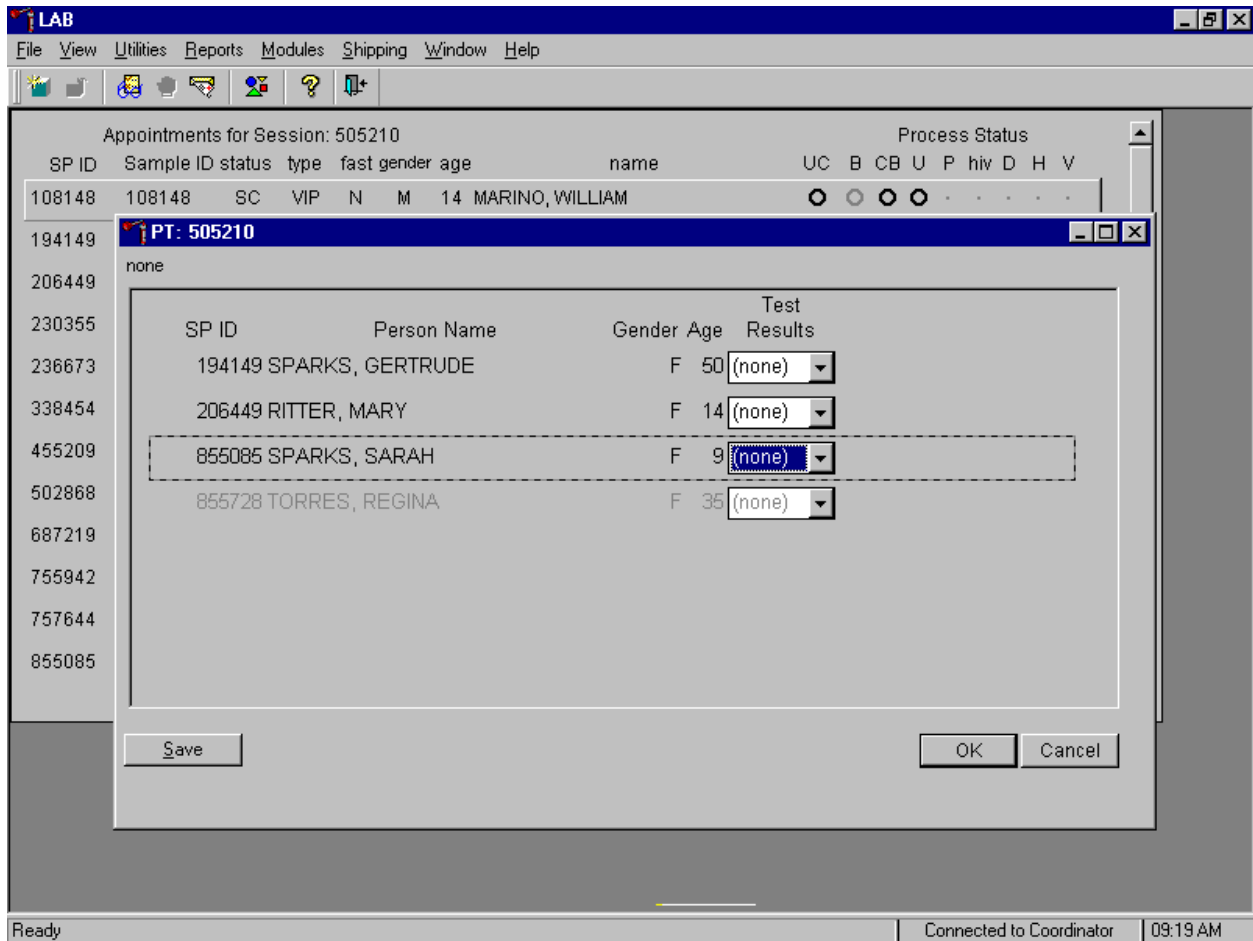
Use the heads-up display and the Pregnancy Testing module to enter the results of the Nimbus® Plus SU test kit pregnancy test result for each SP.

Use the heads-up display to access the Pregnancy Testing module.



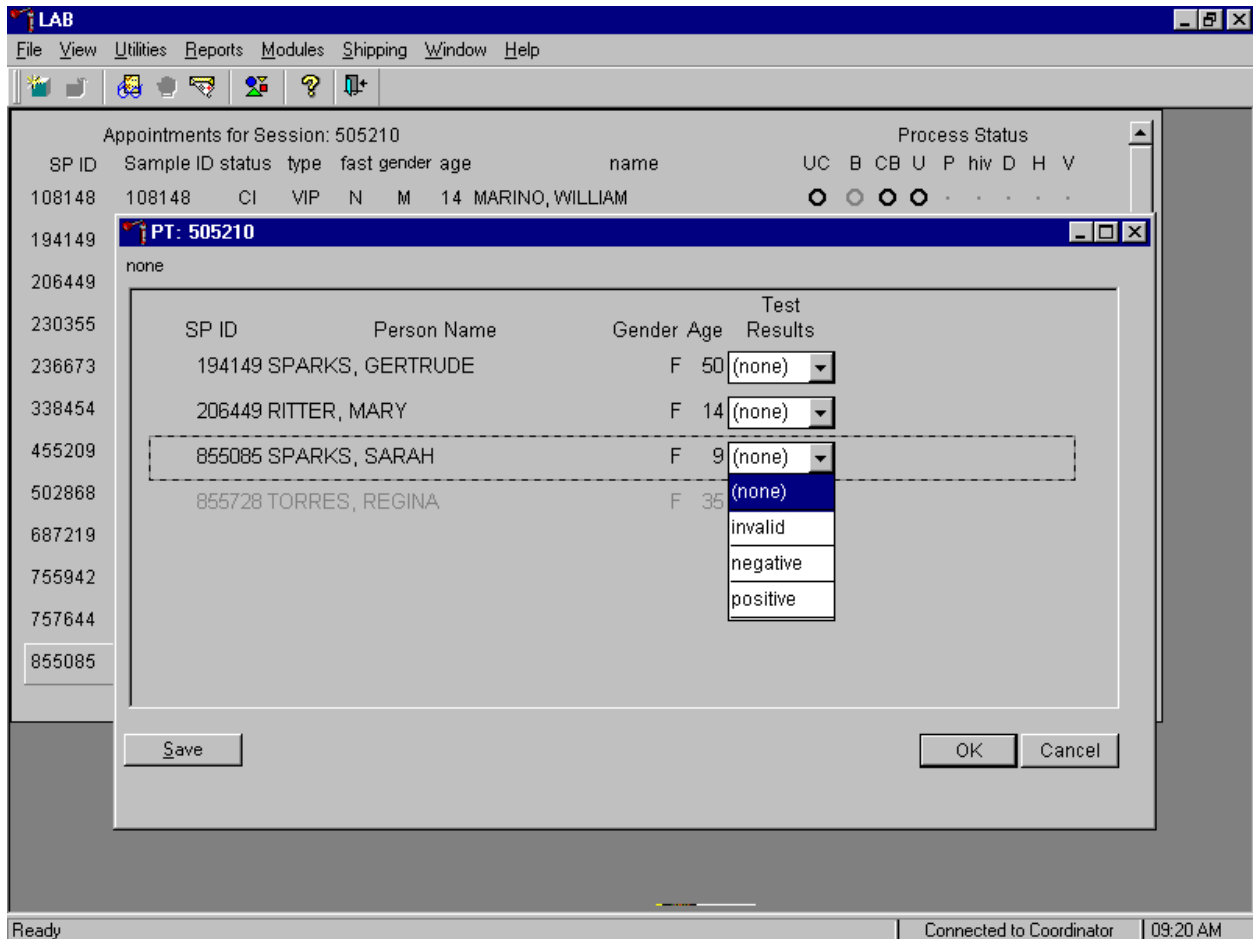
To access the Pregnancy Testing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click, or type [P/p]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Pregnancy Testing}, and left click or type [P].

The Pregnancy Testing window displays.



SPs who have urine collection results recorded as “yes” or “yes/QNS” appear black in the window. SPs who do not have urine collection results recorded appear gray in the window. The window lists the SP ID, Person Name, Gender, Age, and includes a Test Results column.

Report the results for each SP as Positive, Negative, or Invalid.



If the Test Result field is black or highlighted, record the result by typing [P/p] for Positive, [N/n] for Negative, or [I/i] for an invalid result. Alternatively, to record a result, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct choice and left click. To update the results without exiting the window, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S]. To update the results and exit the window, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue performing pregnancy tests and recording the results.

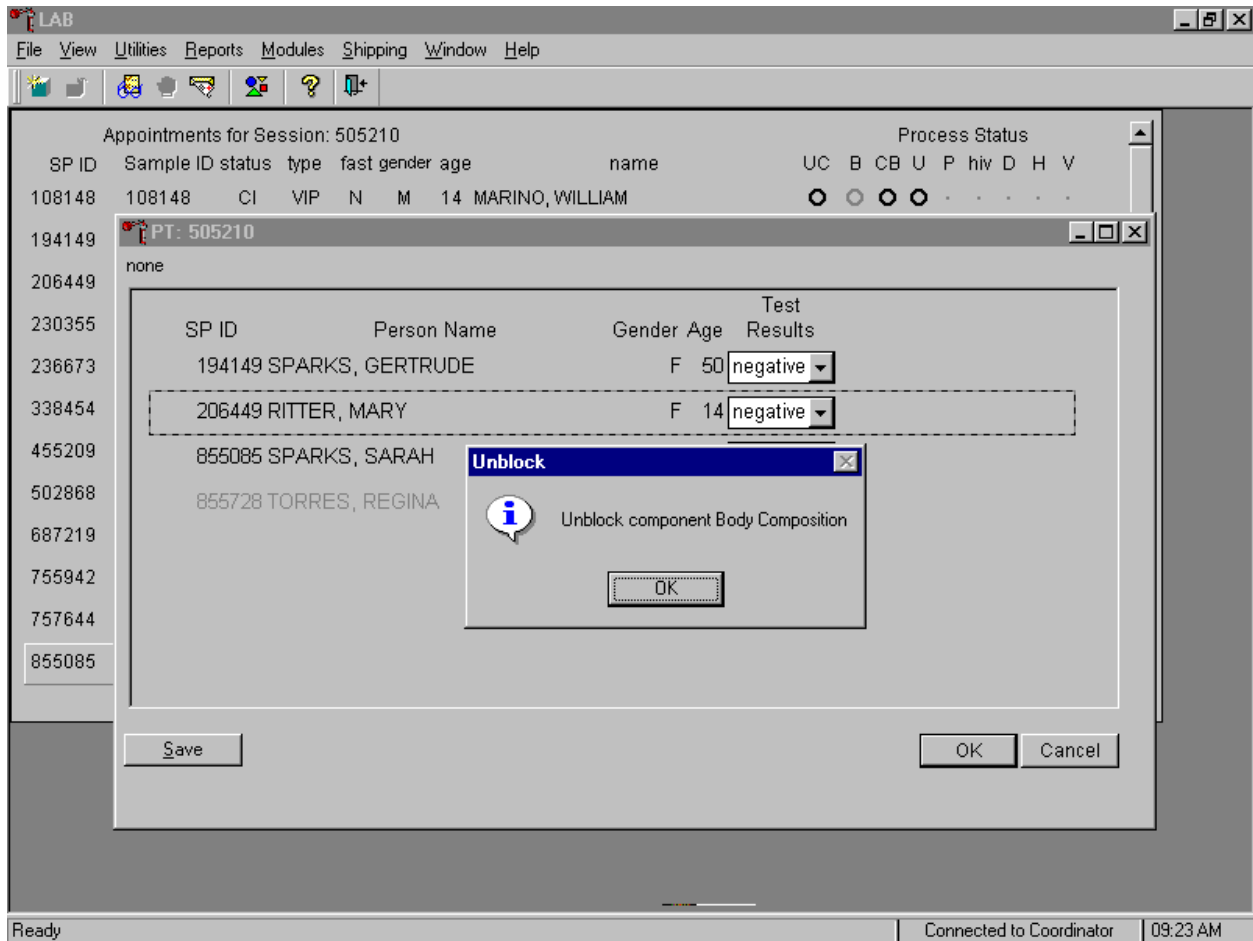
The screenshot shows a software window titled "LAB" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area displays "Appointments for Session: 505210" with a table of patient appointments. A pop-up window titled "PT: 505210" is open, showing a detailed view of a pregnancy test result for SPARKS, MARY. The test result is "negative".

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
108148	108148	CI	VIP	N	M	14	MARINO, WILLIAM	○	○	○	○

SP ID	Person Name	Gender	Age	Test Results
194149	SPARKS, GERTRUDE	F	50	negative
206449	RITTER, MARY	F	14	negative
855085	SPARKS, SARAH	F	9	positive
855728	TORRES, REGINA	F	35	(none)

Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, use the mouse to direct the mouse arrow to the **S**ave button and left click or type [S]. To update the results and exit the window, use the mouse to direct the mouse arrow to the **O**K button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

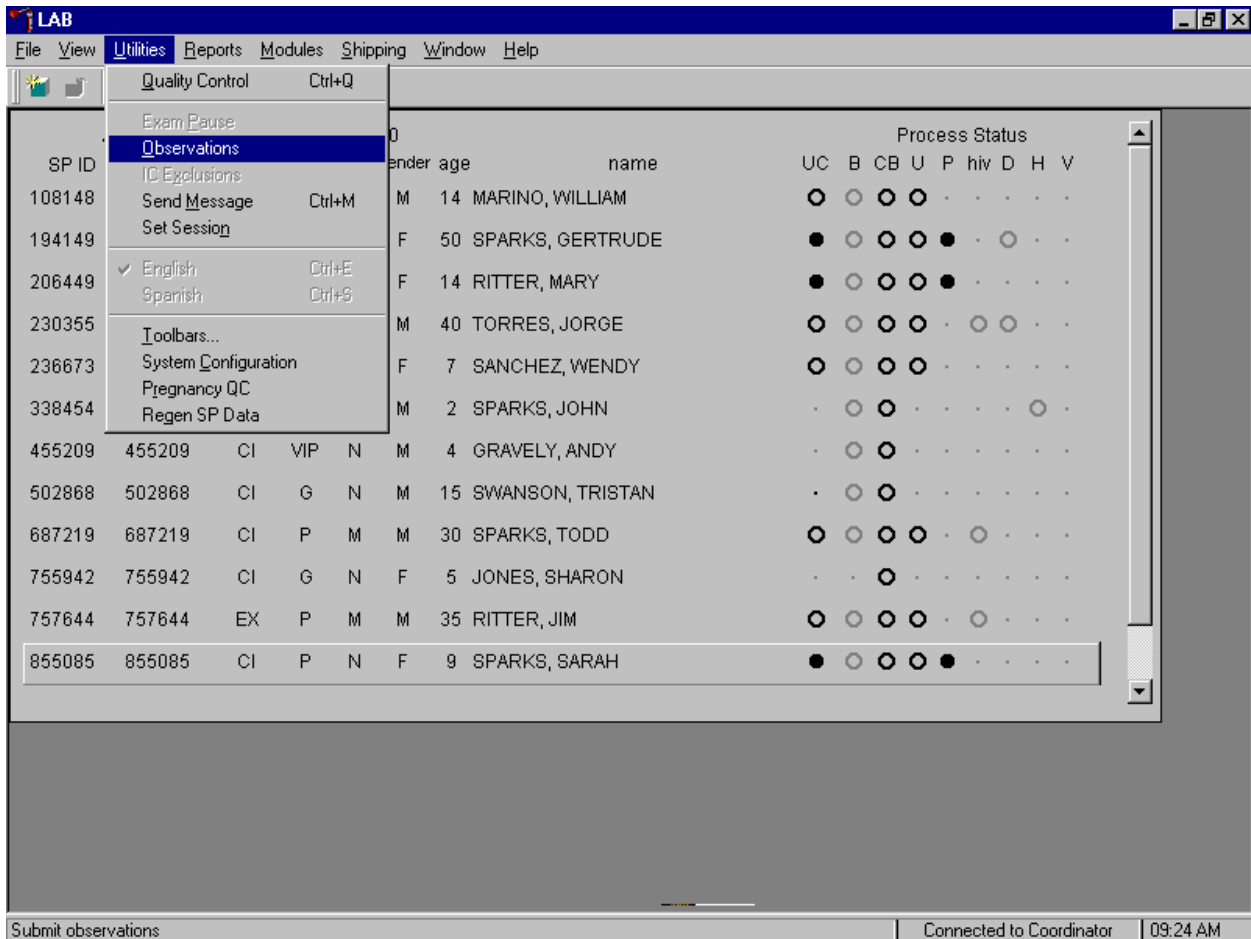
After each negative result is saved to the database, an unblocking message box displays.



To remove the informational message box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

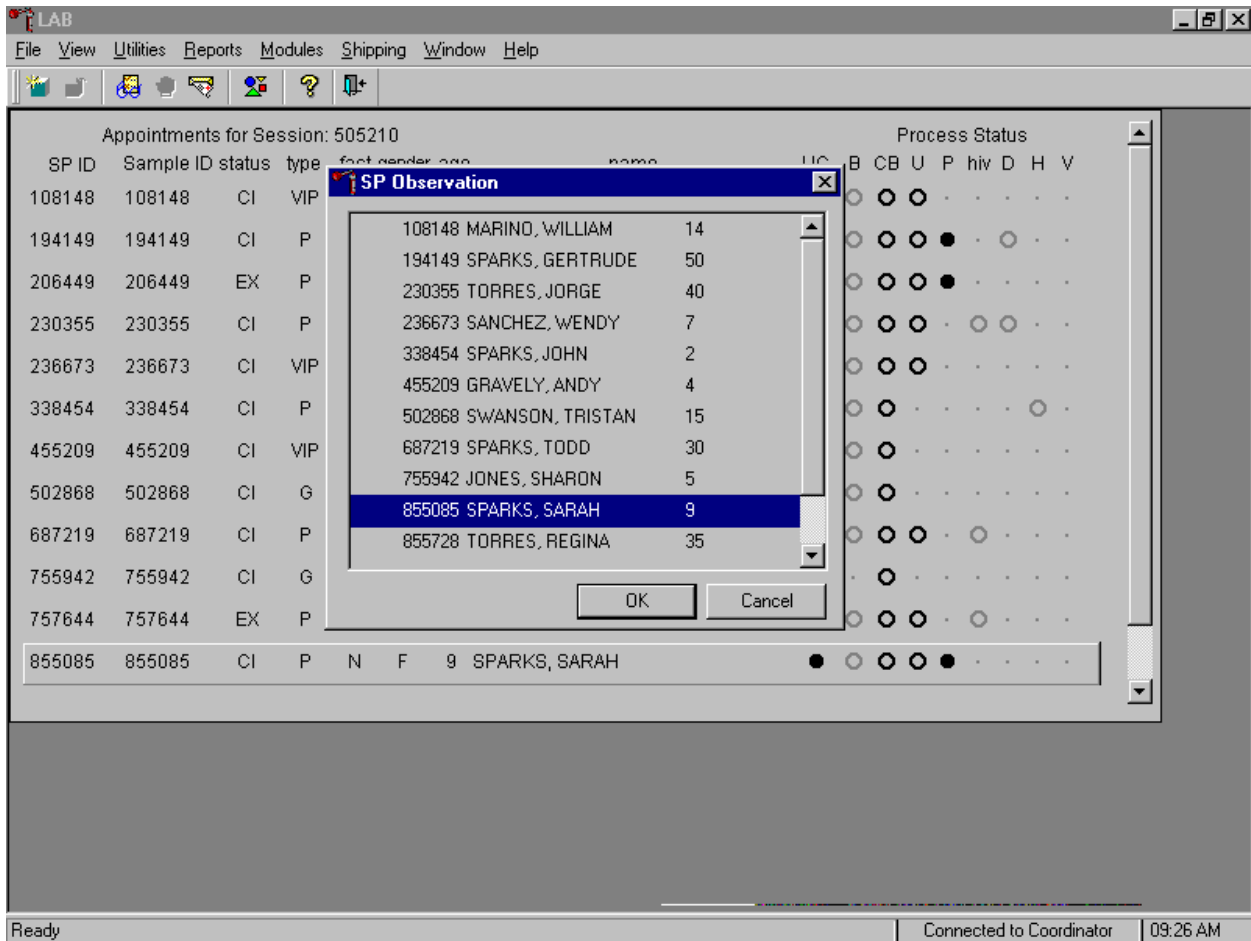
If a urine pregnancy test is positive on any female SPs ages 8-17, confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

Access the observation function to send an observation to the physician.



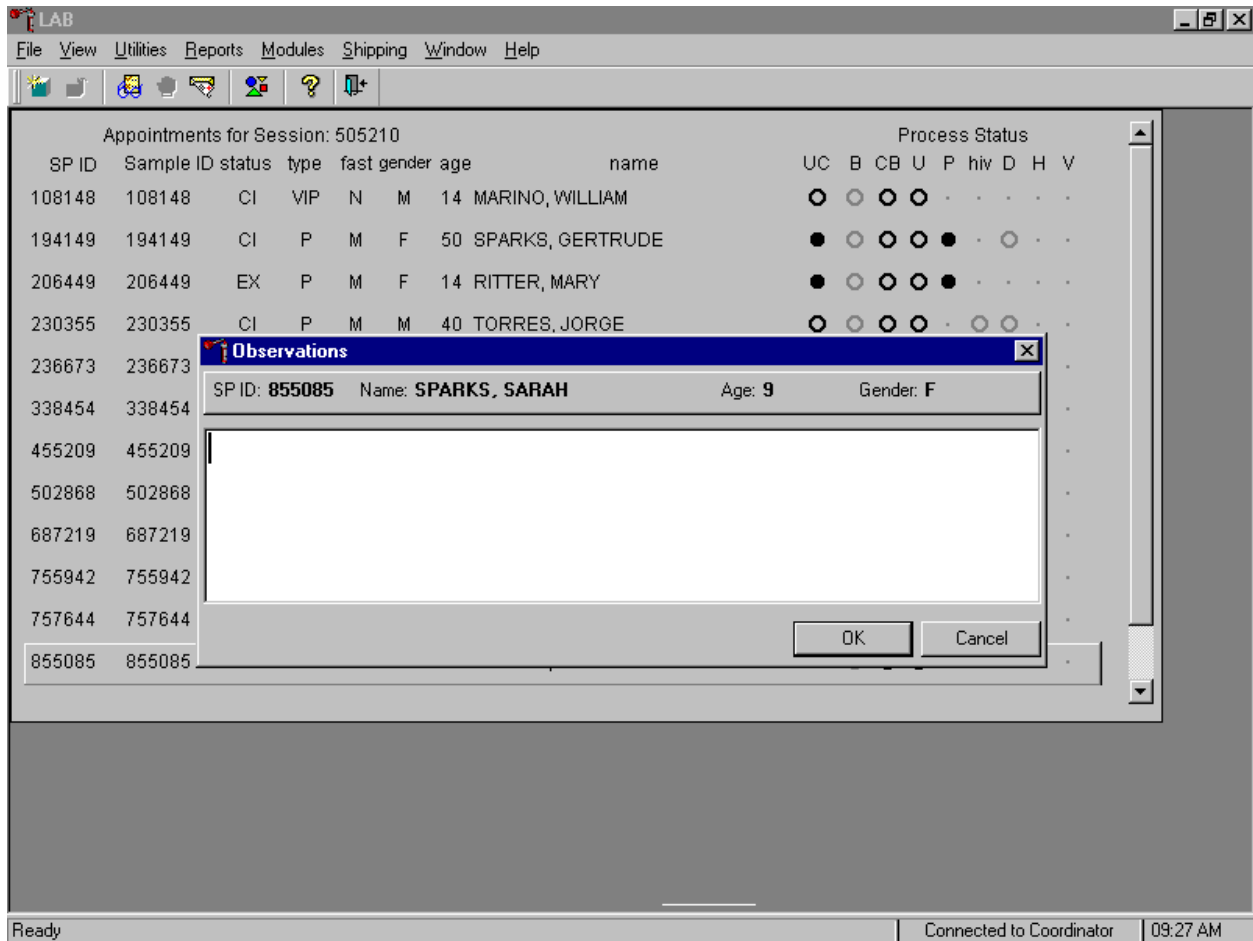
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the mouse arrow to {Observations} and left click or type [Alt] [U], [O].

Select or highlight the correct SP.



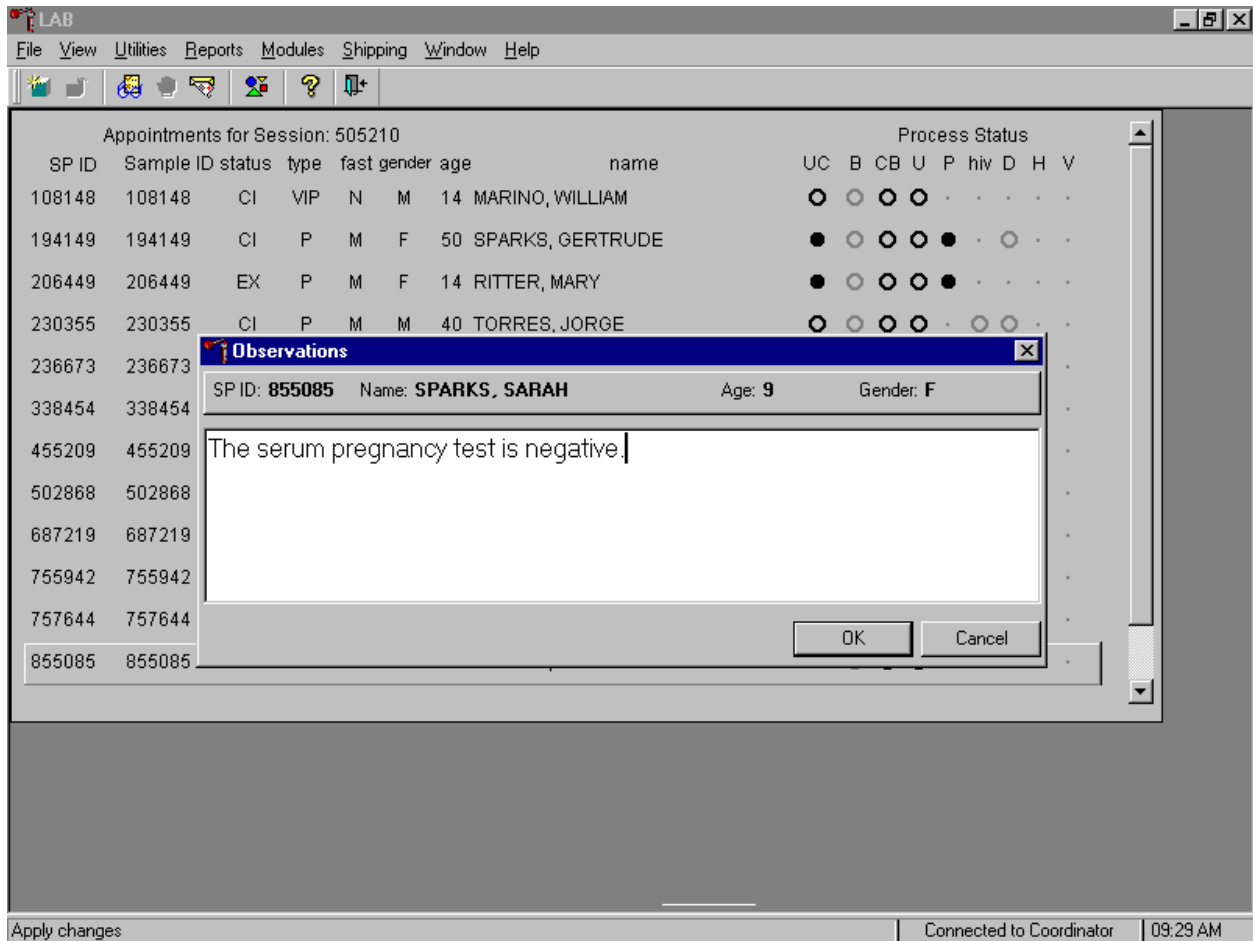
To select or highlight a SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the vertical scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The observation text window displays.



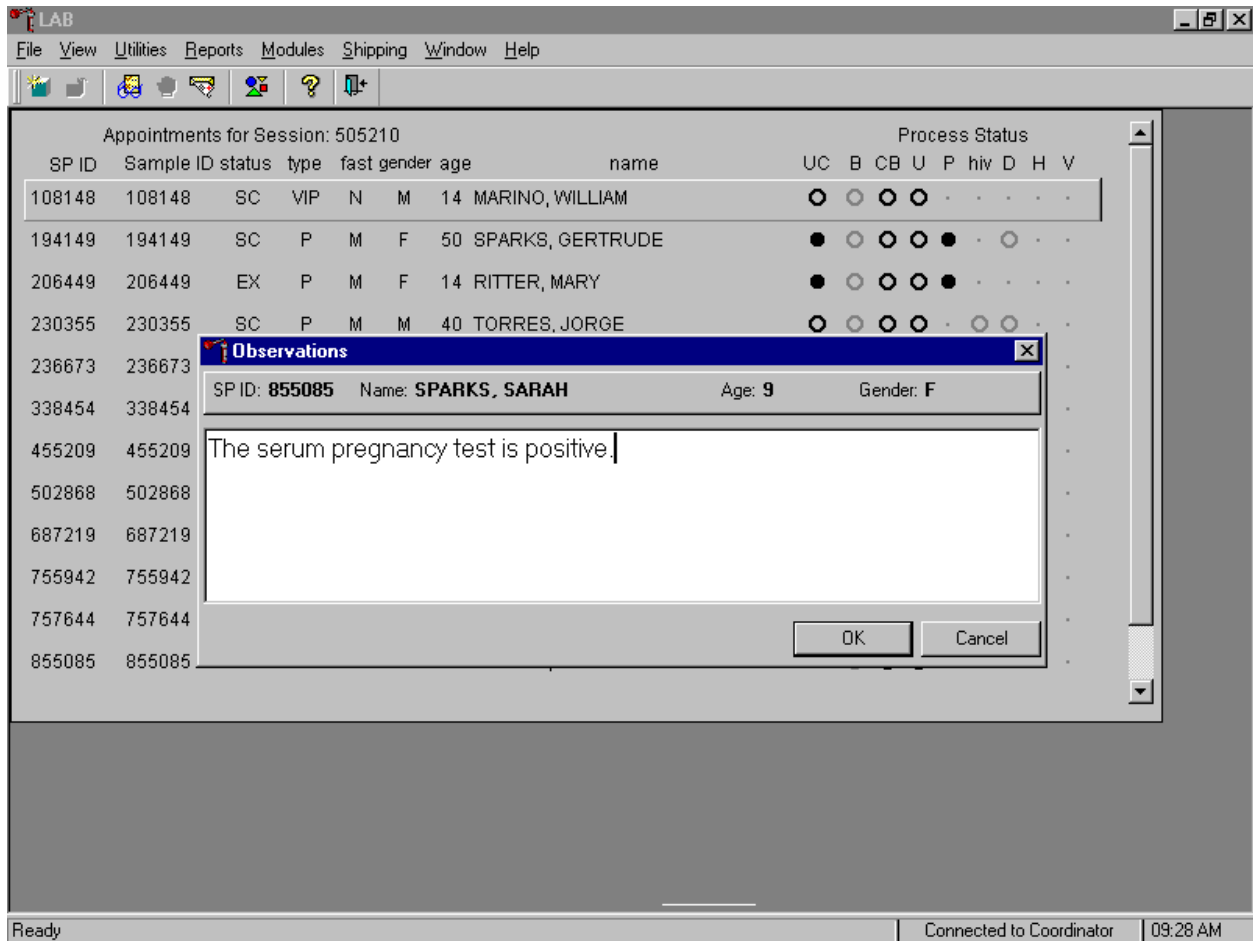
The observation text window contains the SP ID, name, age, and gender. Type the observation using the keyboard's keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Send an observation to report a negative serum test result on SPs ages 8-17.



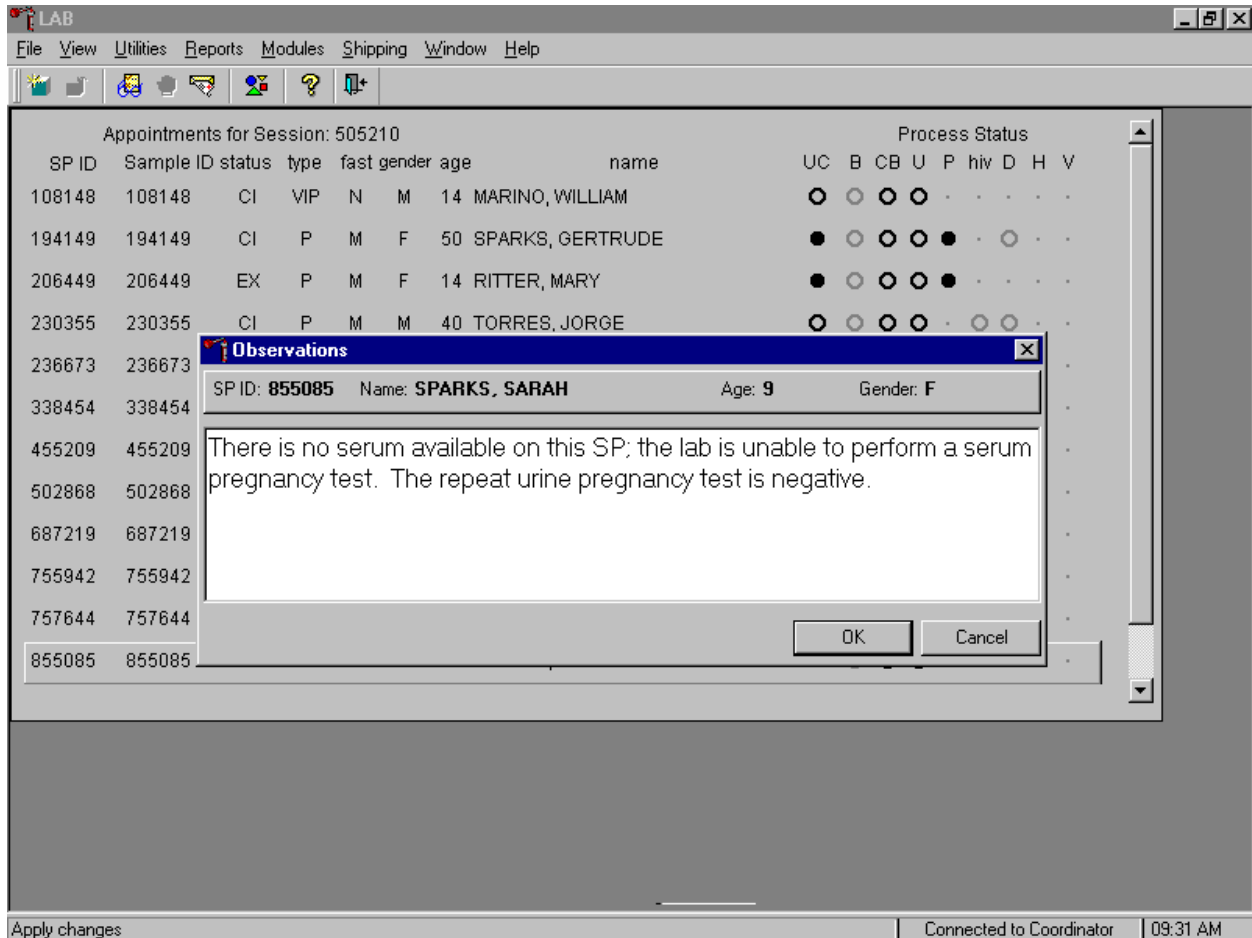
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum pregnancy test is negative” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Send an observation to report positive serum test results on SPs ages 8-17.



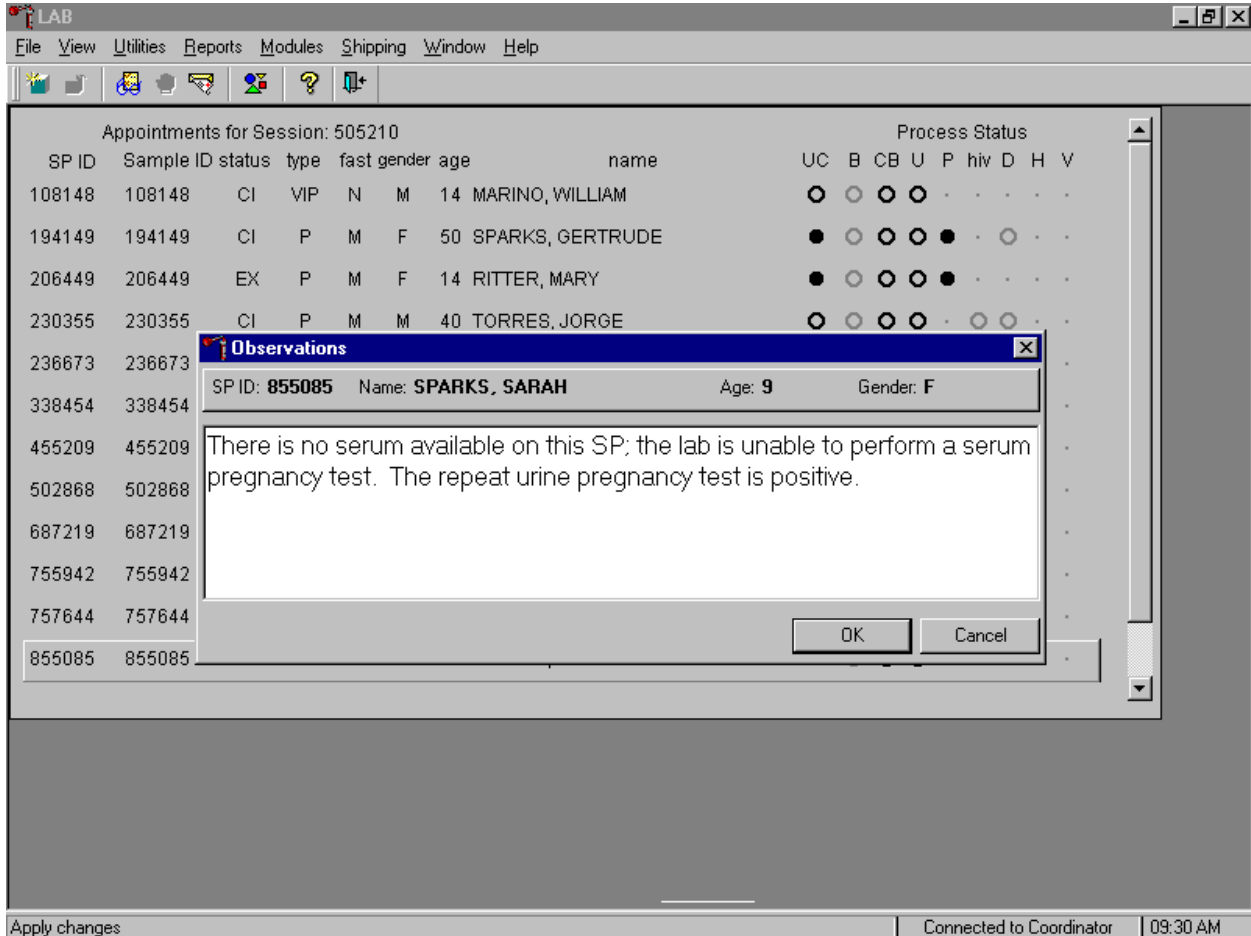
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum pregnancy test is positive” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat negative urine test on female SPs ages 8-17.



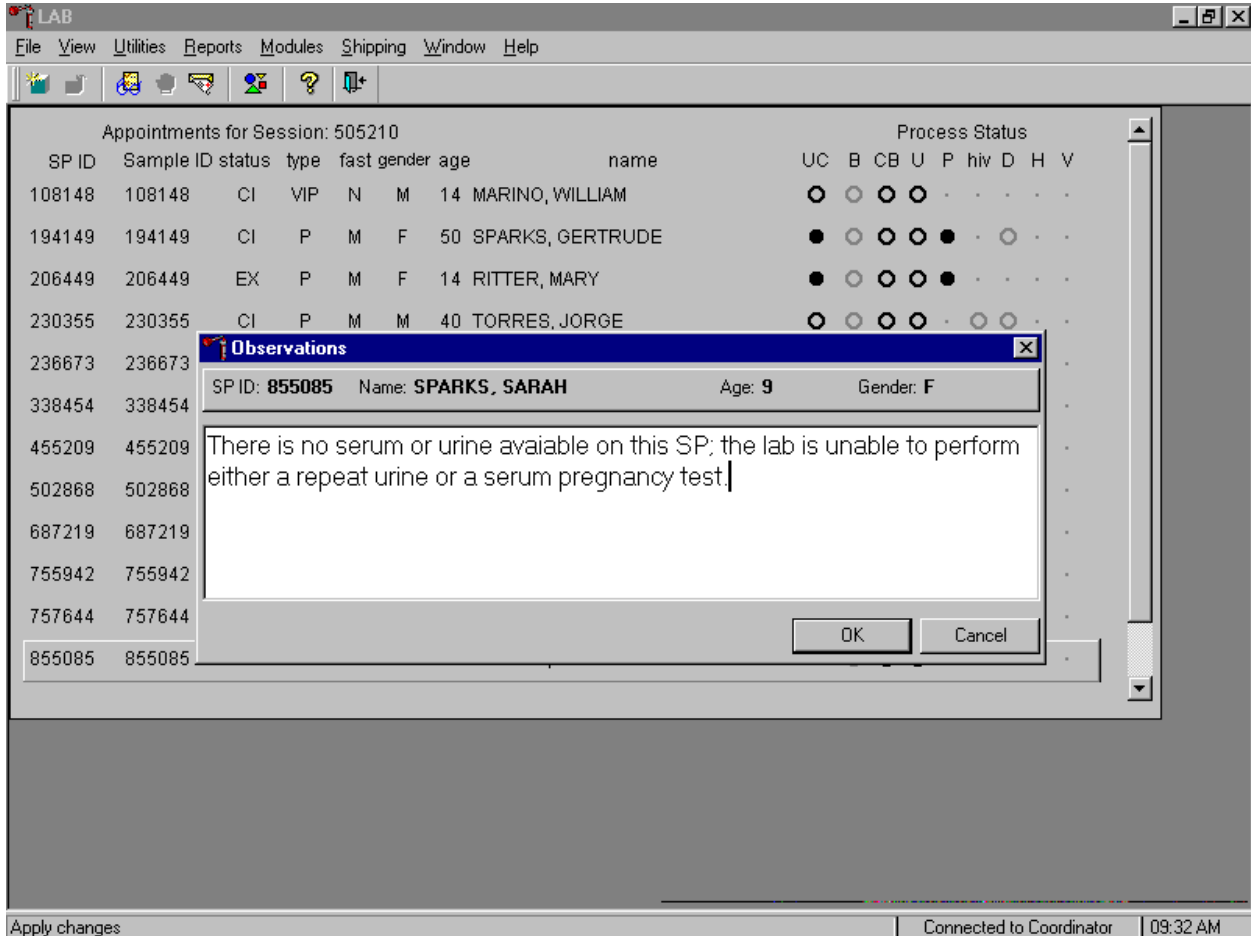
The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum available on this SP; the lab is unable to perform a serum pregnancy test. The repeat urine pregnancy test is negative.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat positive urine test on female SPs ages 8-17.



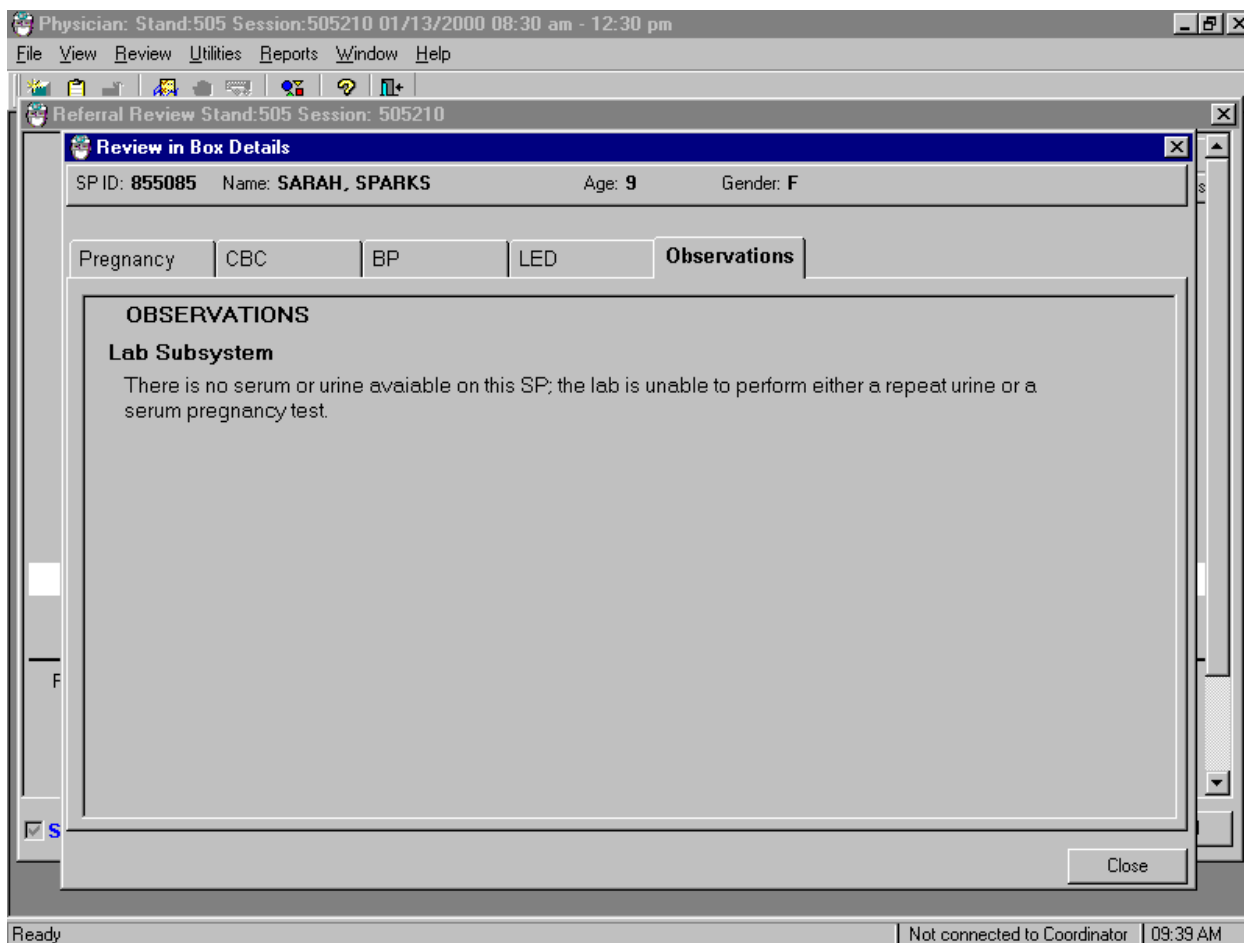
The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum available on this SP; the lab is unable to perform a serum pregnancy test. The repeat urine pregnancy test is positive.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Send an observation to report the inability to perform either the serum confirmation test or to repeat the urine test on female SPs ages 8-17.



The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum or urine on this SP; the lab is unable to perform either a repeat urine or serum pregnancy test.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The physician reviews all observations.



The physician accesses the observations using the Review in Box Details.

XII. Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

Read the following procedural notes to ensure the best results with the Nimbus® Plus SU test kit.

- Dispensing Specimen
 1. Do not substitute any other pipette for the transfer dropper.

2. Do not reuse a Test Device or use a Test Device for multiple patient samples or controls, as this will produce inaccurate results.

- Incubation Times

1. The Nimbus® Plus SU test kit yields the stated sensitivity at room temperature of 23°C (74°F). Room temperatures lower than this will result in less color development at the end of the 5-minute incubation period.
2. Specimens containing very high concentrations of hCG will produce positive results in less than 5 minutes. For such specimens, it is not necessary to wait the full 5 minutes to obtain a valid result.

- Batch Processing

If several specimens are to be tested during one run, perform each test step for all specimens and controls at timed intervals before proceeding to the next test step. It is recommended that no more than ten (10) Test Devices be run in one batch.

- Specimens Containing Particulate Matter

Particulate matter in specimens slows the rate at which fluids pass through the sample membrane. If flow stops, clarify the specimens by centrifugation and retest in a fresh Test Device.

- The Nimbus® Plus SU pregnancy test does not normally detect HCG in the serum or urine of healthy men and healthy nonpregnant women. Concentrations of hCG in pregnant women are generally between 10 and 30 mIU hCG/mL in the 7-10 days following implantation or 3 weeks after the last menstrual period (LMP). During the latter part of the first trimester of pregnancy, the hCG concentration reaches a maximum level of greater than 100,000 mIU/mL.
- The Nimbus® Plus SU pregnancy test detects urine/serum hCG concentrations of 25 mIU/mL or greater (referenced to the World Health Organization Third International Standard, previously known as the First International Reference Preparation).

- While pregnancy is the most likely reason for the presence of hCG in serum or urine, other clinical conditions that produce hCG include menopause, ectopic pregnancies, subclinical abortions, gestational trophoblastic disease, and malignancies, which produce hCG ectopically. Very dilute urine specimens may not contain representative urinary hCG concentrations. The presence of hCG in serum or urine should be interpreted in conjunction with other clinical and laboratory data available to the physician.
- Do not use urine samples containing grossly hemolyzed blood since they may give inaccurate or erratic results.
- Interpret detection of hCG in conjunction with other clinical information about the person.

Sensitivity and Specificity

Accuracy

A study was performed using a total of 186 positive and negative urine/serum specimens. These specimens were assayed with the Nimbus® Plus One-Step pregnancy test and a commercially available test, according to their package inserts.

		Commercially Available Test	
		+	-
Nimbus® Plus	+	102	0
	-	0	80

The latter data does not include four specimens which were weakly reactive with both a commercially available test and Nimbus® Plus. These reactions were considered inconclusive. The four specimens were further tested by a qualitative RIA method and the results indicated that the samples contained between 20 and 35 mIU/mL of hCG.

This data demonstrates the excellent correlation between the Nimbus® Plus and another commercially available test. The clinical significance of the two tests is comparable.

Sensitivity

- The analytical sensitivity of the Nimbus® Plus SU pregnancy test of 25 mIU hCG/mL has been established by repeat testing on urine/serum samples containing 25 mIU hCG/mL hCG over the course of several weeks. The addition of 1000 mIU/mL of luteinizing hormone, (LH), 1000 mIU/mL of follicle stimulating hormone (FSH), or 1000 mIU/mL of thyroid stimulating hormone (TSH) to negative (0 mIU/mL hCG) urine/serum specimens and to positive (25mIU/mL hCG) urine/serum specimens did not exhibit cross-reactivity in the assay.

Specificity

- The following substances were added to specimens containing hCG levels of 0 mIU/mL and 25 mIU/mL to urine/serum. In each case, no interference with the expected Nimbus® Plus test results was observed.

Interfering Substances

- Potential interfering substances were added to serum and to urine samples and tested with the Nimbus® Plus one step hCG test.

Substance Added	Concentration
Acetaminophen	20 mg/dL
Ascorbic Acid	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Salicylic Acid	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Atropine	20 mg/dL
Ampicillin	20 mg/dL
Tetracycline	20 mg/dL
Albumin	2000 mg/dL
Human Serum Protein	2000 mg/dL
Uric Acid	10 mg/dL
Glucose	2000 mg/dL
Cortisol	200 ng/mL
DHEA-S	500 ng/mL
Estriol (E-3)	25 ng/mL
Estradiol (E-2)	25 ng/mL

XIII. Reference Ranges

The Nimbus® Plus SU pregnancy test does not normally detect hCG in the serum or urine of healthy men and healthy nonpregnant women.

XIV. Action Limits

Not applicable.

XV. Specimen Storage and Handling During Testing

Serum:

Serum is required; do not use plasma. Specimens may be stored for 48 hours at 2°C - 8°C (36°F - 46°F) prior to assaying. Specimens held for longer times should be frozen at -20°C (-4°F) prior to testing. Bring all specimens to room temperature before beginning the assay procedure. Centrifuge specimens that appear cloudy or contain particulate matter prior to testing.

Urine:

Centrifuge very turbid urine specimens at 2500 RPM for 5 minutes before use. Do not shake or disturb specimens containing particulate matter, such as salts that have settled out of solution; pipette samples from the clear supernatant of such specimens.

XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for testing.

XVII. Test Results Reporting System Protocol for Reporting Action Limits

Not applicable.

XVIII. Specimen Accountability and Tracking

All records, including QA/QC data are maintained for 6 years. Use only numerical identifiers for SP results.

XIX. Quality Control Summary Statistics and Graphs

Quality control reports are monitored by stand and maintained for 6 years.

XX. References

Armstrong, E.G., Ehrlich, P.H., Birken, S., Schlatterer, J.P., Siris, E., Hembree, W.C., and Canfield, R.E. (1984). *J. Clin. Endocrinol. Metab.*, 59, 867-874.

Batzer, F.R. (1980). *Fertility & Sterility*, 34, 1.

Braunstein, G.D., Rasor, J., Adler, D., Danzer, H., and Wade, M.E. (1976). Serum human chorionic gonadotropin level throughout normal pregnancy. *AM. J. Obstet. Gynecol.*, 126, 678.

Catt, K.J., Dufan, M.L., and Vaitukaitis, J.L. (1975). *J. Clin. Endocrinol. & Metab.*, 40, 537.

Dawood, M.Y., Saxeba, B.B., and Landersman, H. (1977). *Ob. Gyn.*, 50, 172.

Galfre, G., Howe, S.C., Milstein, C., Butcher, G.N. and Howard, J.C. (1977). *Nature*, 266, 550.

Hussa, R. O. (1981). Human chorionic gonadotropin, a clinical marker; review of its biosynthesis. *The Ligand Review*, 3, 6.

Hussa, R. O. (1987). *The Clinical Marker hCG*. New York: Praeger Publishers.

Lenton, E.A., Neal, L.M., and Sulaiman, R.. (1982). *Fertility & Sterility*, 37, 773-778.

**National Health and Nutrition Examination Survey
National Center for Health Statistics
United States Public Health Service
Procedure: Complete Blood Count (CBC)**

Prepared by _____

Date Adopted _____

Approved by _____

Director

Signed _____

Director

Dated _____

Director

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

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Date Reviewed _____

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7. COMPLETE BLOOD COUNT

Introduction

Perform a complete blood count (CBC) in duplicate on all Sample Persons (SPs) age 1 and older. Perform the CBC on the Beckman Coulter® MAXM.

The three Coulter MAXMs serial numbers and system IDs are:

MAXM #1	Serial # AA06042	System ID # 13017
MAXM #2	Serial # AA31227	System ID # 29894
MAXM #3	Serial # AB08075	System ID # 31831

I. Purpose and Principle of Test

The Beckman Coulter® method of sizing and counting particles uses measurable changes in electrical resistance produced by nonconductive particles suspended in an electrolyte.

A suspension of blood cells passes through a small orifice simultaneously with an electric current. A small opening (aperture) between electrodes is the sensing zone through which suspended particles pass. In the sensing zone each particle displaces its volume of electrolyte. Beckman Coulter® measures the displaced volume as a voltage pulse, the height of each pulse being proportional to the volume of the particle.

The quantity of suspension drawn through the aperture is for an exact reproducible volume. Beckman Coulter® counts and sizes individual particles at a rate of several thousand per second. This method is independent of particle shape, color, and density.

The MAXM is a quantitative, automated, differential cell counter for *in vitro* diagnostic use.

The MAXM measures these parameters in whole blood:

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
WBC	White Blood Cell Count	WBC bath	≥35 fL	n x 10 ³ cells/μL
RBC	Red Blood Cell Count	RBC bath	36 to 360 fL	n x 10 ⁶ cells/μL

Hgb	Hemoglobin Concentration	WBC bath	525 nm	g/dL
Hct	Hematocrit	Computed	RBC x MCV/10	% Percent
MCV	Mean Cell Volume	Derived from RBC histogram	# x size of RBC/Total RBC	fL
MCH	Mean Cell Hemoglobin	Computer	Hgb/RBC x 10	pg
MCHC	Mean Cell Hemoglobin Concentration	Computed	Hgb/Hct x 100	g/dL
RDW	Red Cell Distribution Width	Derived from RBC histogram	CV expressed in % of the RBC size distribution	% Percent
Plt	Platelet Count	RBC bath	2 to 20 fL	$n \times 10^3$ cells/ μ L
MPV	Mean Platelet Volume	Derived from Plt histogram	Mean volume of Plt population under the fitted curve x constant	fL
NE%	Neutrophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
NE #	Neutrophil Number	Absolute number	NE%/100 x WBC Count	10^3 cells/ μ L
LY%	Lymphocyte Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
LY#	Lymphocyte Number	Absolute number	Ly%/100 x WBC Count	10^3 cells/ μ L
MO%	Monocyte Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	% Percent
MO#	Monocyte Number	Absolute number	MO%/100 x WBC Count	10^3 cells/ μ L

EO%	Eosinophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	EO % Percent
EO#	Eosinophil Number	Absolute number	EO%/100 x WBC Count	10 ³ cells/μL
BA%	Basophil Percent	Derived from scatterplot	# cells inside area/# cells inside total cell area x 100	BA % Percent
BA#	Basophil Number	Absolute number	BA%/100 x WBC Count	10 ³ cells/μL

***PDW -- Platelet Distribution Width and Pct -- Platelet Crit are NOT for diagnostic use and do not print. Coulter uses the value for PDW as an internal check on the reported platelet parameters, Pct and MPV.**

Methodology: The methods used to derive CBC parameters are based on the Beckman Coulter® method of counting and sizing, in combination with an automatic diluting and mixing device for sample processing, and a single beam photometer for hemoglobinometry. The WBC differential uses VCS technology. Analysis and classification of WBCs use three simultaneous measurements of individual cell volume (V), high frequency conductivity (C), and laser light scatter (S). The scattergram plots the cells based upon the measurements of these three parameters.

II. Special Safety Precautions

All specimens may be potentially positive for infectious agents including HIV and the hepatitis B and C virus. Observe universal precautions. Wear gloves and lab coat when handling all human blood products and Beckman Coulter® controls. Wear safety glasses whenever operating the instrument in SECONDARY mode. Dispose of all biological samples in a biohazard container and wipe down all work surfaces with 1% bleach solution at the end of each session.

The Mobile Examination Center (MEC) Hazardous Chemicals Manual contains all Coulter material safety data sheets (MSDS).

III. Computerization: Integrated Survey and Information System (ISIS)

The MAXM Data Management System (DMS) transmits individual SP results to the MEC automated ISIS system. Review all SP results at the Coulter DMS monitor. ISIS automatically receives the results or manually transmit them to the ISIS system. ISIS evaluates the data for completeness and accuracy. The final decision to accept or reject a result is the responsibility of the medical technologist.

All data are backed up and stored at Westat's home office.

IV. Specimen Collection and Preparation

A. Specimen collection

1. The phlebotomist collects a 3 or 5-mL K₃ EDTA tube on all SP's age 1+ following established venipuncture protocol and procedures. (A 1-2% dilution effect occurs in this liquid EDTA tube.)

B. Specimen preparation

1. The blood specimen-processing technologist initially processes the tube by taking off whole blood for various tests. The blood specimen processing technologist places the specimen on a rocker until the hematology technologist performs the CBC.

V. Procedure for Microscopic Examination

Not Applicable - Do not prepare differential microscopic slides.

VI. Reagents and Supplies

Inventory all reagents into the Supply Use Log.

A. Reagents, controls and calibrators

1. Isoton III® -- PN 8546733 (20 L) -- an isotonic electrolyte
 - Expires on expiration date printed on container.
2. Beckman Coulter® Clenz -- PN 8546930 (5L) -- a cleaning agent that cleans and rinses diluter parts
 - Expires 90 days after being opened and installed on the instrument.
3. Lyse-S III® diff lytic reagent- PN 8546983 (1L) -- a lytic reagent used for the CBC mode
 - Expires 60 days after being opened and installed on the instrument.
4. Scatter Pak® -- PN 8546917
 - Diff Lytic Reagent -- Erythrolyse II® erythrocyte lytic reagent
 - Diff Leukocyte Preservative -- StabiLyse® leukocyte preservative
 - Expires 60 days after being opened and installed on the instrument.
5. Latron® Controls - PN 7546914 (5 x 16-mL)
 - Expires 30 days after being opened.
6. Latron® Primer - PN 7546915 (5 x 16-mL)
 - Expires 30 days after being opened.
7. 5C® Cell Controls Tri Pack contains Normal, Abnormal I, Abnormal II - PN 7547001 (9 x 3.3-mL)
 - Expires 13 days or 13 events after being opened.

8. Calibration S-CAL® - PN 7546808 (2 x 6-mL) (With Lin-C PN 6605374)

- Use at the start of each stand. Expires 1 hour after being opened.

9. 5C® Cell Control Normal - PN 7546923 (9 x 3.3-mL)

- Use when calibrating with S-CAL for reproducibility study.

B. Supplies

1. 3-mL K₃ EDTA Becton Dickinson Hemogard Vacutainer® tube
2. Tube rocker
3. Clorox® Bleach, 5.25% Sodium Hypochlorite 1-800-292-2200
4. Bottled distilled water
5. Three 30 mL plastic containers with lid
6. Two one-liter containers with lid
7. Plastic squirt bottle
8. Cotton gauze pads
9. 3 hole paper punch
10. Notebook

C. Notes

1. If reagents become frozen in transit, mix thoroughly by inversion and let bubbles settle before use.
2. Do not place reagents on or near electric cords or lines to avoid electrical interference.

VII. Calibration

S-CAL® (PN 7546808 - 2 x 6-mL) The S-CAL® calibrator kit determines the adjustment factors for the calibration of the Beckman Coulter® MAXM. Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. Perform calibration in the close-vial mode; at ambient room temperature range (16-32°C, 60-90°F), using S-CAL® as an alternative to whole blood.

A. Perform calibration:

- At the beginning of each stand;
- After replacing any component dealing with dilution preparation, such as BSV or primary measurement, such as an aperture;
- If the Beckman Coulter® representative suggests calibration;
- If controls show unusual trends or are outside limits; and
- When room temperature varies more than 10°F (5.5°C) from the room temperature during the last calibration.

1. Principle - The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the **WBC, RBC, Hgb, MCV, Plt, and MPV** parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration.

The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give the Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

2. Reagents - S-CAL® consists of treated, stabilized, human erythrocytes and platelet sized components in an isotonic bacteriostatic medium. Fixed erythrocytes simulate leukocytes.

Materials required -- Before calibrating, assemble the following materials:
S-CAL® kit containing two 6-mL vials of S-CAL® calibrator, one plastic pipette,
and two empty glass-mixing tubes with pierceable caps.

3. Storage, handling and stability -- Sealed vials are stable through the expiration date when stored at 2-8°C (35-46°F). Open and/or pooled vials are stable for 1 hour.

Potential biohazard – Each human donor used in preparation of this material was tested by an FDA approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- The supernatant should show no gross turbidity and be light red in color. Significant darkening of the supernatant might indicate hemolysis and a reduction of the red cell count.

B. Pre-calibration, reproducibility, and carryover check

Perform a calibration after the instrument has been "Shut Down" (Section VIII D.) for at least 30 minutes. Select **DILUTER FUNCTIONS, START-UP**.

1. Pre-calibration procedure

Bleach the aspiration system using the Clean Needle procedure.

- a) Prepare a fresh bleach solution. Put one-mL Clorox bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.
- b) Stop the system before it performs the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE, [F3], Run**. Press [F9] Stop.

- c) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE**. Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.

To rinse the system, perform daily Start Up. Select **DILUTOR FUNCTIONS; START UP** [Enter].

Run 5C® cell controls.

2. Reproducibility check

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Select [F5] to access options. Change [F5] Print: to none and [F6] Host to Off.
- b) Use an unopened, normal-level, 5C®-cell control for reproducibility studies. Label the control vial with date and initial. Use of expired controls for this procedure is acceptable.
- c) Select **SPECIAL FUNCTIONS, CALIBRATION, REPRODUCIBILITY** [Enter].
- d) Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop.
- e) Press [F6]. Press space bar to turn the DIFF ON. Press [Enter]. Press [F2] *START PRIMARY*.
- f) Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.

If there are runs present in the table and the message does not appear, press [F8] Delete. Press the space bar to answer "YES." Press [Enter]. This deletes the old data.

- (1) Follow the directions listed in Section X for preparation and mixing the 5C®-cell control.
- (2) Cycle the sample 11 times. Do not use the bar code reader. Mix gently before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.
- (3) Check the results. Verify the average %CV does not exceed these limits:
 - WBC 2.5%
 - RBC 2.0%
 - Hgb 1.5%
 - MCV 2.0%
 - Plt 5.0%
 - MPV 3.0%

Check the low to high difference (bottom line, right hand side) for the diff parameters with these limits:

- LY% ≤4.8
- MO% ≤3.2
- NE% ≤4.8
- EO% ≤1.6
- BA% ≤1.6

If the results are outside the limits, call the Beckman Coulter® representative.

- (4) Press [F4] to print the screen for the logbook. Press [F3] Run [F9] STOP. Press [Esc]. Proceed with a Carryover Check.

g) Notes

- (1) Be sure the PR↓ is on the status line before starting the reproducibility study.
- (2) Be sure to delete any data on the reproducibility screen before starting a new study.
- (3) On the reproducibility screen, use the %CV line for CBC parameters only and the Diff line for the DIFF parameters only.

3. Carryover check (Draw two 5-mL EDTA tubes of normal blood)

a) Select **SPECIAL FUNCTIONS, CALIBRATION, and CARRYOVER**. Press [F2] *START PRIMARY*. Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.

- (1) Use a routine 5-mL Vacutainer® EDTA (BD #369614) for the carryover check clean vials. Fill three separate vials with diluent, then cap.
- (2) Follow the screen directions. Cycle two vials of normal blood and three vials of diluent. Do not use the bar code reader. Insert the tube into the carousel when the green light appears.
- (3) Check the lower right corner of the screen for CARRYOVER ACCEPTABLE. If the result is not acceptable and the H flags appear next to the carryover value results, repeat the procedure. If results are still OUT, call the Beckman Coulter® representative.

(4) Press [F4] to print the carryover screen for the logbook. Press [F9] to return to the main menu.

b) Notes

(1) Choose a sample with a WBC count of $10,000 \pm 1,000$ if possible. All other parameters should be within normal ranges.

(2) Ignore count period (CP) voteouts on diluent runs.

(3) Percent carryover is calculated by the formula

(4)
$$\frac{\text{1st diluent sample} - \text{3rd diluent sample}}{\text{2nd sample}} \times 100 = \% \text{ carryover}$$

C. CBC calibration with S-CAL® calibrator

Take the S-CAL® calibrator from the refrigerator. Let it warm to ambient temperature for 20 minutes. Meanwhile, continue with the following steps:

1. Select **SPECIAL FUNCTIONS, CALIBRATION, and CBC CALIBRATION**. Press [F2] START PRIMARY. Delete any data in the table. Press [F8]. Press the space bar to answer "yes." Press [Enter].

2. Prepare the CBC calibration screen.

a) Enter the S-CAL® calibrator assigned values from the Table of Assigned Values on the package insert on the REF: VALUES line at the cursor. The Hct is not calibrated although the value is listed on the package insert.

b) Enter the expiration date and the lot number.

3. Prepare and cycle the calibrator

- a) Mix by hand as follows: Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.
- b) Determine that all cells are uniformly distributed by inspecting the vial contents. If the cells are not totally distributed, repeat the mixing procedure. Use cotton gauze pads to remove the rubber stopper from the vial. Absorb any spray produced by pressure within the vial by using the gauze pads, avoiding accidental contact with the product.
- c) With the pipette, fill each of two mixing tubes to within 1/4 inch of the top. Dispose of extra S-Cal. Set one of these tubes aside in a test tube rack. Do not refrigerate or place on rocker. Use Tube #1 for calibration and tube #2 is for verification if needed.
- d) Cycle the first cap-pierceable calibrator 11 times. Do not use the bar code reader. Invert the vial and mix the S-CAL® calibrator before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.
- e) After the cycles are complete, press [F4] Print to print the screen for the logbook. Press [F3] Run, [F9] STOP. Press [Esc.]

4. Assess the run

- a) Check for trending. If trending is present, stop and contact a Beckman Coulter® representative.

- b) Check the %CV values against these precision %CV limits. If any parameter exceeds the limit, STOP and contact a Beckman Coulter® representative.

Parameter	Precision (CV%)
WBC	≤2.5
RBC	≤2.0
Hgb	≤1.5
MCV	≤2.0
Plt	≤5.0
MPV	≤3.0

- c) FAC %DIFF values against these limits (disregard minus signs. The values are absolute numbers). If any parameter exceeds its limit, STOP and call a Beckman Coulter® representative.

Parameter	Acceptable FAC %DIFF
WBC	≤5.0
RBC	≤2.0
Hgb	≤3.0
MCV	≤2.5
Plt	≤9.0
MPV	≤20.0

- d) Determine the need for calibration. Check the FAC %DIFF and DELTA DIFF values against these limits (disregard minus signs. The values are absolute numbers).

Parameter	Do not calibrate if FAC %DIFF is:	Do not calibrate if DELTA DIFF is:
WBC	≤1.25	≤0.10
RBC	≤0.70	≤0.03
Hgb	≤0.78	≤0.10
MCV	≤1.18	≤1.00
Plt	≤2.70	≤6.0
MPV	≤5.00	≤0.50

- e) If both the FAC %DIFF and DELTA DIFF values for all parameters are less than or equal to these limits, DO NOT calibrate: Press [F4] to print the screen for the logbook.
- f) If the FAC %DIFF or DELTA DIFF value of any of these parameters is greater than these limits continue with the next steps to verify the calibration.

5. To verify calibration:

- a) Determine which calibration factors to change. Check the FAC % DIFF and DELTA DIFF values against these ranges.

Parameter	Calibrate if FAC %DIFF is:	Calibrate if DELTA DIFF is:
WBC	>1.25 but ≤5.00	>0.10 but ≤0.40
RBC	>0.70 but ≤2.00	>0.03 but ≤0.09
Hgb	>0.78 but ≤3.00	>0.10 but ≤0.40
MCV	>1.18 but ≤2.50	>1.00 but ≤2.00
Plt	>2.70 but ≤9.00	>6.0 but ≤20.0
MPV	>5.00 but ≤20.00	>0.50 but ≤2.00

- b) If any value is outside these ranges, then, is *Select Function* displayed? If NO, press [F3] Run [F9] STOP [Esc]. If YES, Press [F5]. Choose SELECT PARAMETERS. Press [Enter]. Use the space bar to select YES for parameters that need adjusting, NO for others. Press [Esc]. Select TRANSMIT FACTORS. Press [Enter]. The following message appears: "WARNING -- DATA WILL BE CLEARED AFTER TRANSMISSION. DO YOU WANT TO PRINT DATA? Y/N" Select N since the values have already been printed.
- c) Press [F3] Run [F2] START PRIMARY. Gently invert the second cap-pierceable vial of S-CAL® calibrator 8-10 times. Cycle the S-CAL® calibrator 11 times. Before each cycle, invert the vial and mix the S-CAL® calibrator. Check the FAC %DIFF and DELTA DIFF values

results for all parameters against these limits (disregard minus signs) to be sure that they are below the lower limit.

Parameter	FAC %DIFF	DELTA DIFF
WBC	≤1.25	≤0.10
RBC	≤0.70	≤0.03
Hgb	≤0.78	≤0.10
MCV	≤1.18	≤1.00
Plt	≤2.70	≤6.0
MPV	≤5.00	≤0.50

- d) If any value is above these limits, call a Beckman Coulter® representative. Turn the printer back on using Options. Press [F4] to print the screen for the logbook. Rerun controls.

6. Calibration terms and formulas

a) MEAN

- The average of the 10 S-CAL calibrator runs.

b) NEW CAL FAC

- The calibration factor needed to obtain the S-CAL Calibrator Reference value. The instrument calculates and displays it whether or not it needs to be changed.
- $\frac{\text{Reference Value} \times \text{Old Cal Factor}}{\text{S-CAL mean value (n=10)}} = \text{NEW CAL FAC}$

c) OLD CAL FAC

- The current calibration factor.

d) %CV

- Indicates the reproducibility of the S-CAL calibrator run. Check to ensure that the data being used is valid when making decisions to recalibrate or not.

e) FAC % DIFF

- The difference between the OLD CAL FAC and the NEW CAL FAC expressed as a percentage.
- $$\frac{\text{NEW CAL FAC} - \text{OLD CAL FAC}}{\text{OLD CAL FAC}} \times 100 = \text{FAC \%DIFF}$$

f) DELTA DIFF

- The absolute difference between the reference value and the S-CAL calibrator MEAN.

g) REF VALUES.

- The assigned value for each parameter.

VIII. Assay Procedure

A. Run Start Up at the beginning of the first session each operational day.

1. Leave the instrument on and operate the MAXM with all panels closed. Check to make sure the date and time displayed are correct. To set date and time select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP, SET DATE/TIME**. Move the cursor and enter the correct date or time and press [Enter] or the arrow keys. Press [F10] to save and exit.
2. To begin Start Up, select **DILUTER FUNCTIONS, and START UP**. Press [Enter]. Follow the instructions on the screen.
3. After Start Up is complete, evaluate the display. Expired reagents and failed checks appear in red. Press [F2] to view detailed results. Make sure the Background and other Start Up results are within limits. Results outside limits turn red. Results automatically print. File in the logbook.
4. Review and verify sample analysis set up.
 - a) Select **SAMPLE ANALYSIS, RUN SAMPLE** [F3]. Sample mode? Press [F5] for options. Press the corresponding function key to enter specific options. Use [F6] to turn the Diff ON. Use [F5] to change XB and DB to ON, Print to NONE, Host to ON, and Display Only to OFF. Press [Esc] to exit.

B. Run controls

Run Beckman Coulter® LATRON primer and latex control, and all three levels, normal (blue), abnormal I (yellow), and abnormal II (pink), of Beckman Coulter® 5C® cell control daily at the beginning of the first session. Run all three levels (normal, abnormal I, and abnormal II) of Beckman Coulter® 5C® cell control at the beginning of the second session.

C. Run Sample Persons

1. Review the placement of the bar code on the sample tube to make sure it is parallel to the stopper and does not cover the bottom of the tube.
2. Run all samples in duplicate.
3. Run samples in the primary mode.

Check to verify connection and working order of the printer.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].
 - b) Is Sample Mode? Displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.
 - c) Press [F2] START PRIMARY.
 - d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep -- Place the tube in the carousel. If the red light appears, wait and try reading the bar code label again.
4. Alternatively, cycle samples in the SECONDARY mode.

Blood detectors are inactive in the SECONDARY mode. This mode does not check sample and aspiration integrity. Run samples in the SECONDARY mode only if the primary mode is unavailable.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].
- b) Is Sample Mode? displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.
- c) Press [F3] SECONDARY.

- d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep. If the red light appears, wait and try reading the bar code label again.
 - e) Cycle the sample in the SECONDARY mode:
 - (1) Mix the sample gently.
 - (2) Open the tube and immerse the aspirator tip in the sample.
 - (3) Press and release the sample bar.
 - (4) Remove the sample when the instrument beeps.
 - (5) Monitor the aperture-viewing screens for debris during the COUNT period.
5. Review data and transmit
- a) Review the data using the criteria described in Section X.
 - b) Set host computer to ↑. Data from the Coulter DMS is automatically transmitted to the ISIS system.

D. Daily Shut Down

1. Shut down the instrument at the end of each day. Shut down the instrument for at least 30 minutes but less than 48 hours.
2. To begin shut down make sure the status line displays *Select Function*. Select **DILUTER FUNCTIONS** and **SHUT DOWN**. Press [Enter].

3. When it is time to use the instrument, perform Start Up. Results must be within tolerance.
4. Perform daily QC and operate as usual.

E. Prolonged Shut Down

1. If the instrument is going to be shut down for 48-72 hours, perform the following steps:
 - a) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.
 - b) Perform Start Up to put diluent in the system.
 - c) Turn off the power.
 - d) When it is time to use the instrument, turn power on, and perform Start Up. Results must be within tolerance.
 - e) Perform daily QC and operate as usual.
2. If the instrument is going to be shut down for more than 72 hours, perform the following steps:
 - a) Place all reagent pickup tubes into distilled water.
 - b) Repeatedly perform Shut Down and Start Up procedures throughout the day.
 - c) Let distilled water remain in the reagent lines.
 - d) Turn off the power.

- e) Place reagent caps on all open containers.
- f) When it is time to use the instrument, turn on the power and place the reagent pickup tubes into the reagent containers, prime all reagents, and perform Start Up. Results must be within tolerance.
- g) Perform daily QC and operate as usual.

F. Beginning and end of stand operations

1. Beginning of stand

- a) Obtain one urine collection container or a 50-mL conical tube, seven 3 or 5-mL EDTA tubes (1 clean aspiration system, 3 reproducibility, 3 carryover), enough supplies to draw two 5-mL EDTA blood tubes, and a few plastic transfer pipettes.
- b) Using all new containers of reagents, carefully unwrap and place all reagent pickup tubes in their appropriate container after pouring 30-mL Isoton® III into 30-mL plastic container. Use the Isoton® when performing the calibration carryover check. Handle reagent tubes by the collar only to avoid contamination. Turn the power ON. Prime reagents through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**.
- c) Perform the Start Up procedure. This should take approximately 5-6 minutes. Results should be within tolerance.
- d) Contact the local Beckman Coulter® representative to perform an instrument verification procedure on set up day or as soon as possible.
- e) Calibrate and perform and verify QC checks according to procedure.

f) Review and verify system set up. Select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP:**

(1) Select **SHIFT**

- (a) Move the cursor and set up the starting times for each shift and press [Enter] or the arrow keys. The system automatically calculates the end of the shift to prevent overlap.
- (b) Set shift 1 "Time" at 0600.
Set shift 2 "Time" at 1700.
Set shift 3 "Time" at 0558.
- (c) Press [F10] to save and return to the previous screen.

(2) Select **REAGENTS** - Update reagent logs

- (a) To record new reagent information: Key in the new reagent information: lot number, date reagent opened (pressing [Enter] automatically gives today's date), and the expiration date. Do not forget to enter revised expiration dates where appropriate. Press [Enter] after each item. Press [F10] to save the data and leave the reagent screen.

(3) Select **INSTITUTION.**

- (a) Enter the "SUPER" password. Type in:
Name, NHANES
Lab Director, Brenda Lewis
Address, NCHS
Maryland
Telephone, 301-436-7080
(Default) Instrument, AA06042
AA31227
AB08075

Use space bar to choose YES for Name Printed on Graphic Printer and NO for all other information. Press [F10] to save.

- (4) Select **COMMUNICATION DEF.** Enter the **SUPERVISOR PASSWORD, "super."** Select, **HOST COMPUTER DEFINITION.**

- (a) Use [Enter] or arrow keys to move to the appropriate field.
- (b) Type in the following information where necessary and use the space bar to choose between the responses.

STKS 2A Host Mode	No	Enable Spooler	Yes
		Replace Null by SP	No
Timeout (secs)	8		
Baud rate	9600		
Parity	none		
Stop bits	1		
Handshake	Yes		
Block size	256		
Graphic transmission			
DF1	No		
DF2	No		
CVS histograms	No		
RBC histograms	No		
PLT histograms	No		

- (c) Press [F10] to save and [Esc] to return to previous screen.

- (5) Select **Language.**

Ensure the default is "ENG." Press [F10] to save and exit.

- (6) Select **IQAP ID#.**

Type in the IQAP number.

Enter 32979 1 T1 for instrument AA06042

32979 1 T2 for instrument AA31227

32979 1 T3 for instrument AB08075

Press [F10] to save and exit.

- (7) Select **SET DATE/TIME**.
Move the cursor and enter the correct date or time and press [Enter] or use the arrow keys. Press [F10] to save and exit.
- (8) Select **LYSE VOLUME**.
Press space bar to choose 1 L. Press [F10] to save and exit.
- (9) Select **OPTIMIZE HARD DISK**.
Type in the password "super" at the prompt and then press [Enter].
Use the spacebar to select YES. Press [F10] to save. Press [F9] to return to the main menu.

g) Review sample analysis set up. Select **SPECIAL FUNCTIONS, SET UP, and SAMPLE ANALYSIS SET UP**. Type in the password "super."

- (1) Select **DISPLAY FORMATS, REPORTING UNITS**.
Use the space bar to toggle to US 1. Press [F10] to save and [F9] to return to main menu.

- (2) Select **PRINT OPTIONS**.
Auto Print Format
Select **[GRAPHIC FORMAT]**

Ticket Options

Verify the following settings.

PRINT UNITS:	Y
PRINT NORMAL RANGES:	Y
PRINT PARAMETER LABELS:	Y
TICKET PRINTER CONNECTED:	N
S/D FLAGS:	Y
DIFF ORDER:	Standard
AUTO-TICKET PRINT:	N
TICKET FORMAT START OF NEXT FORM	Continuous

Spooler Priority

Leave [AUTO PRINT] as the default.

Graphic Options

Verify the following settings.

	Width/Font
Page Format	Wide/Large
DF 1. RBC, PLT	: Yes
DF2, DF3	: No
VCS Histograms	: No
Demographics	: No
S/D flags	: Yes
Print Units	: No
Print Diff Box	: No
Print Normal Ranges	: No

Optional Printer

Select "N."

- (3) Select **ACTION LIMITS** [Enter], **DEFINITIVE FLAG LIMITS** [Enter].

Disable definitive flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

- (4) Select **ACTION LIMITS** [Enter], **HIGH/LOW FLAG LIMITS** [Enter].

Disable High/Low flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and

PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

(5) Select **XB LIMITS**.

Enter target and limit percent values.

XB Limits

	Target	Limit %
MCV	88.5	3
MCH	29.5	3
MCHC	33.5	3

Press [F10] to save and exit.

2. End of stand

a) Obtain three urine collection cups and three 5-mL EDTA blood tubes.

b) Review, print, and clear error file.

(1) Select **SPECIAL FUNCTIONS, ERROR FILE** [Enter]. Review data and print [F4]. Document any relevant information on the print out and file in the logbook. Delete file [F8] -- "Do you want to delete error file; NO" message will appear. Use the space bar to change NO to YES [Enter]. Return to main menu [F9].

c) Download IQAP files to diskette following procedure in Section X.D.1.

d) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.

e) Perform Start-up.

f) Disable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTIONS, , FLUIDIC TESTS**, and

DISABLE REAGENT SENSORS. Toggle through each reagent line using the space bar to change "ON" to "OFF."

- g) Bleach the reagent lines.
 - (1) Remove all reagent pickup tubes from the reagent containers. Dispose of all open containers. Wash and save the reagent collars.
 - (2) Prepare a 25% solution of Clorox bleach (250-mL) and distilled water (750-mL) in one liter bottle. Place all reagent pickup tubes into the 25% bleach/distilled water solution. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL**. Press [Enter]. Repeat this procedure two more times.
- h) Place all reagent pickup tubes into containers of distilled water.
- i) Bleach the apertures and flow cell.
 - (1) Mix 15-mL Clorox bleach and 15-mL distilled water in a plastic container.
 - (2) Put 30-mL of distilled water in a second plastic container.
 - (3) Open the front panel.
 - (4) Select **DILUTER FUNCTIONS**, and **DISINFECT**. Press [Enter].
 - (5) The instrument defaults to 15 minutes; stop the procedure after 3 minutes. Press [Enter].
 - (6) Immerse the bleach probe in the bleach solution when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE BLEACH." Press any key. Aspirate all the bleach solution.

- (7) Immerse the bleach probe in the distilled water when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE WATER." Press any key. Aspirate all the distilled water. Stop the cycle after 3 minutes by pressing [F4].
 - (8) Wait until the screen displays *Select Function* before touching any keys. When *Select Function* is displayed, continue with the following procedure.
- j) Disinfect the needle. Bleach the aspiration system using the Clean Needle procedure.
- (1) Prepare a fresh bleach solution. Put one-mL Clorox bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.
 - (2) Stop the system before beginning the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE**, [F3], Run. Press [F9] Stop.
 - (3) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE**. Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.
- k) Perform reproducibility in Primary and Secondary mode using this 1% bleach solution. Prepare a 1% bleach solution and fill one 5-mL EDTA blood tube with this solution. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY*. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select Primary and aspirate 3 samples of 1% bleach. Enter [F3]; sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of 1% bleach solution.

- l) Rinse the reagent lines. Make sure all reagent lines are immersed in containers of distilled water. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL**. Press [Enter]. Repeat this procedure two more times.
- m) Perform a Start Up. Make sure containers are full.
- n) Perform reproducibility in Primary and Secondary mode by using distilled water. Fill one 5-mL EDTA blood tube with this distilled water. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY*. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select Primary and aspirate three samples of distilled water. Enter [F3], sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of distilled water. Press [Enter].
- o) Select **DILUTER FUNCTIONS, START-UP**. Press [Enter]. Perform one additional Start-Up procedure with the lines in the distilled water containers.
- p) Cycle the instrument dry.
 - (1) Remove all reagent pickup tubes from the distilled water containers.
 - (2) Continue to cycle the instrument dry by priming air through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**. Repeat these actions at least three times.

- (3) Open front cover. Using hemostats, seal tubing with check valve coming out of the bottom of the sheath tank. Loosen the four large screws that hold the panel containing the sheath tank. Gently pull panel away from instrument. Trace two red wires from top of sheath tank to plastic electrical connection. Disconnect the junction. Insert paper clip into junction so that a circuit is formed on the instrument side of the connector. Do this by bending paper clip into a U and placing one end of paper clip into each of the open sockets on the instrument side of the junction. This will allow the instrument to Drain and Vent and Shut Down without reagent. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTION**, and **DRAIN AND VENT**. Press [Enter.]
- (4) Select **DILUTER FUNCTIONS**, and **SHUT DOWN**. Press [Enter].
- (5) After cycles are complete, remove paper clip, reconnect junction, put panel back into instrument and tighten screws, then remove hemostats.
- q) Enable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, FLUIDIC TESTS**, and **DISABLE REAGENT SENSORS**. Toggle through each reagent line using the space bar to change "No" to "Yes."
- r) To protect the reagent pickup tubes from contamination, wrap them securely in paper towels. Allow air to continue to dry the tubes.
- s) Turn off the power.
- t) Rinse exterior of BSV with distilled water to remove built up Isoton and blue Clenz agent. Blot the BSV dry with lint free tissue. Do not use gauze.

- u) Wash exterior of instrument with distilled water.
- v) Empty waste and rinse container.

IX. Beckman Coulter® Reportable Range of Results

Parameter	Linearity	Limits: The greater of
WBC x 10 ³ cells/μL	0 to 99.9	0.2 or 3.0%
RBC x 10 ⁶ cells/μL	0 to 7.00	0.05 or 2.0%
Hgb g/dL	0 to 25.0	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10 ³ cells/μL	0 to 999	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

X. Quality Control

A. Latron® latex controls (PN 7546914 - 5 x 16-mL) The Latron® control is for use in monitoring the volume, conductivity, and light scatter (VCS) parameters on the MAXM. Use the Latron® control immediately following the Latron® primer. Run this control at the beginning of each day. Date and initial the vials when opened.

1. Principle - The Latron® control is a ready-to-use suspension of latex particles. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter.
2. Reagents - Latex particles suspended in a buffered bacteriostatic and fungistatic medium containing a surfactant.
3. Storage, handling, and stability -- Sealed vials are stable until their expiration date when stored and used at 2-30°C (35-86°F). Once open, date, and initial vials. Opened vials are stable for 30 days when stored at recommended temperatures. Keep vials tightly capped when not in use.
4. Indications of instability or deterioration -- Inability to recover expected results might indicate product instability or deterioration due to improper storage, handling, or contamination. Discard vial if debris is visible and put new vial into use.
5. Instructions for use -- Before running control, verify that a Start Up has been performed.
 - a) Run Latron® primer in the secondary mode. Select **CONTROLS**, then **CONTROL RUN** and press [Enter]. If the **LATEX FILE** does not appear, press [F2] File. Select the **LATEX FILE**. Press [Enter]. Press [F3] Run [F4] Primer. Cycle the primer by immersing the aspirator tip completely in the primer. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the primer. Remove vial when

the audible "beep" occurs. Evaluate primer results. Results should be less than 500. Press [Esc] to remove the primer run.

- b) Run the latex control. Mix a room-temperature control vial gently by inverting five (5) to eight (8) times. Be careful to avoid foaming. When *Select Function* appears on the status line, press [F3] Run, [F3] Control (SECONDARY). Cycle the control by immersing the aspirator tip completely in the vial. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the control. Remove vial when the audible "beep" occurs.

- c) Examine the Mean Channel and Coefficient of Variation for volume, conductivity, and light scatter for the Diff Mode only. Compare the results to the Assigned Mean Values and Expected Coefficient of Variation. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. Press [F4] to print results for the logbook. If a H or L displays, do the following:
 - (1) Bubbles in the flow cell or improper vial handling -- Rerun the primer and control.

 - (2) Contaminated control, improperly mixed, or past open vial expiration date -- Wipe the aspirator tip. Try a new vial of Latron® control. Mix gently according to directions.

 - (3) ":::::" System detects a clog in the flow cell. Press [F3]. Press [F7] to PURGE the flow cell. Press [F4]. Cycle the Latron® primer again. Press [Esc] [F3] [F3]. Cycle the Latron® latex control again. If the control is still "out" of range, repeat the actions 2 or 3 more times. If the problem remains, perform a ShutDown and Start Up procedure. If problem continues, call a Beckman Coulter® representative for assistance.

- (4) Assigned value or range is incorrect -- Be sure the assigned values and ranges match the ones on the Latron® package insert. If in error, correct them by selecting **SPECIAL FUNCTIONS, SET-UP, CONTROL SET UP**.

6. Setting up a Latex control file

Set up a file each time a new lot number is received. Assigned channel, expected range, and %CV are automatically entered; change them to assigned values on assay sheet, if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, CONTROL SET-UP, LATEX FILE**. Select a NOT SET-UP or an inactive file. Enter the name of the file, (Latex), Lot #, expiration date, and technician initials. Check entries. Press [F10] to save and exit.

B. 5C® Cell Controls Tri Pack contains Normal (blue), Abnormal I (yellow), Abnormal II (pink) (PN 7547001 - 9 x 3.3 mL.) The 5C®-cell control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. Run this control at the beginning of each session. Date and initial the open vials.

1. Principle - The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible.
2. Reagents -- 5C®-cell control consists of treated, stabilized human erythrocytes in an isotonic bacteriostatic medium. 5C®-cell control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Store 5C®-cell control at 2-8°C. When stored at 2-8°C, sealed vials are stable at least until the expiration date shown on the Table of Expected Results. Note: The MCV and/or RDW parameters may show trending through the shelf life of the product. This is inherent to the product and is not an

indicator of product stability. Date and initial open vials. Opened vials are stable for 13 days or 13 events when stored at 2-8°C.

Potential biohazard – Each human donor used in preparation of this material was tested by an FDA approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (darkly colored supernatant) indicate product deterioration. However, a slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.
5. Instructions for use -- Remove 5C® cell control tubes from refrigerator and warm to ambient temperature for 10-15 minutes. After warming, mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.

- a) Run the 5C®-cell control in the Primary Mode of the instrument. Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Is **SAMPLE MODE** displayed? If no, press [F9] STOP. Make sure the DIFF is on. If it is off, press [F6]. Press [F2] START PRIMARY. Complete the entire procedure and return the controls to the refrigerator within 30 minutes.
- b) Identify the sample by holding the bar code label in front of the reader. Place the control in the carousel. Repeat for other levels of controls.

c) Check the results of each control. Select **CONTROLS, REVIEW, OR REPORT** and [F2] to select a file for review. Choose one control file and [Enter]. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. To print results for the logbook for the last control run, press [F4] Print. Use [F2] to select another file and repeat actions. Review and print reports for all three controls and file in the logbook. If a **H** or **L** displays, consider the following reasons and perform and document the following actions:

- (1) Improper mixing -- Follow instructions and rerun control.
- (2) Control files set-up incorrectly -- Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting, **SPECIAL FUNCTIONS, SET UP, CONTROL SET UP.**
- (3) Chance (statistical outlier) -- Rerun the control. If it is still out, continue with the following actions.
- (4) Change in the control -- Try another vial or level of control.
- (5) Instrument change -- Watch for normal sample flow. Call Beckman Coulter® representative to help troubleshoot abnormal operation.

6. Setting up a CBC/Diff control file

Set up a file whenever receiving a new lot number of control. Enter control package insert information for control with differential. Enter information using the bar code wand. Enter information manually if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, and CONTROL SET-UP.** Select **CBC DIFF/FILE.** Select a NOT SET-UP or an inactive file.

a) Using bar code scanner

Scanning bar code units -- Choose the correct section of the package insert to scan making sure to select the part with the correct Unit Format (US), for the correct instrument (MAXM).

- (1) Hold the wand like a pencil.
- (2) Place the wand in section 1, Lot No. Read this section first.
- (3) Gently slide the wand back and forth over the bar code until the instrument beeps. The lot number is now entered. Start and end each scan in the white space.
- (4) Beckman Coulter®'s expected ranges appear automatically when the control lot number is entered in an empty file.
- (5) Follow the same procedure for the expiration date and assigned values. (Values 2-10)
- (6) Manually select and enter Shift and Operator ID.
Check all entries to make sure they are correct. Press [F10] to save and exit.

b) Manual entry

Enter lot number. This enters the IQAP number automatically. Enter the expiration date, shift, and operator code. Continue to enter the package insert data. Press [Enter] after each entry. Press [↓] at the end of each row. The system automatically enters the level and default ranges based on the first two digits of the lot number. Check to make sure all entries are correct. Press [F10] to save and return to the previous screen.

C. Control statistics and graphs

1. Use to review and print:

Control results, cumulative statistics and graphs for CBC/DIFF files or
Control results, cumulative statistics and histograms for LATEX Files or
Check cumulative results for trends or shifts as necessary for troubleshooting.

Print, review, and delete cumulative statistics and graphs for all CBC/DIFF and LATEX files at the end of each month after transferring information to the IQAP disk and file in the logbook.

2. CBC/DIFF control review and report

- a) Use this report to review and print control results and cumulative statistics for CBC files. Select **CONTROLS, REVIEW OR REPORT**, and [Enter]. Press [F2] to select one of the following files, Normal, Abnormal I, Abnormal II, and Latex [Enter]. Press [F4] to print. Review and file in logbook. Continue to select each file in turn, print, and file.

Screen-specific function keys:

[F2] File Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print Prints the entire control file in a line list format on 8.5 x 11 in paper.

[F6] Remove/Restore
Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No.

[←] [→] Press [←] or [→] to see parameters not currently displayed on the screen.

[F9] Menu Displays the main menu.

3. Latex control review and report

a) Use this report to review and print control results and cumulative statistics and histograms for LATEX files. Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.

b) Screen-specific function keys:

Press [←] to go back to DIFF Latex Control Review

[F2] File Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print Prints the entire control on a graphic printer.

[F6] Remove/Restore

Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] again restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No

[←] [→] Press [←] or [→] to see parameters not currently display on the screen.

[F9] Menu Displays the main menu.

D. Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Beckman Coulter®'s IQAP program. The IQAP program includes saving results of 5C® Cell controls, transferring them to a disk, and sending them to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure on the last day of each month, at the end of each stand, or when a lot expires.

Follow procedure for CBC/DIFF and Latex control review and report. After downloading and printing results, delete control files [F8].

1. Procedure to download IQAP files to diskette.
 - a) Slide the diskette into the drive with the arrow side up and pointed toward the drive in the Beckman Coulter® Data Management System. Gently push the diskette until it clicks into place.
 - b) Turn the computer OFF. Wait 15 seconds, and then turn the computer back ON. A screen will appear showing the Beckman Coulter® Corporation logo. To exit this screen, follow the instructions on the bottom left portion of the screen, and press [Esc].
 - c) The screen will indicate the process the system is performing. Read the instructions on the screen. When the process is complete, the DMS displays the list of possible files on the screen for review and selection. If some of the values are incorrect, edit or delete the fields on this screen. Any alteration to this screen will effect only data on the IQAP diskette, not in the MAXM computer.

- d) FILE_NAME indicates the files by file number for downloading to the diskette.
- LOT_# indicates the type of control. Prefixes 86, 87 and 88 refer to 5C® Cell Controls.
 - SHIFT refers to the shift designation selected for running the controls. Edit this field if necessary. Use arrow keys to position.
 - START and END indicate beginning and end dates for each file. These fields are not editable.
 - REPORT indicates whether IQAP will issue a report on the lot number.
 - N_REC indicates the number of records found in the file.
- e) Press [Esc] to leave this screen. If the IQAP# and Serial # are present and valid, the following screen message will appear, "Updating the IQAP Disk." After writing the control files to the diskette, a screen message will give instructions to follow. Follow these instructions and the computer will reboot to the routine program. To remove the diskette, press the eject button on the lower right of the diskette drive opening. Do not remove the diskette until the drive indicator light is off.
- f) Label the diskette with the supplied IQAP ID label. Place the diskette in pre-addressed mailer provided and mail. Do not place the label over the drive spindle or high-density hole.

E. X_B analysis

1. X_B analysis is a QC method monitoring instrument performance by tracking the MCV, MCH, and MCHC parameters of SP samples. These indices are very stable and show little variance between SP samples. This method displays the moving average of SP samples and compares it to established target values. Target values are MCV = 88.5, MCH = 29.5, and MCHC = 33.5. Review and print the X_B current batch at the beginning on each session when printing the 5C Cell control results.

Review, print, and file the Coulter X_B current batch at the beginning of each session when printing the 5C Cell control results.

2. X_B batch means

Use to view the calculated means for the last batch of 20 SP results. The MAXM calculates MCV, MCH, and MCHC means. Review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Evaluate the percentage difference from the target limit to determine whether the batch is in or out of control. Select **SAMPLE ANALYSIS, X_B , and CURRENT X_B BATCH**. Press [F2] [F4]. Print and file in logbook.

To change the status of X_B , select [F5] Optns on the **RUN SAMPLES** screen.

Screen-specific function keys:

[F4] Print Prints the table.

[F6] Delete Last Batch

Deletes the last batch. Delete only if the batch is badly skewed because of non-random sampling or an instrument problem that it will adversely effect many later batches.

[F8] Delete Table

Deletes the entire table.

[←] [→]

Press [←] or [→] to see parameters not currently displays on the screen.

[F9] Menu

Displays the main menu.

3. X_B Graphs

Review, print, file, and delete the Batch Means and graphs at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Select **SAMPLE ANALYSIS, X_B , X_B GRAPHS**, and [F4] to print. File in the logbook.

F. Proficiency testing

Evaluation and participation in the College of American Pathologist (CAP) proficiency testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of 5 3-mL whole blood specimens. Follow all CAP instruction in preparing the materials before performing the test. Run specimens in a manner identical to routine specimens. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

G. Linearity for WBC, RBC, Hgb and Plt parameters

Lin-C™ (PN 7547065 - 5 x 3.3-mL) The Lin-C™ linearity controls verifies the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent.

OR

CAP Hematology Calibration Verification/Linearity Survey (LN9) - These materials are shipped twice per year and consist of 18 3-mL liquid specimens. Follow all CAP instruction in preparing and running the materials before performing the test. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

Run either the Lin-C™ or CAP LN9 survey material:

- At installation;
- At least yearly; and
- Whenever experiencing an altitude change of 1 mile or more between stands.

1. Principle - Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems. Controls contain one each of Ultra Low Range, Low Range, Mid Range, High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Beckman Coulter® system calibrates with S-CAL® calibrator.

2. Reagents - Lin-C™ controls consist of treated, stabilized, human erythrocytes in an isotonic bacteriostatic medium. Linearity controls also contain a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Ship Lin-C™ controls in thermally insulated containers designed to keep kits cool. Store Lin-C™ linearity controls between 2-8°C (35-46°F). Store vials in an upright position to achieve maximum product yield. Storage of the control product in a cap down position might require additional mixing or complete resuspension of cellular components.

Potential biohazard – Each human donor used in preparation of this material was tested by an FDA approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive.) Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (dark colored supernatant) indicates product deterioration. A slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.
5. Instructions for use -- Remove Lin-C™ controls from refrigerator and warm to ambient temperature for 10-15 minutes. After warming mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube

and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again. Controls expire 7 days after opening.

- a) Turn the blood detectors off to analyze the Ultra Low Range. Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, BSV TESTS, and BLOOD DETECTOR ON/OFF**. Press [Enter]. Use space bar to select On or OFF. Press [Enter].
- b) Disable the differential before analyzing Lin-C™ linearity controls. Is SAMPLE MODE displayed? If no, press [F9] STOP. Make sure the DIFF is off. If it is on, press [F6].
- c) When analyzing Lin-C™ linearity controls, flags such as L, LL, H, HH, R, RR, *, *R, and *V will occur. Ignore these flags if a numerical result is obtained. When ---- (voteout), (incomplete computation) or ++++ (over range) flags occur, the sample should be repeated. Ignore Beckman Coulter® histogram differential flags and results.
- d) Run the Lin-C™ controls in the Primary Mode of the instrument. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Press [Enter]. Press [F2] START PRIMARY. Analyze controls six times and record the results for WBC, RBC, Hgb, and Plt parameters for each sample on the worksheet. Repeat flagged samples with non-numeric results.
- e) Beckman Coulter® recommends that five sample results should be used to calculate the mean value. Use a minimum of three samples to calculate the mean when repetitive results with non-numeric values occur. Delete the first sample result. Plot mean recovered values on the Lin-C™ linearity control graphs.
- f) Compare the mean value to the linearity control ranges listed on the Table of Expected Results on the package insert. Mean values should recover

within the ranges. Use the ranges established by Beckman Coulter® Corporation as a guideline.

- g) Plot the instrument background count as a zero value to extend the reportable range. Beckman Coulter® will prepare tabular summaries and graphic presentations of the data. Submit the top copy of the worksheet to IQAP at the following address:

Beckman Coulter® Corporation
IQAP (M/C 31 B04)
PO BOX 169015
Miami, FL 33116-9015

XI. Interpretation of Results and Remedial Action

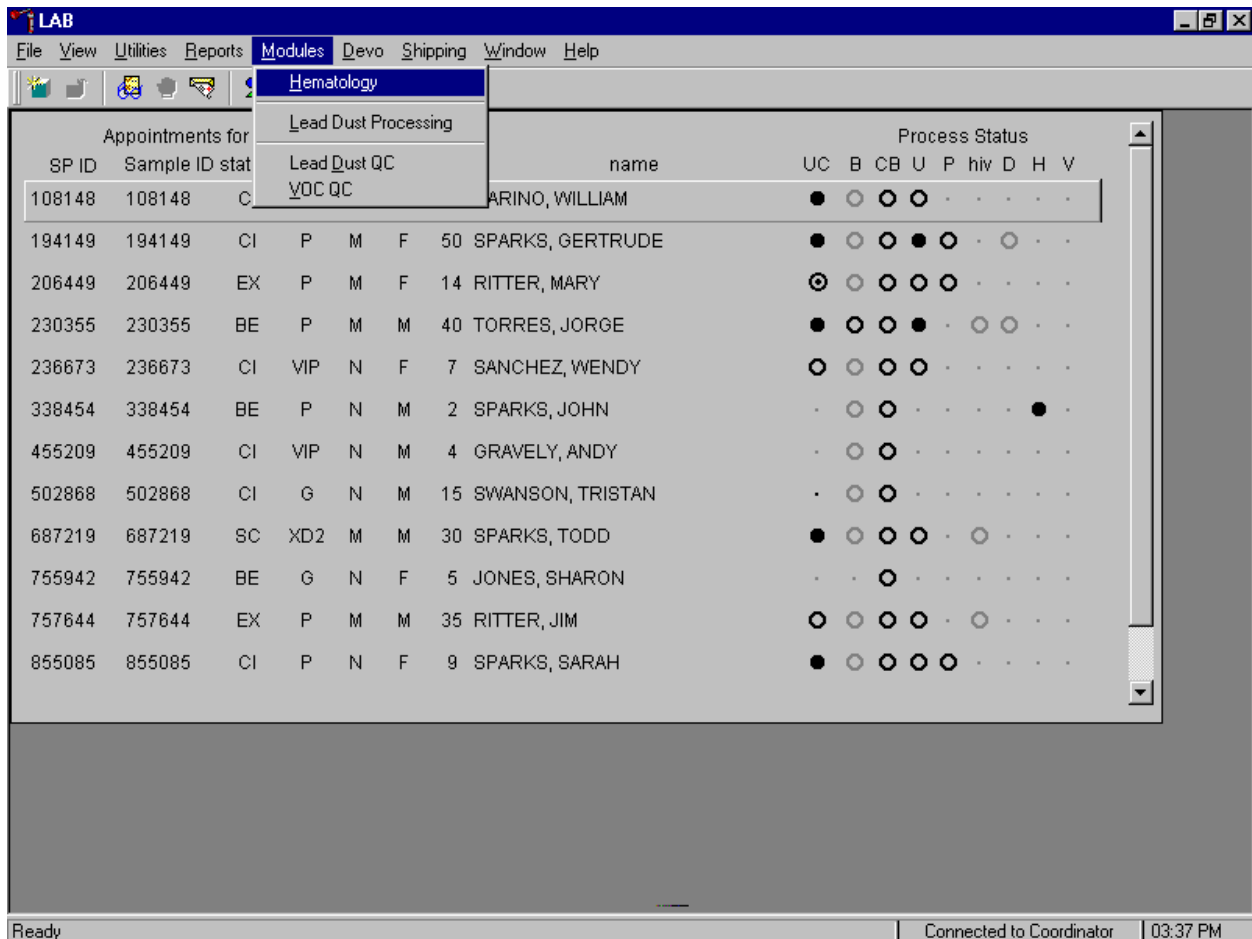
A. Sample Person hemoglobin and hematocrit review and remedial actions.

1. Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin.

B. Sample Person review and remedial actions.

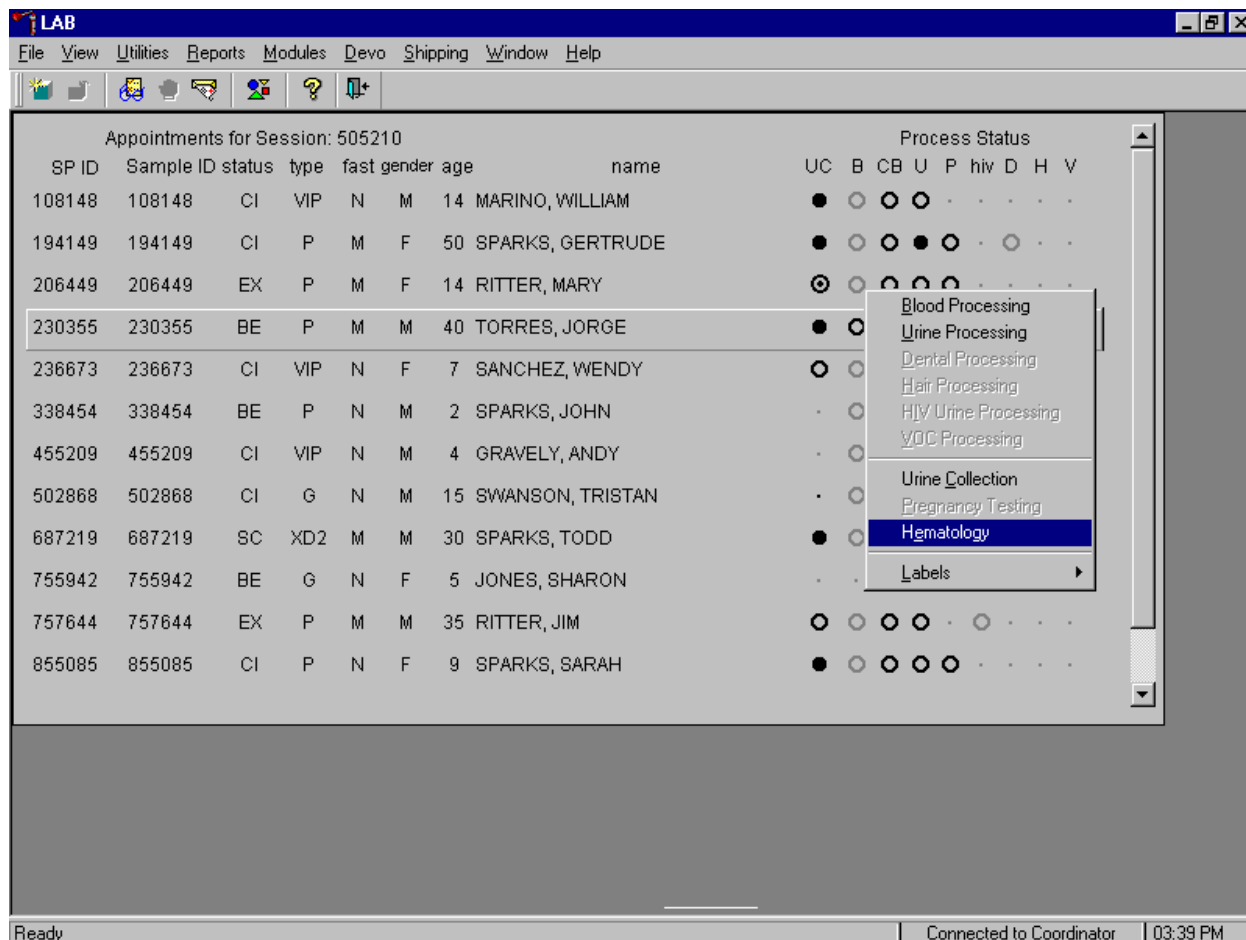
1. Run all samples in duplicate. Make sure the Hematology module is open before running SP samples on the MAXM.

Open the hematology module.



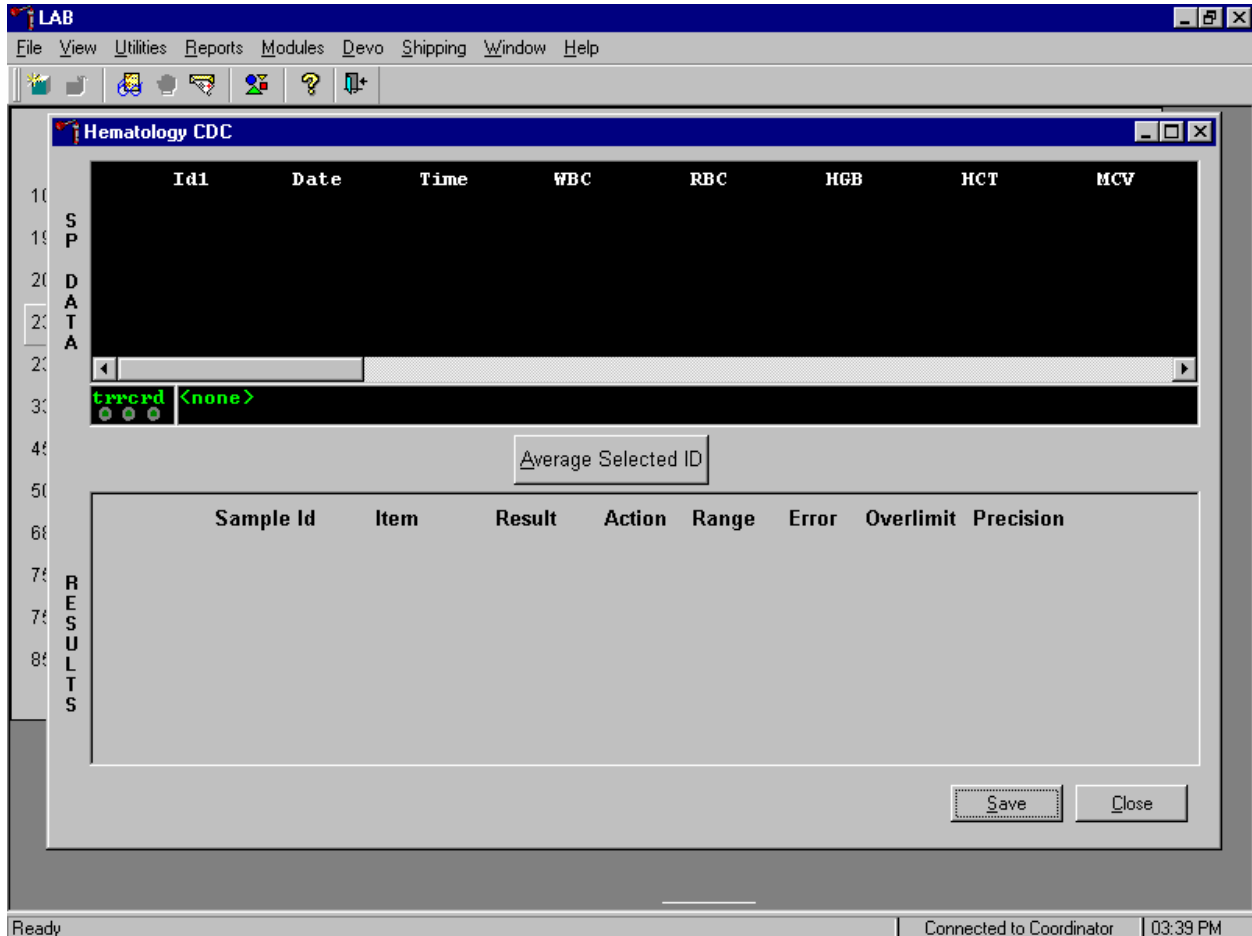
To open the hematology module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Hematology}, and right click, or type [Alt] [M], [H].

2. Alternatively, open the Hematology module from the heads-up display.



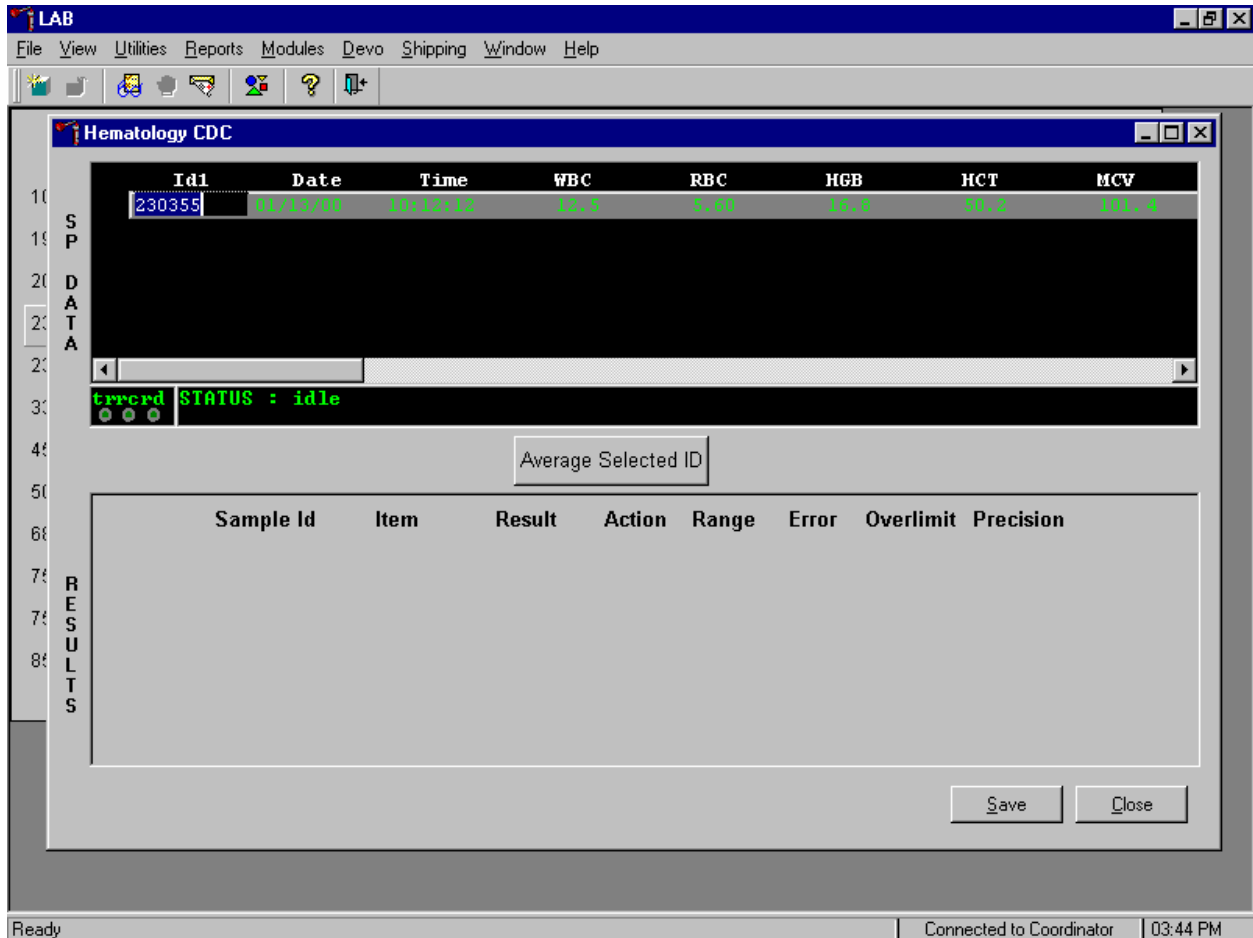
To access the Hematology module, use the mouse to direct the mouse arrow any SP, right click, drag the mouse arrow to {Hematology}, and right click or type [E/e]. Alternatively, use the up and down keys to move up and down the list until a particular SP is highlighted, right click, drag the mouse arrow to {Hematology}, and right click or type [E/e].

3. Coulter automatically transmits results to the laboratory application. Make sure the Beckman Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



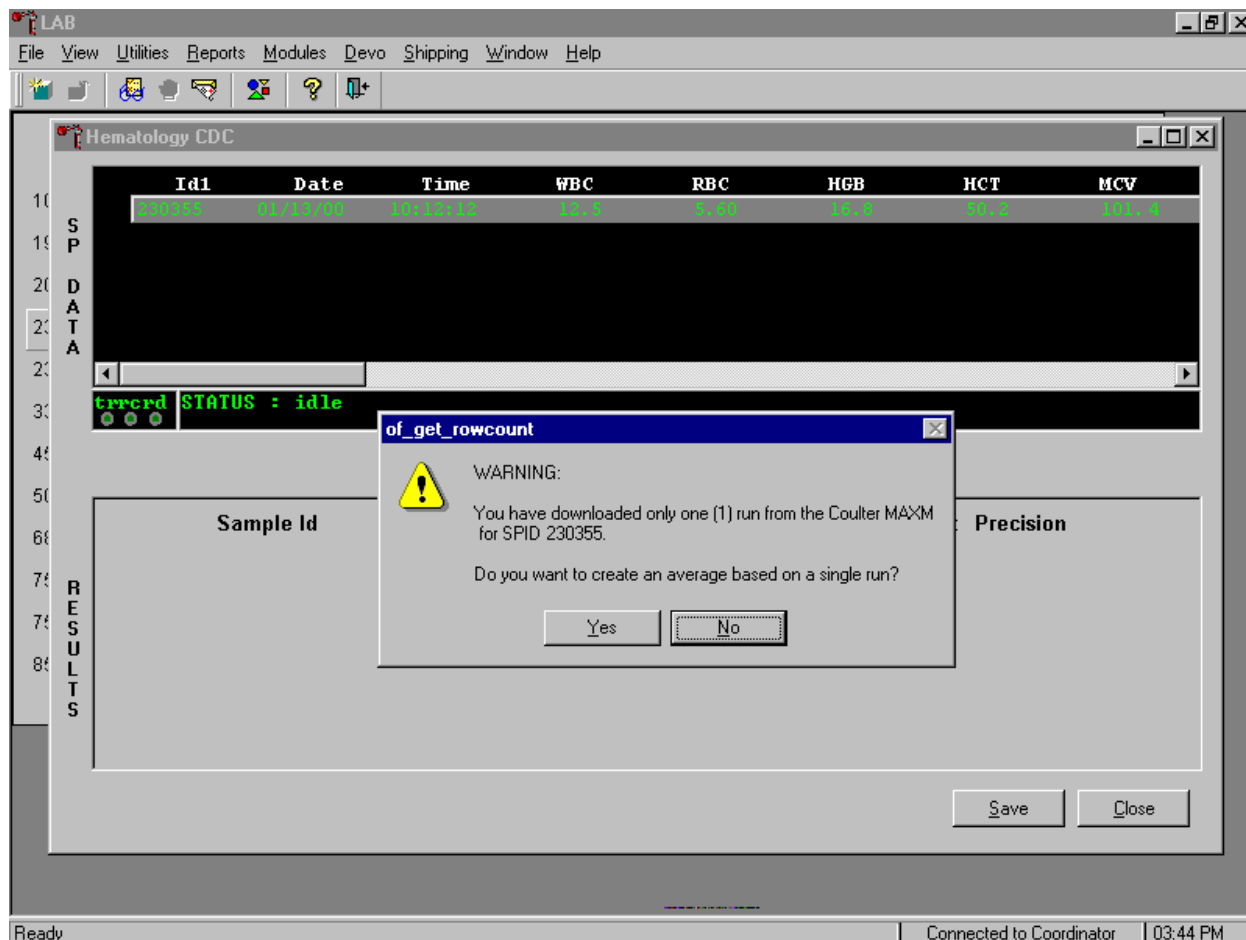
SP data transmits to the hematology module and displays it in the top portion of the window, the SP Data section. This section includes the SP ID, the date and time the CBC was run, and columns for each individual parameter. The bottom portion of the window is the Results section. Results display after the Average Selected ID button is selected.

- Review all Coulter data in the SP Data section after transmission.



To view SP data for all parameters, use the mouse to direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, use the mouse to direct the mouse arrow to the small scroll arrows on the left and right edges of the horizontal scroll bar, and left click.

5. Save results where only one run was possible.



Run samples in duplicate whenever possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To average results where only one run is possible, use the mouse to direct the mouse arrow to the **Average Selected ID** box and left click or type [A/a]. A warning message text box displays that states, "You have downloaded only one (1) run from the Coulter MAXM for SPID XXXXXX" and asks, "Do you want to create an average based on a single run?" To record a "Yes" response, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Y/y]. To record a "No" response, use the mouse to direct the mouse arrow to the **No** button and left click or type [N/n] or press [Enter]. If a Yes response is recorded, the CBC results display in the bottom Results section of the window. A "No" response cancels the action and returns the window to its previous state.

The Hematology screen overview.

LAB

File View Utilities Reports Modules Devo Shipping Window Help

Hematology CDC

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
230355	01/13/00	10:12:12	12.5	5.60	16.8	50.2	101.4

errord STATUS : idle

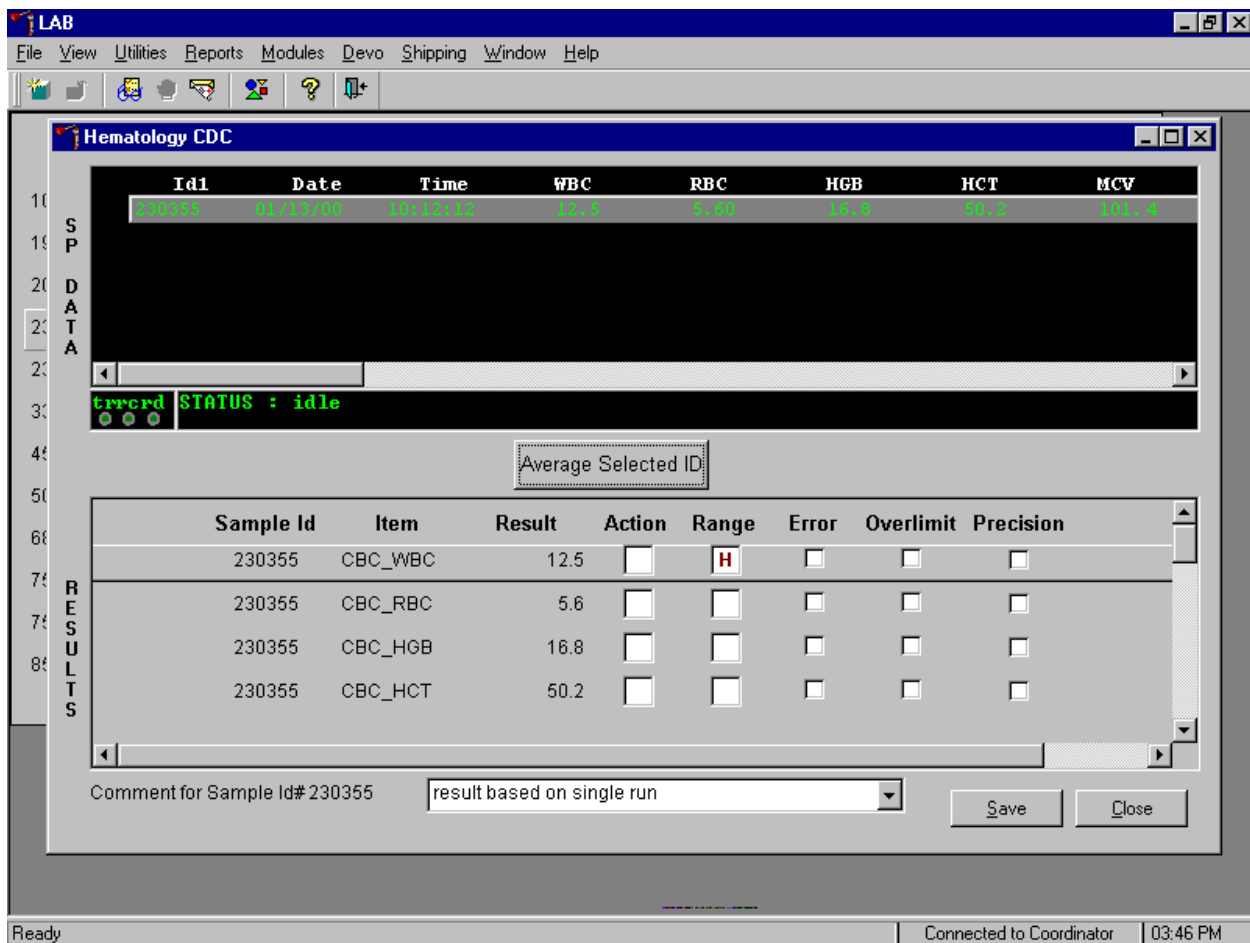
Average Selected ID:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
230355	CBC_WBC	12.5	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_RBC	5.6	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HGB	16.8	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HCT	50.2	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id#230355: result based on single run

Save Close

Ready | Connected to Coordinator | 03:46 PM

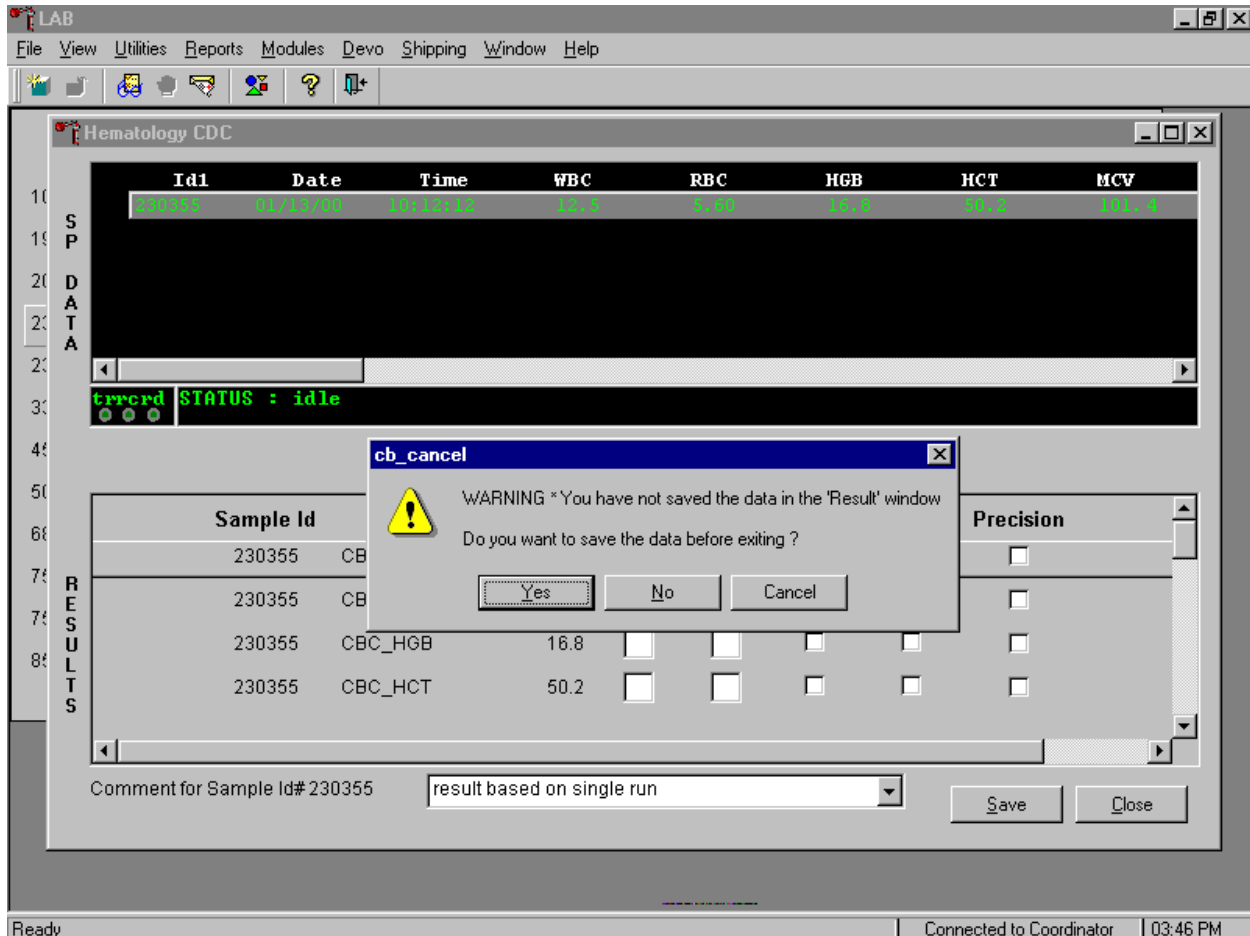


The Result columns include, Sample ID, Item (CBC parameter), Result (Coulter data for a single run or the ISIS averaged result for multiple runs), Action (CDC established critical limits), Range (CDC established reference ranges for both genders and 4 age groups), Error (Coulter transmitted instrument errors), Overlimit (Coulter transmitted result that exceeds the instrument's linearity limit), and Precision (CDC established values for the difference between any two runs.) Checkmarks display in boxes for parameters that have errors, are overlimit, or for those that exceed precision limits. A "H" for "high" and "L" for "low" display for parameters that exceed action limits or reference ranges.

Average, evaluate, and save results for all parameters. The SP's results display in the bottom portion of the window after the Average Selected ID button is selected. To view results for all parameters, use the mouse to direct the mouse arrow to the vertical scroll bar at the right side of the Results section and drag the bar up or down. Alternatively, to view all the results, use the mouse to direct the mouse arrow to the small scroll arrows on the top and bottom edges of the vertical scroll bar, and left click. Evaluate each

parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. To save the result to the database, use the mouse to direct the mouse arrow to the button and left click or type [S]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the button and left click or type [C].

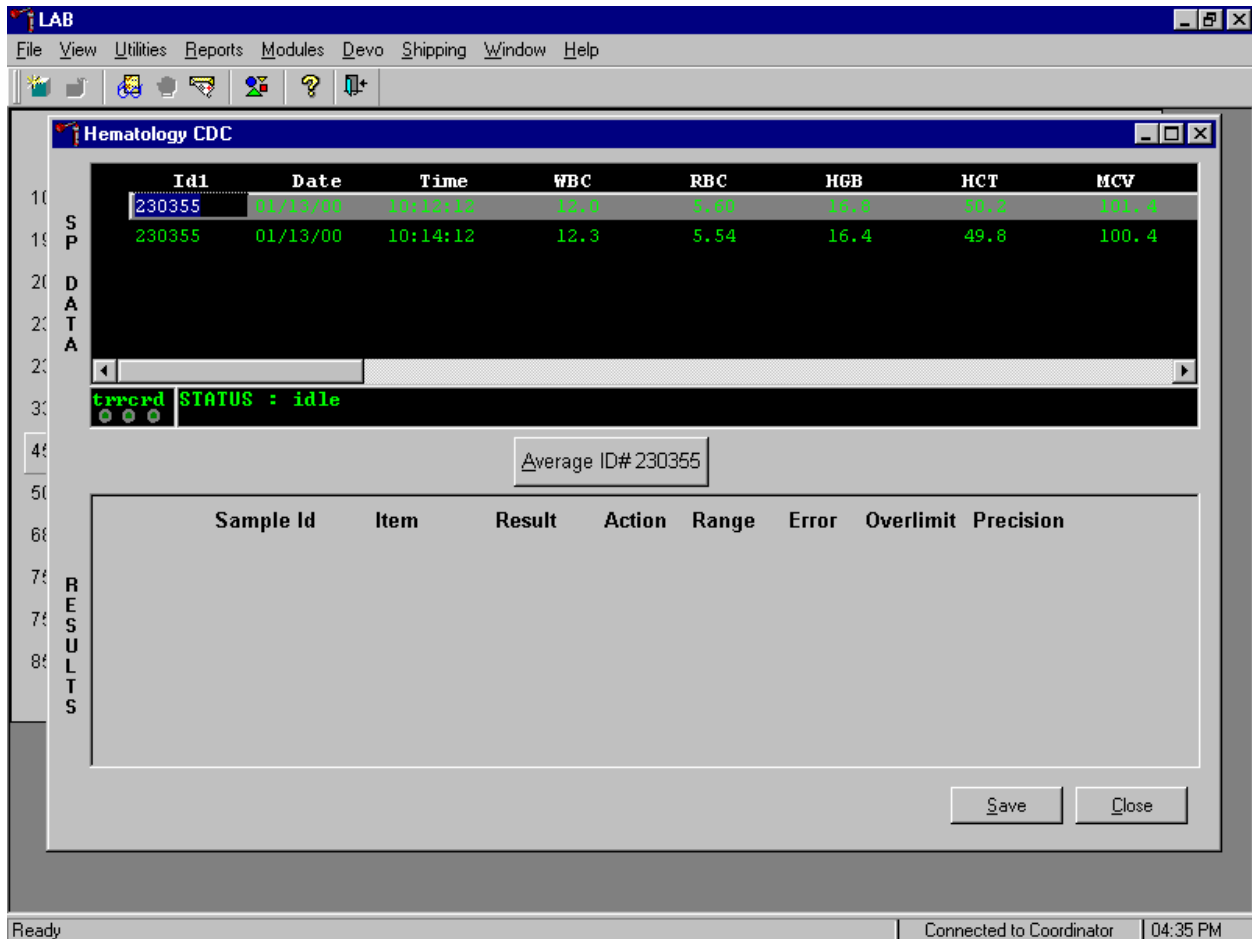
A warning text box displays if the **Close** button is selected before the **Save** button.



If the **Close** button is selected before the results are saved to the database, a warning message text box displays that states, "WARNING *You have not saved the data in the 'Result' window" and asks, "Do you want to save the data before exiting?" To record a "Yes" response, use the mouse to direct the mouse arrow to the **Yes** button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N/n]. To cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click. If a Yes response is recorded, the CBC results are saved to the database and erased. If a No response is recorded, no results are saved to the database and the data in the Results section is erased. A Cancel response returns the screen to its previous state.

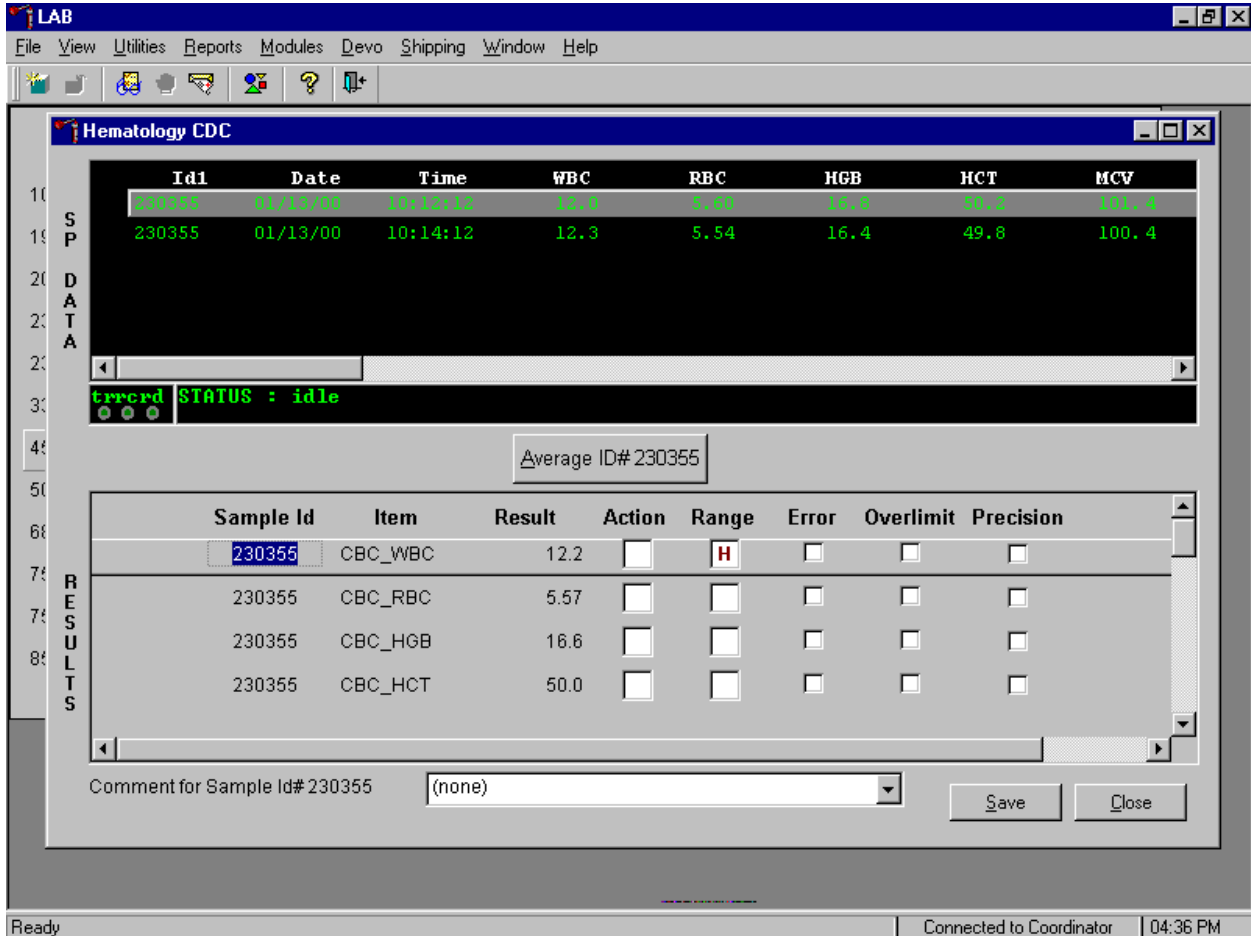
For results where only one run was possible, the **Comment** box at the bottom of the window defaults to "result based on single run."

6. Run all samples in duplicate and average the data.



Whenever a sample is run in duplicate, both results display in the SP Data section. To average these two results, use the mouse to direct the mouse arrow to **Average ID#XXXXXX** button and left click or type [A/a].

7. Results display in the lower section of the window.



The difference between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if the differences are within the following CDC established precision limits.

Test	Precision Limits
WBC	0.4×10^3
RBC	0.1×10^6
Hgb	0.4 g/dL
MCV	2.2 fL
Plt	23×10^3

NE#	0.4×10^3
LY#	0.2×10^3
MO#	0.2×10^3
EO#	0.2×10^3
BA#	0.2×10^3

If RBC parameters are out of range, evaluate XB for a drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range, check the WBC scattergram for abnormal cell population(s).

- Evaluate and save results when precision limits are not exceeded.

The screenshot shows the LAB Hematology CDC software interface. The main window displays a table of sample data and a detailed results table.

Sample Data Table:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
230355	01/13/00	10:12:12	12.0	5.60	16.6	50.2	101.4
230355	01/13/00	10:14:12	12.3	5.54	16.4	49.8	100.4

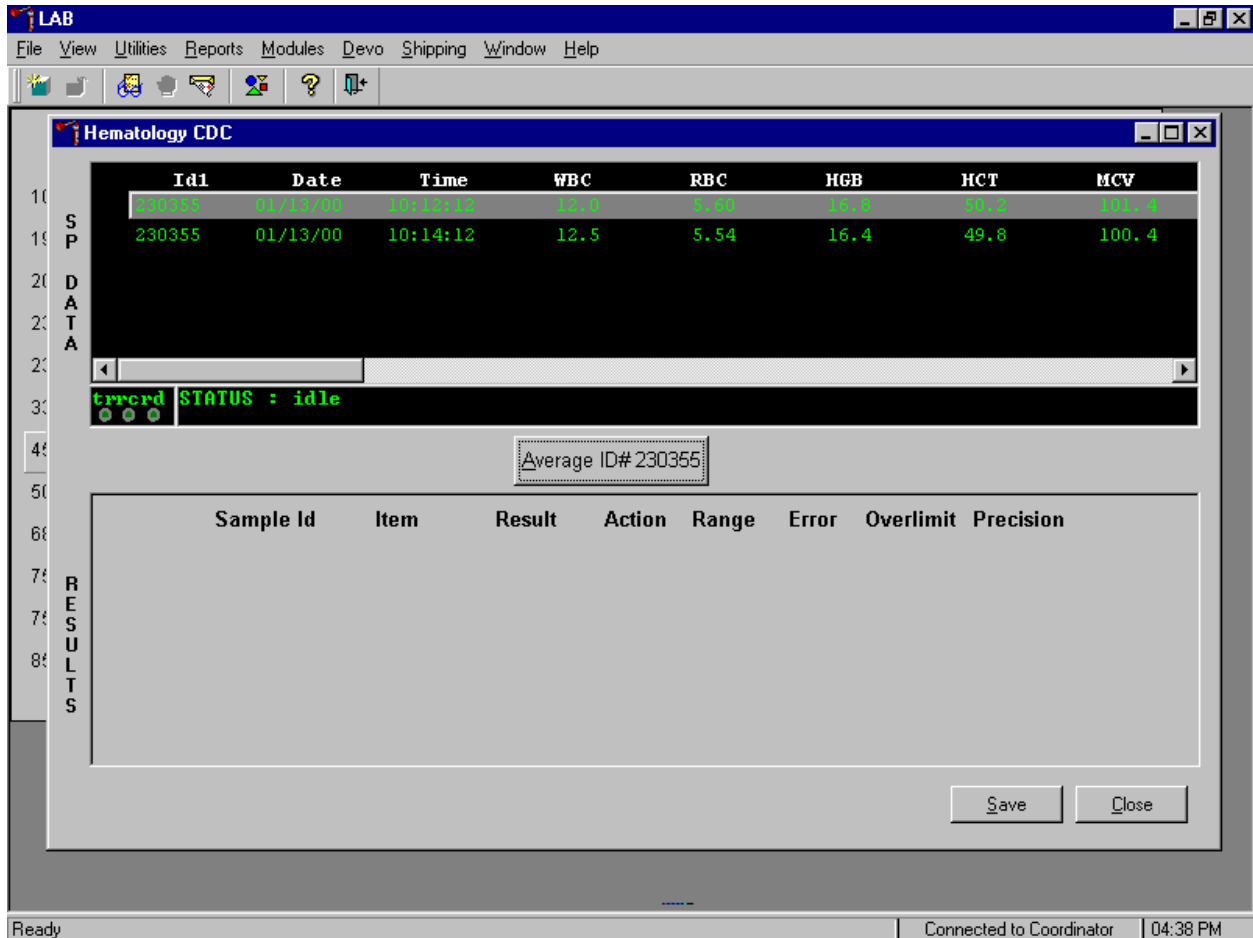
Results Table:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
230355	CBC_WBC	12.2	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HGB	16.6	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HCT	50.0	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional interface elements include a status bar at the bottom showing 'Ready', 'Connected to Coordinator', and '04:36 PM'. The 'Save' and 'Close' buttons are visible at the bottom right of the results section.

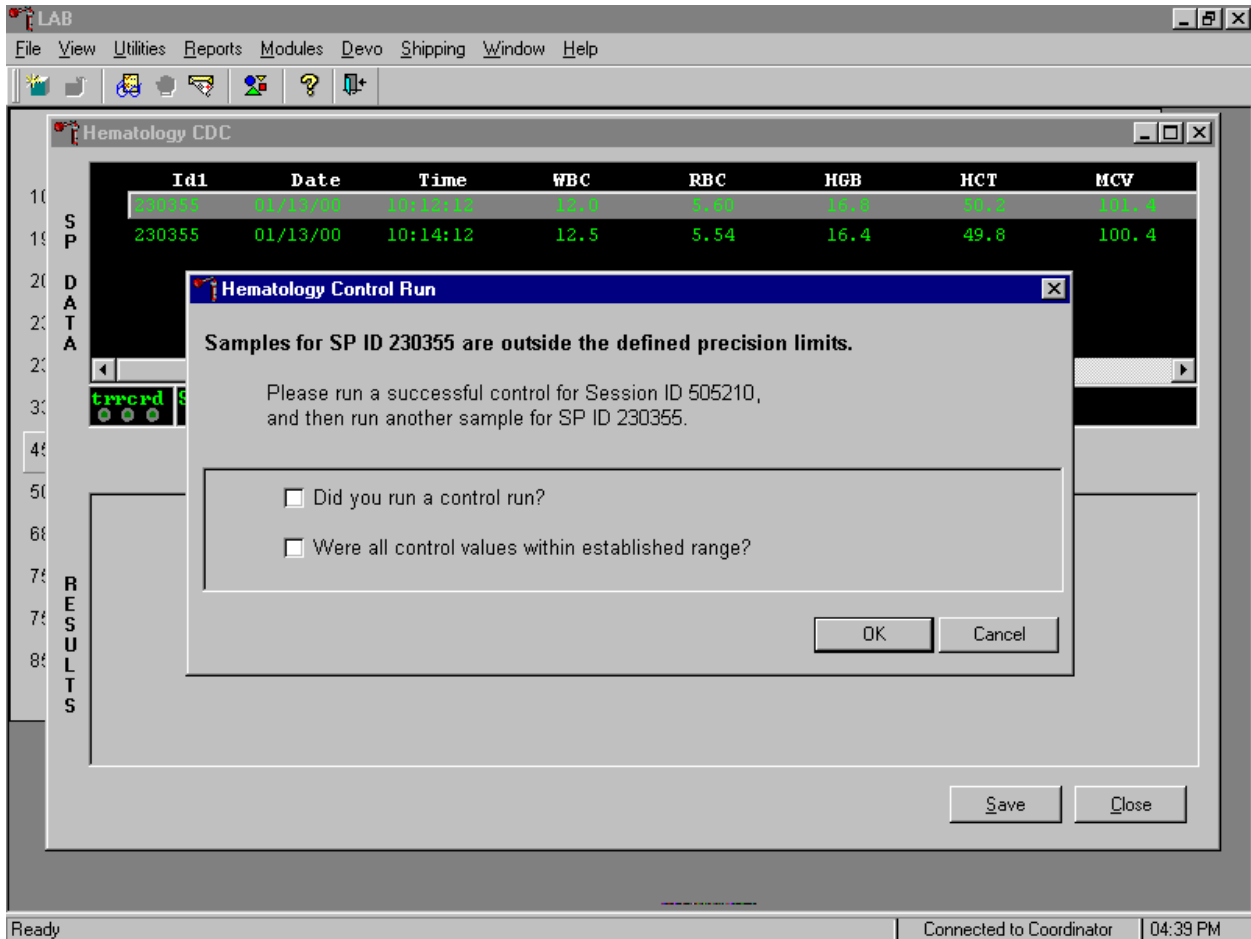
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c].

- Average, evaluate, and rerun specimens that exceed precision limits.



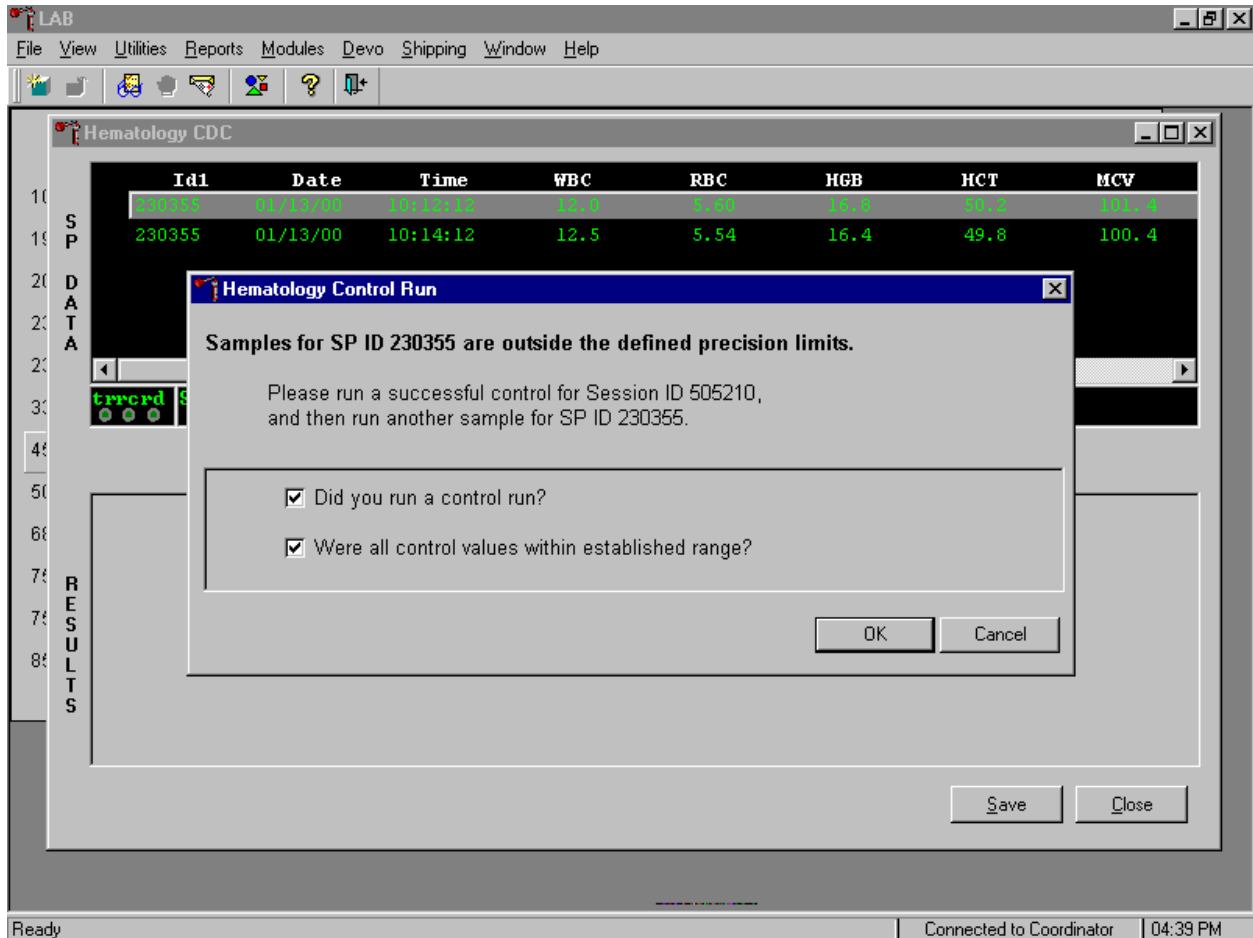
Average the two results by using the mouse to direct the mouse arrow to the **Average ID#XXXXXX** button and left click or type [A/a]. If at this point, precision limits are not met for any individual parameter, the technologist is prompted to run a control and evaluate the control to determine if all control values fall within the control's established range.

10. If any parameter exceeds its precision limit, the Hematology Control Run window displays.



The Hematology Control Run window indicates that the "Samples for SP ID XXXXXX are outside the defined precision limits." It instructs the technologist to, "Please run a successful control for Session ID XXXXXX, and then run another sample for SP ID XXXXXX." Run any one level of 5C Cell control and evaluate the results. Respond to the two questions, "Did you run a control run?" and "Were all control values within established range?" To confirm these actions, use the mouse to direct the mouse arrow to each of the two check boxes and left click to record the check marks.

Save the responses to the check box questions.



To save these responses to the database, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter], or to exit the Hematology Control Run window without saving the responses, use the mouse to direct the mouse arrow to the **Cancel** button and left click. As soon as the **OK** button is selected, the averages display in the Results section of the window.

Evaluate the results displayed in the Results section of the window.

The screenshot shows the LAB Hematology CDC software interface. The main window displays a table of sample data and a detailed results section.

Sample Data Table:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
230355	01/13/00	10:12:12	12.0	5.60	16.6	50.2	101.4
230355	01/13/00	10:14:12	12.5	5.54	16.4	49.8	100.4

Results Section:

Average ID# 230355

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
230355	CBC_WBC	12.3	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
230355	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HGB	16.6	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HCT	50.0	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 230355: (none)

Buttons: Save, Close

Status bar: Ready | Connected to Coordinator | 04:40 PM

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. Use the scroll bar to view all results. When there are checkmarks in any of the Precision columns, meaning that the precision limit was exceeded, rerun the blood sample a third time. If there is insufficient blood to run the CBC a third time, save the result to the database. To save the results to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c].

- Run the specimen a third time when any precision limit is exceeded.

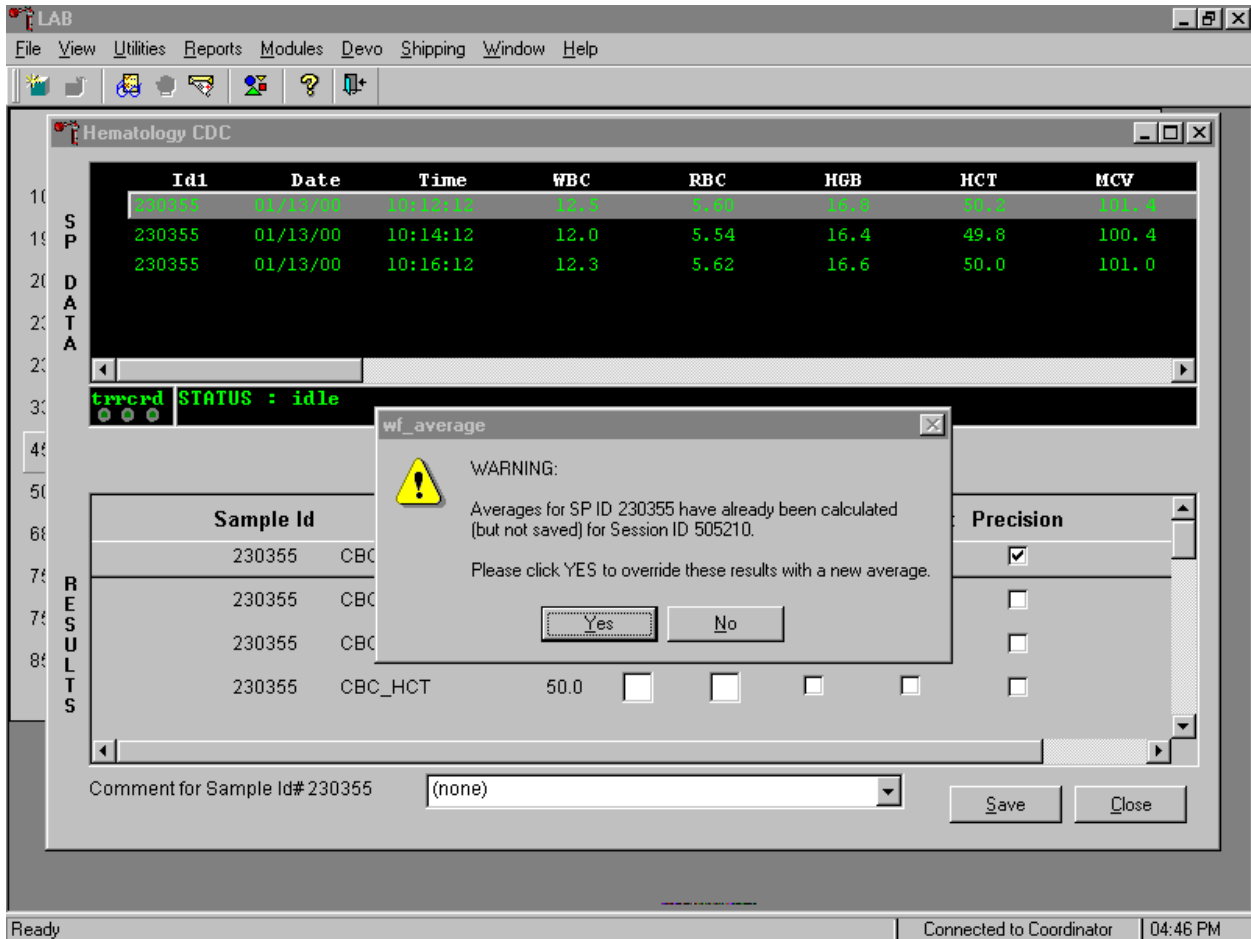
The screenshot shows the LAB Hematology CDC software interface. The main window displays a table of sample data under the 'SP DATA' section. Below this, there is a 'RESULTS' section with a table of results for sample ID 230355. The results table includes columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The WBC result is 12.3, which is highlighted with a red 'H' in the Action column, indicating it is over the precision limit. The other results are CBC_RBC (5.57), CBC_HGB (16.6), and CBC_HCT (50.0). The interface also shows a status bar at the bottom with 'Cancel changes', 'Connected to Coordinator', and '04:45 PM'.

SP DATA	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
	230355	01/13/00	10:12:12	12.5	5.60	16.8	50.2	101.4
	230355	01/13/00	10:14:12	12.0	5.54	16.4	49.8	100.4
	230355	01/13/00	10:16:12	12.3	5.62	16.6	50.0	101.0

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
	230355	CBC_WBC	12.3	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	230355	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	230355	CBC_HGB	16.6	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	230355	CBC_HCT	50.0	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Run the blood sample a third time. Whenever a sample is run more than once, all results in the SP Data section are displayed. To re-average these results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click or type [A/a]. The initial averaged result for parameters that do not exceed precision limits are fixed and are not recalculated.

12. Override the current averaged results for parameters that exceeded the precision limit with a new average.



Whenever a sample has previously been averaged, and a new average is calculated, a Warning message text box displays stating that "Averages for SP ID XXXXXX have already been calculated (but not saved) for session ID XXXXXX." The text box instructs, "Please click YES to override these results with a new average." To override the current average with a new average (but for only those parameters that exceeded precision limits), use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Y/y], or press [Enter]. To exit or return to the previous screen containing the previous averages, use the mouse to direct the mouse arrow to **No** button and left click, or type [N/n].

13. Evaluate the new results.

The screenshot shows the LAB Hematology CDC software interface. The main window displays a table of test results for sample ID 230355. The table has columns for Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. The results are as follows:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
230355	01/13/00	10:12:12	12.5	5.60	16.8	50.2	101.4
230355	01/13/00	10:14:12	12.0	5.54	16.4	49.8	100.4
230355	01/13/00	10:16:12	12.3	5.62	16.6	50.0	101.0

Below the table, the status is shown as "errord STATUS : idle". The average ID# is 230355. The RESULTS section contains a table with the following data:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
230355	CBC_WBC	12.4	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HGB	16.6	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
230355	CBC_HCT	50.0	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

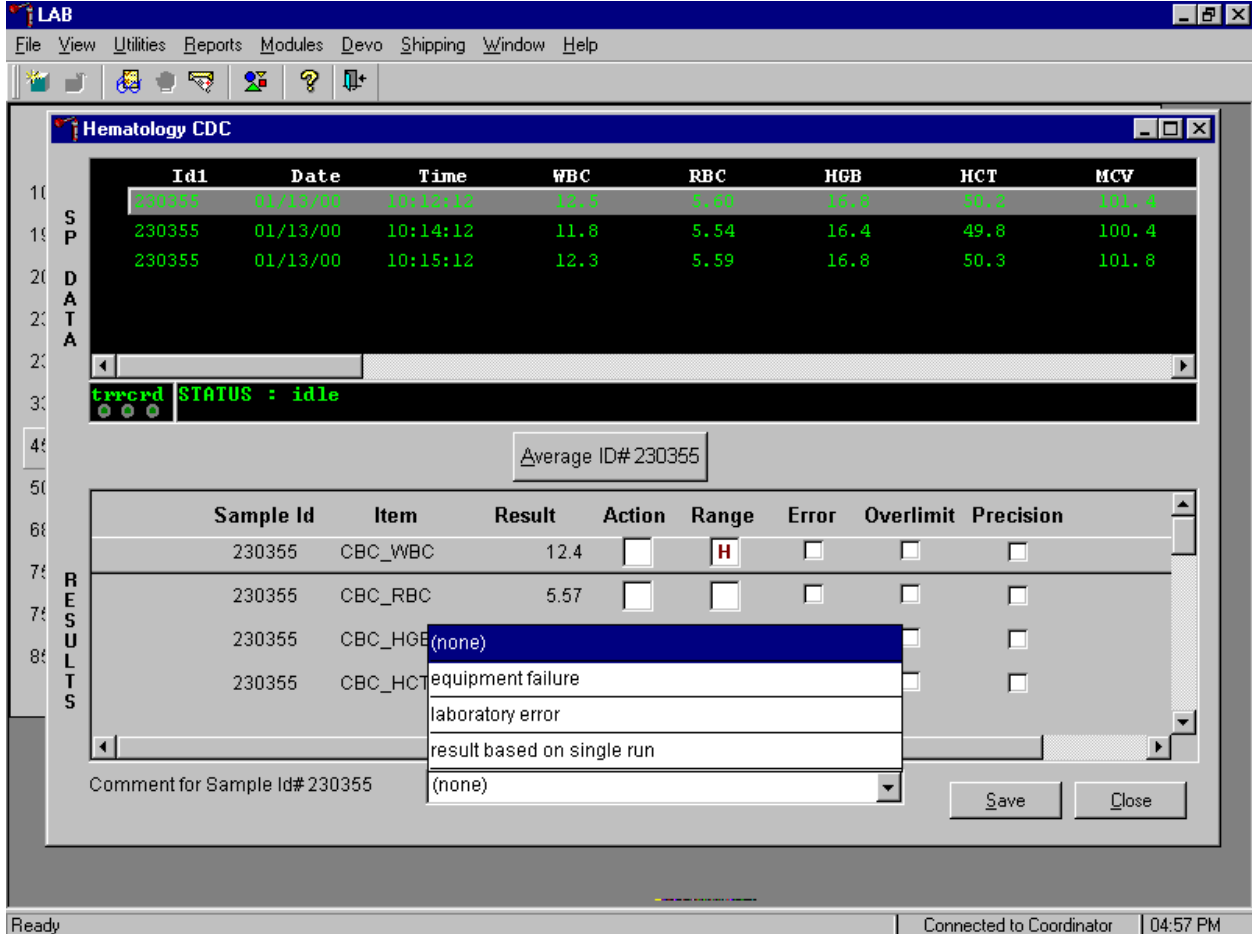
At the bottom, the comment for sample ID# 230355 is "(none)". There are "Save" and "Close" buttons. The status bar at the bottom shows "Ready", "Connected to Coordinator", and "04:46 PM".

The first three runs are recalculated to find the closest two results for parameters where the difference between any two results exceeded its precision limits. If all parameters now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the result to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c].

14. If necessary, run the specimen a fourth time and evaluate.

If precision limits are still not met for any parameter, run the blood tube a fourth time. Re-average, evaluate, and save the results. If after four runs precision limits are still not met for any parameter, a comment is automatically attached to the results. Do not run a specimen more than 4 times.

15. Enter a comment for selected results.



To attach a comment to the results in the database, use the mouse to direct the mouse arrow to the drop down list on the **Comment** box, left click to display the codes, drag the mouse arrow to the most appropriate choice, and left click. Alternatively, to record a comment, use the mouse to direct the mouse arrow to the drop down list on the **Comment** box, click to display the codes, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. To save the averaged result and to update the comment, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. To exit without saving any data to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c].

Comment	Use when:
Equipment failure	The Coulter malfunctions.
Laboratory error	Technologist error.
Results based on single run	The quantity of specimen is insufficient to run more than once.

- Retain data for multiple SPs in the SP Data section of the window.



In general, run one SP in duplicate through the Coulter, average the result, and save the data to the database. The Hematology module will display data for multiple SPs in the SP Data section. Each individual SP's results or pairs of results are displayed in a different color. To select or highlight any one SP, use the mouse to direct the mouse arrow to the row containing the correct SP ID and left click.

Average the results for one SP at a time.

The screenshot shows the 'LAB Hematology CDC' window. The top section displays a table of test results for multiple samples. Below this, the 'Average ID# 230355' is highlighted. The bottom section shows a detailed results table for sample ID 230355, including columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The 'Action' column shows 'H' for WBC and 'L' for RBC, HGB, and HCT. The 'Precision' column has empty checkboxes for all items. A 'Comment for Sample Id# 230355' field is set to '(none)', and 'Save' and 'Close' buttons are visible.

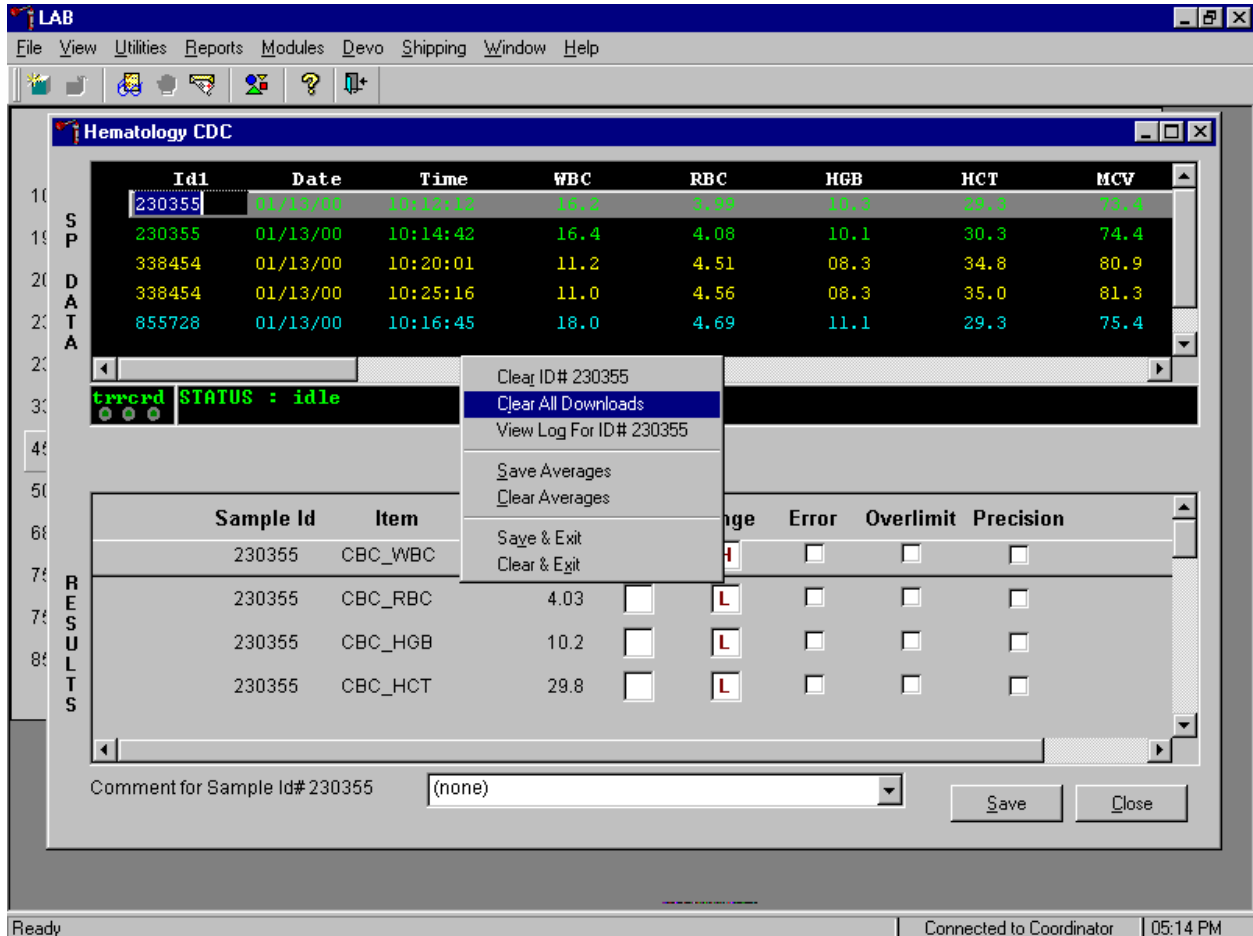
SP DATA	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
10	230355	01/13/00	10:12:12	16.2	3.89	10.3	29.3	75.4
15	230355	01/13/00	10:14:42	16.4	4.08	10.1	30.3	74.4
20	338454	01/13/00	10:20:01	11.2	4.51	08.3	34.8	80.9
25	338454	01/13/00	10:25:16	11.0	4.56	08.3	35.0	81.3
25	855728	01/13/00	10:16:45	18.0	4.69	11.1	29.3	75.4

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
60	230355	CBC_WBC	16.3	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
70	230355	CBC_RBC	4.03	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
75	230355	CBC_HGB	10.2	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
80	230355	CBC_HCT	29.8	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c]. If there are any Precision checkmarks, run a 5C Cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

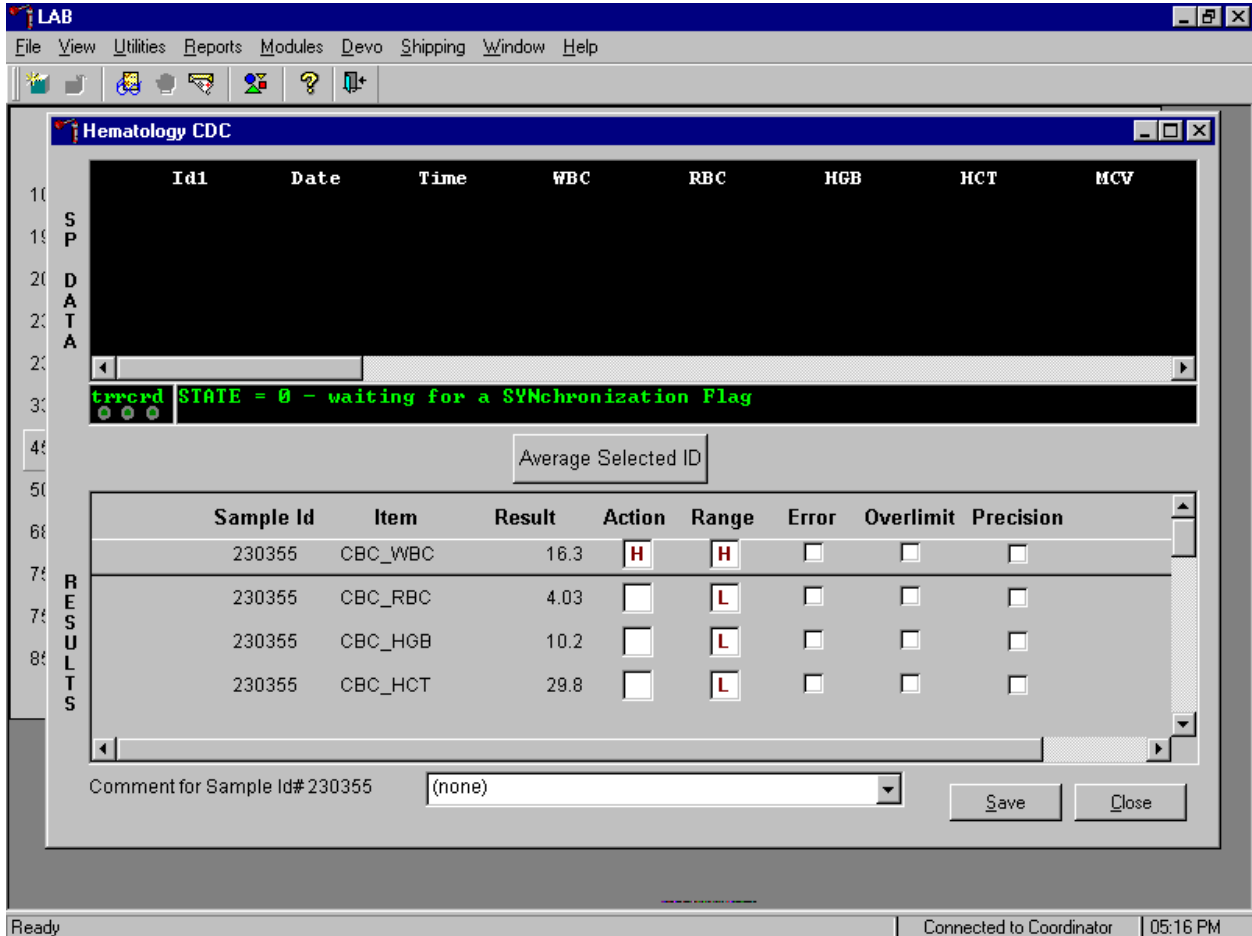
17. Use alternative data manipulation choices as desired.

Use the "Clear All Downloads" function to delete all data for all SPs in the SP Data section.



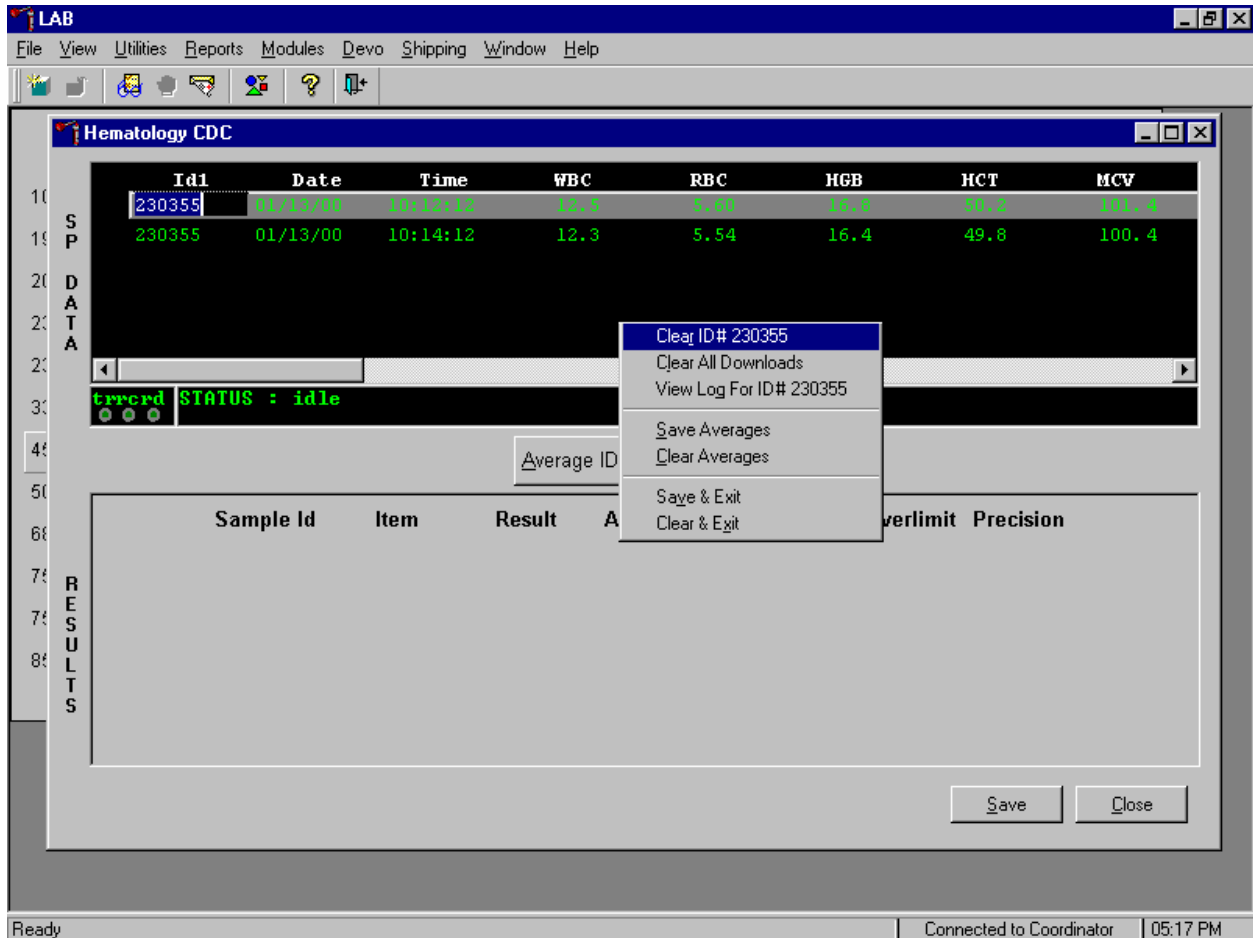
To clear all downloads from the SP Data section, use the mouse to direct the mouse arrow to any individual row in the SP Data section and right click to display the alternative data manipulation choices. To select "Clear All Downloads," drag the mouse arrow to Clear All Downloads and left click or type [L/I].

Release the mouse button to clear all downloads.



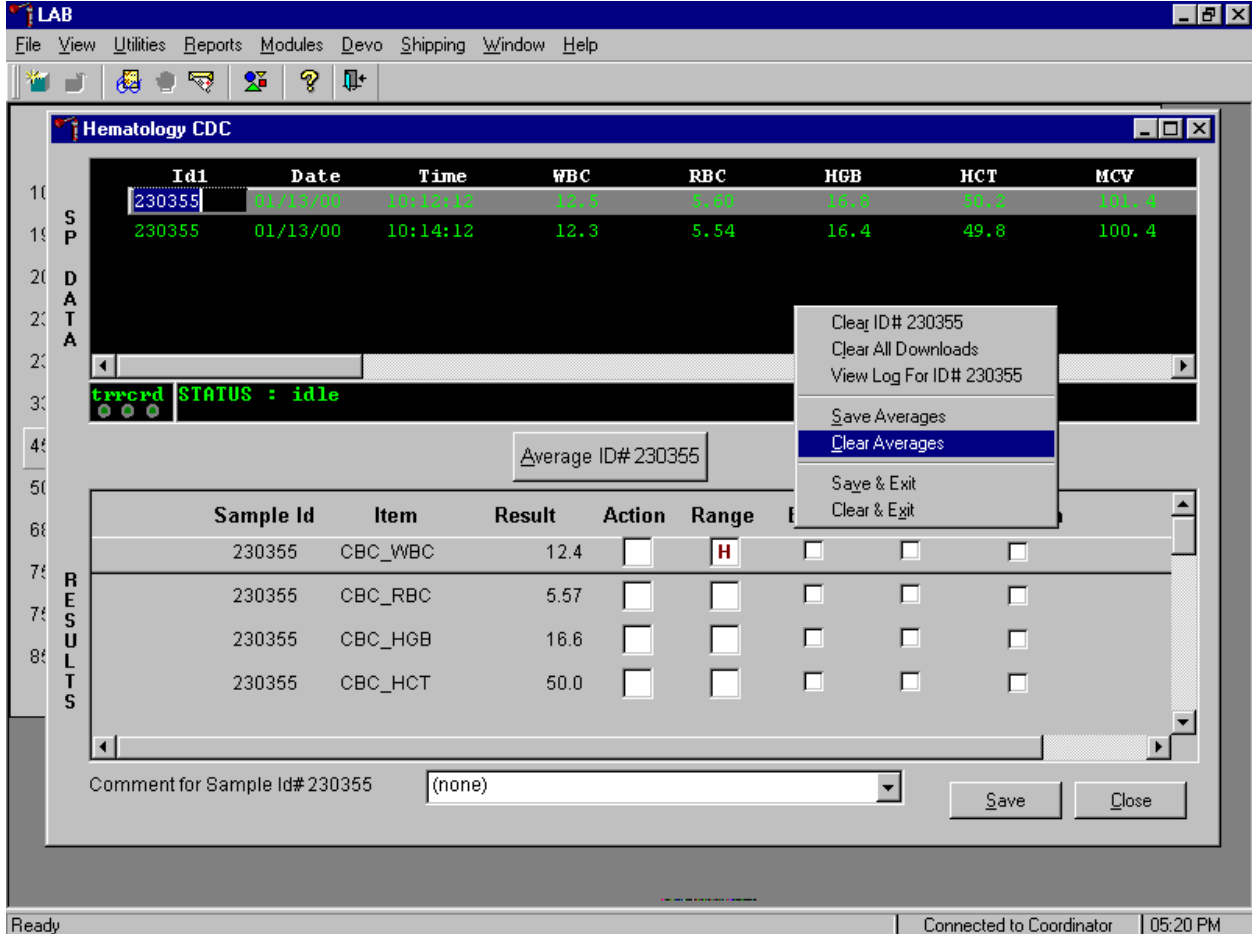
All data in the SP Data section is erased but the last averaged result remains in the Results section of the window. To clear the results, close the hematology module. To close the hematology module, use the mouse to direct the mouse arrow to the **Close** button and left click or type [C/c].

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



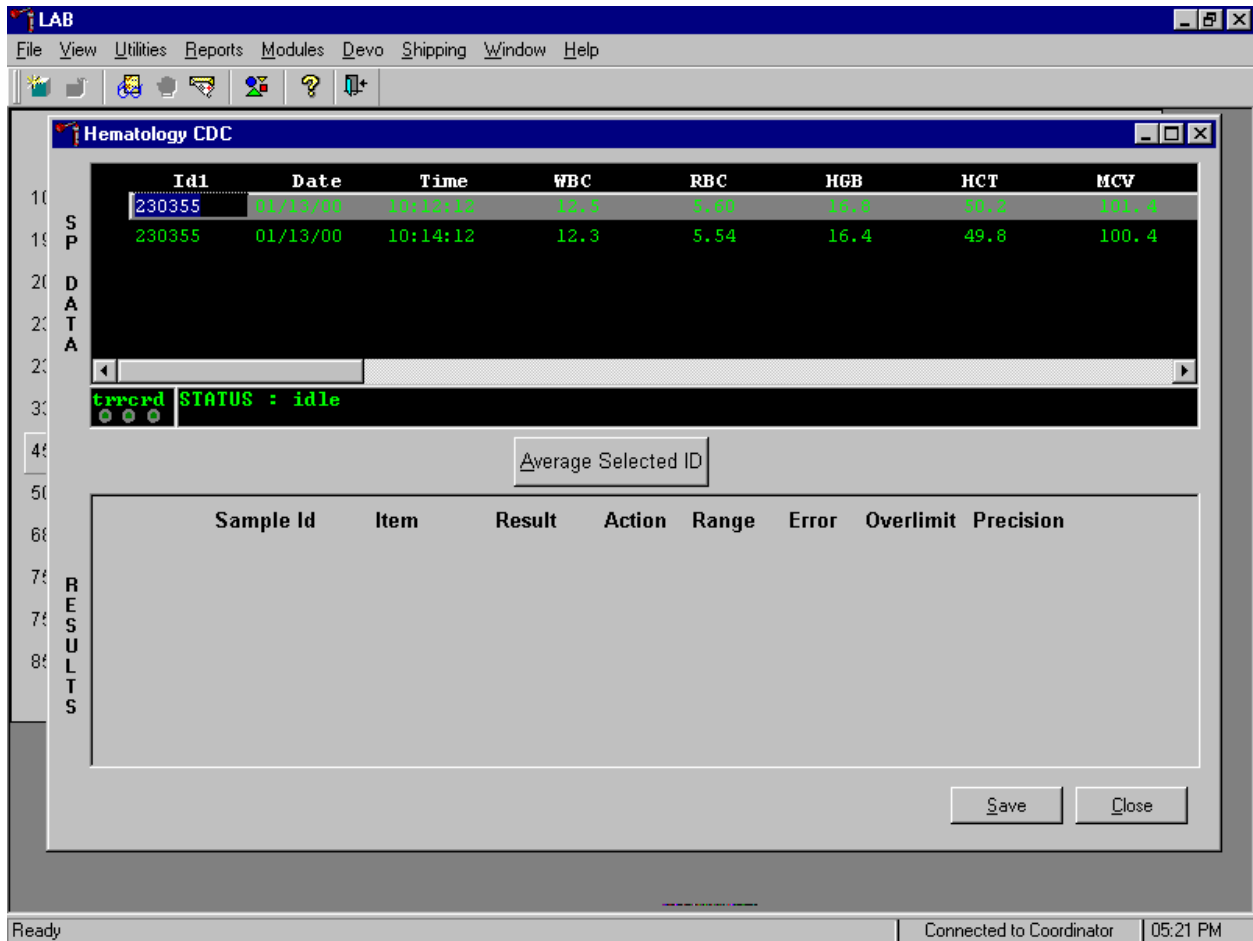
To clear the Coulter downloads for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to the Clear ID#XXXXXX line, and right or left click or type [R/r]. Release the mouse button to clear this download. Retransmit, average, and save the data.

Clear only the averaged results for any SP using data manipulation choices.



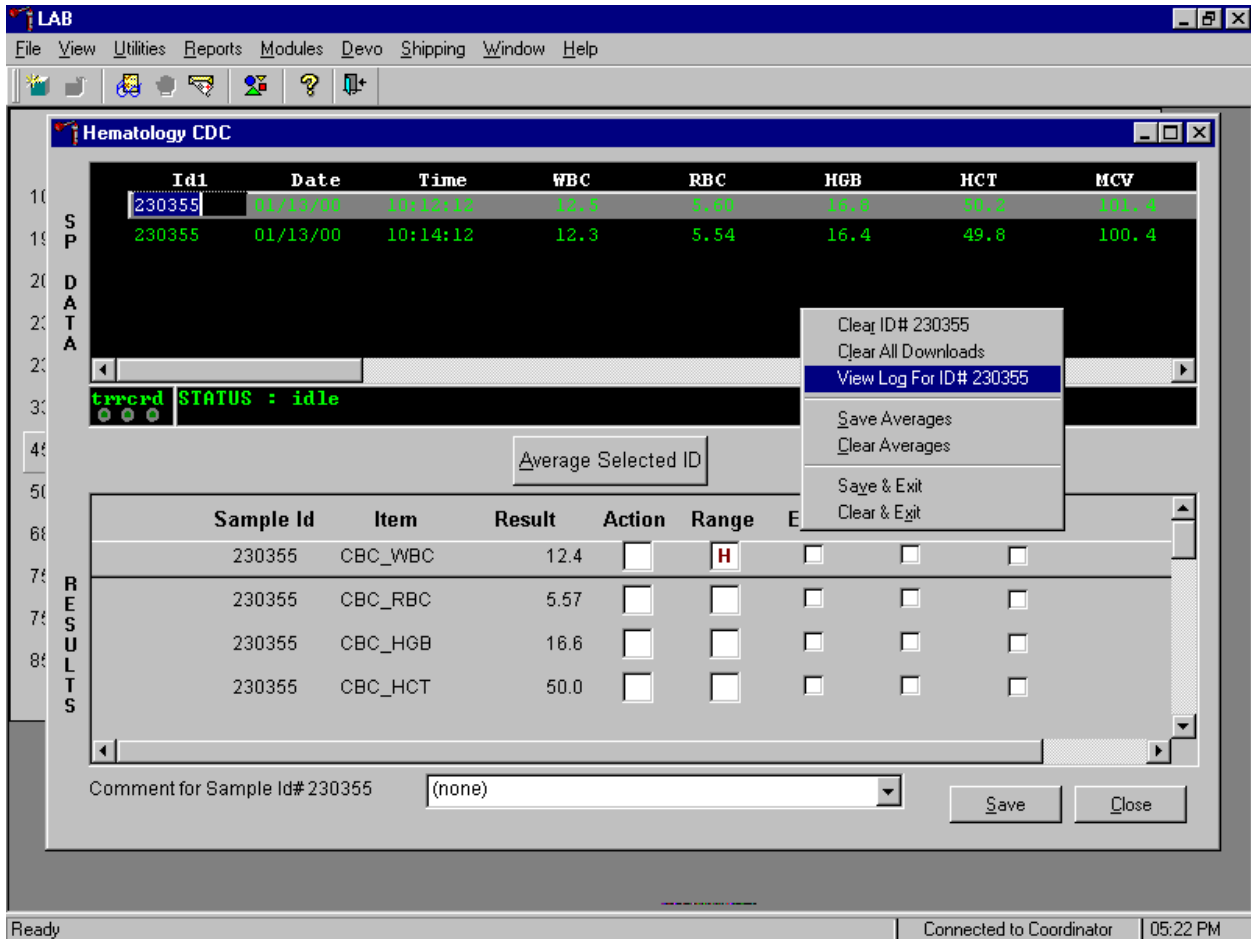
To clear the averaged results for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to the Clear Averages line, and right or left click or type [C/c].

Release the mouse button to clear the results.



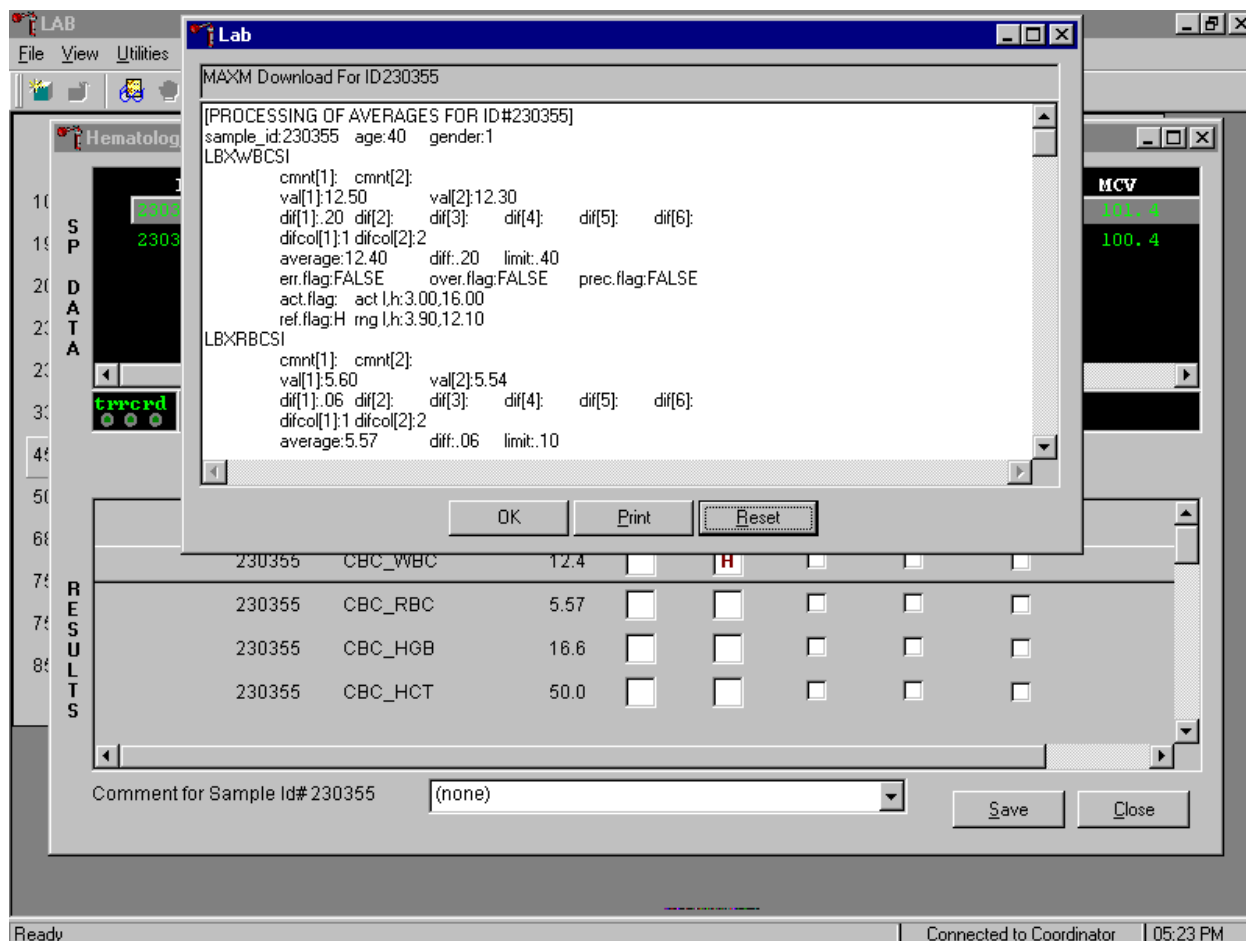
All results in the Results section of the window are erased. Re-average and save the data.

Use the "View Log for ID# XXXXXX" choice to view all Coulter data, averages, and precision limit values for any SP.



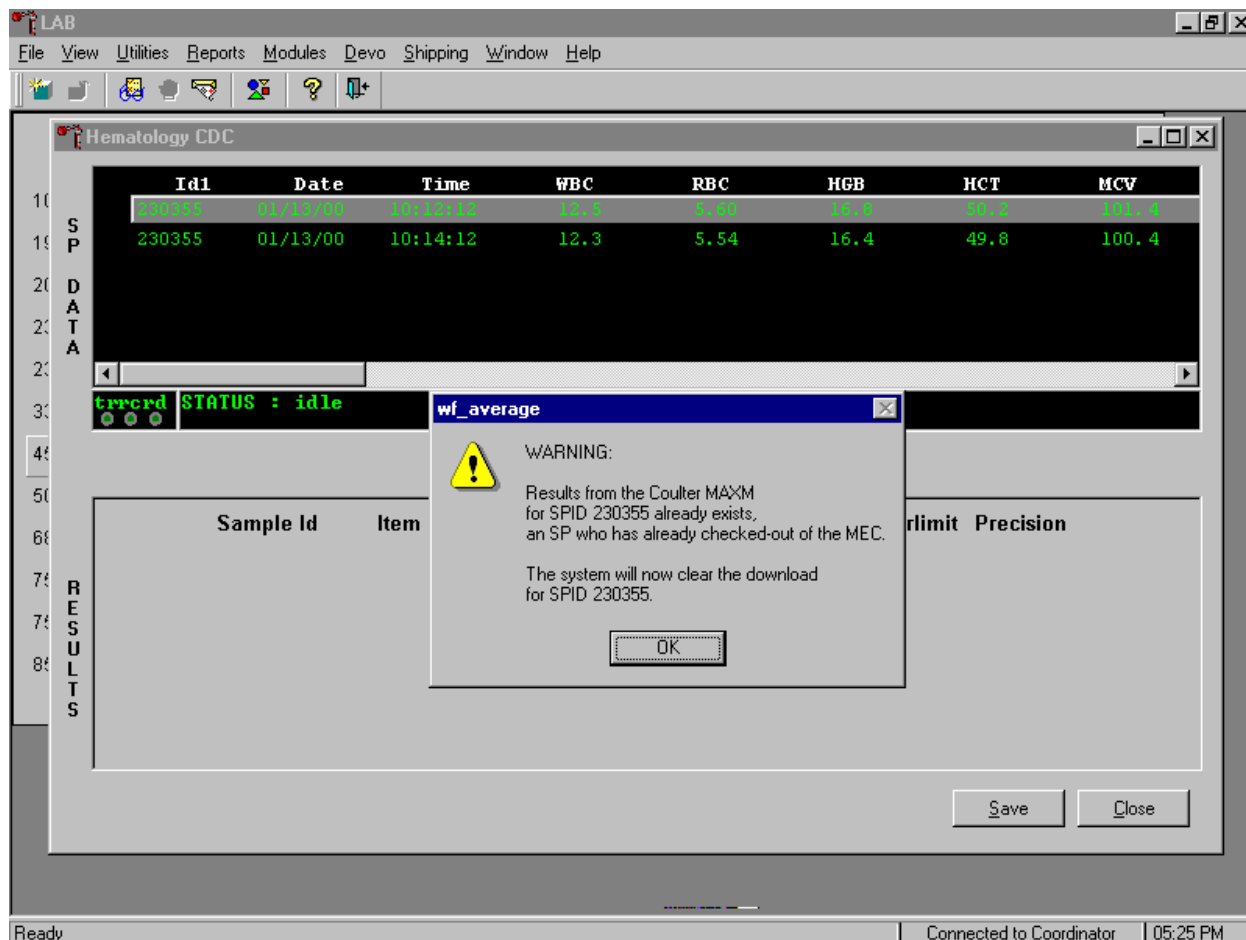
To view the detailed log for any one SP's result, use the mouse to direct the mouse arrow to the individual row in the SP Data section and right click to display the alternative data manipulation choices. Drag the mouse arrow to the View Log for IDXXXXXX line and release the mouse button to view the detailed log for this SP's results.

Review the SP's log.



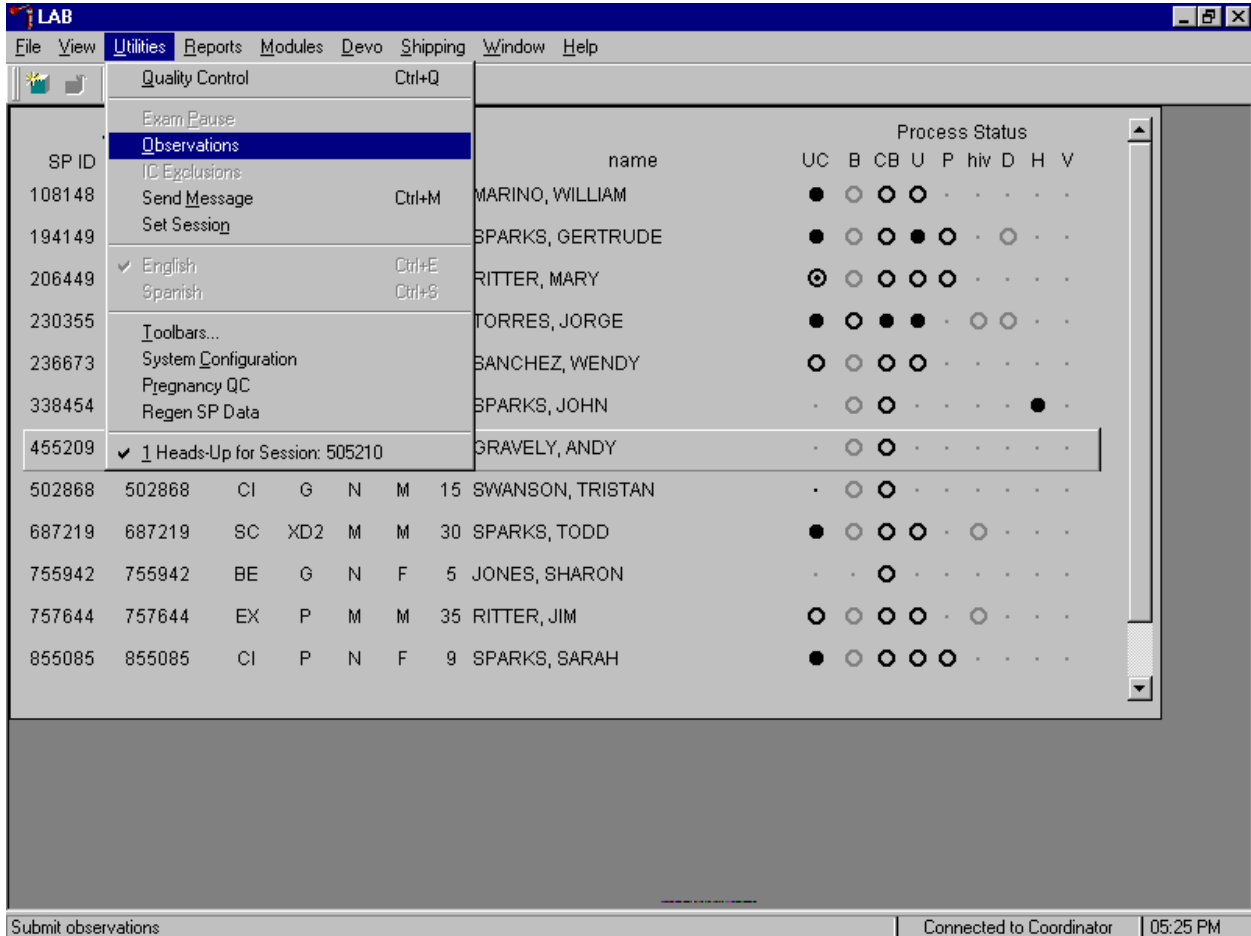
The SP's log contains detailed information for each parameter and each run. When finished reviewing the information, use the mouse to direct the mouse arrow to the **OK** button to close the window. To print the log, drag the mouse arrow to the **Print** button and left click or type [P/p]. To clear the log and close the screen, use the mouse to direct the mouse arrow to the **Reset** button and left click, or type [R/r], or select [Enter].

18. Re-average a result that has previously been saved to the database.



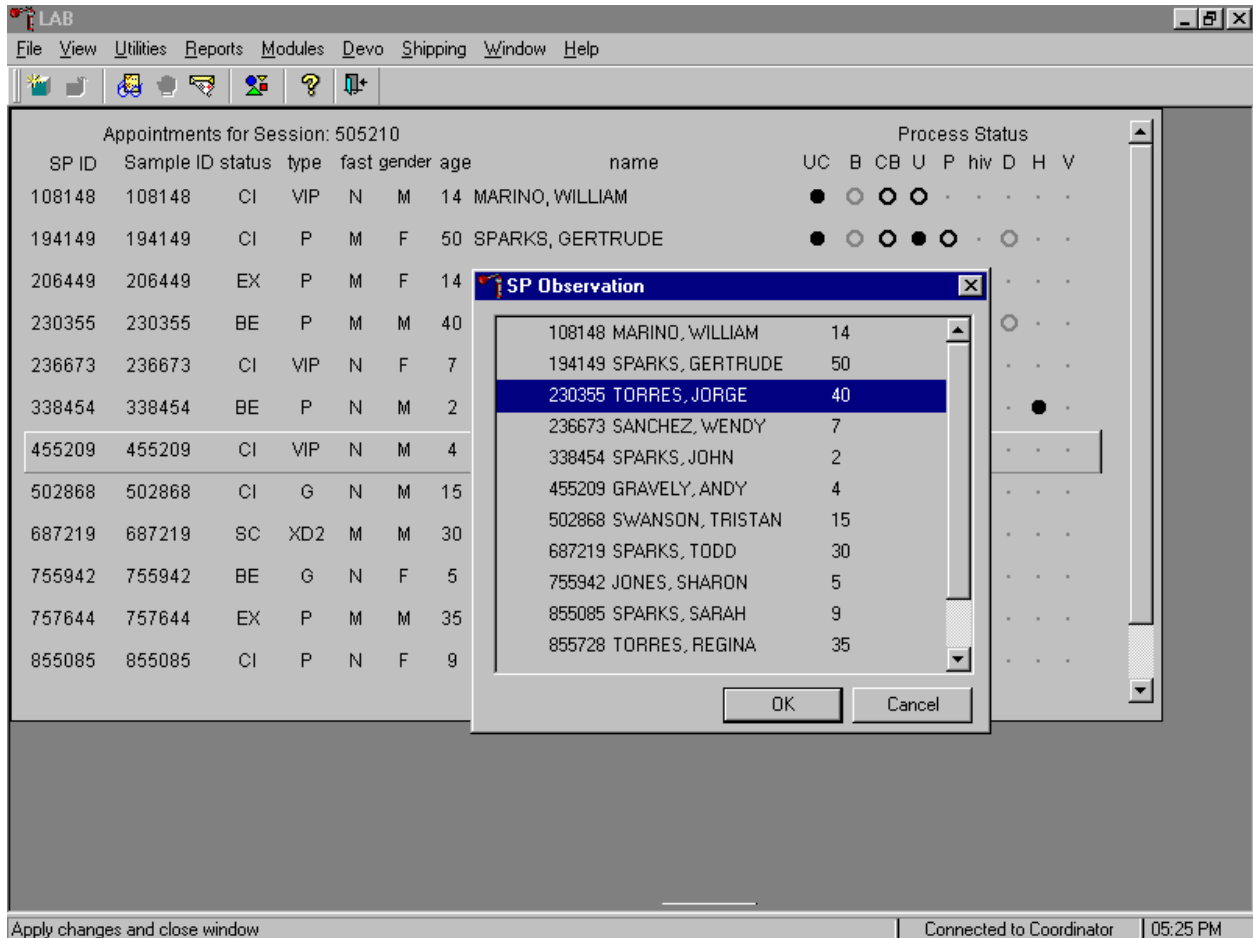
If a SP has not exited the MEC and the Report of Findings has not been printed, it is possible to retransmit and re-average the results for a SP and overwrite (save) the results in the database. If the SP has exited the MEC or the Report of Findings has been printed, it is impossible to overwrite (save) the results in the database. A warning message text box displays when an attempt is made to save the data on a SP who has either exited the MEC or for whom a Report of Findings has been printed. This text states, "Results from the Coulter MAXM for SPID XXXXXX already exist for an SP who has already checked out of the MEC. The system will now clear the download for SP ID XXXXXX." To remove the text box, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter]. The downloaded data, including the results, are automatically erased.

19. Send an observation to the physician.



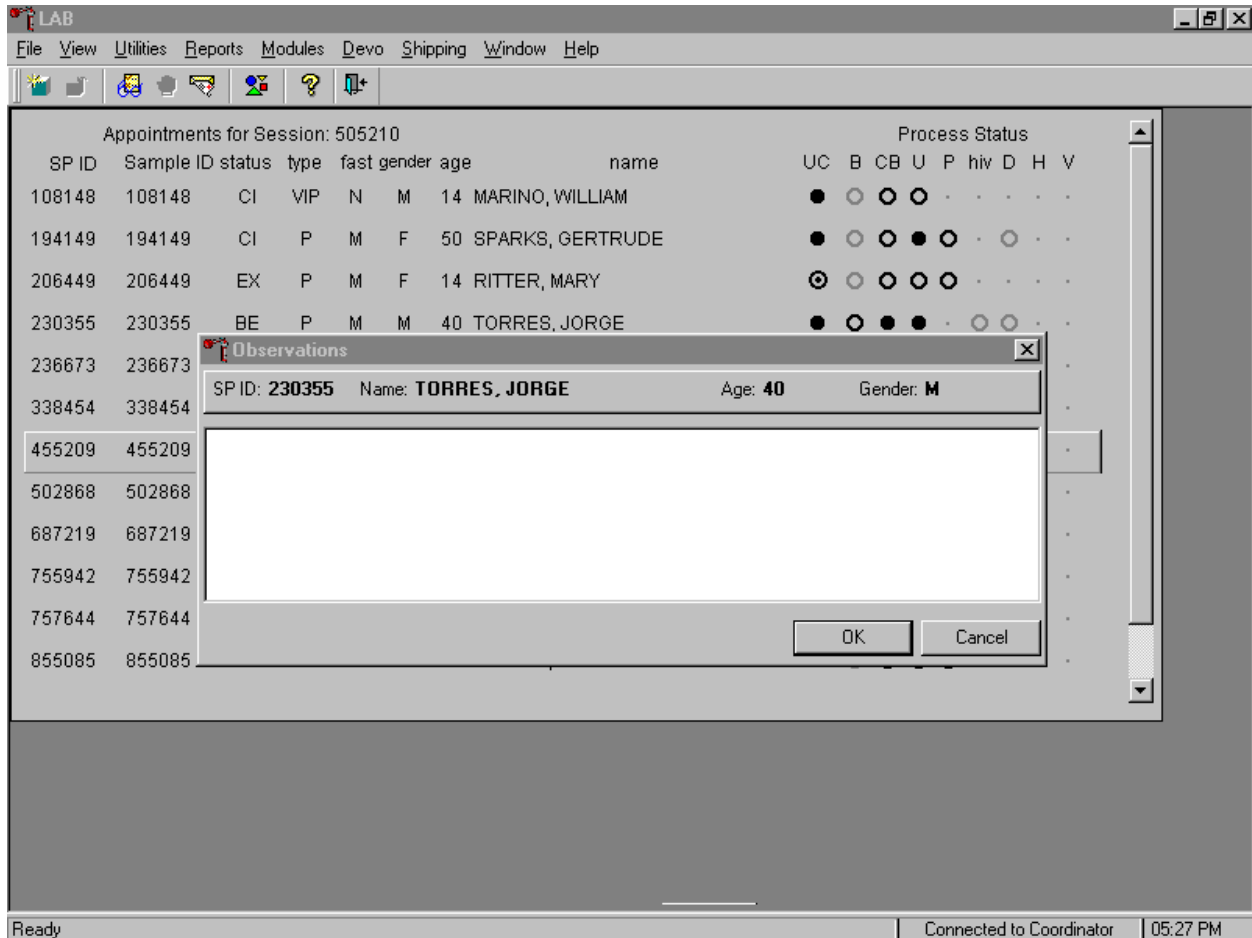
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, left click, drag the mouse arrow to {Observations}, and left click or type [Alt] [U], [O].

Select or highlight the correct SP.



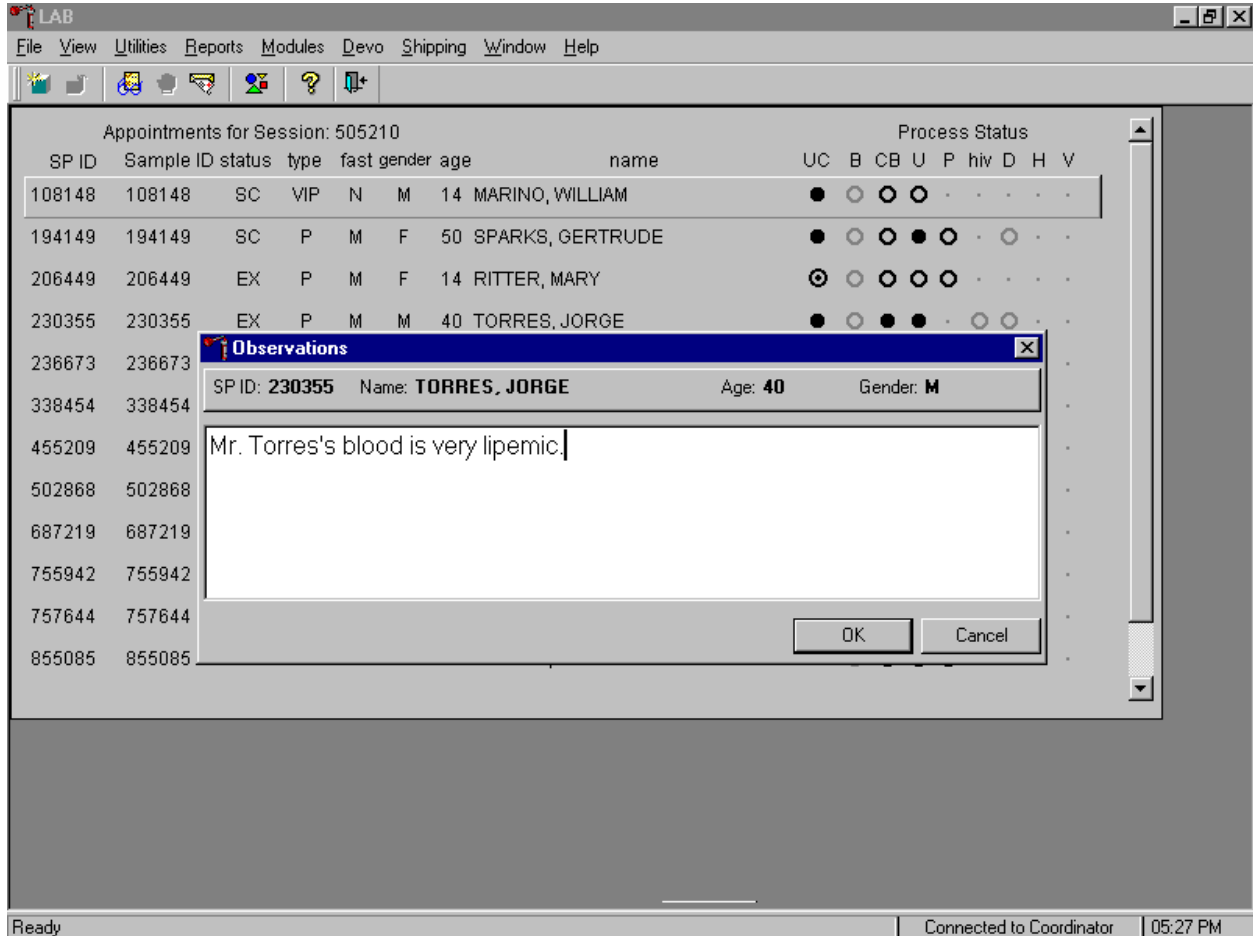
To select or highlight a SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard.

Send the observation to the physician.



To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click, or type [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

C. MAXM parameter codes

1. Review the message

The Beckman Coulter® MAXM uses triplicate counting with strict voting criteria. It has proprietary flagging algorithms to confirm parameter results before reporting. Rarely, the instrument may not detect a transient or partial aperture blockage by any of these processes. A partial aperture blockage may cause erroneous results, such as, WBC count lower than what is present. Monitor the aperture-viewing screen when cycling specimens that are likely to contain fibrin or debris.

The MAXM displays abnormal parameter results for all cell populations and values. The following table describes the display and cause for the parameter codes.

Display	Cause
All Parameters	
"●●●●" for a single parameter result	Incomplete or abnormal computation
"●●●●" for all parameter results and PART.ASP message displayed	Sample integrity check failed, short sample or clot
"-----" for CBC parameter results, and no average histogram for the affected parameter If WBC is "-----", then LY#, MO#, NE#, EO# and BA# are "●●●●" If RBC is "-----", then MCH, MCHC, Hct are "-----"	Total voteout (none of the three counts agreed); Diff parameters do not vote out
"*V"	Single-count period voteout; May indicate an erroneous result due to aperture blockage or lack of mixing bubble

"V"	Appears next to parameter derived from the parameter with the single count period voteout
<p data-bbox="488 380 906 422">"+++++" for parameter results</p> <p data-bbox="488 485 906 709" style="text-align: center;">IMPORTANT If the WBC, RBC, Hgb, or Plt result is +++++, run a blank cycle to prevent carryover to the next sample.</p>	<p data-bbox="911 380 1455 422">Result exceeds:</p> <p data-bbox="911 428 1455 470">WBC $\geq 100.0 \times 10^3$ cells/μL</p> <p data-bbox="911 476 1455 518">RBC $\geq 10.00 \times 10^6$ cells/μL</p> <p data-bbox="911 525 1455 567">Plt $\geq 1000 \times 10^3$ cells/μL</p> <p data-bbox="911 573 1455 615">MCV ≥ 1000</p> <p data-bbox="911 621 1455 663">If WBC is over range</p> <p data-bbox="911 669 1455 852">an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, MPV, Plt and Diff % results. Results for Diff% are dots (.....).</p> <p data-bbox="911 858 1455 900">If RBC is over range</p> <p data-bbox="911 907 1455 991">an R appears next to Hct, MCH, and MCHC results.</p> <p data-bbox="911 997 1455 1039">If Hgb is over range</p> <p data-bbox="911 1045 1455 1129">an R appears next to MCH, and MCHC results.</p> <p data-bbox="911 1136 1455 1178">If MCV is over range</p> <p data-bbox="911 1184 1455 1268">an R appears next to Hct, MCHC, and RDW results.</p> <p data-bbox="911 1274 1455 1316">If Plt is over range</p> <p data-bbox="911 1323 1455 1407">an R appears next to WBC, Hgb, MCH, MCHC, diff# and Pct results.</p> <p data-bbox="911 1413 1455 1665">Data Base Query displays average values for over range WBC, RBC, or Plt. [F3] Results or [F3] Edit, beneath the definitive flag section. These values are for review only; do not report them.</p>

	<p style="text-align: center;">IMPORTANT</p> <p>Sample dilution may result in erroneous differential results.</p> <p>Set DIFF to OFF before cycling the diluted sample when WBC is over range.</p>
"?????" for Diff results	Questionable data
Plt Parameter	
"R" next to Plt and MPV result	<p>PDW >20% mode not between 3 and 15 fL, or non-positive curve detected, or</p> <p>Plt <20,000, or</p> <p>Total voteout of fitted curve, or WBC is over range.</p>
RBC Parameters	
"R" next to RDW result	Excessive asymmetry in RBC histogram, or WBC or MCV over range.
"*R" next to MCV; also "R" next to RBC, Hct, MCH, MCH, RDW, Plt, and MPV	MCV below lower limit of <50 fL
WBC Parameters	
"*R" next to WBC; also "R" next to Diff numbers	<p>Check of WBC lower threshold failed. Particles are present at the 35 fL threshold (Plt clump, giant Plt, nrbc, lyse resistant RBC, malarial parasites)</p>
"R" next to Diff percentages and numbers	<p>Low differential count statistics. These messages occur also:</p> <p style="padding-left: 40px;">Population message: ABNORMAL WBC POP</p> <p style="padding-left: 40px;">Suspect message: REVIEW SLIDE</p>
":::": for Diff results	<p>System detects a clog in the flow cell. There are three types of clogs:</p> <p style="padding-left: 40px;">FC = Full Clog</p> <p style="padding-left: 40px;">PC1 = Partial Clog 1 (partial clog in the flow cell or sample line)</p> <p style="padding-left: 40px;">PC2 = Partial Clog 2 (partial clog in the sheath system)</p>

2. Remedial action

Review the result for the affected parameter. Rerun the specimen if any of the parameter flags occurs.

D. MAXM suspect messages

1. Suspect messages flag an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Specific suspect messages indicate some abnormalities that exhibit characteristic cluster patterns. Suspect messages indicate the possibility of a particular abnormality. Not every atypical scatterplot has a corresponding suspect message.
2. Remedial action -- Rerun the specimen.

E. Physician review

1. The MEC physician reviews and interprets all CBC results. Results outside action limits flash and transmit to the physician immediately. The physician determines if referral for the SP for treatment is necessary.

XII. Limitations of Method: Specimen Rejection, Interfering Substances and Conditions

This method limits samples to human whole blood.

A. Specimen rejection

1. Reject clotted specimens and recollect.

B. Interfering Substances and Conditions

Since the Coulter directly measures RBC, WBC, Hgb, and Diff % it is most important to concentrate on analytes and substances that interfere with these parameters. The Coulter calculates HCT, MCH, MCHC, and DIFF # parameters. The Coulter derives MCV, RDW, PLT, and MPV from RBC or platelet histograms. The following are possible interfering substances or conditions:

- Abnormal BUN, glucose or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC count could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate CBC result carefully and report all parameters except the hemoglobin result
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

XIII. Reference Ranges

1. Males

Age in Years	1-5	6-18	19-65	66+
Test				
WBC (x 10 ³ μ L)	4.3-14.1	3.7-11.9	3.9-12.1	3.9-12.3
RBC (x 10 ⁶ μ L)	4.00 - 5.30	4.10-5.60	4.10-5.80	4.00-5.60
Hgb (g/dL)	10.5-13.7	11.5-16.3	12.7-17.1	11.0-16.8
HCT (%)	31.8-40.8	34.4-48.3	38.0-50.3	33.1-50.2
MCV (fL)	67.6-88.2	74.3-93.0	78.1-99.2	78.9-101.4
MCH (pg)	21.7-29.8	24.3-31.7	25.7-33.8	25.6-34.4
MCHC (g/dL)	31.5-35.0	31.9-35.1	32.0-35.3	31.8-35.1
RDW (%)	11.7-16.5	11.7-14.3	11.8-15.3	12.1-16.6
Plt (x 10 ³ μ L)	224-568	194-477	157-414	138-407
MPV (fL)	6.3-9.3	6.6-9.9	6.8-10.4	6.7-10.6
LY (%)	24.5-70.0	20.0-56.6	17.8-51.8	13.0-48.3
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.4-70.5	33.2-74.7	39.7-77.3	44.7-81.9
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

2. Females

Age in Years	1-5	6-18	19-65	66+
Test				
WBC (x 10 ³ μL)	4.2-13.6	4.0-12.4	3.9-12.5	4.0-12.3
RBC (x 10 ⁶ μL)	3.90 - 5.20	3.90-5.20	3.70-5.20	3.50-5.20
Hgb (g/dL)	10.5-13.7	11.1-14.7	10.4-15.2	10.5-15.5
HCT (%)	32.0-40.6	33.4-43.4	32.0-45.0	32.0-46.0
MCV (fL)	69.0-88.6	74.5-93.9	73.4-98.3	79.7-100.2
MCH (pg)	22.3-30.1	24.2-31.8	23.2-33.3	25.9-33.8
MCHC (g/dL)	31.8-35.1	31.7-35.0	31.4-35.1	31.6-35.0
RDW (%)	11.4-15.4	11.6-14.8	11.8-16.6	12.0-16.1
Plt (x 10 ³ μL)	229-581	202-476	172-453	147-440
MPV (fL)	6.3-9.2	6.7-10.0	6.9-10.7	6.8-10.8
LY (%)	24.9-70.5	18.7-58.5	17.8-52.8	15.7-51.1
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.3-69.3	32.9-77.2	39.6-77.8	42.0-79.8
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

3. Reference ranges for normal values were calculated from NHANES III data set using 95% reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

XIV. Action Limits

Action limits are a guide to inform the physician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- WBC male and female (all ages) < or = to 3 x 10³ μL or > or = to 16.0 x 10³ μL
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL

- Hgb female (>6 years) <6.5 g/dL or <16.0 g/dL
- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL
- PLT male and female (all ages) <50 x 10³ μ L or >800 x 10³ μ L

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT -- dehydration, polycythemia, shock, chronic hypoxia
- Low RBC, Hgb or HCT -- anemia, thalassemia and other hemoglobinopathies
- Low MCV -- microcytic anemia
- High MCV -- macrocytic anemia, liver disease
- Low WBC -- sepsis, marrow hypoplasia
- High WBC -- acute stress, infection, malignancies
- Low platelets -- risk of bleeding
- High platelets -- risk of thrombosis

XV. Specimen Storage and Handling During Testing

A. Specimen storage

1. Store specimens capped and place on a rocker at room temperature until processed.
2. Run within 24 hours of drawing.

XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for this test. Store EDTA tube at room temperature for no more than 24 hours. Restore the instrument to functionality and then run the specimen.

XVII. Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are automatically brought to the physician's attention for a decision as to "course-to-follow."

XVIII. Specimen Accountability and Tracking

All records, including QA/QC data will be maintained for 6 years. Use only numerical identifiers for SP results.

XIX. Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 5C® Cell control results for bias and maintain results for the entire study period. Compare all three instruments CAP proficiency results.

XX. References

1. Beckman Coulter® MAXM Analyzer Operator's Guide. (1992, January 21). PN 4235935J.
2. Beckman Coulter® MAXM Analyzer Use and Function. (1995, January). PN 4235933H.
3. Beckman Coulter® MAXM Analyzer Special Procedures and Troubleshooting. (1995, December). PN 4235934J.
4. Corash L. (1983). Platelet Sizing: Techniques, Biological Significance, and Clinical Applications. Current Topics in Hematology. New York: Alan R. Wise, Inc.
5. Geigy Scientific Tables. (1984). Vol. 3, 210.
6. Jones AR, Twedl D, Swaim W, Gottfried E. (1996). Diurnal change of blood count analytes in normal subjects. *Am J Clin Path*, 106, 723-7.
7. NCCLS document H15-A. (1984). Reference procedure for the quantitative determination of hemoglobin in blood. National Committee for Clinical Laboratory Standards, Villanova, PA.
8. NCCLS document H7-A. (1985). Procedure for determining packed cell volume by the micro hematocrit method. National Committee for Clinical Laboratory Standards, Villanova, PA.
9. NCCLS document H18-A. (1990). Procedures for the handling and processing of blood specimens. National Committee for Clinical Laboratory Standards, Villanova, PA.
10. NCCLS document H3-A3. (1991). Procedures for the collection of diagnostic blood specimens by venipuncture. National Committee for Clinical Laboratory Standards, Villanova, PA.
11. NCCLS document H4-A3. (1991). Procedures for the collection of diagnostic blood specimens by skin puncture. National Committee for Clinical Laboratory Standards, Villanova, PA.

12. NCCLS document H26-A. (1996). Performance goals for the internal quality control of multichannel hematology analyzers; Approved Standard. NCCLS, Wayne, PA.
13. Standard 493-1211 *Federal Register*/57: 40, (1992, February 28). Rules and Regulations, p. 7164.
14. Threatte GA, Andradós C, Ebbe S and Brecher G. (1984). Mean platelet volume: The need for a reference method. *AJCP*, 81, 769-772.

8. BLOOD AND HIV URINE PROCESSING AND STORAGE

8.1 Introduction

The purpose of blood specimen processing and storage is to process and allocate blood to storage vessels for transport to laboratories that conduct analysis of samples or store the specimens for future research. Processing includes centrifuging and storing blood collection tubes, aliquoting whole blood to storage vessels, centrifuging, separating, and aliquoting plasma and serum to storage vessels, performing a dilution, and storing the specimens.

Process urine for HIV urine if no blood was collected or the quantity of serum was insufficient for serum HIV (for primary SPs aged 18-49) and the SP has not refused the HIV test.

8.2 Equipment and Supplies

The blood processing area includes two under-counter refrigerators, four under-counter freezers, two refrigerated centrifuges, two data terminals, a laminar flow hood, and two specimen rockers. This area also includes counter space for processing blood. Store extra supplies for processing in cabinets and the trailer compartments.

Exhibit 8-1. Laboratory equipment

Two under-counter refrigerators	Four under-counter freezers
One laminar flow hood	Two refrigerated centrifuges
Two data terminals	Two specimen rockers

Exhibit 8-2. Supplies for blood processing

2.0-mL cryovial	Polypropylene cube test tube racks
5.0-mL cryovial	Test tube racks
Caps for 2-mL cryovial	8 gallon biohazard sharps container
14-mL snap cap tube	Biohazard bags 25 x 35
50-mL polypropylene tube	Disposable lab coats
Large Styrofoam processing racks	Safety glasses or face masks
3.0-mL plastic transfer pipettes	Bench covers
Serum filters 13mm x 4 inches	Nonsterile, powder free, latex gloves – small, medium, and large
Serum filters 16mm x 6 inches	Bottled distilled water
Wooden applicator sticks	Ascorbic acid 0.5 gm per vessel
MLA Pipettes, 100, 200, 400, 500, 1000- μ L	50-mL graduated cylinder
Pipette tips 50-200 μ L	Eppendorf® pipette
Pipette tips 200-1000 μ L	Eppendorf® Combitips Plus 5-mL
Blood-processing templates 1-11, 12+	MLA pipette nozzles
Cotton swabs	Lab marker – extra fine
Kimwipes	Lab marker – fine
Temperature charts	Temperature pens
6 x 6 Zip-loc bags	

8.3 Protocols

Exhibits 8-3 through 8-5 illustrate the primary SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-3. Primary SP's whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	1-11 12+	0.3 0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	3+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1-5 16-49 women	0.5 1.0	Whole blood	EDTA	2-mL	
6	CD4	18-49	0.5	Whole blood	EDTA	2-mL	

Exhibit 8-4. Primary SP's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
7	Homocys/MMA	3+	1.0	Plasma	EDTA	2-mL	Plasma must be off the cells within 30 minutes.
8	Xtra Plasma	6+	0.5	Plasma	EDTA	2-mL	
9	Glucose	12+	0.5	Plasma	Gray	2-mL	Morning SPs only.
10	Fibrin	40+	1.0	Plasma	Blue	2-mL	

Exhibit 8-5. Primary SP's serum, clot, and ACD processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	1-2 3+	1.2 1.0	Serum	Red	2-mL	
68	Ferritin	1+	0.3	Serum	Red	2-mL	
12	Fol/B12	3-5 6+	0.8 1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	3+	0.5	Serum	Red	2-mL	
14	Hepatitis	2-5 6+	0.2 1.5	Serum	Red	2-mL	
15	Vit A/E/Car	3-11 12+	0.3 0.4	Serum	Red	2-mL	
16	Rub/Mea/Var	6-49	0.4	Serum	Red	2-mL	
17	Cotinine	3-11 12+	1.5 2.0	Serum	Red	2-mL	
18	Biochem	12+	0.8	Serum	Red	2-mL	
19	Bn Alk Phos	8+	0.5	Serum	Red	2-mL	
20	Crypto	6-11 12-49	0.2 0.5	Serum	Red	2-mL	
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	Serum	Red	2-mL	
22	HIV	18-49	0.5	Serum	Red	2-mL	
23	Insul/Cpep	12+	1.0	Serum	Red	2-mL	Morning SPs only.
24	HSV	14-49	0.5	Serum	Red	2-mL	

Exhibit 8-5. Primary SP's serum, clot, and ACD processing protocol (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	
26	Selenium	3-11	0.3	Serum	Red	2-mL	
27	Latex	12-59	0.5	Serum	Red	2-mL	
28	TSH/Thyrox	12+	1.0	Serum	Red	2-mL	
70	Vitamin D	6+	0.5	Serum	Red	2-mL	
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
63	Dioxins	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
64	Phytoestro	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
32	Xtra Sera	6+	0.5	Serum	Red	2-mL	
33	Xtra Sera	6+	0.5	Serum	Red	2-mL	
34	Xtra Sera	6+	0.5	Serum	Red	2-mL	
35	Xtra Sera	12+	0.5	Serum	Red	2-mL	
36	Xtra Sera	12+	0.5	Serum	Red	2-mL	
37	Xtra Sera	12+	0.5	Serum	Red	2-mL	
38	Xtra Sera	12+	0.5	Serum	Red	2-mL	
39	Xtra Sera	12+	0.5	Serum	Red	2-mL	
40	Xtra Sera	12+	0.5	Serum	Red	2-mL	
41	Xtra Sera	12+	0.5	Serum	Red	2-mL	
42	Xtra Sera	12+	0.5	Serum	Red	2-mL	
43	DNA	20+	17.0	Clot	One 15- mL Red	14-mL	
44	WBC/DNA	20+	Whole blood	ACD tube	8-mL ACD	8-mL	
71	WBC/DNA	20+	Whole blood	ACD tube	8-mL ACD	8-mL	

Exhibits 8-6 through 8-8 illustrate the home exam SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-6. Home exam blood whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	50+	0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	50+	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	50+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	50+	0.4	Whole blood	EDTA	2-mL	

Exhibit 8-7. Home exam plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
7	Homocys/MMA	50+	1.0	Plasma	EDTA	2-mL	Tube must be kept at 4-8°C.
10	Fibrin	50+	1.0	Plasma	Blue	2-mL	

Exhibit 8-8. Home exam serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	50+	1.0	Serum	Red	2-mL	
68	Ferritin	50+	0.3	Serum	Red	2-mL	
12	Fol/B12	50+	1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	50+	0.5	Serum	Red	2-mL	
14	Hepatitis	50+	1.5	Serum	Red	2-mL	
15	Vit A/E/Car	50+	0.4	Serum	Red	2-mL	
18	Biochem	50+	0.8	Serum	Red	2-mL	
21	Lipids	50+	2.0	Serum	Red	2-mL	

Exhibits 8-9 through 8-11 illustrate the second exam SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-9. Second exam SP's whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	12-69	0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	12-69	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	12-69	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12-69	0.4	Whole blood	EDTA	2-mL	

Exhibit 8-10. Second exam SP's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
7	Homocys/MMA	12-69	1.0	Plasma	EDTA	2-mL	Plasma must be off the cells within 30 minutes.
9	Glucose	12-69	0.5	Plasma	Gray	2-mL	Morning SPs only.
10	Fibrin	12-69	1.0	Plasma	Blue	2-mL	

Exhibit 8-11. Second exam SP's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	12-69	1.0	Serum	Red	2-mL	
68	Ferritin	12-69	0.3	Serum	Red	2-mL	
12	Fol/B12	12-69	1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	12-69	0.5	Serum	Red	2-mL	
15	Vit A/E/Car	12-69	0.4	Serum	Red	2-mL	
16	Rub/Mea/Var	12-49	0.4	Serum	Red	2-mL	
17	Cotinine	12-69	2.0	Serum	Red	2-mL	
18	Biochem	12-69	0.8	Serum	Red	2-mL	
19	Bn Alk Phos	12-69	0.5	Serum	Red	2-mL	
21	Lipids	12-69	2.0	Serum	Red	2-mL	
23	Insul/Cpep	12-69	1.0	Serum	Red	2-mL	Morning SPs only.
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	
27	Latex	12-59	0.5	Serum	Red	2-mL	
70	Vitamin D	12-69	0.5	Serum	Red	2-mL	

Exhibits 8-12 through 8-14 illustrate the VIP guest's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-12. VIP guest's blood whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	1-11 12+	0.3 0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	3+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1-5 16-49 women	0.5 1.0	Whole blood	EDTA	2-mL	

Exhibit 8-13. VIP guest's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
9	Glucose	12+	0.5	Plasma	Gray	2-mL	Morning SPs only.

Exhibit 8-14. VIP guest's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	1-2 3+	1.2 1.0	Serum	Red	2-mL	
68	Ferritin	1+	0.3	Serum	Red	2-mL	
12	Fol/B12	3-5 6+	0.8 1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
15	Vit A/E/Car	3-11 12+	0.3 0.4	Serum	Red	2-mL	
18	Biochem	12+	0.8	Serum	Red	2-mL	
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	Serum	Red	2-mL	
23	Insul/Cpep	12+	1.0	Serum	Red	2-mL	Morning SPs only.
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	

Exhibit 8-15 illustrates the guest and surplus protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-15. Guest and surplus serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
18	Biochem	12+	0.8	Serum	Red	2-mL	

8.4 Labeling Vessels

The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood processing racks and in labeling the vessels with the appropriate bar code label.

Use the following materials to set up and label blood racks:

- Styrofoam rack
- Age appropriate processing template
- Storage vessels of the following sizes:
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, person type, and subsample selection. When possible, prepare the racks at least one day before the SP arrives for the MEC examination.

Before each session, the technologist at workstation 3 prints all labels for all SPs. The correct bar-coded labels automatically print for each SP based on the SP's age, sex, person type, and subsample selection.

Distribute labels and assemble blood-processing racks:

- Place pregnancy, urine, and one set of dental labels at workstation 2 in the laboratory.
- Clip the second set of dental labels and the hair labels on the wall grid in the label/shipping area.
- Label one 50-ml conical tube with the blood processing pool label.
- Place the pre-labeled blood processing racks in the laboratory at the start of each session.

While the technologist assigned to shipping is responsible for labeling the vessels and setting up the blood processing racks, it is the blood-processing technologist's responsibility to verify that each vessel has the correct label before filling. Do not rely only upon memory or the positioning of the vessels in a rack to indicate which vessels to fill. Always double check:

- The SP's ID number on the bar-coded label,
- The vessel number on the label,
- The adhesion quality of the labels, and
- That specimens are not missing labels or incorrectly labeled.

Save and recycle unused vessels:

- If the SP does not show up for the appointment, it is possible they will reschedule.
- Store the SPs labels in a zip lock bag until the end of the stand.
- If the SP has not shown up by the end of the stand, recycle the unused vessels.

8.5 Blood Processing Age Specific Protocols

Exhibits 8-16 through 8-19 illustrate the blood processing vessels for each primary SP.

Exhibit 8-16. Blood processing protocol for primary SPs age 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	1-2	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	1-2	0.3	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	1-2	1.2	Serum	3-mL Red	2-mL
68	Ferritin	1-2	0.3	Serum	3-mL Red	2-mL
14	Hepatitis	2	0.2	Serum	3-mL Red	2-mL

Exhibit 8-17. Blood processing protocol for primary SPs age 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.5	Whole blood	5-mL EDTA	2-mL
7	Homocys/MMA	3-5	1.0	Plasma	5-mL EDTA	2-mL
11	Iron/TIBC	3-5	1.0	Serum	7-mL Red	2-mL
68	Ferritin	3-5	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	3-5	0.8	Serum	7-mL Red	2-mL
13	CRP/Hpylori	3-5	0.5	Serum	7-mL Red	2-mL
14	Hepatitis	3-5	0.2	Serum	7-mL Red	2-mL
15	Vit A/E/Car	3-5	0.3	Serum	7-mL Red	2-mL
17	Cotinine	3-5	1.5	Serum	7-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	7-mL Red	2-mL
26	Selenium	3-5	0.3	Serum	7-mL Red	2-mL

Exhibit 8-18. Blood processing protocol for primary SPs age 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	6-11	0.6	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	6-11	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
7	Homocys/MMA	6-11	1.0	Plasma	5-mL EDTA	2-mL
8	Xtra Plasma	6-11	0.5	Plasma	5-mL EDTA	2-mL
11	Iron/TIBC	6-11	1.0	Serum	15-mL Red	2-mL
68	Ferritin	6-11	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	6-11	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	6-11	0.5	Serum	15-mL Red	2-mL
14	Hepatitis	6-11	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	6-11	0.3	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	6-11	0.4	Serum	15-mL Red	2-mL
17	Cotinine	6-11	1.5	Serum	15-mL Red	2-mL
19	Bn Alk Phos	8-11	0.5	Serum	15-mL Red	2-mL
20	Crypto	6-11	0.2	Serum	15-mL Red	2-mL
21	Lipids	6-11	1.5	Serum	15-mL Red	2-mL
26	Selenium	6-11	0.3	Serum	15-mL Red	2-mL
70	Vitamin D	6-11	0.5	Serum	15-mL Red	2-mL
32	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL
33	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL
34	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL

Exhibit 8-19. Blood processing protocol for primary SPs age 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	12+	0.5	Whole blood	First 5-mL EDTA	2-mL
2	Ery Proto	12+	0.4	Whole blood	First 5-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	First 5-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	First 5-mL EDTA	2-mL
5	Mercury	16-49	1.0	Whole blood	First 5-mL EDTA	2-mL
6	CD4	18-49	0.5	Whole blood	First 5-mL EDTA	2-mL
7	Homocys/MMA	12+	1.0	Plasma	Second 5-mL EDTA	2-mL
8	Xtra Plasma	12+	0.5	Plasma	Second 5-mL EDTA	2-mL
9	Glucose	12+	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	40+	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	12+	1.0	Serum	15-mL Red	2-mL
68	Ferritin	12+	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12+	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	12+	0.5	Serum	15-mL Red	2-mL

Exhibit 8-19. Blood processing protocol for primary SPs age 12+ years (continued)

14	Hepatitis	12+	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12+	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	12-49	0.4	Serum	15-mL Red	2-mL
17	Cotinine	12+	2.0	Serum	15-mL Red	2-mL
18	Biochem	12+	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	12+	0.5	Serum	15-mL Red	2-mL
20	Crypto	12-49	0.5	Serum	15-mL Red	2-mL
21	Lipids	12+	2.0	Serum	15-mL Red	2-mL
22	HIV	18-49	0.5	Serum	15-mL Red	2-mL
23	Insul/Cpep	12+	1.0	Serum	15-mL Red	2-mL
24	HSV	14-49	0.5	Serum	15-mL Red	2-mL
25	FSH/LH	35-60	0.8	Serum	15-mL Red	2-mL
27	Latex	12-59	0.5	Serum	15-mL Red	2-mL
28	TSH/Thyrox	12+	1.0	Serum	15-mL Red	2-mL
70	Vitamin D	12+	0.5	Serum	15-mL Red	2-mL
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL
63	Dioxins	12+	4.0	Serum	10-mL Red	5-mL
64	Phytoestro	12+	4.0	Serum	10-mL Red	2-mL
32	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
33	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
34	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
35	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
36	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
37	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
38	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
39	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
40	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
41	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
42	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
43	DNA	20+	One	Clot	15-mL Red	14-mL
44	WBC/DNA	20+	ACD	Whole blood	8-mL ACD	8-mL ACD
71	WBC/DNA	20+	ACD	Whole blood	8-mL ACD	8-mL ACD

Exhibit 8-20 illustrates blood processing vessels for each home exam SP.

Exhibit 8-20. Blood processing protocol for home exam age 50+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	50+	0.5	Whole blood	First 5-mL EDTA	2-mL
2	Ery Proto	50+	0.4	Whole blood	First 5-mL EDTA	2-mL
3	RBC Folate	50+	0.1	Whole blood	First 5-mL EDTA	2-mL
4	Glycohem	50+	0.4	Whole blood	First 5-mL EDTA	2-mL
7	Homocys/MMA	50+	1.0	Plasma	Second 5-mL EDTA	2-mL
10	Fibrin	50+	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	50+	1.0	Serum	7-mL Red	2-mL
68	Ferritin	50+	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	50+	1.3	Serum	7-mL Red	2-mL
13	CRP/Hpylori	50+	0.5	Serum	7-mL Red	2-mL
14	Hepatitis	50+	1.5	Serum	7-mL Red	2-mL
15	Vit A/E/Car	50+	0.4	Serum	7-mL Red	2-mL
18	Biochem	50+	0.8	Serum	7-mL Red	2-mL
21	Lipids	50+	2.0	Serum	7-mL Red	2-mL

Exhibit 8-21 illustrates the blood processing vessels for each second exam SP.

Exhibit 8-21. Blood processing protocol for second exam SPs age 12-69 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	12-69	0.5	Whole blood	5-mL EDTA	2-mL
2	Ery Proto	12-69	0.4	Whole blood	5-mL EDTA	2-mL
3	RBC Folate	12-69	0.1	Whole blood	5-mL EDTA	2-mL
4	Glycohem	12-69	0.4	Whole blood	5-mL EDTA	2-mL
7	Homocys/MMA	12-69	1.0	Plasma	Second 5-mL EDTA	2-mL
9	Glucose	12-69	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	40-69	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	12-69	1.0	Serum	15-mL Red	2-mL
68	Ferritin	12-69	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12-69	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	12-69	0.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12-69	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	12-49	0.4	Serum	15-mL Red	2-mL
17	Cotinine	12-69	2.0	Serum	15-mL Red	2-mL
18	Biochem	12-69	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	12-69	0.5	Serum	15-mL Red	2-mL
21	Lipids	12-69	2.0	Serum	15-mL Red	2-mL
23	Insul/Cpep	12-69	1.0	Serum	15-mL Red	2-mL
25	FSH/LH	35-60	0.8	Serum	15-mL Red	2-mL
27	Latex	12-59	0.5	Serum	15-mL Red	2-mL
70	Vitamin D	12-69	0.5	Serum	15-mL Red	2-mL

Exhibits 8-22 through 8-25 illustrate the blood processing vessels for each VIP guest.

Exhibit 8-22. Blood processing protocol for VIP guest age 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	1-2	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	1-2	0.3	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	1-2	1.2	Serum	3-mL Red	2-mL
68	Ferritin	1-2	0.3	Serum	3-mL Red	2-mL

Exhibit 8-23. Blood processing protocol for VIP guest age 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	3-5	1.0	Serum	7-mL Red	2-mL
68	Ferritin	3-5	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	3-5	0.8	Serum	7-mL Red	2-mL
15	Vit A/E/Car	3-5	0.3	Serum	7-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	7-mL Red	2-mL

Exhibit 8-24. Blood processing protocol for VIP guest age 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	6-11	0.6	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	6-11	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	6-11	1.0	Serum	15-mL Red	2-mL
68	Ferritin	6-11	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	6-11	1.3	Serum	15-mL Red	2-mL
15	Vit A/E/Car	6-11	0.3	Serum	15-mL Red	2-mL
21	Lipids	6-11	1.5	Serum	15-mL Red	2-mL

Exhibit 8-25. Blood processing protocol for VIP guest age 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	12+	0.5	Whole blood	5-mL EDTA	2-mL
2	Ery Proto	12+	0.4	Whole blood	5-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	5-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	5-mL EDTA	2-mL
5	Mercury	16-49	1.0	Whole blood	5-mL EDTA	2-mL
9	Glucose	12+	0.5	Plasma	3-mL Gray	2-mL
11	Iron/TIBC	12+	1.0	Serum	15-mL Red	2-mL
68	Ferritin	12+	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12+	1.3	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12+	0.4	Serum	15-mL Red	2-mL
18	Biochem	12+	0.8	Serum	15-mL Red	2-mL
21	Lipids	12+	2.0	Serum	15-mL Red	2-mL
25	FSH/LH	35-60	0.8	Serum	15-mL Red	2-mL

Exhibit 8-26 illustrates the blood processing vessel for each guest and surplus.

Exhibit 8-26. Blood processing protocol for guest and surplus age 1+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
18	Biochem	12+	0.8	Serum	3-mL Red	2-mL

8.6 Equipment

8.6.1 Benchtop Centrifuges

Each laboratory contains two benchtop refrigerated Beckman GS-6R centrifuges.

The centrifuge has the following safety features:

- An imbalance detector triggers an automatic shutdown if rotor loads are severely out of balance.
- A safety-lock mechanism and secondary manual latch prohibit opening the centrifuge door during a run until the rotor is virtually stopped.
- A lockout system requires the door to be closed and latched before the centrifuge will start.
- An anchoring system secures the centrifuge in place. Anchoring systems reduce the possibility of injury or damage that could result from centrifuge movement in case of a major rotor mishap.

The control panel is mounted at an angle on the centrifuge front for easy visibility and access. The control panel has the following features:

- Power - This rocker switch, labeled I (ON), and O (OFF), controls electrical power to the centrifuge. The chamber door cannot be opened unless the power is turned ON.
- Door - When pressed to the OPEN position, this switch releases the latch mechanism and allows the door to be opened when the secondary manual latch lever is switched to UNLOCK (the rotor must be stopped and the power switched on).
- Brake - Use this switch to select the brake mode used during deceleration. Set the position to HIGH or LOW. The HIGH break position activates the dynamic and the

electromechanical disk breaking. Dynamic breaking starts immediately after the timer turns the rotor off. At 1600 rpm the disk break engages, and remains on until the speed reaches 400 rpm, followed by dynamic breaking alone to 50 RPM. At 50 rpm, all breaking stops and the rotor coasts to a stop.

- Time - This knob may be set for any run time between 2 and 30 minutes in 1-minute increments. During a run, the timer rotates back to zero, at which point the centrifuge begins deceleration. A HOLD setting enables longer-duration runs - the centrifuge will run until turned off. Stop runs at any time by turning the knob to OFF. Set appropriate time and temperature for each tube as follows:

-	5-mL EDTA	10 minutes	4-8°C
-	3-mL gray	10 minutes	17-25°C or 4-8°C
-	3-mL blue	10 minute	17-25°C or 4-8°C
-	3-mL, 7-mL, 10-mL or 15-mL red	15 minutes	17-25°C
- Speed and ACCU-SET - Use this knob to set the drive speed, in 200-rpm increments, up to 8000 rpm. For precise adjustments, the ACCU-SET button can be pressed as the speed knob is turned until the desired speed appears on the RPM display. ACCU-SET can be adjusted at any time during a run. Set the speed at 2,900 rpm.
- RPM - During the run, the display indicates the actual rotor speed to the nearest increment of 10 rpm.
- Temperature - Use this knob to set operating temperature. The dial is marked from -10 to +40°C in 1°C increments. Set the refrigerated centrifuge at 4°C and the room temperature centrifuge at 22°C. The display indicates the temperature (+/-2°C) within the bowl in increments of 1°C.

Run Procedure:

1. Press the POWER to switch to ON.
2. Move the door latch lever to UNLOCK. Press the DOOR switch to OPEN and lift the centrifuge door up; it will remain in the open positions.
3. Load the Aerosolve canisters symmetrically. If only two canisters are being run, place the canisters in opposite buckets; and place two empty buckets for balance in the other two buckets. If only three canisters are required, balance tubes in empty canister across from third canister.
4. Close the centrifuge door and push firmly down on it until hearing a clicking or latching sound. Move the secondary latch lock to LOCK position.
5. Set the TEMPERATURE knob to the required run temperature.

6. Set the run speed using the following procedure:
 - Press the small ACCU-SET button in; rotate the SPEED dial until the required speed shows on the display.
 - While holding the ACCU-SET button in, rotate the SPEED dial until the required speed shows on the display.
 - When the selected speed is displayed, release the ACCU-SET button.
7. Select the HIGH brake position for the EDTA, gray and blue top tubes and select the LOW brake for the red top tubes.
8. Turn the timer to the required time. The centrifuge will start. As the run begins, acceleration control protects delicate gradients; when the rotor speed reaches about 200 rpm, full acceleration to set speed occurs.
9. To end a run in progress for any reason:
 - Turn the timer knob to OFF. The door interlock system keeps the door latched until the rotor has virtually stopped.
 - After the rotor stops spinning move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
10. After the rotor stops spinning move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
11. After completing a run, unload the canisters.

Leave the door open in order to prevent chamber icing.

8.6.2 Laminar Flow Biological Safety Cabinet Operating Sequence

- Turn on the cabinet blower and lights, check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the magnehelic gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the biomedical engineer. Record the pressure reading and any comments in the Laboratory QC module.
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.
- Disinfect the interior of the workspace by wiping it down with a 1% solution of bleach and water (1:100).

- Place a disposable paper blotter on the work surface. Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange and separate clean and contaminated materials.
- Wait 2-3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all "loose" contamination.
- Wear a long sleeved laboratory coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect hands and arms from viable agent contamination. Wash hands with soap and water before and after working in the cabinet.
- After completing work, leave the blower on for 2-3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazard waste by wiping them with a 1% solution of bleach and water (1:100).
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

8.7 Blood Processing Procedures

8.7.1 Overview

Centrifuge all blood specimens unopened, then transport to, uncap, and process in the laminar flow hood. The laminar flow hood provides a HEPA filtered, recirculated mass airflow within the workspace, and protects from any spattering that may occur when opening the Vacutainer® tubes or when pouring or pipetting the specimens. It also prevents drawing contaminated air or dust over the specimens. It is mandatory to use the blower.

Always wear gloves when handling specimens. Check gloves for small holes or tears. Change gloves if they become visibly contaminated with blood. Immediately soak visibly contaminated racks in 1:100 bleach solution.

Decontaminate racks and template by soaking in 1% bleach solution at the end of each session. Place on blotter to air dry.

Pipette whole blood and make dilutions using the MLA® pipettes. Pipette plasma using plastic transfer pipettes. Pool serum and aliquot using the Eppendorf® Repeater™ pipette.

- Use the MLA™ pipette, trace metal free pipette tips to aliquot whole blood, and perform the dilution for RBC Folate using 1.0-uL ascorbic acid.

- Pipetting Procedure

1. Using the pipette tip dispenser tray, press the pipette nozzle firmly into a fresh tip.
2. Fully depress the pipette plunger and then immerse the tip into the whole blood or ascorbic acid (approximately 1/2 inch or 3mm deep).
3. Smoothly return the pipette plunger to the release position and allow the whole blood or ascorbic acid to enter the pipette tip.
4. Remove the tip from the whole blood or ascorbic acid.
5. Place the tip against the inner wall of the cryovial as close to the bottom as possible. Smoothly depress the plunger and while holding the plunger depressed slowly withdraw the tip keeping it against the wall of the container.
6. Return the plunger to the release position.
7. Remove the pipette tip by grasping the pipette between the four fingers and the thumb. With thumb and forefinger, apply slight upward pressure to the pipette bonnet. Discard the tip in the sharps container.
8. Cover the pipette tips at the end of each session to prevent contamination.

8.7.2 Process the 3-mL and 5-mL EDTA Tubes

Use the well-mixed lavender 3-mL and 5-mL EDTA tubes for the hematology profile (CBC) and certain blood tests. The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation.

8.7.2.1 Process the 3-mL or 5-mL EDTA Tube for Lead/Cad, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4

The hematology technologist runs the CBC on the room temperature 3-mL or 5-mL EDTA tube after the blood processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4 vessels using the MLA™ pipettes.

Complete the following process for all SPs.

- The blood-processing technologist initially processes the 3-mL or 5-mL EDTA tube.
 - Invert the appropriate EDTA tube several times to remix contents thoroughly. Use trace metal free pipette tips and the 100µL and the 200µL MLA pipettes to pipette 0.3-mL whole blood for vessel 1 (Lead/Cad) on primary SPs and VIP guests aged 1-5 into a 2-mL vessel. Use trace metal free pipette tips and the 500µL MLA pipette and the 100µL MLA pipette to pipette 0.6-mL whole blood for vessel 1 (Lead/Cad) on primary SPs and VIP guests aged 6-11 into a 2-mL vessel. Use trace metal free pipette tips and the 500µL MLA pipette to pipette 0.5-mL whole blood for vessel 1 (Lead/Cad) on primary, home, and second exam SPs and VIP guests aged 12+ into a 2-mL vessel.
 - Use trace metal free pipette tips and the 300µL MLA pipette to pipette 0.3-mL whole blood for vessel 2 (Ery Proto) on primary SPs and VIP guests aged 1-11 into a 2-mL vessel. Use trace metal free pipette tips and the 400µL MLA pipette to pipette 0.4-mL whole blood for vessel 2 (Ery Proto) on primary, home, and second exam SPs and VIP guests aged 12+ into a 2-mL vessel.
 - Use trace metal free pipette tips and the 100µL MLA pipette to pipette 0.1-mL whole blood for vessel 3 (RBC Folate) on primary, home, and second exam SPs and VIP guests aged 3+ into a 2-mL vessel. It is not necessary to prewet the pipette tips. Dilute the whole blood with ascorbic acid. Use trace metal free pipette tips and the 1000µL MLA pipette to immediately pipette 1.0-mL ascorbic acid into the 2-mL vessel. Mix well. Refrigerate L-ascorbic acid diluent when not in use. Discard unused diluent at end of each stand.
 - Use trace metal free pipette tips and the 400µL MLA pipette to pipette 0.4-mL whole blood for vessel 4 (Glycohem) on primary, home, and second exam SPs and VIP guests into a 2-mL vessel.
 - Use trace metal free pipette tips and the 500µL MLA pipette to pipette 0.5-mL whole blood for vessel 5 (Mercury) on primary SPs and VIP guests aged 1-5 into a 2-mL vessel. Use trace metal free pipette tips and the 1000µL MLA

pipette to pipette 1.0-mL whole blood for vessel 5 (Mercury) on female primary SPs and female VIP guests aged 16-49 into a 2-mL vessel.

- Use trace metal free pipette tips and the 500 μ L MLA pipette to pipette 0.5-mL whole blood for vessel 6 (CD4) on primary SPs aged 18-49 into a 2-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.
- Place the EDTA tube on a hematology rocker until the hematology technologist performs the CBC.

Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 2-mL EDTA blood tube at room temperature for no more than 24 hours. After 24 hours, the blood will undergo changes that will render the WBC, RBC, HgB, and HCT results inaccurate.

8.7.2.2 Process Second 5-mL EDTA Tube for Plasma for Homocys/MMA and Extra Plasma

Process the second 5-mL EDTA tube for Homocys/MMA and Xtra Plasma immediately and centrifuge at 4-8°C or refrigerate the tube until it can be centrifuged. Remove the plasma from the cells within 30 minutes. Red blood cells synthesize homocysteine, which results in a 10% increase after 30 minutes. After 1 hour, the increase in homocysteine is 2-16%, after 2 hours 11-30%, after 4 hours 23-35%, and after 6 hours 22-42%.

- Place the tube in the centrifuge carrier of the refrigerated tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Immediately centrifuge the remaining whole blood from the first 5-mL EDTA tube or the whole blood in the second 5-mL EDTA tube in the at 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 7 (Homocys/MMA) and vessel 8 (Xtra Plasma.)
- Use a calibrated plastic transfer pipette to pipette at least 1.0-mL plasma for vessel 7 (Homocys/MMA) on primary and second exam SPs age 3+ and home exam SP's age 50+ into a 2-mL vessel.
- Use a calibrated plastic transfer pipette to pipette at least 0.5-mL plasma for vessel 8 (Xtra Plasma) on primary SPs age 6+ into a 2-mL vessel.
- If there is excess plasma, add 1.0-mL to vessel 7 and any remainder to vessel 8.

- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.3 Process the 3-mL Gray Tube for Glucose

Centrifuge and separate the plasma from the 3-mL gray top tube as soon as possible.

Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 3-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (Glucose.)
- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 9 (Glucose) on primary and second exam SPs and VIP guests age 12+ into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.4 Process the 3-mL Blue Top Tube for Fibrin

Centrifuge and separate the plasma from the 3-mL blue top tube as soon as possible. Process the specimen even if the contents of the tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 3-mL blue tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 10 (Fibrin.)

- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 1.0-mL for vessel 10 (Fibrin) on primary and second exam SPs age 40+ and home exam SPs age 50+ into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.5 Process the 3-mL, 7-mL, and 15-mL Red Top Tubes for Pooled Sera

- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in each 3-mL, 7-mL, and 15-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.

If the serum in any one red top tube from a SP is grossly hemolyzed, do not pool it with serum from the remaining tubes. Reserve it for the storage vessels 32-42.

If the serum in all red top tubes for a SP is turbid, lipemic, or icteric, pool it and allocate as usual.

- Use a serum separator to remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard. Do not touch the serum separator to the clot barrier.
- Label the 50-mL conical tube with SP ID # label. Pool all clear sera. For each SP pool the serum from all red top tubes by decanting the separated serum into the 50-mL polypropylene tube. Hold the tube and the separator level while decanting the serum. Be careful to avoid introducing any cellular debris. Reserve one 15-mL tube for the DNA vessel 43. Discard the other original tubes and separators in a sharps container.

- Securely close the 50-mL polypropylene tube and mix its contents by gentle inversion.
- Confirm that all vessels have the correct information with the appropriate SP's bar-coded ID label before filling them.
- Use the Eppendorf® pipette and 5-mL Combitip to aliquot the serum.

A. Design Principle of the Eppendorf Repeater

1. Volume selection dial – To determine the pipetting volume, the dial setting (1-5) is multiplied by the minimum pipetting volume.
2. Pipetting lever – The volume is pipetted by pressing the pipette lever down until it stops.
3. Filling lever – The Combitip is filled by sliding the lever upward.
4. Locking clamp – The locking clamp serves to firmly clamp the Combitip into the Repeater.

B. Combitip

Combitip nose cone

- Volume Selection and Choice of Combitip

1. Combitip – The minimum pipetting volume and the maximum filling capacity are given on each Combitip. The scale facilitates drawing off partial quantities and permits estimating the amount of liquid still available for operation. The volume to be pipetted is obtained by multiplying the set number located on the volume selection dial by the minimum pipetting volume of the Combitip (e.g. 5-mL Combitip minimum volume: 1=100 μ L. At setting 4: 4 x 100 μ L= pipetted volume 400 μ L.)

- Inserting the Combitip

1. Slide the filling lever down until it stops.
2. Raise the locking clamp upward.
3. Insert the Combitip until it clicks into position. Be sure the Combitip plunger is fully inserted into the barrel before attaching it to the repeater.
4. Be sure the filling lever is down and then lower the locking clamp to secure the Combitip in place.

- Filling the Combitip

1. Immerse the cone into the serum.

2. Fill by slowly sliding the filling lever upward. Sliding the lever too quickly can cause excessive vacuum. This can cause tiny air bubbles to accumulate in the serum, which may lead to pipetting inaccuracies.
3. Discard the first pipetting step back into the pooled serum. It is important to discard the first pipetting step in order to release any residual pressure from the pipetting system after filling and to prepare the system for precise pipetting.

Note - Small bubbles in the Combitip beneath the piston do not affect pipetting accuracy due to an incorporated residual stroke lock, which prevents the pipetting of any residual material after the last dispensing.

Note - It is not necessary to completely fill the Combitip. Partially filling Combitips does not affect pipetting accuracy.

- Pipetting

1. Check the volume selection dial.
2. Wipe off the Combitip nose cone with lint free tissue.
3. Hold the Repeater at an angle so that the Combitip nose cone touches the inner wall of the vessel.
4. Dispense the serum by completely depressing the pipette lever.

- Removing the Combitip

1. Hold the Repeater over the 50-mL pooled serum tube.
2. Depress the filling lever slowly downwards to the stop, to completely empty the Combitip.
3. Raise the locking clamp upward.
4. Remove the Combitip.

- Safety Precautions and Operational Limitations

1. When removing the Combitip do not touch the tip and avoid splashing.
2. Repeaters with partially filled Combitips should be stored upright in the stand to prevent air from entering the Combitip.

- Using clear serum only, fill as many vessels as possible in the priority order shown in Section 8.5. Exhibits 8.16 – 8.26 describe the order of allocation and specific procedures to follow for each person type and vessel.

- If excess serum remains after completing the entire protocol, add an additional 1.5-mL serum beginning with vessel 32 and continuing through vessel 42 until the serum is exhausted. If extra serum remains, continue to top off the other serum vessels beginning with vessel 11 until the serum is exhausted.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.
- If the serum cannot be aliquoted immediately, refrigerate it at 4°C for no more than 4 hours.

8.7.6 Process the 10-mL Red Top Tube for Persis Pest, Dioxins, and Phytoestro

- Do not substitute any other red top tube for these vessels; this tube is prescreened by the CDC for these tests.
- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in the 10-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
- Use a serum separator to carefully remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flow through may occur. Do not touch the serum separator to the clot barrier.
- Aliquot the serum immediately by pouring the serum for vessel 29 (Persis Pest) or vessel 63 (Dioxins) or vessel 64 (Phytoestro) on primary SPs 12+ into a 5.0-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.7 Process One 15-mL Red Top Tube for Clots

- After decanting and processing the sera from one 15-mL red top tube, discard the serum separator(s), and loosen the remaining clot with a wooden stirring rod.
- Decant the loosened clot for vessel 43 (DNA) on primary SPs 20+ into a 14-mL vessel.
- Discard the empty red top tube and the wooden stirring rod in a sharps container.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.8 Process the 8-mL ACD Tubes for WBC/DNA

Process the two 8-mL ACD tubes 44 and 71 (WBC/DNA) on primary SPs 20+. Keep the tube upright at room temperature. Label and verify that a minimum of 6-mL of blood is in the tube by comparing the volume in the tube to a calibrated tube. Do not expose tubes to extreme temperatures.

- Mix the blood by gently inverting the tubes 5-6 times.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately at room temperature as outlined in Section 8.10.

8.7.9 Reagent Processing and Preparation

The Centers for Disease Control and Prevention supplies premeasured 1% ascorbic acid (AA) for the RBC Folate assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use calibrated MLA pipettes to make the dilution. Add 1.0-mL ascorbic acid to 0.1-mL whole blood for the RBC Folate assay. Mix by gentle inversion.

- The ascorbic acid powder is in a 50-mL Falcon tube. Dissolve the powder in 50-mL of distilled water using a graduated cylinder to measure the water and mix gently.

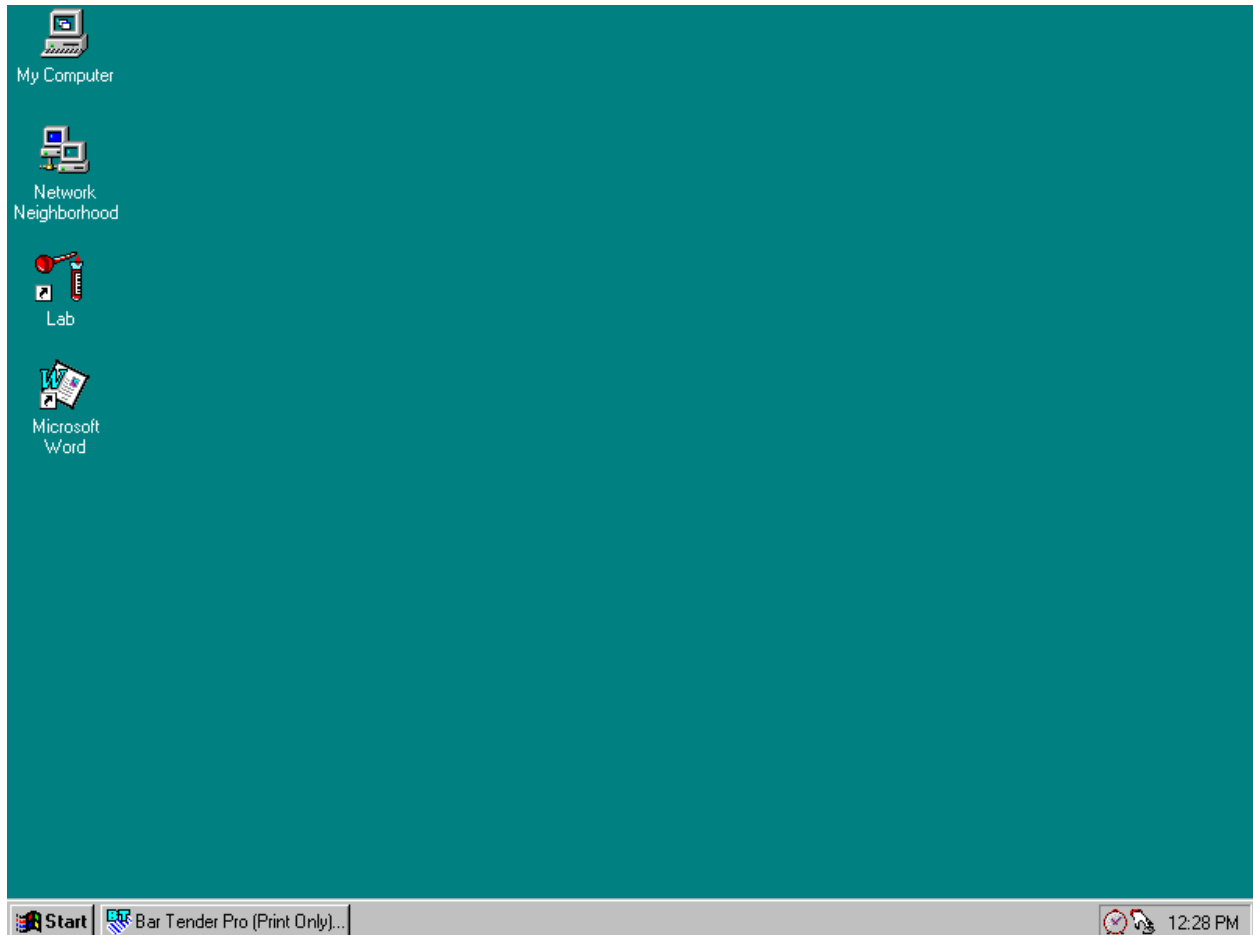
Prepare this reagent weekly. Date and label the Falcon tube. If the powder appears discolored or the solution appears cloudy, discard and prepare fresh reagent. If no bottled distilled water is available, use tap water. Record the reagent in the Supply use Control Log each time it is prepared.

- Re-refrigerate the prepared reagent at the end of each day to maintain its stability and bring the reagent back to room temperature the next day.

8.8 Record the Results of Specimen Processing

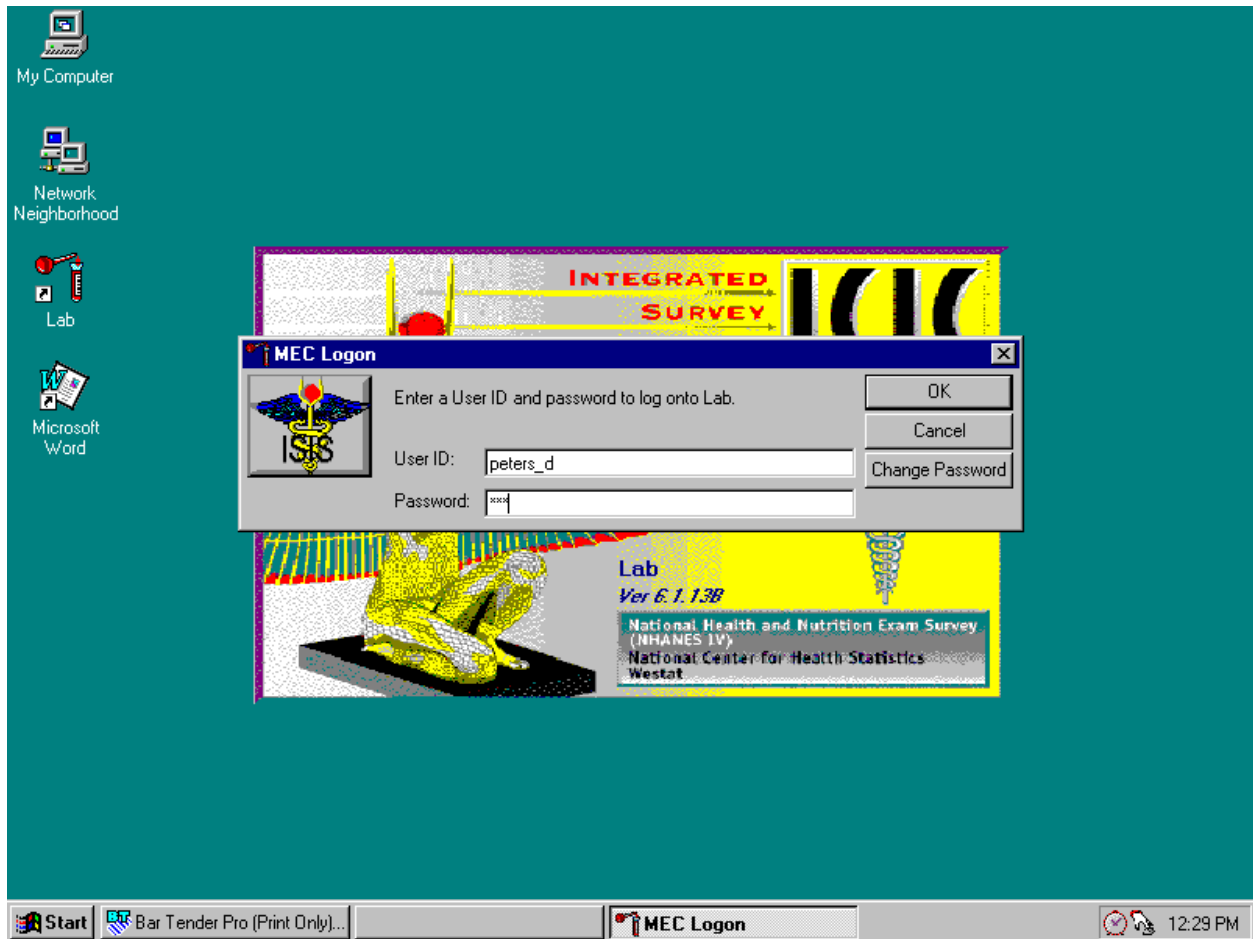
After filling or processing the whole blood, plasma, serum, clot vessels and/or the ACD tubes for each SP, use the Blood Processing module to enter the blood processing results.

Open the Laboratory application.



To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Log onto the laboratory application.



The MEC Logon screen displays. Type last name, underscore first initial, in the User ID space and [Tab] or [Enter]. Enter password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the **Cancel** button and left click.

Use the heads-up display to view the SPs, the modules for which they are eligible and their current process status.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Message
Appointments for Session: 505210

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
108148	108148	CI	VIP	N	M	14	MARINO, WILLIAM	○	○	○	○	•	•	•	•	•
194149	194149	SC	P	M	F	50	SPARKS, GERTRUDE	○	○	○	○	○	•	○	•	•
206449	206449	EX	P	M	F	14	RITTER, MARY	○	○	○	○	○	•	•	•	•
230355	230355	SC	P	M	M	40	TORRES, JORGE	○	○	○	○	•	○	○	•	•
236673	236673	CI	VIP	N	F	7	SANCHEZ, WENDY	○	○	○	○	•	•	•	•	•
338454	338454	CI	P	N	M	2	SPARKS, JOHN	•	○	○	•	•	•	•	○	•
455209	455209	CI	VIP	N	M	4	GRAVELY, ANDY	•	○	○	•	•	•	•	•	•
502868	502868	CI	G	N	M	15	SWANSON, TRISTAN	•	○	○	•	•	•	•	•	•
687219	687219	CI	XD2	M	M	30	SPARKS, TODD	○	○	○	○	•	○	•	•	•
755942	755942	BE	G	N	F	5	JONES, SHARON	•	•	○	•	•	•	•	•	•
757644	757644	EX	P	M	M	35	RITTER, JIM	○	○	○	○	•	○	•	•	•
855085	855085	CI	P	N	F	9	SPARKS, SARAH	○	○	○	○	○	•	•	•	•

Send a Message to Coordinator | Connected to Coordinator | 10:59 AM

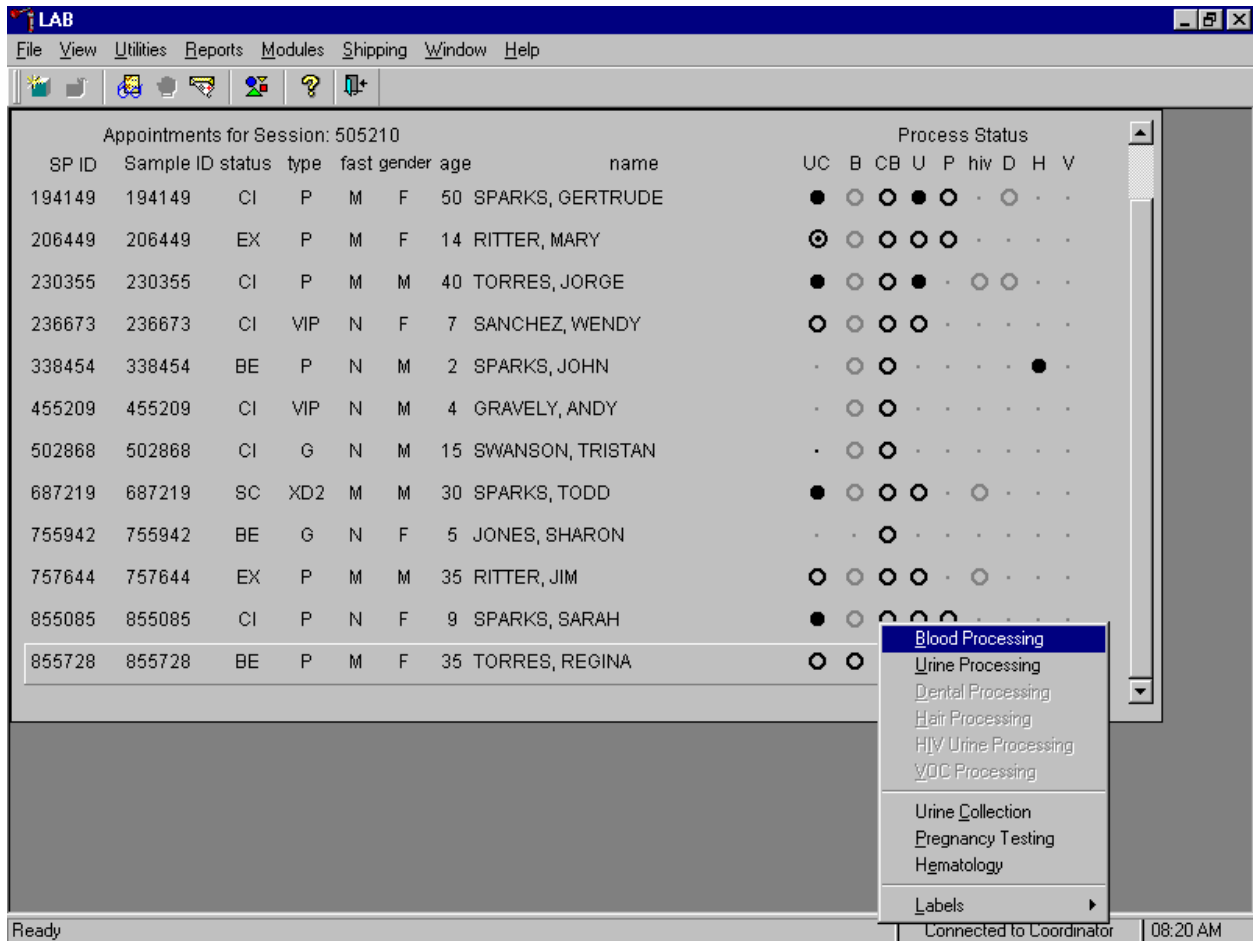
The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run), fast (M=morning, A=afternoon, E=evening, N=none), Gender, Age, and Name (first and last.)

The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), Hiv (HIV urine processing), D (dental saliva), H (hair), and V (VOC). The SP is ineligible for a module when the process status is •. The SP is eligible for a module but no results have been recorded when the process status is ○. The SP is eligible for a module and some results have been recorded when

the process status is **⊙**. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is **●**. The SP is eligible for a module but the process status is **O** until the SP's blood, dental saliva, and hair samples are recorded as collected. Once the sample is collected, the process status will change from **O** to **○**. The SP is eligible for the HIV module but the status is **O** until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from **O** to **○**. The process status updates and changes after each result is saved.

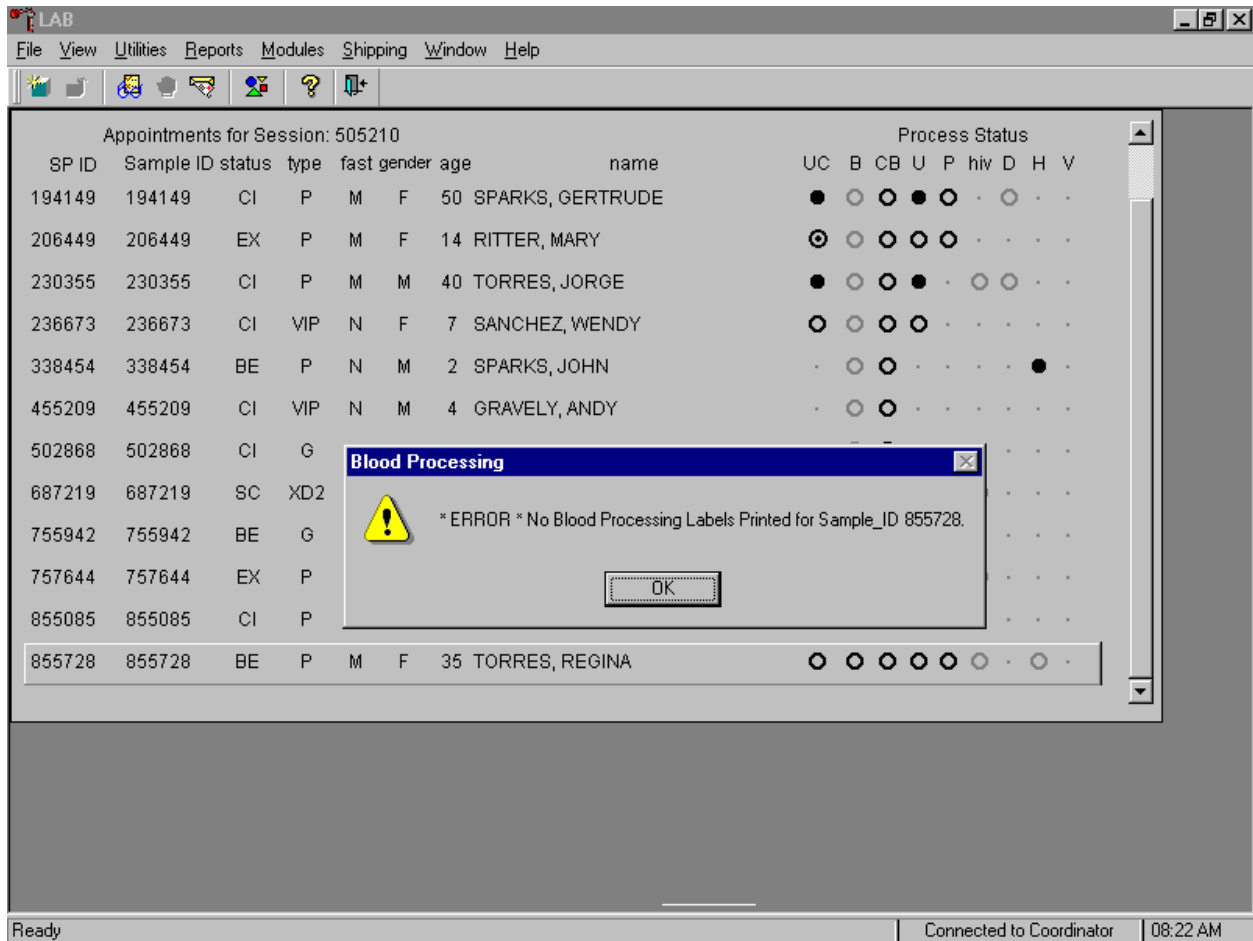
The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP for blood processing. Select a different SP if active SP is not the SP of choice.

Select the correct SP and access the Blood Processing module.



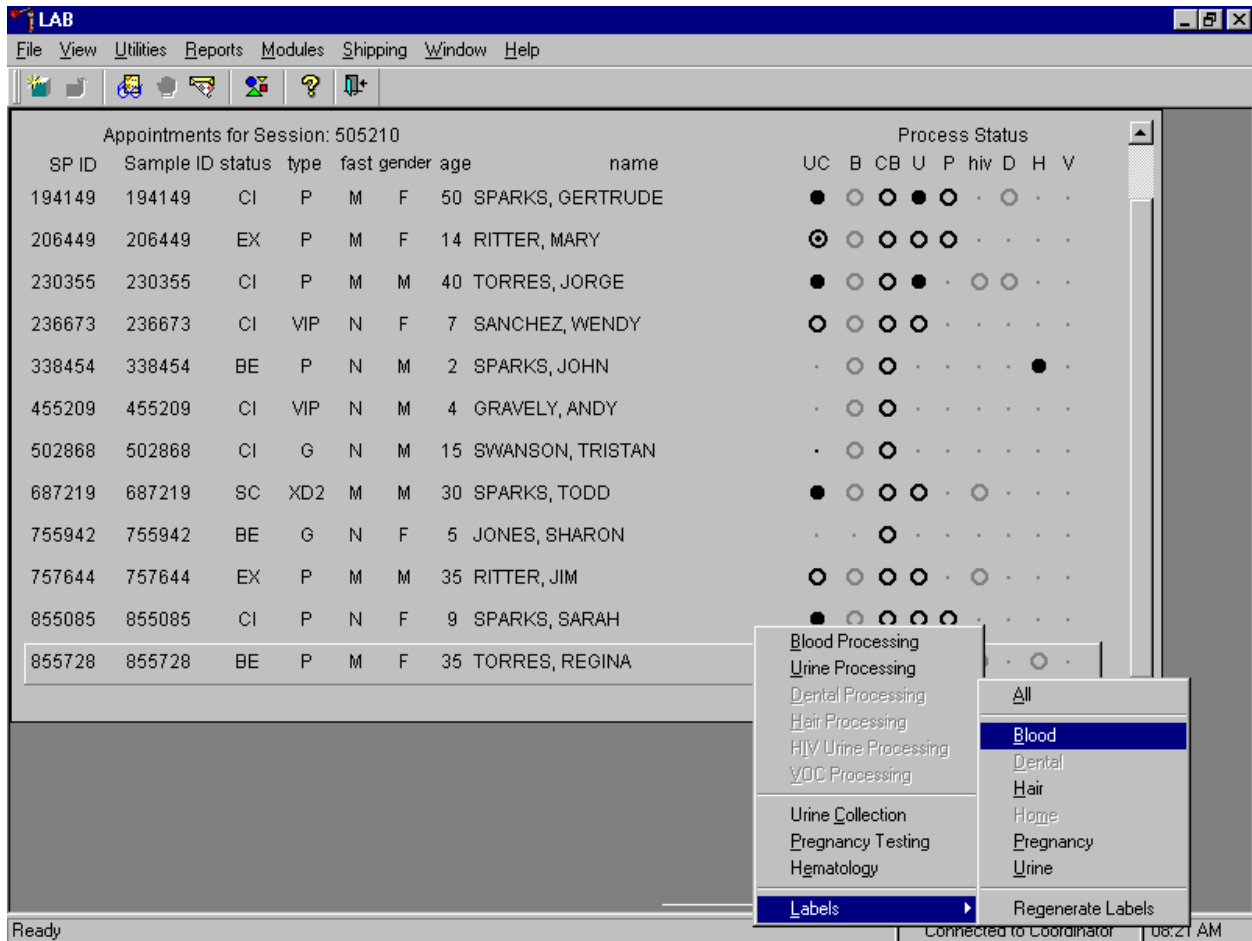
To access the Blood Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Blood Processing} and right click or type [B/b]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Blood Processing}, and right click or type [B/b].

If labels have not been printed in advance, a Blood Processing message text box displays.



Blood processing cannot occur unless labels have been printed in advance. To remove the Blood Processing message text box, use the mouse to direct the mouse arrow to the **OK** button and left click.

Print labels for an individual SP using the heads-up display.



To print labels for a SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {Blood}, and left click or type [B]. Labels print in the label/ship area.

The SP's blood processing screen displays.

The screenshot shows a software window titled "LAB" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main window is titled "BP: 855728" and contains the following information:

none

Tech ID: 1115 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

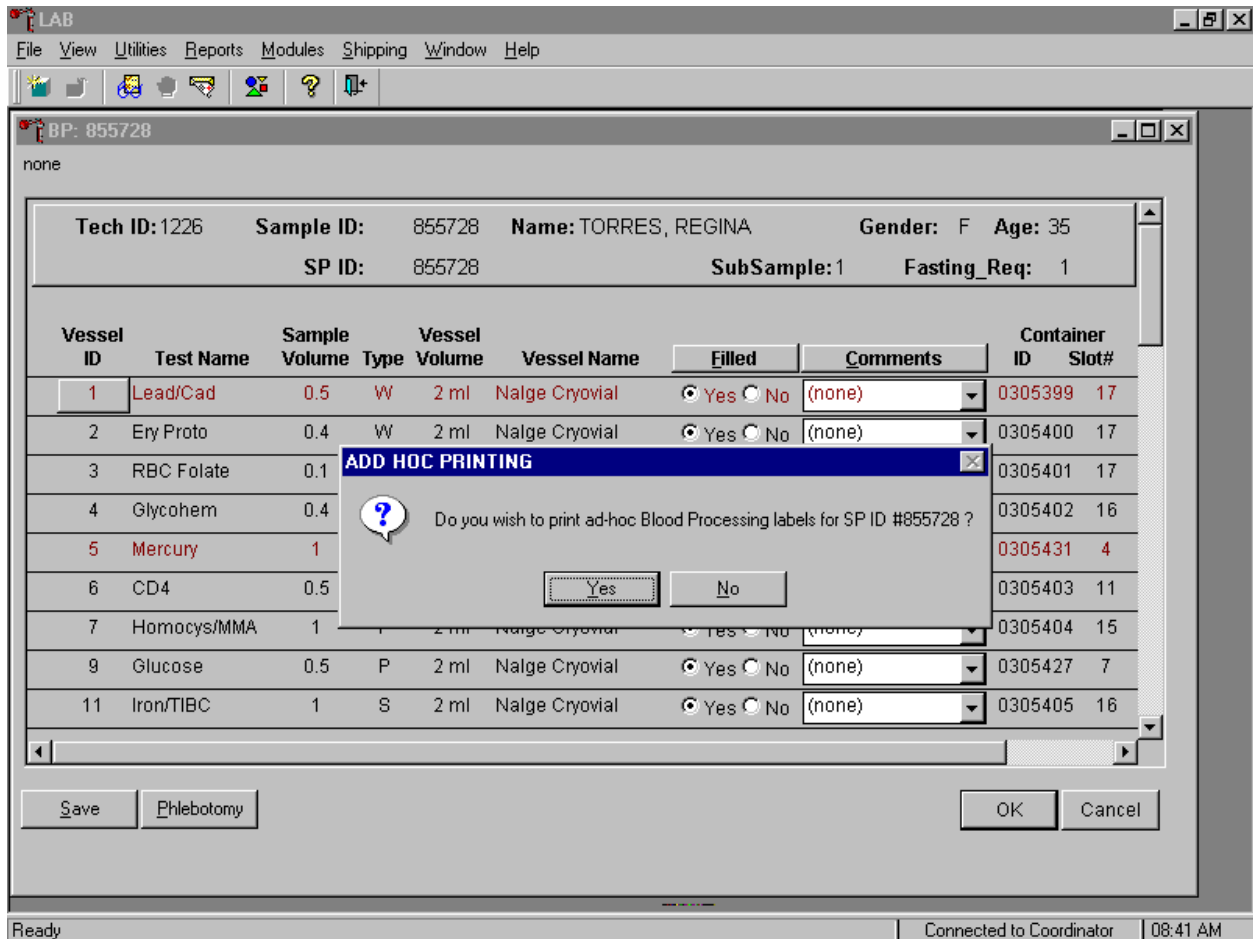
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
5	Mercury	1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
7	Homocys/MMA	1	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
11	Iron/TIBC	1	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Buttons: Save, Phlebotomy, OK, Cancel

Status bar: Ready | Connected to Coordinator | 08:26 AM

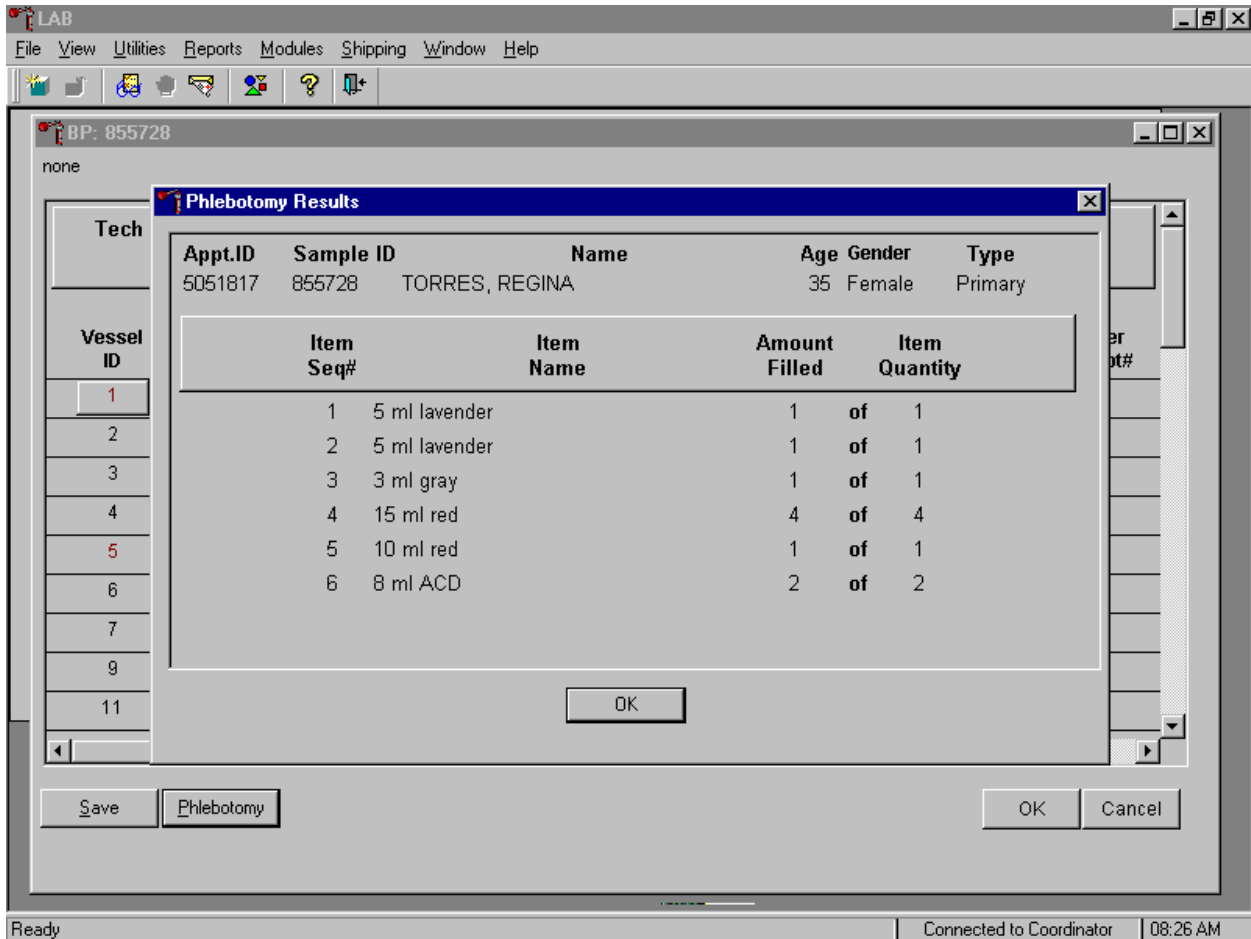
The blood processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum, clots), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons.

Print an ad-hoc label for any individual vessel.



To print one ad-hoc label for one vessel, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the text box request. To print the label and remove the text box, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Y/y]. To remove the text box without printing a label, use the mouse to direct the mouse arrow to the **No** button and left click or type [N/n].

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the bar code label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



To review the phlebotomy results, use the mouse to direct the mouse arrow to the **Phlebotomy** button on the blood processing screen and left click. The phlebotomy protocol and number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the **OK** button and left click.

Record blood-processing results for each SP. Individually mark each vessel as Filled - "Yes."

BP: 855728
none

Tech ID: 1226 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

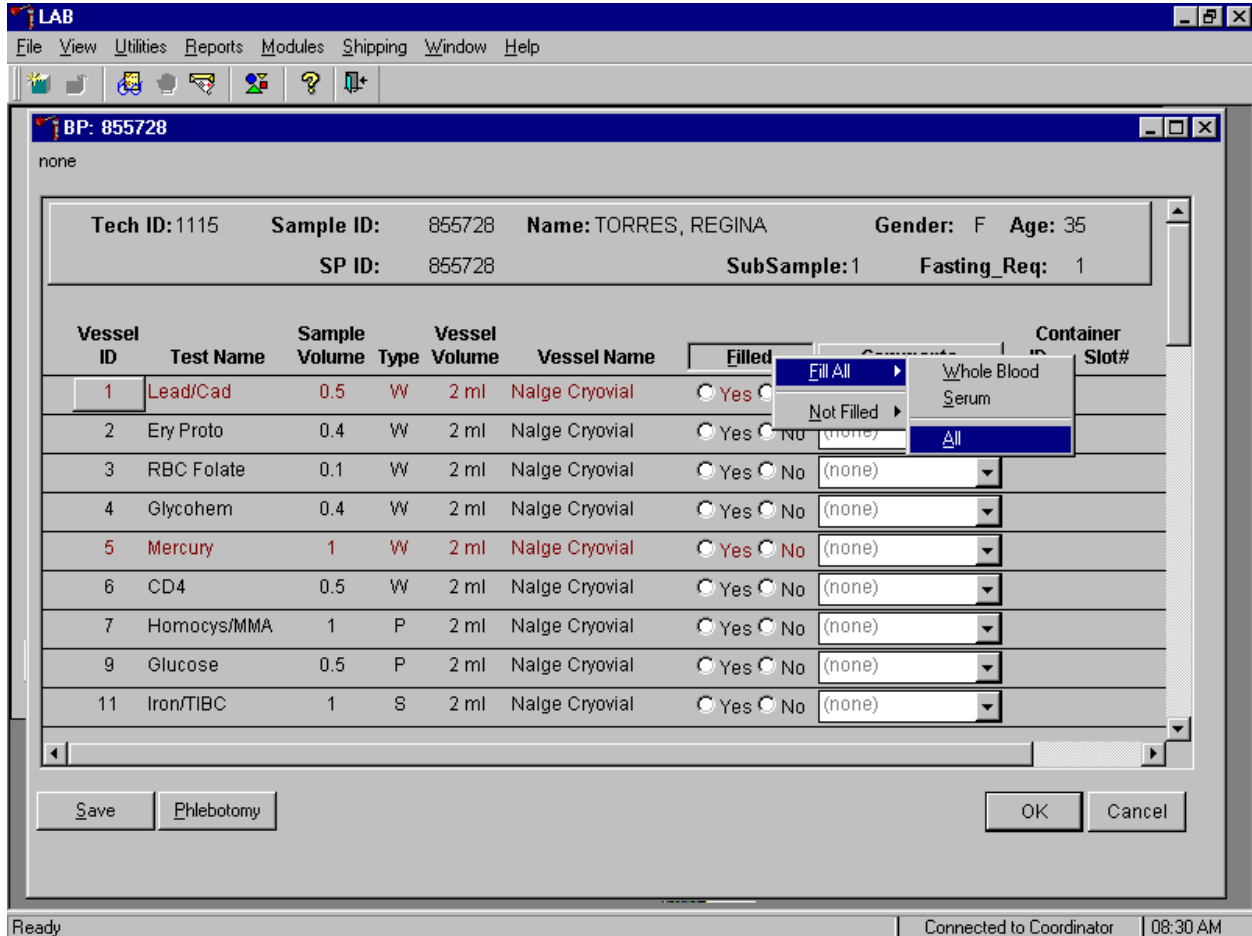
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305399	15
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305400	15
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305401	15
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305402	14
5	Mercury	1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
7	Homocys/MMA	1	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
11	Iron/TIBC	1	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Ready Connected to Coordinator 08:28 AM

To mark an individual blood vessel as collected or Filled – "Yes," use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As each vessel is marked as Filled – "Yes," it is automatically assigned to a slot in an existing (open) container.

Collectively mark all vessels as Filled - "Yes" or all whole blood or serum vessels as Filled – "Yes."



To collectively mark all vessels as Filled - "Yes," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click or type [F/f], drag the arrow to {Fill All} or type [F/f], drag the mouse arrow to {All} or type [A/a], and left click. To collectively mark all whole blood vessels as Filled - "Yes," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click or type [F/f], drag the arrow to {Fill All} or type [F/f], drag the mouse arrow to {Whole Blood} or type [W/w], and left click. To collectively mark all serum vessels as Filled - "Yes," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click or type [F/f], drag the arrow to {Fill All} or type [F/f], drag the mouse arrow to {Serum} or type [S/s], and left click. As each vessel is marked as "Filled," it is automatically assigned to a slot in an existing (open) container. All plasma and clot vessels and the ACD tubes must be marked individually.

Quality comment codes are available to describe the quality of the specimen.

Comment for filled vessels	Use when:
Icteric	There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible "jaundice" color when the concentration of bilirubin is above 430 $\mu\text{mol/L}$.
Lipemic	There is turbid appearance to the serum or plasma. Lipemia refers to the presence of lipid particles (usually very low-density lipoprotein) in a sample, which gives the sample a turbid appearance. Plasma appears visibly lactescent or lipemic when the concentration of triglycerides exceeds 4.6 mmol/L .
Equipment failure	Pipettes are malfunctioning.
Clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
Hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture (<i>in vivo</i> hemolysis) or during the analytic procedure (<i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 mg/L .

Quality comment codes are available to describe the quality of the specimen. Attach a comment to an individual filled vessel.

LAB

File View Utilities Reports Modules Shipping Window Help

BP: 855728

none

Tech ID: 1226 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

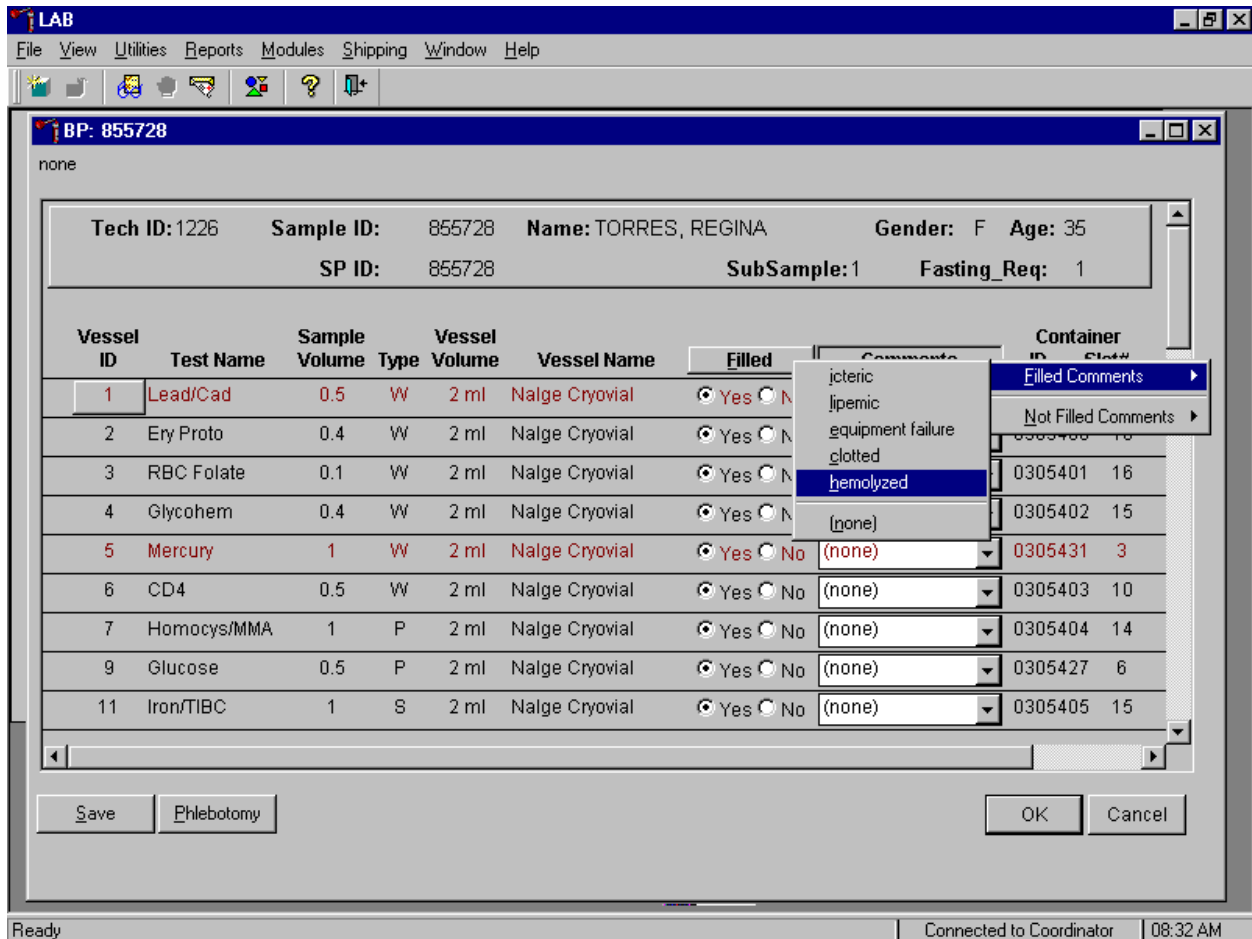
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305399	17
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305400	17
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305401	17
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305402	16
5	Mercury	1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305431	4
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
7	Homocys/MMA	1	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	clotted		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	equipment failure		
11	Iron/TIBC	1	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	hemolyzed		
							icteric		
							lipemic		

Save Phlebotomy OK Cancel

Ready Connected to Coordinator 08:33 AM

To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop down list under the **Comments** button to display the choices, drag the arrow to the correct choice, and left click.

Use the following procedure when all filled vessels require the same comment.



To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the **Comments** button on the top of the radio buttons, left click or type [C/c], drag the arrow to {Filled Comments} or type [F/f], drag the mouse arrow to the correct choice or type the first letter of the correct choice, and left click.

Record blood-processing results for each SP. Individually mark each vessel as Filled - "No."

The screenshot shows a software window titled "LAB" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. A sub-window titled "BP: 855728" is open, displaying patient details and a table of blood vessels.

none

Tech ID: 1226 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

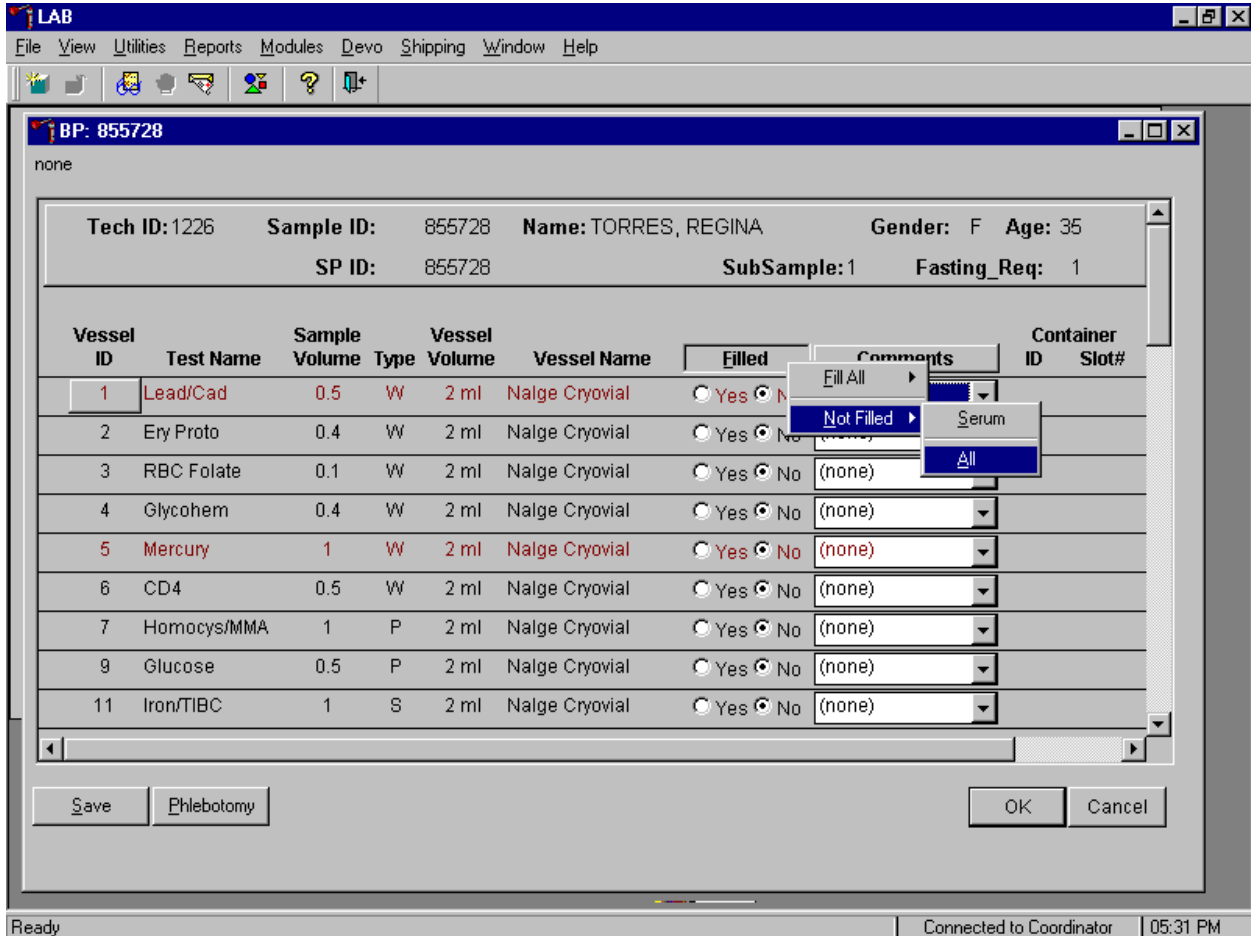
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305399	15
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305400	15
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305401	15
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305402	14
5	Mercury	1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
7	Homocys/MMA	1	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
9	Glucose	0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
11	Iron/TIBC	1	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Buttons: Save, Phlebotomy, OK, Cancel

Ready | Connected to Coordinator | 08:29 AM

To mark an individual blood vessel as collected or Filled – "No," use the mouse to direct the mouse arrow to the "No" radio button and left click.

Collectively mark all vessels as Filled - "No" or all whole blood or serum vessels as Filled – "No."

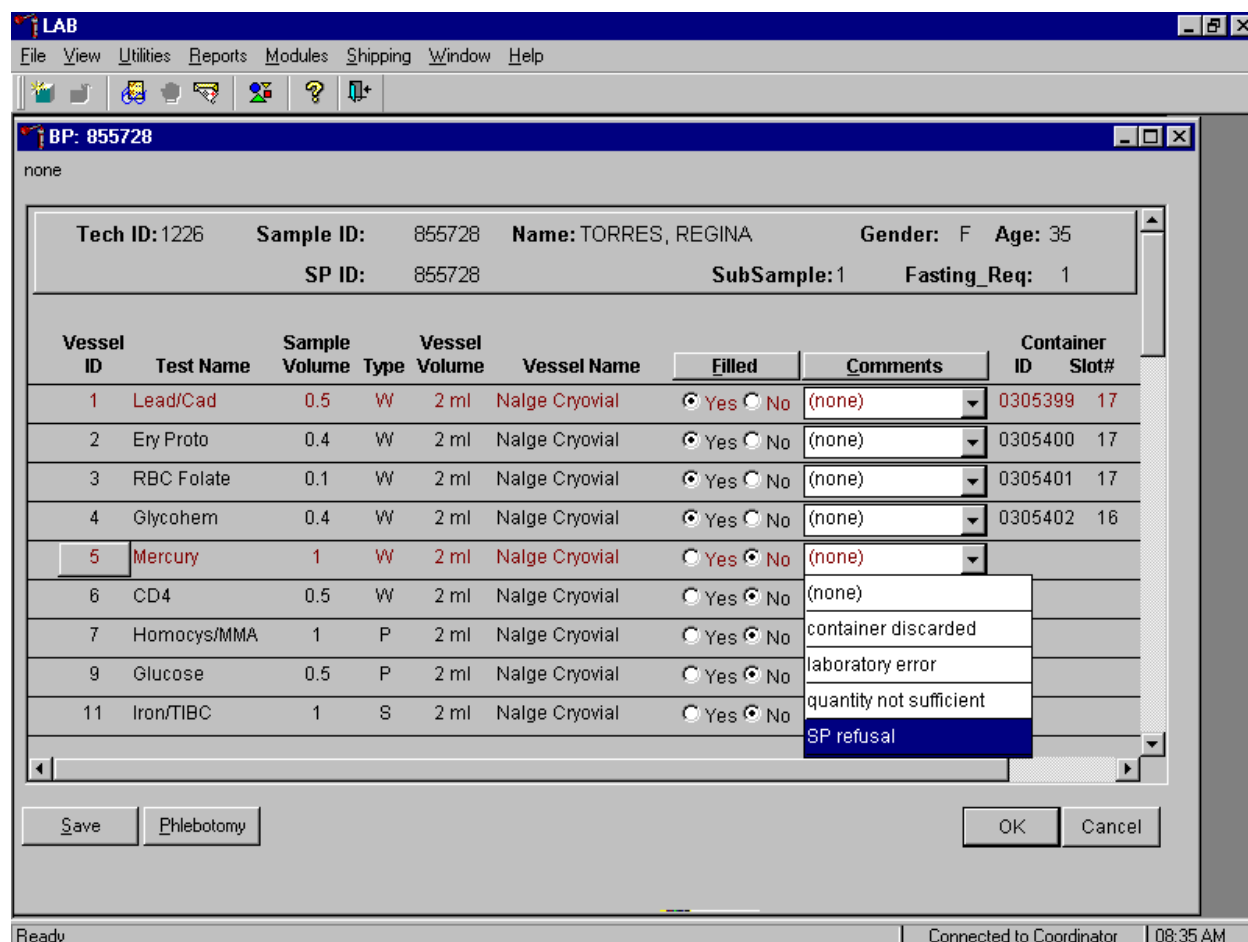


To collectively mark all vessels as Filled - "No," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click or type [F/f], drag the arrow to {Not Filled} or type [N/n], drag the mouse arrow to {All} or type [A/a], and left click. To collectively mark all serum vessels as Filled - "No," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click or type [F/f], drag the arrow to {Not Filled} or type [N/n], drag the mouse arrow to {Serum} or type [S/s], and left click. All whole blood, plasma and clot vessels and the ACD tubes must be marked individually. All Vessels marked as Filled – "No" require a comment or explanation.

Enter comment codes to describe the reasons why a vessel is marked as Filled – "No," or why the protocol is not complete.

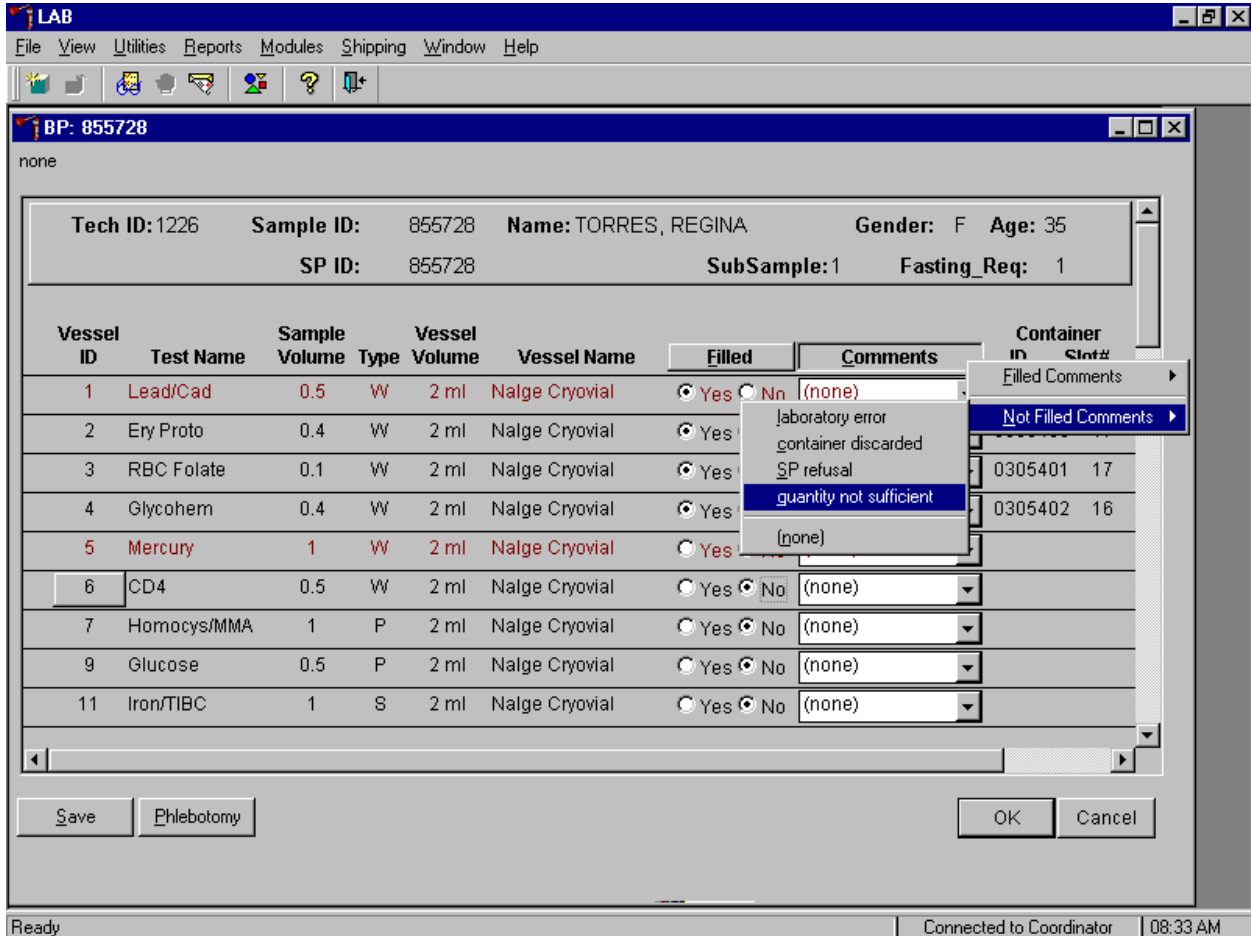
Comment for not filled vessels	Use when:
quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP does not provide consent and consequently, excluded from HIV or genetic testing.
laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist error.
container discarded	Do not use this comment.

Attach a comment to an individual Filled – "No" vessel.



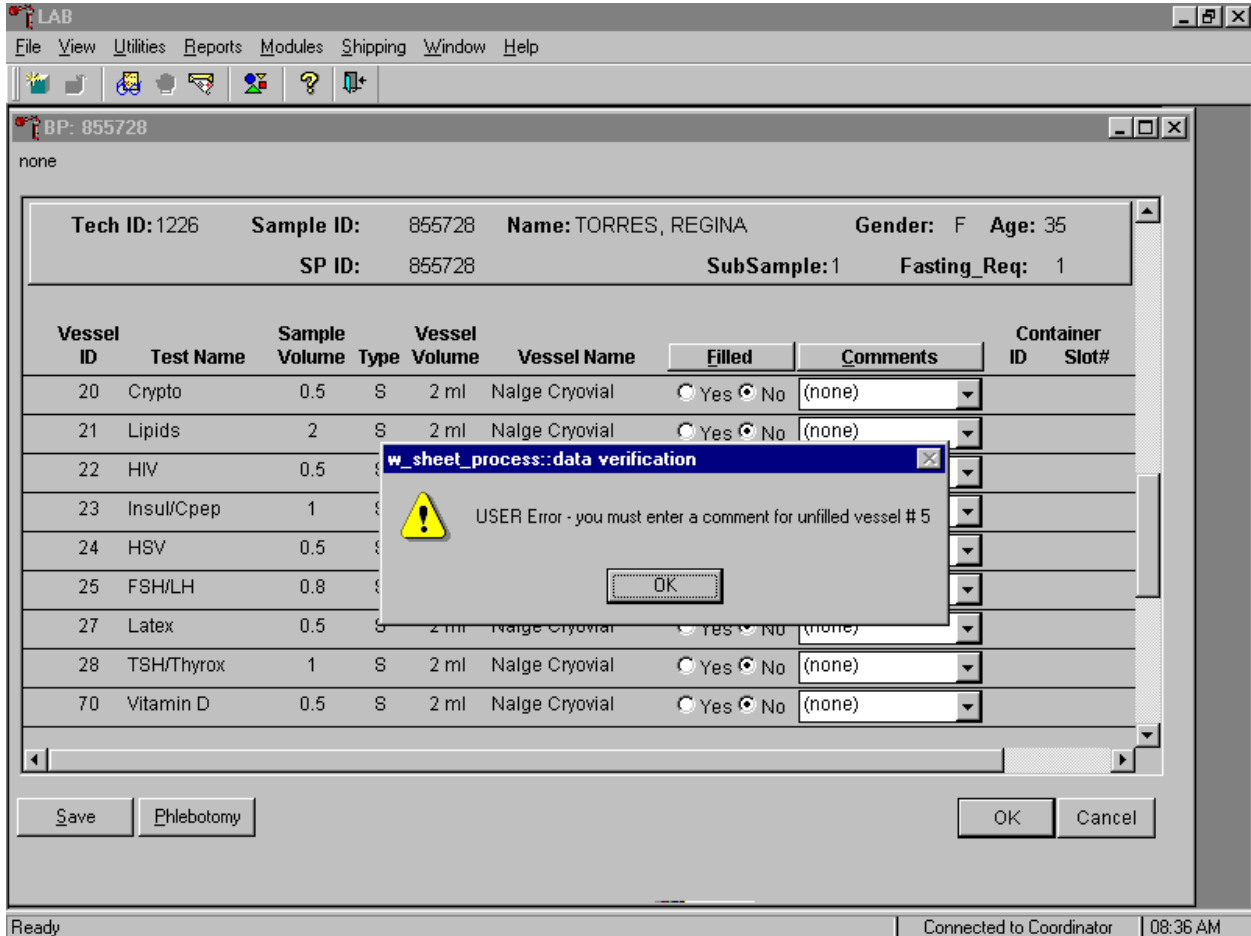
To attach a Filled – "No" comment to an individual vessel, use the mouse to direct the mouse arrow to the drop down list under the **Comments** button to display the choices, drag the arrow to the correct choice, and left click.

Use the following procedure when all Filled – "No" vessels require the same comment.



To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the **Comments** button on the top of the radio buttons, left click or type [C/c], drag the arrow to {Not Filled Comments} or type [N/n], drag the mouse arrow to the correct choice or type the first letter of the correct choice and left click.

Continue to enter results as vessels are processed. Review the information in the blood-processing window and save the data to the database.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

If the **Save** or the **OK** button is selected and all vessels are not marked as either Filled - "Yes" or Filled - "No," a warning message text box displays requesting a comment for each unfilled vessel. To remove the text box, use the mouse to direct the mouse arrow to the **OK** button and left click.

8.9 Process HIV Urine

At the end of each session, process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for SPs 18-49) and the primary SP has not refused the HIV test. Record and save to the database, the HIV vessel 22 result.

LAB

File View Utilities Reports Modules Shipping Window Help

BP: 855728

none

Tech ID: 1226 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

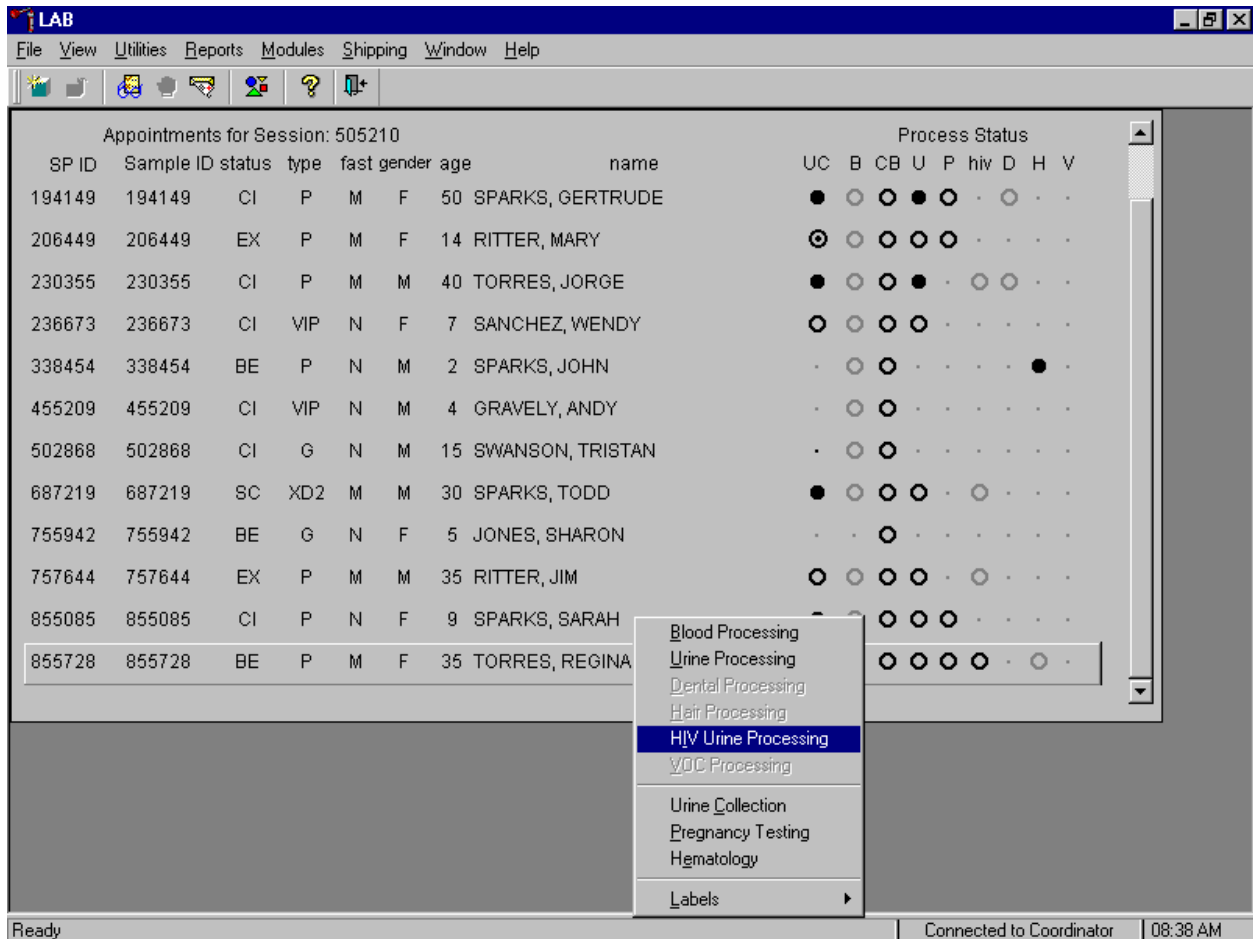
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
20	Crypto	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305415	12
21	Lipids	2	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305416	16
22	HIV	0.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	SP refusal		
23	Insul/Cpep	1	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305423	8
24	HSV	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305418	11
25	FSH/LH	0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305437	3
27	Latex	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305419	14
28	TSH/Thyrox	1	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305429	5
70	Vitamin D	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305420	16

Save Phlebotomy OK Cancel

Ready Connected to Coordinator 08:37 AM

Once the blood processing result for vessel #22 (HIV) is Filled - "No" and the result is saved to the database, the HIV Urine Processing module becomes enabled.

Select the correct SP and access the HIV Urine Processing module.



To access the HIV Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {HIV Urine Processing} and right click or type [I/i]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {HIV Urine Processing}, and right click or type [I/i].

The HIV Urine Processing screen displays.

LAB

File View Utilities Reports Modules Shipping Window Help

HIV: 855728

none

Tech ID: 1115 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
 SP ID: 855728 SubSample: 1 Fasting_Req: 1

Vessel ID	Test Name	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		

Save OK Cancel

Apply changes and close window Connected to Coordinator 08:44 AM

The HIV Urine Processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Type (U=urine), Vessel Volume, Container ID/Slot #, and Filled and Comments buttons.

To mark the HIV urine vessel as collected or Filled – "Yes," use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As this vessel is marked as Filled – "Yes," it is automatically assigned to a slot in an existing (open) container. To mark the HIV urine vessel as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click.

Use the quality comment code to indicate if blood is present.

LAB

File View Utilities Reports Modules Shipping Window Help

HIV: 855728

none

Tech ID: 1226 Sample ID: 855728 Name: TORRES, REGINA Gender: F Age: 35
SP ID: 855728 SubSample: 1 Fasting_Req: 1

Vessel ID	Test Name	Vessel Type	Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none) blood present	0305422	2

Save OK Cancel

Ready Connected to Coordinator 08:46 AM

To enter the quality control comment "blood present" for a filled vessel, use the mouse to direct the mouse arrow to the drop down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present} and left click.

If this vessel is marked as Filled "No," the comment, "quantity not sufficient" is automatically entered in the Comments column.

The screenshot shows a software window titled "LAB" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a sub-window titled "HIV: 855728" with a "none" label. The main area contains a form with the following fields:

Tech ID: 1226	Sample ID: 855728	Name: TORRES, REGINA	Gender: F	Age: 35
SP ID: 855728	SubSample: 1	Fasting_Req: 1		

Vessel ID	Test Name	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not suffic		

At the bottom of the window are buttons for "Save", "OK", and "Cancel". The status bar at the very bottom shows "Ready", "Connected to Coordinator", and "08:46 AM".

Review the information in the urine-processing window and save the data to the database. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **S**ave button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

8.10 Blood Specimen Storage

8.10.1 Blood Specimen Storage Protocol

Fill the blood vessels, enter the blood and HIV urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 8-1.

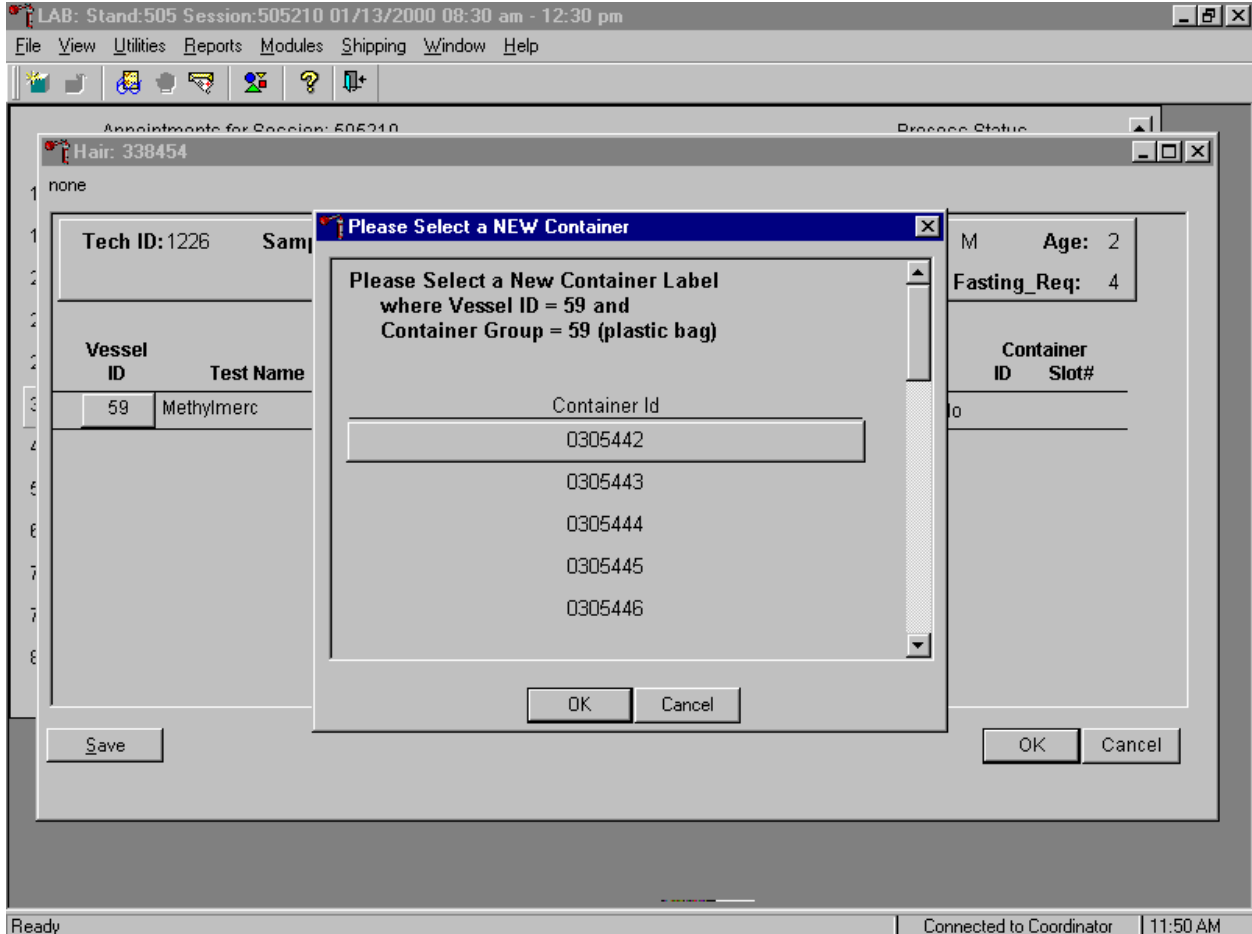
At the beginning of each stand, generate and print a series of bar coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process "opens" a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 8.1. Storage protocol for blood and HIV urine

Shipping Location	Vessels	Conditions	Vessel Storage
CASPIR	1 Lead/Cad	Frozen	9 x 9 two inch box
CASPIR	2 Ery Proto	Frozen	9 x 9 two inch box
CASPIR	3 RBC Folate	Frozen	9 x 9 two inch box
University of Missouri	4 Glycohem	Refrigerated	9 x 9 two inch box
CASPIR	5 Mercury	Frozen	9 x 9 two inch box
CASPIR	6 CD4	Frozen	9 x 9 two inch box
CASPIR	7 Homocys/MMA	Frozen	9 x 9 two inch box
CASPIR	8 Xtra Plasma	Frozen	9 x 9 two inch box
University of Missouri	9 Glucose	Frozen	9 x 9 two inch box
University of Washington	10 Fibrin	Frozen	9 x 9 two inch box
CASPIR	11 Iron/TIBC	Frozen	9 x 9 two inch box
CASPIR	Ferritin	Frozen	9 x 9 two inch box
CASPIR	12 Fol/B12	Frozen	9 x 9 two inch box
University of Washington	13 CRP/Hpylori	Frozen	9 x 9 two inch box
CDC/NCID/Hepatitis Reference	14 Hepatitis	Frozen	9 x 9 two inch box
CASPIR	15 Vit A/E/Car	Frozen	9 x 9 two inch box
Viral and Rickettsial Laboratory	16 Rub/Mea/Var	Frozen	9 x 9 two inch box
CASPIR	17 Cotinine	Frozen	9 x 9 two inch box
Coulston Foundation	18 Biochem	Refrigerated	9 x 9 two inch box
University of Washington	19 Bn Alk Phos	Frozen	9 x 9 two inch box
CDC/Div of Parasitic Diseases	20 Crypto	Frozen	9 x 9 two inch box
Lipoprotein Analytical Laboratory/JHU	21 Lipids	Frozen	9 x 9 two inch box
CDC/NCID/AIDS Division	22 HIV	Frozen	9 x 9 two inch box
University of Missouri	23 Insul/Cpep	Frozen	9 x 9 two inch box
Emory University	24 HSV	Frozen	9 x 9 two inch box
Coulston Foundation	25 FSH/LH	Frozen	9 x 9 two inch box
CASPIR	26 Selenium	Frozen	9 x 9 two inch box
CDC/Hospital Infections Program	27 Latex	Frozen	9 x 9 two inch box
Coulston Foundation	28 TSH/Thyrox	Frozen	9 x 9 two inch box
CASPIR	70 Vitamin D	Frozen	9 x 9 two inch box
CASPIR/Dr. Wayman Turner	29 Persis Pest	Frozen	9 x 9 three inch box
CASPIR/Dr. Wayman Turner	63 Dioxins	Frozen	9 x 9 three inch box
CASPIR/Dr. Charles Dodson	64 Phytoestro	Frozen	9 x 9 three inch box
CASPIR	32-42 Xtra Serum	Frozen	9 x 9 two inch box
CASPIR	43 DNA	Frozen	5 x 5 three inch box
Molecular Biology Branch	44 & 71 WBC/DNA	Room temperature	5 x 5 five inch box
CDC/NCID/AIDS Division	53 HIV Urine	Refrigerated	9 x 9 three inch box

8.10.2 Opening New Containers

When a container is full, the container will automatically "close." Open a new container to replace the closed container.

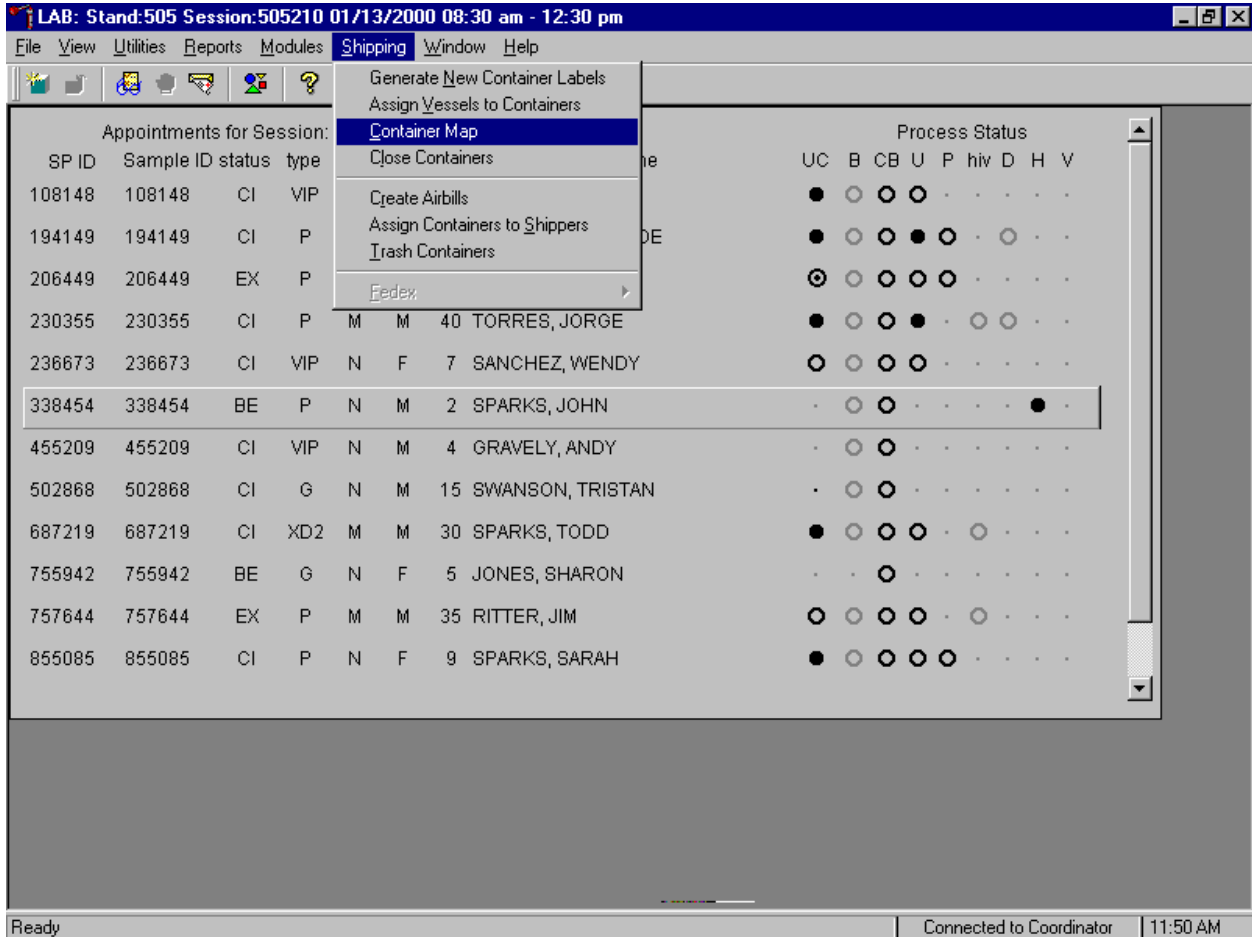


When a container is full, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

8.10.3 Check Storage Containers

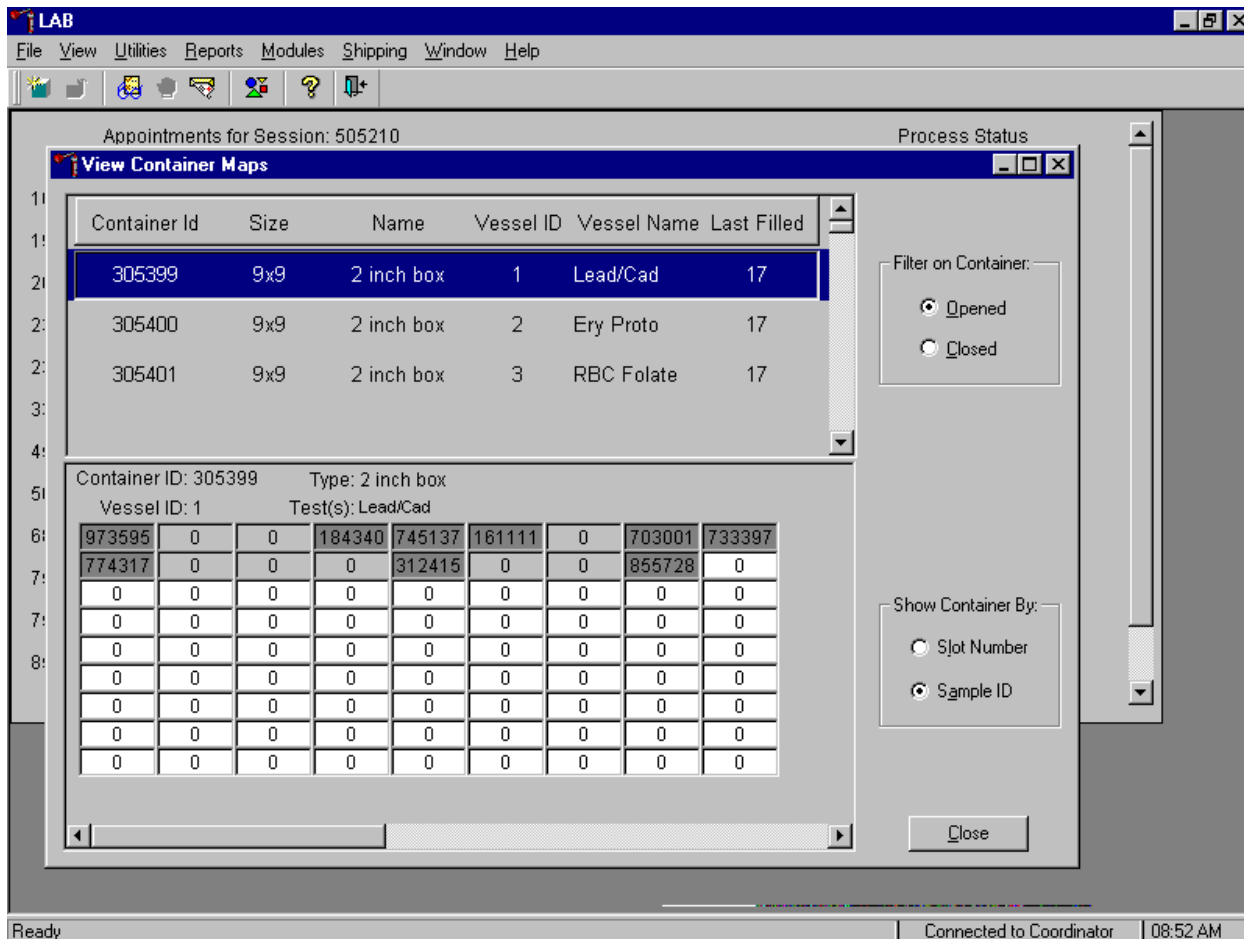
Check the slot assignment of containers associated with vessels 1-32, 43-44, 63-64 and 68, at the end of each session.

Access the Container Map report.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping}, drag the arrow to {Container Map} and left click or type [Alt] [S], [C] or [Alt] [R], [C].

Verify the contents of each container against the container map.

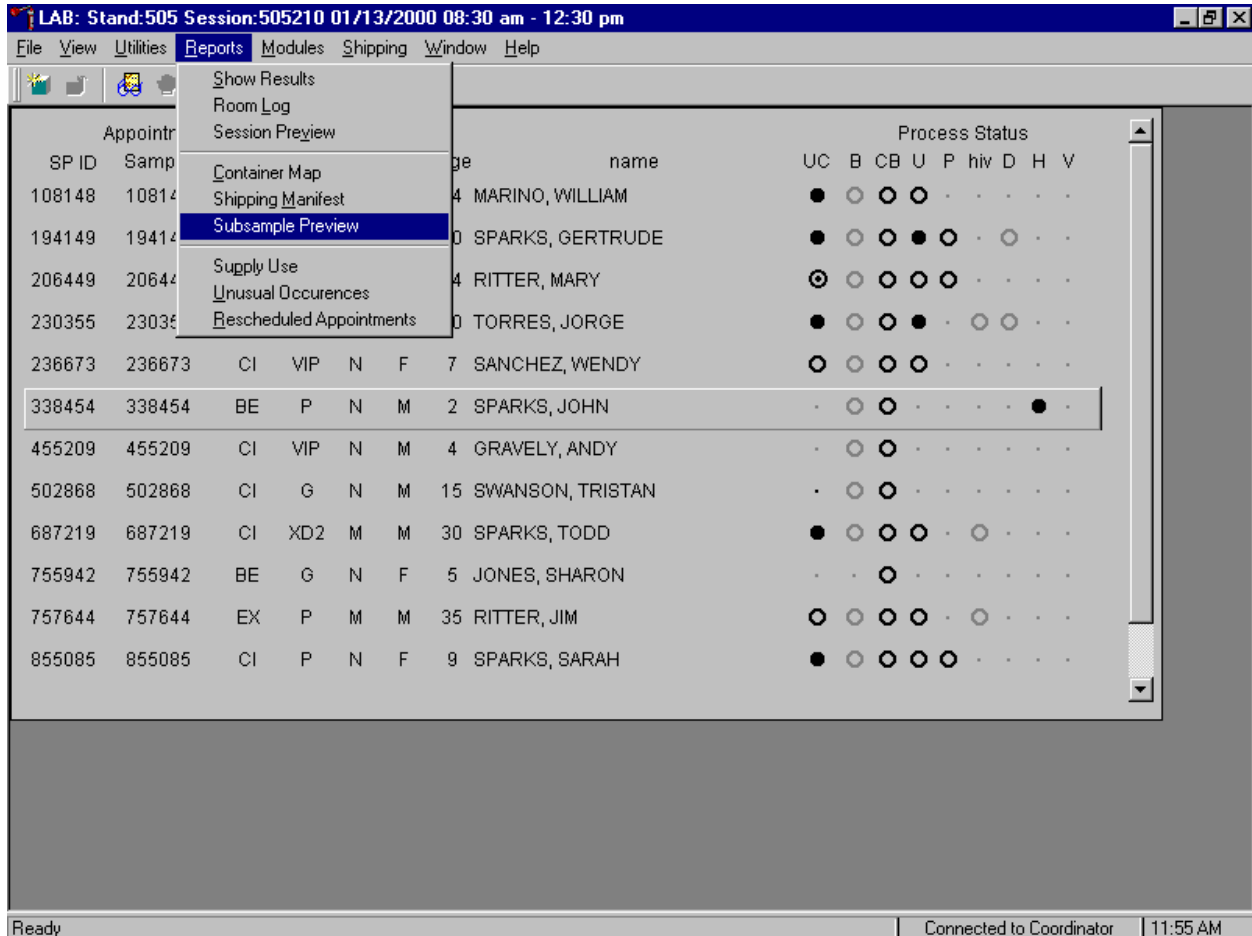


- Set the Filter on Container to "Opened" by using the mouse to direct the mouse arrow to "Opened" and left click.
- Set the Show Container By to "Sample ID" by using the mouse to direct the mouse arrow to "Sample ID" and left click.
- Highlight or select the first container ID for vessel 1 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 1.
- To sort on Container ID, Size, Name, Vessel ID, Vessel Name, or Last Filled, use the mouse to direct the mouse arrow to any column title and right click. To reverse the order, use the mouse to direct the mouse arrow to the column title and right click.

- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining blood and HIV urine containers.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

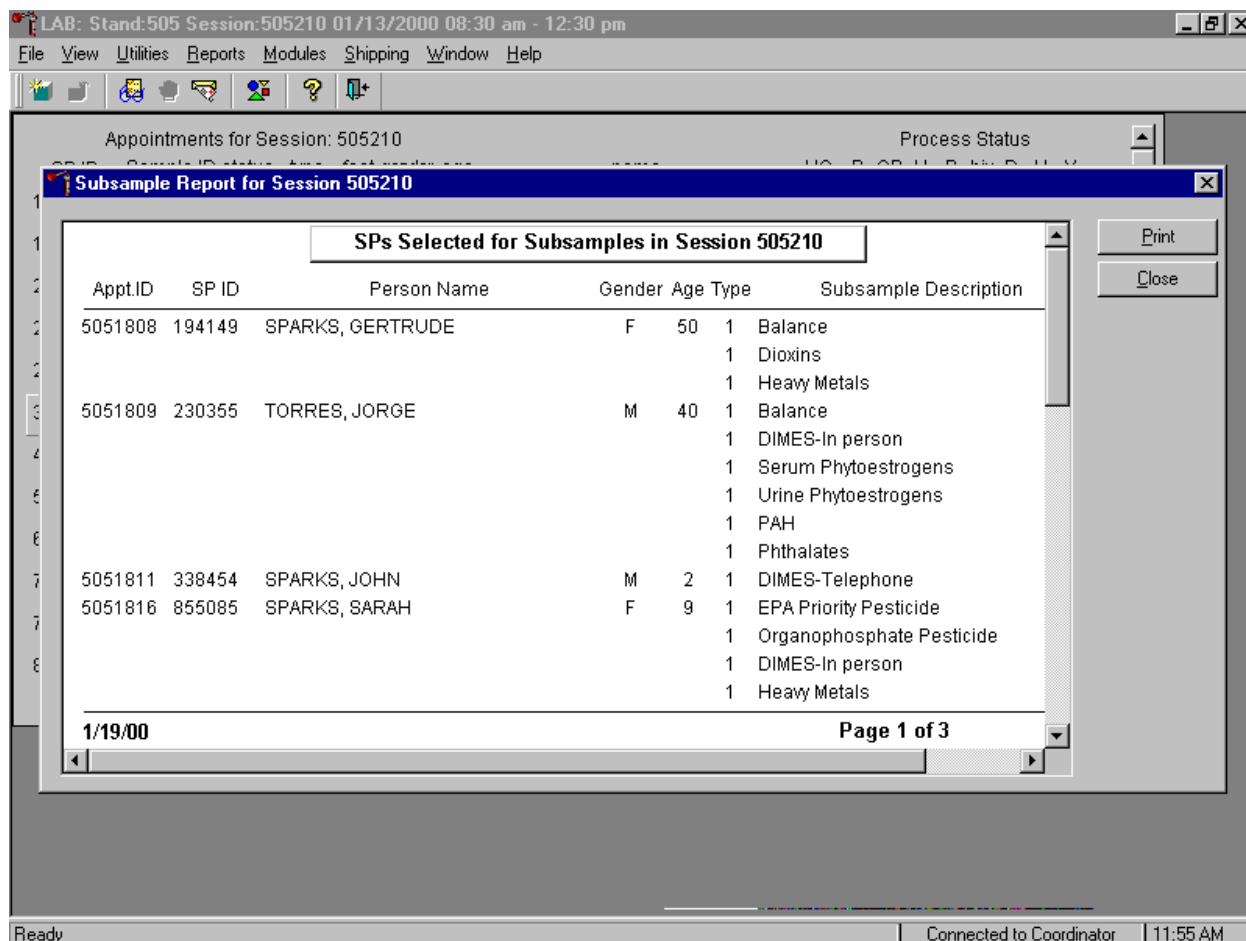
8.11 Subsample and Session Previews

Access the Subsample Preview report to view all SPs in the current session and the selected subsamples for which they are eligible.



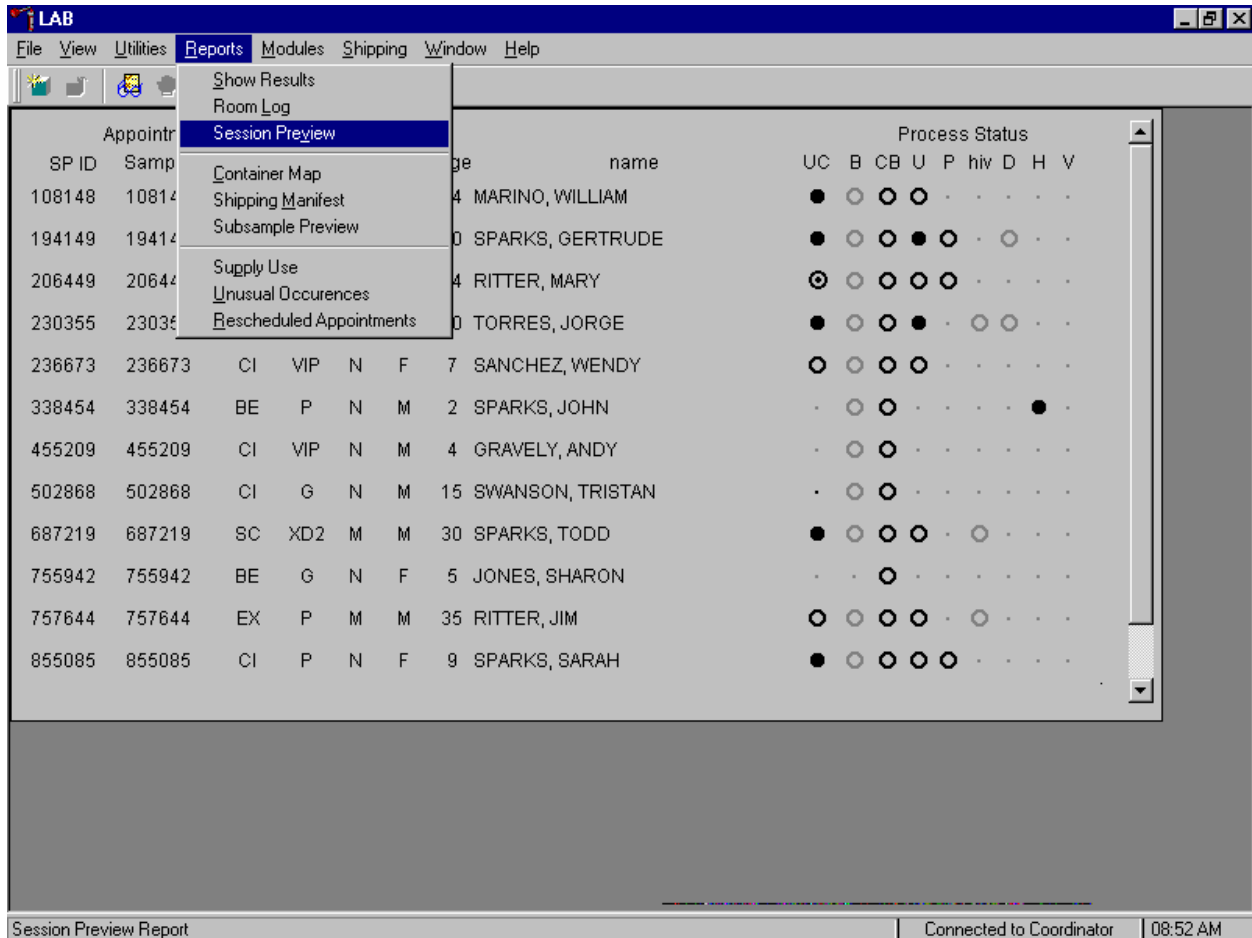
To access the Subsample Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Subsample Preview}, and left click.

Review the Subsample Preview report.



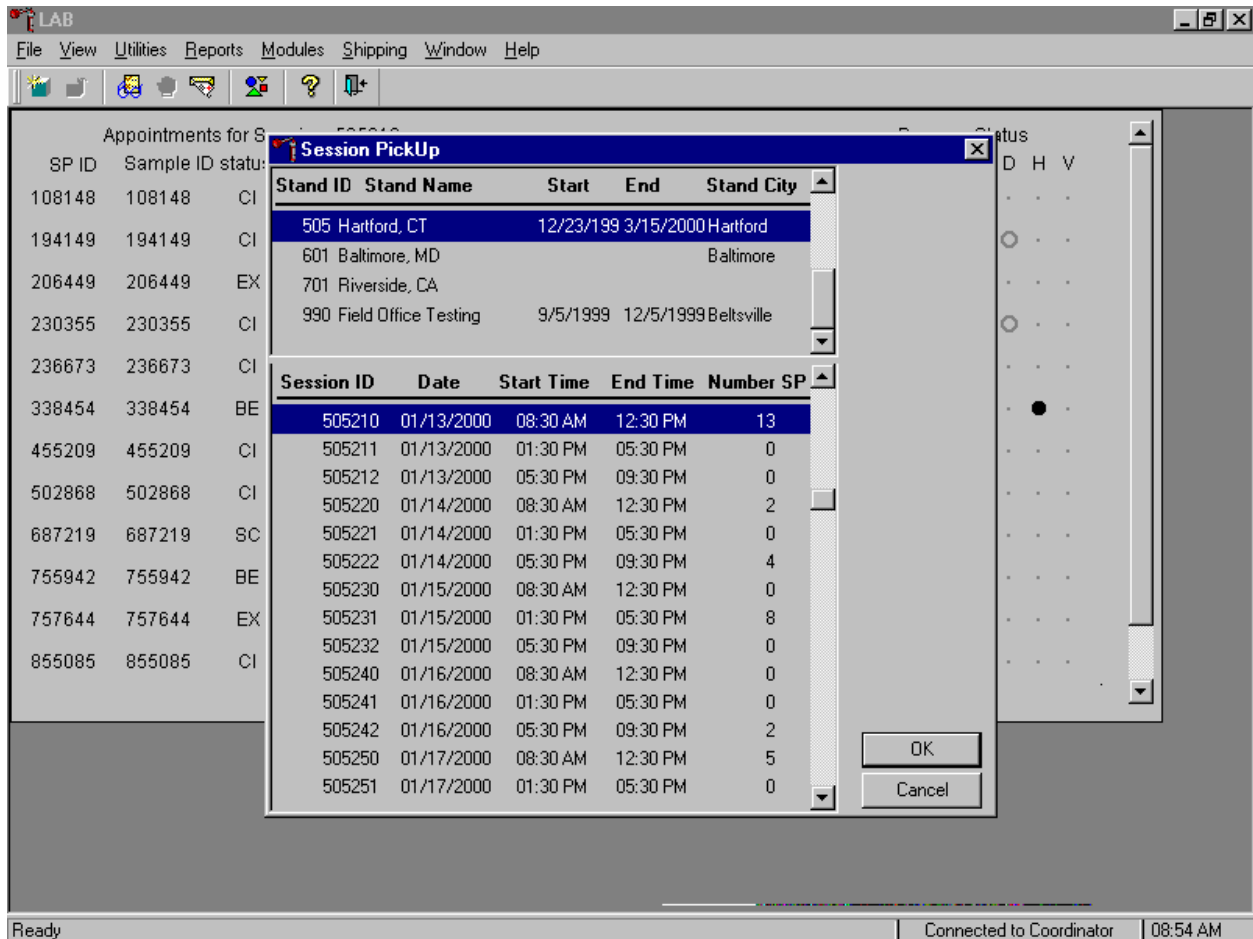
The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible to have the related vessel filled. To view the entire report, use the mouse to direct the mouse arrow to the vertical scroll bar, and drag the bar up or down. To print a copy of the report, use the mouse to direct the mouse arrow to the **Print** button and left click. To exit and close the report, use the mouse to direct the mouse arrow to the **Close** button and left click.

Access the Session Preview report to view all SPs scheduled into any session including the current session.



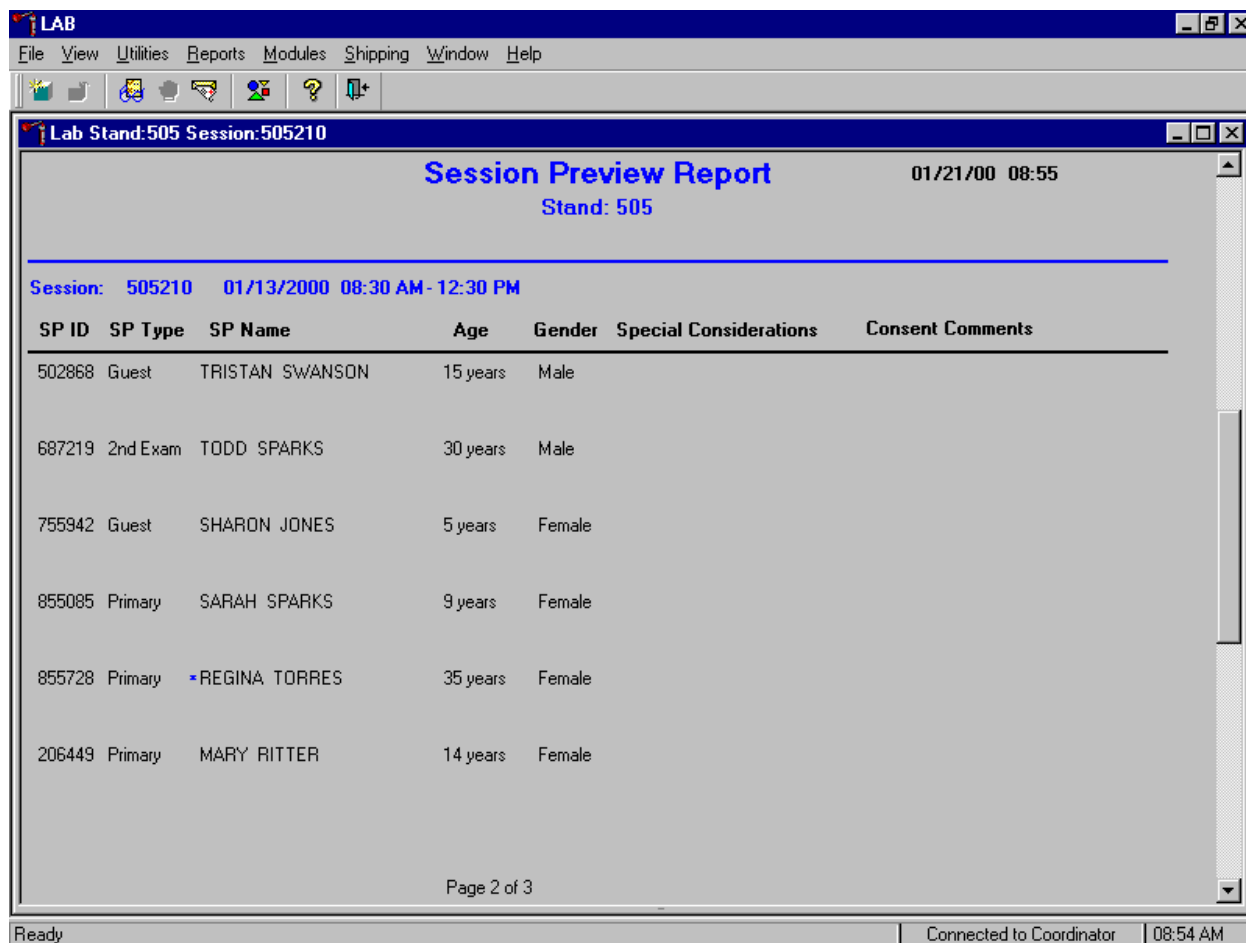
To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Session Preview} and left click or type [Alt] [R], [V].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The Session Preview Report displays.



The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last) Age, Gender and any special considerations or consent comments. A blue asterisk in front of the name indicates that the SP is eligible for the VOC component.

8.12 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 1 Processing Worksheet (Exhibit 8-27). Complete a Workstation 1 worksheet for each SP while processing the blood and HIV urine specimens. Enter the results after the system is operational.

Exhibit 8-27. Workstation 1 worksheet

BLOOD PROCESSING AND HIV URINE PROCESSING

SP ID _____

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>QNS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	WB				
2	Ery Proto	1-11 12+	0.3 0.4	WB				
3	RBC Folate	3+	0.1	WB				
4	Glycohem	12+	0.4	WB				
5	Mercury	1-5 16-49	0.5 1.0	WB				
6	CD4	18-49	0.5	WB				
7	Homocys/MM A	3+	1.0	P				
8	Xtra Plasma	6+	0.5	P				
9	Glucose	12+	0.5	P				
10	Fibrin	40+	1.0	P				
11	Iron/TIBC	1-2 3+	1.2 1.0	S				
68	Ferritin	1+	0.3	S				
12	Fol/B12	3-5 6+	0.8 1.3	S				
13	CRP/Hpylori	3+	0.5	S				
14	Hepatitis	2-5 6+	0.2 1.5	S				
15	Vit A/E/Car	3-11 12+	0.3 0.4	S				
16	Rub/Mea/Var	6-49	0.4	S				
17	Cotinine	3-11 12+	1.5 2.0	S				
18	Biochem	12-150	0.8	S				
19	<i>Bn Alk Phos</i>	8+	0.5	S				
20	Crypto	6-11 12-49	0.2 0.5	S				

Exhibit 8-27. Workstation 1 worksheet (continued)

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>QNS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	S				
22	HIV	18-49	0.5	S				
23	Insul/Cpep	12+	1.0	S				
24	HSV	14-49	0.5	S				
25	FSH/LH	35-60	0.8	S				
26	Selenium	3-11	0.3	S				
27	Latex	12-59	0.5	S				
28	TSH/Thyrox	12+	1.0	S				
70	Vitamin D	6+	0.5	S				
29	Persis Pest	12+	4.0	S				
63	Dioxins	12+	4.0	S				
64	Phytoestro	12+	4.0	S				
32	Xtra Sera	6+	0.5	S				
33	Xtra Sera	6+	0.5	S				
34	Xtra Sera	6+	0.5	S				
35	Xtra Sera	12+	0.5	S				
36	Xtra Sera	12+	0.5	S				
37	Xtra Sera	12+	0.5	S				
38	Xtra Sera	12+	0.5	S				
39	Xtra Sera	12+	0.5	S				
40	Xtra Sera	12+	0.5	S				
41	Xtra Sera	12+	0.5	S				
42	Xtra Sera	12+	0.5	S				
43	DNA	20+	17.0	C				
44	WBC/DNA	20+	8.0	WB				
71	WBC/DNA	20+	8.0	WB				
53	HIV Urine	18-49	5.0	U				

WB = Whole Blood P = Plasma S = Serum C = Clot U = Urine

9. PRINTING LABELS AND SPECIMEN SHIPMENT

9.1 Introduction

Labels are essential to the laboratory component. Labels support each SP's unique processing protocol. When blood, urine, hair, and dental vessel labels, and pregnancy test labels are generated, the laboratory record is created. This record forms the basis for each SP's data in the database. Container labels are generated and assigned to vessel storage containers and allow a processed sample to be tracked from MEC processing through contract laboratory receipt.

Ship biological specimens to a variety of contract laboratories in double-sided Styrofoam and corrugated cardboard shippers using dry ice or wet ice (refrigerant packs), or padded envelopes. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 9.1, the Shipping Protocol, illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Ship packages using Federal Express, if possible. The chief medical technologist is responsible for contacting Federal Express at the start of each stand to determine availability. The MEC manager arranges for the delivery of dry ice on shipping days. It is the shipping technologist's responsibility to confirm the arrangements for shipping and dry ice delivery with the MEC manager at the beginning of each stand.

The chief medical technologist works with the MEC manager and the home office to determine exactly which days to ship specimens to the contract laboratories. As a rule, pack and ship most specimens once a week during MEC split exam sessions. The only exception is the 8-mL ACD genetic tube. These tubes are shipped within 48 hours of collection, whenever possible. All specimens should arrive at the destination the day after shipping. The next-day limitation may conflict with off days, holidays, and vacations. If a conflict with the shipping schedule, working schedule, or the contract laboratory schedule occurs, consult the MEC manager and the home office.

Exhibit 9-1. Shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Blood				
CASPIR	Lead/Cad	Frozen	9 x 9 two inch box	Weekly
CASPIR	Ery Proto	Frozen	9 x 9 two inch box	Weekly
CASPIR	RBC Folate	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Glycohem	Refrigerated	9 x 9 two inch box	Weekly
CASPIR	Mercury	Frozen	9 x 9 two inch box	Weekly
CASPIR	CD4	Frozen	9 x 9 two inch box	Weekly
CASPIR	Homocys/MMA	Frozen	9 x 9 two inch box	Weekly
CASPIR	Xtra Plasma	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Glucose	Frozen	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	Fibrin	Frozen	9 x 9 two inch box	Weekly
CASPIR	Iron/TIBC	Frozen	9 x 9 two inch box	Weekly
CASPIR	Ferritin	Frozen	9 x 9 two inch box	Weekly
CASPIR	Fol/B12	Frozen	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	CRP/Hpylori	Frozen	9 x 9 two inch box	Weekly
CDC/HRL (Hepatitis Reference Lab)	Hepatitis	Frozen	9 x 9 two inch box	Weekly
CASPIR	Vit A/E/Car	Frozen	9 x 9 two inch box	Weekly
Viral & Rickettsial Disease Lab	Rub/Mea/Var	Frozen	9 x 9 two inch box	Weekly
CASPIR	Cotinine	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	Biochem	Refrigerated	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	Bn Alk Phos	Frozen	9 x 9 two inch box	Weekly
CDC/Div of Parasitic Diseases	Crypto	Frozen	9 x 9 two inch box	Weekly
Lipoprotein Analytical Lab Johns Hopkins University	Lipids	Frozen	9 x 9 two inch box	Weekly
CDC/NCID AIDS Division	HIV - serum	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Insul/Cpep	Frozen	9 x 9 two inch box	Weekly
Emory University (School of Medicine)	HSV	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	FSH/LH	Frozen	9 x 9 two inch box	Weekly
CASPIR	Selenium	Frozen	9 x 9 two inch box	Weekly
Hospital Infections Program/CDC	Latex	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	TSH/Thyrox	Frozen	9 x 9 two inch box	Weekly
CASPIR	Vitamin D	Frozen	9 x 9 two inch box	Weekly
CASPIR/Dr. Wayman Turner	Persis Pest	Frozen	9 x 9 three inch box	Weekly
CASPIR/Dr. Wayman Turner	Dioxins	Frozen	9 x 9 three inch box	Weekly

Exhibit 9-1. Shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
CASPIR/Dr. Charles Dodson	Phytoestro	Frozen	9 x 9 three inch box	Weekly
CASPIR	Xtra Sera	Frozen	9 x 9 two inch box	Weekly
CASPIR	DNA	Frozen	5 x 5 three inch box	Weekly
CDC/MBB (Molecular Biology Branch)	WBC/DNA	Room temperature	5 x 5 five inch box	48 hours
Urine				
University of Minnesota (School of Medicine)	Alb/Creat	Frozen	9 x 9 three inch box	Weekly
CDC/NCID/NCHSTP	Chlam/GC	Frozen	9 x 9 three inch box	Weekly
University of Washington (Immunology Division)	NTX	Frozen	9 x 9 two inch box	Weekly
CASPIR	Urn Iodine	Frozen	9 x 9 three inch box	Weekly
CDC/Dr. Dana Barr	Prior Pest	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	Organophos	Frozen	5 x 5 three inch box	Weekly
CASPIR	Urn Merc	Frozen	9 x 9 three inch box	Weekly
CASPIR	Heavy Metal	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	Urn Phytoes	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	PAH	Frozen	9 x 9 three inch box	Weekly
CDC/Dr. John Brock	Phthalates	Frozen	9 x 9 three inch box	Weekly
CASPIR	Xtra Urine	Frozen	9 x 9 three inch box	Weekly
CDC/NCID AIDS Laboratory	HIV	Refrigerated	9 x 9 three inch box	Weekly
Dental				
CASPIR	Saliva	Frozen	9 x 9 three inch box	Weekly
Hair				
Research Triangle Institute	Methylmerc	Room temperature	12 x 12 bag	Weekly
Lead Dust				
University of Cincinnati	Lead Dust	Room temperature	4 x 4 five inch box	Weekly

9.2 Equipment and Supplies

Exhibit 9-2 contains a list of label/shipping supplies.

Exhibit 9-2. Supplies for labels/shipping

Small Styrofoam shippers	Medium Styrofoam shippers
9 x 9 two inch box	9 x 9 three inch box
5 x 5 five inch box (foam insert)	5 x 5 three inch box
4 x 4 five inch box	Zip closable bags – Quart size
Padded envelope	Newsprint paper
Absorbent packets	Biohazard label
Rubber bands	Keep Frozen label
Tape gun	Refrigerate label
Cryo gloves	Avery 5160 labels
Eye shields	Label stock
Hammer	Printer ribbons
Dry ice scoop	Sheet-fed laser labels
FedEx large boxes	Packaging tape
Clear FedEx label pouches	FedEx preprinted return labels - FO
FedEx Class 9 label	FedEx preprinted return labels - Warehouse
U-TEK Reusable Refrigerant Packs Large	FedEx preprinted return labels - Blank
	U-TEK Reusable Refrigerant Packs Small

9.3 **Print Vessel Labels and Label Blood-Processing Racks**

Before each session, the technologist at workstation 3 prints all labels for all SPs assigned to a session. The correct bar coded labels automatically print for each SP based on the SP's age, sex, person type, and subsample selection. Print pregnancy, urine, blood processing, dental saliva, and hair labels for all SPs in the MEC or home exam session. The phlebotomist, home examiner, and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks.

Distribute labels and assemble blood-processing racks.

- Place pregnancy, urine, and one set of dental labels at workstation 2 in the laboratory.
- Clip the second set of dental labels and the hair labels on the wall grid in the label/shipping area.

Save and recycle unused vessels.

- If the SP does not show up for the appointment, it is possible they will reschedule.
- Store the SP's labels in a zip closable bag until the end of the stand.
- If the SP has not shown up by the end of the stand, recycle the unused vessels.

Assemble blood-processing racks

The home examiner and the medical technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting-up the blood vessel racks and in labeling the vessels with the appropriate bar code label.

Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally making sure the label wraps onto itself. Place the label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

Use the following materials to set up and label blood racks:

- Styrofoam rack
- Age appropriate processing template
- Storage vessels of the following sizes:
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, person type, and subsample selection. When possible, prepare the racks at least one day before the SP arrives for the MEC examination.

- Place the prelabeled blood processing racks in the laboratory at the start of each session.

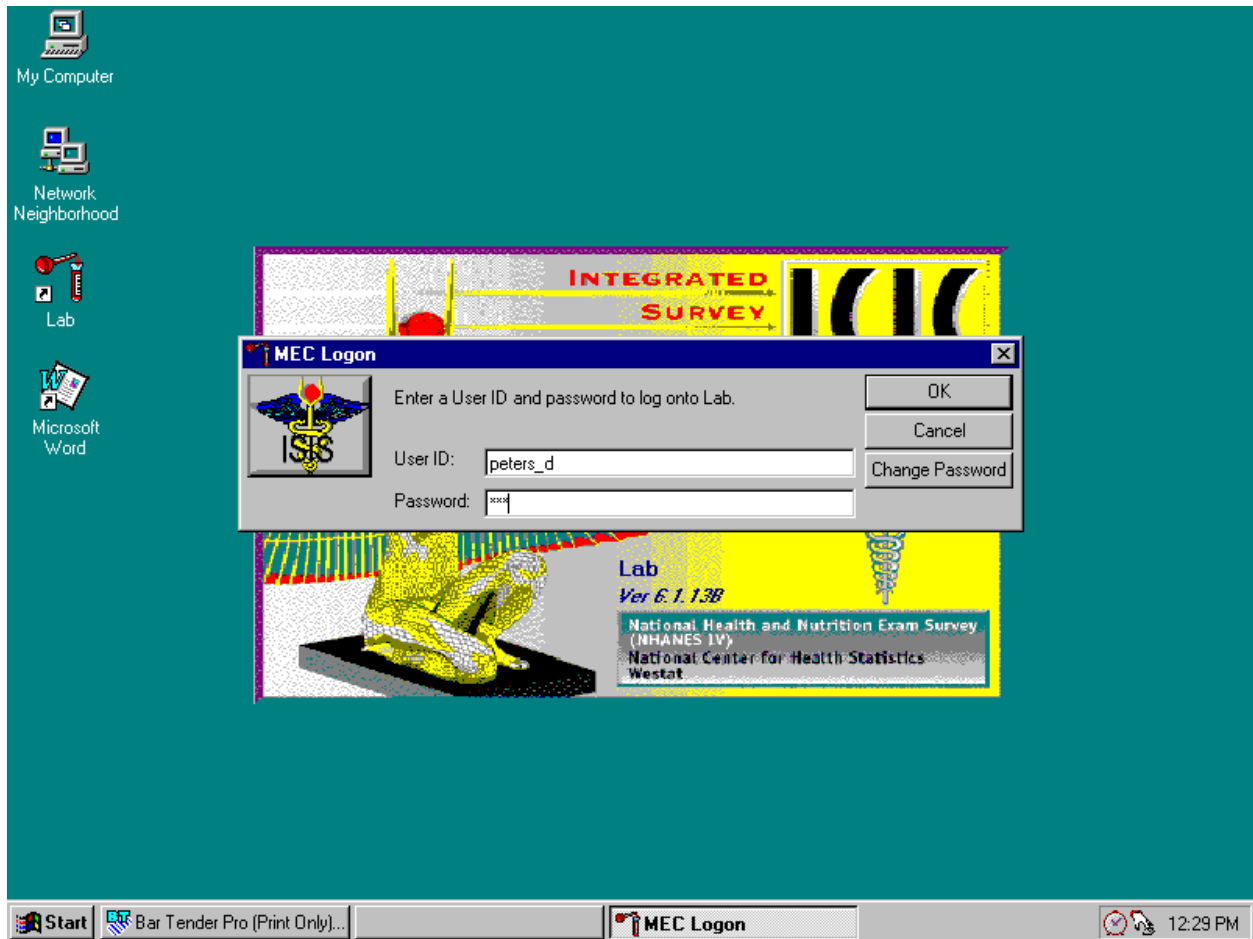
9.3.1 Print Vessel Labels Using the Print Labels Module

Open the laboratory application.



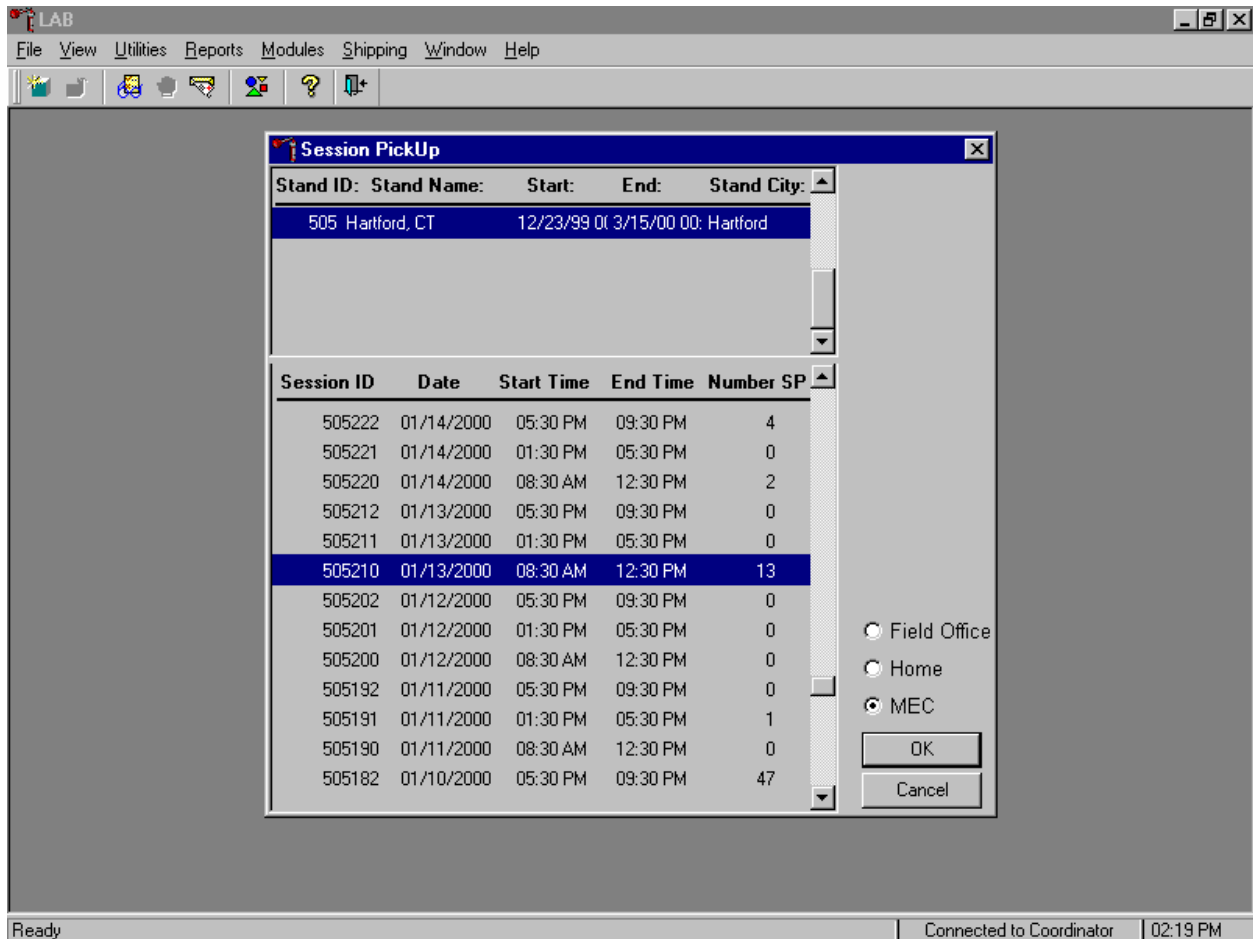
To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Sign onto the computer terminal.



The MEC Logon window displays. Type last name, underscore first initial in the User ID space, and [Tab] or [Enter]. Enter password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the **Cancel** button and left click.

Select the correct filter and session if the MEC is not conducting a session.



The Session Pickup window displays. To select the correct filter, use the mouse to direct the mouse arrow to the MEC or Home radio button and right click to pick up (or filter on) either MEC or home exam sessions. The current stand is displayed in the top section of the window. To select or highlight the correct MEC or home session, use the mouse to direct the mouse arrow to the correct session, date, and time and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter]. The heads-up screen displays. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The laboratory heads-up screen displays.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

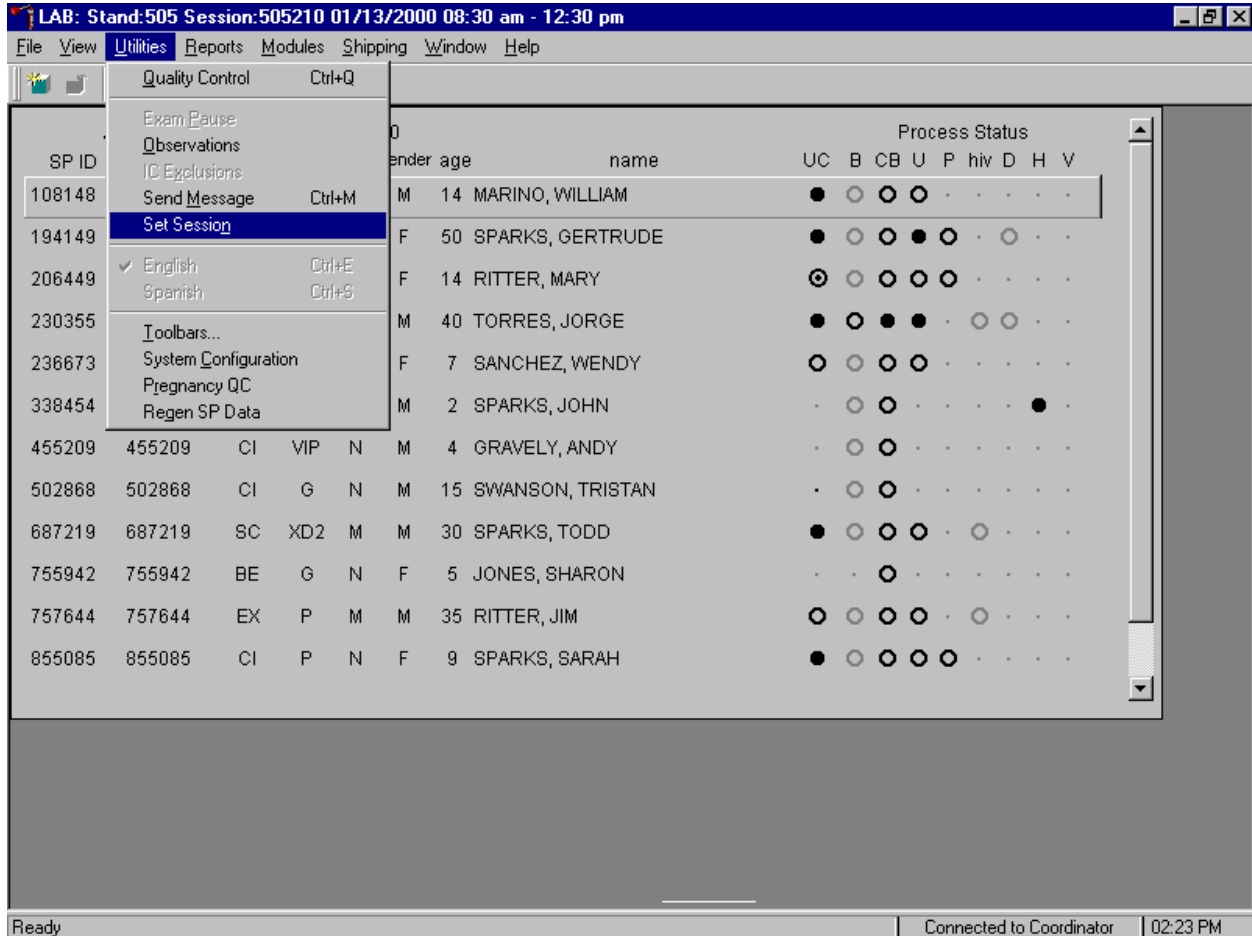
Appointments for Session: 505130

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status								
								UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	●	○	○	○	·	○	·	·	●
213096	213096	SC	P	M	M	89	EPCOT, DRAKE	○	○	○	○	·	·	○	·	·
306541	306541	SC	P	M	F	59	HOFF, GERTA	○	○	○	○	○	·	○	·	·
623410	612408	SC	XD2	M	F	70	LOEWS, FREDERICA	○	○	○	○	·	·	○	·	·
735768	735768	SC	P	M	F	59	RESPOT, FIG	○	○	○	○	○	·	○	·	·
745137	278169	SC	XD2	M	F	22	FELLOWS, STACY	○	○	○	○	○	○	·	○	●
878700	878700	SC	P	M	F	80	EPCOT, EDNA	○	○	○	○	·	·	○	·	·
905688	905688	SC	P	M	M	78	REPOT, ROLAND	○	○	○	○	·	·	○	·	·

Ready | Connected to Coordinator | 02:35 PM

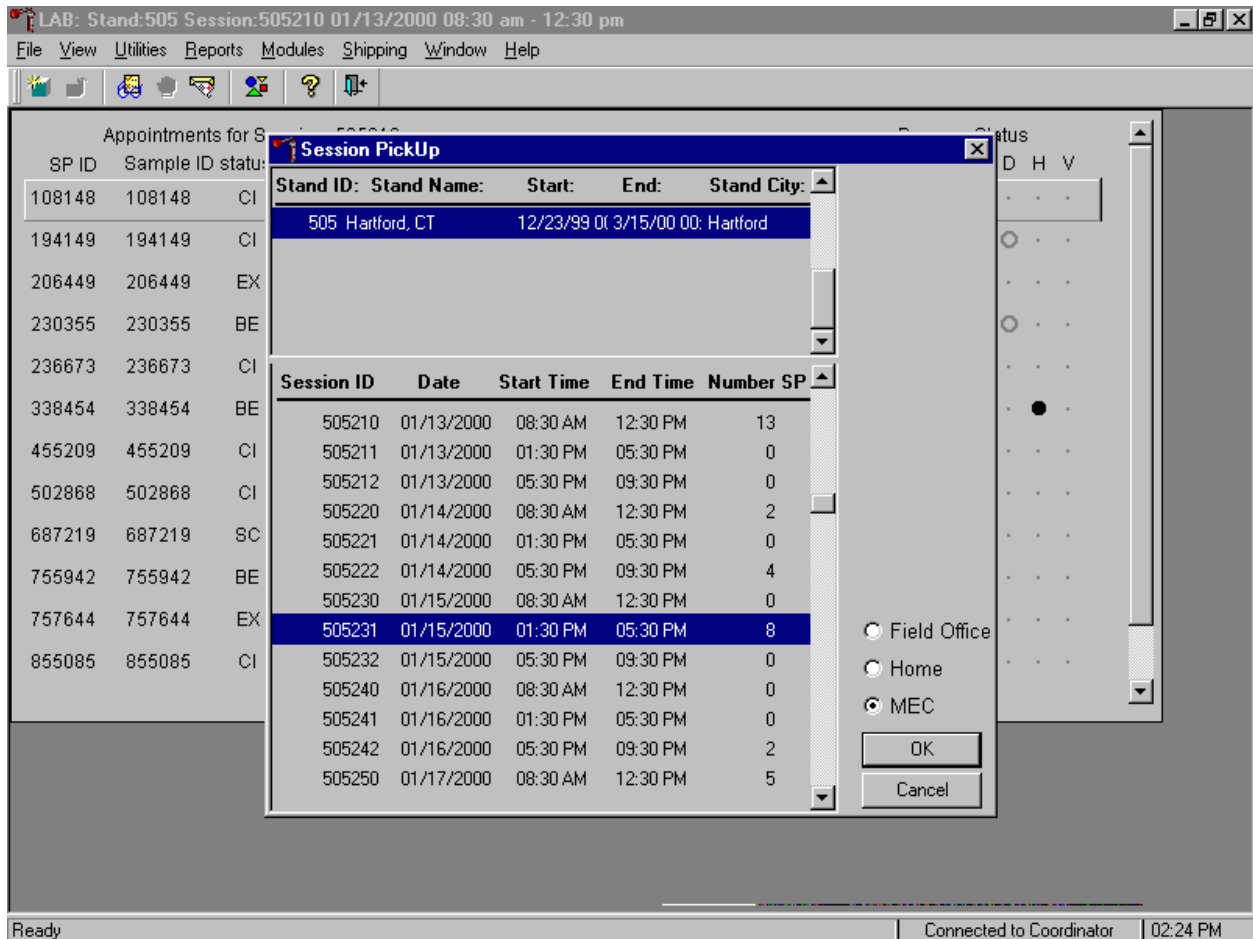
After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays. If the MEC session is in process, the laboratory application defaults to the current MEC session heads-up screen.

Use the Set Session laboratory module to access a different MEC or home examination session.



To access a different MEC or home examination session, use the mouse to direct the mouse arrow to the {Utilities} module in the top menu bar, drag the mouse arrow to {Set Session} and left click, or type [Alt] [U], [N]. The Session Pickup window displays.

Select a different filter and/or session type.



To select a different filter, use the mouse to direct the mouse arrow to the MEC or Home radio button and left click to pick up (or filter on) either MEC or home exam sessions. The current stand is displayed in the top section of the window. To select or highlight a different MEC or home session, use the mouse to direct the mouse arrow to the correct session date and time and left click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter]. The heads-up screen displays. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Use the MEC heads-up display to view the SPs, the modules for which they are eligible and their current process status to access the various laboratory collection, processing and testing modules, and/or to print blood processing labels.

Appointments for Session: 505130								Process Status								
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	●	○	○	○	·	○	·	·	●
213096	213096	SC	P	M	M	89	EPCOT, DRAKE	○	○	○	○	·	·	○	·	·
306541	306541	SC	P	M	F	59	HOFF, GERTA	○	○	○	○	○	·	○	·	·
623410	612408	SC	XD2	M	F	70	LOEWS, FREDERICA	○	○	○	○	·	·	○	·	·
735768	735768	SC	P	M	F	59	RESPOT, FIG	○	○	○	○	○	·	○	·	·
745137	278169	SC	XD2	M	F	22	FELLOWS, STACY	○	○	○	○	○	○	·	○	●
878700	878700	SC	P	M	F	80	EPCOT, EDNA	○	○	○	○	·	·	○	·	·
905688	905688	SC	P	M	M	78	REPOT, ROLAND	○	○	○	○	·	·	○	·	·

The MEC session heads-up display lists all SPs with appointments for the current MEC session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run), fast (M=morning, A=afternoon, E=evening, N=none), Gender, Age, and Name (first and last.)

Use the Home Exam heads-up display to view the home exam SPs, the modules for which they are eligible and their current process status to access the various laboratory collection, processing and testing modules, and/or to print blood processing labels.

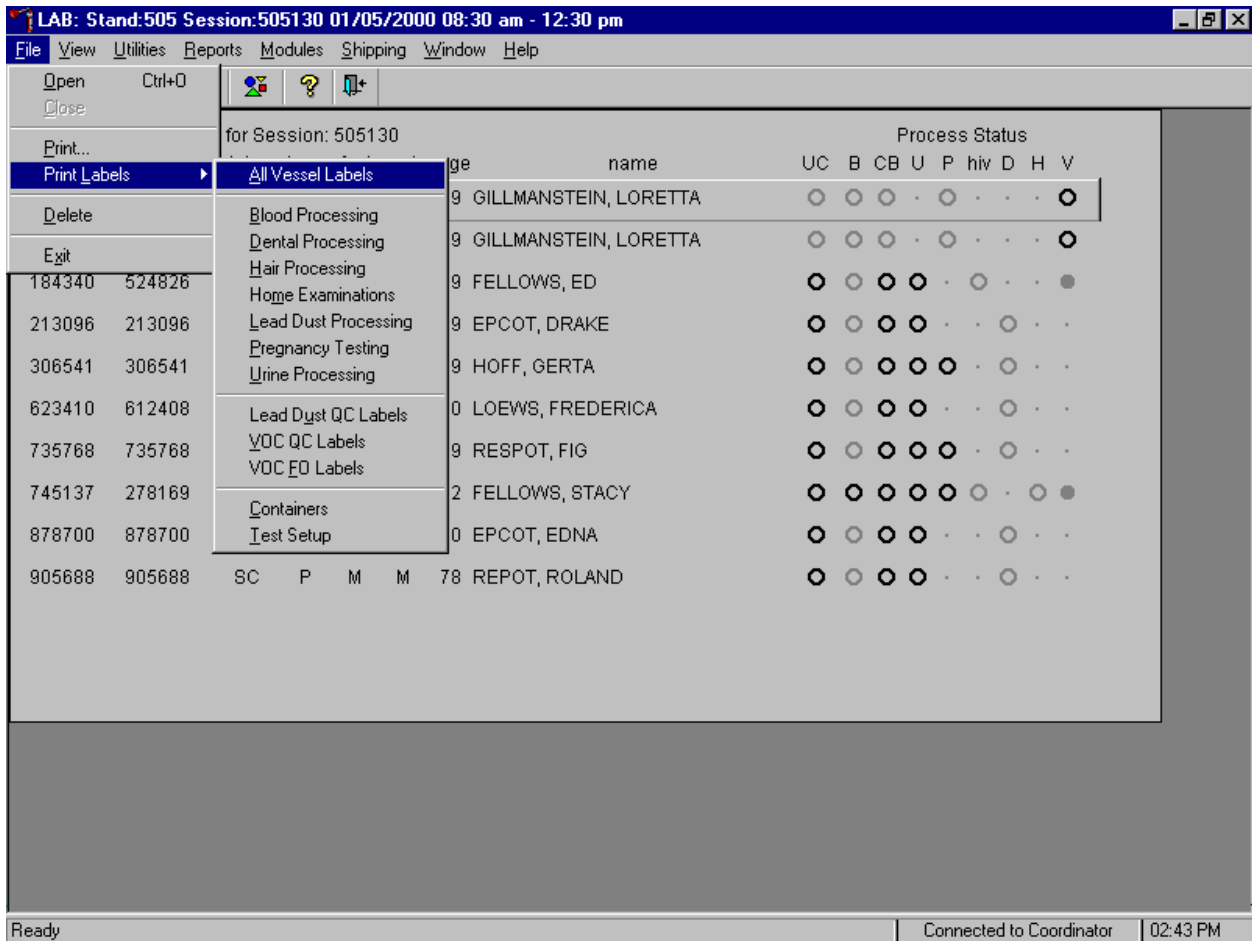
Appointments for Session: 709109								Process Status								
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
559925	559925	EX	H	N	F	99	DEDSAM, HARLIE	.	●	●
888181	888181	SC	H	N	F	63	WELLMAN, ENNIS	.	○	●
918489	918489	EX	H	N	M	89	DEDSAM, ALFRED	.	●	●

Ready | Not connected to Coordinator | 10:20 AM

The Home Exam heads-up display lists home exam SPs scheduled for the session. It lists the SP ID, Sample ID, Status (SC=scheduled, EX=examined), Type (H=home exam), fast (N=none), Gender, Age, and Name (last then first.)

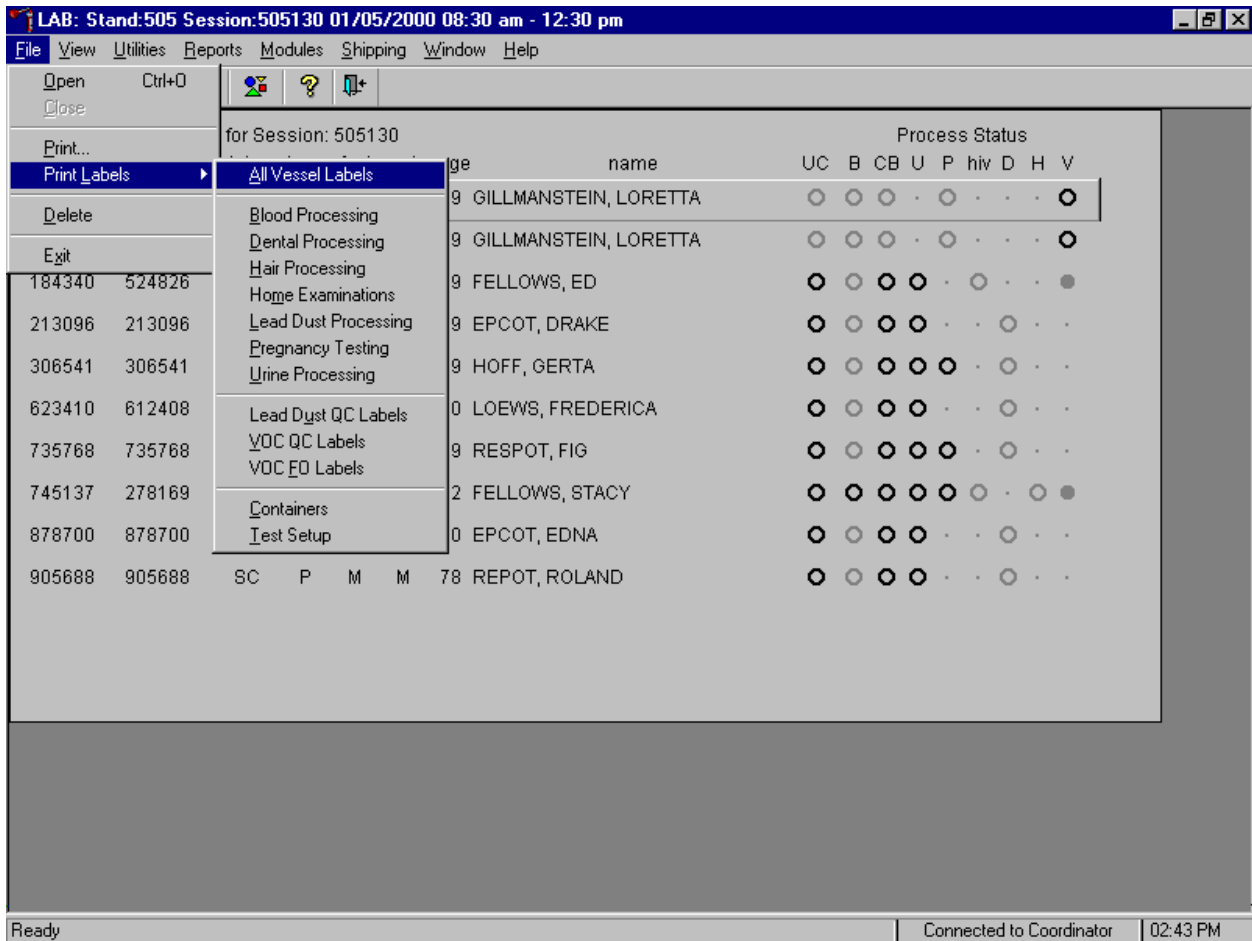
The Home Exam heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), hiv (HIV urine processing), D (dental saliva), H (hair), and V (VOC). The home exam SP is ineligible for all modules except blood processing and CB (complete blood count).

Print vessel labels.



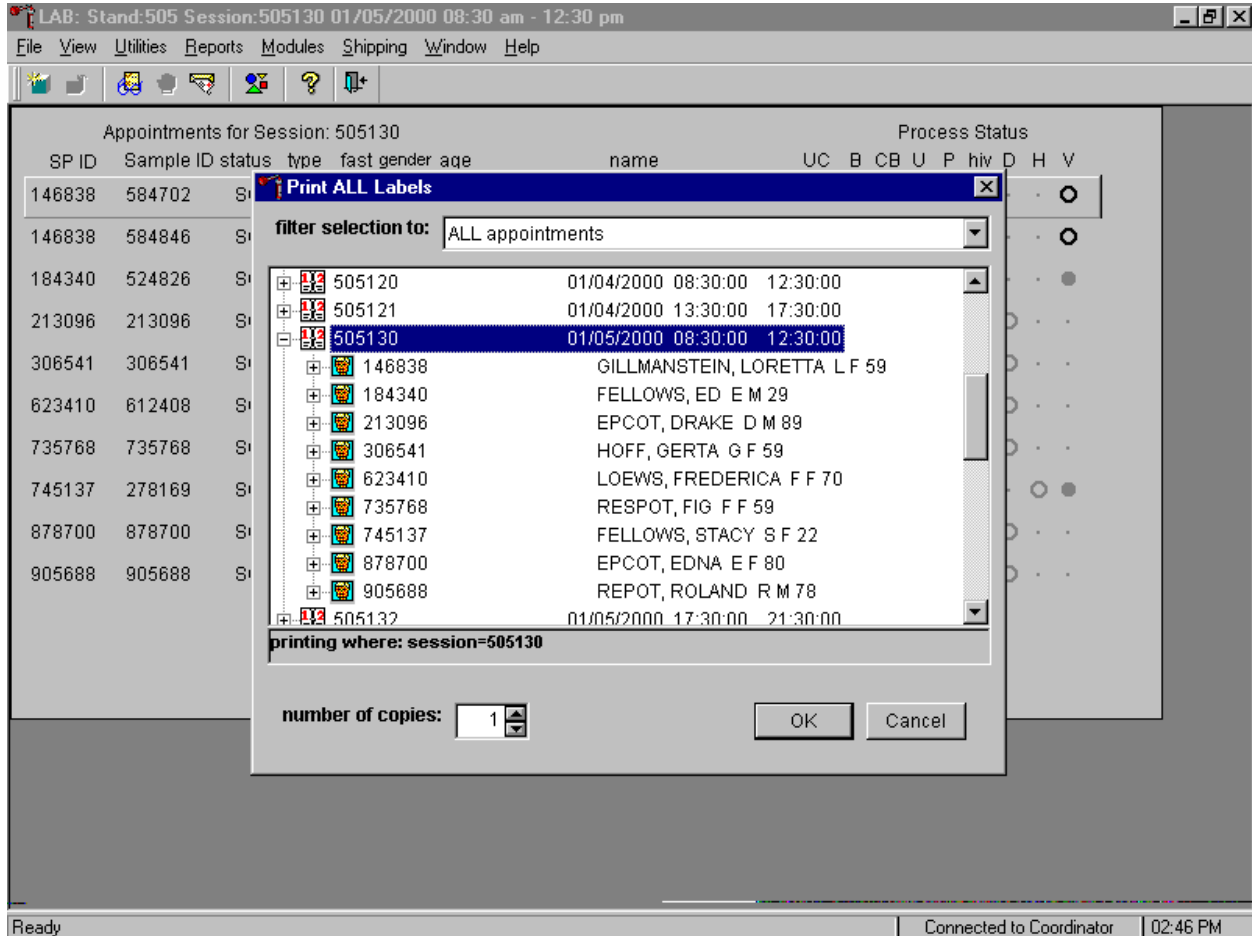
It is possible to (1) print labels for all modules (blood, dental, hair, home, pregnancy and urine), or individual modules; (2) print labels for all SPs in a session or individual SPs; or (3) print labels for ALL appointments, appointments NOT previously printed, or appointments PREVIOUSLY printed.

Print vessel labels for all modules.



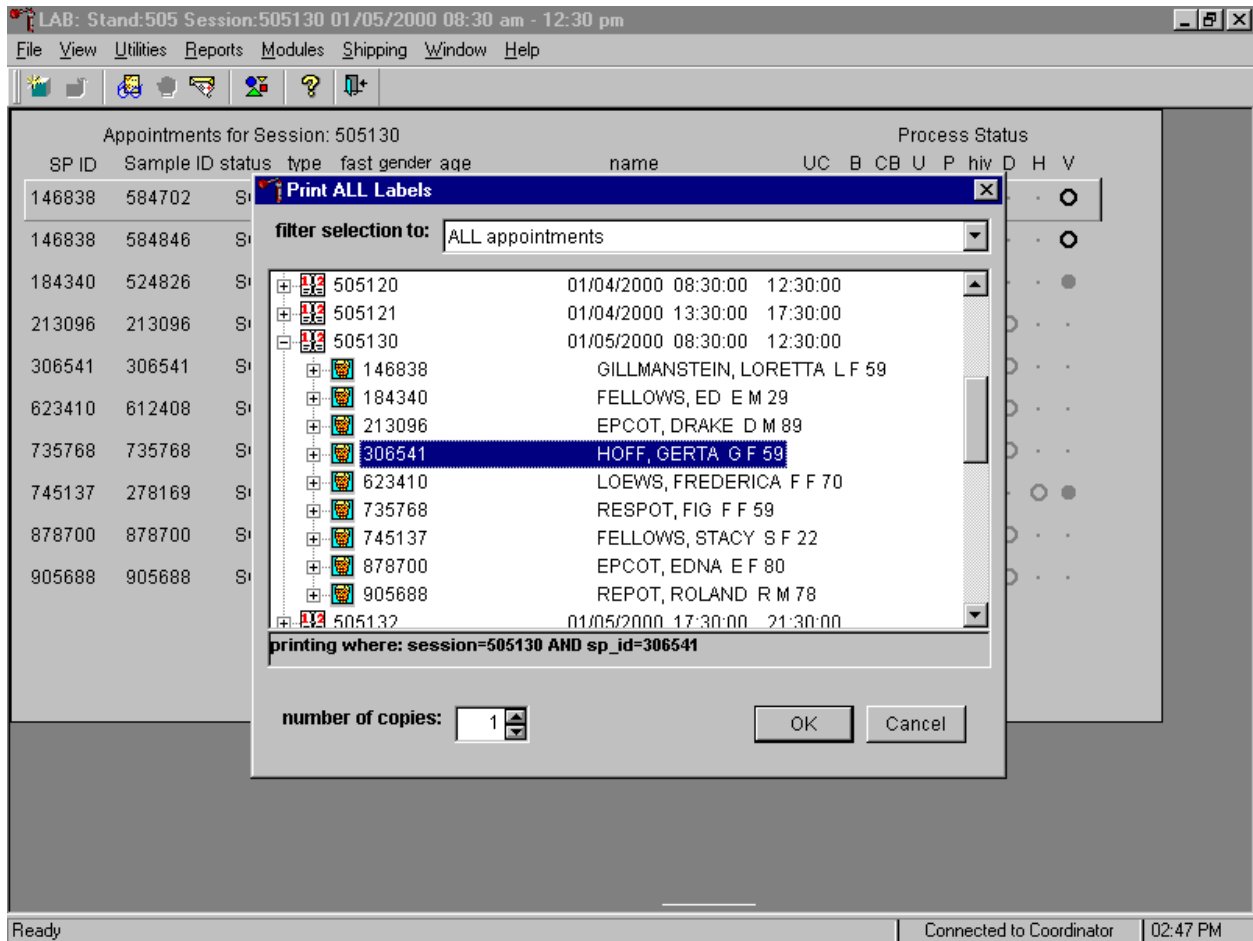
To print vessel labels for all modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {All Vessel Labels} and left click or type [Alt] [F], [L], [A]. Selecting {All Vessel Labels} prints a complete set of blood processing, urine processing, pregnancy testing, dental, and hair labels. The Print All Labels window displays.

Use the Print All Labels window to print vessel labels for all modules for all SPs in either a MEC or home exam session.



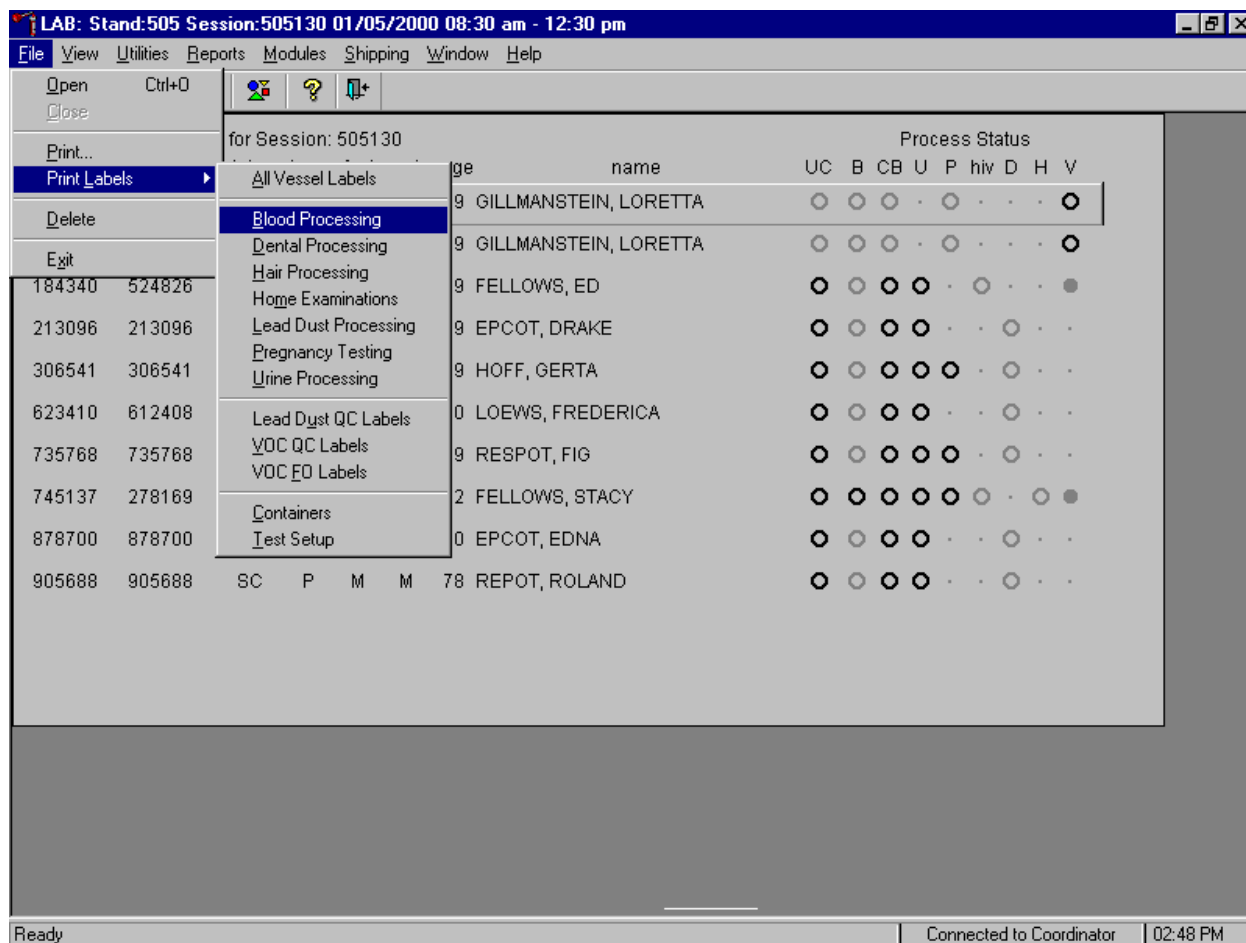
To print vessel labels for all modules for all SPs in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Print vessel labels for all modules for one SP in a MEC or home exam session.



To print vessel labels for all modules for one SP in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Print labels for one specific module for all SPs or one SP in a MEC or home exam session.



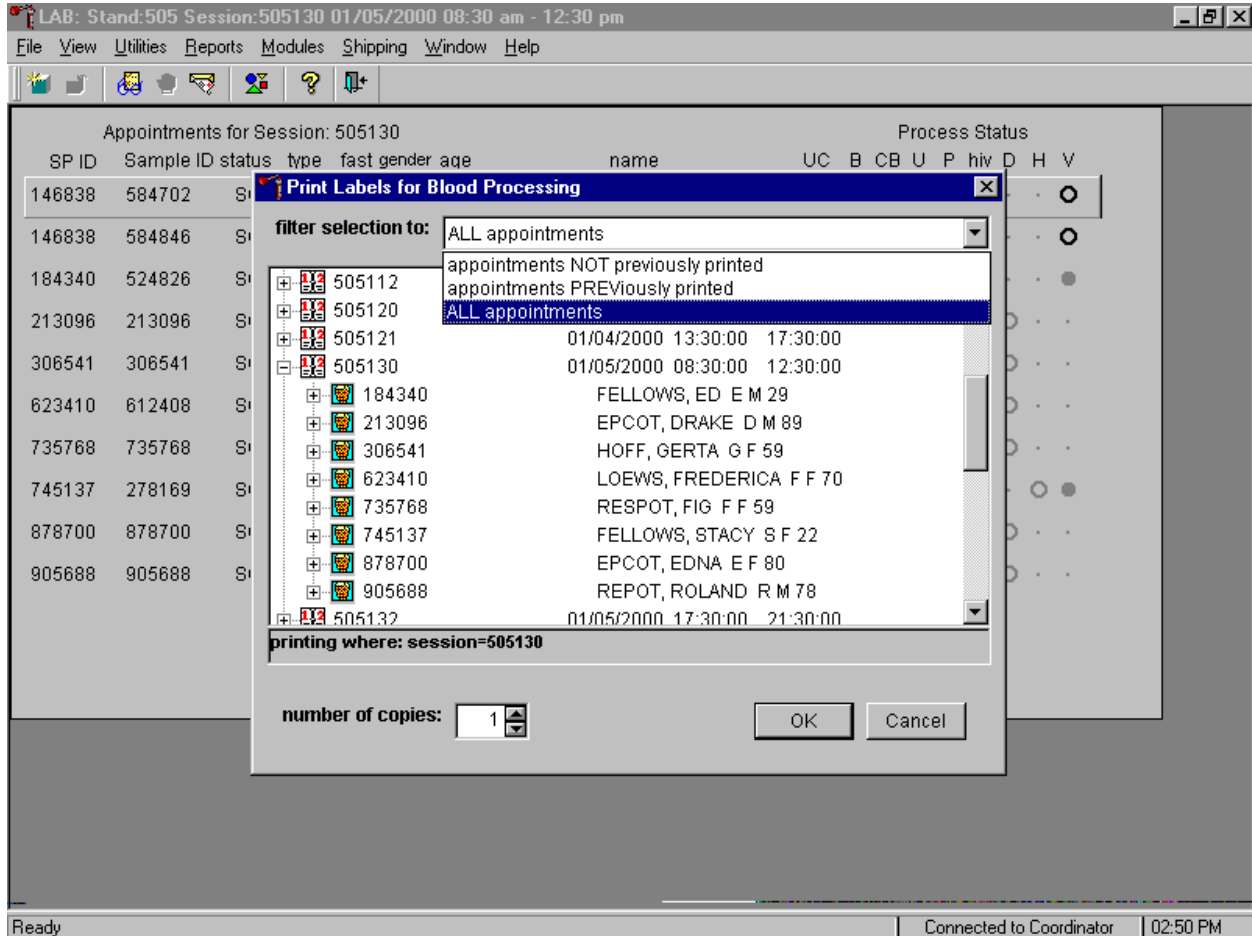
To print labels for one specific module, use the mouse to direct the mouse arrow to {File} and left click, drag the mouse arrow to {Print Labels}, then to {Blood Processing}, {Dental Processing}, {Hair Processing}, {Home Examinations}, {Pregnancy Testing}, or {Urine Processing}, and left click. Alternatively, to print labels for one specific module, type [Alt] [F], [L], then identify the module by typing [B]{Blood Processing}, [D]{Dental Processing}, [H]{Hair Processing}, [M]{Home Examinations}, [P]{Pregnancy Testing}, or [U]{Urine Processing}. The Print Labels window displays.

To print vessel labels for one specific module for all SPs in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using

the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the button and left click or select [Enter]. To exit without printing any labels use the mouse to direct the mouse arrow to the button and left click.

To print vessel labels for one specific module for one SP in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the button and left click or select [Enter]. To exit without printing any labels use the mouse to direct the mouse arrow to the button and left click.

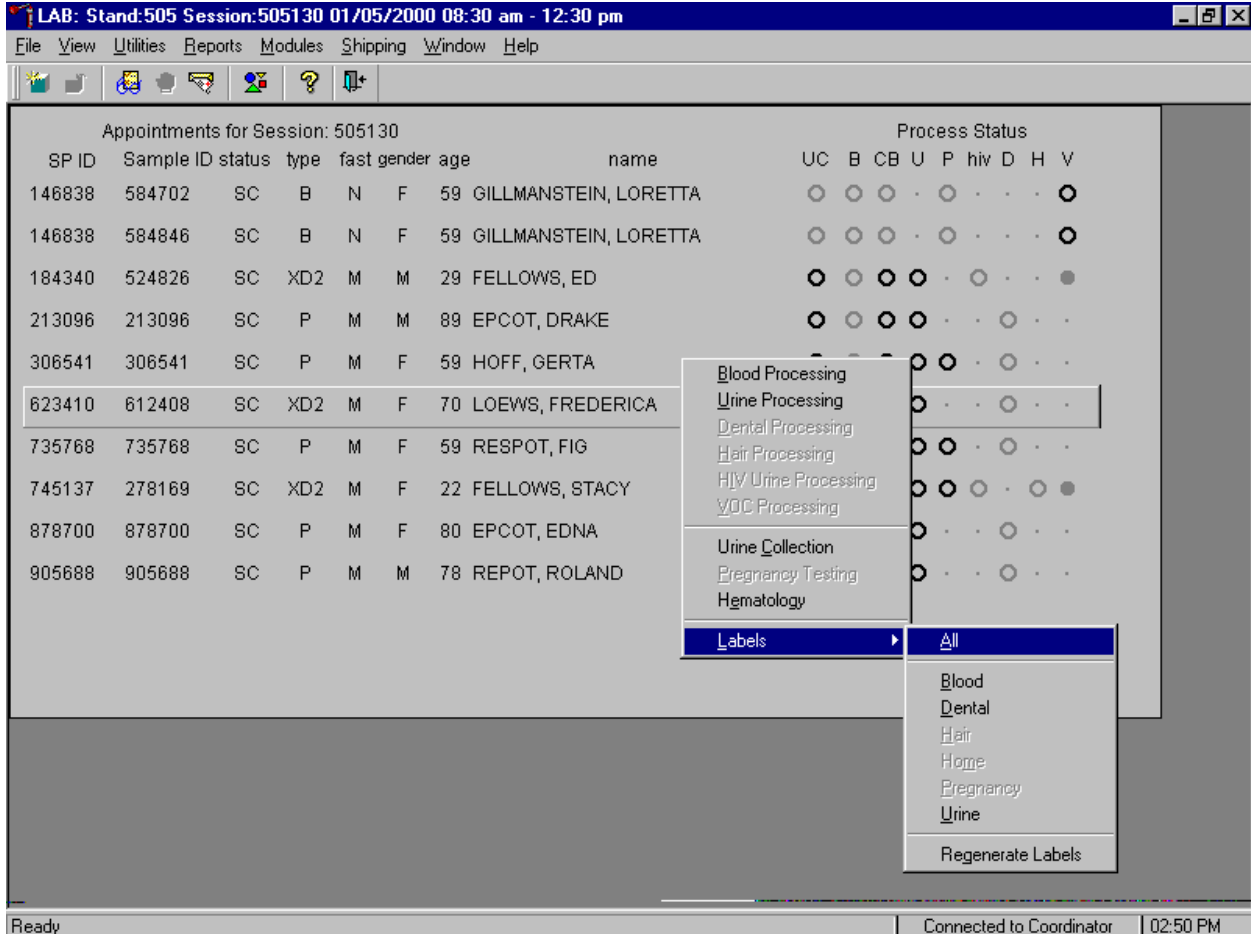
It is also possible to print labels for specific SPs using criteria such as “appointments NOT previously printed,” or “appointments PREVIOUSLY printed” by using a filter.



The default filter selection is “ALL appointments.” To select or change a filter, use the mouse to direct the mouse arrow to the drop down list on the “Filter Selection to:” box and drag the mouse arrow to “Appointments NOT previously printed,” “Appointments PREVIOUSLY printed,” or “All appointments” and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

9.3.2 Print Vessel Labels Using the Heads-up Display

Print labels for a particular MEC or home exam SP using the heads-up display. Print labels for all modules or for a specific module.



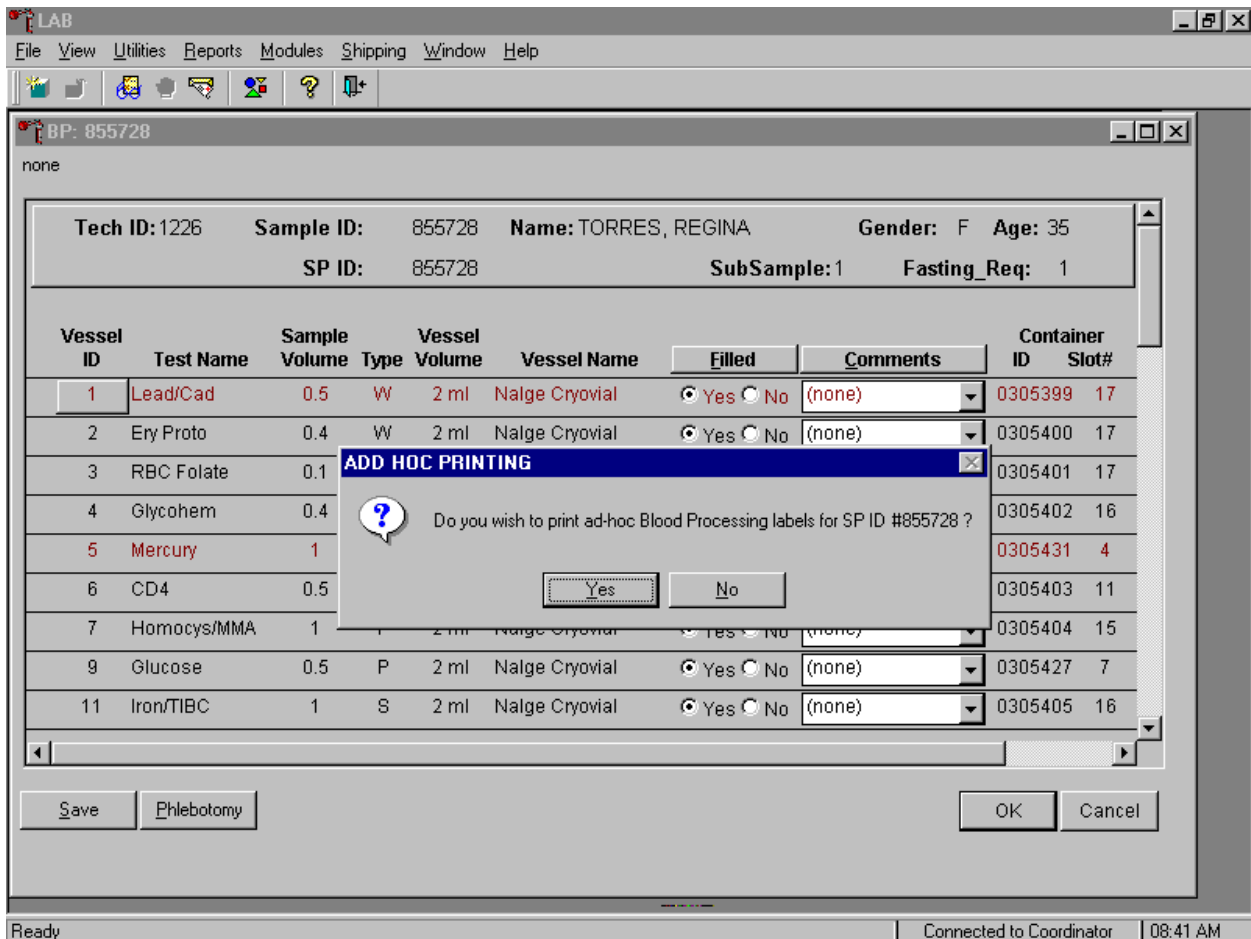
To print labels for all modules for a particular MEC or home exam SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to {All} and left click or use the mouse to direct the mouse arrow to the correct SP, right click and type [L], [A]. Labels print in the label/ship area.

To print labels for one module (Blood, Dental, Hair, Home, Pregnancy, Urine) for a particular MEC or home exam SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to the specific module and left click, or use the mouse to direct the mouse

arrow to the correct SP, right click and type [L], and the first letter of the module name. Labels print in the label/ship area.

9.3.3 Print an Ad-Hoc Vessel Label Using the Heads-up Display

Print an ad-hoc label for any individual vessel.



To print one ad-hoc label for any one vessel, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the message text box request. To print the label and remove the message text box, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y] or select [Enter]. To remove the message text box

without printing a label, use the mouse to direct the mouse arrow to the **No** button and left click or type [N].

9.3.4 Rescheduled Appointments

If the SP does not show up for a MEC exam or the home exam is cancelled, it is possible they will reschedule. Previously generated labels and vessels may be stored in individual zip closable bags. At the beginning of each session, use the Rescheduled Appointments report to view a list of rescheduled SPs.

SP ID	Samp	Appointr	ge	name	UC	B	CB	U	P	hiv	D	H	V
146838	58470			GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
146838	58484			GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●
184340	52482			FELLOWS, ED	●	○	○	○	·	○	·	·	●
213096	21309			EPCOT, DRAKE	○	○	○	○	·	·	○	·	·
306541	306541	CI	P	M	F	59							
623410	612408	SC	XD2	M	F	70							
735768	735768	CI	P	M	F	14							
745137	278169	SC	XD2	M	F	22							●
878700	878700	CI	P	M	F	80							
905688	905688	SC	P	M	M	78							

Ready | Connected to Coordinator | 02:59 PM

To access the Rescheduled Appointments report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, left click, drag the mouse arrow to {Rescheduled Appointments} and left click or type [Alt] [R], [[R].

The Rescheduled Appointments report or a message text box displays indicating that no appointments have been rescheduled for the current session.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505130								Process Status								
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
213096	213096	SC	P	M	M	89	EPCOT, DRAKE	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
306541	306541	CI	P	M	F	59	HOFF, GERTA	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
623410	612408	SC	XD2	M	F	70	LOEWS, FREDERICA	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
735768	735768	CI	P	M	F	14	R	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
745137	278169	SC	XD2	M	F	22	FI	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
878700	878700	CI	P	M	F	80	E	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
905688	905688	SC	P	M	M	78	R	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Rescheduled Appointments

None of the appointments for Session ID#505130 have been identified as Rescheduled.

OK

Ready | Connected to Coordinator | 03:02 PM

If no appointments have been rescheduled for the current session, the Rescheduled Appointments message text box displays. To remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

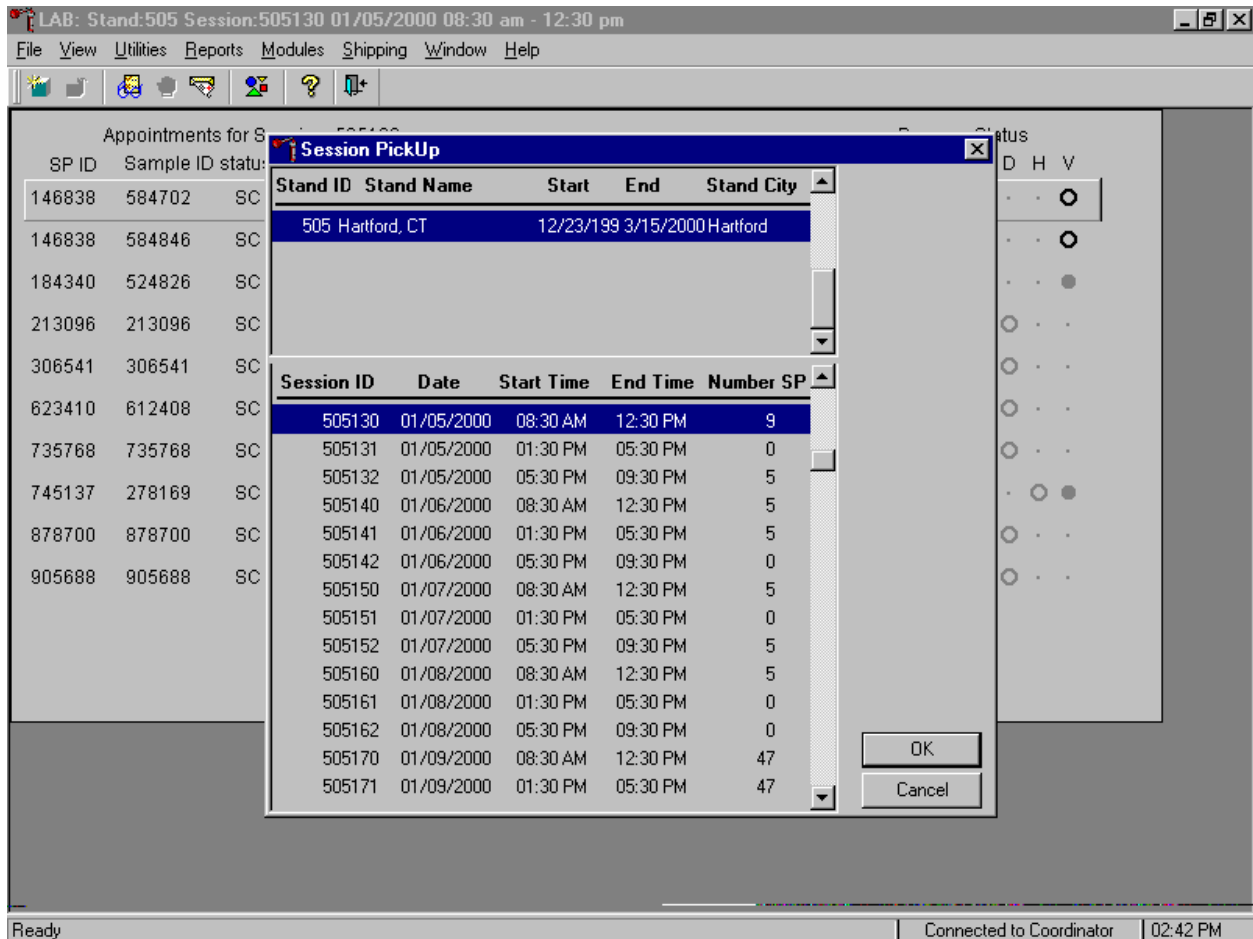
9.3.5 Session Preview Report

Use the MEC Session Preview report as an aid to assist in printing labels.



To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, left click, drag the mouse arrow to {Session Preview} and left click or type [Alt] [R], [V].

Select or identify the session.



The Session Pickup list displays and defaults to the current MEC session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or select [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The Session Preview Report displays.

Session Preview Report 01/26/00 14:43
Stand: 505

Session: 505130 01/05/2000 08:30 AM - 12:30 PM

SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
213096	Primary	DRAKE EPCOT	89 years	Male		
306541	Primary	GERTA HOFF	59 years	Female		
735768	Primary	FIG RESPOT	59 years	Female		
878700	Primary	EDNA EPCOT	80 years	Female		
905688	Primary	ROLAND REPOT	78 years	Male		
184340	2nd Exam	*ED FELLOWS	29 years	Male		

Page 1 of 3

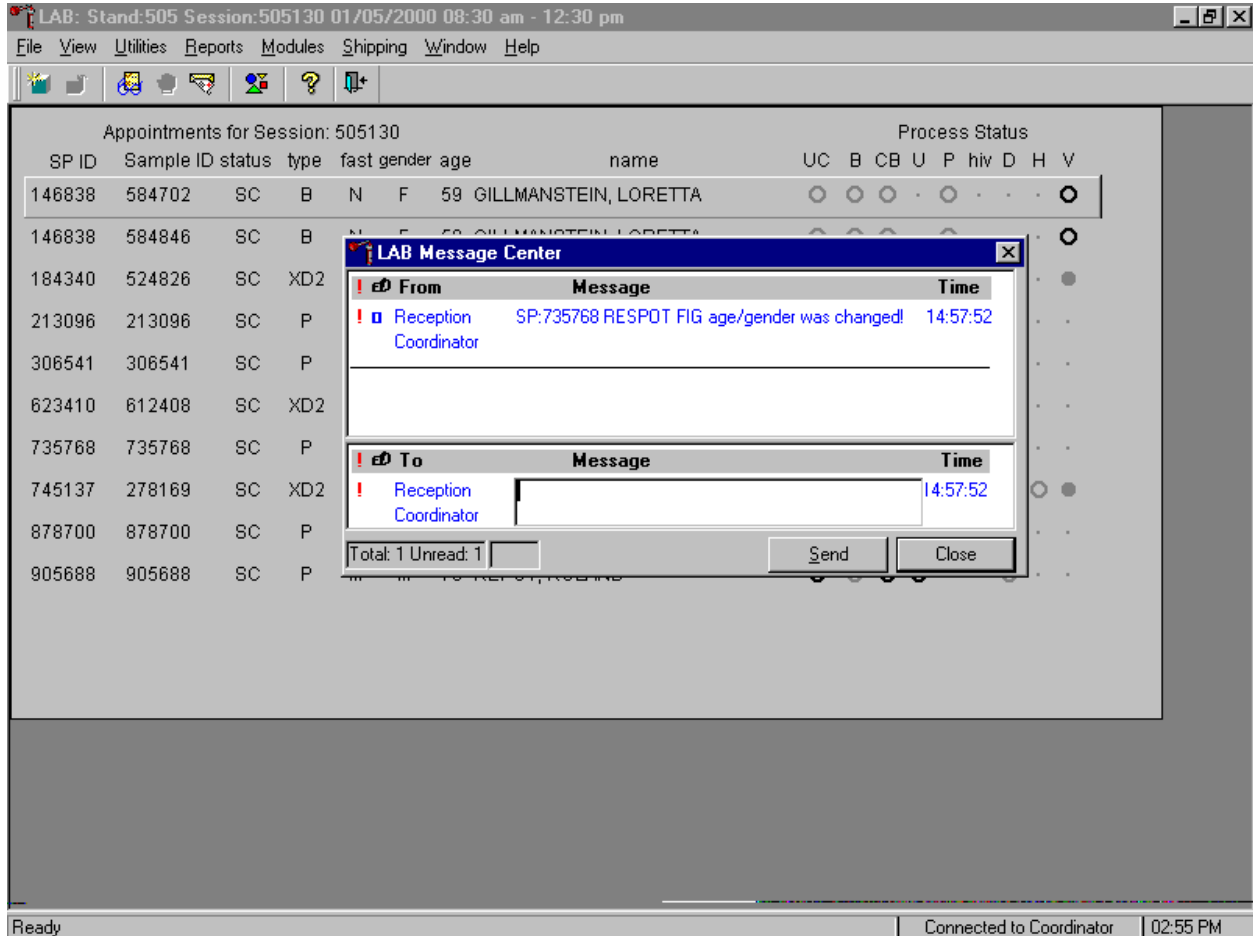
Ready | Connected to Coordinator | 02:42 PM

The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any special considerations or consent comments. A blue asterisk in front of a SP's name indicates that the SP is eligible for the VOC component.

9.4 Regeneration of Data

Processing protocols are SP specific and are based on the age and gender information obtained during the home interview. Protocols are also dependent on session times and person type. Labels are based on the SP's unique protocol. When labels are generated, the laboratory record is created. If the age or gender information obtained during the home interview is incorrect, or the session time or person type changes, the processing protocol may be affected. If the incorrect information is corrected before labels are generated, no action is necessary. If the incorrect information is corrected after the labels have been generated (and laboratory record created), the color of the SP's row on the heads-up display turns red.

If the coordinator changes an SP's age and/or the gender, a message center text box displays on all three laboratory terminals.



Review the information. To send a response to the coordinator, type the text of the response into the lower Message text box, use the mouse to direct the mouse arrow to the **Send** button, and left click, or type [S]. To close the Message Center text box without responding to the message, use the mouse to direct the mouse arrow to the **Close** button and left click, type [C], or select [Enter].

If all SP rows in the heads-up display are black, then none of the SPs require data regeneration.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505130

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status									
								UC	B	CB	U	P	hiv	D	H	V	
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●	
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	○	○	○	·	○	·	·	·	●	
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	●	○	○	○	·	○	·	·	●	
213096	213096	SC	P	M	M	89	EPCOT, DRAKE	○	○	○	○	·	·	○	·	·	
306541	306541	CI	P	M	F	59	HOFF, GERTA	○	○	○	○	○	·	○	·	·	
623410	612408	SC	XD2	M	F	70	LOEWS, FREDERICA	○	○	○	○	·	·	○	·	·	
735768	735768	CI	P	M	F	14	RESPOT, FIG	○	○	○	○	○	·	○	·	·	
745137	278169	SC	XD2	M	F	22	FELLOWS, STACY	○	○	○	○	○	○	·	○	●	
878700	878700	CI	P	M	F	80	EPCOT, EDNA	○	○	○	○	·	·	○	·	·	
905688	905688	SC	P	M	M	78	REPOT, ROLAND	○	○	○	○	·	·	○	·	·	

Ready | Connected to Coordinator | 02:58 PM

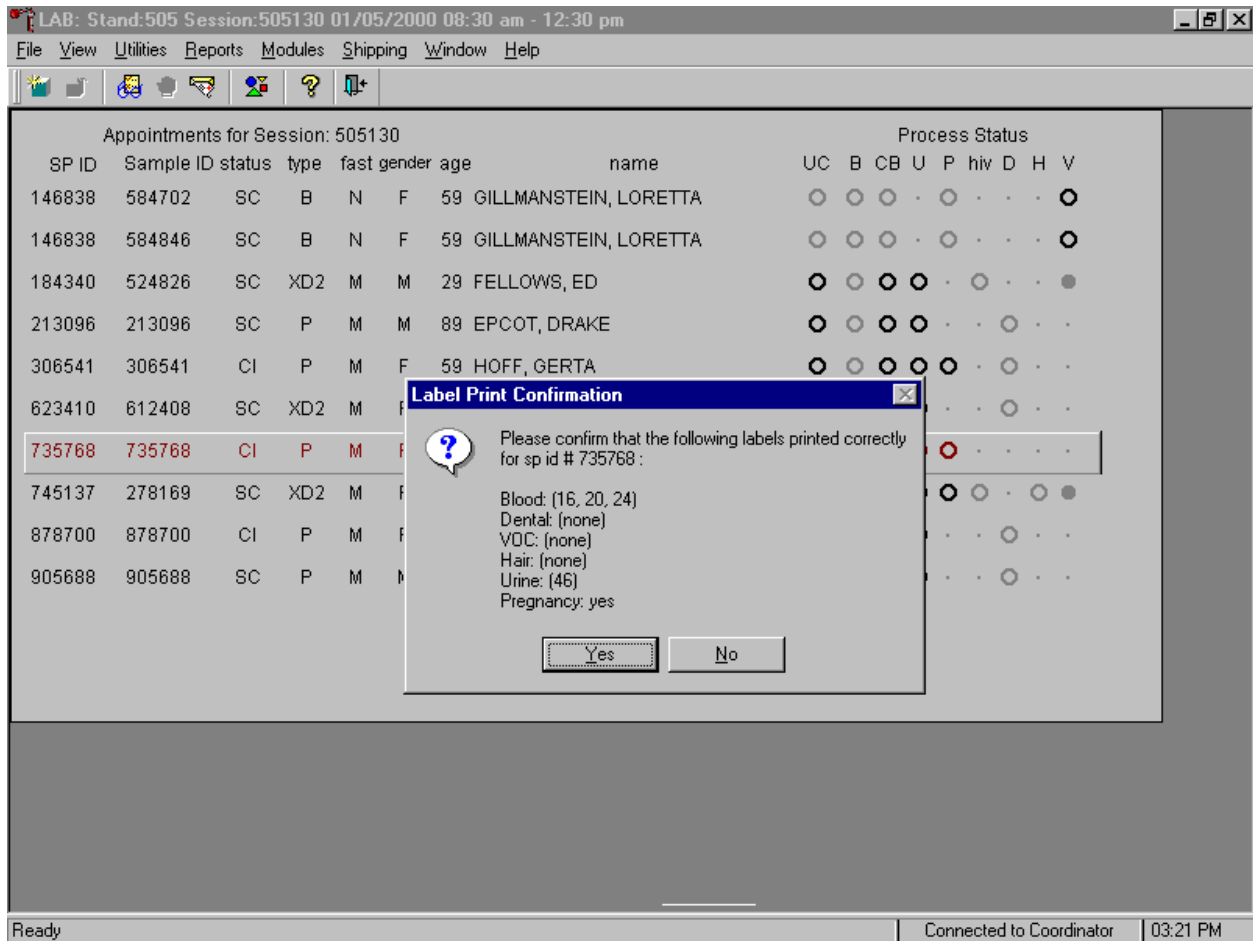
Regenerate the data for each MEC or home exam SP indicated in red on the heads-up display.

Select the correct SP and regenerate the data.



To regenerate the data for the SP, drag the mouse arrow to the SP's row, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and left click. Alternatively, use the up and down keys to move up and down the list until the correct SP is selected or highlighted, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and right click.

New labels print.



New labels print for vessels that are in addition to the existing vessels. The Label Print Confirmation message text box displays and asks, "Please confirm that the following labels printed correctly for sp id # xxxxxx:

Blood:

Dental:

VOC:

Hair:

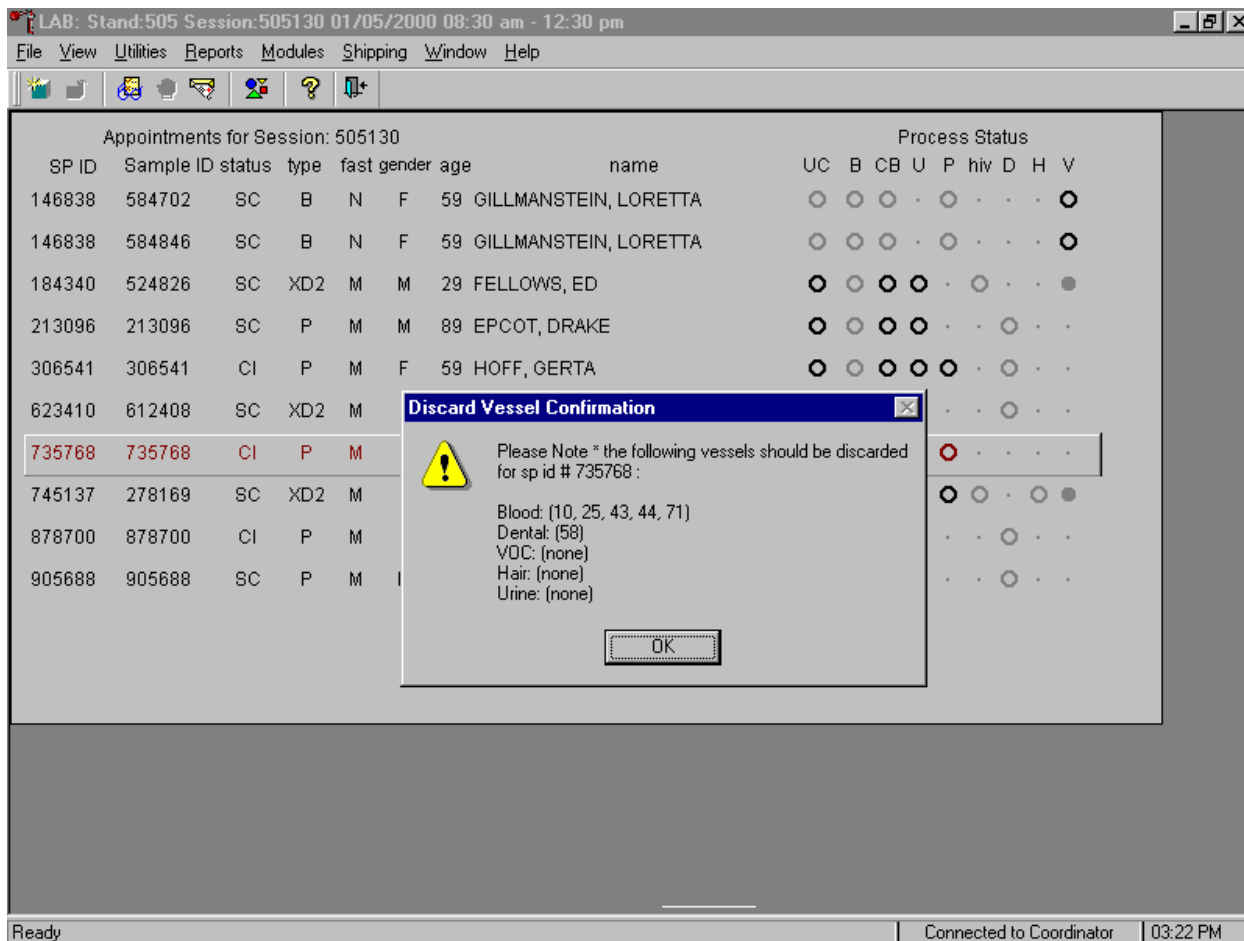
Urine:

Pregnancy:

Examine the new printed labels and compare them to the list presented on the Label Print Confirmation message text box. To respond affirmatively to the message, use the mouse to direct the mouse

arrow to the **Yes** button and left click, or type [Y], or select [Enter]. To respond negatively to the message, use the mouse to direct the mouse arrow to the **No** button and left click or type [N]. If a negative response is recorded, labels reprint.

The Discard Vessel Confirmation message text box displays.



The Discard Vessel Confirmation message text box displays and states, “Please Note *the following vessels should be discarded for sp id # xxxxxx:

- Blood:
- Dental:
- VOC:
- Hair:
- Urine:

Pregnancy:

Discard (destroy) the vessels indicated in the message. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Enter].

Allow the heads-up screen to update.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505130

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
213096	213096	SC	P	M	M	89	EPCOT, DRAKE	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
306541	306541	CI	P	M	F	59	HOFF, GERTA	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
623410	612408	SC	XD2	M	F	70	LOEWS, FREDERICA	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
735768	735768	CI	P	M	F	14	RESPOT, FIG	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
745137	278169	SC	XD2	M	F	22	FELLOWS, STACY	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
878700	878700	CI	P	M	F	80	EPCOT, EDNA	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
905688	905688	SC	P	M	M	78	REPOT, ROLAND	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

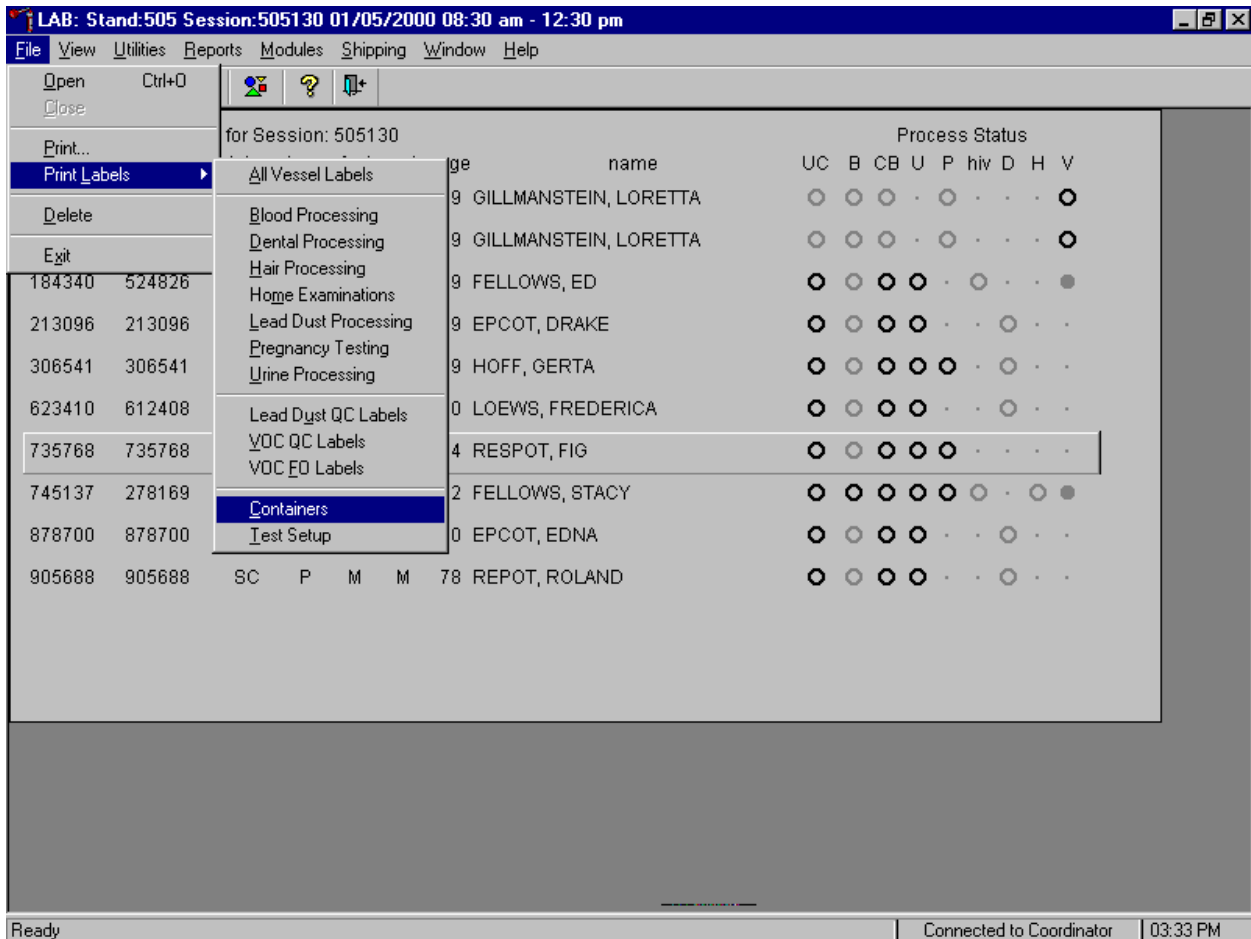
Ready | Connected to Coordinator | 03:27 PM

Allow the heads-up display to update before proceeding. After the screen updates, the SP's row turns from red to black.

9.5 Generate, Print, and Assign Container IDs or Labels

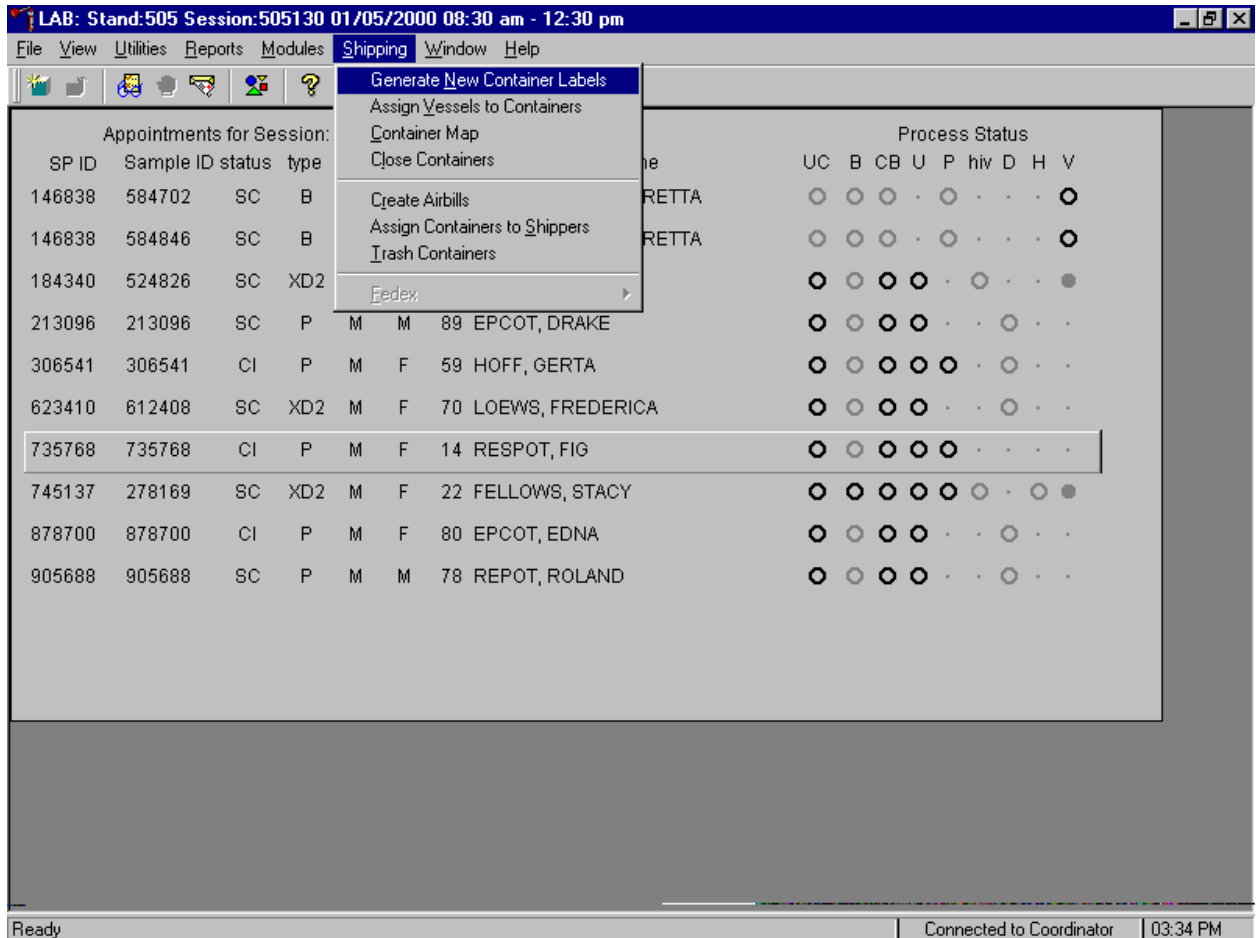
Store processed vessels and biological samples in boxes or bags (containers.) Generate container labels with unique IDs. At the beginning of each stand, specify the initial number of container IDs to generate or print, then assign or associate a container ID with a vessel.

At the beginning of each stand specify the initial number of container IDs to generate or as needed, specify an additional number of container IDs, using the Print Labels module.



To generate new container IDs or labels using the Print Labels module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, then drag the mouse arrow to {Print Labels}, {Containers}, and left click or type [Alt] [F], [L], [C].

At the beginning of each stand specify the initial number of container IDs to generate or as needed, specify an additional number of container IDs, using the Shipping module.



To access the Generate New Container Labels module, use the mouse to direct the mouse arrow to {Shipping} in the menu bar and left click, drag the mouse arrow to {Generate New Container Labels}, and left click or type [Alt] [S], [N].

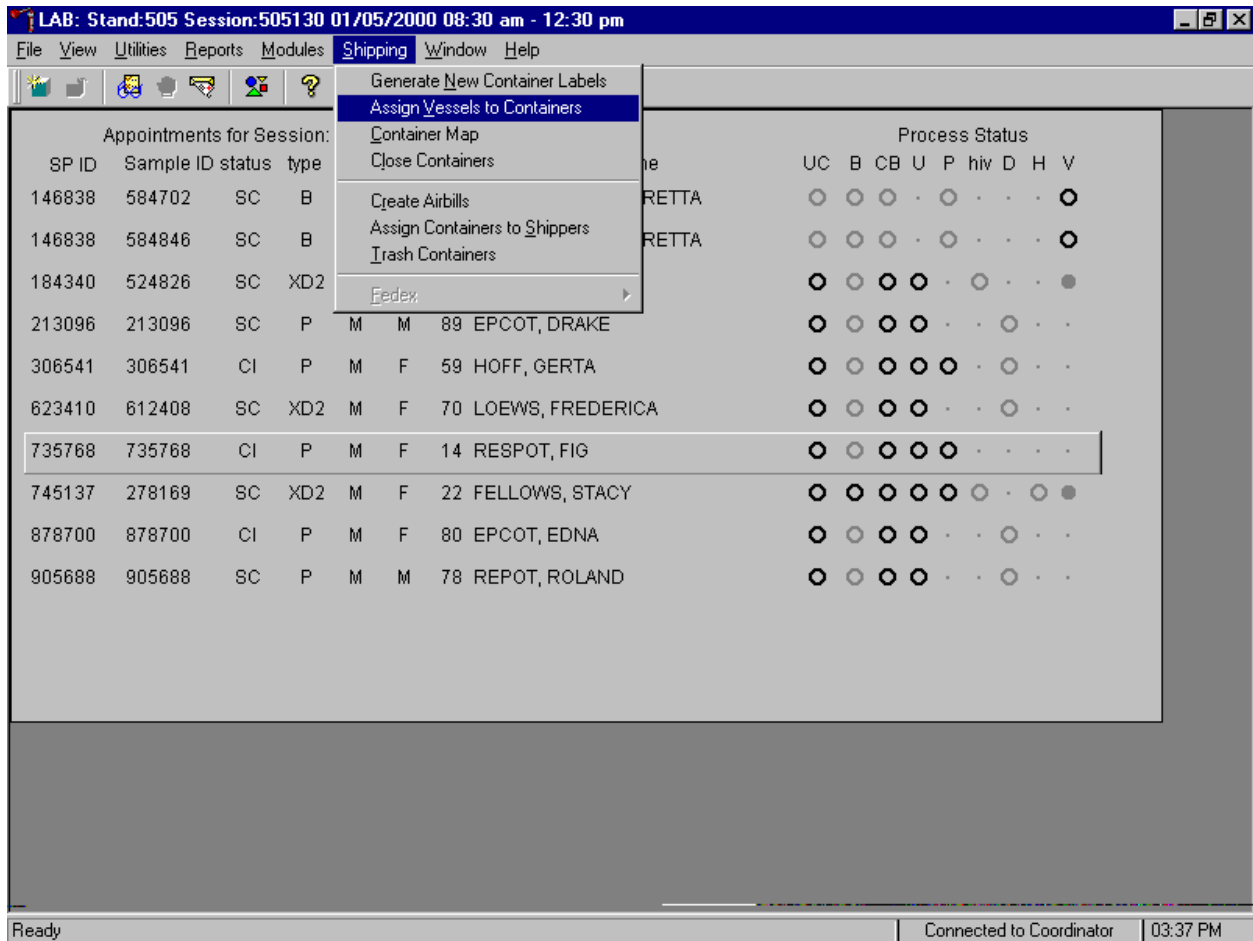
Specify the initial or additional number of container labels.

The screenshot shows a software window titled "LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a table of appointments for session 505130. The table has columns for SP ID, Sample ID, status, type, fast, gender, age, name, and Process Status (UC, B, CB, U, P, hiv, D, H, V). A dialog box titled "Generate Container Labels" is overlaid on the table. The dialog box contains the text "Please enter a value in the box below indicating the number of container labels you wish to generate:" and a text input field containing the number "300". There are "OK" and "Cancel" buttons at the bottom of the dialog box. The status bar at the bottom of the window shows "Ready", "Connected to Coordinator", and "03:35 PM".

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
184340	524826	SC	XD2	M	M	29	FELLOWS, ED	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
213096	213096	SC	P	M	M	89	FPCOT DRAKE	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
306541	306541	CI	P	M	F			<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
623410	612408	SC	XD2	M	F			<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
735768	735768	CI	P	M	F			<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
745137	278169	SC	XD2	M	F			<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
878700	878700	CI	P	M	F			<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
905688	905688	SC	P	M	M			<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

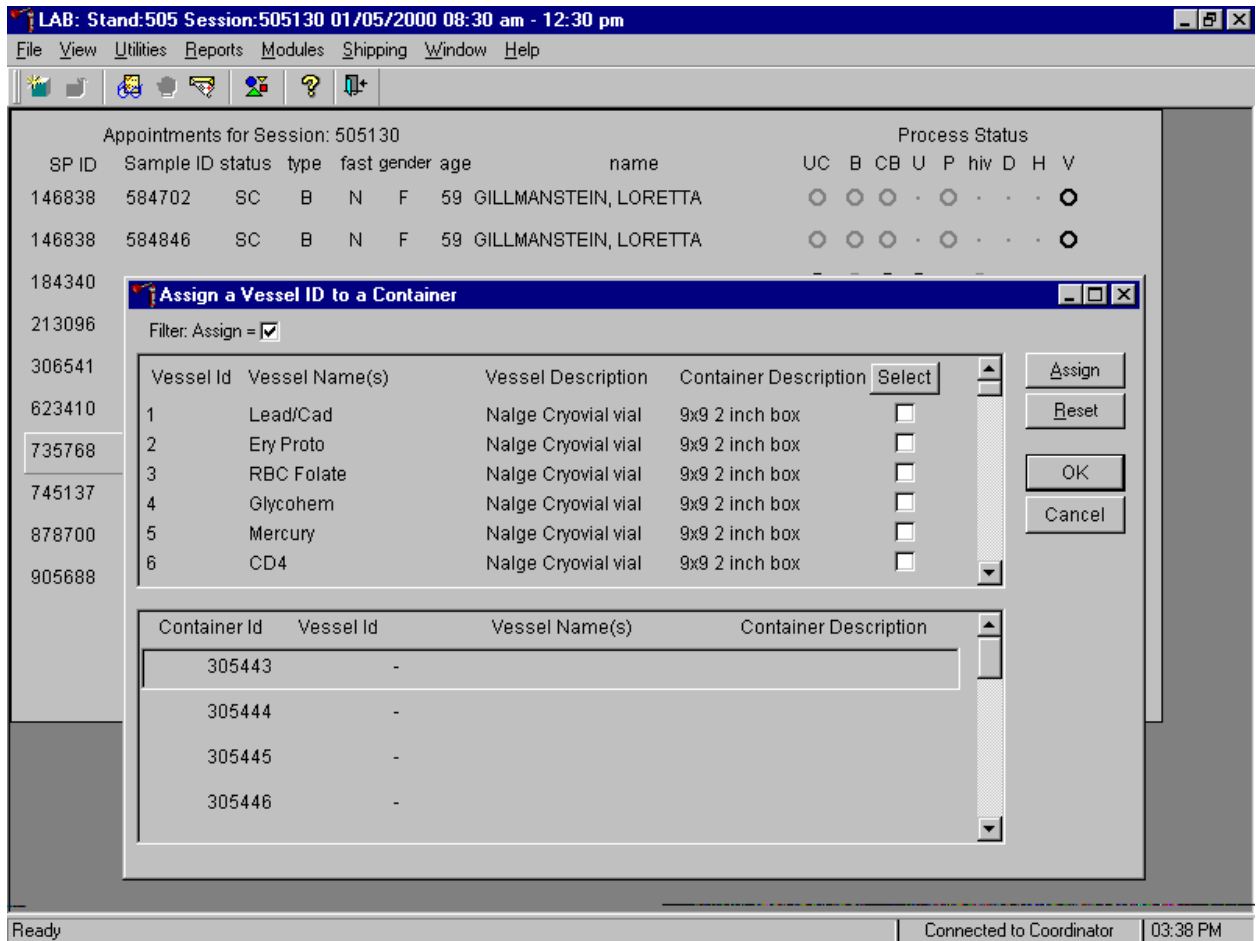
The Generate Container Labels text box displays. Specify the initial number of labels as 300; type this number into the box using the keyboard. To print the labels and remove the Generate Container Labels text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or type [O], or select [Enter]. To cancel these actions and remove the Generate Container Labels text box, use the mouse arrow to direct the mouse arrow to the **Cancel** button and left click, or type [C].

Access the Assign Vessels to Containers module.



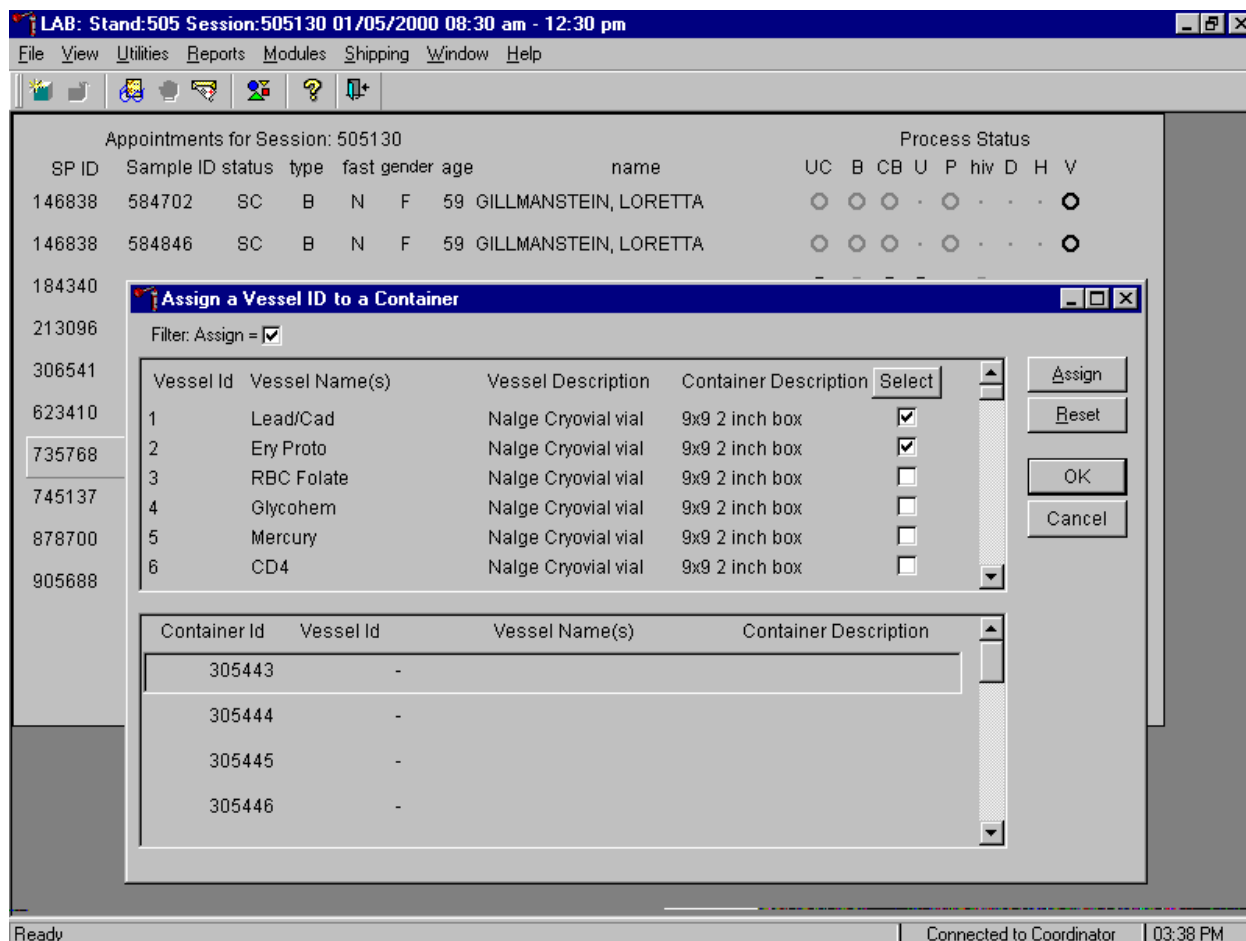
To access the Assign Vessels to Containers module, use the mouse to direct the mouse arrow to {Shipping} and left click, drag the mouse arrow to {Assign Vessels to Containers} and left click or type [Alt] [S], [V].

The Assign a Vessel ID to a Container window displays.



The top half of the Assign a Vessel to a Containers window contains a complete list of Vessel IDs, Vessel Names, Vessel Descriptions, Container Descriptions, and Select check boxes. Use the vertical scroll bar to view all rows.

Individually mark vessels for container ID assignment.



To individually mark or identify a vessel as requiring container ID assignment, use the mouse to direct the mouse arrow to an individual "Select" check box and left click.

Mark or select all vessels for container ID assignment.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505130

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
146838	584702	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
146838	584846	SC	B	N	F	59	GILLMANSTEIN, LORETTA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Process Status

184340

213096

306541

623410

735768

745137

878700

905688

Assign a Vessel ID to a Container

Filter: Assign =

Vessel Id	Vessel Name(s)	Vessel Description	Container Description	Select
1	Lead/Cad	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>
2	Ery Proto	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>
3	RBC Folate	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>
4	Glycohem	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>
5	Mercury	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>
6	CD4	Nalge Cryovial vial	9x9 2 inch box	<input checked="" type="checkbox"/>

Assign

Reset

OK

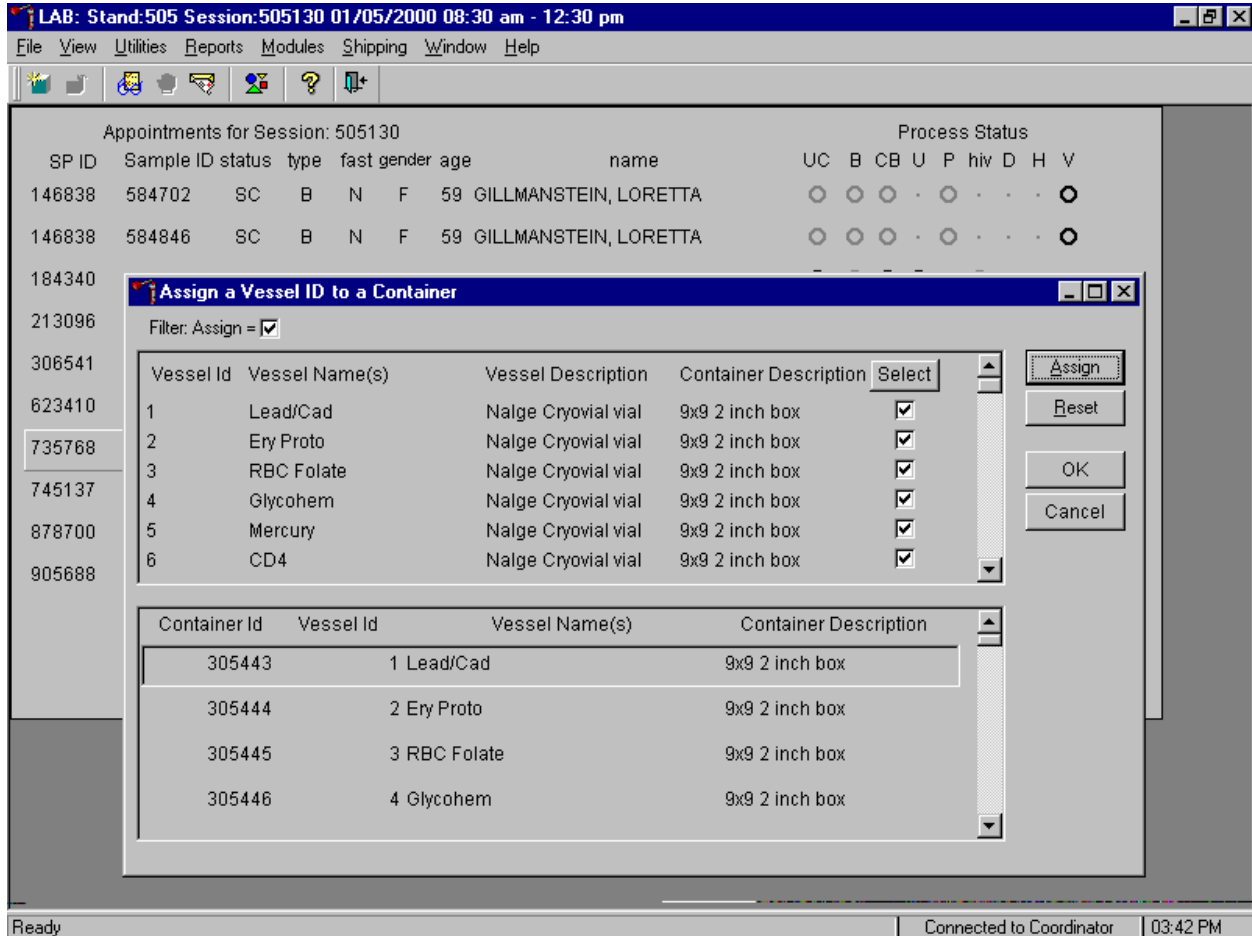
Cancel

Container Id	Vessel Id	Vessel Name(s)	Container Description
305443	-		
305444	-		
305445	-		
305446	-		

Ready | Connected to Coordinator | 03:39 PM

To mark all vessels for container ID assignment, use the mouse to direct the mouse arrow to the **Select** button and left click. Check marks fill in all the check boxes.

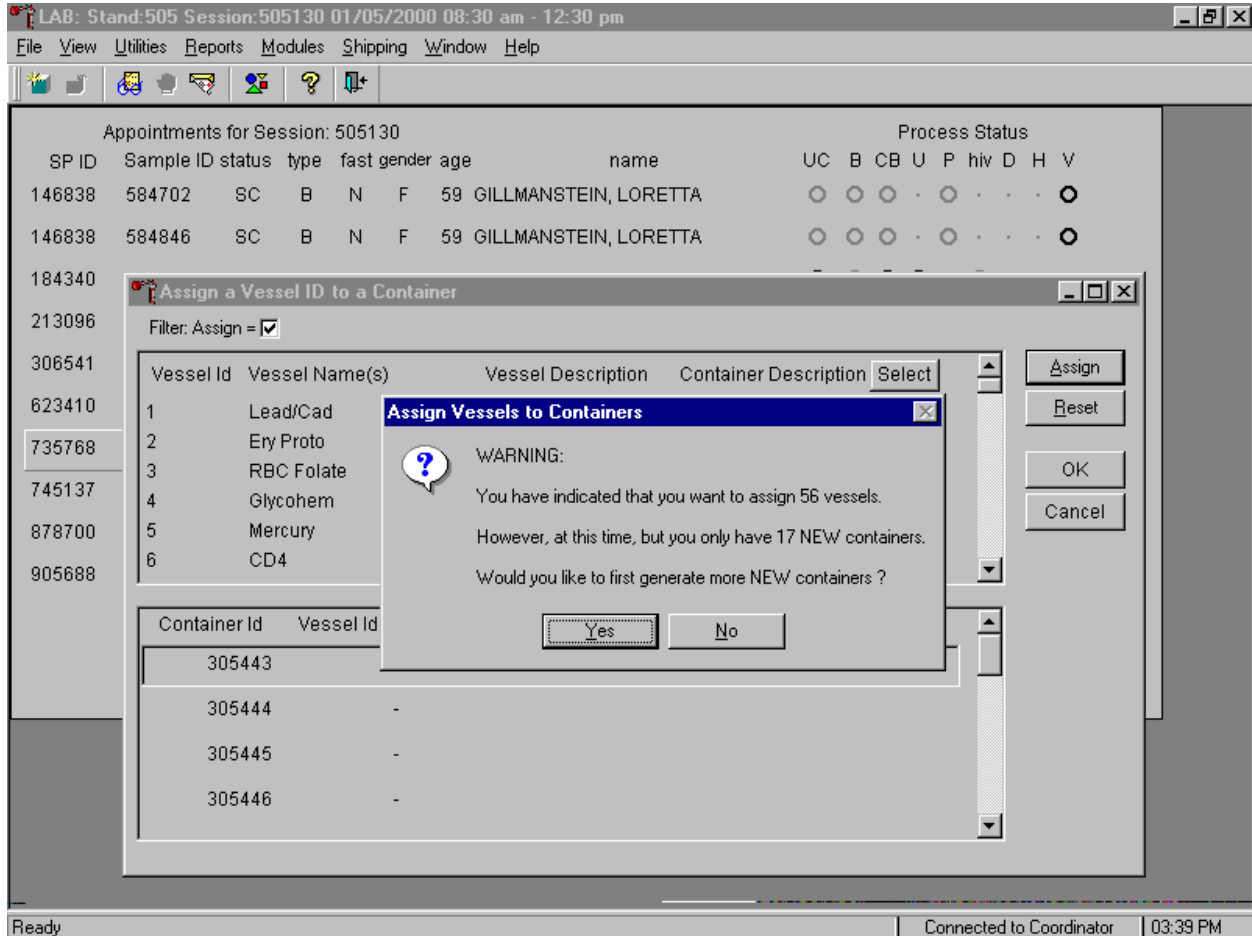
Once the vessels are marked with a check mark or selected for container assignment, they are ready for automatic assignment. Each vessel is assigned a container ID.



The lower section of the Assign a Vessel ID to a Container window contains a list of available (generated) Container IDs, and columns for Vessel id, Vessel Name(s) and Container description.

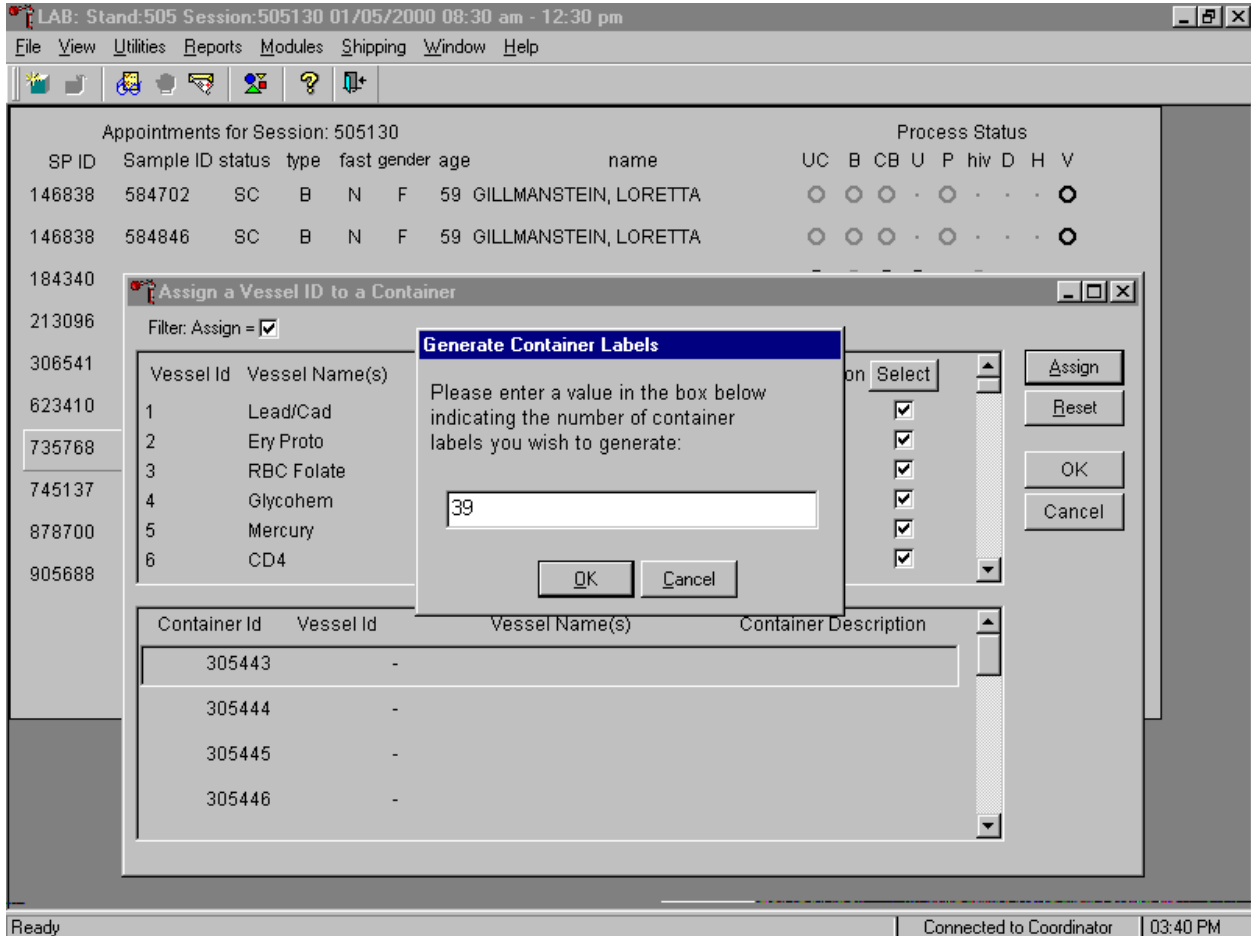
To automatically assign vessels to containers, use the mouse to direct the mouse arrow to the **Assign** button and left click, or press [Enter]. All marked vessels are assigned sequentially to the generated (available) container IDs.

If there are insufficient container labels available to assign a container ID to each check marked vessel, a warning message text box displays.



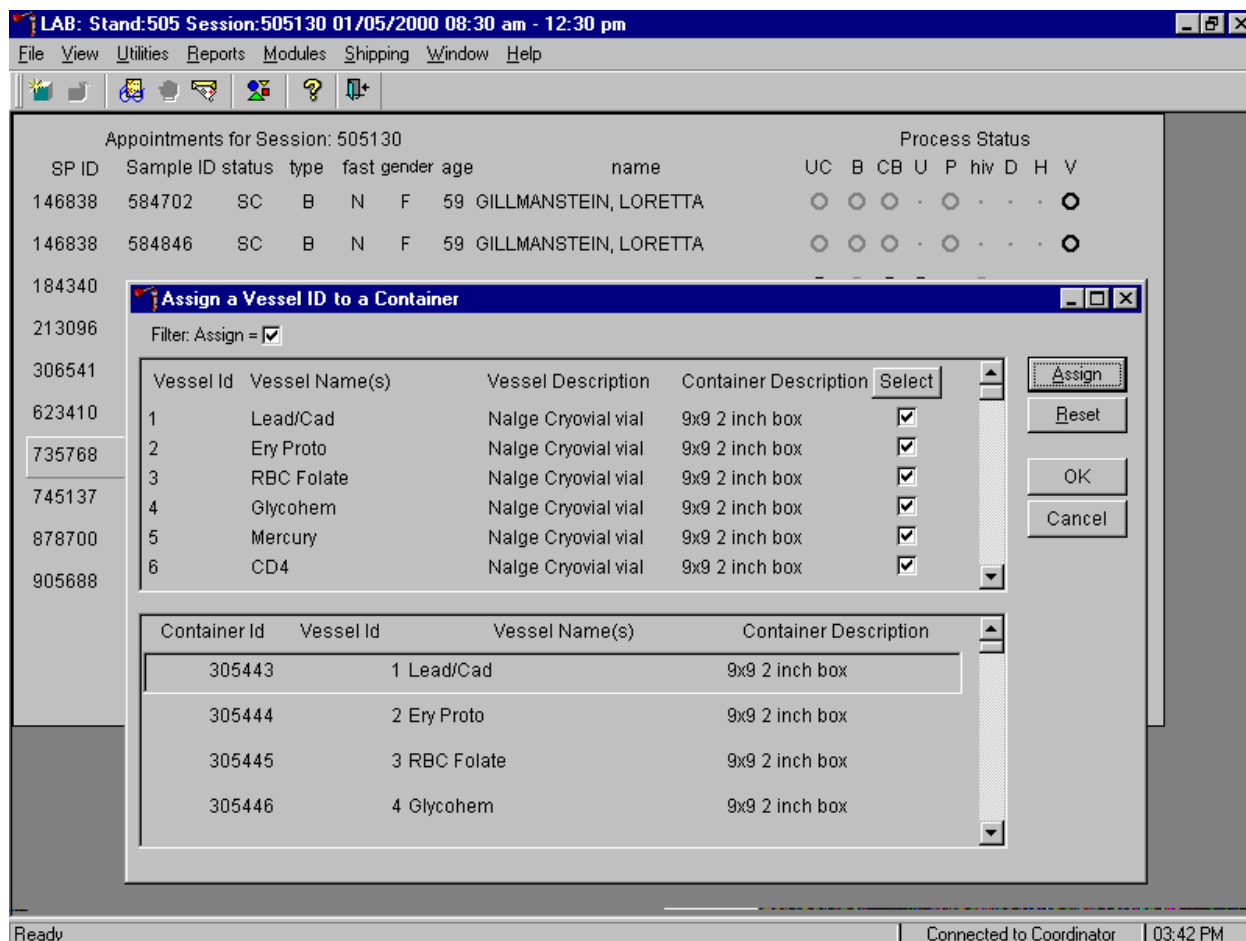
The warning message text box reports the number of check-marked vessels (those ready for assignment), and the difference between the number of check-marked vessels and the number of available container IDs. The text box provides an opportunity to create new container IDs without exiting the module. To create the additional number of container IDs necessary to complete the assignment process, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y], or select [Enter]. To decline the opportunity to create additional container IDs, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N].

If the response to the previous warning message text box is “Yes,” the Generate Container Labels text box displays.



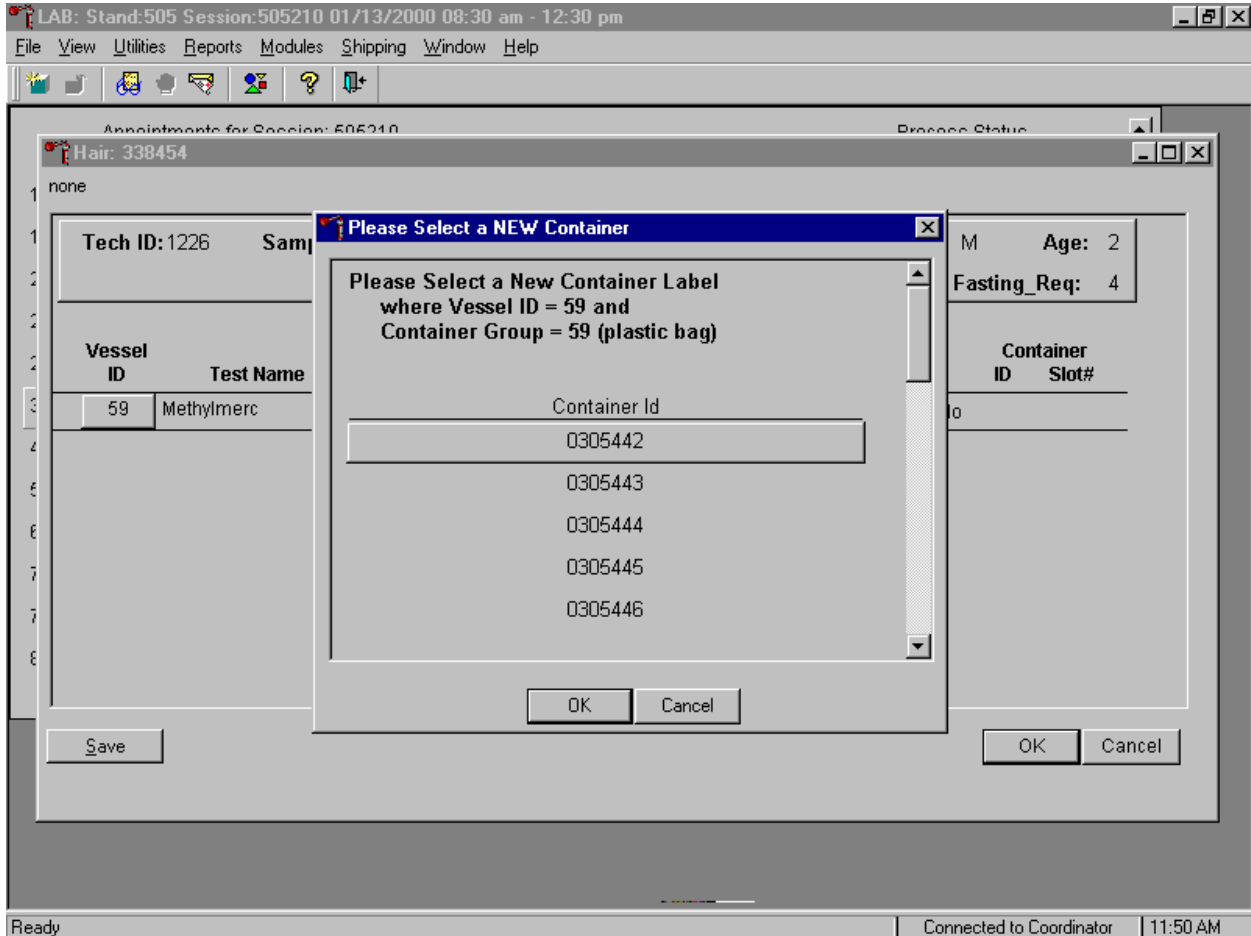
The Generate Container Labels message text box fills in with the exact number of container IDs necessary to complete the assign containers to vessel request. To create these additional container IDs, use the mouse to direct the mouse arrow to the **OK** button and left click, or type [O], or type [Enter]. To remove the text box without creating new container IDs, use the mouse to direct the mouse arrow to the **Cancel** button and left click, or type [C]. To change the number of labels in the text box, type a different number in the space using the keyboard, then select the **OK** button.

Complete the assignment process.



After reviewing the screen, affix the designated (assigned) container ID label to a container of the correct type and manually write the test/vessel ID on the container. To accept and register the assignments, use the mouse to direct the mouse arrow to the **OK** button and left click. To erase all assignments and restart the process, use the mouse to direct the mouse arrow to the **Reset** button and left click, or type [R]. To exit the module without recording any actions to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

When a container is full, the container will automatically “close.” Open a new container to replace the closed container.

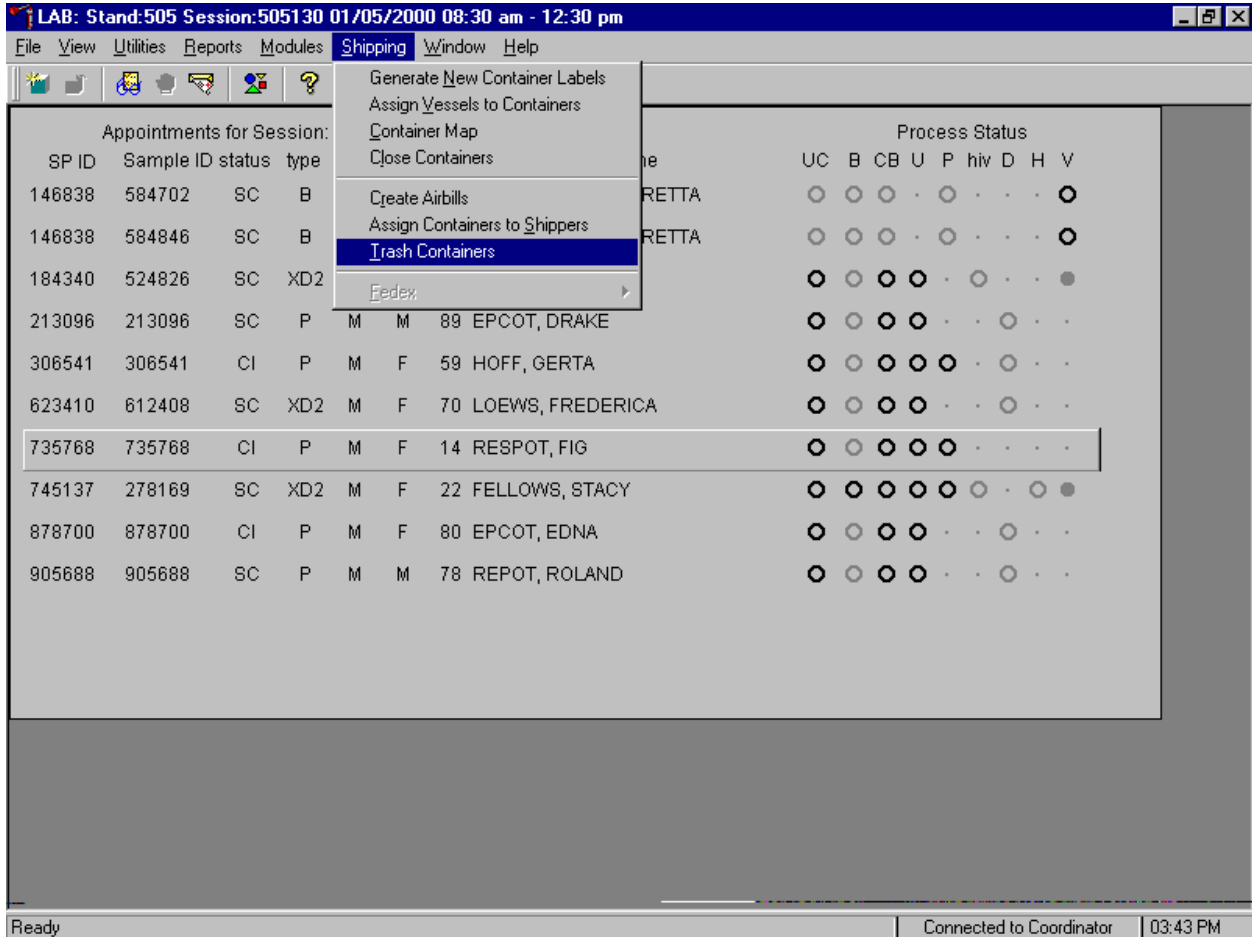


When a container is full, an opportunity to open a new container is automatically displayed on the “Please Select a NEW Container” window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

9.6 Trash Containers

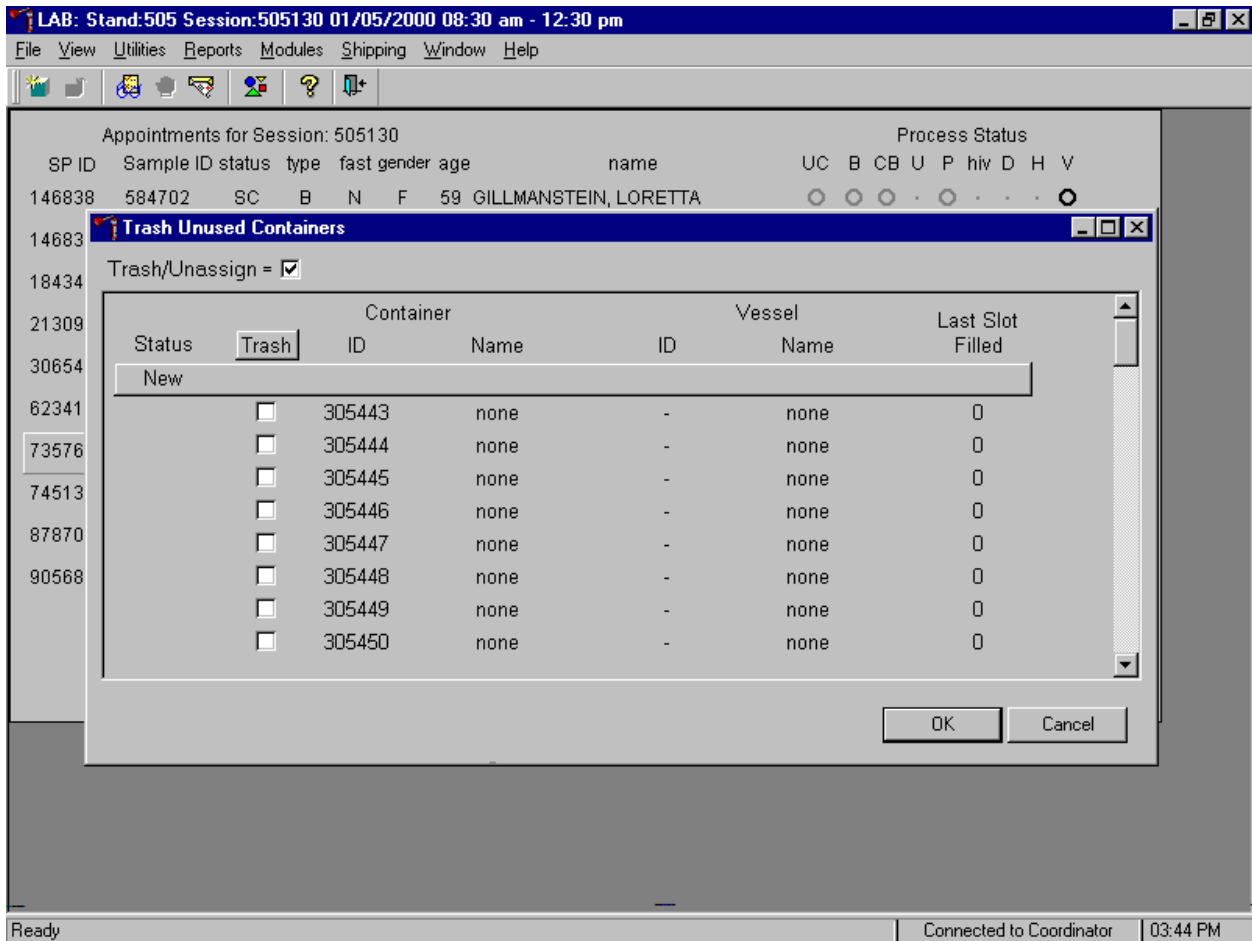
Each stand is allocated a maximum of 750 container IDs.

If container labels become lost or damaged, use the Trash Container module to delete the container IDs. Access the Trash Containers module.



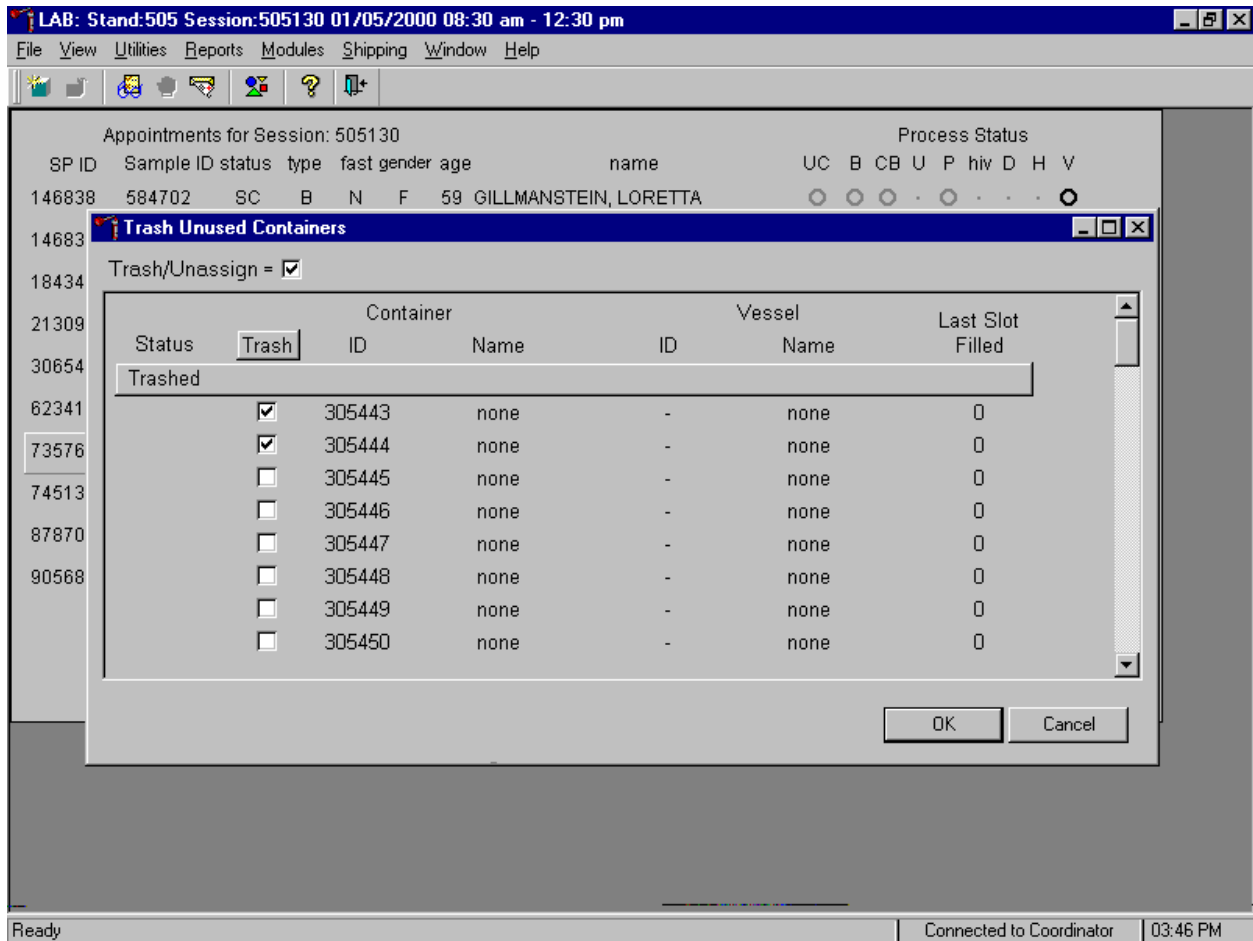
To access the Trash Containers module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Trash Containers}, and left click, or type [Alt] [S], [T].

The Trash Unused Containers window displays.



The status of each container ID is “New.” To individually mark the container IDs for deletion, use the mouse to direct the mouse arrow to the check boxes and individually left click on specific boxes or, to mark all outstanding container IDs for deletion, use the mouse to direct the mouse arrow to the **Trash** button and left click.

As the container IDs are marked for deletion, the status changes from “New” to “Trashed.”



To record these actions and execute the Trash Unused Container function, use the mouse to direct the mouse arrow to **OK** button and left click, or select [Enter]. To exit the Trash Unused Container module without recording or executing the Trash Container function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

9.7 Shipping Overview

The integrity of laboratory specimens is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contact laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient dry ice, refrigerant packs, and sending specimens FedEx priority overnight.

Overnight delivery by FedEx can be delayed due to a weekend or holiday. This extraordinary circumstance usually occurs at the end of a stand or just before vacation. In any case, all specimens must be shipped before vacations. In extreme heat take the following actions:

- Consider using medium shippers instead of small shippers for all laboratories east of the Mississippi when shipping from areas west of the Mississippi and for all laboratories west of the Mississippi when shipping from areas east of the Mississippi. Substitute a larger shipper when shipping specimens in extreme summer heat or whenever professional judgement dictates added precautions.
- Use dry ice in blocks instead of pellets since blocks sublime at a slower rate.
- Increase the number of refrigerant packs from four to at least six per shipper. Use the smallest shipper possible for these specimens.

The shipping technologist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other medical technologists, the phlebotomist and the home examiner assist in performing each of the steps listed below to complete the shipping procedures.

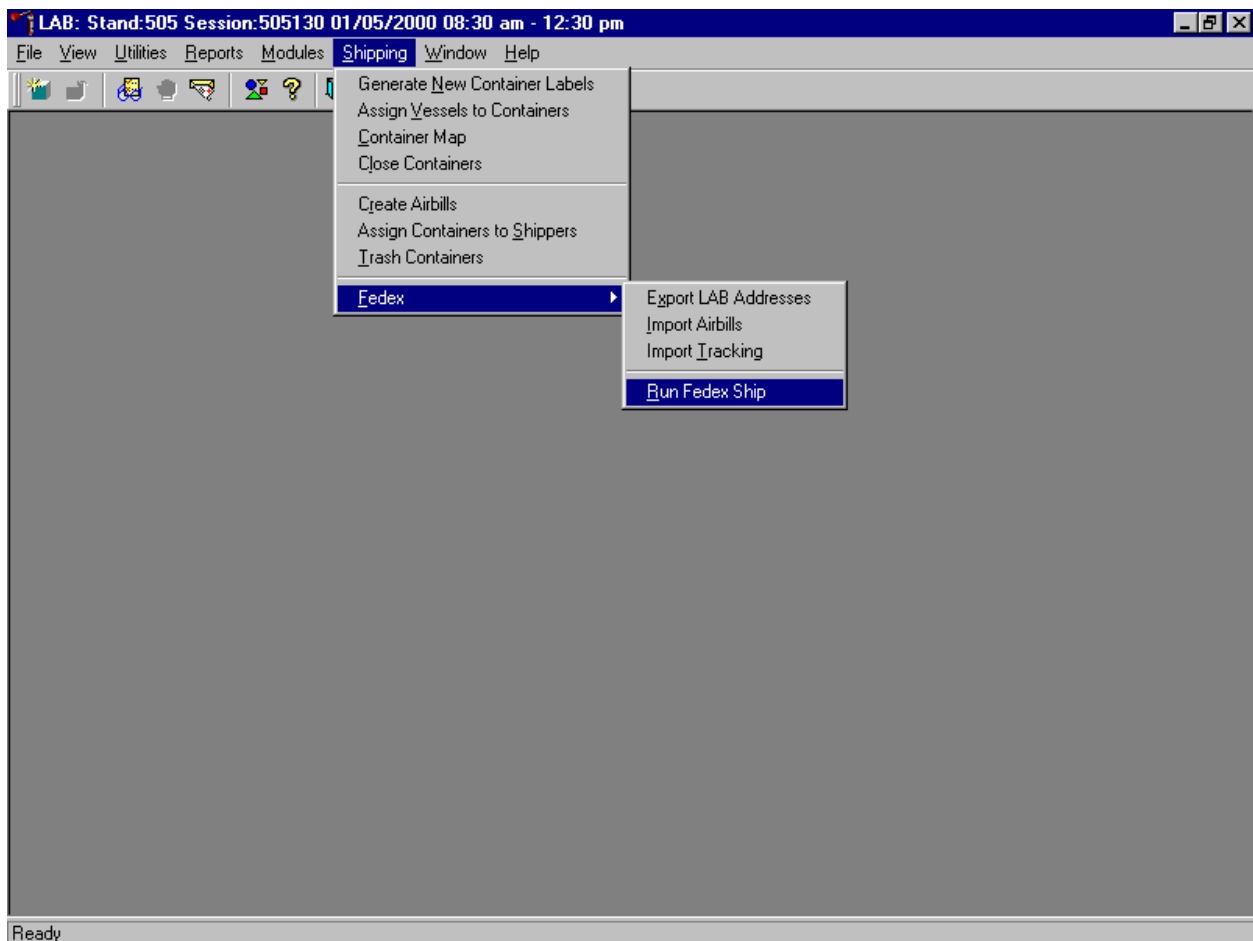
- On the day before a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software and prepare the Class 9 labels.
- On the morning of a shipping day, close all containers, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.

- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of dry ice or refrigerant packs as appropriate.
- Place the appropriate paper manifest and the FedEx return airbill in a 12 x 12 plastic bag and place the plastic bag on top of the Styrofoam shipper lid.
- Label each shipper with the appropriate FedEx label and warning labels.
- When the contract laboratory personnel receive the shippers, they will unpack the specimens and return the shippers and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

9.8 Create Federal Express Airbills

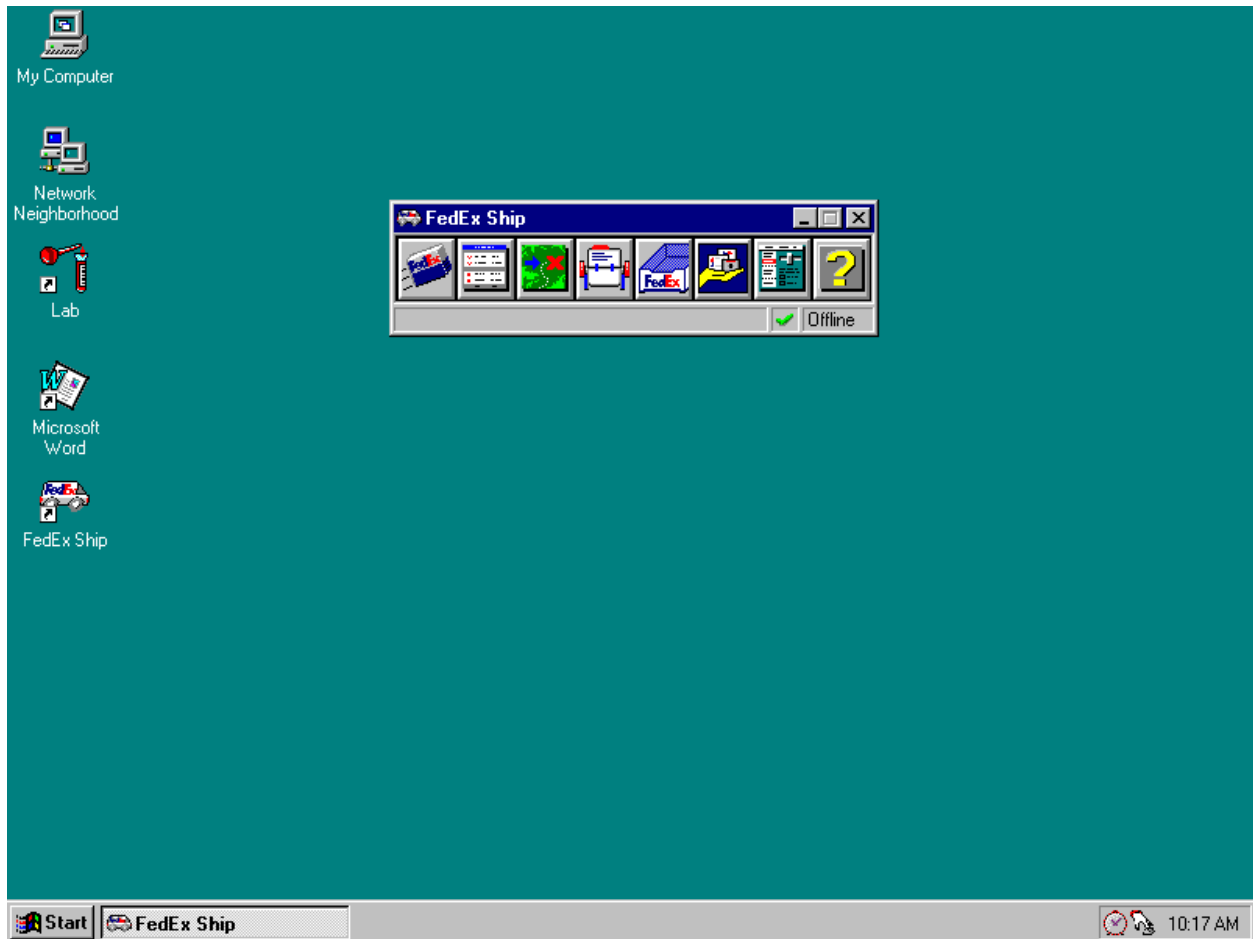
9.8.1 Start FedEx Ship

Each week on shipping day, create one airbill using FedEx Ship software for each shipper. Create two airbills for Coulston Foundation and the University of Missouri; create one airbill for the frozen shipper and the other airbill for the refrigerated shipment. Launch the FedEx Ship software.



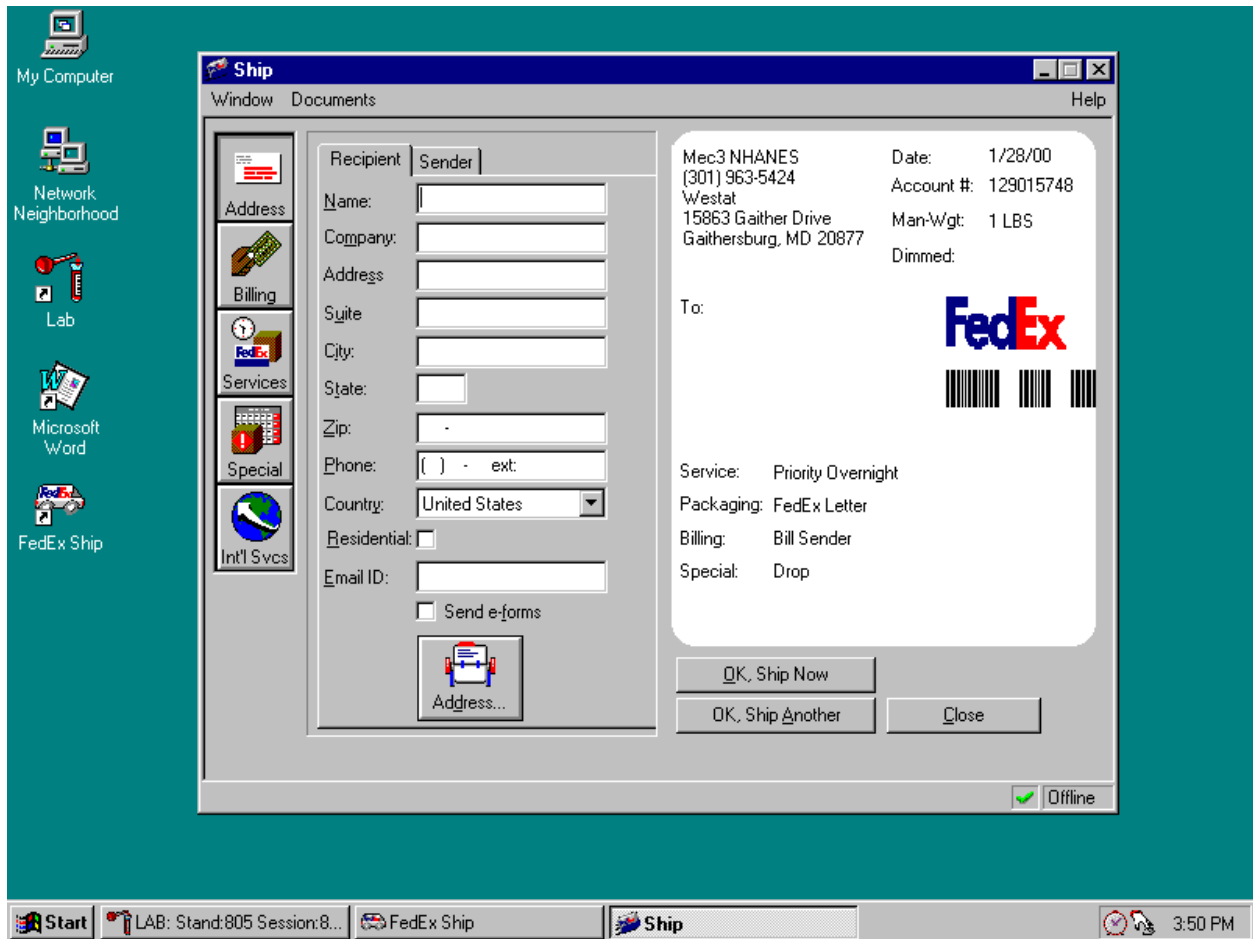
To launch the FedEx Ship software from within the laboratory application, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {FedEx}, then to {Run FedEx Ship}, and left click, or type [Alt] [S], [F], [R].

Alternatively, launch FedEx Ship software from the desktop.



To launch the FedEx Ship application from the desktop, use the mouse to direct the mouse arrow to the FedEx icon on the desktop and double click.

Click on the Ship icon in the navigator bar to display the Ship window.

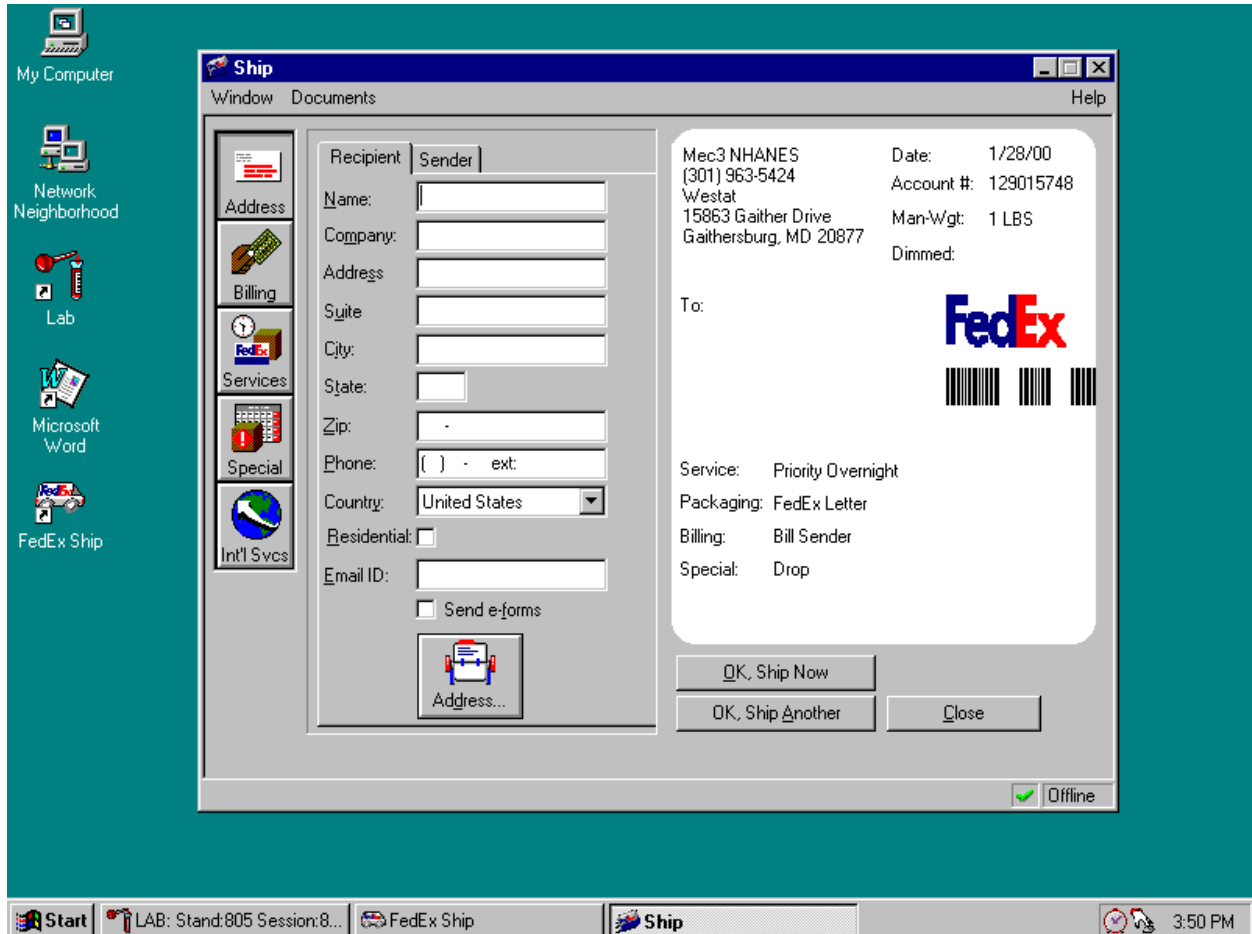


The window displays a blank form for entering recipient information. The right side of the window incorporates the shipment information in an on-screen version of the shipping label.

Each shipper must have a separate label. Enter shipment information for more than one shipment at one time by using the **OK, Ship Another** button. Enter shipment information for several shipments while in the Ship window. Preparing a shipment involves entering and verifying shipment information, sending shipment information to FedEx, and printing the shipping label and placing it on the shippers that make up the shipment. The following sections explain how to complete these tasks.

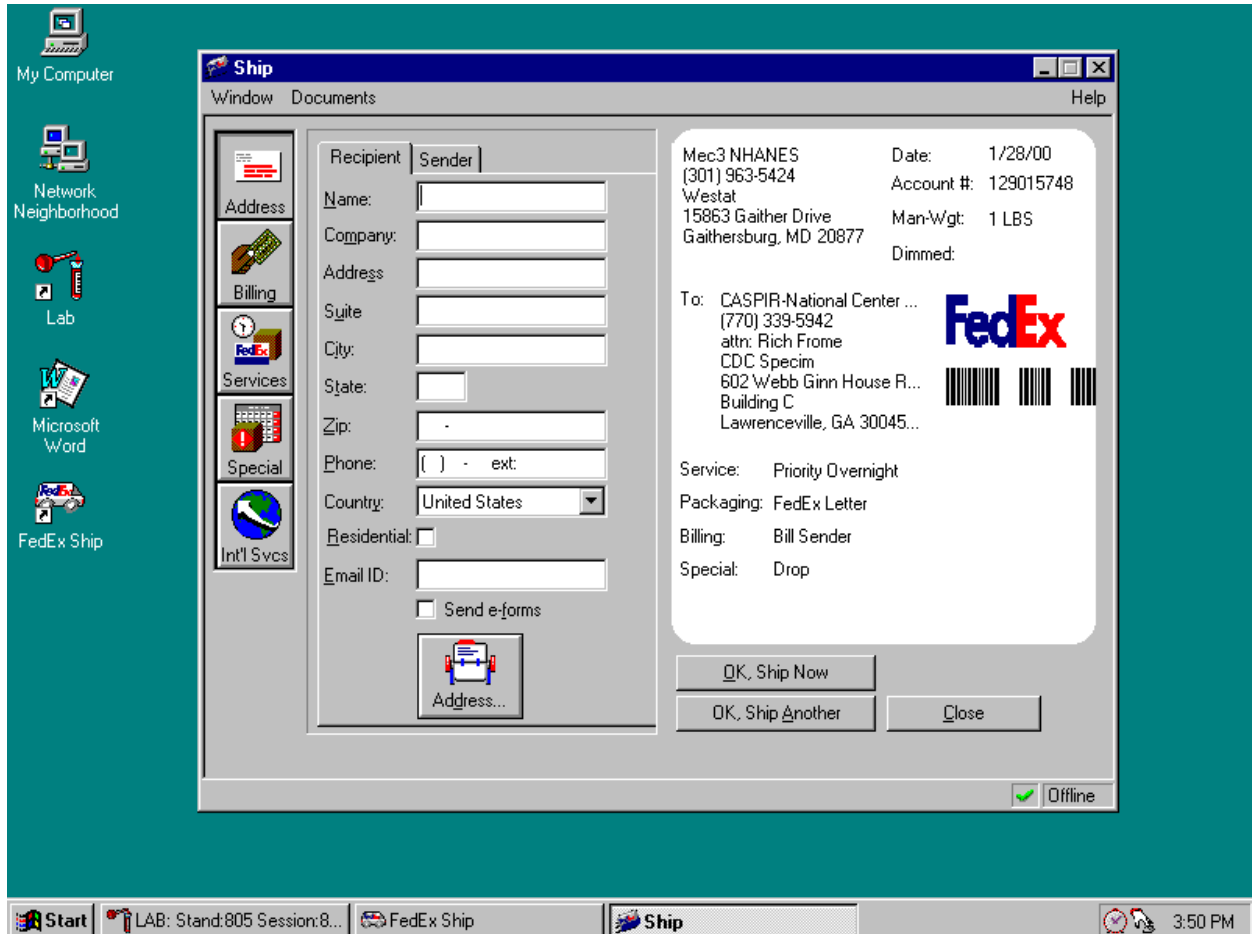
Enter Shipment Information

- From the navigator bar, click on the Ship icon. FedEx displays the Ship window.



The FedEx Ship window includes tabs for the Recipient and Sender.

- Enter the recipient's name, company, full address, and telephone number in the text boxes provided or use the Address book to drag and drop the recipient's information.

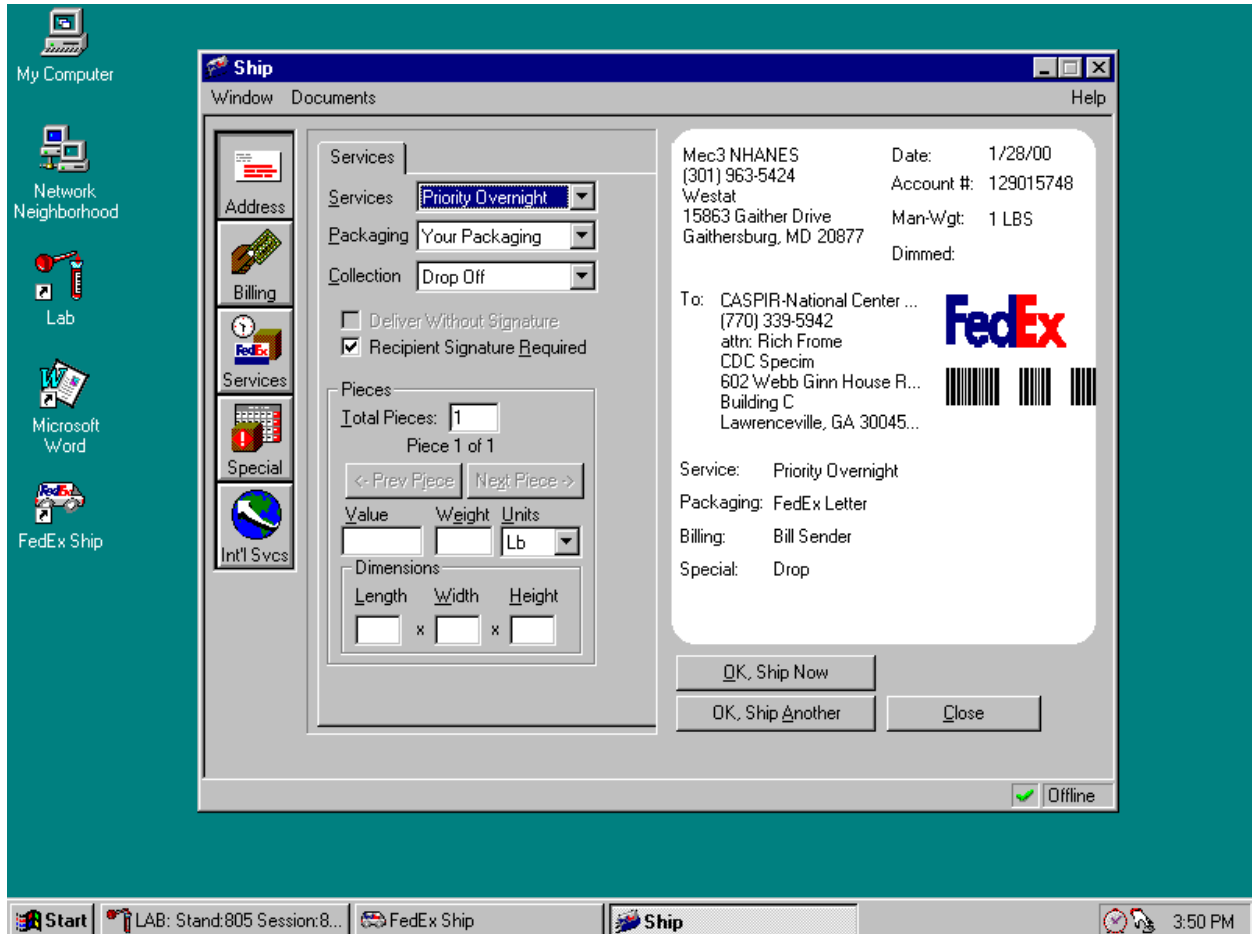


Verify Sender Information

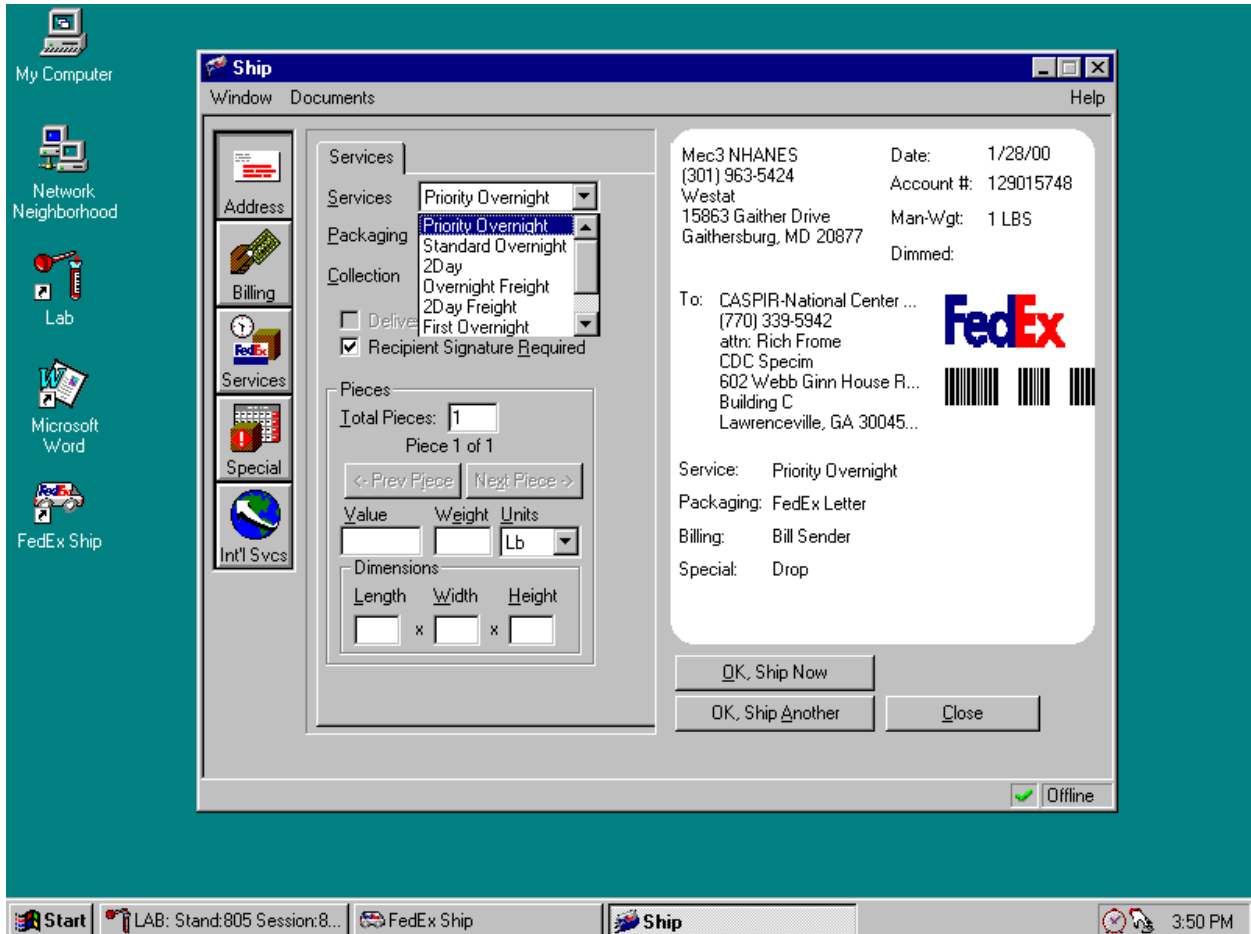
- Verify the sender information shown on the screen label. Contact the Data Manager to make any changes.

Select Services

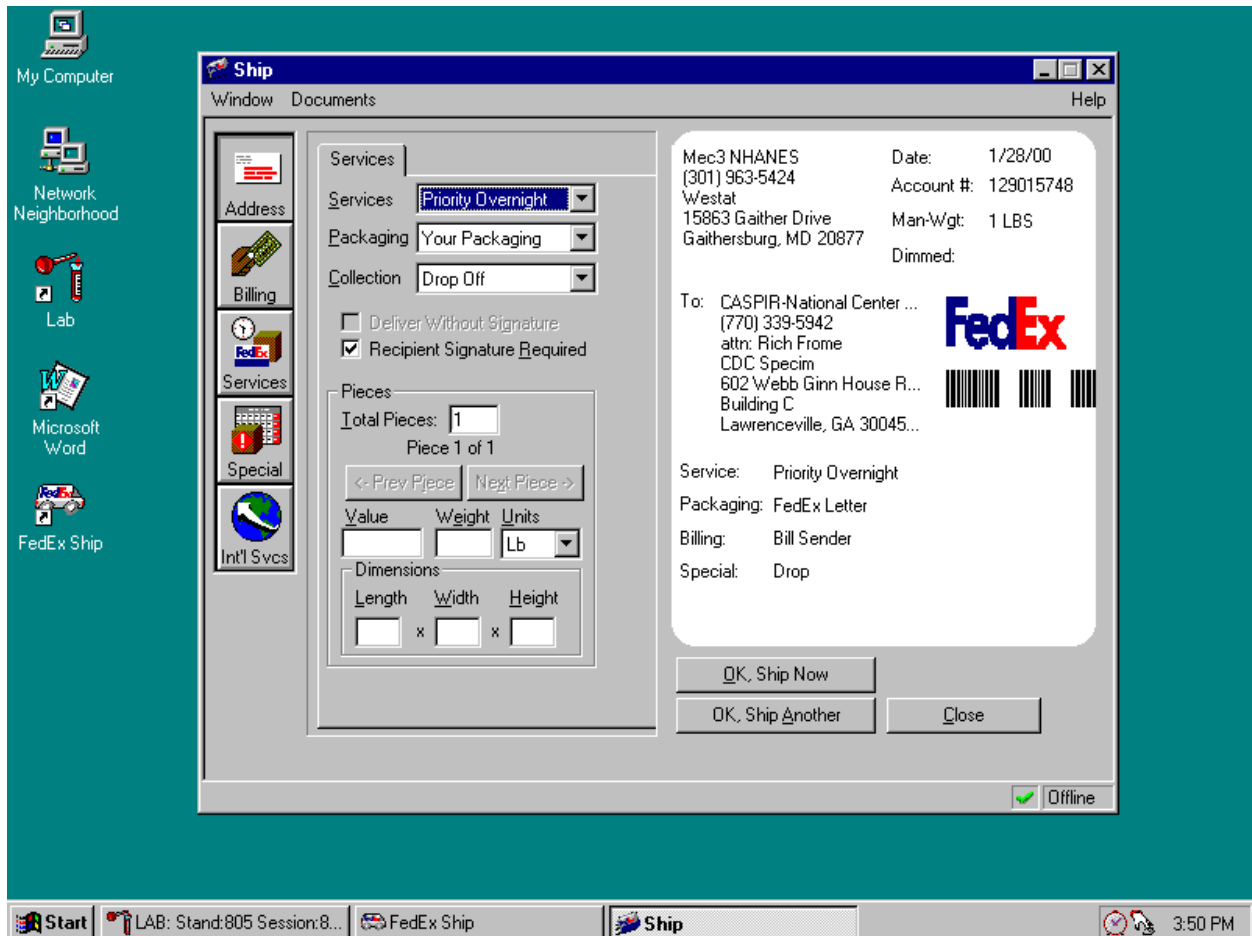
- Click on the Services icon. FedEx Ship displays the Services page.



1. Choose the type of FedEx service and packing or accept the default. Select Priority Overnight and Your Packing.

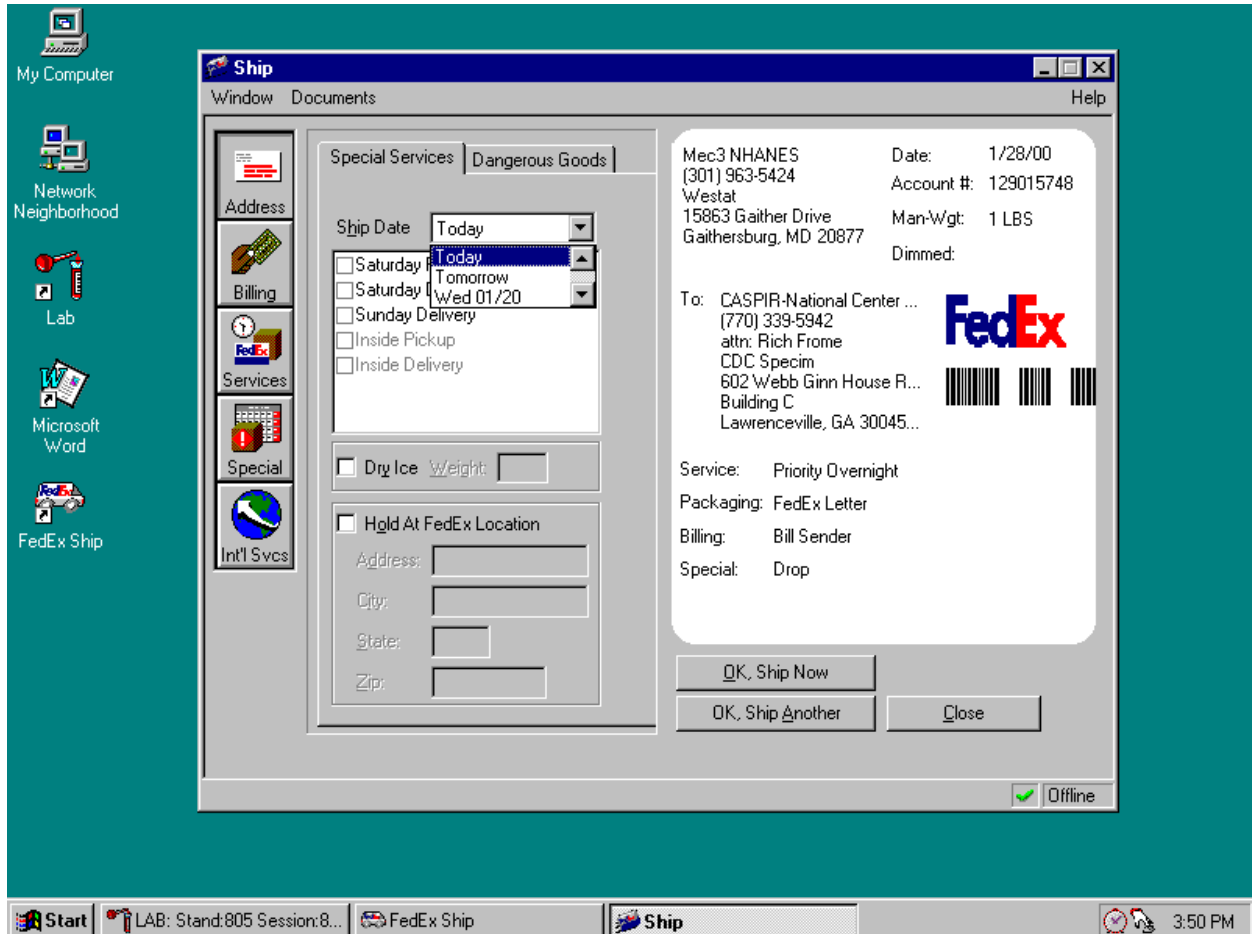


2. Choose Drop-Off, Request Courier, or Regular pickup by clicking the appropriate button. Select Drop Off. **NOTE:** You cannot request a courier until the date of the shipment.



3. FedEx cannot deliver the shipment if someone is not available to sign for it. This feature is disabled.
4. If the shipment contains more than one shipper, enter the total number of pieces in the Total Pieces text box, then enter the Weight and Units for each piece.
5. Use the Next Piece and Previous Piece buttons located above the Value and weight fields to display information for each of the pieces.

- To select special services, click on the Special icon. FedEx Ship displays the Special Services page.



- Create a Future Day Shipment

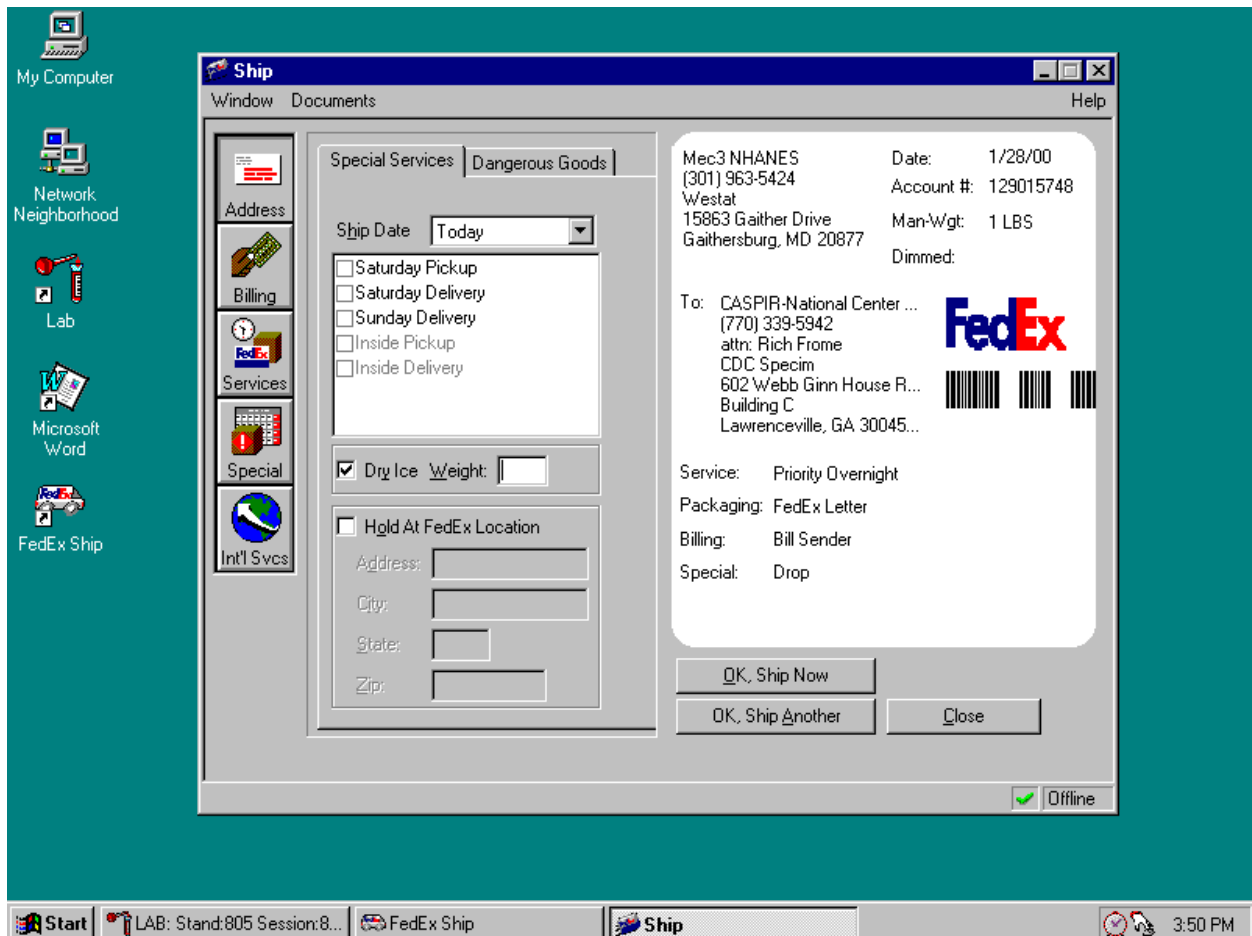
If preparing a label today for a shipment that will be picked up (or dropped off) up to 10 days from the present day, use the Future Day option.

- From the Ship window, click the Special icon. The Special Services page displays.
- From the Ship Date drop-down list, choose the day the shipment will be picked up (or dropped off.) Choose a date up to 10 days into the future.
- When finished entering all the information, click the **OK, Ship Now** button to finish, or click **OK, Ship Another** button to enter another shipment.

4. When finished printing the labels, make sure to attach them to the package or keep them until the actual ship date.

Any future day shipments are saved in the Future Shipments page of the Log. On the day the shipment is to be picked up (or dropped off), it (they) will move to the Today's Shipment page in the Log.

- From the Ship window, click the Special icon. The Special Services page displays. Click the Dry ice check box and enter the weight.



- When finished entering all the information for a shipment in the Ship window, finish processing the shipment, enter the information for another shipment, or save the shipment information and complete the process at a later time. The procedures for each of these processes are provided below.
 - To complete the session, click the **OK, Ship Now** button. Follow the steps in the section “sending Shipment Information to FedEx.”

- To prepare another shipment, click the **OK, Ship Another** button. FedEx Ship automatically saves the shipment information in the Log, then displays a blank Ship window, ready for the next shipment's information. Enter the shipment information in the Ship window as described earlier. After entering the last shipment, click the **OK, Ship Now** button, and go to the next section "Sending Shipment Information to FedEx."
- To save the shipment information and to complete the process at a later time, click **Close** and then click **Yes** to respond to the message "Would you like to keep the changes to the present shipment?" Processing the shipment can be completed from the Log window later.

Sending Shipment Information to FedEx

- If selecting a Request Courier when entering the shipment(s), FedEx Ship displays the "Do you want to request a courier for this shipment now?" prompt. If requesting a courier now, click Yes. FedEx Ship displays the Courier Pickup Request window.
- Make any necessary changes to the information in the Courier Pickup request window, then click **OK**. Make sure the packages are ready by the time indicated as the package ready time.
- The modem automatically dials FedEx, transmits the shipment information, and logs out. When complete, print the labels for the shipment(s) following the instructions in the next section.

Printing the Shipping Label

- After sending the information to FedEx, print the shipping label for each piece in the shipment. Print the labels immediately, as a reminder to label the package. To print the label(s) for the shipment:
 1. Click the **Yes** button when FedEx displays the "Print Labels Now?" message. FedEx Ship displays a Print dialog box.
 2. Click **OK**. Make sure the printer is using 8.5" x 11" paper in tray 2 of the Label/Ship printer.
 3. After the label is printed, fold the paper in half and insert it into a FedEx clear plastic pouch.
 4. Peel the backing off the pouch and place the adhesive side on the top of the package.
- If there are multiple pieces in a shipment, match the labels with the corresponding pieces. Check the labels' Man-Wgt to match labels with their corresponding pieces.

- The shipment processing is complete once a shipment is processed and the label is printed and attached to the piece. The shipment is ready for pickup by a FedEx courier.

Editing a Shipment

- Make changes to any pending shipment before having it picked up by the courier.

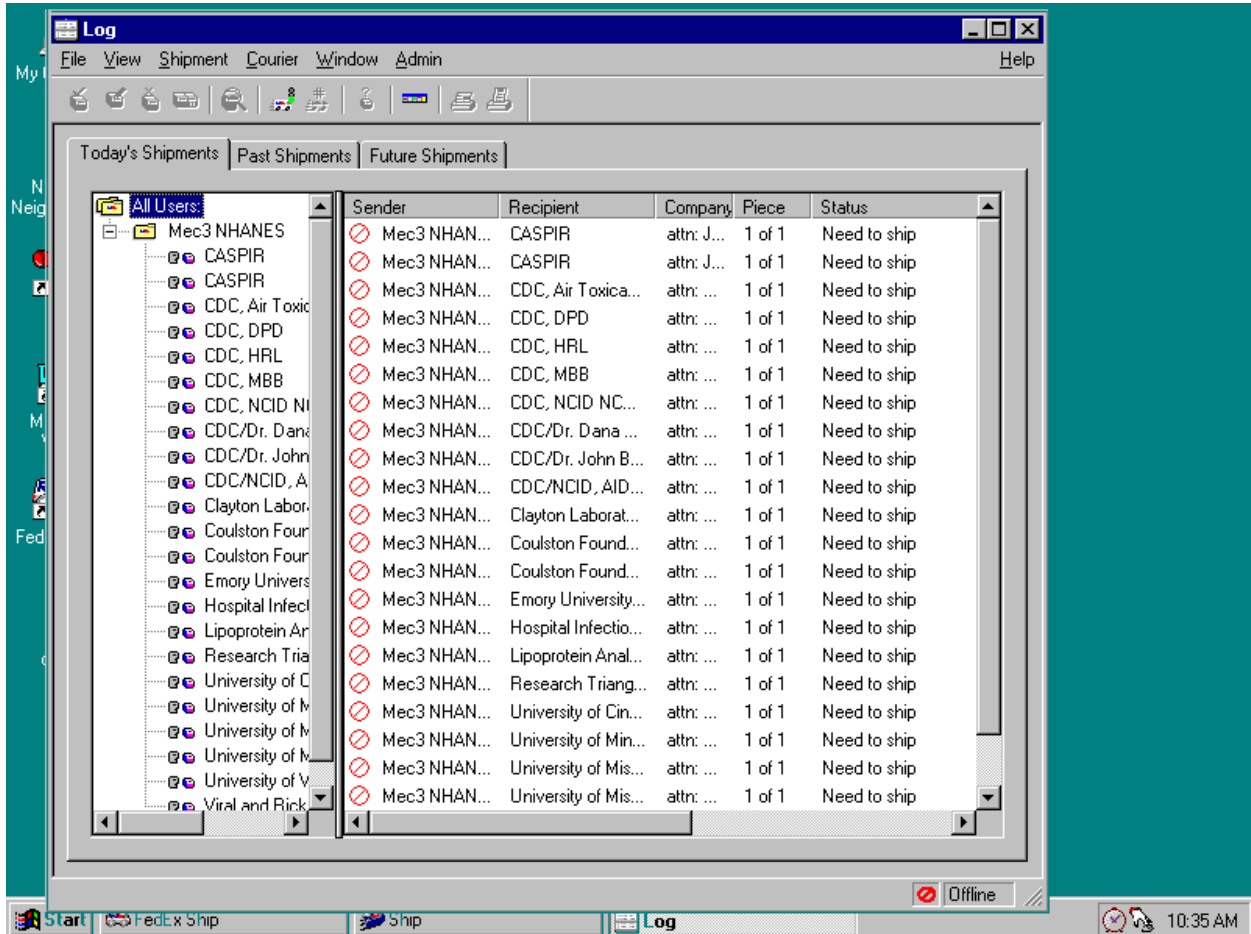
9.8.2 FedEx Log

The Log is a central work area that maintains records of shipment, tracks remaining activities for pending shipments, and maintains a history of previous shipments.

The Log:

- Modifies shipments (edit shipment information);
- Repeats previous shipments;
- Cancels shipments;
- Views today's, past, and future shipments;
- Views the courtesy rate quote (the shipment's receipt);
- Prints shipping labels and receipts;
- Requests courier pickup;
- Processes incomplete shipments; and
- Tracks shipments.

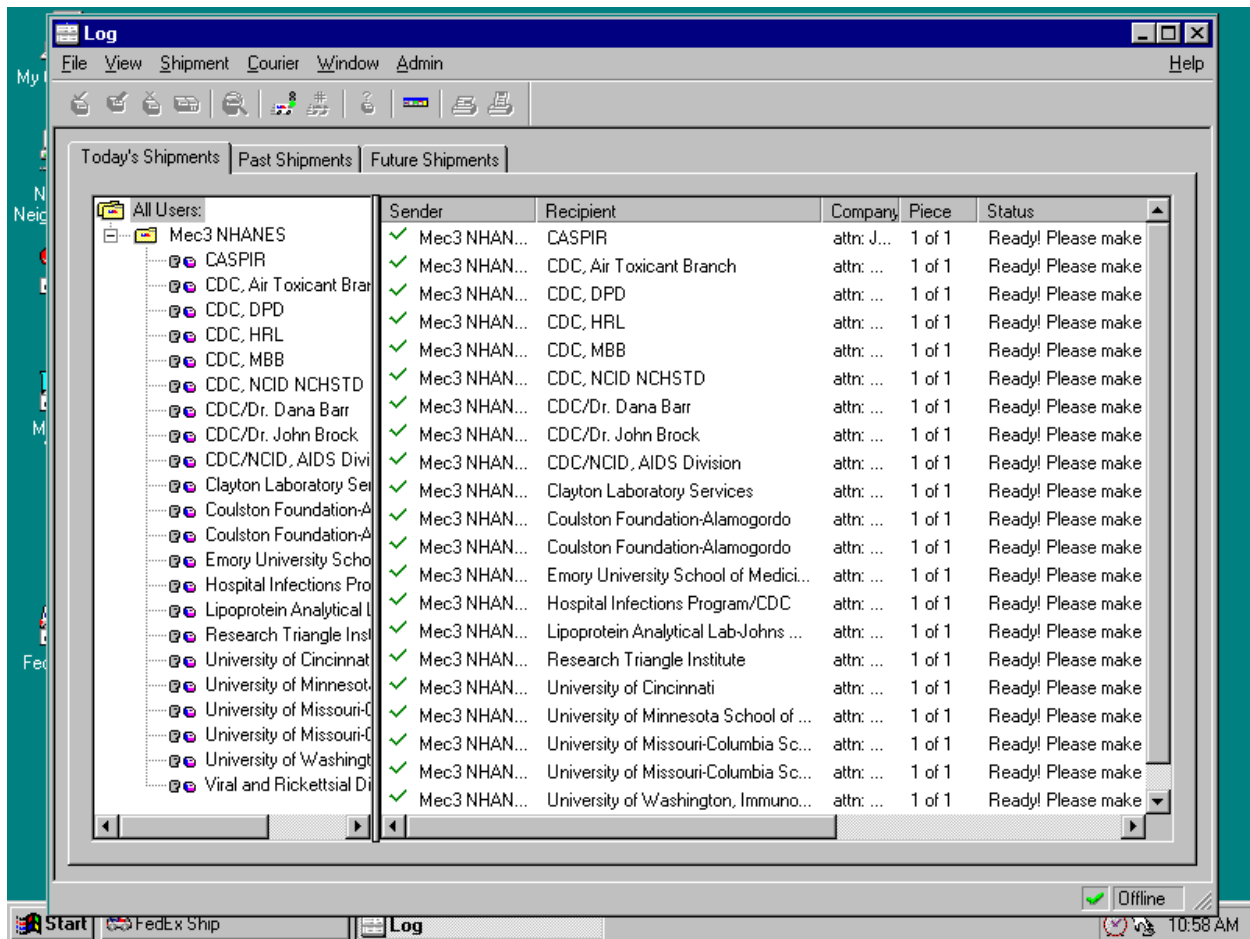
The Log window displays shipments in three pages: Today's Shipments, Past Shipments, and Future Shipments. Select the tab that corresponds to the shipment in question.



- The Today's Shipment page displays all shipments entered today (and shipped from previous days that are still unprocessed). If a shipment in the Today's Shipment page requires further processing, the status column indicates the steps required to complete the shipment.
- The Past Shipment page displays shipments shipped prior to today's date.
- The Future Shipment page displays shipment entered and processed but not shipped.

Today's Shipment

- Today's shipments include shipments that have been shipped today and pending shipments. Shipments remain in the Today's Shipment list until they are completed. To view today's shipments, click the Log icon in the FedEx navigator bar. The Log window



4. To print a shipment receipt, select the shipment from the list and choose Print/Print Receipt from the File menu, or click the Print Receipt icon on the toolbar.
5. FedEx tags shipments that need courier pickup with the “Need to Request Courier” in the status column of the Log window. To request courier pickup:
 - Select the shipment from the list (hold down the Ctrl key and click the left mouse button to select additional shipments).
 - Choose Request Courier from the Courier menu. If this option is gray (not available), edit the shipment to indicate a courier is needed for the shipment.
 - Complete the Courier Pickup Request dialog box.
 - Click OK. FedEx Ship will call to request a courier. After placing the call, a print labels prompt displays (if labels have not already been printed.)

6. To view a courtesy rate quote, select the shipment from the list and choose Show Details from the shipment menu.
7. To cancel a shipment, select the shipment from the list and choose Delete Shipment from the Shipment menu, or click the Delete Shipment icon on the toolbar.

■ Past Shipment

FedEx automatically transfers all completed shipments from Today's Shipments to Past Shipments the day after shipping. Any incomplete shipments remain on the Today's Shipment page until they are processed. To view past shipments, click on the Log icon in the FedEx Ship navigator bar. The Log window displays with the Today's Shipment page active. Click the Past Shipments tab. FedEx displays previous shipments in the Past Shipments page. To display the information for a shipment or track a shipment, select a shipment and choose the operation from the pull-down menus or toolbar icons.

1. To view a shipment's details, select the shipment from the list and choose Show Details from the Shipment menu. The Shipment Details window displays showing the tracking number and courtesy rate quote.
2. To copy or repeat a shipment, select the shipment from the list and choose Repeat Shipment from the Shipment menu. FedEx displays the receipt page with all the information from the previous shipment filled in. Make any changes. When ready to send the shipment, follow the instructions for "Sending Shipment Information to FedEx."
3. To print detail, summary, and historical reports, select the shipment(s) from the list and choose Print/Print History from the file menu. From the Print History sub-menu, select the report: Detail History, Summary by Date, Summary by Recipient, or Summary by Reference.
4. To export historical information from the Log to a spreadsheet or database program, see the online help topic "Exporting Information from the Log."

Future Shipments

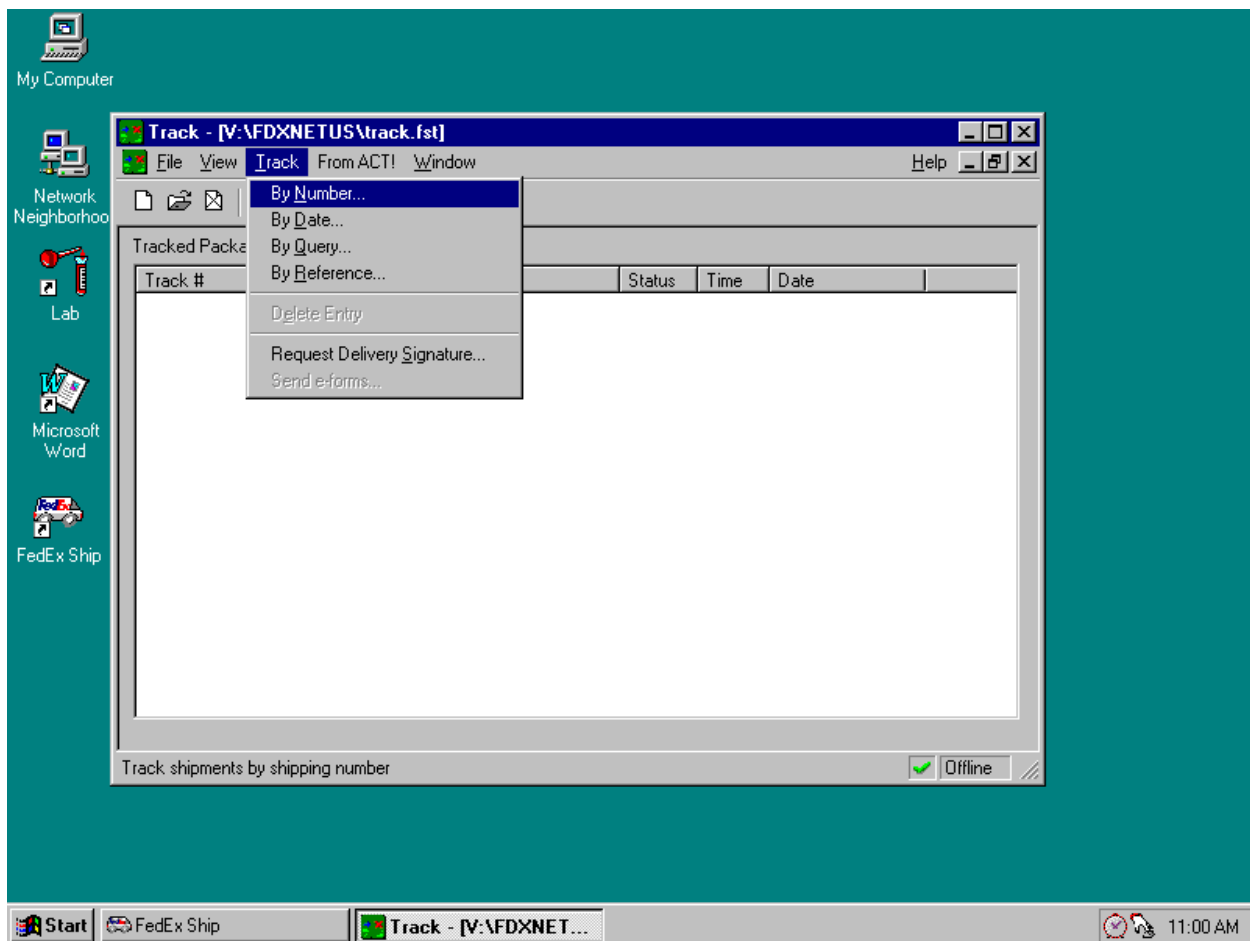
- Shipments scheduled for a future date appear in the Future Shipments page of the Log until the shipping day. FedEx automatically transfers all shipments from Future Shipment to the Today's Shipment page on the day they are scheduled to be shipped. Incomplete shipments remain on the Today's Shipment page until completed. The Future Shipment page in the Log allows all the same functions as the Today page with the exception of requesting a courier.
- To view future shipments, click the Log icon in the FedEx navigator bar. The Log window displays with Today's Shipment page active. Click the Future Shipment tab. Select a shipment and choose the required operation from the pull-down menu.

- For instructions on using the Log, see online help topic “Log” and the individual help topics for performing operations using the Log.

9.8.3 Track Shipments

FedEx automatically assigns a tracking number to the shipment. FedEx Ship can track the delivery status of a shipment at any time using this tracking number.

Track shipments from the Track window. After FedEx Ship obtains the latest delivery information from FedEx, it places the shipment status information in the Track window. If the package has been delivered, the delivery confirmation displays on the screen. If the shipment was sent over 14 days ago, FedEx provides only the final delivery information. Final delivery information is retained for 120 days.



Tracking a Shipment

- The Track window provides up-to-the-minute location and delivery of shipments. Use this feature to find out when, where, and to whom the package was delivered. To track a shipment, identify the package by tracking number, date, query, or reference. Use the tracking option by Number when a tracking number is known. The Track by Date option searches past shipments in the Log by searching on approximate shipping date or time. The Track by Query option searches past shipments in the Log by searching on shipment's information or recipient's name or type of service. The Track by Reference searches the entire FedEx database for shipments matching designated criteria. It requires exact reference information.
 1. To track shipments by number:
 - Click the Track icon in the FedEx Ship navigator bar. The Track window displays.
 - From the Track menu, choose By Number. The Track by Number window displays.

- Enter the tracking number of each piece or shipment, then click the Add button. To enter multiple tracking numbers, click the Add button after entering each number.
 - Click the Track button to initiate the tracking request. FedEx displays a message indicating that it is connecting to FedEx to obtain the latest tracking information.
 - Click the OK button after receiving the information from FedEx. All shipments that match the entered tracking numbers will be tracked and displayed in the Track window.
 - To view details about a shipment, select the shipment and click the Show details icon on the toolbar. The Detailed tracking Information displays detailed tracking information about the shipment.
2. To track shipments by the date they were sent:
- Click the Track icon in the FedEx navigator bar. The Track window displays.
 - From the Track menu, choose By Date. The Track by Date window displays.
 - Specify the date or range of dates to search for shipments. Type the start and end dates into text boxes below the calendars or select the dates by clicking on the calendar. To view another month, click on the desired month. To view another year, click on the arrows next to the calendar.
 - Click the Add to List button to initiate the search request. All shipments in the Past Shipments that match the information are displayed in the Track window.
 - Select the shipment in question and click the Track Now button to initiate the tracking request. FedEx displays a message indicating that it is connecting to FedEx to obtain the latest tracking information.
 - Click the OK button after receiving the information from FedEx. All shipments that match the entered tracking numbers will be tracked and displayed in the Track window.
 - To view details about a shipment, select the shipment and click the Show details icon on the toolbar. The Detailed Tracking Information displays detailed tracking information about the shipment.
3. To track shipments by the query:
- Click the Track icon in the FedEx navigator bar. The Track window displays.

- From the Track menu, choose By Query. The Track by Query window displays.
 - Choose the search criteria. Choose a field from the Field drop-down option (for example, “recipient Name”) Choose a qualifier from the Operator drop-down options (for example, “contents”) Choose or enter the criteria in the value text box.
 - To narrow or expand the search criteria, click the “Add” button or the “Or” button. Use the “Add” operator to narrow the search and use the “Or” button to expand the search criteria.
 - Click the Track button to initiate the search request. FedEx Ship displays all shipments that match the criteria in the Track window.
 - Select the shipment in question and click the Track Now button to initiate the tracking request. FedEx displays a message indicating that it is connecting to FedEx to obtain the latest tracking information.
 - Click the OK button after receiving the information from FedEx. The Track window displays all shipments matching the entered tracking numbers.
 - To view details about a shipment, select the shipment and click the Show details icon on the toolbar. The Detailed Tracking Information displays detailed tracking information about the shipment.
4. To track shipments by the Reference:
- Click the Track icon in the FedEx navigator bar. The Track window displays.
 - From the Track menu, choose By Reference. The Track by Reference window displays.
- Enter the exact reference information on which the search is based. This can be any reference specified on the shipment. The information must match exactly the information specified in the billing reference field of the Ship window, including spaces and punctuation. Specify additional

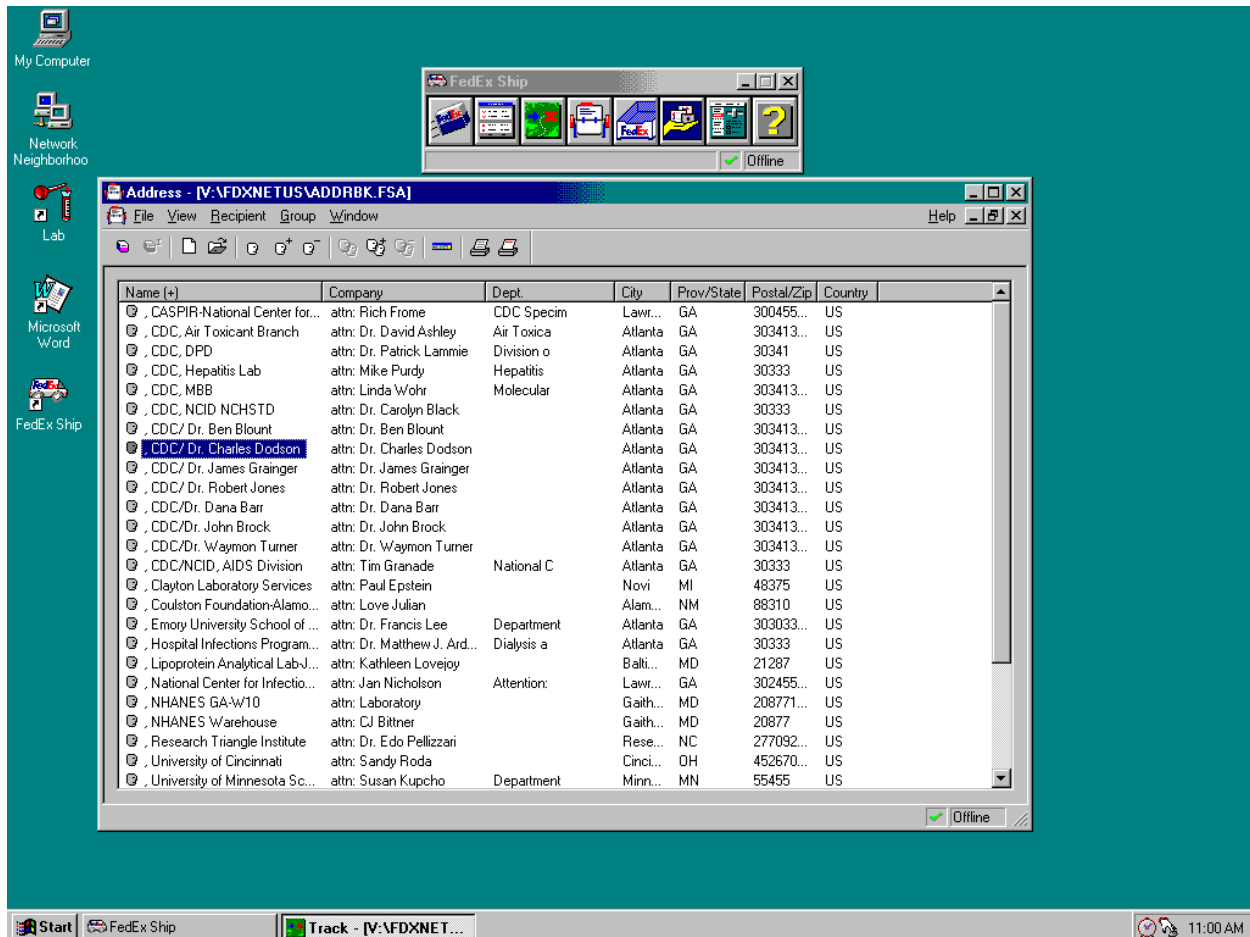
search criteria, if desired. To narrow the search, enter any or all of the following information:

Shipping date;
Shipper's ZIP code;
Shipper's FedEx account number; and
Recipient's ZIP code.

- Click the Add button to add search criteria. FedEx ship displays the search information in the list box. To see more of the information in any column, position the cursor over the column border and drag the border.
- Click the Track button to search for matching shipments. FedEx Ship dials and searches for shipments based on the specified criteria. The Track by Reference Results window displays all shipments that match the criteria.
- Select each shipment in question by clicking on the first column of the entry. To select multiple shipments, hold down the Ctrl key while clicking.
- Click the OK button to initiate the tracking request. FedEx Ship dials FedEx to obtain the latest tracking information.
- Click the OK button after receiving the information from FedEx. FedEx Ship updates the Track window with the shipment status and delivery information.
- To view details about a shipment, select the shipment and click the Show details icon on the toolbar. The Detailed Tracking Information displays detailed tracking information about the shipment.

9.8.4 Address Book

The Address Book stores names and addresses of people and companies to whom shipments are sent. Records are imported directly from ISIS. Do not change or edit this information unless authorized by the technical supervisor at the home office.



Using the Address Book

- Use the address book to quickly select address information for creating shipping labels. This can be done several ways and from different places within FedEx Ship.
 1. From the Ship Window
 - To open the Address Book, click on the Address Book icon on the Recipient page in the Ship window.

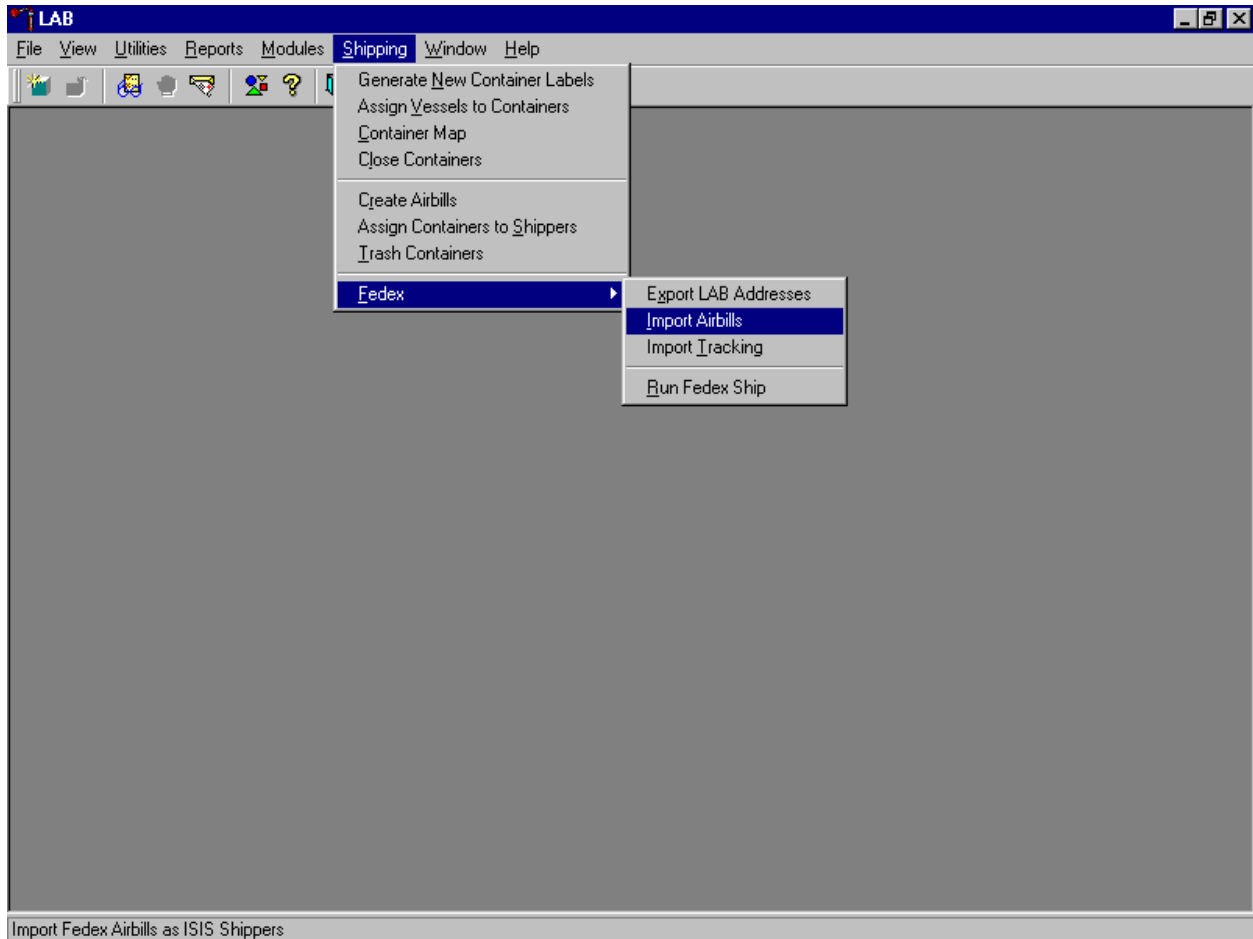
- Select a record.
 - Click the Ship To icon on the toolbar. FedEx Ship automatically enters the name and address information into the Recipient page of the Ship window. Alternatively, start typing the recipient's name in the recipient page in the Ship window. FedEx Ship searches the address book and, if it finds a match, completes the name and address information from the Address Book.
2. From the FedEx Ship Navigator Bar
- Click the Address Book icon to open the Address Book window.
 - Select a record, and then click Ship To icon on the toolbar.
3. From the Address Book Window
- Windows desktop allows FedEx to display the FedEx navigator bar, the Ship window, and the Address Book window simultaneously. Drag and drop a recipient's address information:
 - Drag and drop a record from the Address Book window onto the Ship icon in the navigator bar.
 - Drag and drop a record from the Address Book window into Recipient page of the Ship window.

9.8.5 Shipping Preferences

The Settings Window allows customization to reflect preferences. The data manager uses this window to specify preferences for services, packaging, and shipment collection method.

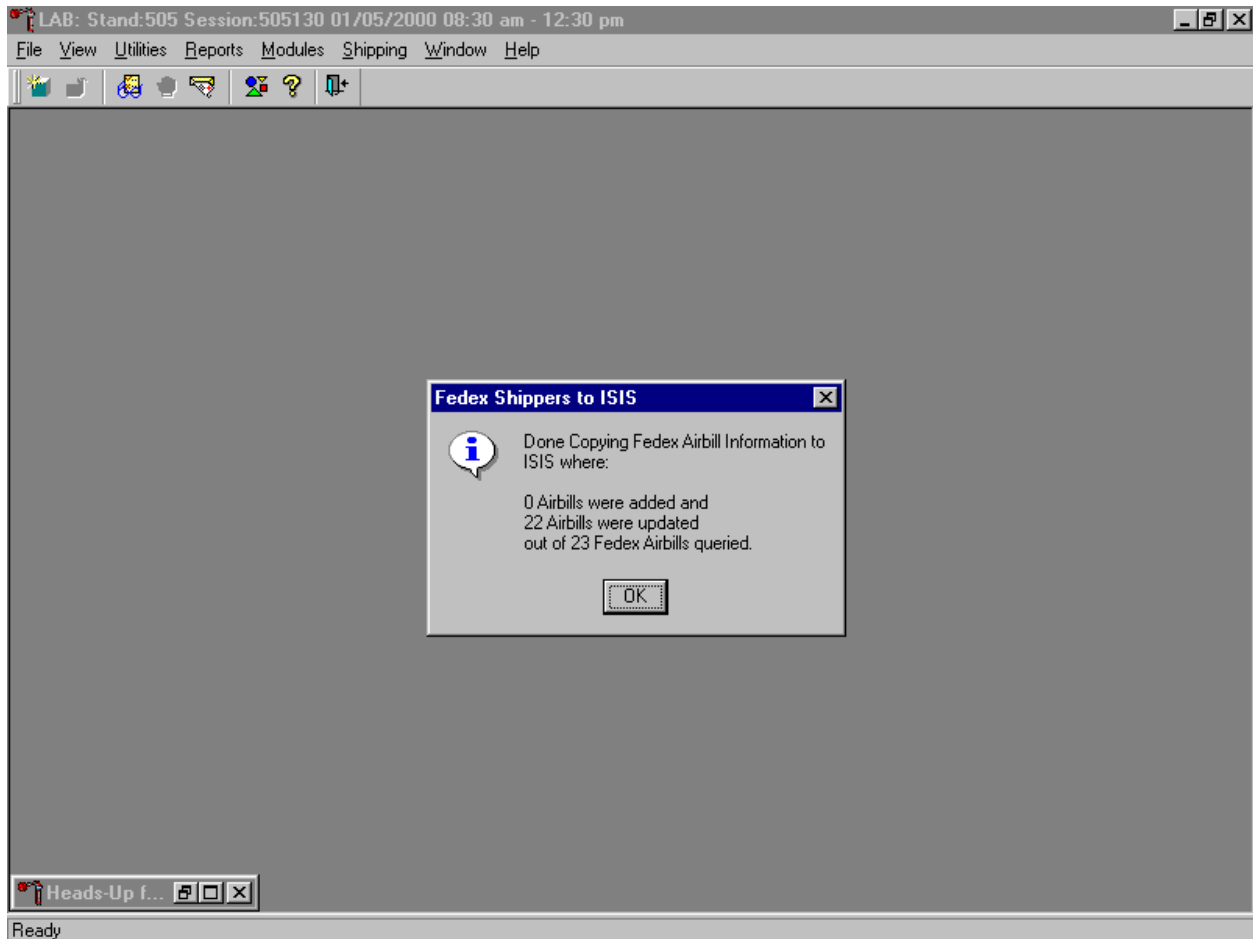
9.8.6 Import FedEx Airbills

Import FedEx airbills.



To import FedEx airbills, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Fed Ex}, then to {Import Airbills} and left click, or type [Alt] [S], [F], [I].

Airbills are now accessible from within the Shipping module.

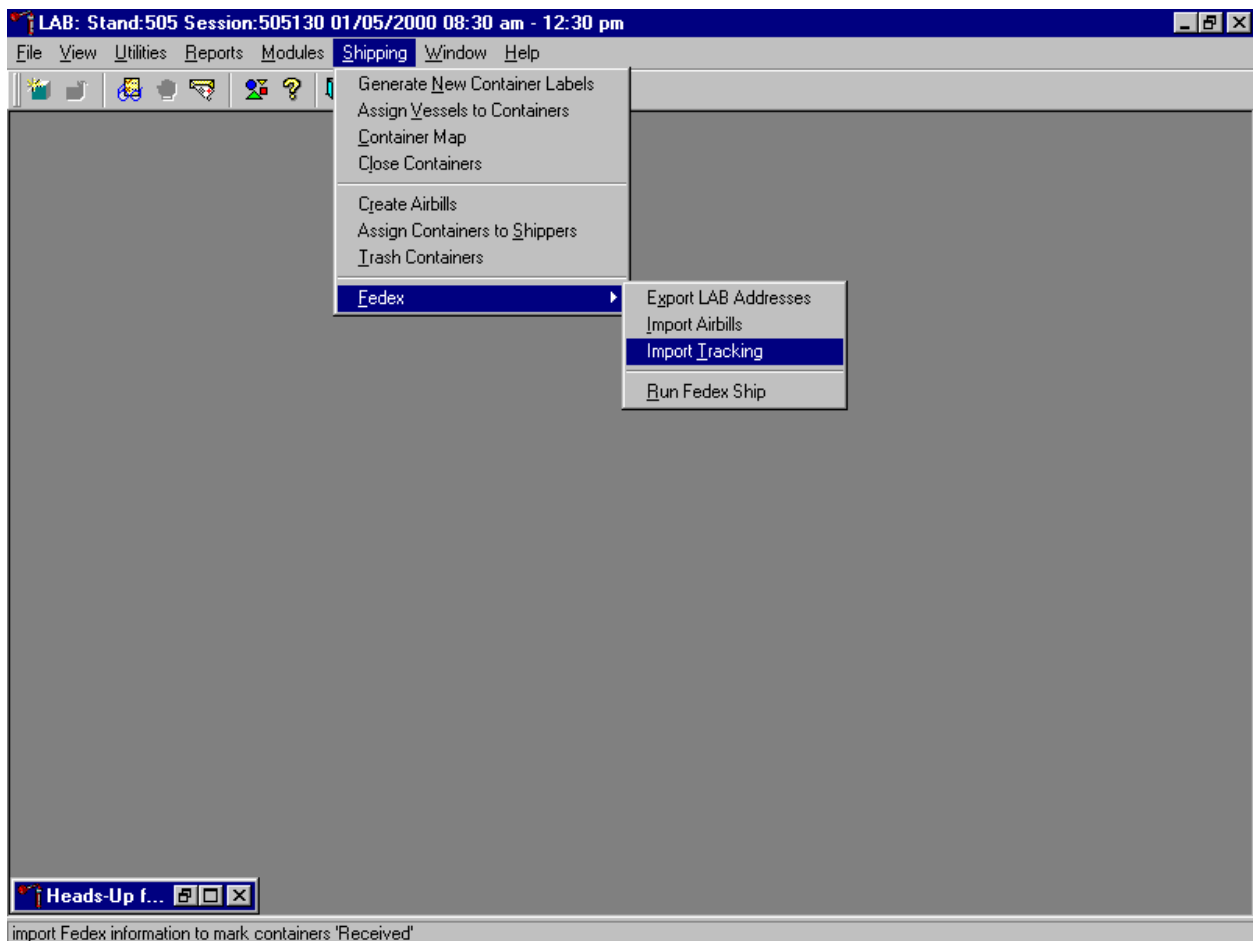


A FedEx Shippers to ISIS informational message text box displays indicating the number of airbills added, updated, and queried. To close this box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

9.8.7 Import Tracking Information and Export LAB Addresses

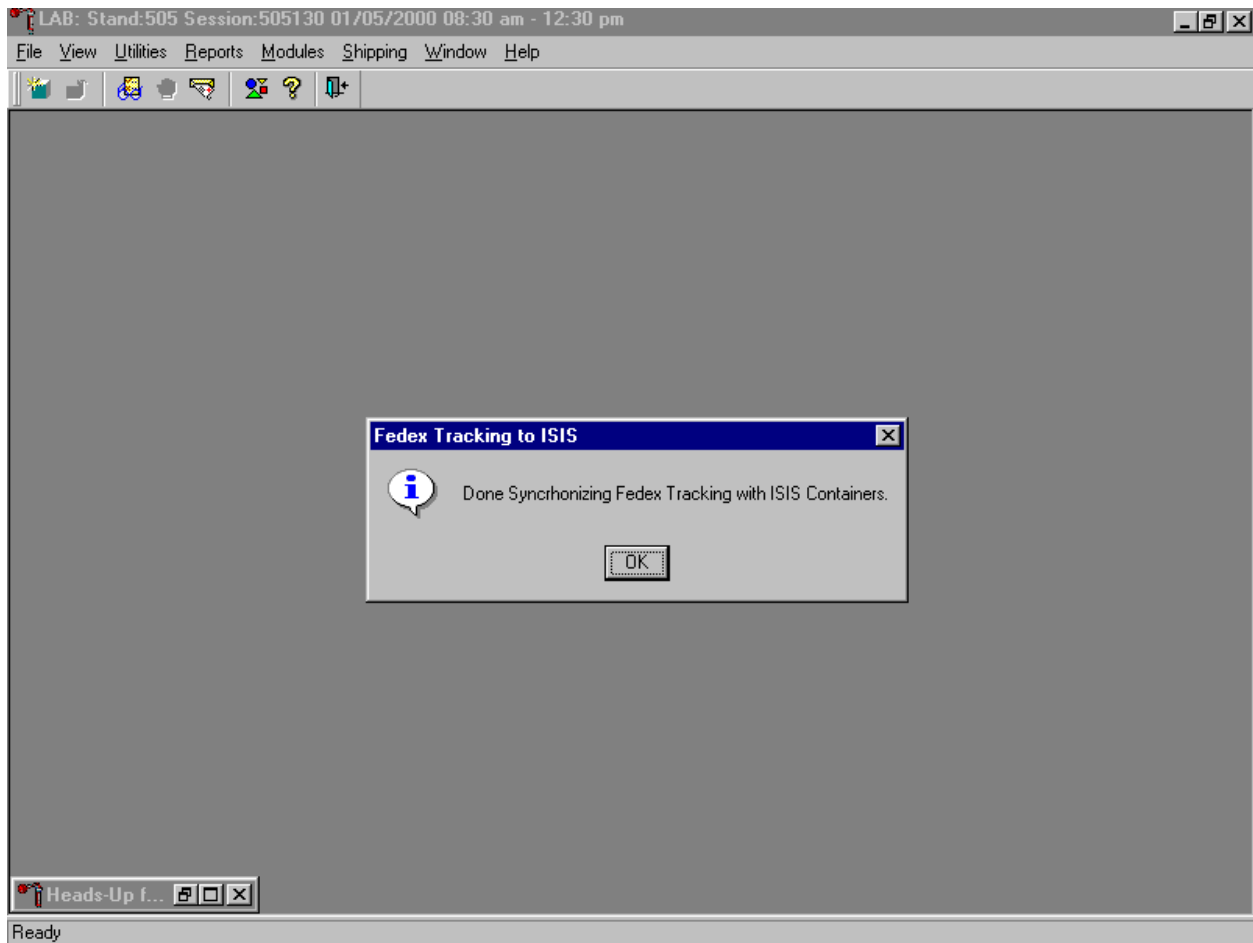
The data manager is the only individual authorized to export LAB addresses from FedEx into the laboratory system.

Import FedEx tracking information into ISIS daily. This is a mandatory maintenance function that allows FedEx to synchronize tracking information with ISIS.



To import tracking information from FedEx, use the mouse to direct the mouse arrow to {Shipping} and left click, drag the arrow to {Fed Ex}, then to {Import Tracking} and left click, or type [Alt] [S], [F], [T].

An informational message text box displays.



A FedEx Tracking to ISIS informational message text box confirms the transfer of tracking information. To close this box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

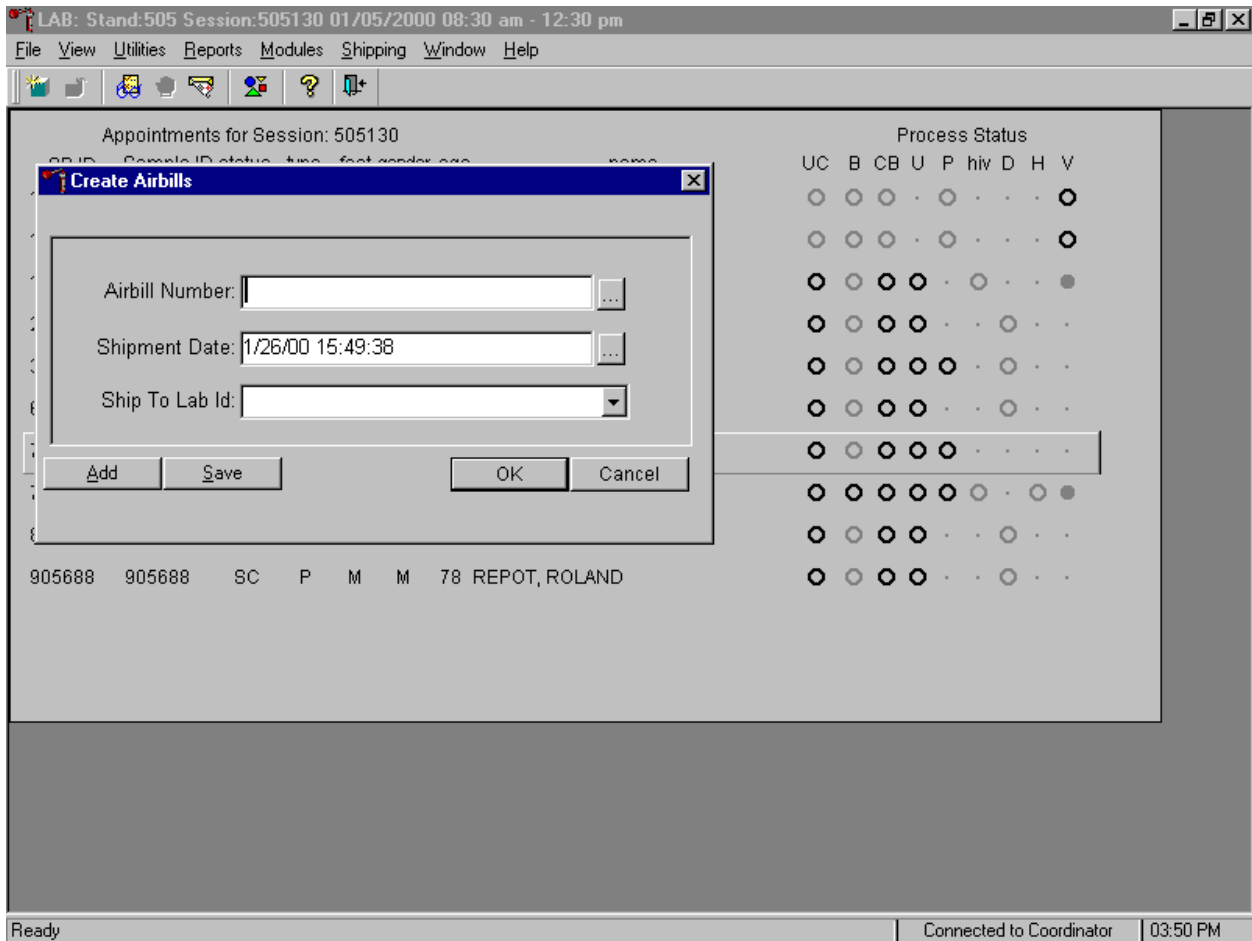
9.9 Create Airbills

Manually create airbills when FedEx Ship is inoperable or edit existing airbills using the Create Airbills module. Access the Create Airbills module.



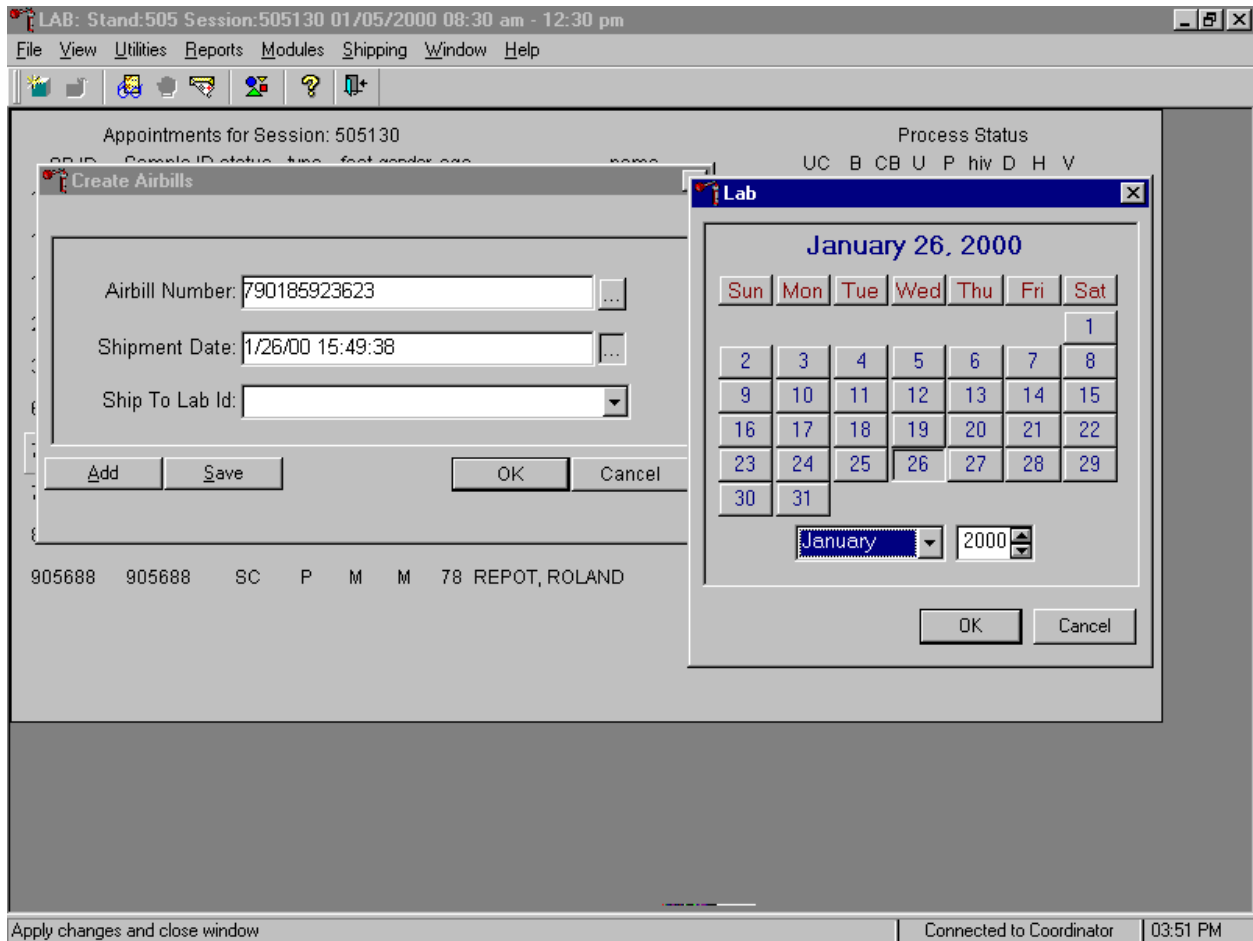
To access the Create Airbills module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Create Airbills} and left click, or type [Alt] [S], [R].

The Create Airbills window displays.



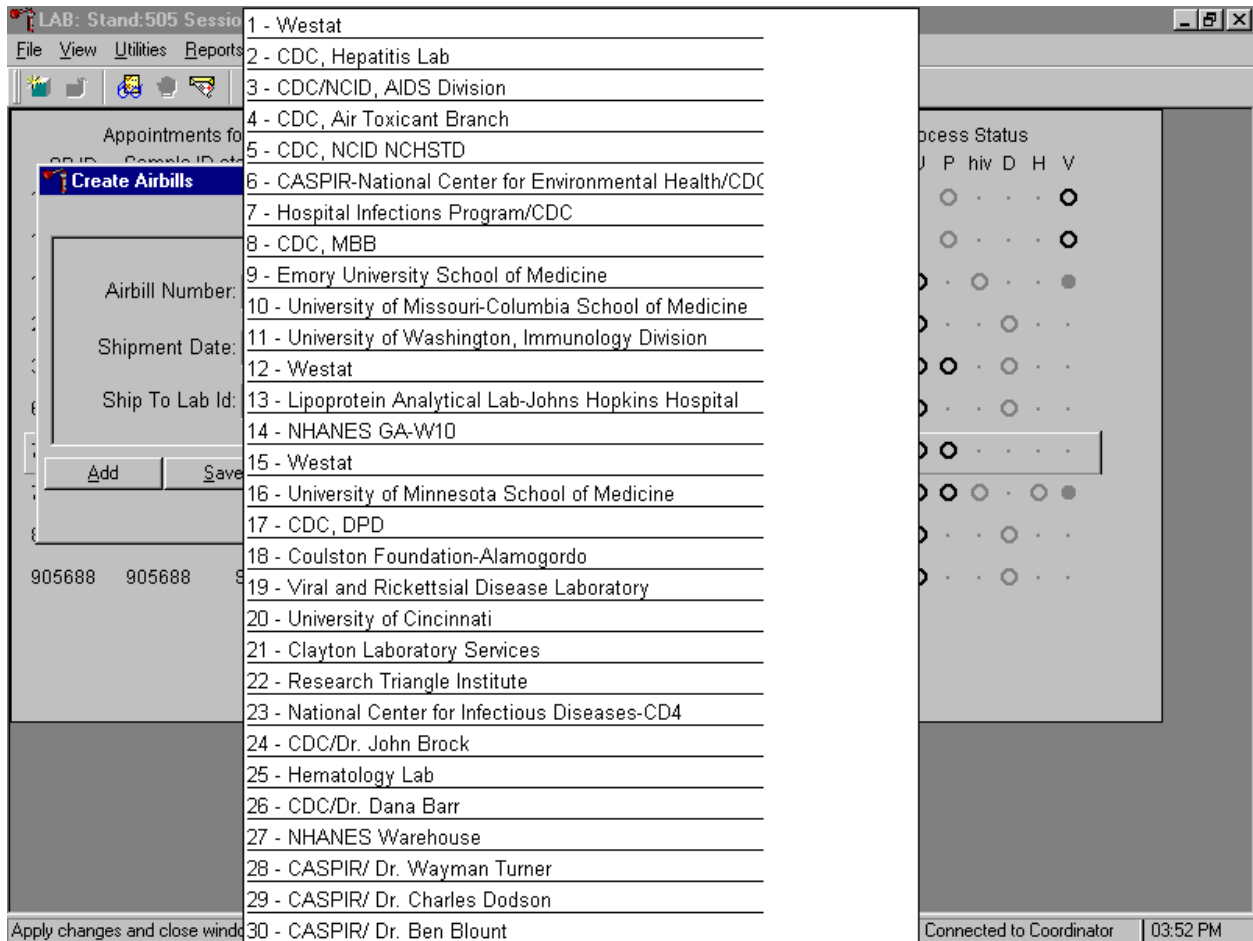
To manually create an airbill, type a FedEx airbill number (from a blank FedEx airbill) into the Airbill Number text box. The Shipment Date defaults to today's date and time. To enter a different date, access the calendar by using the mouse to direct the mouse arrow to the ellipsis button on the right side of the Shipment Date box and left click to display the calendar.

The calendar displays.



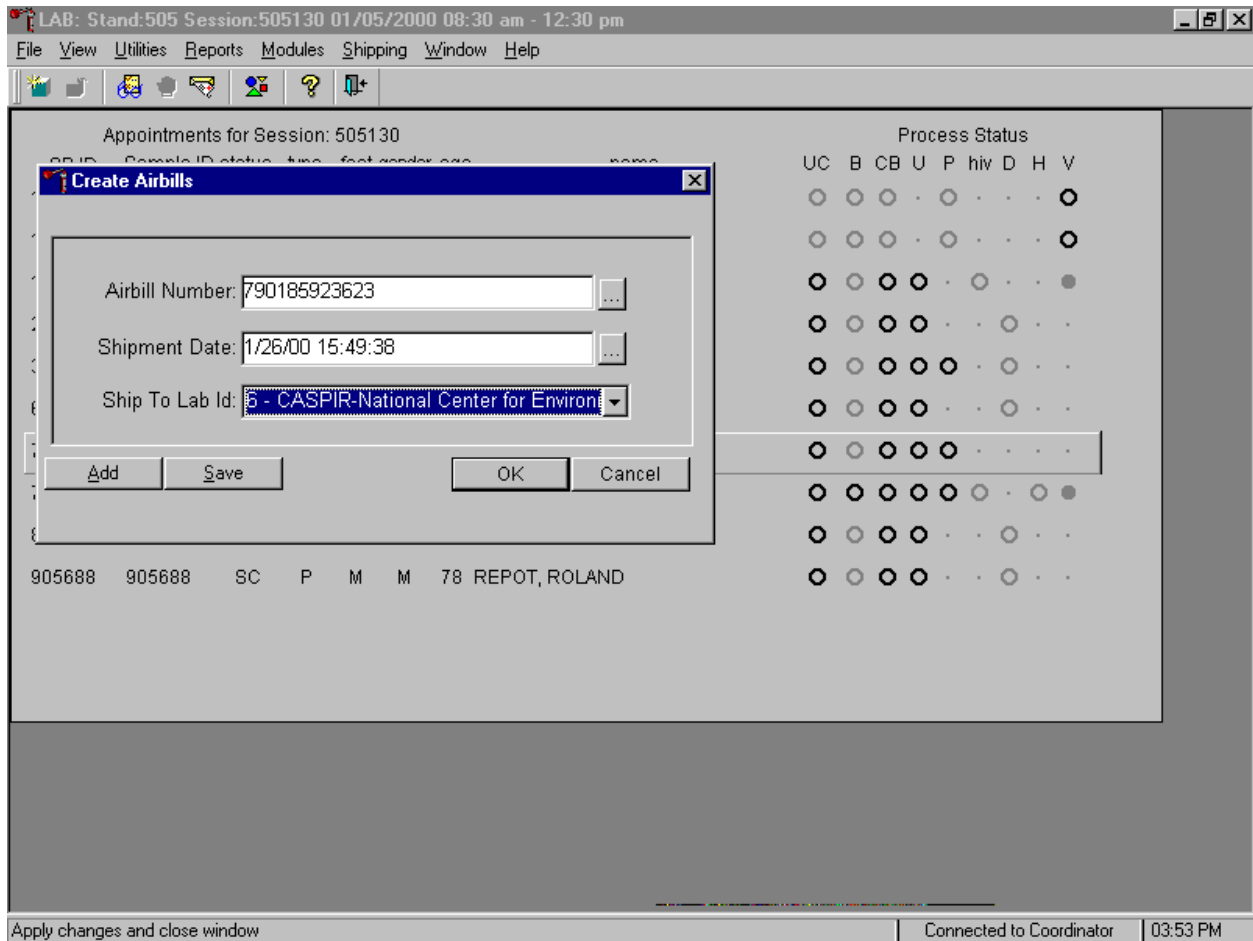
To select or specify a date, use the mouse to direct the mouse arrow to the month drop down list, drag the arrow to the correct month (use the vertical scroll bar if necessary) and left click. Select the correct day by using the mouse to direct the mouse arrow to the correct day on the displayed month and left click. Correct the year by using the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer the day, month, and year into the date space and to exit the calendar window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar window without entering or transferring a date into the date space, use the mouse to direct the mouse arrow to **Cancel** button and left click.

Associate a specific laboratory with each airbill.



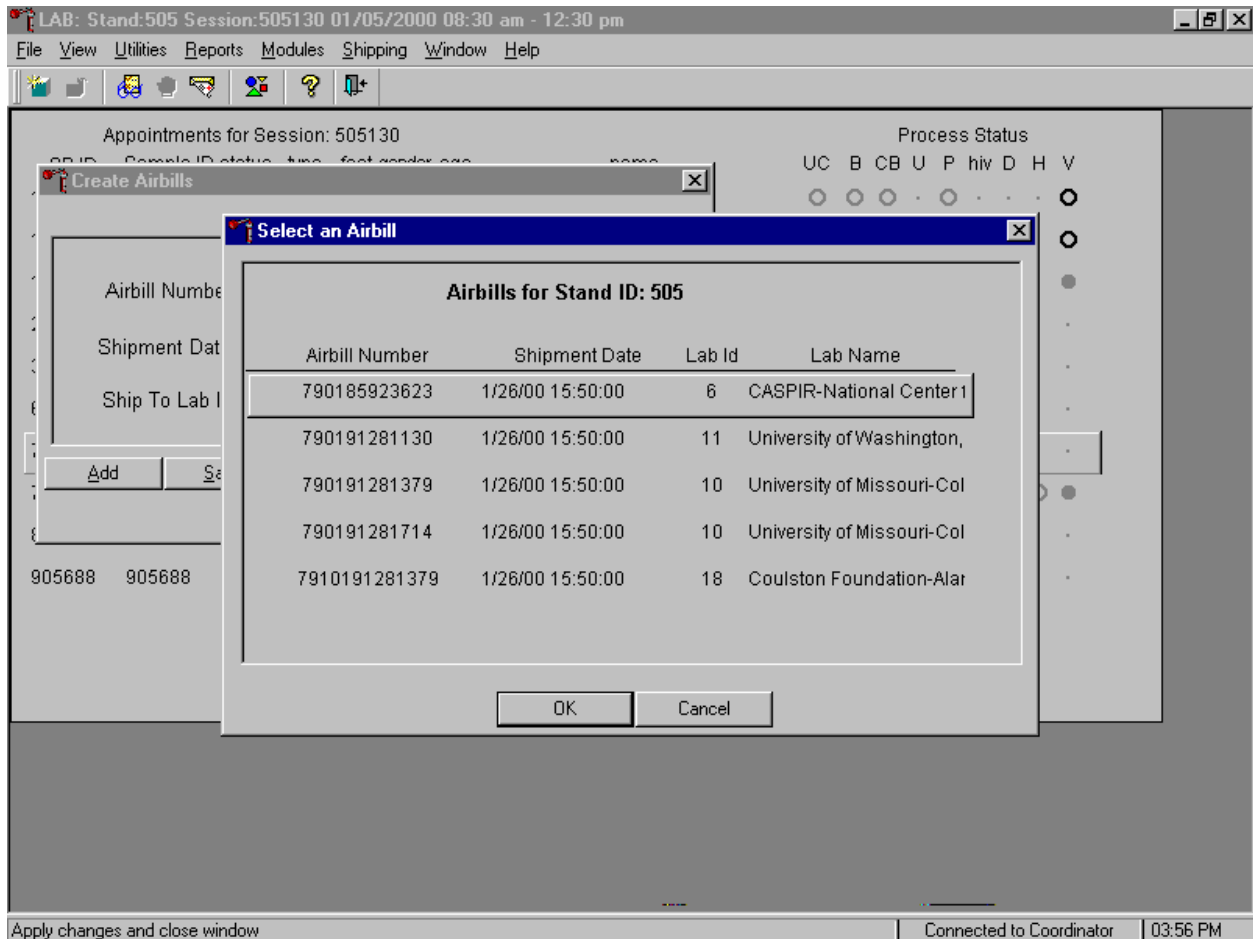
To display the list of contract laboratories and to select one laboratory, use the mouse to direct the mouse arrow to the drop down list on the right side of the Ship To Lab ID box, left click, drag the arrow to the correct laboratory, and left click.

Save the information or continue creating additional airbills.



To complete this process of associating a specific laboratory with this airbill number and date, use the mouse to direct the mouse arrow to the **S**ave button and left click, or type [S]. To continue creating additional airbills, and to save the current airbill, use the mouse to direct the mouse arrow to the **A**dd button and left click, or type [A]. To record or save the information and exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click, or select [Enter]. To exit the module without recording or saving the information, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

Use the Create Airbill module to edit an existing airbill.



To select an existing airbill to edit, type the existing FedEx airbill number into the “Airbill Number” text field, or use the mouse to direct the mouse arrow to the ellipsis button on the right of the Airbill Number box and left click to display existing airbills. To select an airbill from the list, use the mouse to direct the mouse arrow to the correct choice and left click. Alternatively, use the up and down keyboard keys to move up and down the list and left click when the correct choice is enclosed in the box. When the correct airbill is selected, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. Continue to edit the information associated with this airbill. To exit the window without recording or saving the information, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

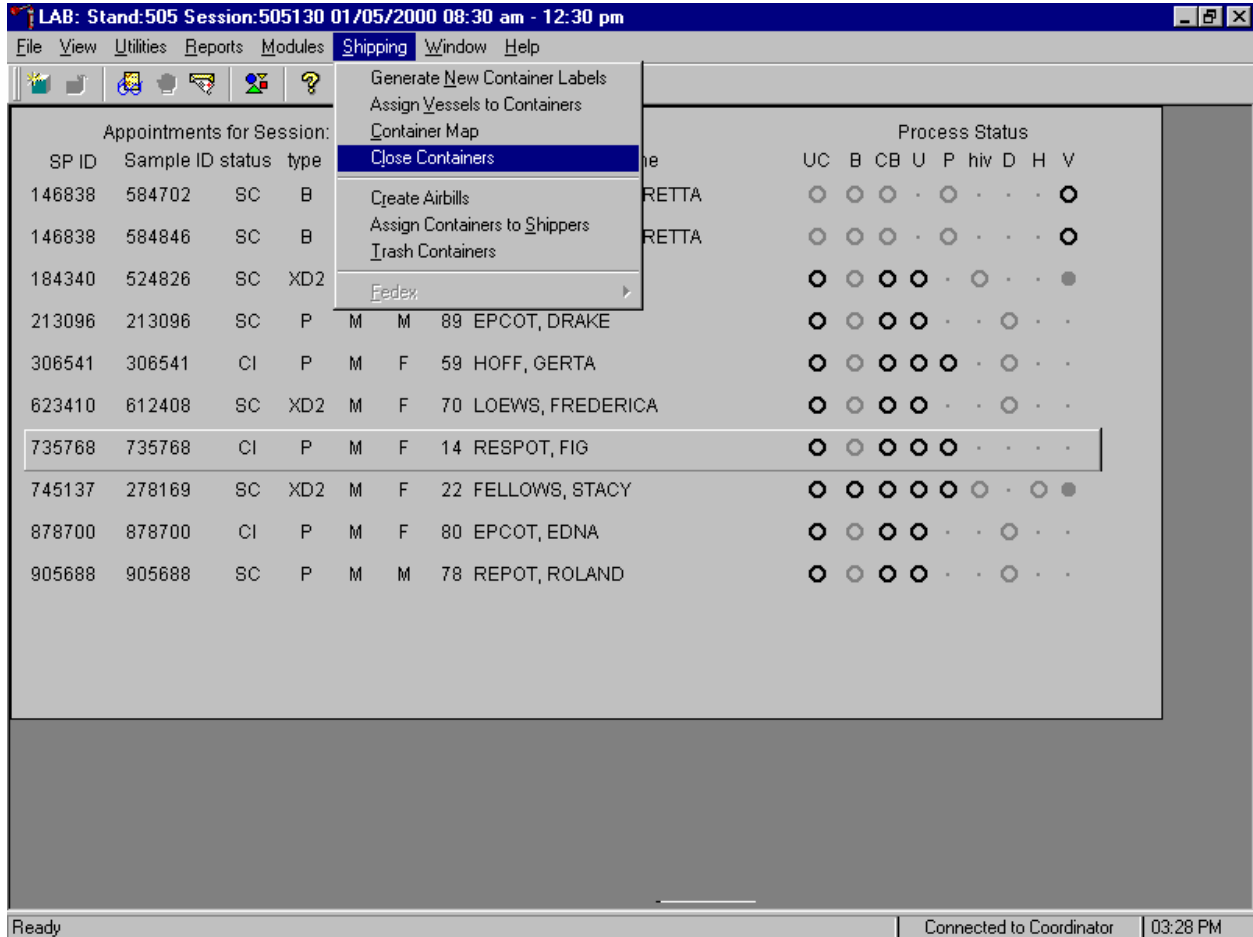
Edit the shipping date by using the mouse to direct the mouse arrow to the ellipsis button on the right side of the Shipment Date text box, left click and enter the new date. Correct the Ship to Lab ID

information. To display the list of contract laboratories and to select one laboratory, use the mouse to direct the mouse arrow to the drop down list on the right side of the Ship To Lab ID box, left click, drag the arrow to the correct laboratory, and left click. To complete this process of associating a specific laboratory with this airbill number and date, use the mouse to direct the mouse arrow to the **S** button and left click, or type [S]. To continue creating additional airbills, and to save the current airbill, use the mouse to direct the mouse arrow to the **A** button and left click, or type [A]. To record or save the information and exit the module, use the mouse to direct the mouse arrow to the **O** button and left click, or select [Enter]. To exit the module without recording or saving the information, use the mouse to direct the mouse arrow to the **C** button and left click.

9.10 Close Containers

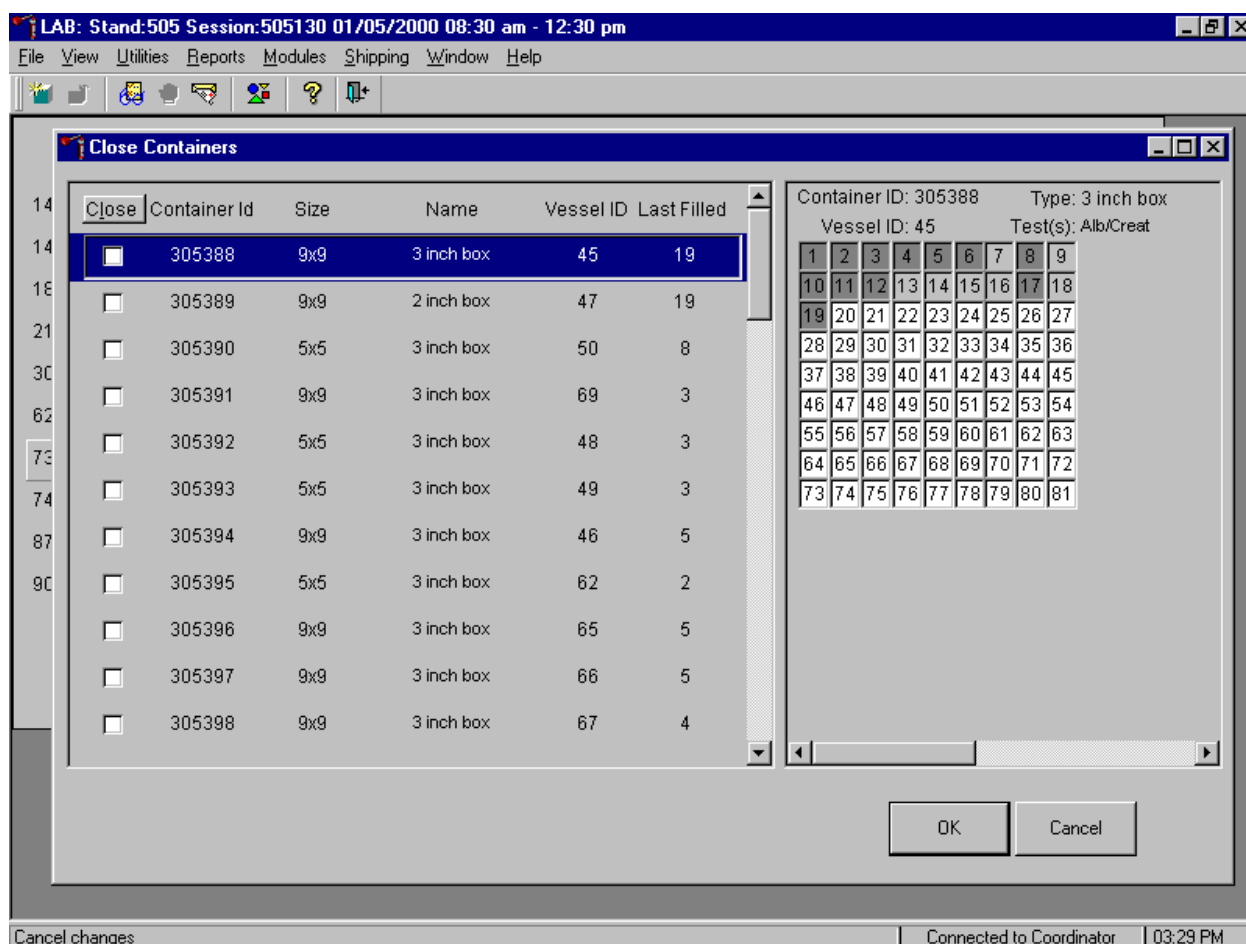
After a container is full, it is automatically closed. All open containers must be manually closed before shipping.

Access the Close Containers module.



To open the Close Container module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Close Containers} and left click, or type [Alt] [S], [L].

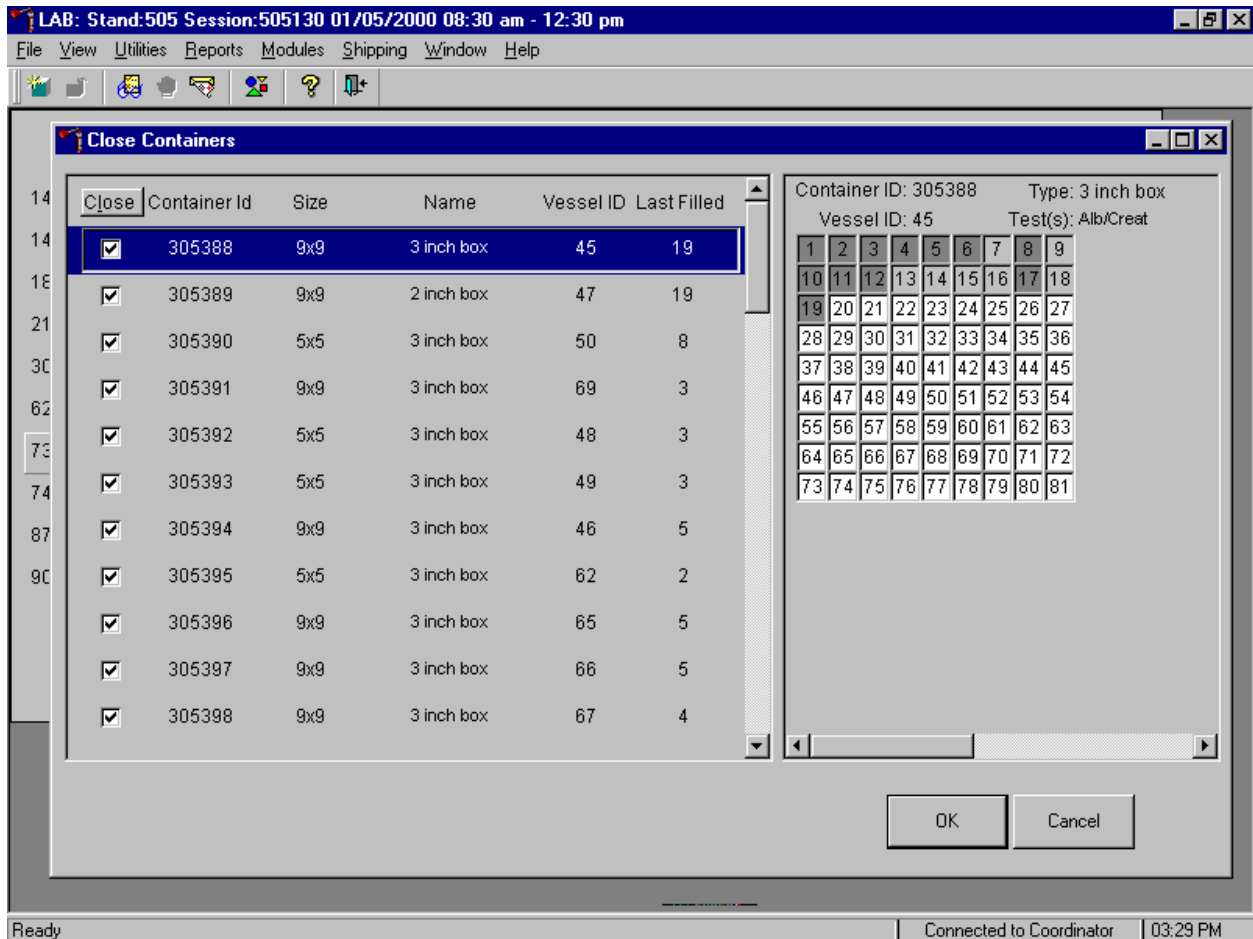
Individually close open containers or collectively close all open containers.



The left side of the Close Container screen includes a check box for each open container, the container ID, size, name, vessel ID, and number of the last slot filled. The container line in the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. To move up and down the list, use the up and down keyboard arrows or use the mouse to direct the mouse arrow to any individual line. Use the vertical scroll bar to view all containers.

To mark individual containers, use the mouse to direct the mouse arrow to individual Close button check boxes and left click.

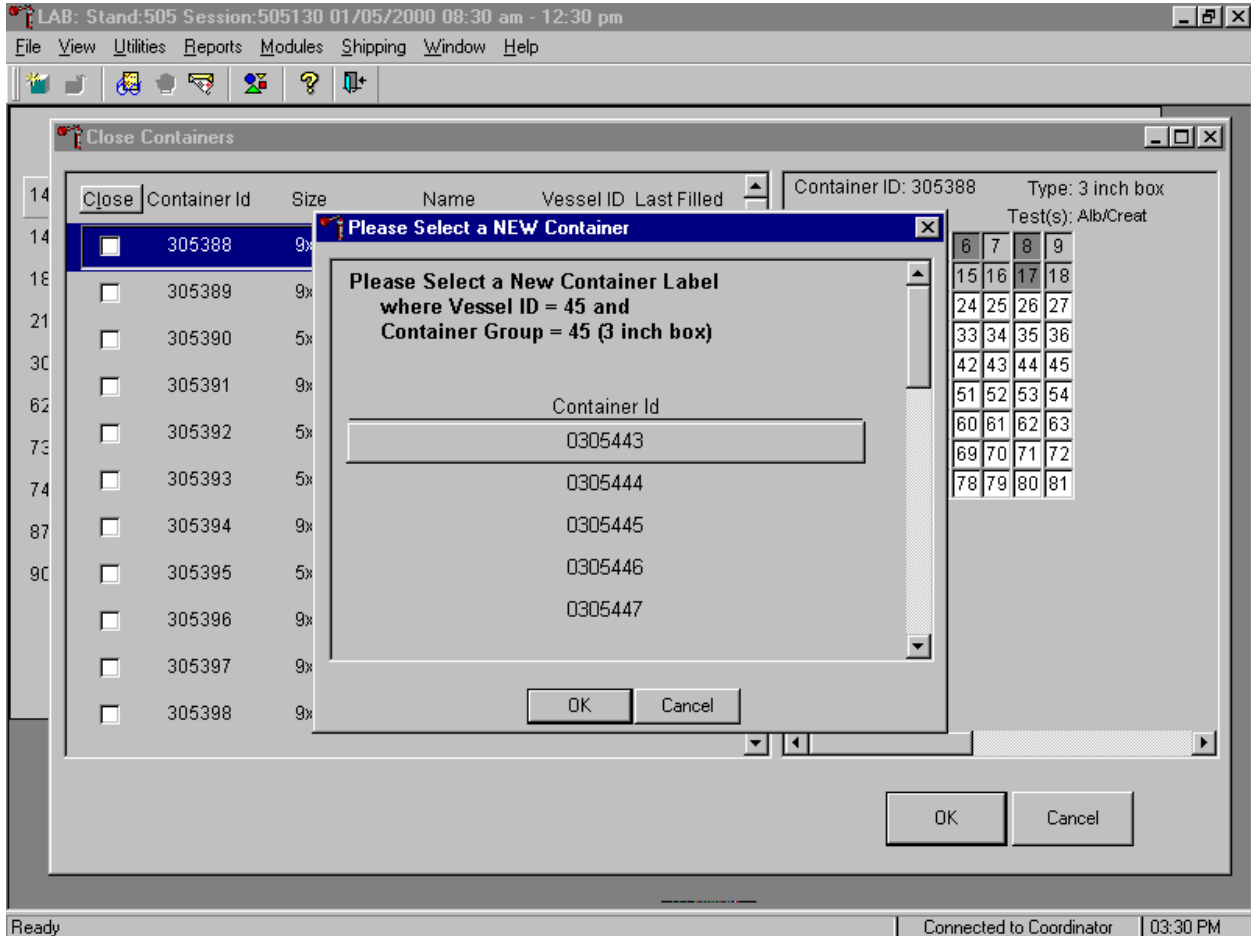
Collectively close all containers.



To close all open containers, use the mouse to direct the mouse arrow to the **C**lose button and left click. To remove the check marks, use the mouse to direct the mouse arrow to the **C**lose button and left click a second time.

Verify the contents of each closed box by visually matching the contents of the box to the map. To record these actions, use the mouse to direct the mouse arrow to the **O**K button and left click, or select [Enter]. To exit the Close Containers module without recording these actions, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

As each container's check box is individually marked, the opportunity to open a new container to replace the closed container is presented.



Do not individually mark containers in this manner on a routine basis. When a container is individually marked, an opportunity to open a new container is automatically displayed on the “Please Select a NEW Container” window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit the window without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

9.11 Assign Containers to Shippers

Assign closed containers to or associate closed containers with a specific airbill. Use the Auto-Assign feature to automatically assign all closed containers associated with a specific laboratory to that laboratory's airbill. Manually verify and correct the assignment of Coulston Foundation's refrigerated vessel 18 (Biochem) and frozen vessels 25 (FSH/LH) and 28 (TSH/Thyrox). Manually verify and correct the assignment of the University of Missouri's refrigerated vessel 4 (Glycohem) and frozen vessels 9 (Glucose) and 23 (Insul/Cpep). Manually verify and correct the assignment of the CDC/AIDS Division's refrigerated vessel 53 (urine HIV) and frozen vessel 22 (serum HIV). Verify and correct the assignment of the vessels to CASPIR, since there are multiple airbills.

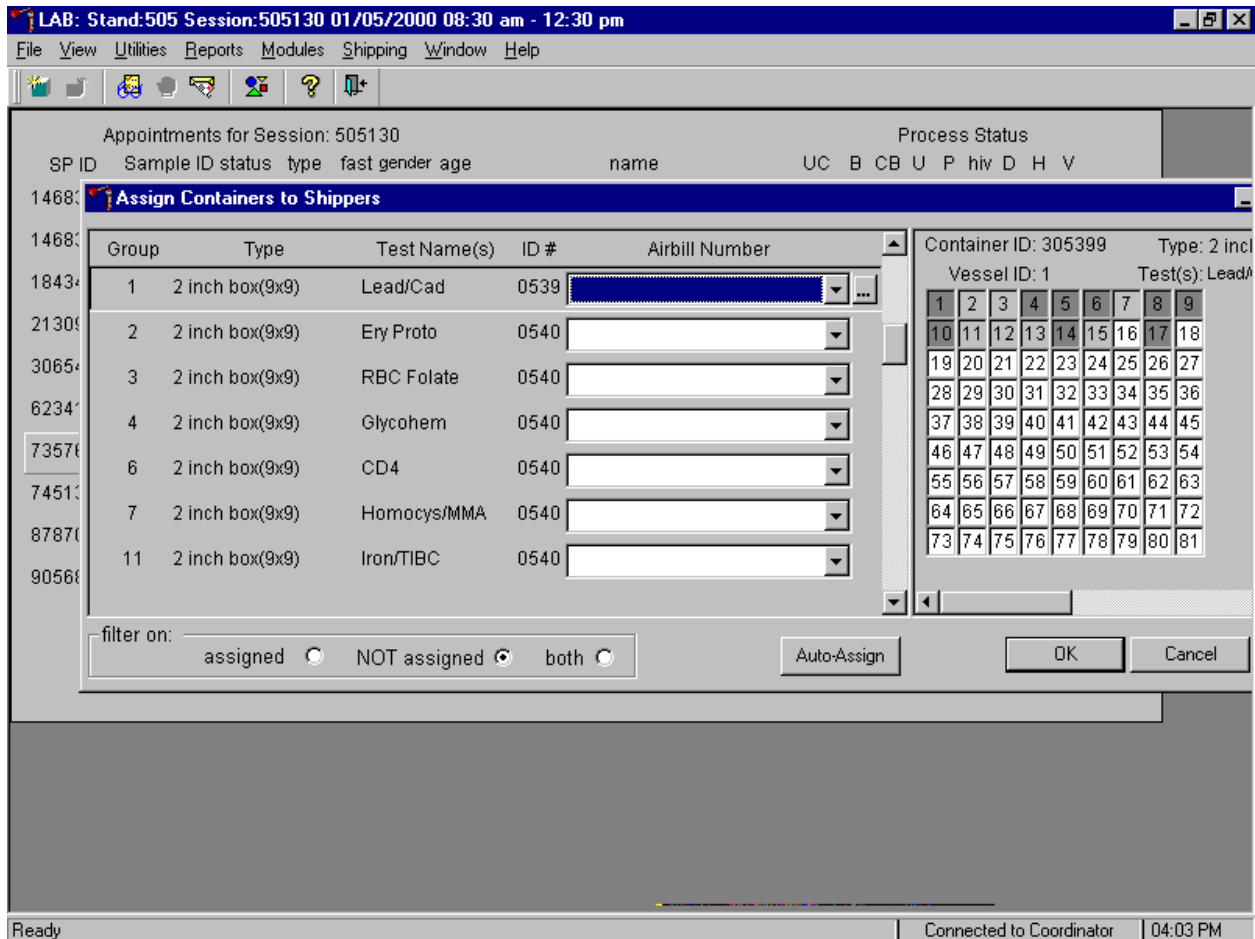
Access the Assign Containers to Shipper module.

The screenshot shows a software window titled "LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. A context menu is open over a table, with "Assign Containers to Shippers" highlighted. The table has columns for SP ID, Sample ID, status, type, and Process Status (UC, B, CB, U, P, hiv, D, H, V). The table contains several rows of appointment data.

SP ID	Sample ID	status	type	Process Status
146838	584702	SC	B	UC B CB U P hiv D H V
146838	584846	SC	B	UC B CB U P hiv D H V
184340	524826	SC	XD2	UC B CB U P hiv D H V
213096	213096	SC	P	UC B CB U P hiv D H V
306541	306541	CI	P	UC B CB U P hiv D H V
623410	612408	SC	XD2	UC B CB U P hiv D H V
735768	735768	CI	P	UC B CB U P hiv D H V
745137	278169	SC	XD2	UC B CB U P hiv D H V
878700	878700	CI	P	UC B CB U P hiv D H V
905688	905688	SC	P	UC B CB U P hiv D H V

To access the Assign Containers to Shippers module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Assign Vessels to Containers} module and left click, or type [Alt] [S], [S].

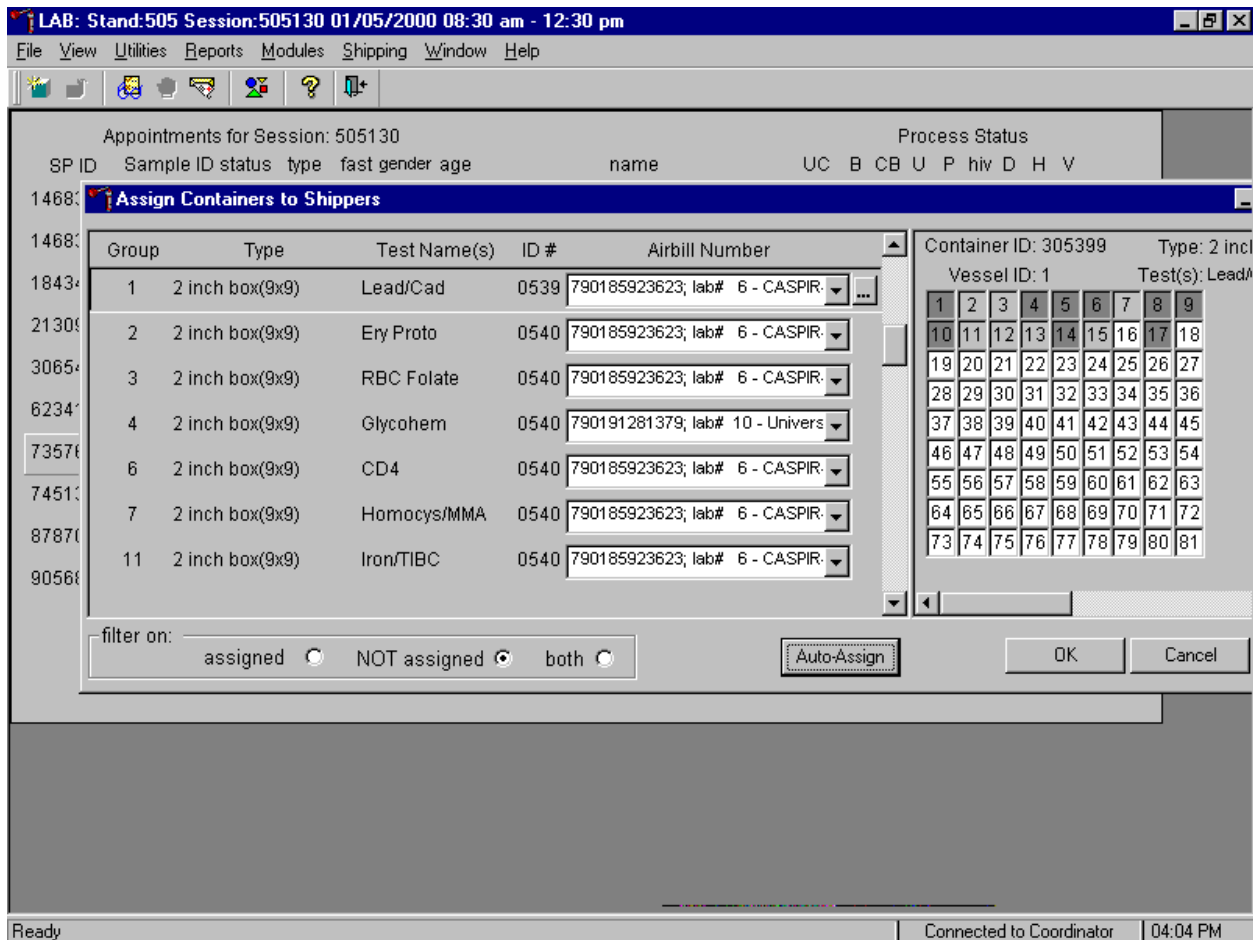
The Assign Containers to Shippers window displays.



This left side of the screen includes columns for a group designation (which represents one laboratory), Type of container, Test Name(s), Container ID number, and an Airbill Number. The Airbill Number text box includes a drop down list. The container line within the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. The bottom of the window contains three “filter on” radio buttons: “assigned”, “NOT assigned”, and “both,” and an **Auto-Assign** button.

To auto assign all containers to their corresponding airbill,

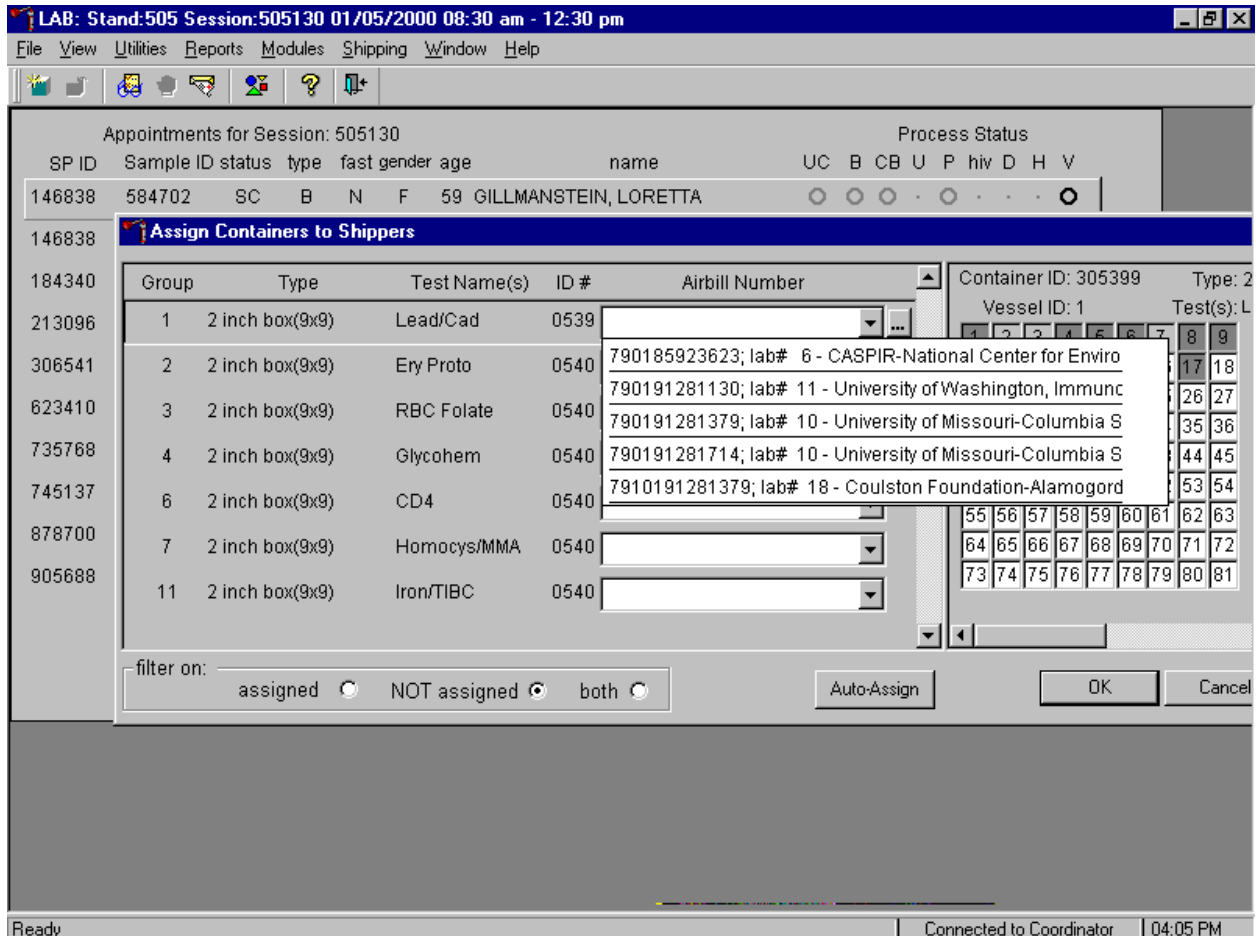
- Set the filter on: to NOT assigned.
- Use the mouse to direct the mouse arrow to the **Auto-Assign** button and left click.



- Containers are automatically assigned to the correct airbill associated with the correct laboratory with a few exceptions. Remember to verify and correct the assignment of airbills to Couston Foundation, University of Missouri, CDC/NCID AIDS Division and CASPIR.

To assign individual containers to the a shipper,

- Set the filter on: to NOT assigned.
- Use the mouse to direct the mouse arrow to the drop down list of the Airbill Number text box and left click to display the list of airbills.



- To select or identify a specific airbill, use the up and down keyboard arrows to move up and down the list, use the mouse to direct the mouse arrow to the correct airbill, and left click.
- To view all choices, use the vertical scroll bar.

If necessary, verify the contents of each closed box by matching the contents of the box to the map. To record the assignment of containers to shippers, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. This step is required to save the information. To exit the Assign

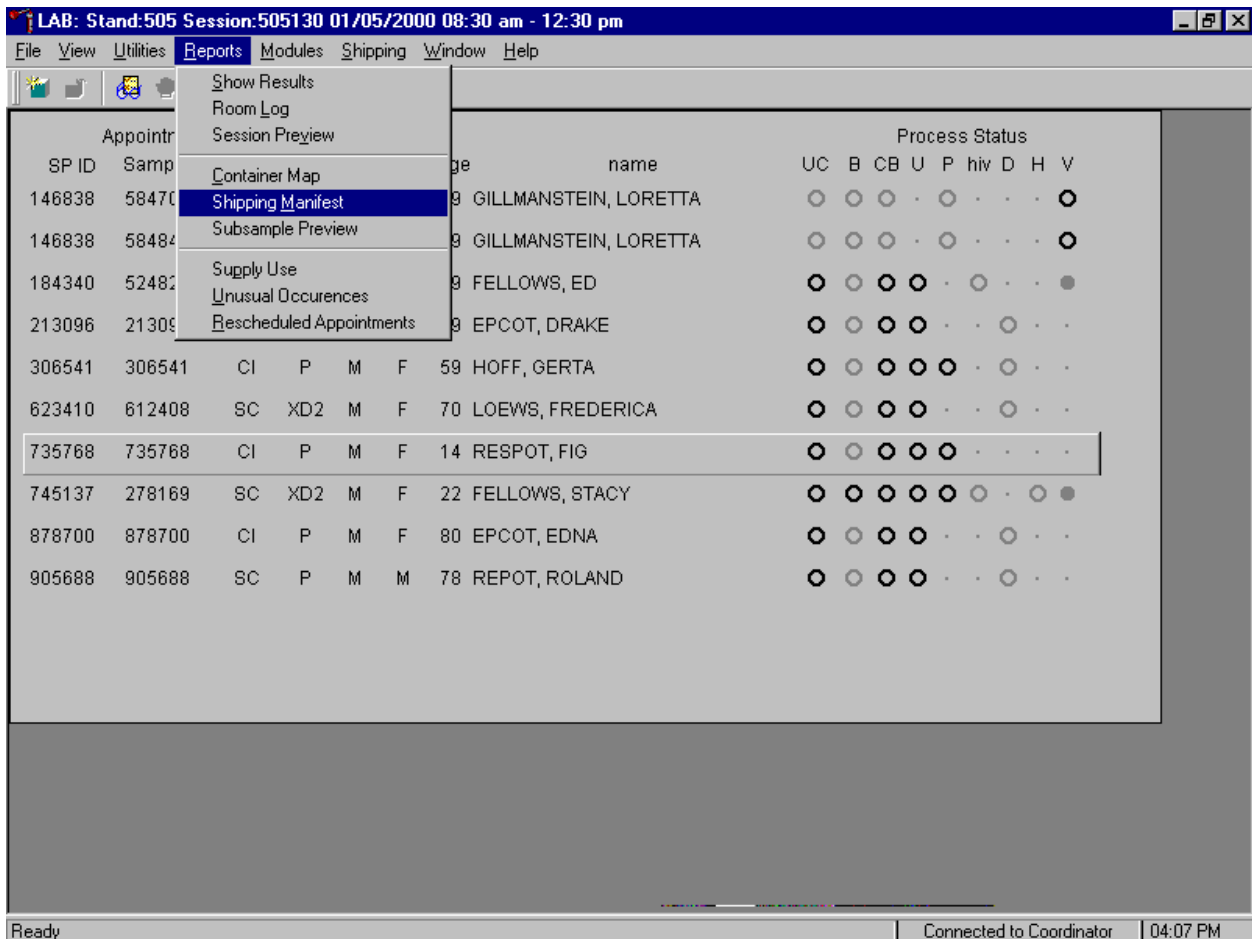
Containers to Shippers module without recording any assignments, use the mouse to direct the mouse arrow to the button and left click.

The shipper(s) is(are) ready to pack and ship.

9.12 Create Shipping Manifests

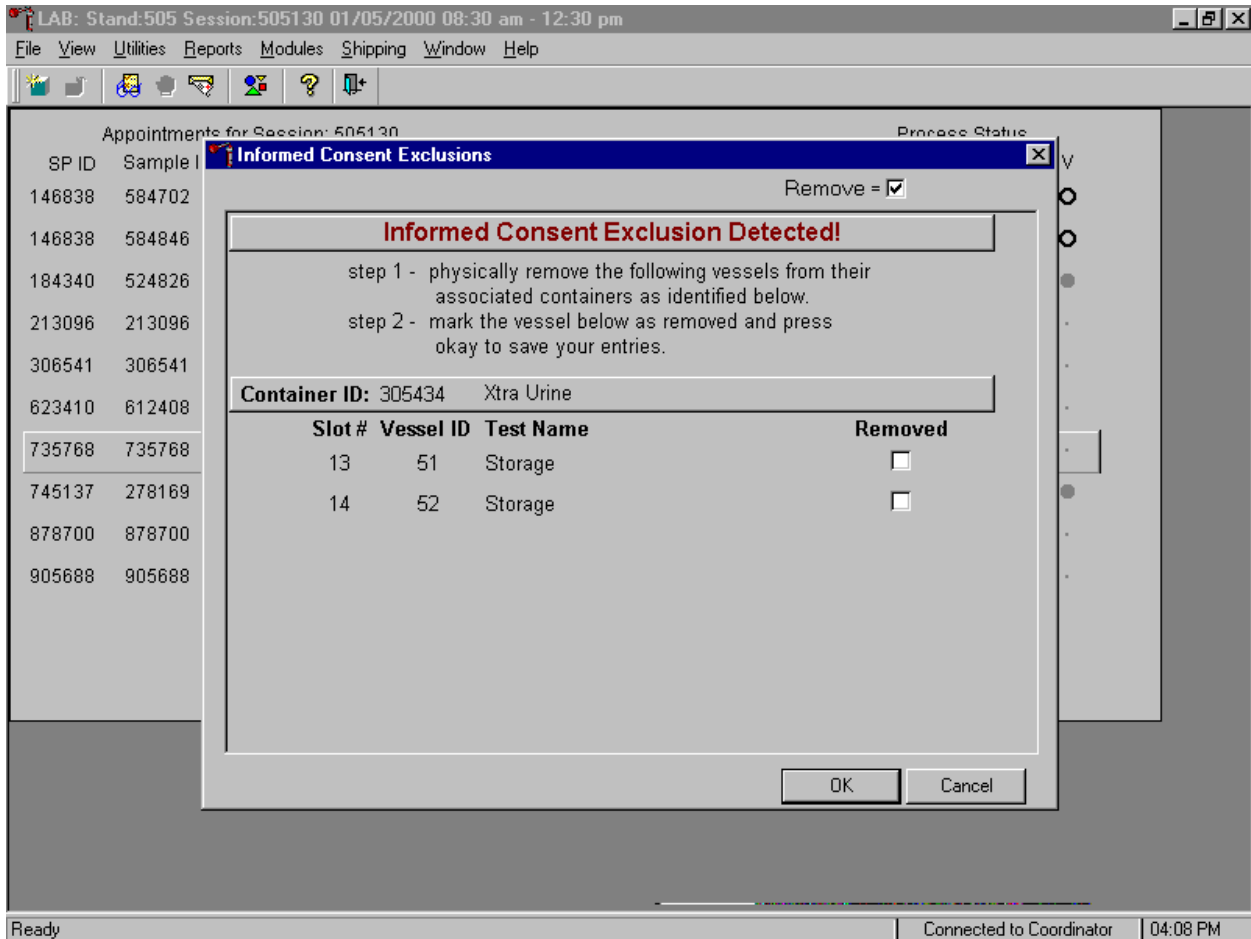
Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed below to prepare the paper manifest and to send the electronic file.

Access the Shipping Manifest module.



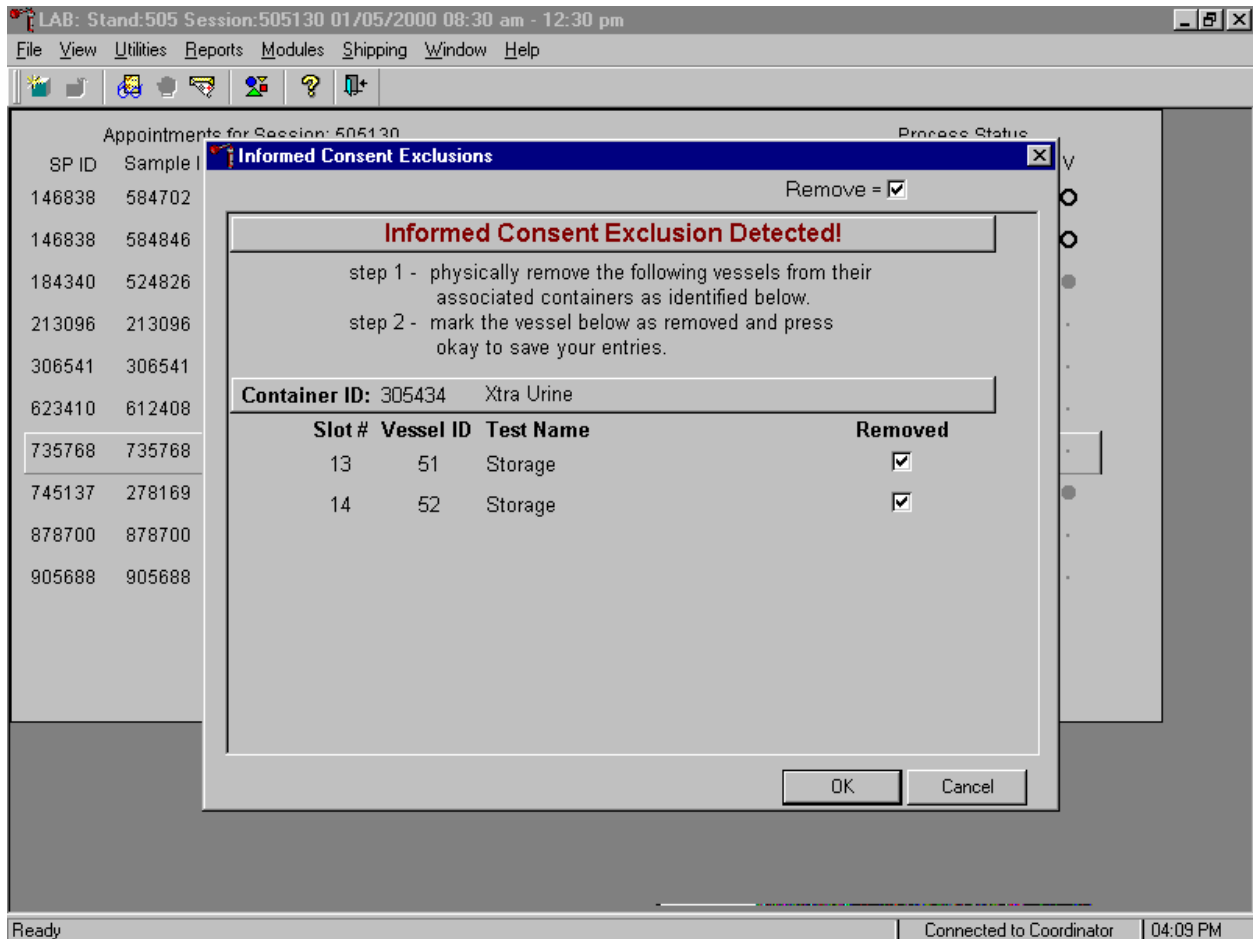
To access the Shipping Manifest module, use the mouse to direct the mouse arrow to {Reports}, left click, drag the mouse arrow to {Shipping Manifest} and left click, or type [Alt] [R] [M]

If an SP initially signed their STD and/or future research consent form and subsequently refused, and the associated vessels have already been processed, the Informed Consent Exclusions window displays.



These vessels must be removed from the container and destroyed before the container is shipped. Follow the exact instructions contained in the window.

Affirm the actions taken to resolve these exclusions.



After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To remove the window and exit without saving the actions to the database, use the mouse to direct the mouse arrow to **Cancel** button and left click.

When the manifest window displays it defaults to all airbills.

LAB: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Manifest

Airbill Id Start Date End Date Ship To Lab Id

Reset

Mode

Print Only

E-Mail Only

Print & E-Mail

Process

Close

Shipping Manifest Report

Shipment ID: 790185923623
Shipment Date: 1/26/00 15:50:00

Lab Name: CASPIR-National Center for Environmental Health/C Lab ID: 6

Address: CDC Specimen Repository Contact: Frome, Rich
602 Webb Ginn House Roa Phone: 7703395942
Building C E-Mail: rlj0@cdc.gov
Lawrenceville, GA 300455427

Container Id: 305390 Size: 5x5 Type: 3 inch box Test(s):

Slot Id	Sample/Vessel Id	Astro Id	Date Collected
1	524953-050	000OW188	1/3/00

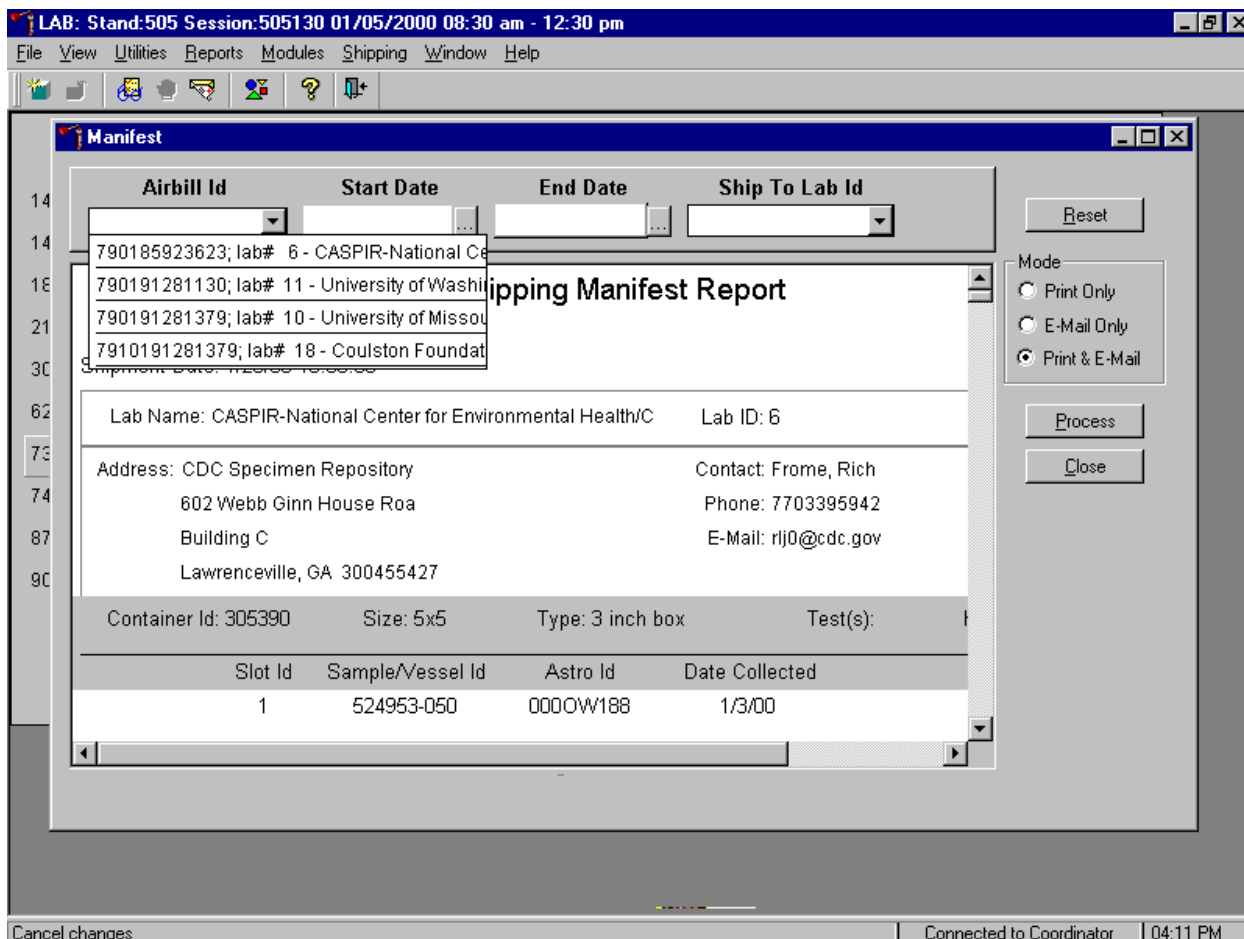
Cancel changes Connected to Coordinator 04:11 PM

The Shipping Manifest Report contains the Shipment ID or airbill number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Container IDs associated with the shipment ID, container Size, container Type, Test(s) associated with the container, and a list by Slot ID of the Sample/Vessel ID, Astro ID, and Date Collected.

Set the Mode to “Print Only” to print the manifest(s), “E-mail Only” to send an electronic manifest to the analysis laboratory, or to “Print & E-mail” to print all manifests and send an electronic file to each laboratory. Select “Print & E-mail” as the default. Use “Print Only” and “E-mail Only” when necessary. To print the manifest and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [P]. To exit the module without printing the manifest or sending the

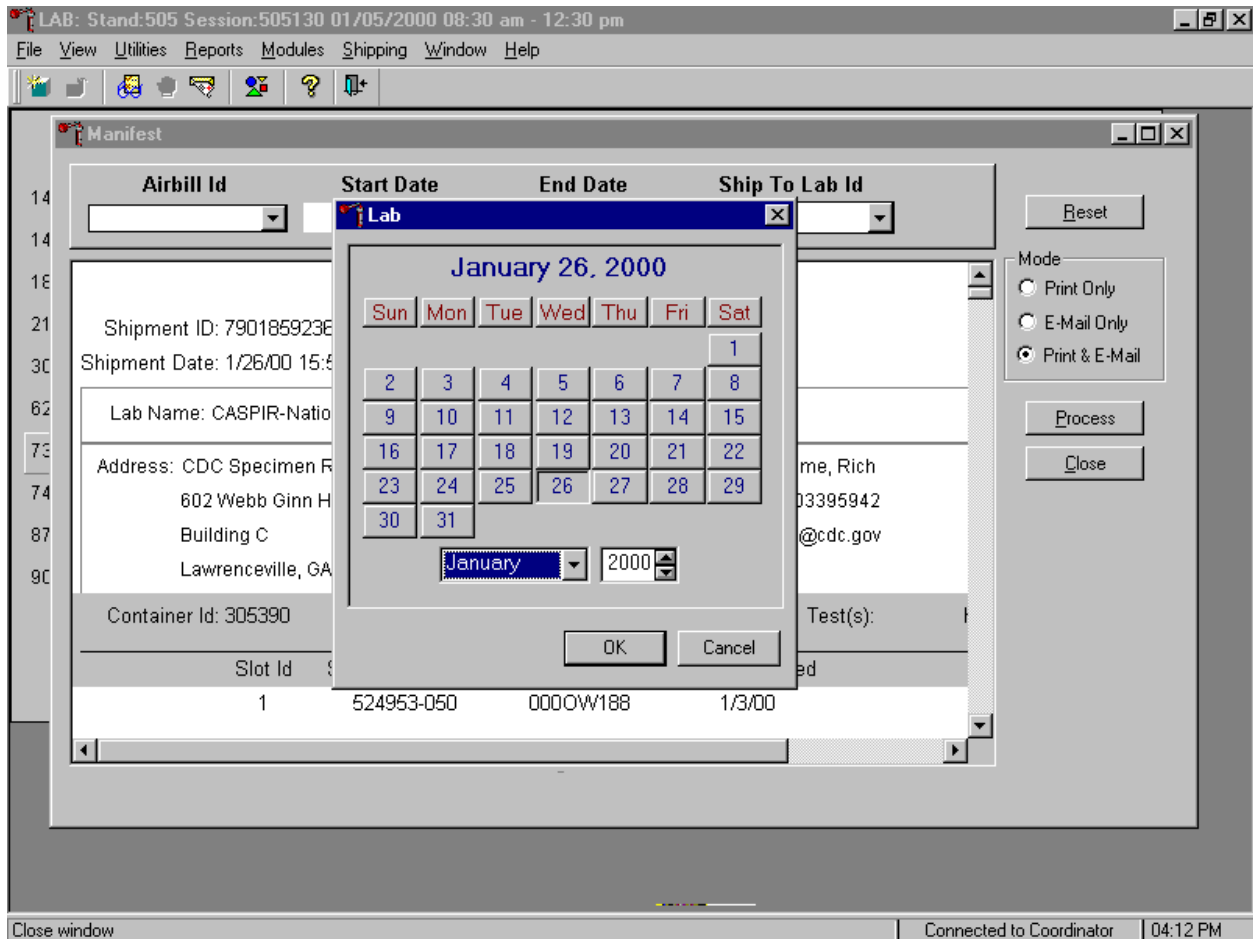
electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [C]. Use the **Reset** button to clear the requirements and begin again.

Select one manifest at a time by using the Airbill ID filter.



To print and/or email one manifest at a time, use the mouse to direct the mouse arrow to the drop down list on the right side of the Airbill ID text box and left click to display all existing airbills. Drag the arrow to the appropriate airbill number and left click. The Shipping Manifest Report associated with that airbill displays. To print the manifests and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [P]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [C]. Use the **Reset** button to clear the requirements and begin again.

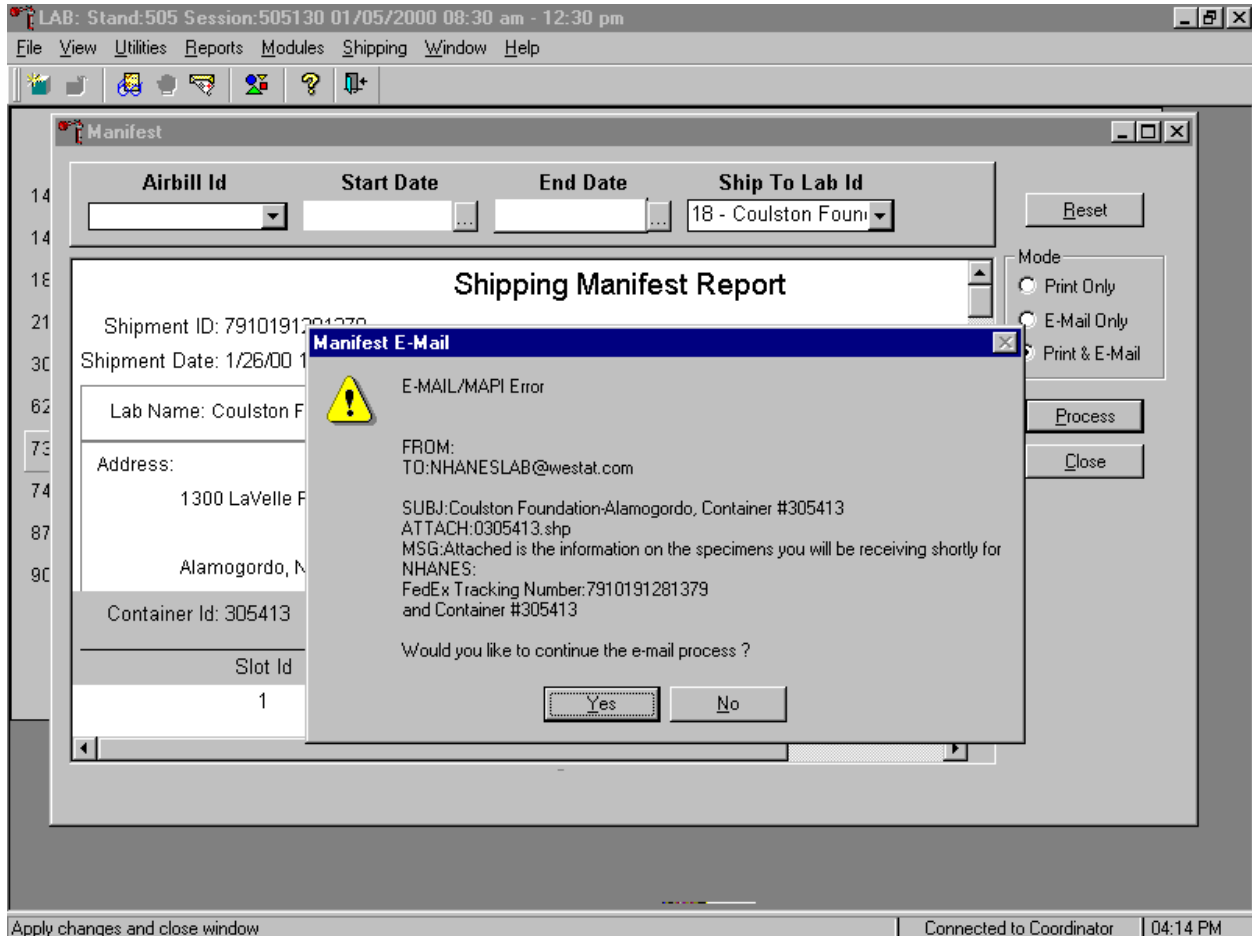
Select one or more manifests by using the Start Date and End Date filters.



To print and/or email one or more manifests at a time, use the calendar function on the Start and End Date filters. To access the calendar on either filter, use the mouse to direct the mouse arrow to the ellipsis button and left click. Alternatively, use the keyboard and press [Shift] then [C/c] to display the calendar. To select or specify a date, use the mouse to direct the mouse arrow to the month drop down list, drag the arrow to the correct month (use the vertical scroll bar if necessary) and left click. Select the correct day by using the mouse to direct the mouse arrow to the correct day on the displayed month and left click. Correct the year by using the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer the day, month, and year into the date space and to exit the calendar window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar window without entering or transferring a date into the date space, use the mouse to

direct the mouse arrow to **Cancel** button and left click. The airbills generated between those start and end dates are included in the Shipping Manifest.

Print the manifest and send the electronic files.

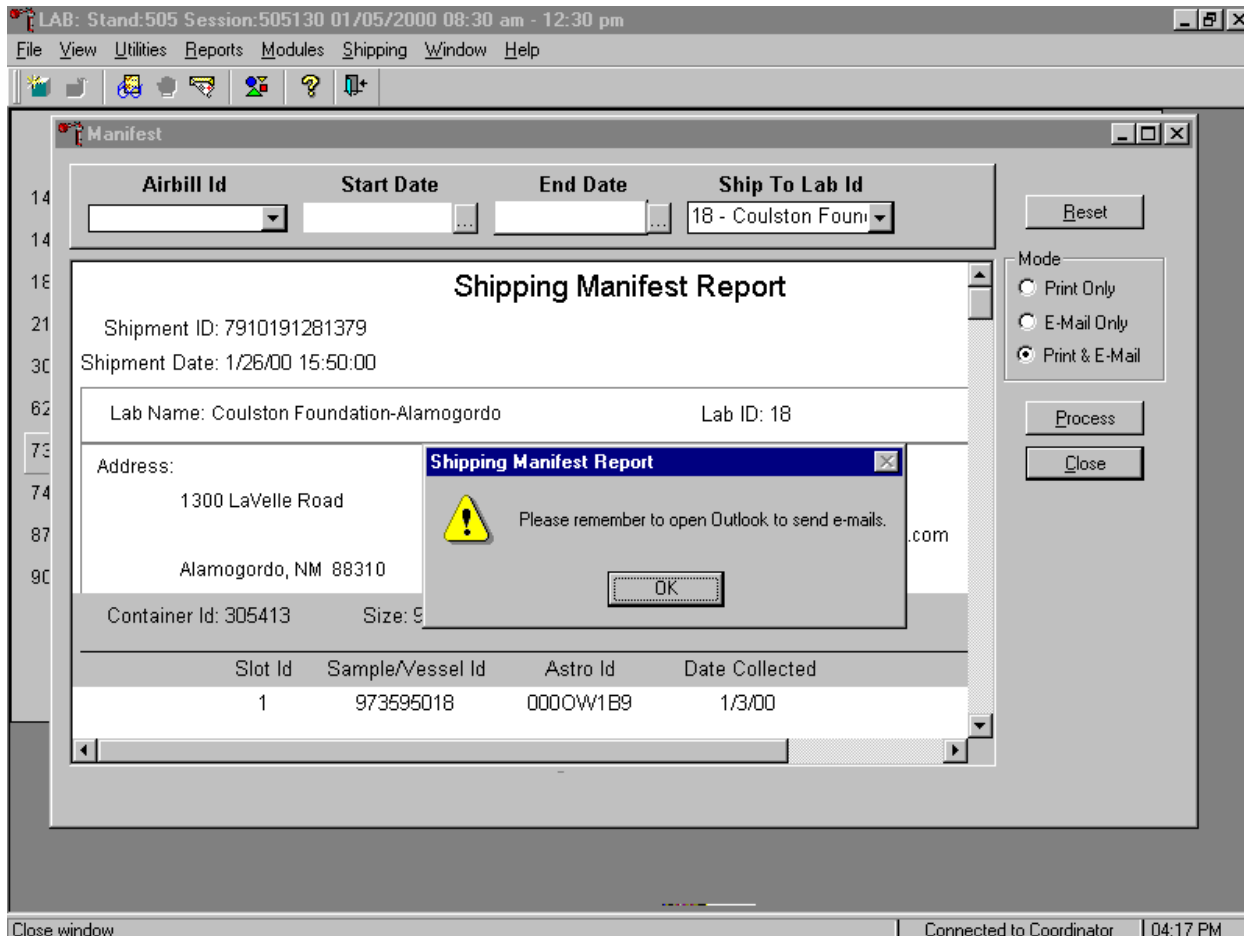


To print the manifests and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [P]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [C]. Use the **Reset** button to clear the requirements and begin again.

If the modem is not operating, a Manifest E-mail warning message text box displays. Report this message to the data manager. Review the information in the warning text box. To continue to process the hard copy manifests, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type

[Y,] or select [Enter]. To quit the manifest process, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N].

After the **Close** button is selected, a Shipping Manifest Report message text box displays.



It is essential to open the Outlook email program to send the electronic files each time a manifest is created and a package is sent. It is the medical technologist's responsibility to open the Outlook program immediately after shipping containers. Opening Outlook sends an email to each laboratory that receives a shipment. The email contains critical information and the contract laboratories rely on the electronic file contained in the email to prepare in advance for the shipment. Laboratories also use the airbill number in the email to track the shipment with FedEx. The data manager can explain the procedure to access and open Outlook.

To acknowledge the reminder and to remove the message box, use the mouse to direct the mouse arrow to the button and left click, or select [Enter].

9.13 Packing Procedure for the Shippers

Most of the shipments require dry ice to keep the specimens frozen during shipment. Some shipments require reusable refrigerant packs to keep specimens cold but not frozen. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.) Some shipments require neither dry ice nor refrigeration. Ship these specimens at ambient temperature. It is the MEC manager's responsibility to arrange for delivery of dry ice pellets or blocks for shipping specimens. Use sliced blocks whenever possible since these sublimate less than pellets. Well in advance of a scheduled shipment, the shipping technologist estimates how much dry ice to order for the shipment and informs the MEC manager. Store the dry ice in extra shipping containers. When handling dry ice, wear cryo gloves to avoid burning hands. Also wear an eye shield when filling bags with ice chips or breaking blocks into chunks. Exhibit 9-3 contains a list of all contract laboratory addresses.

Exhibit 9-3. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CASPIR 602 Webb Ginn House Road Building C Lawrenceville, GA 30045-5427 770-339-5942	Lead/Cad Ery Proto RBC Folate Mercury CD4 Homocys/MMA Xtra Plasma Iron/TIBC Ferritin Fol/B12 Vit A/E/Car Cotinine Selenium Vitamin D Env Serum Xtra Sera DNA Urn Iodine Urn Merc Heavy Metal	Frozen	Richard Frome 770-339-5917 Elaine Gunter, MT (ASCP) 770-488-7938 Ewg1@cdc.gov

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
	Xtra Urine Saliva		
University of Missouri Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	Glycohem	Refrigerated	Hsiao-Mei Wiedmeyer 573-882-2705 weidmeyerh@missouri.edu
University of Missouri Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	Glucose Insul/Cpep	Frozen	Hsiao-Mei Wiedmeyer 573-882-2705 weidmeyerh@missouri.edu
University of Washington Attn: Phyllis Daum Immunology 1959 NE. Pacific Avenue Room NW 176 Seattle, WA 98195 206-548-6149	Fibrin CRP/Hpylori Bn Alk Phos NTX	Frozen	Phyllis Daum 206-548-6149 daum@mail.labmed.washington. edu
CDC/NCID Hepatitis Ref Lab Attn: Mike Purdy Code NH4 1600 Clifton Road Building 1, Room 1389 Atlanta, GA 30333 404-639-2331	Hepatitis	Frozen	Mike Purdy 404-639-3103 404-639-2331 (lab) lqm6@cdc.gov
Viral and Rickettsial Laboratory Attn: Cynthia Cossen 2151 Berkeley Way Berkeley, CA 94704 510-540-3318	Rub/Mea/Var	Frozen	Cynthia Cossen 510-540-3318 ccossen@dhs.ca.gov
Coulston Foundation Attn: Love Julian 1300 LaVelle Road Alamogordo, NM 88310 505-434-1725	Biochem	Refrigerated	Love Julian 505-434-1725 ext 41 clinpath@zianet.com

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CDC/Div of Parasitic Diseases Attn: Dr. Patrick Lammie 4770 Buford Highway. Atlanta, GA 30341 770-488-4054	Crypto	Frozen	Dr. Patrick Lammie 770-488-4054 jip8@cdc.gov
Lipoprotein Analytical Lab/JHU Attn: Kathleen Lovejoy 600 North Wolfe Street Blaylock 1379 Baltimore, MD 21287 410-614-2519	Lipids	Frozen	Kathleen Lovejoy 410-614-2519 klovejoy@welchlink.welch.jhu.edu
CDC/NCID AIDS Division Attn: Tim Granade 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	HIV	Frozen	Tim Granade 404-639-3174 lqm6@cdc.gov
CDC/NCID AIDS Division Attn: Tim Granade 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	HIV Urine	Refrigerated	Tim Granade 404-639-3174 lqm6@cdc.gov
Emory University Dept of Pediatrics Attn: Dr. Francis Lee 46 Armstrong Street SE Room 219 Atlanta, GA 30303 404-616-4997	HSV	Frozen	Dr. Francis Lee Fax: 404-616-0129 Phone:404-616-6229 Francis Lee@emory.edu
Coulston Foundation Attn: Love Julian 1300 LaVelle Road Alamogordo, NM 88310 505-434-1725	FSH/LH TSH/Thyrox	Frozen	Love Julian 505-434-1725 ext 41
CDC/Hospital Infections Program Attn: Dr. Matthew Arduino 1600 Clifton Road, NE MS C01 Atlanta, GA 30333 404-639-2318	Latex	Frozen	Dr. Matthew J. Arduino 404-639-2318 mja4@cdc.gov Phyllis Miller 404-639-3475

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CASPIR/Dr. Wayman Turner Attn: Dr. Wayman Turner 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-7974	Pesis Pest Dioxins	Frozen	Dr. Wayman Turner 770-488-7974 pcm5@cdc.gov
CASPIR/Dr. Charles Dodson Attn: Dr. Charles Dodson 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-788-4504	Phytoestro	Frozen	Dr. Charles Dodson 770-788-4504 wcd1@cdc.gov
CDC/Molecular Biology Branch Attn: Linda Wohr 4770 Buford Highway Building 32, Room 1505 MS F24 Atlanta, GA 30341-3724 770-488-4313	WBC/DNA	Room temperature	Linda Wohr 770-488-4313 FAX: 770-488-4005 lsw@cdc.gov
University of Minnesota Attn: Susan Kupcho Department of Pediatrics 515 Delaware St. S.E. Room 13-219 - MOOS Tower Minneapolis, MN 55455 612-624-6153	Alb/Creat	Frozen	Susan Kupcho 612-624-6153 kupch001@aroon.tc.umn.edu
CDC/NCID/NCHSTD Attn: Dr. Carolyn Black 1600 Clifton Road, NE MS D13 Atlanta, GA 30333 404-639-2870 or Debra Candal	Chlam/GC	Frozen	Dr. Carolyn Black 404-639-2870 CXB2@cdc.gov
CDC/Dr. Dana Barr Attn: Dr Dana Barr 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341-3724 770-488-7839	Prior Pest Organophos Urn Phytoes	Frozen	Dr Dana Barr 770-488-7839

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CASPIR/Dr. James Grainger 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-4815	PAH	Frozen	Dr. James Grainger 770-488-4815 jag2@cdc.gov
CDC/Dr. John Brock Attn: Dr. John Brock 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341-3724	Phthalates	Frozen	Dr. John Brock Jbw6@cdc.gov jar2@cdc.gov
Research Triangle Institute Attn: Dr. Edo Pellizzari 3040 Cornwallis Road Dryfus Bldg Research Triangle Park, NC 27709-2194 919-541-6000	Methylmerc	Room Temperature	Dr. Edo Pellizzari 919-541-6000 edp@rti.org
University of Cincinnati Attn: Sandy Rhoda Dept of Env Services 3223 Eden Avenue Cincinnati, OH 45267-0056 513-558-1705	F Lead Dust W Lead Dust	Room Temperature	Sandy Rhoda 513-558-1705

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. The federal regulations include:

- A watertight primary receptacle e.g., sealed cryovial, sealed Vacutainer®, and sealed Falcon tubes;
- A watertight secondary packaging e.g., a sealed plastic storage bag;
- Ensuring that there is sufficient absorbent material between the primary receptacle and the secondary receptacle to absorb the entire contents of all primary receptacles;
- If multiple glass primary receptacles are placed in a secondary packaging, they must be wrapped individually to ensure that contact between them is prevented; and
- Use of a sturdy outside packaging constructed of corrugated fiberboard.

9.13.1 Pack Boxed Specimens

Store the blood and urine vessels, dental saliva, and ACD tubes in the 2, 3, and 5-inch storage boxes. Separate the boxed specimens with cardboard grids or foam inserts. Secure the top of the box to the bottom with a rubber band. Place the box in a plastic bag, add one absorbent paper, and seal the bag.

9.13.2 Pack Medium Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place a layer 3-inches thick (15 pounds for medium shipper) of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper;
- Place a single layer of newsprint between the box and the dry ice;
- Place the sealed boxes on top of the dry ice;
- Pack the sides with crumbled newsprint;
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim (10 pounds);
- Place the Styrofoam lid on top of the Styrofoam bottom;
- Place a plastic envelope containing the appropriate shipping manifest and return address label on top of the Styrofoam lid;
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 35 pounds; and
- Record the weight of the dry ice (25 pounds for a medium shipper) on the FedEx Class 9 label.

9.13.3 Pack Medium Shipping Container for Refrigerated Shipment

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 20 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper;
- Place the sealed boxes on top of the refrigerant pack;
- Pack the sides with crumbled newsprint;
- Place two or three additional refrigerant packs on top of the containers;
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid;
- Weigh the shipper on the scale or assume that the package weighs 10 pounds; and
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

9.13.4 Pack Ambient Temperature Padded Envelope

Ship hair specimens at ambient temperature.

- Place the bag of hair specimens in a padded envelope;
- Place a plastic envelope containing the appropriate shipping manifest in the envelope,
- Assume the package weighs 1 pound; and
- Record the total weight of the envelope (1 pound) on the appropriate FedEx label.

9.13.5 Pack a Medium or Small Shipper for Ambient Temperature Shipment

Ship lead dust specimens and ACD tubes at ambient temperature.

- Pack the bottom of the Styrofoam shipper with crumbled newsprint;
- Place the sealed boxes on top of the newsprint;
- Pack the sides with crumbled newsprint;
- Place more crumpled newsprint on top so that the shipper is filled to 1/4" below the rim;

- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid;
- Weigh the shipper on the scale or assume that the package weighs 10 pounds; and
- Record the total weight of the envelope (10 pounds) on the appropriate FedEx label.

9.14 Label Shippers

All shippers must contain a FedEx bar coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing dry ice with a “Keep Frozen” label and a FedEx Class 9 -- Miscellaneous Dangerous Goods label;
- Label shippers containing refrigerant packs with a “Refrigerate” label;
- Label shippers containing whole blood, serum, plasma, saliva, or urine with a “Biohazard” label;
- Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper;
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper;

For all destinations include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand.

Exhibit 9-4. Container protocol

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
1	Lead/Cad	WB	2 mL	9 x 9 two inch box	Freezer #2
2	Ery Proto	WB	2 mL	9 x 9 two inch box	Freezer #2
3	RBC Folate	WB	2 mL	9 x 9 two inch box	Freezer #2
4	Glycohem	WB	2-mL	9 x 9 two inch box	Refrigerator # 1
5	Mercury	WB	2 mL	9 x 9 two inch box	Freezer #2
6	CD4	WB	2 mL	9 x 9 two inch box	Freezer #2
7	Homocys/MMA	Plasma	2 mL	9 x 9 two inch box	Freezer #2
8	Xtra Plasma	Plasma	2 mL	9 x 9 two inch box	Freezer #2
9	Glucose	Plasma	2 mL	9 x 9 two inch box	Freezer #2
10	Fibrin	Plasma	2 mL	9 x 9 two inch box	Freezer #2
11	Iron/TIBC	Serum	2 mL	9 x 9 two inch box	Freezer #2
68	Ferritin	Serum	2-mL	9 x 9 two inch box	Freezer #2
12	Fol/B12	Serum	2 mL	9 x 9 two inch box	Freezer #2
13	CRP/Hpylori	Serum	2 mL	9 x 9 two inch box	Freezer #2
14	Hepatitis	Serum	2 mL	9 x 9 two inch box	Freezer #2
15	Vit A/E/Car	Serum	2 mL	9 x 9 two inch box	Freezer #2
16	Rub/Mea/Var	Serum	2-mL	9 x 9 two inch box	Freezer #2
17	Cotinine	Serum	2 mL	9 x 9 two inch box	Freezer #2
18	Biochem	Serum	2 mL	9 x 9 two inch box	Refrigerator # 1
19	Bn Alk Phos	Serum	2 mL	9 x 9 two inch box	Freezer #2
20	Crypto	Serum	2 mL	9 x 9 two inch box	Freezer #3
21	Lipids	Serum	2 mL	9 x 9 two inch box	Freezer #3
22	HIV	Serum	2 mL	9 x 9 two inch box	Freezer #3
23	Insul/Cpep	Serum	2 mL	9 x 9 two inch box	Freezer #3
24	HSV	Serum	2 mL	9 x 9 two inch box	Freezer #3
25	FSH/LH	Serum	2 mL	9 x 9 two inch box	Freezer #3
26	Selenium	Serum	2 mL	9 x 9 two inch box	Freezer #3
27	Latex	Serum	2 mL	9 x 9 two inch box	Freezer #3
28	TSH/Thyrox	Serum	2 mL	9 x 9 two inch box	Freezer #3
70	Vitamin D	Serum	2-mL	9 x 9 two inch box	Freezer #3
29	Persis Pest	Serum	5 mL	9 x 9 three inch box	Freezer #3
63	Dioxins	Serum	5 mL	9 x 9 three inch box	Freezer #3
64	Phytoestro	Serum	5-mL	9 x 9 three inch box	Freezer #3
32-42	Xtra Sera	Serum	2 mL	9 x 9 two inch box	Freezer #3
43	DNA	Clot	14 mL tube	5 x 5 three inch box	Freezer #3
44 & 71	WBC/DNA	WB	8 mL ACD	5 x 5 five inch box (foam insert)	Workstation #1
45	Alb/Creat	Urine	5 mL	9 x 9 three inch box	Freezer #1
46	Chlam/GC	Urine	5 mL	9 x 9 three inch box	Freezer #1
47	NTX	Urine	2 mL	9 x 9 two inch box	Freezer #1
69	Urn Iodine	Urine	5 mL	9 x 9 three inch box	Freezer #1
48	Prior Pest	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
49	Organophos	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
62	Urn Merc	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
50	Heavy Metal	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
65	Urn Phytoes	Urine	5 mL	9 x 9 three inch box	Freezer #1
66	PAH	Urine	5 mL	9 x 9 three inch box	Freezer #1
67	Phthalates	Urine	5 mL	9 x 9 three inch box	Freezer #1

Exhibit 9-4. Container protocol (continued)

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
51 & 52	Xtra Urine	Urine	5 mL	9 x 9 three inch box	Freezer #1
53	HIV Urine	Urine	5 mL	9 x 9 three inch box	Refrigerator #1
54	VOC Blood	WB	7 mL Gray top	1 x 5 foam mailer	Refrigerator #2
55	VOC Blood	WB	7 mL Gray top	1 x 5 foam mailer	Refrigerator #2
56	VOC Water	Water	10 mL glass vial	1 x 3 foam mailer	Refrigerator #2
57	VOC Badge	Badge	Badge	12 x 12 plastic bag	Refrigerator #2
58	Saliva	Saliva	5 mL	9 x 9 three inch box	Freezer #1
59	Methylmerc	Hair	Plastic bag	12 x 12 plastic bag	Workstation 2
60-61	Lead Dust	Dust	50-mL tube	4 x 4 five inch box	Workstation 2

Number of Boxes Per Week

Number	Box type	Number	Box type
32	9 x 9 two inch box	2	1 x 5 foam mailer
12	9 x 9 three inch box	1	1 x 3 foam mailer
5	5 x 5 three inch box	2	12 x 12 plastic bag
1	5 x 5 five inch box (foam insert)	1	4 x 4 five inch box

Exhibit 9-5. FedEx Weekly Shipping List

Laboratory/Destination	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
CASPIR	1	Lead/Cad	Frozen	35	25	12
	2	Ery Proto				
	3	RBC Folate				
	5	Mercury				
	6	CD4				
	7	Homocys/MMA				
	8	Xtra Plasma				
	11	Iron/TIBC				
	68	Ferritin				
	12	Fol/B12				
	15	Vit A/E/Car				
	17	Cotinine				
	26	Selenium				
	70	Vitamin D				
	32-42	Xtra Sera				
	43	DNA				
	69	Urn Iodine				
	62	Urn Merc				
50	Heavy Metal					
51-52	Xtra Urine					
	58	Saliva				
CASPIR/Dr Charles Dodson	64	Phytoestro	Frozen	25	20	10
CASPIR/Dr. James Grainger	66	PAH	Frozen	25	20	10
CASPIR/Dr. Wayman Turner	29	Persis Pest	Frozen	35	25	12
	63	Dioxins				
CDC, Air Toxicant Branch	54	VOC Blood	Refrigerated	10		
	55	VOC Blood				
	56	VOC Water				
CDC, DPD	20	Crypto	Frozen	25	20	10
CDC, Hepatitis Lab	14	Hepatitis	Frozen	25	20	10
CDC, MBB	44	WBC/DNA	Room Temperature	10		
	71					
CDC, NCID NCHSTD	46	Chlam/GC	Frozen	25	20	10
CDC/Dr. Dana Barr	48	Prior Pest	Frozen	35	25	12
	49	Organophos				
	65	Urn Phytoestro				
CDC/Dr. John Brock	67	Phthalates	Frozen	25	20	10
CDC/NCID, AIDS Division	22	HIV	Frozen	25	20	10
CDC/NCID, AIDS Division	53	HIV Urine	Refrigerated	10		
Clayton Laboratory Services	57	VOC Badge	Refrigerated	10		
Coulston Foundation-Alamogordo	18	Biochem	Refrigerated	10		
Coulston Foundation-Alamogordo	25	FSH/LH	Frozen	25	20	10
	28	TSH/Thyrox				
Emory University School of Medicine	24	HSV	Frozen	25	20	10

Exhibit 9-5. FedEx Weekly Shipping List (continued)

Laboratory/Destination	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
Hospital Infections Program/CDC	27	Latex	Frozen	25	20	10
Lipoprotein Analytical Lab Johns Hopkins	21	Lipids	Frozen	25	20	10
Research Triangle Institute	59	Methylmerc	Room Temperature	1		
University of Cincinnati	60	F Lead Dust	Room Temperature	5		
	61	W Lead Dust				
University of Minnesota School of Medicine	45	Alb/Creat	Frozen	25	20	10
University of Missouri Columbia School of Medicine	4	Glycohem	Refrigerated	10		
University of Missouri Columbia School of Medicine	9	Glucose	Frozen	25	20	10
	23	Insul/Cpep				
University of Washington Immunology Division	10	Fibrin	Frozen	35	25	12
	13	CRP/Hpylori				
	19	Bn Alk Phos				
	47	NTX				
Viral and Rickettsial Disease Laboratory	16	Rub/Mea/Var	Frozen	25	20	10

Shaded = Verify correct assignment of container to FedEx airbill

10. QUALITY CONTROL AND QUALITY ASSURANCE - POLICIES AND PROCEDURES

National Health and Nutritional Examination Survey 1999-2004
National Center for Health Statistics
Centers for Disease Control and Prevention
Public Health Service
Department of Health and Human Services

Current revision: 3/1/00

Approval: _____ Date: _____
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Technical Supervisor, Westat

Abbreviations

NCHS - National Center for Health Statistics
CDC - Centers for Disease Control and Prevention
NHANES - National Health and Nutrition Examination Survey
MEC - mobile examination center
LPM - NHANES Laboratory Procedures Manual
U.S. - United States
CBC - complete blood count
IRB - institutional review board
QC - quality control
QA - quality assurance
IQAP- Interlaboratory Quality Assurance Program
PT - proficiency testing
CLIA - Clinical Laboratory Improvement Amendments of 1988
HCFA - Health Care Finance Administration
ISIS - Integrated Survey and Information System
PC - personal computer
LAN - local area network

This policies and procedure quality control and quality assurance chapter is an adjunct to the Westat Policies Manual.

10.1 Safety

10.1.1 Introduction

NCHS and Westat maintain an ongoing Health and Safety Committee that acts in cooperation with the CDC Office of Health and Safety to assure safe working conditions for technologists in the NHANES MEC. Safety precautions for all methods are documented in the Biosafety chapter in the NHANES Laboratory Procedures Manual, 2000. This manual is readily available to all laboratory staff. In addition to annual safety training, the NCHS Biomedical Engineer performs safety inspections at the beginning of each location. The technical supervisor assures that the primary laboratory analyst reads and is familiar with safety precautions.

10.2 Specimen Submission and Handling

10.2.1 Introduction

The goal of specimen submission and handling is to optimize the accurate and reliable measurement of analytes of interest. Each analytical procedure used in NHANES is documented in the NHANES Laboratory Procedures Manual (LPM). Each method in the LPM specifies the procedure to be used for preparation of the sample person, specimen collection, labeling, processing, and preservation, and conditions for specimen transport that are appropriate for that method. The methods may refer to the NHANES blood collection protocol, or urine collection protocol, noting any special requirements specific to the particular method. These protocols are a starting point. This is due to the special contamination requirements needed for collection of specimens analyzed for metals.

10.2.2 Identification of Specimens

Personal identifiers (e.g., names) are not included on test specimens. NHANES uses a random internal specimen ID number to identify and track individual samples. The Integrated Survey and Information System (ISIS) system at Westat and NCHS maintains information that links the specimen ID number to the sample person's name.

10.2.3 Questions on Specimen Submission and Handling

The Chief Medical Technologist addresses questions concerning specimen collection including handling and testing.

10.3 Test Requisition

10.3.1 Introduction

Under a congressional mandate since 1960, the National Center for Health Statistics (NCHS) has collected data on the health of the people of the United States through interviews and extensive physical examinations. As in previous NHANES programs, the survey's primary purpose is to produce descriptive statistics that can be used to measure and monitor the health and nutritional status of the civilian, noninstitutional U.S. population. Data collection for the entire survey of about 40,000 sample persons, of whom about 75 percent are expected to be examined, begins in April 1999 and continues for about 6 years at about 90 locations (stands). NHANES performs a complete blood count on sample persons 1 year and older. A record of the test result report is maintained for a period of 7 years by Westat, the primary NHANES contractor and by NCHS for an indefinite period.

10.3.2 Laboratory Tests

"Panic" or abnormally high CBC results are reported to the sample person. The report includes laboratory tests that will be performed. The NCHS Medical Officer or MEC physician involved in the

measurement may also confer with the sample person to obtain any other pertinent information, which might facilitate the laboratory measurement process.

10.3.3 Human Subjects Review

All laboratory analyses conducted on human specimens, which are part of a "survey," as defined by the CDC institutional review board (IRB) criteria, shall be performed only after approval of the survey by the NCHS IRB.

10.4 Test Records

10.4.1 Introduction

The purpose of test records is to ensure correct and reliable identification of sample person specimens and to report accurate test results. The laboratory test record system is distinguished from the test report that is provided to the sample person.

10.4.2 Components of Test Records

Test records include:

1. Person performing the test (may be identified by initials);
2. Printed or electronically stored output from instrumentation which the technical supervisor judges as necessary to document the analytical result;
3. Date of specimen analysis;
4. Date and time specimen was collected into the laboratory; and
5. Condition of specimens that did not meet criteria for acceptable specimens (e.g., hemolyzed or insufficient quantity for test).

Test records are maintained for at minimum of 7 years. Records may be bound in laboratory notebooks, in loose-leaf form, or stored electronically.

10.5 Test Report

10.5.1 Introduction

The laboratory report is provided promptly to the sample person. This occurs as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the sample person results since it identifies samples only by a specimen ID number. Westat and NCHS maintain the link between the specimen ID number and the identity of the sample person.

10.5.2 Review, Approval, and Release of Test Results

Upon completion of laboratory testing, results are reviewed by laboratory staff responsible for review of the quality control results to assure the measurement process was in-control for each of the sample person's analyses.

For NHANES surveys, the initial evaluation of QC results is accomplished electronically by comparing the QC results to QC limits stored in a relational database. The laboratory staff performing the CBC reviews these QC performance results and assures that only acceptable SP data is reported.

Review and approval of the results by the MEC physician are documented. Review by the MEC physician includes an evaluation of the consistency of sample person results with information that may be available on the sample person (e.g., age, sex). All SP's samples are run in duplicate, whenever possible. If inconsistent results are noted, and an adequate sample is available, the test is repeated a third time. If inconsistent results are again noted, the sample is run a fourth time. If the amount of sample is inadequate for repeat, then the sample person is informed verbally and in writing of the inconsistent result.

The paper hard copy of the results with the NCHS Medical Officer's signature is filed by Westat and kept with the test record for 7 years. The NCHS Medical Officer signs all laboratory reports before release.

Laboratory reports are released only to the authorized sample person. Each method includes a description of actions taken such as when results are markedly elevated or are "panic values." The sample person is contacted immediately by the MEC physician with such results.

In addition to the written laboratory report, the data may be transmitted electronically in a suitable format; for example, a SAS data set or an ASCII file by email to the Westat home office and to NCHS.

10.5.3 List of Methods and Method Details

NHANES maintains a Laboratory Procedures Manual (LPM) which includes detailed descriptions of each analytical procedure including analytical sensitivity, specificity, and accuracy, interfering substances, and other information. This manual is available for more detailed information concerning specific analytical procedures.

10.5.4 Format of the Test Report

The test report includes:

- The name and address of NCHS;
- The test result;
- Units of measurement;
- Reference range for each analyte, if available;
- The condition of specimens not meeting the laboratory's criteria for acceptability; and
- Signature of the NHANES Medical Officer.

The laboratory report consists of:

- 1st page: a cover letter; and
- 2nd page: an analysis summary table.

A corrected laboratory report has the same format except the words "corrected laboratory results" replaces the words "laboratory results" in the letter and title of the pages. In addition, in the text of the cover letter, the date of the previous laboratory report is noted.

10.5.5 Format for Laboratory Report Cover Letter

An example of the Laboratory Report cover letter (report of findings) is available upon request.

10.5.6 Format for Listing of Laboratory Results

An example of the laboratory results is available upon request.

10.6 Quality Control

10.6.1 Introduction

Most quantitative analytical procedures involve several operations, or steps, and each operation is subject to some inaccuracy or imprecision or to the possibility of a mistake. The immediate aim of quality control is to ensure that the analytical values produced by a clinical laboratory are sufficiently reliable for their intended purpose. A broader objective is to ensure that all laboratories produce analytical values that meet acceptable standards of precision and accuracy.

Quality control in laboratory medicine is the study of those errors that are the responsibility of the laboratory, and the procedures used to recognize and minimize them. An alternate term, "quality assurance," represents the techniques available to ensure with a specified degree of confidence that the result reported by the laboratory is correct. Both "precision control," (the agreement between replicate measurements), and "accuracy control" (the agreement between the mean estimate of a quantity and its true value), are evaluated to establish this degree of confidence.

A quality control program also monitors laboratory performance to detect excessive random or systematic error. Factors contributing to random error are those that affect the reproducibility of the measurement. These include instability of the instrumentation, variations in the temperature, and variations

in reagents and calibrators, handling techniques such as pipetting, mixing, and timing, and operators. Terms used to describe random error include precision, imprecision, reproducibility, and repeatability. Systematic error describes the error that is consistently low or high. Factors that contribute to systematic error are independent of the analyte concentration. Examples of these factors include interfering substances, or incorrect assignment of the amount of substance in the calibrator.

A good quality control program includes both internal (intralaboratory) and external (interlaboratory) surveillance and monitors the following five parameters:

- **Clerical Error:** This includes properly documented acknowledgment of transmittal and receipt of specimens (for example, "logging in"), proper labeling of all specimens, correct assignment of laboratory values to the proper SP ID number, and maintenance of proper records for all specimens for future reference;
- **Techniques:** This includes continued assurance that all personnel performing an assay understand the principles underlying a particular assay and are cognizant of the proper technique for that assay; that all personnel use the same technique for a particular assay; that there is ready access to a current technique manual; and that periodic review is undertaken to ensure use of the most current and reliable techniques;
- **Reagents and Materials:** This includes confirmation of commercial standards and controls before they reach the bench; proper labeling of reagents, particularly those prepared in the laboratory; insuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; proper calibration of equipment, such as pipettes; and proper washing of glassware;
- **Bench Performance:** This includes the use of controls and standards for each assay performed, a technique based on sound statistical principles, which allows the technologist performing the assay to detect error outside of previously determined limits before reporting data; and documentation of daily bench performance for detection of less obvious error (particularly those which tend to accumulate over time, so-called "drift"), and established procedures to be followed wherever error is found to exceed previously determined limits; and
- **Instrumentation:** This includes periodic preventive maintenance of all instruments in use in the laboratory and documentation that each instrument is maintaining a previously determined level of each performance at each check.

In this context, quality control (QC) procedures monitor and evaluate the quality of the analytical testing process of each method to assure the accuracy and reliability of test results. Thus, QC procedures referenced here refer to the analytical phase of testing and not to the pre-analytic or post-analytic phases. Quality assurance (QA) addresses all three phases of measurement: pre-analytic, analytic, and post-analytic. QC is therefore viewed here as one part of the overall QA process.

10.6.2 Method Specific QC Procedures

Specific QC procedures exist for each analytical laboratory procedure in the Laboratory Procedures Manual (LPM). The following are some general aspects of QC procedures.

10.6.3 QC Definitions

Internal ("Bench") Quality Control

For purposes of this document, internal quality control (QC) is the evaluation of analytical performance that includes QC bench samples for which the analyst knows the expected measurement result. Internal commercial quality control materials contain predetermined amounts of analyte in the matrix, qualify under Clinical Laboratory Improvement Amendments (CLIA) as "calibration materials," and may be used as a "calibration verification" as defined by CLIA.

- **External ("Blind") Quality Control** – For purposes of this document, external quality control is the evaluation of analytical performance that includes QC samples for which the analyst does *not* know the expected measurement result. The analyst is "blind" to the expected measurement result. Examples include proficiency testing samples.
- **Interlaboratory Quality Assurance Program (IQAP)** – For purposes of this document NHANES participates in Beckman Coulter's® IQAP program. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance.
- **Proficiency testing** – For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).
- **Analytical run (sometimes referred to just as a run)** – An analytical run is a set of samples analyzed in a time within which the measurement system is considered to have stable accuracy and precision. The time for a run may not exceed 24 hours. An analytical run usually consists of both quality control specimens and sample person specimens.
- **Calibration** – Defined by CLIA as "the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure."

- **Calibration material** – Defined by CLIA as "a solution which has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference or definitive test method." Many standards are therefore calibration materials.
- **Calibration verification** – Defined by CLIA as "the assaying of calibration materials in the same manner as sample person samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for sample person test results".
- **QC Requirements of each Analytical Run** – Analysis of sample person samples is organized into analytical runs. The minimum QC requirement for an analytical run, which is analyzing sample person specimens, is that the run includes four internal ("bench") QC specimens.

10.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC

A Beckman Coulter® technical representative performs instrument setup, verification, and performs and verifies QC checks according to their procedure at the beginning of each stand. Medical technologists perform instrument calibration.

Most laboratory quality control programs include running internal ("bench") QC with each analytical run to assure each analytical run is in control. The X_b analysis is a QC method monitoring instrument performance. In addition, the laboratory participates in proficiency testing programs administered by an outside scientific group to be sure on a periodic basis that accuracy and precision are within acceptable limits. The IQAP compares NHANES 5C cell control results to other laboratories. These QC systems are used within NHANES. The linearity of the instrument is evaluated at least once a year.

In addition to these systems, NHANES uses calibration materials at the beginning of each stand to standardize the three Beckman Coulter® MAXM instruments and to provide additional objective evaluation of the quality of specimen analysis. S-CAL is a calibration material as defined by CLIA (i.e., "a solution, which has a known amount of analyte, weighed in or has a value determined by repetitive testing using a reference or definitive test method") which is useful for monitoring method performance.

10.6.5 Internal ("bench") QC

The goal of internal QC is to provide a rapid feedback to the analyst on the performance of the measurement process to be sure analytical results and factors affecting analytical results are within acceptable limits. At least three internal QC specimens (5C® Cell control) are included in each analytical run. The QC material used as internal QC specimen has levels of the analyte, which are useful for monitoring method performance.

The 5C® Cell Control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible. 5C® Cell Controls Tri-Pack contains 3 levels, normal, abnormal I, and abnormal II. When used with Beckman Coulter's® blood diluent, Isoton III, they serve as a check on the accuracy of dilution, WBC counts, RBC counts, platelet counts, hemoglobin determinations, and differential counts.

Run all three levels at the beginning of each session to monitor the precision of the instrument following procedures described in Chapter 7, Section 7.9.

Standard Levy-Jennings QC charts are maintained for this internal QC specimen. A separate QC chart is to be maintained for each QC material used for this internal QC specimen. Standard criteria for run rejection based on statistical probabilities are used to declare a run either in-control or out-of-control. No results for a given analyte are reported from an analytical run that has been declared out-of-control for that analyte as assessed by internal ("bench") QC. Rejection criteria are described in each method procedure in the LPM. Quality control results and remedial actions for out-of-control conditions are documented in a QC logbook.

In addition, a latex control (Latron®) is used to monitor the volume, conductivity, and light scatter (VCS) of the diff mode only. This control is run at the beginning of each day.

The Latron® control is a ready-to-use suspension of latex particles used to monitor differential parameters on the Beckman Coulter® MAXM. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter. Use the Latron® control immediately following the Latron® primer.

10.6.6 Interlaboratory Quality Assurance Program (IQAP)

All MAXM instruments participate in Beckman Coulter's® Interlaboratory Quality Assurance Program (IQAP.) The Beckman Coulter® Data Management System saves results of 5C® cell controls in files. Technologists transfer the files to a disk and then send the disk to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure on the last day of each month, at the end of each stand, or when a control lot expires using procedures described in Chapter 7, Section 9.

10.6.7 Proficiency Testing

Participation in the College of American Pathologist (CAP) proficiency-testing program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

The laboratory will satisfactorily participate in the HCFA-approved PT program for each method used to analyze human samples. Performance in the PT program along with documentation of remedial action taken for unacceptable performance is documented in a QC logbook that is available for review.

CAP samples are sent three times a year for hematology. Each shipment includes five 2.5-mL whole blood specimens. Duplicate Beckman Coulter® CBC determinations are performed on each whole blood sample using procedures described in Chapter 7, Section 7.10. PT samples are handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS at the following address:

Brenda Lewis, MPH
National Center for Health Statistics
Room 900
6525 Belcrest Road
Hyattsville, MD 20782

10.6.8 Calibration Verification

Calibration verification is defined by CLIA as "the assaying of calibration materials in the same manner as sample person specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for sample person test results." Thus, calibration verification assures that the accuracy of the measurement process across the reportable range is maintained over time. For methods approved by FDA, calibration verification is performed according to the manufacturer's specification and at the frequency recommended by the manufacturer.

Note that the calibration materials must bracket the reportable range; i.e., results should not be reported as a numerical value unless they are within the reportable range. If a result is higher than the upper end of the reportable range and the method permits sample dilution, the sample may be diluted to bring it within the reportable range. If dilution has been necessary, the reported value will exceed the upper end of the reportable range. Each analytical procedure specifies acceptable limits for results of analyses of the calibration materials based on the method precision of these materials.

The reliability of analytical values obtained when using a procedure often depends on the quality of the standards and the calibration procedure. The College of American Pathologists (CAP) suggests that automated instruments be calibrated using multiple analytical whole blood specimens or a certified, stabilized whole-blood type preparation. The International Committee for Standardization of Hematology (ICSH) by its definition requires that a calibrator "be based on or traceable to a reference preparation or material."

Beckman Coulter® provides the S-CAL® calibrator to meet these requirements. The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the WBC, RBC, Hgb, MCV, Plt, and MPV parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration. Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give an Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

S-CAL® is used to calibrate the Beckman Coulter® MAXM at the beginning of each stand (once every 6-8 weeks), after replacing any component dealing with dilution preparation, if the Beckman Coulter® representative suggests it, controls demonstrate unusual trends or are outside limits, or when the temperature varies by more than 10°F (5.5°C) from the room temperature during the last calibration.

Instructions for the performance of calibration procedures using S-CAL® calibration are in Section VII of Chapter 7.

10.6.9 X_B Analysis

X_B analysis is a QC method that monitors instrument performance by tracking the MCV, MCH, and MCHC parameters of SP's samples. These indices are very stable and show little variance between patient samples. This method displays the moving average of SP's samples and compares it to established target values. Target values are MCV = 88.5, MCH = 29.5, and MCHC = 33.5. Review and print the X_B current batch at the beginning on each session when printing the 5C Cell control results, using procedures described in Chapter 7, Section 7.9. Review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Evaluate the percentage difference from the target limit to determine whether the batch is in or out of control using procedures described in Chapter 7, Section 7.9. Refer to the troubleshooting section of the Beckman Coulter® manual if the batch is out of control.

10.6.10 Linearity

The linearity controls verify the reportable range of Beckman Coulter® hematology systems. Linearity is performed at installation, at least yearly, and whenever experiencing an altitude change of 1 mile or more between locations using either Beckman Coulter® Lin-C™ or CAP LN9 survey material.

Beckman Coulter® Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent. Controls contain one each of Ultra Low Range, Low

Range, Mid Range, and High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt. Beckman Coulter® Lin-C™.

CAP Hematology Calibration Verification/Linearity Survey (LN9) materials are shipped twice per year and consist of 18 3.0-mL liquid specimens. Follow all CAP instruction in preparing and running the materials before performing the test. Fill out the CAP result form, make a copy for the logbook, send results to CAP, and send the copy back to the home office at the end of the stand.

10.6.11 Quality Control Records

Records of all quality control results are maintained for at least 7 years. A QC logbook is maintained which documents quality control results, out-of-control conditions, and remedial actions taken to correct out-of-control conditions. The QC logbook also includes copies of results for Proficiency Testing.

10.7 Test Methods, Equipment, Reagents, Supplies, and Facilities

10.7.1 Introduction

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the method. The documentation of individual analytical procedures included in the Laboratory Procedures Manual (LPM) specifies acceptable equipment, reagents, materials, and supplies. If special requirements concerning water quality, temperature, humidity, electrical power, or other conditions are required for acceptable method performance, then these are described for each procedure in the LPM. Special procedures to monitor these requirements are also included in the documentation of the individual procedure. A lack of requirements in the documentation of the analytical procedure means that the expected day-to-day variation in any of these parameters is acceptable for proper method performance.

Documentation of problems with conditions required (e.g., water quality) for acceptable method performance is maintained in the logbook of the primary instrument used in the analysis. This documentation includes remedial action.

10.7.2 Labeling of Reagents, Solutions, Supplies

Reagents, solutions, and other supplies are labeled to indicate the identity of contents, the concentration (if significant), the recommended storage requirements, the preparation and expiration date, and any other pertinent information required for proper use. Reagent, solutions, and other supplies are not used when they have exceeded their expiration date.

If a method uses a manufacturer's kit, components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

Beckman Coulter® reagents are monitored and documented in the Beckman Coulter® Data Management System and are additionally located on the daily instrument startup result sheet. A copy of all startup results is filed in the quality control notebook. Document any unusual occurrence or repair of the Beckman Coulter® MAXM on the Unusual Occurrence Log.

Maintain logs for reagents other than the Beckman Coulter® reagents. Document reagent use by entering the reagent's name, date made, date put into use, expiration date, and tech ID on the Supply Use Control Log. Send these logs back to the home office at the end of each stand.

10.7.3 Facilities

Laboratories are arranged to ensure that adequate space, ventilation, and utilities are available for all phases of testing: pre-analytic, analytic, and post-analytic.

10.8 Analytical Procedure Manual

10.8.1 Introduction

All procedures performed in the laboratory on human specimens are documented in the Laboratory Procedure Manual (LPM). A copy of the LPM is maintained at the Westat home office and

NCHS. The individual procedure is also available at or nearby the bench site where the procedure is performed.

10.8.2 Contents of the Analytical Procedure Documentation

Each analytical procedure includes, when applicable:

- Requirements for specimen collection and processing including criteria for specimen rejection;
- Step-by-step performance of the procedure including test calculations and interpretation of results;
- Preparation of reagents, calibrators, controls, solutions, and other materials used in testing;
- Calibration and calibration verification procedures;
- The reportable range for sample person test results;
- Quality control procedures;
- Remedial action to be taken when calibration or control results are outside acceptable limits;
- Limitation in methods, including interfering substances;
- Reference range (normal values);
- Life-threatening or "panic values";
- Pertinent literature references;
- Specimen storage criteria;
- Protocol for reporting panic values;
- Course of action if test system becomes inoperable; and
- Safety considerations for performing the method.

10.8.3 Approval and Record Maintenance

Each procedure is reviewed, approved, signed, and dated by the Clinical Consultant and Technical Supervisor and Laboratory Director of NHANES. Procedures are reapproved, signed, and dated if the Director changes. Each change in a procedure is approved, signed, and dated by the current Director. The procedure includes the dates of initial use and discontinuance, if discontinued. The procedure documentation is maintained for 7 years after discontinuance of the method.

10.8.4 Method Performance Specifications

Method performance specifications for each analytical method is established or verified:

- Accuracy - accuracy of each analytical method will be determined by analysis of calibrators, Xb analysis and yearly linearity checks as described in the section of the LPM on quality control.
- Precision - precision of each analytical method is determined by analysis of QC reference materials as described in the section of this manual on quality control.
- Analytical specificity - analytical specificity is determined for each method including effects of potential interfering substances. This may be verified by testing the effect of potential interfering substances in method development, by analyzing reference materials, by comparing results on split samples with a method considered more definitive, and/or by analyzing a sample of persons (n>20) and examining the measurement output searching for interference. The appropriate procedures for verifying analytical specificity will vary by analytical method. Substances, which interfere with the analysis in the reportable range, are listed in the method procedure.
- Reportable range of test results - the reportable range of test results is described in the documentation of the analytical procedure.
- Reference range (normal range) - if available, the reference range of test results is described in the documentation of the analytical procedure and on the test report.
- Other pertinent performance specifications - other performance specifications that are required for adequate method performance are specified in the documentation of the analytical procedure.

10.9 Equipment Maintenance and Function Checks

10.9.1 Introduction

Laboratory equipment is checked regularly to assure acceptable performance. Maintenance (including preventive maintenance) and function checks are documented in ISIS. The frequency of maintenance and function checks follow manufacturer's recommendations, when available. Manufacturer's recommendations are included in the manuals that are located in notebooks in the laboratory.

Each analytical procedure outlines the equipment maintenance and function checks for proper method performance and acceptable results from the checks. These checks must be made at the interval specified in the documentation of the procedure. Failure of a function check is documented in the Unusual Occurrence Log.

10.9.2 Temperature Monitoring

Temperature recordings are required for storage and preservation of reagents and sample material (analytical specimens), as well as quality control and reference materials.

Beckman Coulter® and Vacutainer have recommended the following storage conditions for reagents and tubes. Quality control temperature ranges have been established based on these recommendations.

Reagent	Manufacturer's recommended storage conditions	Established range
Coulter® reagents Isoton Coulter Clenz Scatter Pack Lyse-S III	2-25°C (36-77°F)	17-25°C (63-77°F)
S-Cal at room temperature	16-32°C (60-90°F)	17-25°C (63 to 77°F)
S-Cal at refrigerated temperature	2-8°C (35-46°F)	2-8°C (36 to 46°F)
Latron	2-30°C (36-86°F)	17-25°C (63 to 77°F)
5C Cell Control	2-8°C (36-46°F)	2-8°C (36 to 46°F)
Vacutainers	Not greater than 77°F	17-25°C (63 to 77°F)

The following ranges have been established for monitoring instrument quality control.

Instrument	Manufacturer's instrument range or limit	Established range
Beckman Centrifuge (Refrigerated)	-5 to +25°C (23-77°F)	2-8°C (36 to 46°F)
Beckman Centrifuge (Room temperature)	-5 to +25°C (23-77°F)	17-25°C (63 to 77°F)
Jewett Freezer	-8.9°C (16°F) Limit	-18 to -23°C (0 to -10°F)
Jewett Refrigerator	2-5°C	2-8°C (36 to 46°F)
LFBSC	0.450	0.350 to 0.550
Phlebotomy Refrigerator	None	2-8°C (36 to 46°F)

Two thermometers monitor ambient temperature in the laboratory and one thermometer monitors ambient temperature in the phlebotomy room. The allowable temperature range for these rooms is 17°C-25°C (63°F to 77°F).

The acceptable temperature range for refrigerators used for storage of CLIA-regulated specimens and reagents is 2-8°C and is checked and recorded daily. If temperatures are recorded automatically on a continuous monitoring system graph, the individual's initials are captured.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. Most NHANES freezers are monitored automatically by built-in visual systems (with thermographic or digital reading). The range of allowable temperature is -18 to -23°C. If this range is exceeded, the technologist contacts the MEC manager.

Freezers and refrigerators are regularly monitored for excessive ice deposit, inoperative cooling fans, and frayed or worn electrical power connections. Problems are reported to the MEC manager.

10.10 Calibration and Calibration Verification

10.10.1 Introduction

Calibration and calibration verification are specified in the documentation of the CBC analytical procedure.

10.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites

At least once every 6 to 8 weeks, each of the three instruments are calibrated with S-Cal.

10.11 Remedial Actions

10.11.1 Introduction

Remedial actions are taken and documented when:

- Test systems perform outside acceptable performance specifications. Remedial action is documented in the appropriate QC manual.
- Results of control materials and calibration materials fail to meet quality control criteria. Remedial action is noted in the appropriate QC logbook.
- The laboratory cannot report sample person test results within its established time frame. If the reporting of data will exceed the agreed upon time frame, the MEC and final Report of Findings indicate that test results are not available.
- Errors in the reported SP test results are detected. When errors are detected in the reporting of sample person results, the MEC physician notifies the sample person by phone, followed by the issuance of a corrected report within a time period suitable to the sample person, but not to exceed 1 week. The corrected report clearly shows the corrected results in the title. Exact duplicates of the original as well as the corrected report are maintained for 7 years.

10.12 Integrated Survey Information System (ISIS)

10.12.1 Introduction

One of the purposes of the ISIS is to store sample person results for retrieval in a period acceptable for the intended use of the data. Sample person test results are stored in a database. The ISIS consists of the PC databases used for storing sample person results. This form for the ISIS facilitates the interfacing of varied and complex instrumentation used in many of the analytical procedures. The MEC LAN hardware serves as the hardware for the ISIS. The identification of the sample person result will be by specimen ID number and the result is accessible by this number.

The minimum amount of data stored for each analytical result is the specimen ID number, the analyte name, and the measured result. If the specimen ID does not provide sufficient information to relate the measured result to the QC data for the run, then the run number and run date must also be stored. The specimen ID, run date, and run number should be sufficient information to relate the measured result to the quality control information for that run. Access to the ISIS database is password protected so that only the persons authorized by the Westat and NCHS may access the data.

10.12.2 Integrated Survey and Information System Data Down Times

Each laboratory method is able to run and temporarily store results even if the MEC LAN is inoperable.

10.12.3 Maintenance of LAN Hardware

After failure of a LAN component, ISIS should be able to be repaired or replaced within a day by a functioning component. LAN hardware is almost totally readily available. PC components and the infrequent problems with this hardware are readily correctable in this period. Westat participates in the standard service contract arranged for NHANES for service of failing or failed computer equipment.

10.12.4 Backup Schedule of Integrated Survey and Information System Data

ISIS data stored on LAN hard disk drives are backed up to tape once each weekday (Monday through Friday). If ISIS data are stored on local PC or minicomputer hard drives, they are archived to a second hard disk, tape, optical diskette, or CD-ROM at least once a week.

10.13 Communications and Complaints

10.13.1 Introduction

Good communication between the laboratory and persons reviewing laboratory analyses is essential for proper use of laboratory results. NHANES encourages collaborative relationships between technologists and physicians utilizing laboratory data. This collaborative interaction is the primary mechanism by which NHANES evaluates the effectiveness of laboratory protocols and other laboratory communications. If the laboratory has a persistent problem with meeting laboratory criteria (e.g., inadequate amount of specimen), the MEC manager, technical supervisor, or laboratory director will discuss the problem with the person in a collaborative spirit.

Similarly, complaints of laboratory performance are carefully considered. Usually, these complaints are fixed with minor adjustment or explanation. Each member of laboratory staff is responsive to complaints that have merit and relate to her/his responsibilities. Nontrivial complaints are reported to supervisors who will decide appropriate actions, including investigation and remedial action. The technical supervisor maintains documentation of nontrivial complaints concerning laboratory performance that are reported to her or him.

10.14 Quality Promotion

10.14.1 Introduction

High quality laboratory results are generated when all phases of the measurement process (i.e., pre-analytic, analytic, and post-analytic) are conducted properly. Factors that promote high quality results include:

- Competent, well-trained and motivated laboratory staff;
- Quality laboratory facilities;
- Well-maintained, high quality laboratory equipment;
- High quality laboratory analytical methods; and
- Clear commitment of management to quality laboratory results.

NHANES is committed to supporting each one of these factors in order to enhance quality.

10.15 Quality Assurance Program

10.15.1 Introduction

The goal of the NHANES Quality Assurance Program (QAP) is to monitor and evaluate the overall quality of the testing process including pre-analytic, analytic, and post-analytic phases.

The initial database and reporting system design included the following requirements:

- All data are released in a timely manner relative to its intended use. All CBC results are provided to the SP in a preliminary Report of Findings when the SP checks out of the MEC. If the results are not available by the time the SP checks out of the MEC, they are reviewed by the MEC physician as soon as they are available and the SP is notified by phone of any abnormal results. A hard copy of the CBC results are included in the final Report of Findings sent to the SP 6-12 weeks after the MEC examination. In the case where no blood was drawn, the preliminary or final Report of Findings states, "Not enough blood drawn to test." In the case where no results were transmitted, the preliminary or final Report of Findings states, "Not Done."
- The preliminary and final Report of Findings are ISIS generated and are based on results in the database; they are not predefined reports stored in the system. The format for the English and Spanish preliminary and final Report of Findings is tested annually to determine if the generic format is legible.
- The preliminary and final Report of Findings format includes reference ranges, units of measure, or notation for inadequate specimen. Sample preliminary and final English and Spanish Report of Findings are printed and the format is tested annually.

- NCHS is responsible for sending the final Report of Findings to each survey participant. Mailing labels are printed, the mailing label is matched to the final Report of Findings, and the final Report of Findings is inserted into the envelope. NCHS monitors communications from SPs who report that they have received the incorrect Report of Findings.
- All results are generated based on results stored in the database. The ISIS system prohibits the MEC technologist from changing data in the database after the SP has checked out of the MEC or if the MEC Report of Findings has been printed. All subsequent copies of results should match the original results. If any result is ever changed in the database, a back-end editing request system form is submitted, tracked and maintained by ISIS.
- A comprehensive security system guards against unauthorized access. A complete description of this system is maintained by and is available through NCHS.

The basic mechanism for the QAP is the quality audit. The quality audit is conducted by the NHANES technical supervisor or laboratory director, who maintains documentation of the results of the quality audits, including remedial actions taken to address conditions that merited corrective action.

10.15.2 Quality Audit: Sample Person Test Management

The quality audit for sample person test management is conducted at least yearly and consists of:

- A survey of the laboratory staff, and of the analytical procedures used in NHANES. The survey includes requests for information on:
 - Any changes which need to be made in sample person preparation, specimen collection, labeling, preservation, and transportation
 - Any changes which need to be made in completeness and relevance of sample person information obtained at the time the specimen is acquired, and the use and appropriateness of specimen rejection criteria based on their experience and interactions with persons requesting the tests
 - Laboratory-reporting errors encountered since the last survey
 - Whether the performance of the Integrated Survey and Information System (ISIS) is adequate for their measurement systems
 - Nontrivial complaints from outside the laboratory about performance of the lab

The technical supervisor and laboratory director assess the results of the audit and in consultation with Beckman Coulter® implement corrective actions that are warranted.

10.15.3 Quality Audit: Quality Control

Quality control addresses the analytic phase of measurement. The purpose of the internal ("bench") quality audit is to assure that the QC analyses were performed and appropriate actions were taken when out-of-control conditions occurred. The quality audit of quality control shall be conducted at least yearly by technical supervisor and laboratory director and shall consist of:

- A review of a random 10 percent sample of 5C Cell and Latron control results. The review evaluates whether appropriate corrective action was performed and documented for out-of-control conditions.
- An analysis of the Proficiency Testing results. The analysis and review will assess PT performance and if unsatisfactory, whether the deficiencies have been adequately addressed. The technical supervisor and laboratory director compare results to determine the correlation coefficient. This correlation must be greater than 0.95 or the laboratory director may give written approval that the methods are sufficiently similar for the intended use of the data.
- The review of documents that demonstrate that at least once every 6 to 8 weeks S-Cal calibrator was run on three instruments.

The technical supervisor and laboratory director assess the results of the audit and in consultation with Beckman Coulter® implement corrective actions that are warranted.

10.15.4 Quality Audit: Personnel

Well-trained and competent personnel are essential components of good laboratory performance. The quality audit of personnel is conducted at least yearly by the technical supervisor and laboratory director and shall consist of:

- A review of the 5C Cell and Latron control ("bench") results or IQAP QC results for 10 percent of the total control runs covering a period of not less than one year. The internal ("bench") QC reflects the performance of persons performing the method. If out-of-control conditions occur with a frequency more than twice the expected statistical probability (e.g., 95% control limits would normally be exceeded by 5% of the

analytical runs), the technical supervisor and laboratory director will assess whether the unacceptable performance is due to the performance of the person in question or other factors (e.g., failing equipment). If the personnel performance is the cause, the technical supervisor and laboratory director determine and implement appropriate remedial action (e.g., training).

- A review of all remedial action since the last audit to assess the effectiveness of the action. Acceptable performance of the method by the person involved for one month after remedial action is acceptable evidence of the effectiveness of remedial action.
- The technical supervisor and laboratory director audit the documentation of personnel training and evaluation to check whether the analyst has been appropriately evaluated in the last year (or 6 months if in first year performing a new method). The evaluation criteria is described in the Personnel Training and Evaluation section of the Laboratory Procedures Manual (Chapter 10, Section 10.16).

The Technical Supervisor maintains documentation of the results of the audit.

10.15.5 Quality Assurance Review with Staff

The technical supervisor and laboratory director prepare a report of the results of quality audits within 3 weeks of the completion of the audit. The technical supervisor and laboratory director review pertinent information with appropriate staff to assure effective remedial actions are taken. The technical supervisor and laboratory director also notify staff members who have been involved in the audit if performance was acceptable and no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

10.16 Personnel Training and Evaluation

The technical supervisor assures that persons performing laboratory tests receive appropriate training. The performance of persons performing laboratory tests is evaluated every 6 months for the first year testing is performed and annually thereafter. The evaluation shall consist of:

- Direct observation of test performance including sample person preparation (if applicable), specimen handling, specimen processing, and testing;
- Direct observation of the recording and reporting of test results;

- Review of QC results, IQAP, PT, Xb analysis, and linearity results and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of testing performance using blind QC materials; and
- Assessment of problem solving skills.

The technical supervisor maintains documentation of the evaluations for at least 7 years. If remedial action is warranted, the technical supervisor shall discuss the results of a personnel evaluation with the person evaluated and implement appropriate action (e.g., training).

11. OPERATIONAL ISSUES

11.1 Start of Stand Activities

The Westat warehouse sends supplies for all stands and schedules them so that they arrive on set-up day. Supplies requiring refrigeration are shipped so that they arrive the day before or the day of set-up. Most laboratory supplies are stored in the MEC trailer compartments.

The advance arrangement staff may assist in completing some set-up activities. On set-up day the phlebotomist, medical technologists, and home examiners work together to complete all activities. These include assisting in unpacking the warehouse pallets, sorting the laboratory supplies by storage location, inventorying all existing and new supplies, organizing and storing all inventoried supplies in the trailer compartments or MEC cabinets, and setting up each work area by stocking the area with appropriate supplies. Maintenance is performed on all instruments and equipment, and equipment functions are tested. Notify the MEC manager if additional supplies are required. Document all instrument and equipment malfunctions in the Unusual Occurrence Log.

Mark and store miscellaneous hardware in a safe location in the laboratory until the end of stand. Hardware includes wood blocks with Velcro, refrigerator and freezer bottle caps, temperature-recording pen protectors, restraining straps, wood boards, and carpeted counter supports for the Beckman Coulter® and Beckman Coulter® printer straps.

Phlebotomy Room

- Phlebotomist
 - Check the sink for hot and cold running water and proper drainage.
 - Remove the wood door and drawer blocks from the refrigerator and store for reuse at end of stand.
 - Turn on the refrigerator.
 - Verify that the refrigerator is operating.
 - Clean the refrigerator.
 - Check to see that the intercom on the telephone is working properly.

- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Record all Vacutainer® tube and needle lot numbers and expiration dates in the Supply Use Control Log.
- Data Manager
 - Check the computer terminal operations. Log onto the terminal, access the ISIS system, and log off.

Laboratory

- Medical Technologists and Home Examiners
 - Check the sink and eyewash for cold running water and proper draining.
 - Remove the wood door blocks from the refrigerators and freezers and store for reuse at end of stand.
 - Replace the freezer and refrigerator temperature probe solid bottle caps with the caps with temperature probe holes. Place the freezer and refrigerator temperature probes back into the bottles. Save the solid bottle caps for reuse at end of stand.
 - Turn on or plug in the refrigerators and freezers.
 - Verify that the refrigerator and freezers are operating.
 - Change temperature-recording charts, and check pen ink to make sure it is dark. Save the black pen protector for use at end of stand.
 - Check light, blowers, and magnehelic pressure gauge reading in the LFBSC.
 - Release the Beckman Coulter®'s restraining straps, remove the wood board, and detach the bolted carpeted counter supports. Store these items until they are required at the end of stand.
 - Remove the restraining strap on the Beckman Coulter® printer. Store this strap until the end of stand.
 - Contact Beckman Coulter® as soon as possible at 1-800-526-7694 to schedule instrument verification by a service technician. Provide Beckman Coulter® with the current address and instrument system ID, which is located on the front of the instrument.

- Perform all Beckman Coulter® beginning of stand operations as described in Chapter 7, Section VIII.F. This includes installing and priming all new reagents, performing a start-up procedure, and reviewing and verifying the system set up.
 - Calibrate the Beckman Coulter® MAXM. This must be completed prior to performing routine CBCs on SPs.
 - Check to see that the telephone is working properly.
 - Refrigerate the serum and urine pregnancy controls, and Beckman Coulter® Latron and 5C Cell controls as soon as they arrive.
 - Clean all work surfaces and storage areas.
 - Stock and organize supplies.
 - Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC.
 - Open and label all new containers.
 - Reconnect the batteries inside the temperature recording units.
 - Check the wall thermometers for damage.
 - Mentally step through labeling, blood processing, urine processing, pregnancy testing, complete blood count, and specimen storage to make sure all the necessary equipment is functioning and all supplies are available in the phlebotomy/laboratory area.
 - Document all readings and activities in the Laboratory QC module.
- NCHS Biomedical Engineer
 - Determine the rpm of the centrifuges using a strobe or tachometer and performing a timer check. Record the results on a piece of paper and tape the paper to the workstation 2 terminal. The medical technologist enters the results in the Laboratory QC module.
 - Verify that both centrifuges are operating at 4-8°C. Fill two 15-mL red top Vacutainer® tubes with water, load and balance the aerosolve buckets, run the centrifuge at 4-8°C for 10 minutes, and immediately place the dial thermometer into the water. Record the results on a piece of paper and tape the paper to the workstation 2 terminal. The medical technologist enters the results in the Laboratory QC module.

- Data Manager
 - Check the computer terminal operations. Log on to each terminal, access the automation system, and log off.

11.2 End of Stand Activities

For security reasons, lock all needles in the cabinet each day after examinations are complete. Turn off the centrifuges. Sign off from all computer terminals.

At the end of a stand, shut down all equipment and inventory all supplies. On teardown day the phlebotomist, medical technologists, and home examiners (if available) work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Lock all cabinets and drawers or secure with Velcro straps. Safely discard all biohazardous waste.

Packing Phlebotomy Room

- Phlebotomist
 - Inventory all supplies and equipment in the phlebotomy room.
 - Turn off and clean the refrigerator in phlebotomy.
 - Place wood blocks with Velcro strips on the refrigerator door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
 - Pack the juice and crackers in labeled plastic boxes and store them in the MEC.
 - Pack and ship (to the warehouse) all unopened VOC canisters and TB antigens.
 - Remove all loose supplies (clock, telephone handset, etc.) and equipment from the counter tops; pack loose supplies in boxes and label "Phlebotomy Room." If possible, place the boxes in the cupboards above the counter, under the bench, or in the corners on the floor in phlebotomy. If these areas are full, place the boxes in the designated compartments under the trailers. Do not store Vacutainer® tubes in these trailer compartments.
 - Lock the wall arm boards.
 - Bolt the room door in the open position.

- Close all cupboards and lock them or secure with Velcro strips. Place a dowel through the drawer handles or secure with a stretch cord.
- Lock all needles in the cupboards or in compartments under the MEC.
- Lay the phlebotomy cart on its side on the floor.

Packing the Laboratory

■ Medical Technologist and Home Examiners

- Perform the Beckman Coulter® end of stand procedure as described in Chapter 7.
 - Review, print, and clear the error file.
 - Download the IQAP files.
 - Perform daily shut down.
 - Bleach the apertures and flow cell.
 - Bleach, rinse, and drain reagent lines.
 - Turn off the power.
 - Rinse exterior of the BSV.
 - Wash exterior of the instrument.
 - Dispose of all opened reagents. Save the empty Isoton® III container for a waste container at the next stand.
- Check the expiration dates on the Beckman Coulter® Latron, Beckman Coulter® 5C Cell control, pregnancy test kit, and pregnancy controls. If unopened and they will not expire before the beginning of the next stand, pack them in a shipper with refrigerant packs, print a label using FedEx Ship, and ship back to the warehouse.
- Unplug the refrigerators and freezers.
- Clean refrigerators and freezers.
- Replace the freezer and refrigerator temperature probe bottle caps (with holes) with the bottle caps without holes. Save the bottle caps (with holes) for reuse at beginning of next stand.

- Place wood blocks with Velcro strips on each refrigerator and freezer door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
- Remove the temperature recording charts and send to the home office. Store the pen arm in the "Change chart" (#3) position. Replace the black pen tip protectors.
- Disconnect the batteries inside the temperature recording units.
- Unplug the LFBSC.
- Close and lock centrifuge lids; turn off centrifuges.
- Pack all tube rockers securely in boxes or in drawers.
- Remove all small supplies from the counters and LFBSC. Pack them in boxes or in cabinets. Place the boxes in cupboards, drawers, or in corners of the laboratory area.
- Close all cupboards and secure with Velcro strips.
- Remove the fire extinguisher from the wall and lay inside the laboratory sink.
- Clean all counters, the LFBSC, and equipment with 1:100 bleach solution.
- Place stools upside down or lay them down on the floor.
- Attach Beckman Coulter®'s bolted carpeted supports to the counter. Secure the Beckman Coulter® by laying the wood board across the top of the instrument and tightening the straps. Place foam blocks behind the instrument. Place a strap around the bottom front of the instrument. (Do not apply too much pressure.)
- Secure the Beckman Coulter® printer by strapping it to the printer shelf.

Sending Laboratory Files and Supplies

At the end of each stand use FedEx Ship to create a label to send the following hard copy documentation to the technical supervisor at the home office:

- Temperature recording charts
- Beckman Coulter® Start Up results
- Beckman Coulter® Latron and 5C Cell Control results
- Calibration printouts

- Linearity printouts
- X_b means and graphs printouts
- Latex CBC/Diff cumulative statistic and graph printouts
- Error file printout
- Proficiency testing copies
- Unusual Occurrence Log
- Supply Use Control Log
- Lead dust transmittals
- Dry ice receipts (at the discretion of the MEC manager)
- Biohazardous receipts (at the discretion of the MEC manager)

At the end of each stand use FedEx Ship to create a label to send the following supplies to the warehouse supervisor:

- Unopened VOC canisters
- Unopened TB antigens – refrigerated
- Unopened pregnancy test kits
- Unopened pregnancy serum and urine controls – refrigerated
- Unopened Coulter® 5C Cell and Latron controls – refrigerated

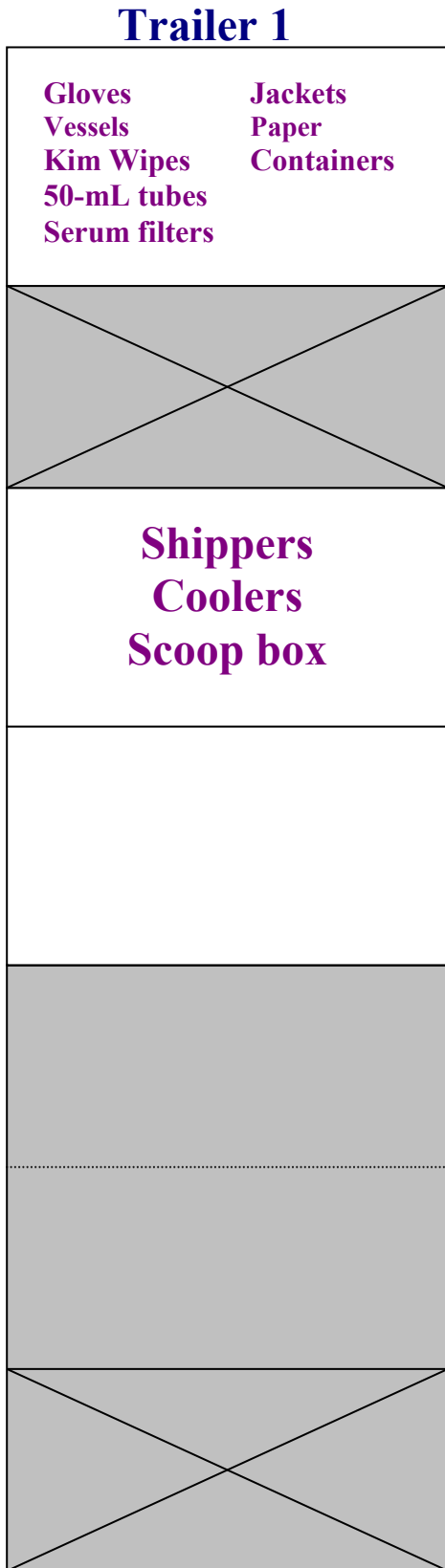
Pack supplies using procedures described in Chapter 9.

Inventory

At the end of each stand, take a complete inventory. The warehouse uses this inventory to stock the MEC for the next stand.

Store supplies in the trailer compartments as indicated in the trailer maps (Figure 11-1).

Figure 11-1. MEC trailer compartment maps



11.3 Ordering Additional Supplies

The chief medical technologist is responsible for notifying the MEC manager if additional supplies are needed during the stand. However, each technologist and phlebotomist is responsible for identifying any potential shortage of supplies at each workstation.

11.4 Dry Run

After setting up the phlebotomy and laboratory rooms at each new stand, a "dry run" session is conducted using volunteers to verify data collection and specimen collection and processing procedures. One purpose of the dry run session is to help identify any problem areas, particularly with equipment, and to resolve the problems before the stand begins. Another purpose is to provide the contract laboratories with blind split samples for quality control determinations. Document the results of the dry run session in a manner identical to an actual session except results are entered twice, first using the SP ID, and second using the Sample ID.

During the dry run session, prepare split samples for each volunteer. Send these split samples to contract laboratories for analysis with the first routine shipment. Collect the amount of blood specified in the Dry Run Venipuncture Protocol (see Exhibit 11-1). This amount is less than the blood required from a routine examinee. Collect 10-mL of urine and process as specified in Dry Run Urine Processing Protocol (see Exhibit 11-2). Process the blood as directed in the Dry Run Blood Processing Protocols (see Exhibits 11-3, 11-4, and 11-5).

11.4.1 Phlebotomy Protocol and Procedures

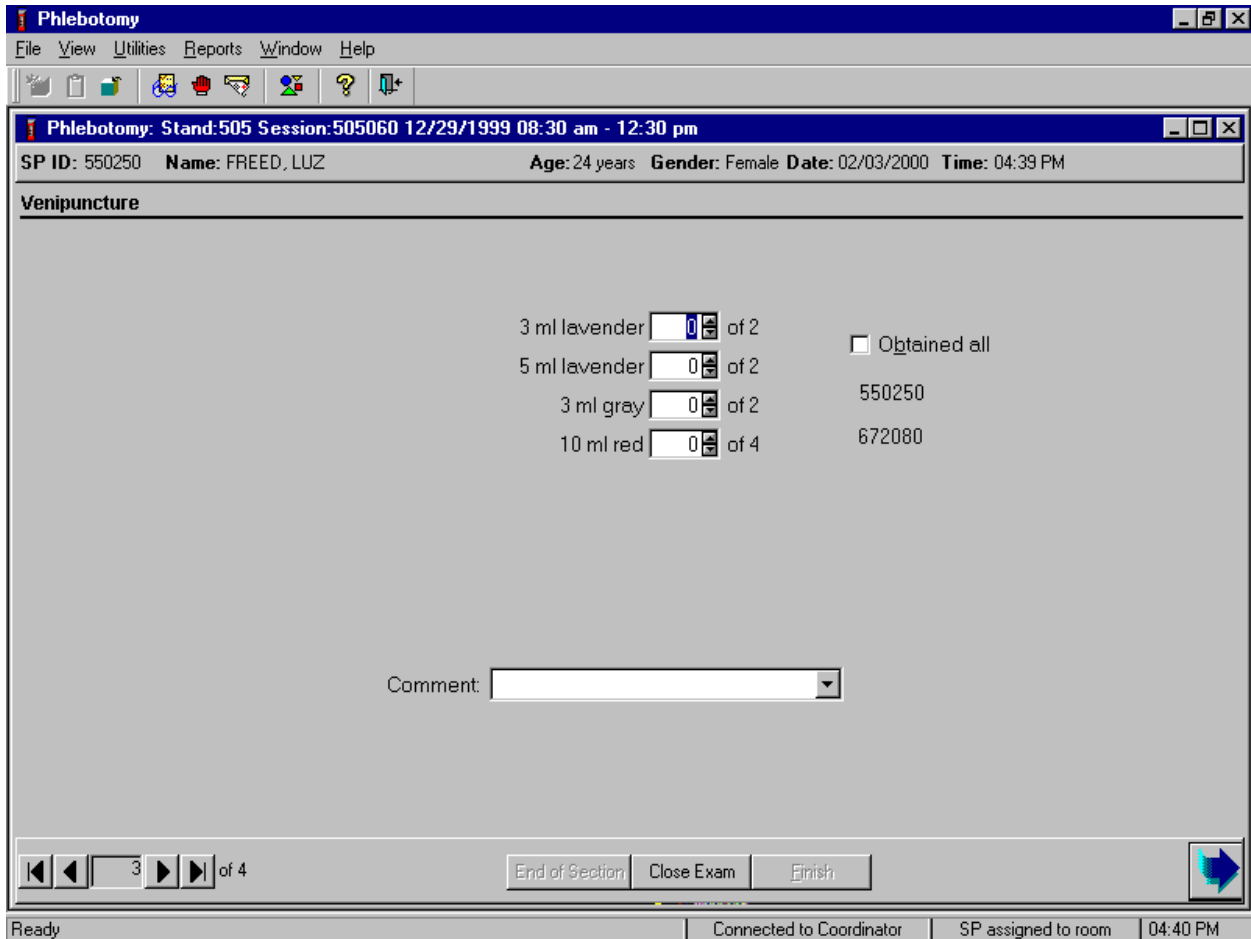
Exhibit 11-1. Dry run venipuncture protocol

Tube type (in priority order)	Number of tubes
3-mL EDTA	2
5-mL EDTA	2
3-mL Gray	2
3-mL Blue	2
10-mL Red	4

On dry run day the phlebotomist refers to the following instructions to conduct the phlebotomy procedures:

- Access the phlebotomy application; open the exam and wand the dry run volunteer into the component.
- Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 4.
- Perform the venipuncture using procedures described in Chapter 4.

The correct dry run venipuncture protocol is based on the session and the volunteer's group designation. The correct venipuncture is displayed. Note the two IDs, the SP ID and the Sample ID are both displayed.



Enter the venipuncture results using procedures described in Chapter 4. Enter any reasons for a tube not being drawn according to protocol, and any comments about the venipuncture. Refer to Chapter 4 for specific instructions.

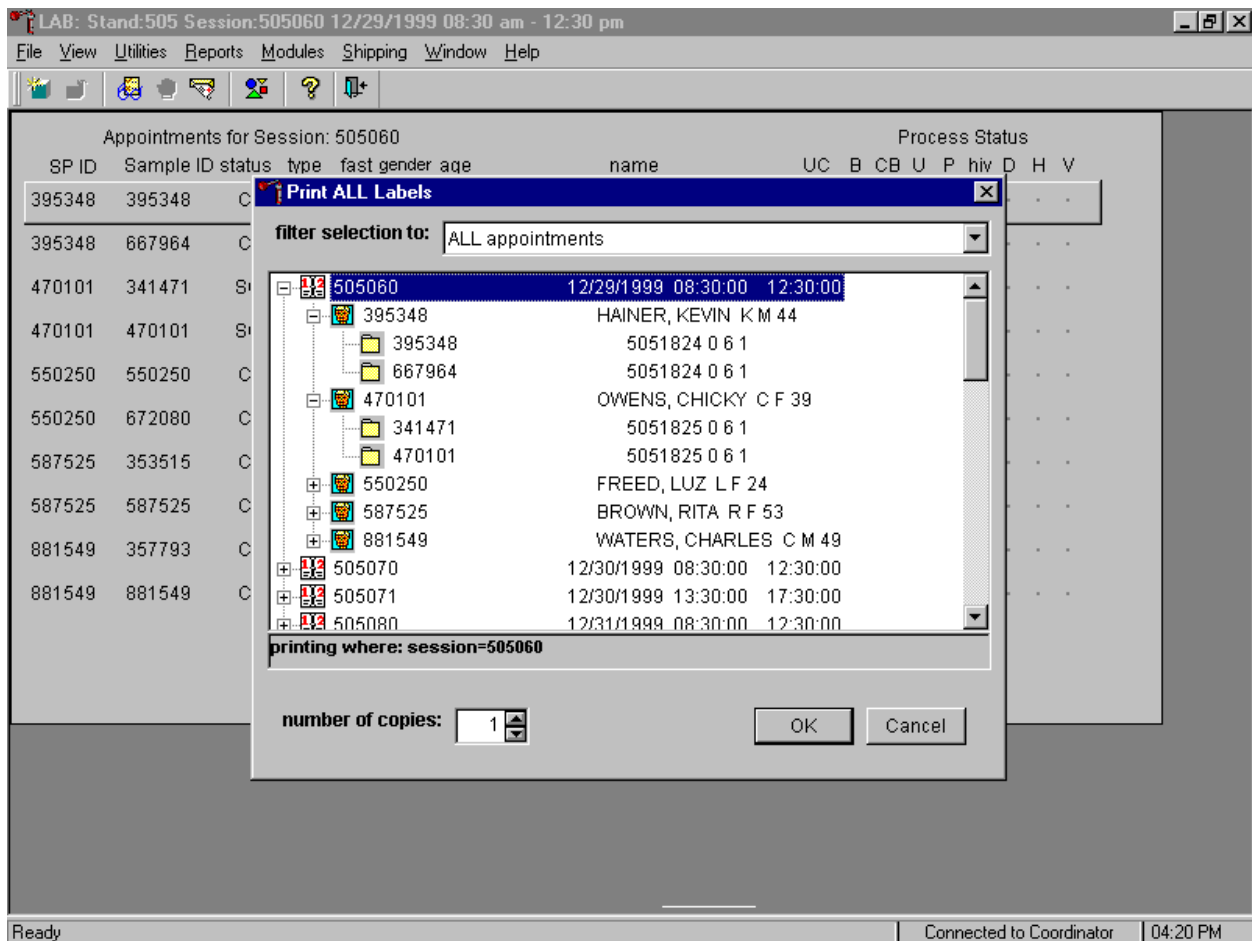
Label half of the tubes with the first SP ID and the other half with the sample ID. Label the Vacutainer® tubes for each volunteer as follows:

- Place the original SP ID number on one tube of the pair of 3-mL EDTA tubes and the second Sample ID number on the other tube of the pair. Follow the same procedure for the pair of 5-mL EDTA, 3-mL gray tubes, and 3-mL blue tubes. Place an original SP ID number on two of

the four 15-mL red tubes and the second Sample ID number on the other two 15-mL red tubes. If only one tube is drawn, discard the tube. If less than four of the 15-mL red tubes are drawn successfully, label the first tube with the original SP ID and the second one with the Sample ID. If an odd number of tubes are drawn, discard the odd tube.

11.4.2 Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window. Two distinct IDs are assigned to each volunteer, the original SP ID and a second unique Sample ID.



The Print All Labels pick list demonstrates that for each dry run volunteer, there are two entries, the original SP ID and the Sample ID. The last digit of both numbers is either even or odd. Volunteers with an original SP ID number ending in an odd digit are assigned to Urine or Blood Processing

Protocol Group 1 and volunteers with an original SP ID number ending in an even digit are assigned to Urine or Blood Processing Protocol Group 2.

There are two sets of urine and blood vessel labels and one pregnancy label (if eligible) for each dry run volunteer. The correct vessel labels automatically print for the correct protocol. Print labels using procedures described in Chapter 9. Place urine and pregnancy labels at workstation 2. Each volunteer will have two unique blood processing racks: one with labels containing the SP ID and the second with labels containing the Sample ID. Assemble and label the blood processing racks for each dry run volunteer using procedures described in Chapter 9.

Review the laboratory heads-up display. Use the heads-up display to view the modules for which the dry run volunteer is eligible and their current process status.

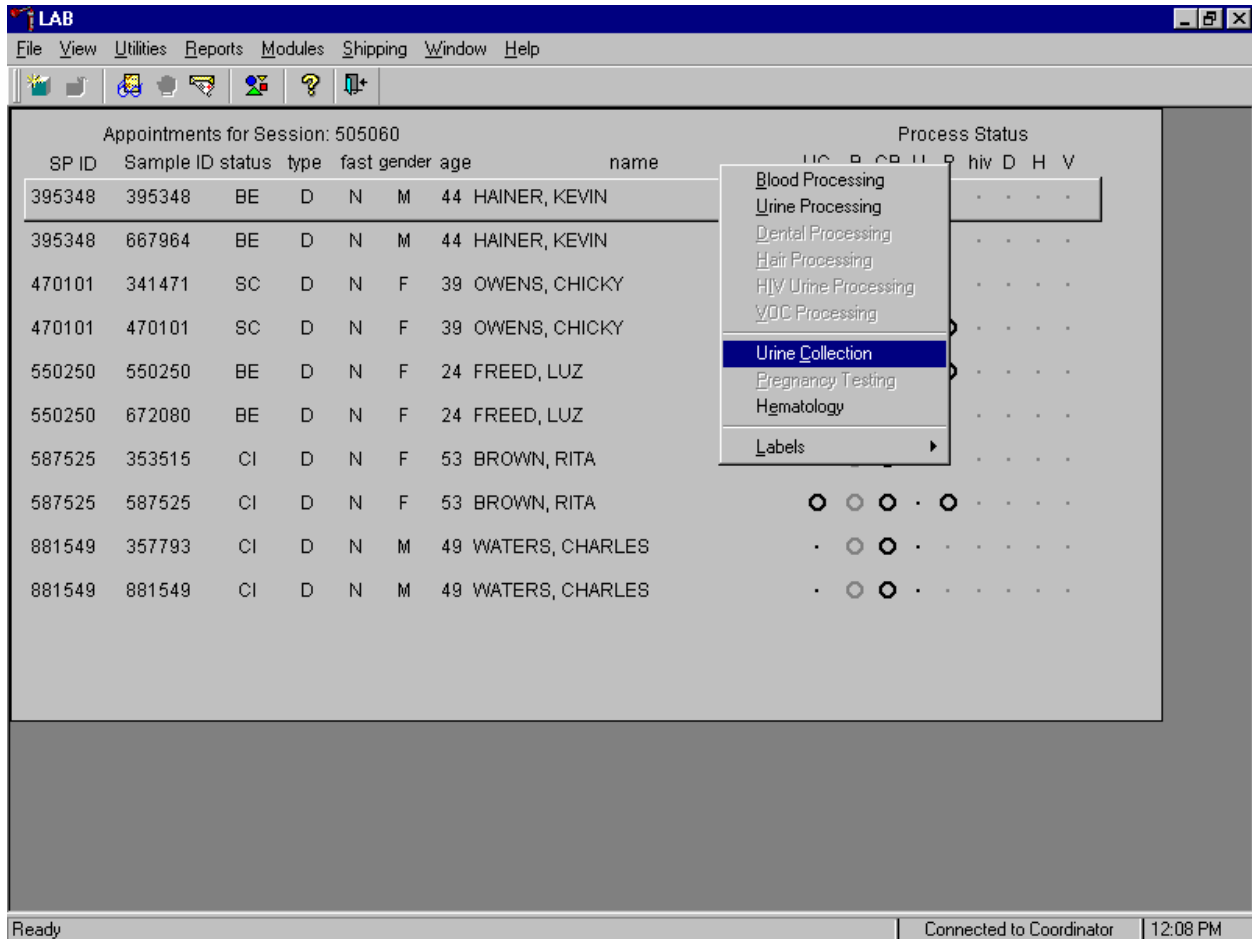
Appointments for Session: 505060								Process Status								
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
395348	395348	CI	D	N	M	44	HAINER, KEVIN	●	○	●	●	·	·	·	·	·
395348	667964	CI	D	N	M	44	HAINER, KEVIN	·	○	●	●	·	·	·	·	·
470101	341471	SC	D	N	F	39	OWENS, CHICKY	·	○	●	●	·	·	·	·	·
470101	470101	SC	D	N	F	39	OWENS, CHICKY	●	○	●	●	○	·	·	·	·
550250	550250	BE	D	N	F	24	FREED, LUZ	●	●	●	●	●	·	·	·	·
550250	672080	BE	D	N	F	24	FREED, LUZ	·	●	●	●	·	·	·	·	·
587525	353515	CI	D	N	F	53	BROWN, RITA	·	○	●	·	·	·	·	·	·
587525	587525	CI	D	N	F	53	BROWN, RITA	●	○	●	·	●	·	·	·	·
881549	357793	CI	D	N	M	49	WATERS, CHARLES	·	○	●	·	·	·	·	·	·
881549	881549	CI	D	N	M	49	WATERS, CHARLES	·	○	●	·	·	·	·	·	·

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The heads-up display lists each dry run volunteer twice. Note the difference between the SP ID and the Sample ID and the types of tests for which the dry run volunteer is eligible. Dry run volunteers are only eligible for urine collection and processing, CBC, blood processing, and the pregnancy test. The urine and blood protocols constitute a limited subset of the primary SP's protocol. Each test has the same age and gender restrictions as a primary SP. Dry run volunteers are never eligible for future research vessels (dental saliva, surplus serum, plasma, or urine), genetic vessels (44, 71 and 43), hair collection, HIV serum or urine, CD4, urine mercury, or any subsamples, including VOC. Notice that only one urine collection and one pregnancy test are required for each dry run volunteer.

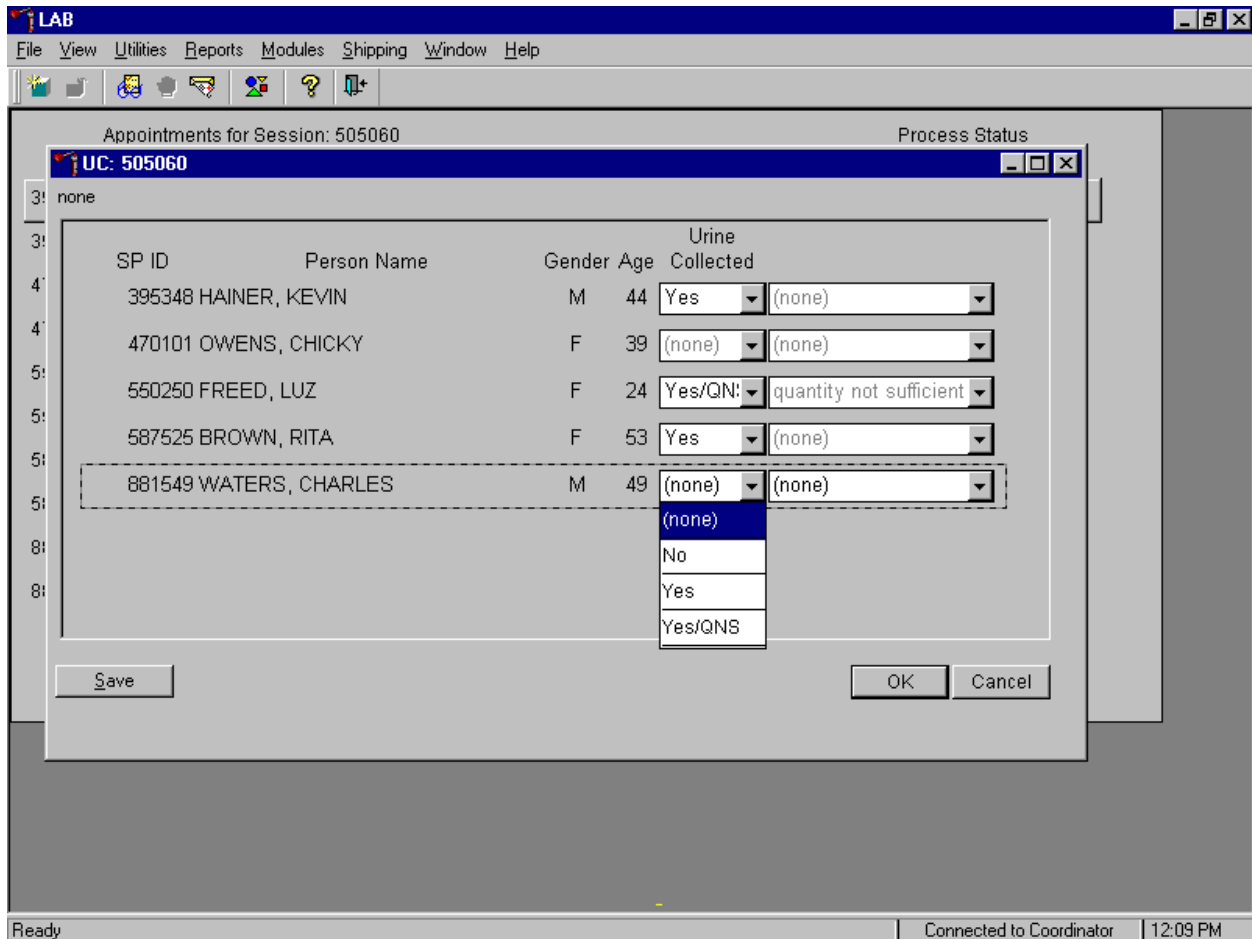
Collect approximately 10-mL urine from all dry run volunteers. The MEC coordinator instructs each volunteer to void at the same time that the volunteer changes clothes or ideally, within 45 minutes after arrival at the MEC. After collection, the coordinator or assistant coordinator transports the initial specimen to the laboratory.

Document the dry run volunteer's urine collection.



To select the correct dry run volunteer's record, locate the record in the heads-up display that contains the urine collection circle. To access the urine collection module, use the up and down keys to move up and down the list until the correct record is highlighted or drag the mouse arrow to the correct volunteer and right click. Continue by dragging the mouse arrow to {Urine Collection} then left click or type [C/c].

The urine collection window displays.



The urine collection window contains columns for the SP ID, Person Name (last, first), Gender, Age, and Urine Collection and Comments result fields. Only dry run volunteers who have checked into the MEC session are available for processing. This result field for checked-in volunteers is indicated in black while the result field for volunteers who have not checked into the MEC session are gray. Use the scroll bar to view all volunteers scheduled into the session.

Evaluate the sufficiency of the quantity of urine received in the laboratory. Use the gradations on the urine collection cup to estimate the amount of urine received. Record the urine collection result for each volunteer by typing [Y/y] for “Yes,” [N/n] for “No” or [Q/q] for “Yes/QNS.” Alternatively to record the collection result, use the mouse to direct the mouse arrow to the drop down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result notifies

the coordinator, who then asks the dry run volunteer to provide an additional urine specimen. Refrigerate all insufficient urine samples. If additional urine is obtained, pool the urine and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each dry run volunteer. Enter “No” in the result field for all volunteers who have not produced a urine sample. Record a result other than “(none)” for all records. Record a comment for all insufficient urine collections.

Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the **Save** button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the **X** in the upper right hand corner of the module and left click.

Use the urine processing labels printed in advance. The correct protocol is determined in advance by assigning dry run volunteers with an original SP ID number that ends in an odd digit to Protocol Group 1 and assigning dry run volunteers with an original SP ID number that ends in an even digit to Protocol Group 2. There are two sets of labels for each dry run volunteer. Label 1 set of vessels with the first set of labels (SP ID) and the second set of vessels with the second set of labels (Sample ID).

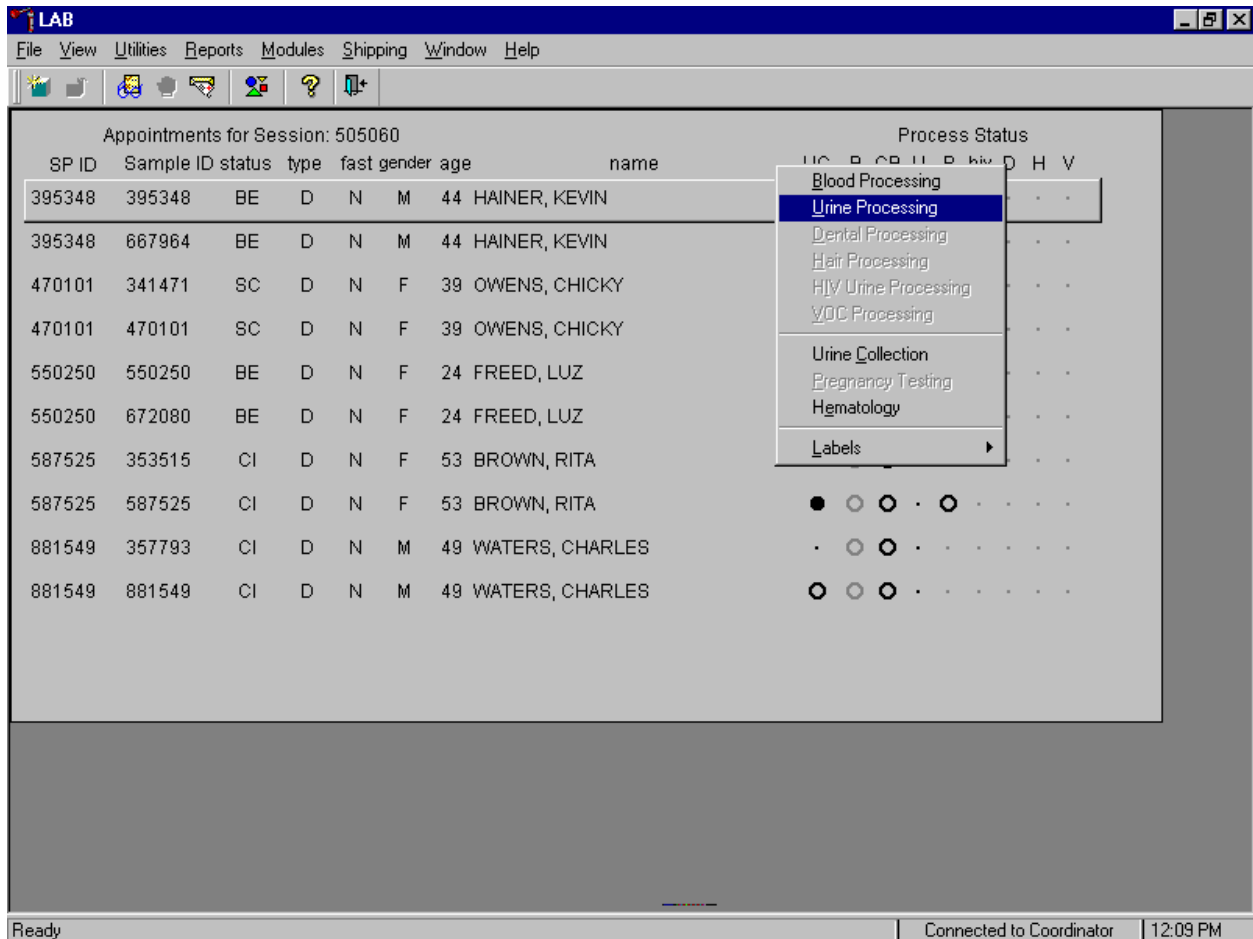
Exhibit 11-2. Dry run urine processing protocol

ID	Assay	Group 1-Odd	Group 2-Even	Sample size mL	Vessel
45	Alb/Creat		6	3	5-mL Cryovial
46	Chlam/GC	8		4	5-mL Cryovial
47	NTX		2	1	2-mL Cryovial

- Label two 5-mL cryovial vessels for the first test - #45 or #46, depending on the protocol group. Label one tube with the volunteer's original SP ID number. Label the other tube with the volunteer's second Sample ID number.
- Pour 3 or 4-mL urine into each of the vessels (this depends on the protocol.)

- Continue processing the NTX vessel for dry run volunteers in protocol group 2 in a manner identical to the first Alb/Creat vessel.
- Enter the results of urine processing for the original SP ID and again for the second Sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the results of urine processing.



To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct volunteer, right click, drag the mouse arrow to {Urine Processing} and right click or type [U]. Alternatively to access the Urine Processing module, use the up and down keys to move up and down the list until the correct volunteer is highlighted, right click, drag the mouse arrow to {Urine Processing}, and right click or type [U].

The volunteer's urine processing screen displays.

Appointments for Session: 505060

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
395348	395348															

UR: 395348

none

Tech ID: 1226 Sample ID: 395348 Name: HAINER, KEVIN Gender: M Age: 44
 SP ID: 395348 SubSample: 6 Fasting_Req: 4

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
47	NTX	1	U	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

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To mark an individual urine vessel as collected or Filled – “Yes” use the mouse to direct the mouse arrow to the “Yes” radio button and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container. To mark an individual urine vessel as not collected or Filled - “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column. To collectively mark all vessels as Filled - “Yes”, use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [F/f]. To mark all vessels as Filled - “No”, use the mouse to direct the mouse arrow to the **Filled** box, left click, drag the mouse arrow to {Not Filled All} and left click or type [N/n]. Use the quality comment code to indicate if blood is present. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow

to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Access the Sample ID record on the heads-up display and record the processing results. Remember that these vessels must be paired and if the quantity of urine is insufficient to fill both vessels, then do not record either vessel as filled.

Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

The urine-processing technologist performs the pregnancy test on female dry run volunteers aged 8-59 years and documents the results following the procedures in Chapter 6.

11.4.3 Hematology

The technologist at workstation 2 runs two CBCs, in duplicate, for each dry run volunteer after the blood processing technologist processes whole blood from the 3-mL EDTA tubes according to the Whole Blood Processing Protocol (see Exhibit 11-3). Run the first CBC in duplicate on the first 3-mL EDTA tube with the original SP ID number on the tube. Evaluate results, and save the data using procedures described in Chapter 7.

Run the second CBC in duplicate on the second 3-mL EDTA tube using the second Sample ID number. Evaluate results, and save the data using procedures described in Chapter 7.

11.4.4 Blood Processing and Storage

Print blood processing labels using procedures described in Chapter 9. There are two sets of labels for each dry run volunteer. Prepare two blood processing racks using the blood-processing template for age 12+.

Treat each set of venipuncture tubes and pre-labeled blood processing racks as two independent and separate dry run volunteers. Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID, then process the second set of venipuncture tubes and blood processing vessels using the second Sample ID.

For each set of tubes, process the 3-mL EDTA top tube (with the original SP ID) for Lead/Cad, Ery Proto, RBC Folate, and Mercury using the same procedures described in Chapter 8. Process the first 5-mL EDTA top tube (with the original SP ID) for Glycohem using the same procedure described in Chapter 8. Reserve the remaining whole blood in the 5-mL EDTA tube for the plasma vessel 7.

Exhibit 11-3. Dry run processing protocol – whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	Both	0.5	Whole Blood	3-mL EDTA	2-mL
2	Ery Proto	Odd	0.4	Whole Blood	3-mL EDTA	2-mL
3	RBC Folate	Odd	0.1	Whole Blood	3-mL EDTA	2-mL
4	Glycohem	Odd	0.4	Whole Blood	5-mL EDTA	2-mL
5	Mercury	Odd	1.0	Whole Blood	3-mL EDTA	2-mL

Follow the identical procedure for processing the second 3-mL and 5-mL EDTA tube with the second Sample ID.

Process the remaining whole blood in the 5-mL EDTA tube, the 3-mL gray and 3-mL blue top tubes for plasma as described in Chapter 8.

Exhibit 11-4. Dry run processing protocol - plasma

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
7	Homocys/MMA	Even	1.0	Plasma	5-mL EDTA	2-mL
9	Glucose	Both	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	Even	1.0	Plasma	3-mL Blue	2-mL

Follow the identical procedure for processing the second 5-mL EDTA tube, the 3-mL gray and 3-mL blue top tubes with the second Sample ID.

Process pooled serum for the dry run volunteers using the Dry run blood processing protocol – serum (Exhibit 11.5).

Exhibit 11-5. Dry run blood processing protocol - serum

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
11	Iron/TIBC	Even	1.0	Serum	15-mL Red	2-mL
12	Fol/B12/Fer	Odd	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	Even	0.5	Serum	15-mL Red	2-mL
14	Hepatitis	Odd	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	Even	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	Odd	0.4	Serum	15-mL Red	2-mL
17	Cotinine	Even	2.0	Serum	15-mL Red	2-mL
18	Biochem	Both	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	Odd	0.5	Serum	15-mL Red	2-mL
20	Crypto	Odd	0.5	Serum	15-mL Red	2-mL
21	Lipids	Both	2.0	Serum	15-mL Red	2-mL
23	Insul/Cpep	Even	1.0	Serum	15-mL Red	2-mL
24	HSV	Odd	0.5	Serum	15-mL Red	2-mL
25	FSH/LH	Odd	0.8	Serum	15-mL Red	2-mL
27	Latex	Even	0.5	Serum	15-mL Red	2-mL

- Fill each vessel as described in the blood processing protocol.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID. Continue to use the labeled vessels in the prepared rack.
- Process the second set of venipuncture tubes and blood processing vessels using the second Sample ID. Continue to use the labeled vessels in the prepared rack.
- Use the same techniques for spinning and separating the blood as described in Chapter 8.
- Check the vessels before filling them making sure that each vessel has the correct SP ID or Sample ID.

Match the two processing racks to each other. Record the blood processing results.

The screenshot shows a LAB software interface with two processing racks. The top rack is for Sample ID 395348 and the bottom rack is for Sample ID 667964. Both racks show patient information and a table of vessels with test names, volumes, and filled status.

Top Rack (UR: 395348):

Tech ID: 1226 Sample ID: 395348 Name: HAINER, KEVIN Gender: M Age: 44
 SP ID: 395348 SubSample: 6 Fasting_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305443	2
47	NTX	1	U	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305448	1

Bottom Rack (UR: 667964):

Tech ID: 1226 Sample ID: 667964 Name: HAINER, KEVIN Gender: M Age: 44
 SP ID: 395348 SubSample: 6 Fasting_Req: 4

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305443	3
47	NTX	1	U	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305448	2

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Enter results for those vessels where both vessels are filled for the whole blood, plasma, and serum protocol. Enter the results of blood processing using the correct Sample ID and SP ID numbers and procedures described in Chapter 8, Section 8.8. Store the blood vessels in a manner identical to blood vessels processed during a regular session.

11.4.5 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 9.

11.5 Centrifuges – Equipment Maintenance

Technologists are responsible for inspecting the centrifuges at the beginning of each stand, and inspecting and cleaning the centrifuges at the end of each stand and whenever necessary. Clean the interior of the chamber with a mild soap, as time permits. Rinse thoroughly and dry completely.

1. Inspect the rotor yolk and buckets.
 - Inspect for rough spots or pitting, white powder deposits or heavy discoloration. If any of these signs are evident, do not use the rotor. Use the second centrifuge and notify the NCHS engineer. Check the condition of the O-ring in the tie-down nut; replace it if it is worn or damaged.
2. Clean the rotor.
 - Use mild detergent, diluted 10 to 1 with water and a soft brush to clean the rotor yolk and tie-down nut. Thoroughly rinse the cleaned rotor and components with water and air-dry upside down. When the rotor is dry, lubricate the bucket sockets and pins by saturating a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk. Before reinstalling the rotor, lightly lubricate the drive hole of the rotor with Anti-Seize to prevent the rotor from sticking, as follows:

Apply the lubricant onto a swab.

Draw the coated swab through a paper towel to remove excess lubricant.

Lightly coat the inside of the drive hole with the lubricant remaining on the swab.
3. Clean the buckets:
 - Remove the O-ring.
 - Clean the bucket and O-ring with a mild detergent diluted 10 to 1 with water, then rinse thoroughly, and dry completely.
 - Coat the O-ring with a light film of silicone vacuum grease. Place the O-ring on the ledge inside the bucket.
 - Once a week and after every cleaning, lubricate contact areas between the buckets and the pins on the rotor. Saturate a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk.
4. Inspect and clean Aerosolve canisters.

- Inspect the O-ring for nicks, abrasions, or other damage. Coat the O-ring with a light film of silicone vacuum grease before installing. Place the O-ring in the groove.
- Inspect the canister and lid threads and bottom of canister for heavy crazing or cracks.
- Inspect the tube racks for heavy scratches or cracks and inspect the rubber cushions for damage or for imbedded glass from broken tubes.
- Clean the canisters, lids, and racks with a mild detergent, diluted 10 to 1 with water, and a soft brush. Thoroughly rinse the cleaned components with water and air-dry upside down. Coat the O-ring with a light film of silicone vacuum grease before reinstalling it into the groove.

The NCHS biomedical engineer certifies both centrifuges at the beginning of each stand. The NCHS engineer determines the rpm of the instruments using a strobe light or a tachometer. The engineer records all three readings for each centrifuge. The Beckman GS-6R centrifuge should exceed 3,750 rpm to ensure adequate centrifugal force development. The engineer checks each centrifuge timer against a stopwatch and records the values on paper. Technologists enter the results in the Laboratory QC module – Start of Stand.

Document beginning and end of stand cleaning procedures in the Laboratory QC module.

11.6 Refrigerators and Freezers – Equipment Maintenance

Quality control procedures for the refrigerators and freezers include cleaning them at the beginning and end of the stand and whenever necessary, continuously monitoring their temperatures on a daily basis and recording the results in the Laboratory QC module. Additionally, monitor temperatures using the automated recording instrument procedure that follows. Before putting a new chart on the recording device, date the chart and record the assigned instrument number.

- Change the tempscribe chart weekly.
- Save and send the used charts to the home office at the end of each stand.

- Document these activities in the Laboratory QC module.
- Change recording pens when necessary.
- Document any necessary unscheduled maintenance in the Unusual Occurrence Log.

Cleaning

Wear rubber gloves when cleaning. Use warm soapy water and avoid the use of abrasive cleansers. After cleaning the unit, disinfect the interior and exterior by cleaning with a 1:100 solution of bleach and water.

11.7 Use of the Temperature Recording Instrument

The Jewett Instrument is a microprocessor based, AC powered operated, temperature recording device which automatically monitors the interior temperature of the refrigerator and freezers. The device continuously graphs this record on a circular paper chart so that a week's worth of temperature data can be inspected easily. When this recorder functions under normal conditions and receives proper care it renders lasting accurate service.

The NHANES engineer is responsible for mounting, installing, and calibrating the recorder as specified in the manufacturer's Operating Manual. Monitor the results of the recorder at the beginning of each day, replace charts on a weekly basis, and replace batteries and pens, as needed.

To monitor the results of the recorder, look at the chart for each refrigerator and freezer at the beginning of each day, read the temperature indicated on the chart, and record it in the Laboratory QC module. Record the highest temperature shown on the chart since the last reading.

The allowable temperature range for the refrigerators is 2°C-8°C, (36°F to 46°F) and the allowable temperature range for the freezers is -18°C-23°C (0 to -10-°F). Note that if the temperature for a refrigerator or freezer exceeds the allowable temperature range, document this in the Unusual Occurrence Log, and inform the MEC manager immediately. Transfer contents of the refrigerator or freezer to a temperature controlled environment.

Maintenance of the Jewett Temperature Recorder involves chart installation on a weekly basis, replacement of the cartridge pen, and replacement of the batteries as needed (approximately once a year).

1. To install the new chart:

- Press and hold the Change Chart push button switch for 1 second until the pen begins to move to the left of the chart.
- To remove the chart, unscrew the knob at the center of the chart.
- Position the new chart so that the correct time line coincides with the timeline groove on the chart plate, then replace the knob and screw tightly against the chart.
- Again, push the Change Chart push button switch for 1 second until the pen begins to move back onto the chart.
- Check to make sure the pen is marking on the paper. If not, lightly adjust the pen arm to establish contact with the paper.

The Jewett temperature recorder uses a standard cartridge pen that requires no filling. It consists of a self-contained ink reservoir with a porous plastic stylus that snaps around the outer edge of the pen. Use the two- (2) screws at the top of the pen arm to adjust the length to ensure that the pen tracks the timeline on the chart. Check the length after each pen replacement and adjust accordingly if required. If the stylus does not touch the chart, make adjustments by slightly bending the pen arm in the center. Do not use more pressure than is necessary to create a fine line. NOTE: As the ink supply runs out, the ink color becomes lighter. Replace the pen when this occurs.

If AC power fails, the LED changes to a flashing green to alert the user of the power failure. The 9-Volt battery allows the recorder to sense and record temperatures for a minimum of 12 hours.

Occasionally, a recorder may malfunction. Contact technical service at 800-879-7767. The manufacturer offers the following troubleshooting guide:

LED status	Chart rotation	Pen location	Battery status	AC power status	Cause	Repair
Green	OK	OK	OK	OK	Normal	None required
Flashing Green	OK	OK	Low	Off	AC failure or Low Battery	Check power source and transformer – Replace battery if necessary.
Green	OK	Inner hub	OK	OK	Probe Failure	Check Connection on board – Replace probe

11.8 Use of the Class II Type A Biological Safety Cabinet

The Class II Laminar Flow Biological Safety Cabinet (LFBSC), with proper technique, provides an effective partial containment system for safe manipulation of moderate and high-risk microorganisms. The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and the technologist. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

Installation, Certification, and Maintenance

The NCHS biomedical engineer will arrange for a certified engineer to perform the required annual certification that includes replacement of HEPA filters as necessary.

The basic concept of the LFBSC is to take air through a blower system, pressurize a plenum, and force air through a filter. Built-in supply and exhaust blowers come with separate HEPA filters. The recirculating airflow pattern directs a portion of the HEPA filtered air straight down over the central work area driving the airborne contaminants into the surrounding grills, allowing a pollution free environment for particular specifications. If a filter is defective, the filtration system no longer filters and becomes a vacuum cleaner, taking in gross contamination and exploding it through the defective filter onto and around the critical work area. The filter of the LFBSC is a permanent part of the disposable plenum. A manometric gauge is calibrated in "inches of water gauge" pressure (w.g.). The gauge indicates when the supply HEPA filter is clogged. As the filter loads with particulate matter, the amount of pressure registered on the gauge will increase. The initial pressure reading is approximately 0.4 w.g. \pm 0.05 w.g. depending on the altitude from sea level. Check and record the reading on the gauge every day. **If the gauge registers an increase in pressure of more than 0.1 w.g., notify the NCHS engineer.** The NCHS engineer will arrange to have the airflow pressure and the HEPA filter system checked. If the HEPA filter is no longer effective, the engineer or MEC manager will discard the entire filter and plenum and substitute a new replacement unit.

Clean the LFBSC at the beginning and end of each stand. Lift the front glass and wash both the interior and exterior glass. Remove all contents from the interior of the cabinet. Remove and wash the front grill. Lift the cover to the table and wash the base underneath. Put table cover and grill back into cabinet. Lock front glass into place. Document these activities in the Laboratory QC module. Take and

record the pressure reading in the Laboratory QC module at the beginning of stand and at the start of each session.

Document all unscheduled maintenance for the LFBSC in the Unusual Occurrence Log.

11.9 Ambient Air Temperature

Two thermometers monitor ambient temperature in the laboratory. Quality control procedures for ambient air temperatures involve checking these thermometers for damage, monitoring the temperature each session, and documenting any unusual occurrences. Check the two wall thermometers for damage at the beginning of each stand. Notify the MEC manager of any damage.

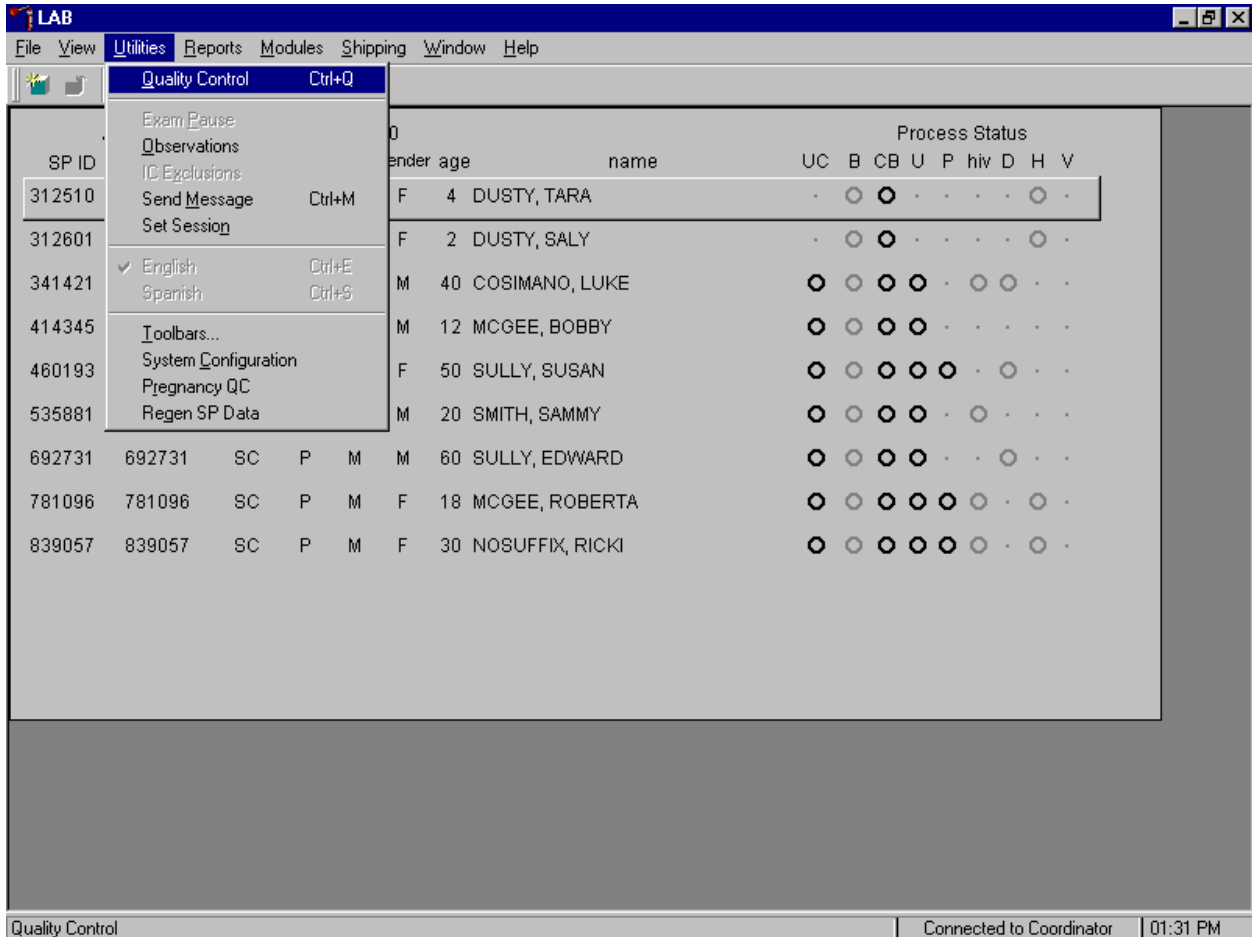
The allowable ambient temperature range for the laboratory is 17°C-25°C (63°F to 77°F).

NOTE: If the room temperature is out of allowable range since the last reading, document this in the Unusual Occurrence Log and inform the MEC manager immediately.

11.10 Laboratory Quality Control Module

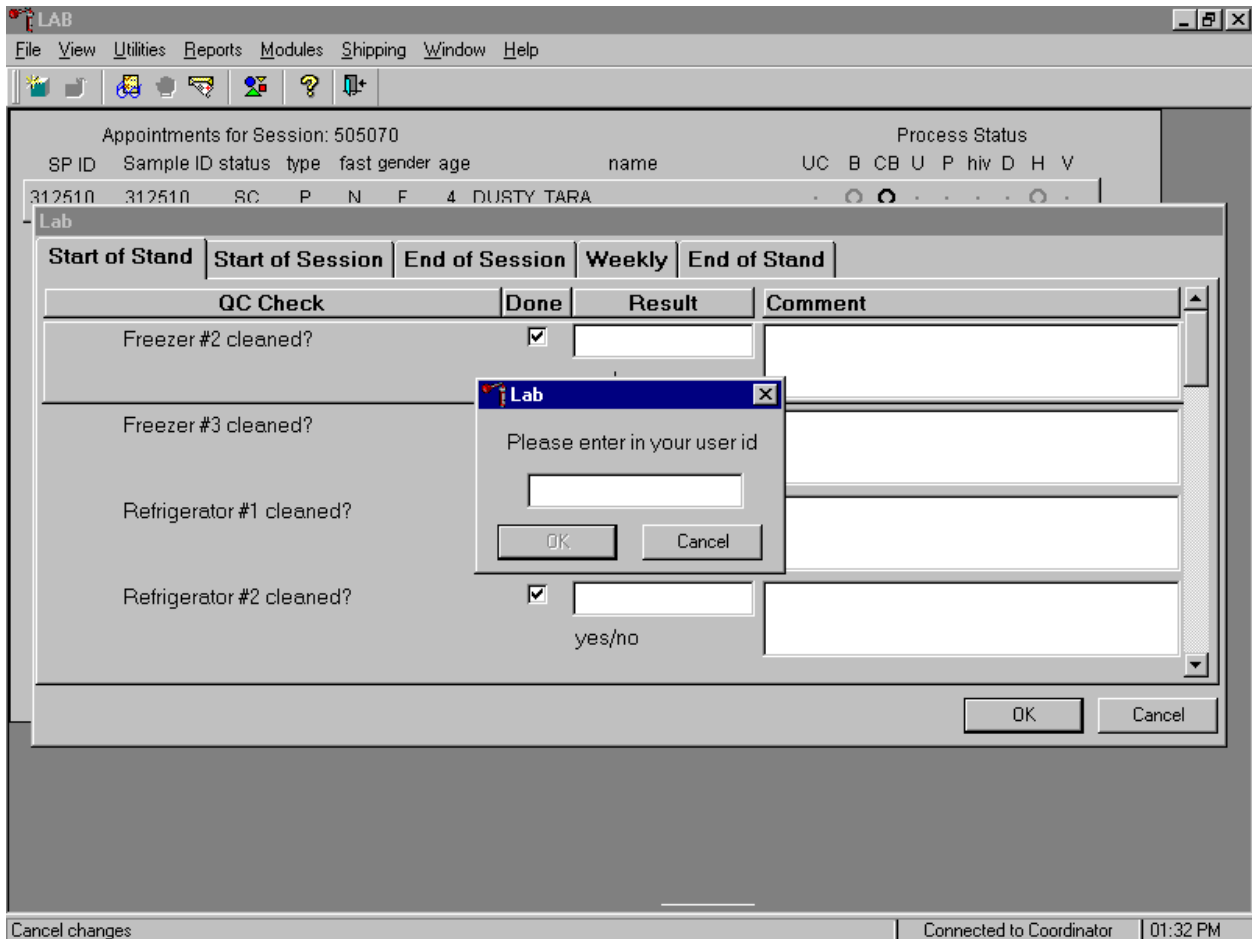
Document all instrument quality control activities in the Laboratory QC module.

Access the Laboratory QC module.



To access the QC module, use the mouse to direct the mouse arrow to {Utilities}, drag the arrow to {Quality Control} and left click or type [Alt] [U], [Q] or [Ctrl] [Q].

Enter the required user ID.



Enter user ID as last name_first initial and [Enter] or type in the user ID and use the mouse to direct the mouse arrow to the **OK** button and left click. To exit without entering a user ID use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Enter quality control activities and readings.

Appointments for Session: 505070

Process Status

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
312510	312510	SC	P	N	F	4	DUSTY TARA									

Lab

QC Check	Done	Result	Comment
Freezer #2 cleaned?	<input type="checkbox"/>	<input type="text"/> yes/no	<input type="text"/>
Freezer #3 cleaned?	<input type="checkbox"/>	<input type="text"/> yes/no	<input type="text"/>
Refrigerator #1 cleaned?	<input type="checkbox"/>	<input type="text"/> yes/no	<input type="text"/>
Refrigerator #2 cleaned?	<input type="checkbox"/>	<input type="text"/> yes/no	<input type="text"/>

OK Cancel

Apply changes and close window | Connected to Coordinator | 01:37 PM

Select the correct activity (Start of Stand, Start of Session, End of Session, Weekly, or End of Stand) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. At each stand, perform and record weekly activities on the same weekday as set up.

Mark activities as done and enter the result.

LAB

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505070 Process Status

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
312510	312510	SC	P	N	F	4	DUSTY TARA									

Lab

Start of Stand Start of Session End of Session Weekly End of Stand

QC Check	Done	Result	Comment
Freezer #1 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-20 degrees C	
Freezer #2 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-21 degrees C	
Freezer #3 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-20 degrees C	
Refrigerator #1 temperature reading (2 to 8 °C)	<input checked="" type="checkbox"/>	-4 degrees C	

OK Cancel

Apply changes and close window Connected to Coordinator 01:38 PM

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box.

Enter the response or reading in the Result text box.

LAB

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505070 Process Status

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
312510	312510	SC	P	N	F	4	DUSTY TARA									

Lab

Start of Stand Start of Session End of Session Weekly End of Stand

QC Check	Done	Result	Comment
Freezer #1 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-20 degrees C	
Freezer #2 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-21 degrees C	
Freezer #3 temperature reading (-18 to -23 °C)	<input checked="" type="checkbox"/>	-30 degrees C	Notified MEC manager
Refrigerator #1 temperature reading (2 to 8 °C)	<input checked="" type="checkbox"/>	-4 degrees C	

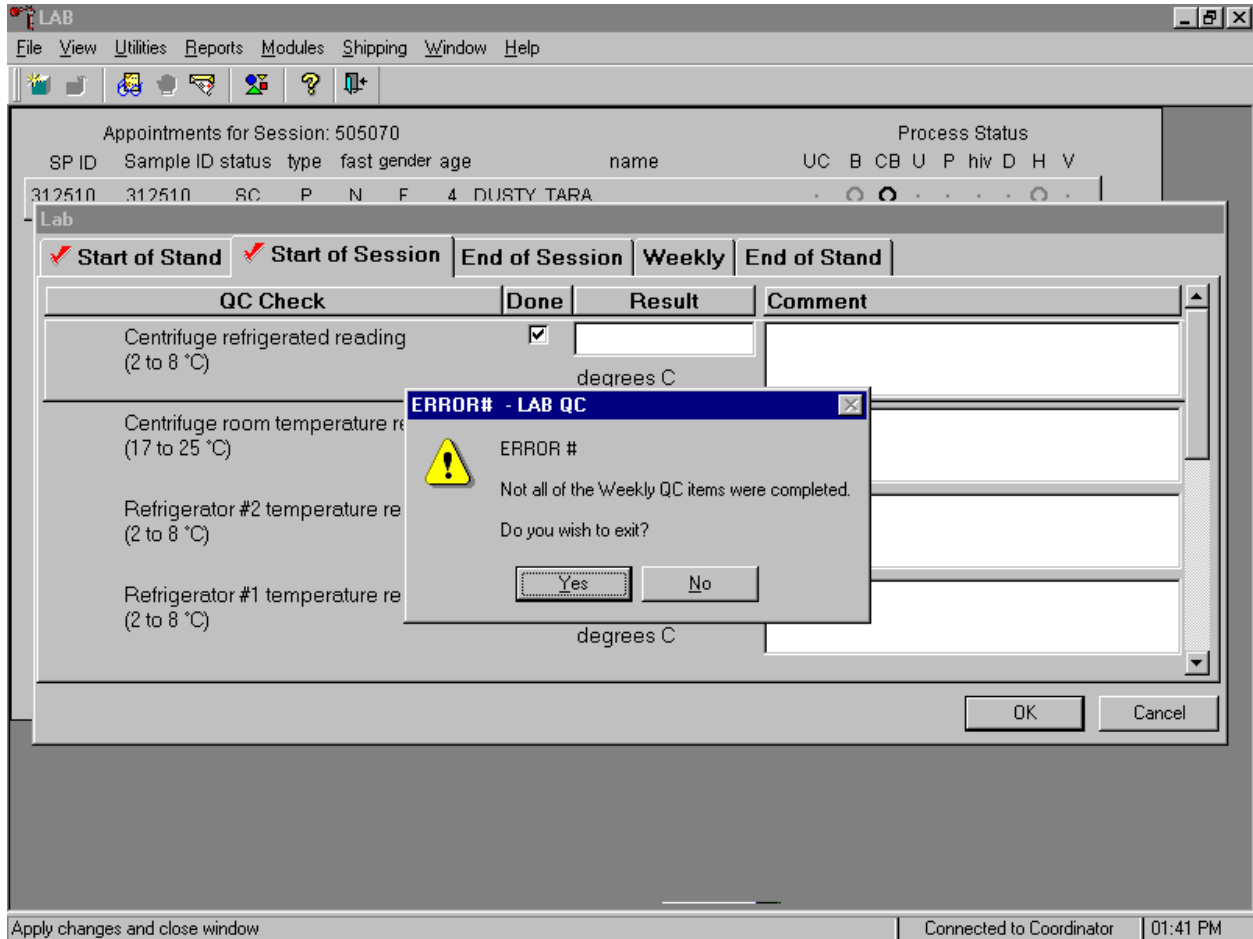
OK Cancel

Apply changes and close window Connected to Coordinator 01:40 PM

Enter "Yes" or "No," for text responses, whole numbers for rpm measurements, minutes and seconds for timer readings, three decimals for w.g., and whole negative and positive numbers for thermometer readings in the Result text box. Select [Tab] or [Enter] to move to the Comment text box. Type any actions associated with an unexpected result in the Comment text box. Select [Tab] to move to the next line.

To save the results to the database, use the mouse to direct the mouse arrow to the **OK** button and left click, or to exit the QC module without saving the results, use the mouse to direct the mouse arrow to the **Cancel** button and left click. Once results are saved to the database, they cannot be changed.

A warning message text box displays if required QC is incomplete.

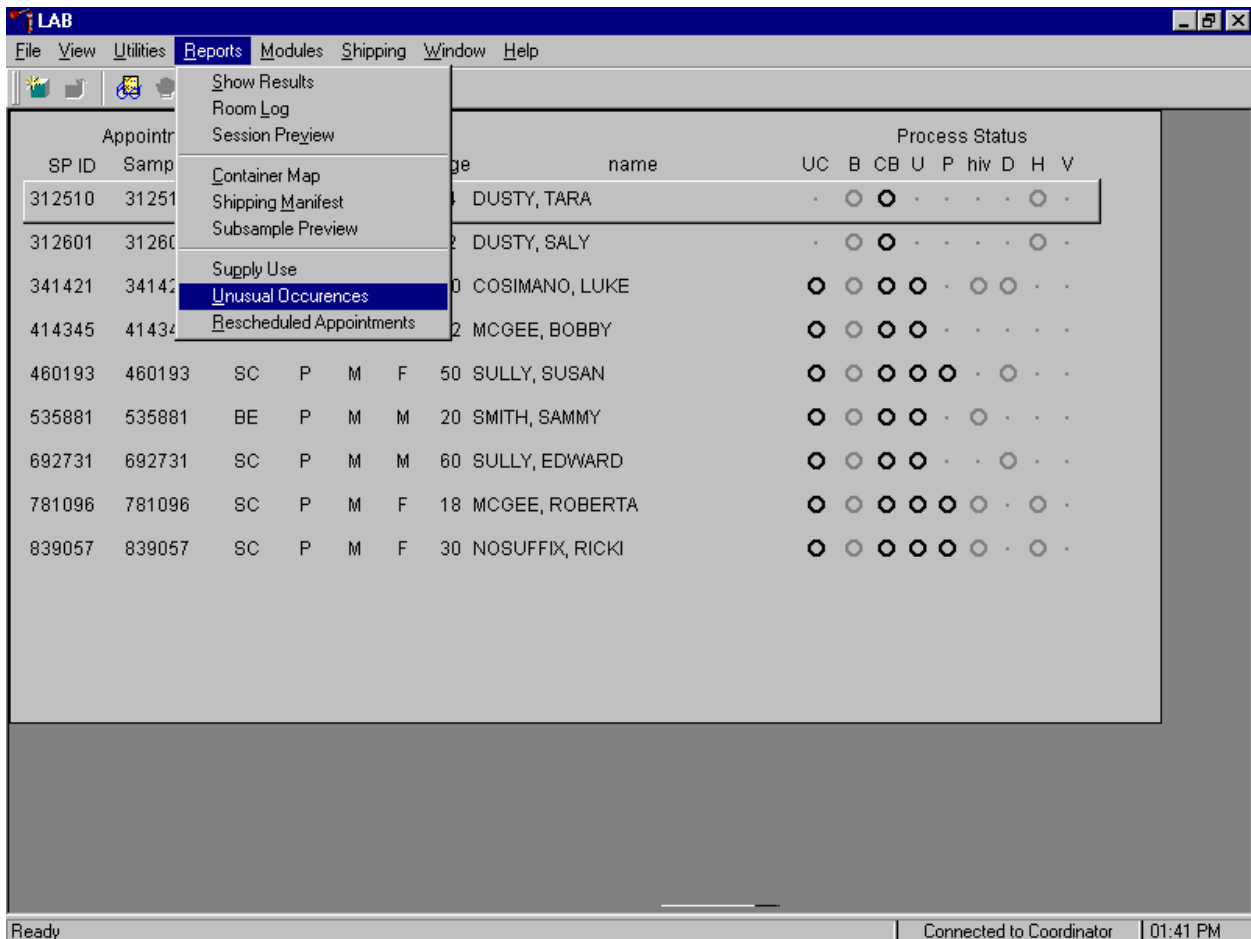


When attempting to access laboratory modules a warning message text box displays if required QC activities have not been performed or if some activities are incomplete. Respond to the message text box. To exit the QC module, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Y] or select [Enter]. To remain in the QC module, use the mouse to direct the mouse arrow to the **No** button and left click or type [N]. Continue to perform the required QC activities and record the results.

11.11 Unusual Occurrence Log

Document any instrument malfunction using the Unusual Occurrence Log (see Exhibit 11-6). Record the date, Tech ID number, an explanation of the incident, and the steps to resolve the incident. Be sure to record the model and the serial number of the instrument.

Access the Unusual Occurrence Log.



To access the Unusual Occurrence Log, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, drag the arrow to {Unusual Occurrence Log} and left click or type [Alt] [R], [U].

Enter information into the appropriate line(s):

- Stand Number;
- Beginning Stand Date;
- Technologist Name and ID;
- Date;
- Time;
- Comments or Issue;
- Action Taken; and
- Resolution.

Do not enter any text in the Reviewed by or Date reviewed lines.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

Exhibit 11-6. Unusual Occurrence Log

**NHANES
Unusual Occurrence Log**

Stand Number _____

Beginning Stand Date _____

Technologist Name and ID

Date

Time

Comments or Issue

Action Taken

Resolution

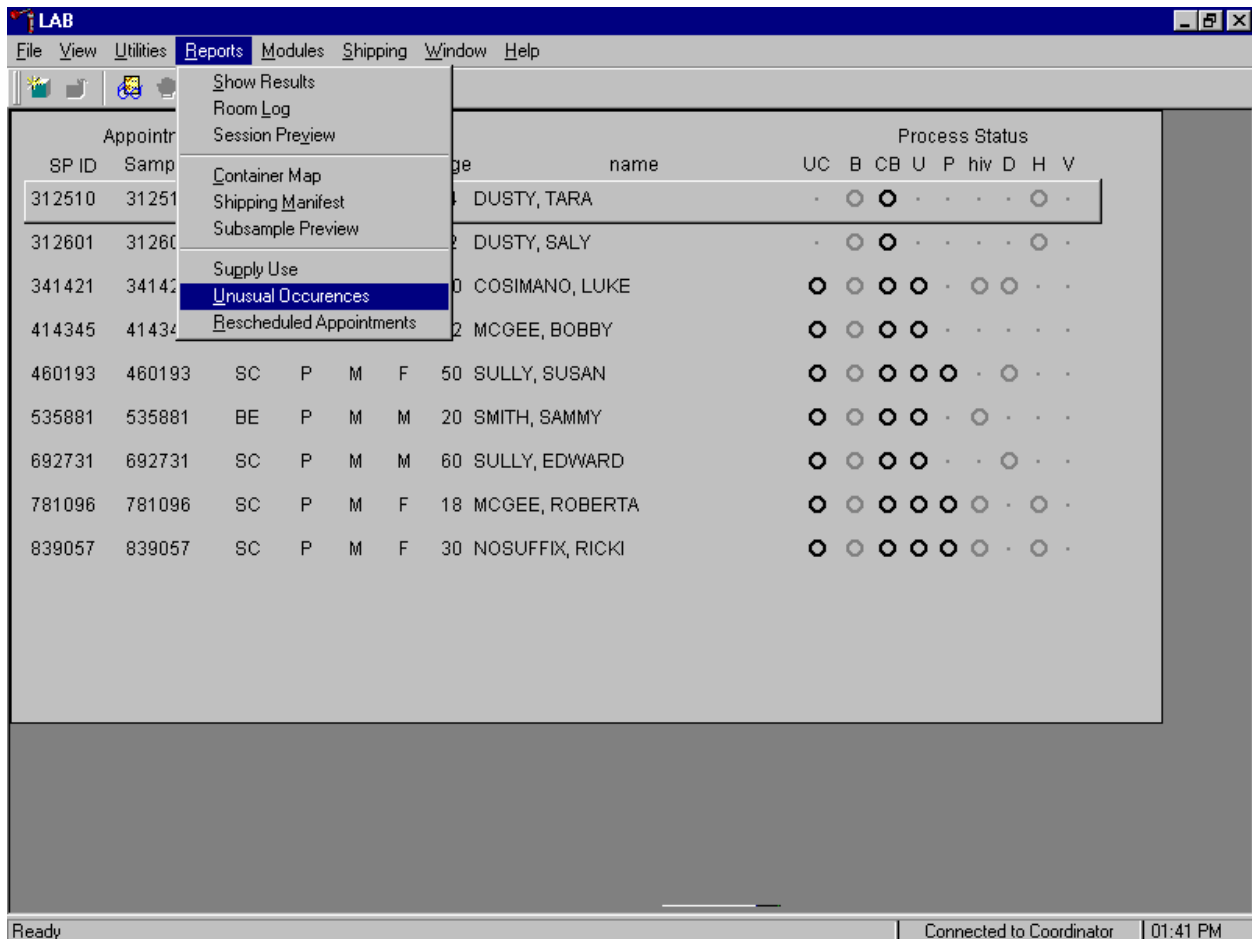
Reviewed by _____

Date reviewed _____

11.12 Supply Use Control Log

Document the lot number and expiration dates for all Vacutainer® tubes, needles, and reagents in the Supply Use Control Log. The pregnancy test kit and the serum and urine pregnancy control lot numbers and expiration dates are captured in the Pregnancy QC module.

Access the Supply Use Control Log.



To access the Supply Use Control Log (see Exhibit 11.7), use the mouse to direct the mouse arrow to {Reports} in the top menu bar, drag the arrow to {Supply Use Control Log} and left click or type [Alt] [R], [S].

Enter information into the appropriate column(s):

- Reagent or Supply Name;
- Beginning Stand Date;
- Lot Number;
- Date in Use;
- Expiration Date; and
- Technologist ID.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

11.13 **MLA Pipette Calibration and Maintenance**

MLA pipette calibration is required at least twice a year, in January and June of every year.

- Calibratable pipettes are supplied with a key for calibration purposes. The pipette is factory calibrated to deliver the stated volume engraved on the pipette bonnet. To change the pipette delivery proceed as follows:
 - Determine the pipette delivered volume by testing the pipette. Use the gravimetric method.
 - Insert the key into the push button end of the pipette.
 - If a volume increase is required, turn the key clockwise. If a volume decrease is required, turn the key counterclockwise. Hold the plunger button while turning the key.
 - Test the pipette again to determine the delivered volume.

Disinfect the pipettes and pack carefully and securely. Replace these pipettes with recalibrated pipettes. Send the pipettes to the warehouse manager. The warehouse manager sends the pipettes to MLA where they are calibrated. The warehouse manager sends the pipettes back to the field and sends the calibration certification certificates to the technical supervisor. Store the recalibrated pipettes.

Pipette Maintenance

During factory assembly, the internal parts of the pipette (plunger, seals, etc.) are lubricated with silicone grease. Normally, cleaning and relubrication should be necessary only at 6-month intervals or if roughness is observed in the plunger movement. If liquid is allowed to enter the pipette nozzle inadvertently during pipetting, cleaning and relubrication should be done immediately. Cleaning should be done with a lint-free cloth dampened with non-aqueous alcohol. Bores should be cleaned with a jet of air.

Appendix A
Protocol for Volatile Organic
Compounds (VOC) Study

APPENDIX A PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS (VOC) STUDY

A.1 Overview

The purpose of the VOC study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs). Approximately 1,000 primary SPs aged 20-59 years are randomly selected to participate in this study. This selection occurs when the SP ID is generated at the time the MEC appointment is made. In addition, all second exam SPs aged 20-59 are included as a convenient sample. The VOC study is conducted during the first 3 years of NHANES.

The phlebotomist recruits the primary SP for the VOC study during their first MEC exam after performing routine venipuncture and administering the tuberculin antigens. If the recruitment is successful, the phlebotomist gives the primary SP a personal exposure monitor (air-monitoring badge), and directions for wearing the exposure badge, records the SPs ID number, badge lot number and expiration date, gives instructions and a water sample vessel to the SP, and schedules a return visit for 46-76 hours later.

If there are MEC appointments available 46-76 hours after the initial recruitment, the primary SP is given a MEC return visit appointment. The SP returns to the MEC where the phlebotomist collects two additional tubes of blood, and the MEC interviewers collect the badge and water and administer the questionnaire. When the second exam SP returns to the MEC they have two additional tubes of blood drawn and the MEC interviewers administer a questionnaire. Payment of \$30 is made at the completion of the second MEC visit for primary SPs.

If there are no MEC appointments available 46-76 hours after the initial recruitment, the primary SP is given a field office (FO) appointment. The primary SP returns to the field office where the TB readers collect the badge and water, administer the questionnaire, and label and store the specimens. Primary SPs who return their badge to the field office receive a \$15 payment. The home examiner coordinates transport of the VOC field office specimens from the field office to the MEC.

The coordinator application identifies primary SPs who are returning to the MEC 46-76 hours later for the VOC return visit and assigns this SP to both the phlebotomy room and the MEC interview room. The two aspects of this component can be done in any order—there are no priorities for the blood or

questionnaire. In phlebotomy, the phlebotomist logs the primary SP into the application, and performs venipuncture to collect the two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer collects the exposure monitor and water sample, and administers a short questionnaire. Labels for the badge and water samples print on the Intermec printer in the phlebotomy room. The coordinator application also identifies second exam SPs who are returning to the MEC and assigns the second exam SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the second exam SP into the application, and performs venipuncture to collect the second exam venipuncture protocol tubes, which include the two 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer administers a short questionnaire.

The laboratory processes, stores, and ships the primary SP's VOC blood tubes, badge, and water specimens, and the second exam SP's blood tubes. The blood samples must be refrigerated within 15 minutes after completion of the venipuncture. Blood, water, and exposure monitors (in their original canister) are shipped once a week via next day courier in insulated containers with enough ice packs to maintain their refrigerated temperature.

There are only two situations that exclude the primary SP from participating in the VOC study. Exclude a primary SP if they are not going to be staying in their primary residence during the following 46-76 hours and/or exclude them if their selection occurs during the last 2 days of the stand. The second exam SP is not selected for a second exam if they were eligible for VOC as a primary SP.

There are four types of QC, one of each is performed weekly. The four types of QC are: repeat participant, field monitoring, positive control, and office air monitoring.

A.2 Supplies

The VOC equipment and supplies are listed in Exhibit A-1.

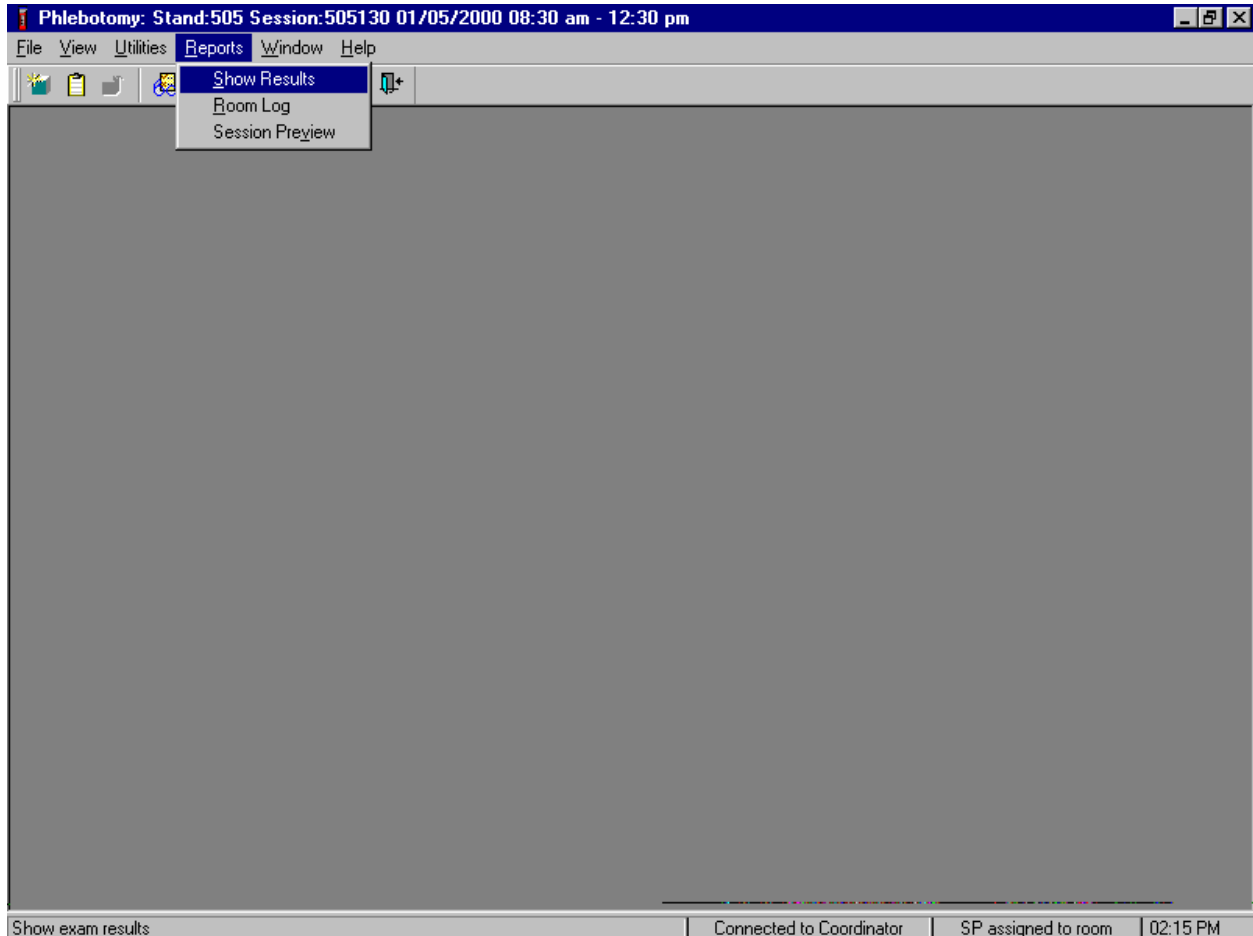
Exhibit A-1. Equipment and supplies - VOC

7-mL gray top blood tubes	Directions for wearing the badge – English
Exposure monitoring badge	Directions for wearing the badge – Spanish
10-mL water collection vessel	Water collection instructions – English
50-mL conical tube	Water collection instructions – Spanish
Small plastic zip sealing bags	Primary SP VOC questionnaire – English
5 place Styrofoam mailer	Primary SP VOC questionnaire – Spanish
3 place Styrofoam mailer	Second exam SP VOC questionnaire – English
Hard-sided cooler	Second exam SP VOC questionnaire – Spanish
12 x 12 plastic bags	Refrigerant gel-packs

At the start of each stand, prepare 50 water collection kits. Enter the current field office telephone number in the blank space on the water collection instructions. Place one 10-mL glass water collection vessel into a 50-mL conical tube. Place the 50-mL conical tube into a zip closable bag and add one hard copy of the instructions for wearing the badge in English or Spanish. Store the collection kits in the phlebotomy cabinet.

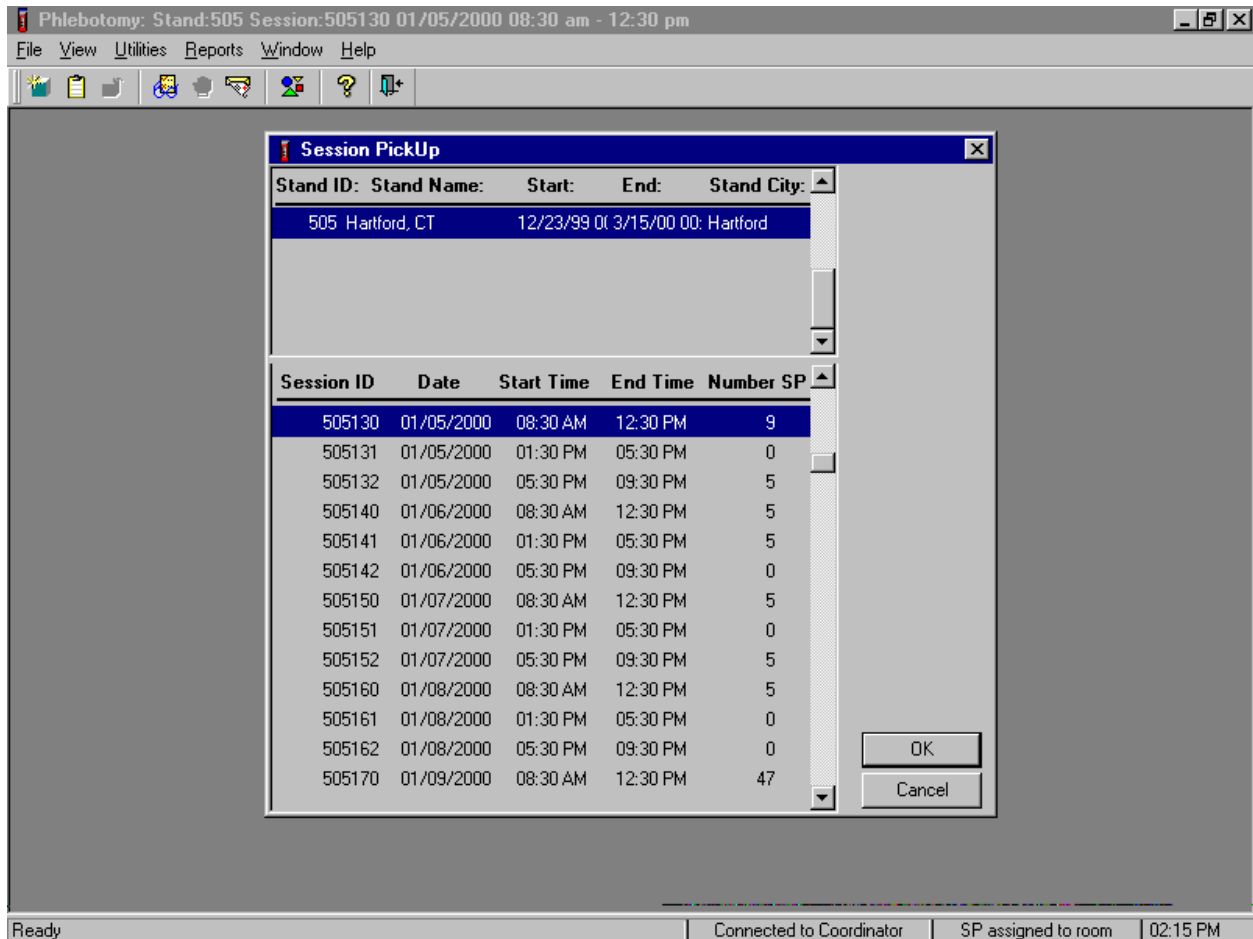
A.3 Session Preview

Access the Session Preview report to view all SPs scheduled into any session including the current session.



To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Session Preview} and left click, or type [Alt] [R], [V].

Select the session.



The Session Pickup list displays and defaults to the current session. To select a different MEC session, use the mouse to drag the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The Session Preview Report displays.

Phlebotomy: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy Subsystem Stand:505 Session:505130

Session Preview Report

01/28/00 14:47

Stand: 505

Session: 505130 01/05/2000 08:30 AM - 12:30 PM

SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
213096	Primary	DRAKE EPCOT	89 years	Male		
306541	Primary	GERTA HOFF	59 years	Female		
735768	Primary	FIG RESPOT	14 years	Female		
878700	Primary	EDNA EPCOT	80 years	Female		
905688	Primary	ROLAND REPOT	78 years	Male		
184340	2nd Exam	*ED FELLOWS	29 years	Male		

Page 1 of 3

Ready | Connected to Coordinator | SP assigned to room | 02:15 PM

The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any special considerations or consent comments. A blue asterisk in front of a name indicates that the SP is eligible for the VOC component. To close the window, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

A.4 Recruiting Primary SPs

The MEC phlebotomist is responsible for recruiting a primary SP for the VOC study, recording the recruitment response, SP ID, badge and water lot and expiration dates. The phlebotomist prints labels for the badge canister, labels and stores the canister, and reviews both the badge and water instructions with the primary SP. It is the MEC interviewer's responsibility to attach the badge to the primary SP as they are leaving the MEC. Always use an exposure badge with a shorter expiration date first.

Following the venipuncture and TB windows, the VOC Introduction window displays for VOC eligible primary SPs.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window has a title bar "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm" and a header area displaying "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM". The main content area is titled "VOC Introduction" and contains the following text and form elements:

Will you participate in this special study?

Airbadge Number:

Airbadge Lot No:

Expiration Date:

At the bottom of the window, there is a navigation bar with left and right arrow buttons, a page indicator "1 of 3", and buttons for "End of Section", "Close Exam", and "Finish". A blue arrow button is also present on the right side of the navigation bar.

The Windows taskbar at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:23 AM".

Personalize the recruitment approach to address each primary SP's specific style. Use language naturally to convey enthusiasm and excitement. Express a positive attitude and explain to the

primary SP that the VOC is the next part of their examination. Do not ask the recruitment question, rather state, “I see that you have been selected to participate in the VOC special study.” Explain the VOC study as an opportunity for the SP and move forward, making sure all questions are addressed. Allow the primary SP to refuse, if necessary.

Explain that the primary SP is eligible to receive a \$30.00 remuneration but they only receive this amount if they are eligible for a MEC return appointment. The remuneration is \$15.00 for primary SPs who are eligible for a field office appointment. (Second exam SPs are not recruited and are not eligible for any additional remuneration.)

Record the response to the recruitment question, “Will you participate in this special study?”

The screenshot shows the Phlebotomy software interface. At the top, the title bar reads "Phlebotomy". Below it is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons. The main window title is "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm". Below the title bar, patient information is displayed: "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM". The section is titled "VOC Introduction". The main content area contains the question "Will you participate in this special study?" followed by a dropdown menu. The dropdown menu is open, showing three options: "Yes", "No", and "No badge available". Below the question, there are labels for "Airbadge Number:", "Airbadge Lot No:", and "Expiration Date:". At the bottom of the main content area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:23 AM".

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” or [N/n] for “No badge available.” Alternatively to record the response, use the mouse to direct the mouse arrow to the drop down arrow on the drop-down list, left click to display the responses, drag the arrow to “Yes,” “No,” or “No badge available” and left click.

If the recruitment response is “Yes,” the following three text boxes are activated.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM

VOC Introduction

Will you participate in this special study? Yes

Airbadge Number: 946144

Airbadge Lot No: 067815

Expiration Date: 10/31/2001

1 of 3

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:23 AM

Locate the badge lot number and expiration date on the bottom of the canister. Always use an exposure badge with a shorter expiration date first. Record the primary SP’s SP ID as the airbadge number and record the badge lot number and expiration date. Type the primary SP’s SP ID number in the Airbadge Number: text box using the keyboard’s numeric keys and select [Tab]. Enter the Airbadge Lot No: and the Expiration Date: boxes using the keyboard. To progress to the appointment (next) window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click, or press [Enter] when the bright blue arrow is highlighted.

NCHS has established priorities for VOC specimen collection and established guidelines for rescheduling missed VOC appointments.

Scheduling VOC appointments in the MEC and FO

- When the primary SP checks out of the MEC, the database captures the start time. The primary SP is eligible to return to the MEC (or the FO if there are no MEC sessions available) 46-76 hours after the primary SP checks out of the MEC. Every attempt should be made in the MEC to schedule primary SPs into the first available MEC session. When there are no MEC sessions, schedule the primary SP into a FO session. When the primary SP refuses to commit to either appointment, leave the session date field blank and select one of the coded reasons.

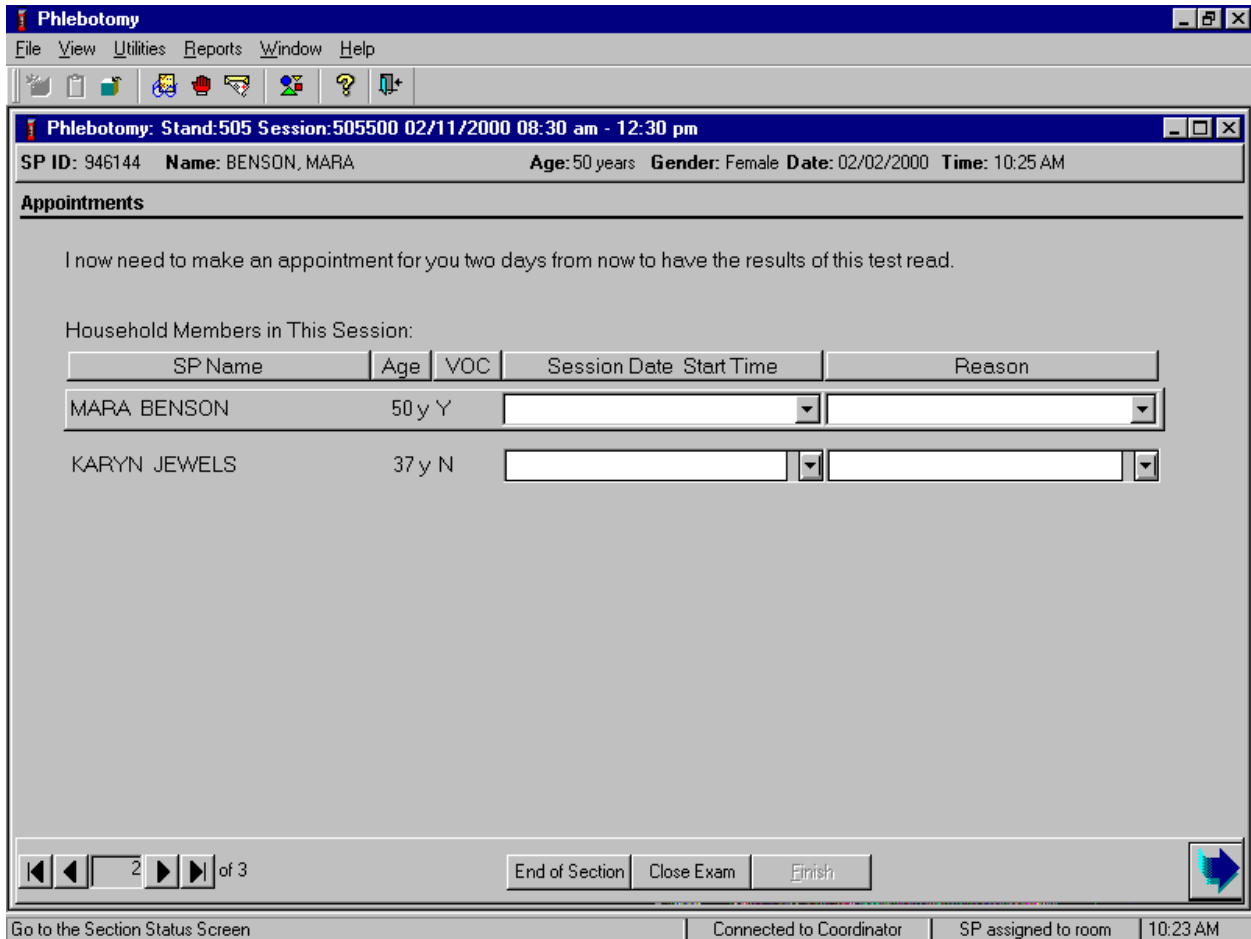
Priorities and collecting specimens in the MEC and FO

- When the primary SP returns to the MEC, attempt to collect the blood, badge, water, and administer the questionnaire. When the primary SP returns to the FO, attempt to collect the badge and water and administer the questionnaire.
- If the primary SP cannot or will not go to the MEC or the FO, and the 76 hour time frame has not expired, the TB readers will attempt to collect the VOC badge and water and administer the questionnaire during a home TB reading.

Rescheduling missed appointments and collecting specimens beyond the 76-hour window or collecting specimens with exposure times less than 46 hours.

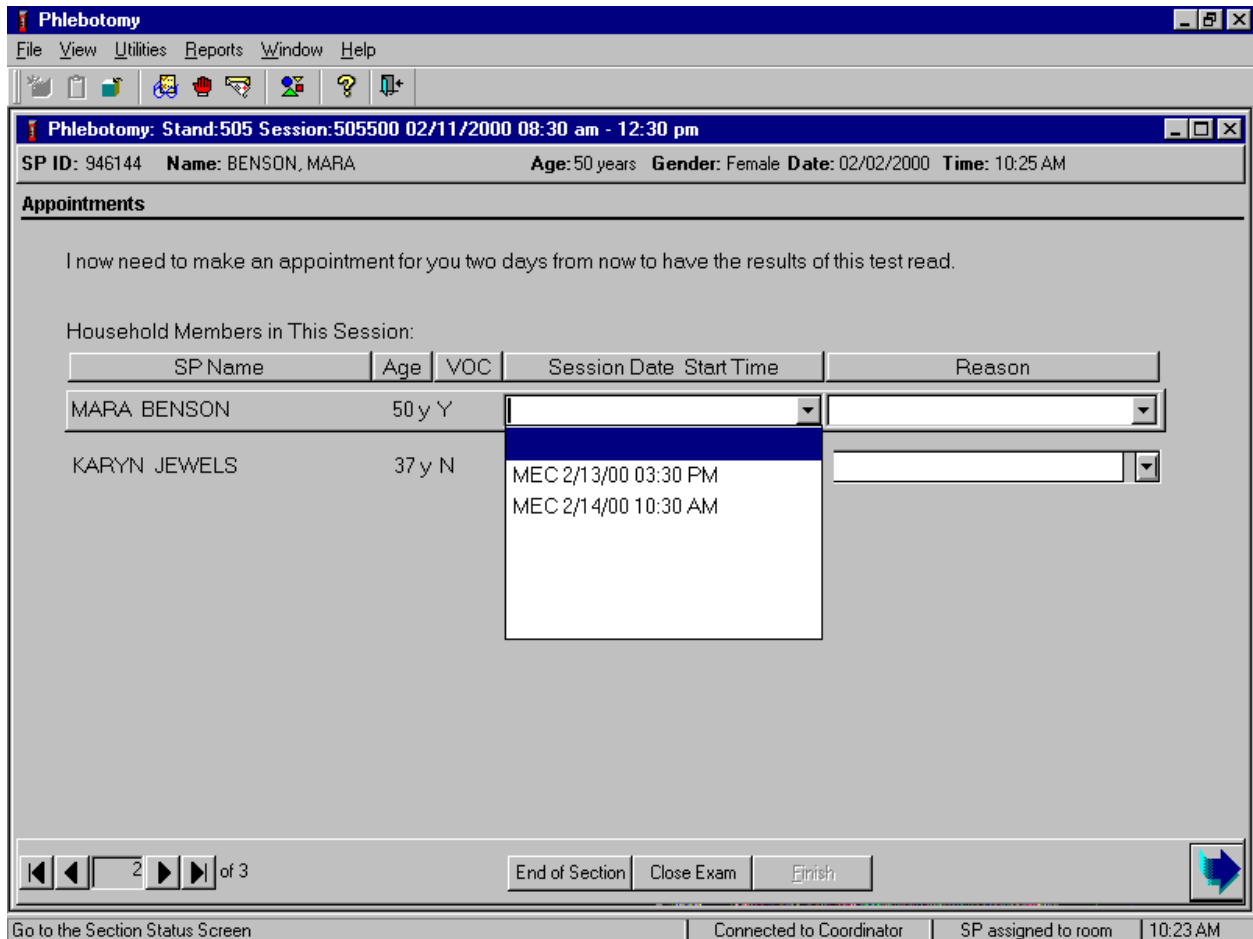
- NCHS has determined that, if a primary SP does not show up for the TB/VOC appointment and the 76-hour time frame has expired, the badge is no longer useful, and should not be collected. If the primary SP provides a badge and the 76-hour time frame has expired, dispose of the badge (outside the presence of the SP). Likewise, NCHS has determined that the time and effort involved with rescheduling no-show primary SPs to the FO (or the MEC) to collect the water and administer the questionnaire after the 76 hour time frame has expired will not produce useful data. Therefore, NCHS does not recommend rescheduling no-show return primary SPs to the MEC or the FO after the 76-hour time frame has expired.
- NCHS has determined that specimens (badge, blood and/or water) collected before the 46-hour exposure window will not produce useful data. Do not collect specimens when the exposure time is less than 46 hours. Do not administer the VOC questionnaire to primary SPs when the exposure time is less than 46 hours.

Schedule the return MEC or FO appointment for the recruited primary SP and any other family members who are present at the same session. Schedule the return appointment even if the TB antigens were refused and no TB appointment scheduled.



Paraphrase or read the script, “ I now need to make an appointment for you two days from now to have the results of this test read.”

Schedule the TB reading/VOC return visit appointment.



To view the available MEC sessions for the return appointment, use the mouse to direct the mouse arrow to the drop-down list and left click to display MEC sessions for which the primary SP is eligible to return to have the additional blood drawn and the water and badge collected. Primary SPs are eligible for return appointments 46-76 hours after they check out of the MEC. Only sessions that fall within this time frame are displayed. MEC appointment times are adjusted so that they begin 2 hours after the start of a MEC session. Returning primary VOC SPs should arrive at the MEC after a routine MEC session is underway. If there are no MEC sessions scheduled for this time frame, then field office sessions display. To select or highlight a specific MEC or field office session, use the mouse to drag the mouse arrow to the desired choice, and left click. The MEC date and time are inserted into the appointment text box.

Attach specific reasons to an appointment, when necessary.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM

Appointments

I now need to make an appointment for you two days from now to have the results of this test read.

Household Members in This Session:

SP Name	Age	VOC	Session Date	Start Time	Reason
MARA BENSON	50 y Y				
KARYN JEWELS	37 y N				

SP refused
SP requested home
SP requested MEC
SP requested FO

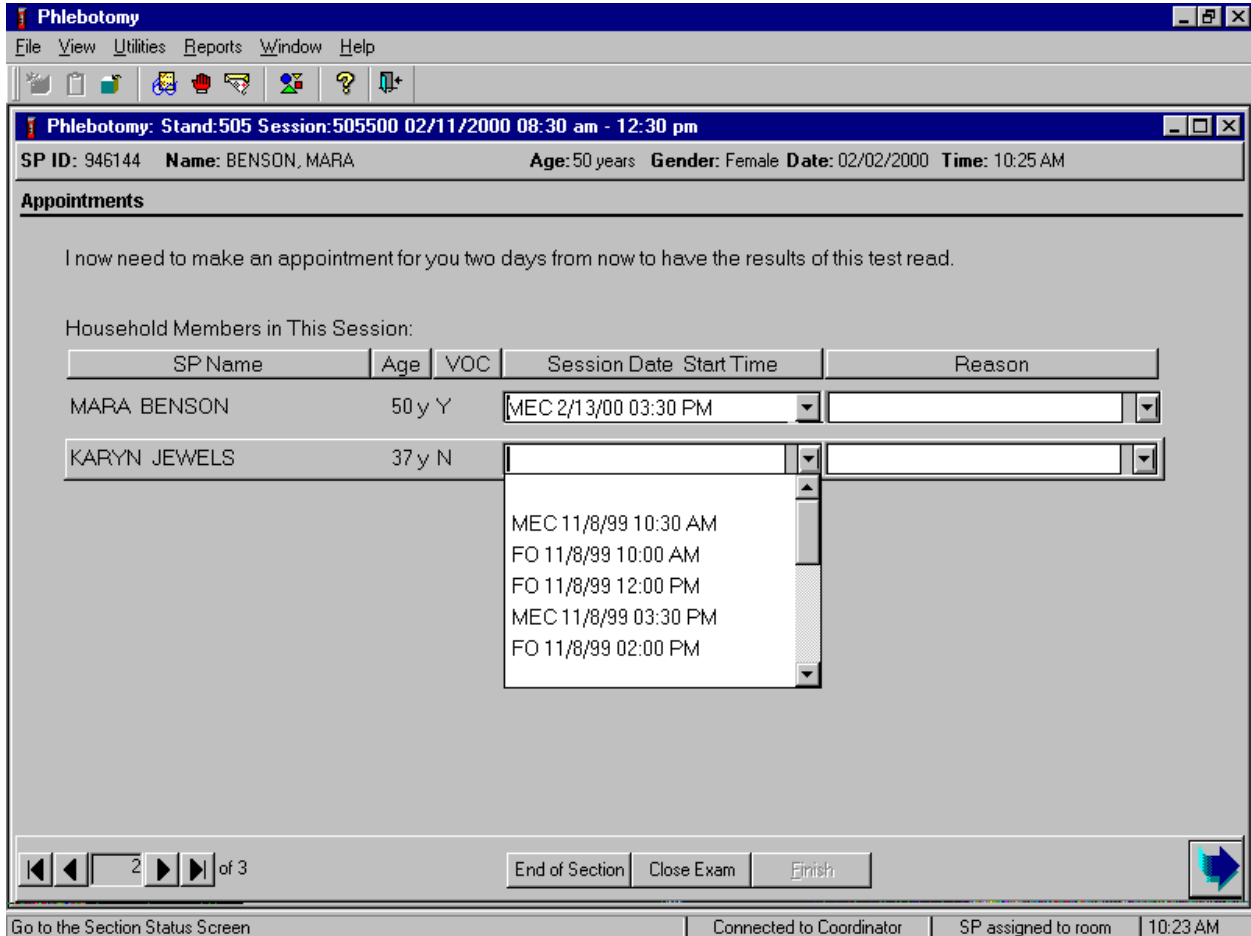
2 of 3

End of Section Close Exam Finish

Go to the Section Status Screen Connected to Coordinator SP assigned to room 10:23 AM

If all displayed MEC and/or FO session dates and times are unacceptable or the primary SP refuses to select a return appointment, indicate this by selecting the appropriate choice from the “Reason” list. Leave the Session Date and Time text box blank. If a primary SP refuses to make an appointment or makes a specific request for a home or field office appointment, add the appropriate reason to the record. To attach a reason to the record, use the mouse to direct the mouse arrow to the drop-down list, left click, drag the arrow to the correct choice, and left click. The TB readers contact the primary SP and attempt to schedule a collection visit.

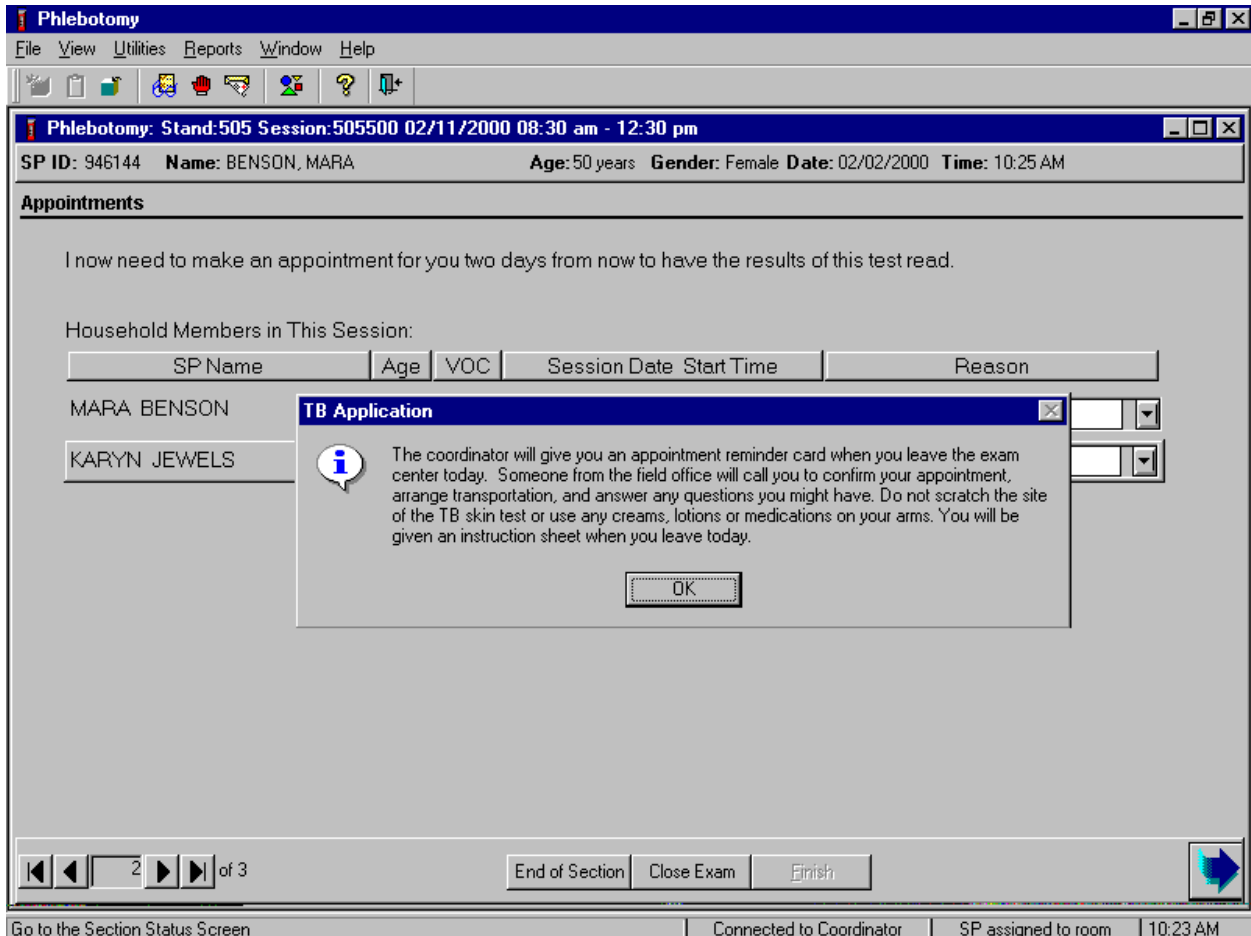
Schedule non-VOC eligible family members for return MEC or field office appointments to have their TB test read.



Family members of VOC recruited primary SPs are eligible to return to the MEC or to the field office to have the results of their TB test read. To view the available MEC and field office sessions for the TB reading appointment, use the mouse to direct the mouse arrow to drop-down list and left click to display MEC and field office sessions for which the primary SP's family member is eligible to return. Family members of primary SPs are eligible for return appointments 46-76 hours after administration of the TB antigens. Only sessions that fall within this time frame are displayed. To select or highlight a specific MEC or field office session, use the mouse to drag the mouse arrow to the desired choice, and left click. The MEC date and time are inserted into the appointment box. Attach specific reasons to an appointment, when necessary.

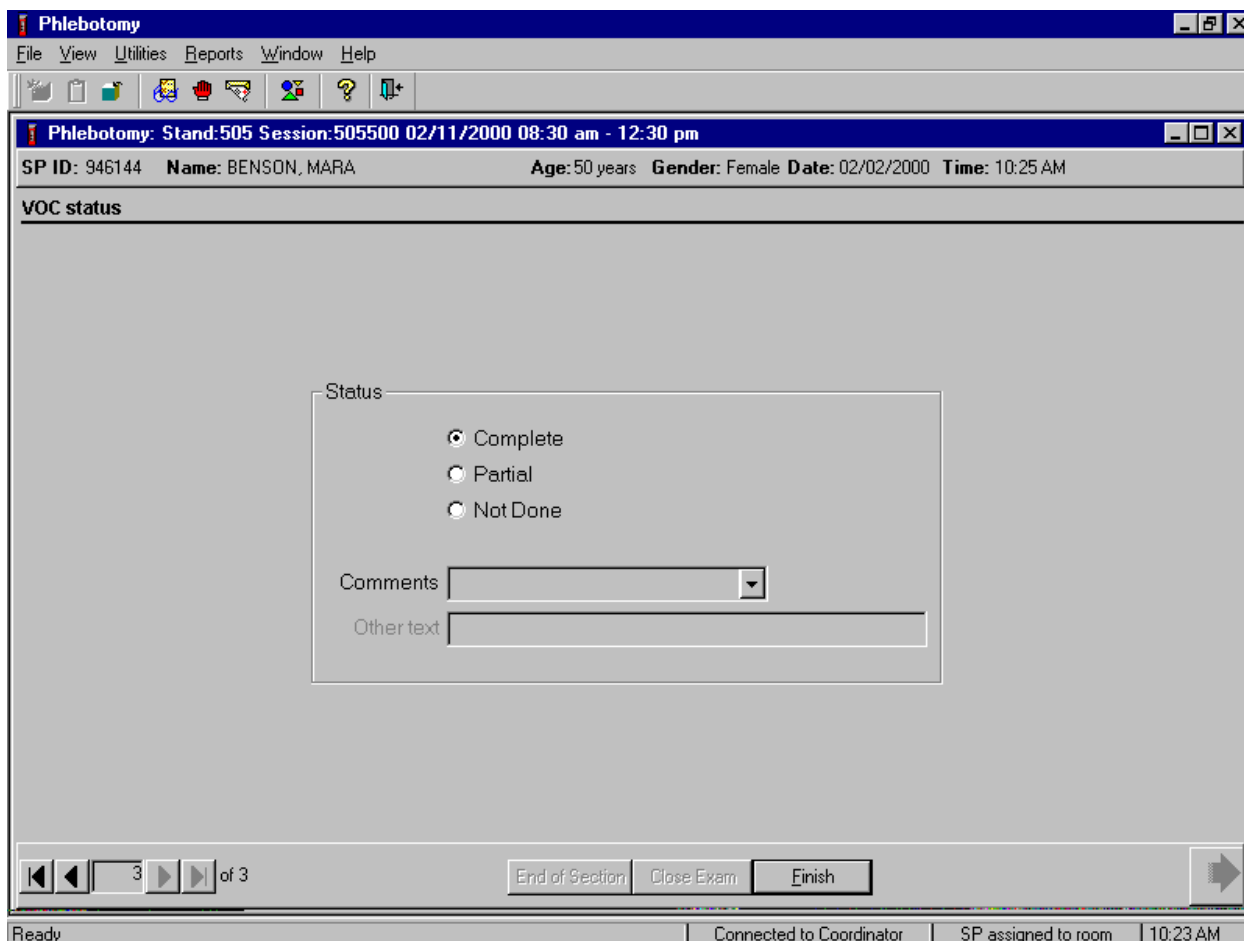
If an appointment has already been made by another family member, an informational message text box stating, “An appointment has already been made for you and the other members of your family. Would you like to review them?” displays. If the session date or time is unacceptable, reschedule them into an acceptable session.

Review the TB application information with the primary SP.



Paraphrase or read the informational TB application message text to the primary SP. Be prepared to answer any questions or to address specific concerns. To remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click. To progress to the next window, use the mouse to direct the mouse arrow to the bright blue right arrow in the navigation bar and left click.

Review the examination status of the VOC section of the phlebotomy examination.



The VOC status is complete if the primary SP was successfully recruited and not done if the primary SP was not recruited. To complete a successful VOC recruitment on a primary SP, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted.

Paper labels print in the phlebotomy room. Attach one bar coded SP ID VOC paper label to the outside of the canister.

Review the water collection instructions (Exhibit A-2), instructions for wearing the badge (Exhibit A-3), and the activity log (Exhibit A-4) with the primary SP. Use a demonstration badge to address any specific concerns that the primary SP may have.

Exhibit A-2. Water collection instructions – English and Spanish

Water Collection Instructions
(To be given to each SP with the glass tube.)

Instructions for collecting tap water sample:

1. Collect the water sample from the bathtub or an outside faucet ONLY.
2. Turn on the cold water.
3. Let the cold water run for 3 minutes.
4. Unscrew the red top cap.
5. Take the glass tube out of the plastic container.
6. Take the black cap off the glass tube. (If the white liner in the cap falls out, put it back into the cap. The shiny side should be facing up.)
7. Fill the tube with water until it overflows.
8. Screw the black cap tightly on the tube.
9. Turn the tube upside down to make sure it does not leak. (If the tube does leak, empty it and refill.)
10. Put the glass tube back into the plastic container with the black cap toward the top.
11. Screw the red top cap tightly onto the plastic container.
12. Bring the water sample with you when you return to the examination trailer.

Call the Field Office at _____ if you have questions.

Water Collection Instructions
(To be given to each SP with the glass tube.)

Instrucciones para recolectar la muestra de agua de la llave:

1. Tome la muestra de agua de la (bañadera/bañera/tina) o de una llave de afuera SOLAMENTE.
2. Abra la llave del agua fría.
3. Deje que el agua fría corra por 3 minutos.
4. Destornille la tapa roja.
5. Saque el tubo de vidrio del envase plástico.
6. Saque la tapa negra del tubo de vidrio. (Si la cubierta blanca de la tapa se sale, póngala nuevamente en el interior de la tapa. El lado brillante debe quedar a la vista.)
7. Llène el tubo con agua hasta que se derrame.
8. Atornille bien apretada la tapa negra al tubo.
9. Dé vuelta el tubo al revés para asegurarse que no se sale. (Si el tubo gotea, vacíelo y llénelo nuevamente.)
10. Ponga el tubo de vidrio nuevamente dentro del envase de plástico con la tapa negra hacia arriba.
11. Atornille la tapa con la superficie roja bien apretada sobre el envase de plástico.
12. Traiga la muestra de agua cuando vuelva al centro móvil de examen.

Llame al centro de operaciones en _____ si desea hacer alguna pregunta.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

DIRECTIONS FOR WEARING EXPOSURE BADGES

- We would like you to use the exposure badge continuously from the time you leave the Mobile Examination Center until you return to have your TB skin test checked.
- Wear the exposure badge as you would wear a nametag -- attached to your clothing in the area of your upper chest. Make sure the white membrane is facing outward and try not to touch the white membrane.
- Wear the exposure badge on your outermost layer of clothing. For example, if you start out wearing a shirt and have the badge attached to your shirt and then put on a jacket, remove the badge and place it so it is attached to the jacket.
- Place the exposure badge on a bedside table or clipped to a nearby lampshade while you are sleeping. Make sure the white membrane is exposed to the air.
- When taking a shower or a bath, leave the exposure badge in another room. The steam from the hot shower or bath may cause the badge to not work properly. A good place to leave the badge might be the same place you leave it while you are sleeping.
- When you return the badge, we will ask you some questions about the amount of time that you spent indoors both at home and at work or school and we will ask you about the amount of time you spent outdoors. Please use the Activity Log on the reverse side to help you remember where you have been during the time you are wearing the exposure badge. You may also wish to keep notes in the space on the reverse side.
- (See other side of page)
You may use the Activity Log to mark hours spent indoors at home, indoors at work or school, and outdoors, and in other places (for example, in a vehicle) for each day that you use the exposure badge.

Exhibit A-3. Directions for wearing exposure badges – Spanish (continued)

ENCUESTA NACIONAL DE EXAMEN DE SALUD Y NUTRICION
INSTRUCCIONES PARA USAR LAS CAJAS DE EXPOSICION

- Quisiéramos que usara la pequeña caja de exposición continuamente desde en el momento que sale del Centro Móvil de Exámen hasta que vuelva para que le revisen su prueba “TB” de la piel.
- Use la caja de exposición de la misma manera que usted usaría una tarjeta de identificación -- sujeta a su ropa en la parte superior del pecho. Asegúrese que la membrana blanca quede hacia afuera y trate de no tocar la membrana blanca.
- Use la caja de exposición en su ropa más externa. Por ejemplo, si usted empieza usando una camisa y tiene la caja sujeta a la camisa y luego se pone una chaqueta, quítese la caja y póngala en la chaqueta.
- Ponga la caja de exposición en una mesa de noche al lado de la cama o sujétela a una pantalla de lámpara cercana mientras está durmiendo. Asegúrese que la membrana blanca esté expuesta al aire.
- Cuando esté dándose una ducha o baño, deje la caja de exposición en otra habitación. El vapor de la ducha o del baño caliente puede causar que la caja no funcione apropiadamente. Un buen lugar para dejar la caja podría ser el mismo lugar en que la deja mientras duerme.
- Cuando devuelva la caja, le haremos algunas preguntas acerca de la cantidad de tiempo que usted pasó adentro en ambos, el hogar y el trabajo o la escuela, y le preguntaremos acerca de la cantidad de tiempo que pasó adentro. Por favor use el Registro de Actividades que aparece en el reverso para ayudarse a recordar donde ha estado durante el tiempo que estaba usando la caja de exposición. Posiblemente también quiera hacer anotaciones en el espacio al reverso.
- (Mire al otro lado de la página.) Usted puede usar el Registro de Actividades para marcar las horas pasadas adentro del hogar, adentro en el trabajo y la escuela y en otros lugares (por ejemplo, en un vehículo) para cada día que use la caja de exposición.

Exhibit A-4. Activity log – English

Activity Log

	Day 1				Day 2				Day 3				Day 4			
	Indoors (home)	Indoors	Outdoors	Other	Indoors (home)	Indoors	Outdoors	Other	Indoors (home)	Indoors	Outdoors	Other	Indoors (home)	Indoors	Outdoors	Other
TIME																
12:00 Midnight																
1:00 am																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 am																
12:00 Noon																
1:00 pm																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 pm																

Exhibit A-4. Activity log – Spanish (continued)

Registro de Actividades

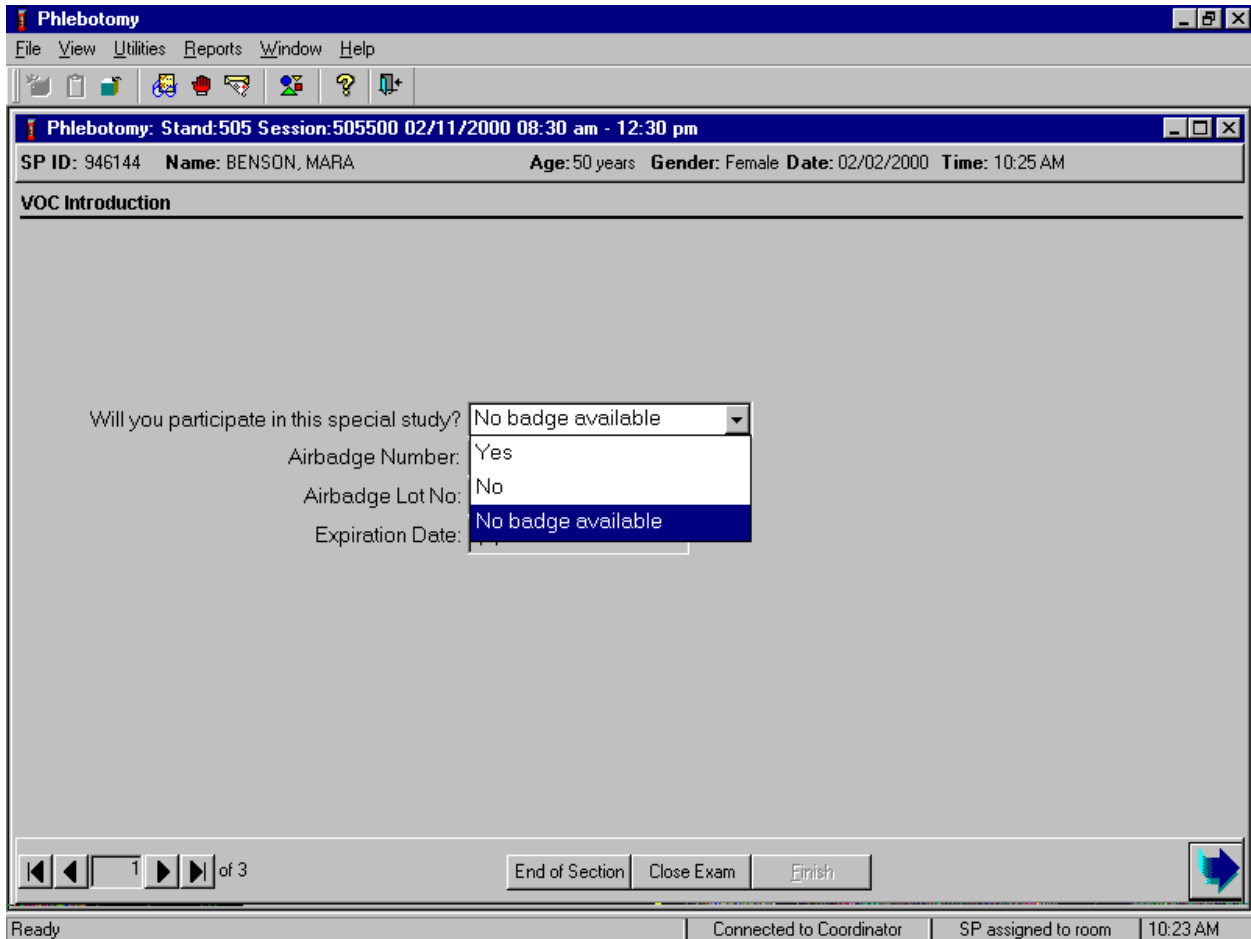
HORA	Día 1				Día 2				Día 3				Día 4			
	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro
12:00 Medianoche																
1:00 am Mañana																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 am																
12:00 Mediodía																
1:00 pm Tarde																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00 Noche																
8:00																
9:00																
10:00																
11:00 pm Noche																

NOTAS:

Escort the recruited primary SP back to the coordinator or to the next component. Store the canister and instructions and the water vial and instructions with the primary SP's clothes. When the primary SP is ready to leave the MEC they change back into their street clothes, attach the badge with the assistance of the MEC interviewer, and take home the directions for wearing the exposure badge and using the water collection kit. Finally, remind the primary SP to please remember to bring the badge and the water sample when they return to the MEC.

Do not discard the empty canister. Store the labeled empty canister in the cabinet above the phlebotomy computer terminal. Use this canister when the primary SP returns 46-76 hours later. If the primary SP does not return for their scheduled MEC appointment or returns to the field office, recycle the empty canister. Share empty canisters with the TB readers in the field office.

The phlebotomist is responsible for checking the availability of badges prior to the start of the stand. If no badges are available do not attempt to recruit the primary SP. Enter “No badges available” in the “Will you participate in this special study?” response text box. Proceed to the next window.



If there are no badges available, record this information by typing [N/n] for “No badge available.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, drag the arrow to “No badge available,” and left click. The Airbadge Number, Airbadge Lot No, and Expiration Date boxes remain grayed out. Only badges with an expiration date of “today” or earlier are eligible for use.

Attempt refusal conversion on all primary VOC eligible primary SPs.

Try to convert all primary SPs who provided a negative response to the recruitment question. Use the following information or “talking points” to convert primary SPs.

Component: Volatile Organic Compounds (VOC)
Who Examined: Selected participants age 20-59
Examination: An air monitoring badge, worn by the participant for 46 - 76 hours
A water sample
A blood sample
Results: Reported only if levels are high
Why we do this:

1. There are chemicals and pollutants in the air we breathe every day. Since many of these chemicals have no odor or color, we do not know they are there. Some of these chemicals are known or thought to cause health problems. In 1990 the Clear Air Act Amendment required the government to take a closer look at these hazardous air pollutants.
2. For this test, we are interested in a group of chemicals called volatile organic compounds, or VOCs. They are commonly used in the manufacture of many household items and things we use every day. Some examples of products that contain VOCs are: household cleaners, furniture polish, gasoline, hair spray, nail polish and remover, air fresheners, mothballs, and paint.
3. We have very little information on the levels of VOCs in the air that we breathe. Our survey is the first time that national levels are being collected to measure how much of these chemicals people are exposed to. We expect that the levels of these chemicals will be low, but need to collect information to determine what the true levels are. From the information collected, we will be able to describe what the levels are in the U.S. and compare them with high levels from places like waste sites and factories.
4. If you are selected to be part of this test, you will be asked to wear a small air-monitoring badge for 46 - 76 hours. When you come back to have your TB reading, you should bring a sample of water from your home. At that time we will collect the badge, and take a small blood sample. We will ask you about some of your activities during the time that you wore the badge. There are no harmful chemicals in the badges that can affect you or any people in your household.
5. This is an important test because it is not currently known how much of these chemicals are in the air that people breathe. You will be part of the first nationwide residential group to have these measurements done.

In addition, use the following information to convert primary SPs.

- This is the only opportunity you will have to join this special study group. I would like to include you as a volunteer.
- This research is sponsored by The Mickey Leland National Urban Air Toxics Research Center (NUATRC), located in the Texas Medical Center. The NUATRC was authorized by the U.S. Congress in the Clean Air Act Amendments of 1990, and incorporated in 1991. It is named after the late Congressman Mickey Leland, whose efforts on behalf of public health contributed significantly to the passage of key amendments to the Clean Air Act.
- The NUATRC is a research facility that has been specifically charged to sponsor and gather scientific information on the human health effects caused by exposure to air toxics. By law, it is a nonprofit corporation, financed by government and private funds.
- As established by law, the NUATRC is governed by a nine-member Board of Directors, and receives scientific guidance from a nationally based thirteen-member Scientific Advisory Panel.
- The primary research mission of the NUATRC is to contribute meaningful and relevant data to the peer-reviewed scientific literature on the potential human health effects of air toxics. NUATRC views this mission as a fundamental component in the national regulatory effort to develop cost-effective and balanced regulations to protect the public from the potential risk from air toxics. NUATRC believes that the participation of all segments of our society is critical to the success of this effort. This includes Federal, state, and local governments, private sector representatives, and public interest organizations. NUATRC has determined that it will be able to most effectively meet its mission by pursuing research activities not being adequately addressed by other organizations and which will contribute data relevant to the national understanding of the human health effects of air toxics. Thus, at this time NUATRC has decided to focus on the following research areas.
 1. Noncancer health effects, primarily those affecting the human respiratory and immune systems; and
 2. Determination of actual human exposures to air toxics in urban environments.
- This study is an epidemiologic data analysis of a population-based study of personal exposures to volatile organic compounds among a subset of participants in a statistically designed national survey.
- The NUATRC is collaborating with the National Center for Health Statistics (NCHS) on a study to collect environmental exposure data for a subset of the US population, as part of a comprehensive nationally based health study.

- The 1,000 participants in this 3-year study constitute a subset of approximately 15,000 subjects selected by NCHS for a national survey of the residential U.S. population for whom household and health status data are collected and physical examinations are performed. The purpose of the national survey is to obtain nationally representative data on the health and nutritional status of the population.
- The 1,000 subjects in the collaborative NCHS-NUATRC study are selected to be a representative subset of the larger study population. Thus, they will provide household and personal data about themselves to the survey regarding socioeconomic, behavioral, demographic and occupational factors.
- The primary aims of the study are:
 1. To characterize the distribution of exposures to selected VOCs within a subpopulation;
 2. To examine the relationship between personal exposures to the VOCs and socioeconomic, behavioral, demographic, and occupational characteristics;
 3. To investigate possible associations between personal exposures to VOCs and some selected indicators of health status for which data are collected as part of the larger study;
 4. To investigate the relationships between local sources of VOCs in subject communities (such as industrial emissions) and personal exposures using available data.
- The purpose of the analysis will be to assess the exposures to the group of VOCs being monitored, as well as exposures to particular VOCs, and to explore potential linkages between exposures and economic, behavioral, and other factors. It is known that an individual's exposure to any form of air pollution is affected by the indoor and outdoor environment, as well as by factors which are related to lifestyle (socioeconomic, behavioral, demographic, and occupational).
- Associations of VOC exposures with potential health outcomes may not be possible to demonstrate because of the size of the sample. However, the opportunity exists to investigate health status markers among the data points collected as part of the larger study to elucidate any patterns which are consistent with published studies of health outcomes.

If the recruitment is unsuccessful, record the negative response as “No” in the “Will you participate in this special study?” text box.

The screenshot shows a software window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and navigation. The main window title bar reads "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm". Below this, a header bar displays patient information: "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM". The main content area is titled "VOC Introduction" and contains the question "Will you participate in this special study?" with a dropdown menu currently set to "No". Below the question are three input fields: "Airbadge Number:", "Airbadge Lot No:", and "Expiration Date: //", all of which are grayed out. At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a bright blue right-pointing arrow. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:23 AM".

Record the “No” response by typing [N/n]. Alternatively, to record a negative response, use the mouse to direct the mouse arrow to the drop down arrow on the drop-down list, left click to display the responses, drag the arrow to “No” and left click. The Airbadge Number, Airbadge Lot No, and Expiration Date boxes remain grayed out. To progress to the next window, use the mouse to direct the mouse arrow to the bright blue right arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Review a previously scheduled appointment for the TB reading, even if the VOC recruitment was unsuccessful.

The screenshot shows the Phlebotomy software interface. The main window title is "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm". Below the title bar, patient information is displayed: "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/02/2000 Time: 10:25 AM".

The "Appointments" section contains the text: "I now need to make an appointment for you two days from now to have the results of this test read." Below this, a section titled "Household Members in This Session:" contains a table with columns for "SP Name", "Age", "VOC", "Session Date", "Start Time", and "Reason".

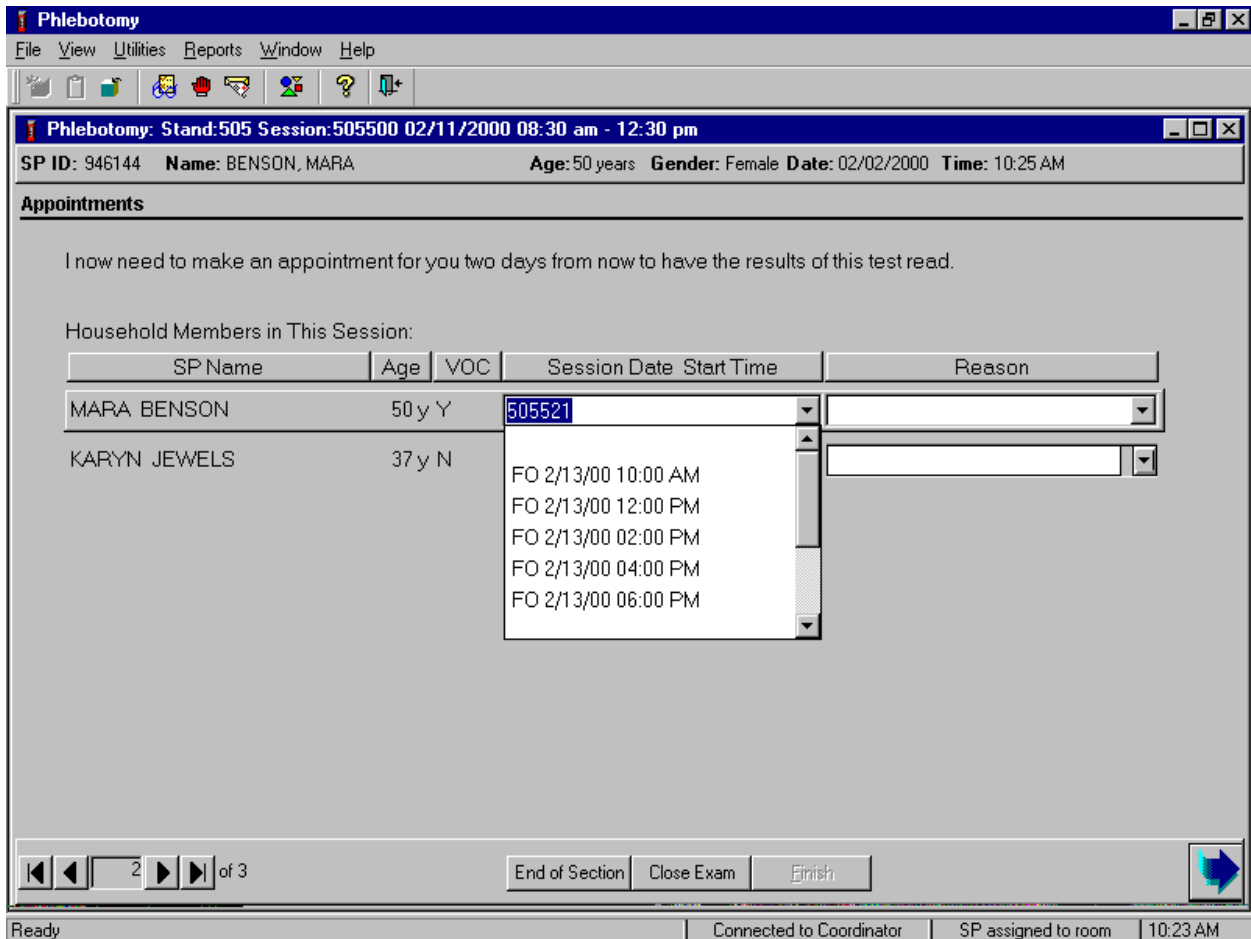
SP Name	Age	VOC	Session Date	Start Time	Reason
MARA BENSON	50 y Y		505521		
KARYN JEWELS	37 y N				

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:23 AM".

If an appointment already exists for the primary SP (another family member has scheduled the appointment), only the session number displays in the Session Date Session Time text box. To change this appointment, use the mouse to direct the mouse arrow to the drop-down list and left click to display FO (field office) sessions for which the primary SP is eligible to return to have their TB reading. Primary SPs are eligible for return appointments 46-76 hours after the antigens have been applied. Only sessions that fall within this time frame are displayed. To select or highlight a specific field office session, use the mouse to drag the mouse arrow to the desired choice, and left click. The FO date and time are inserted into the appointment box. If all displayed session dates and times are unacceptable or a primary SP refuses to select a TB appointment, indicate this by selecting the appropriate choice from the "Reason" list. Leave the Session Date and Time response text box blank and select the "SP refused" reason to the record. If a primary

SP makes a specific request for a home or field office appointment, add the appropriate reason to the record. To attach a reason to the record, use the mouse to direct the mouse arrow to the drop-down list, left click, drag the arrow to the correct choice, and left click.

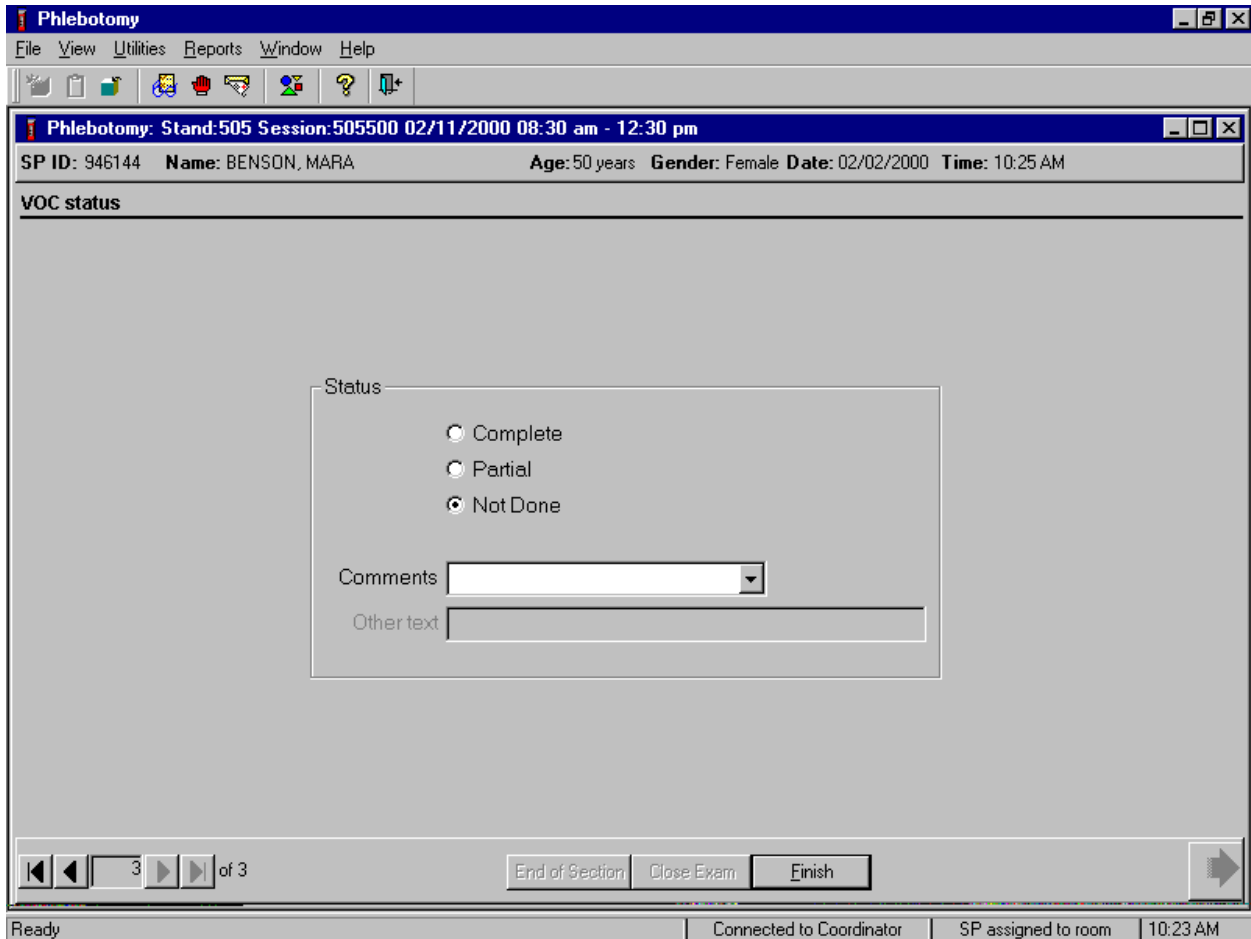
Schedule an appointment for the TB reading, even if the VOC recruitment was unsuccessful.



To schedule a TB reading appointment, use the mouse to direct the mouse arrow to the drop-down list and left click to display FO (field office) sessions for which the primary SP is eligible to return to have their TB reading. SPs are eligible for return appointments 46-76 hours after administration of the TB antigens. Only sessions that fall within this time frame are displayed. To select or highlight a specific field office session, use the mouse to drag the mouse arrow to the desired choice, and left click. The FO date and time are inserted into the appointment text box. If all displayed session dates and times are unacceptable or a SP refuses to select a TB appointment, indicate this by selecting the appropriate choice

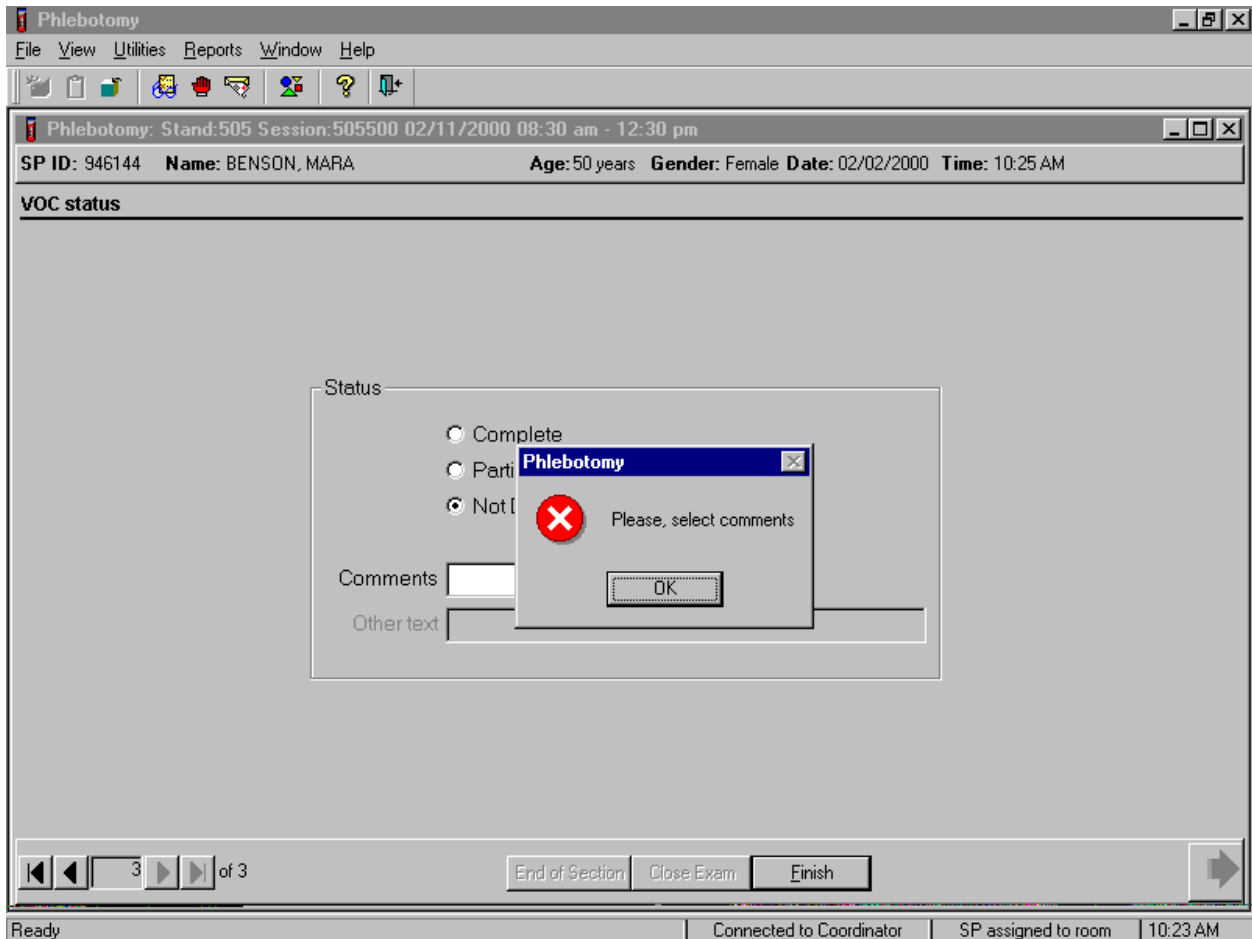
from the “Reason” list. Leave the Session Date and Time response text box blank and select the “SP refused” reason to the record. If a SP makes a specific request for a home or field office appointment, add the appropriate reason to the record. To attach a reason to the record, use the mouse to direct the mouse arrow to the drop down list, left click, drag the arrow to the correct choice, and left click.

Review the examination status of the VOC section of the phlebotomy examination.



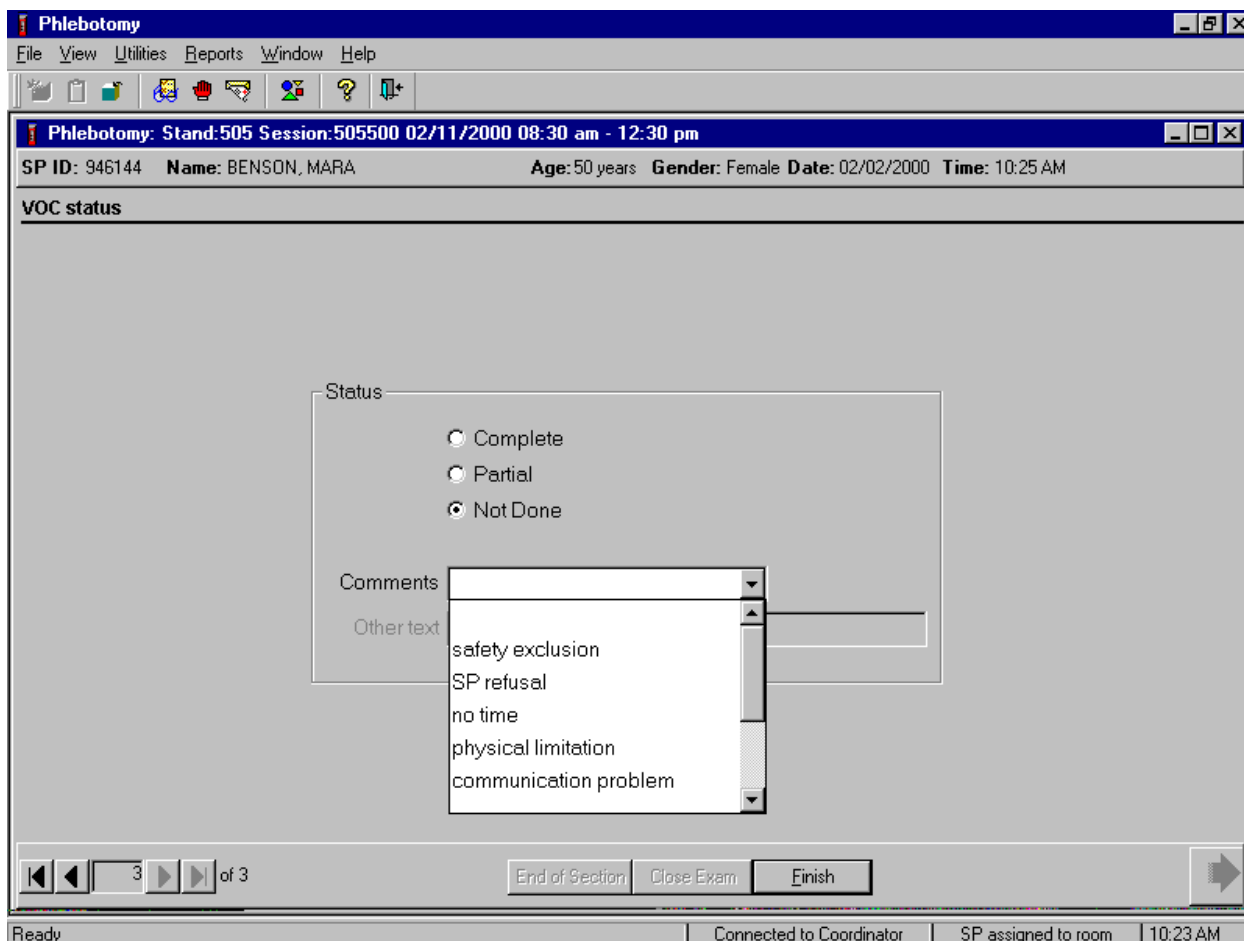
The VOC status is Not Done if the SP was not recruited. Use mandatory comments to explain the not done status.

An error message text box displays if a comment is not selected.



A Not Done VOC exam status requires a comment. If [Enter] is selected before a comment has been entered, an error message text box displays. To remove this window, use the mouse to direct the mouse arrow to the **OK** button and left click. Enter the comment.

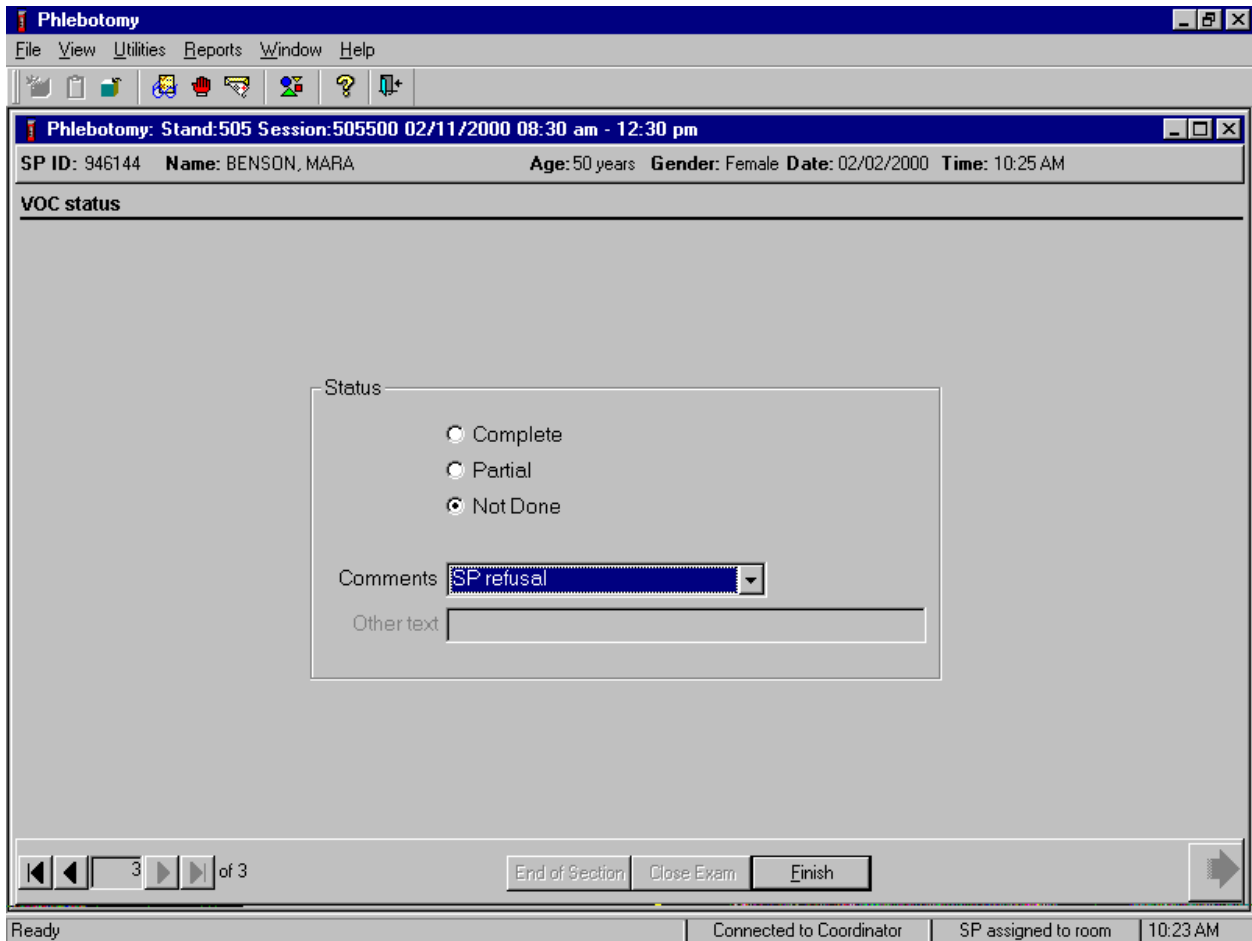
Enter a comment for all primary VOC exams with a Not Done section status.



Choose and enter the appropriate comment code when the VOC section status is Not Done. To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice, and left click. Be sure to view all choices by using the scroll bar on the right side of the drop-down list. Alternatively to select a comment, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code. When the correct choice is highlighted, left click.

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	The primary SP refuses to participate in the special study or wear the badge. This is SP initiated nonresponse due to refusal. The primary SP refuses the component for any reason other than an illness or emergency. If the primary SP refuses in the reception area, the coordinator can code the exam. If the primary SP refuses after starting the exam, the examiner will code the exam.
no time	Not applicable
physical limitation	Not applicable
communication problem	The primary SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable
SP ill/emergency	The primary SP became ill or an emergency occurred and the test could not be performed on the primary SP.
interrupted	Not applicable
other, specify	Choose “other, specify” to free text information. Use this code to document excluded primary SPs. (Type either, “Not staying in their primary residence” or “last two days of stand”.)

Exit the module.



To complete the VOC section of the phlebotomy examination for an unsuccessful VOC recruitment, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted. Escort the primary SP back to the coordinator or to the next component.

A.5 The Return Visit - Primary VOC SPs

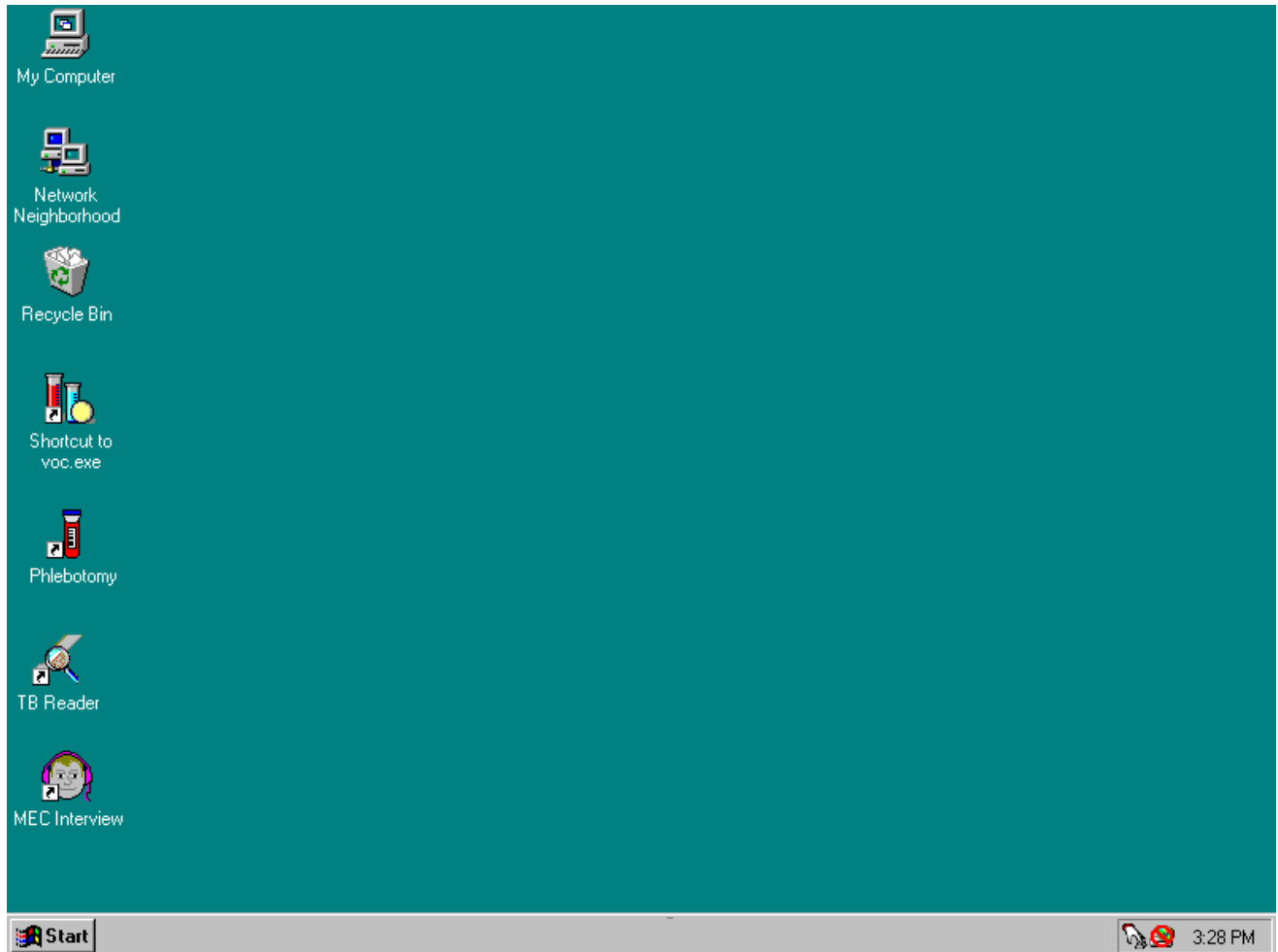
Complete VOC data collection consists of the following: blood tubes, badge, water, and questionnaire. The first priority for VOC data capture is the MEC so that the blood can be collected. If the primary SP cannot come to the MEC, the second priority for VOC is the field office, where the TB readers collect the badge and water and administer the questionnaire. If the SP cannot go to the MEC or the field office, the TB readers attempt to collect the badge and water and administer the questionnaire during a home TB reading.

The coordinator application identifies primary SPs who are returning to the MEC 46-76 hours later for the VOC return visit and assigns the primary SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the primary SP into the application, and performs venipuncture to collect the two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer collects the exposure monitor and water sample, and administers a short questionnaire. Labels for the badge and water samples print on the Intermec printer in the phlebotomy room. When the primary SP returns to the field office to have his or her TB test read, no blood is collected but the TB readers collect the badge and water, administer the questionnaire, and label and store the samples in the field office refrigerator. The data manager transports the field office samples to the MEC where the laboratory medical technologists process, store, and ship the specimens to laboratories for analysis. If the primary SP does not schedule or show up for a return appointment, the TB readers attempt to collect the badge and water and administer the questionnaire in the SP's home.

The phlebotomist, MEC interviewers, and TB readers have access to the complete VOC collection module.

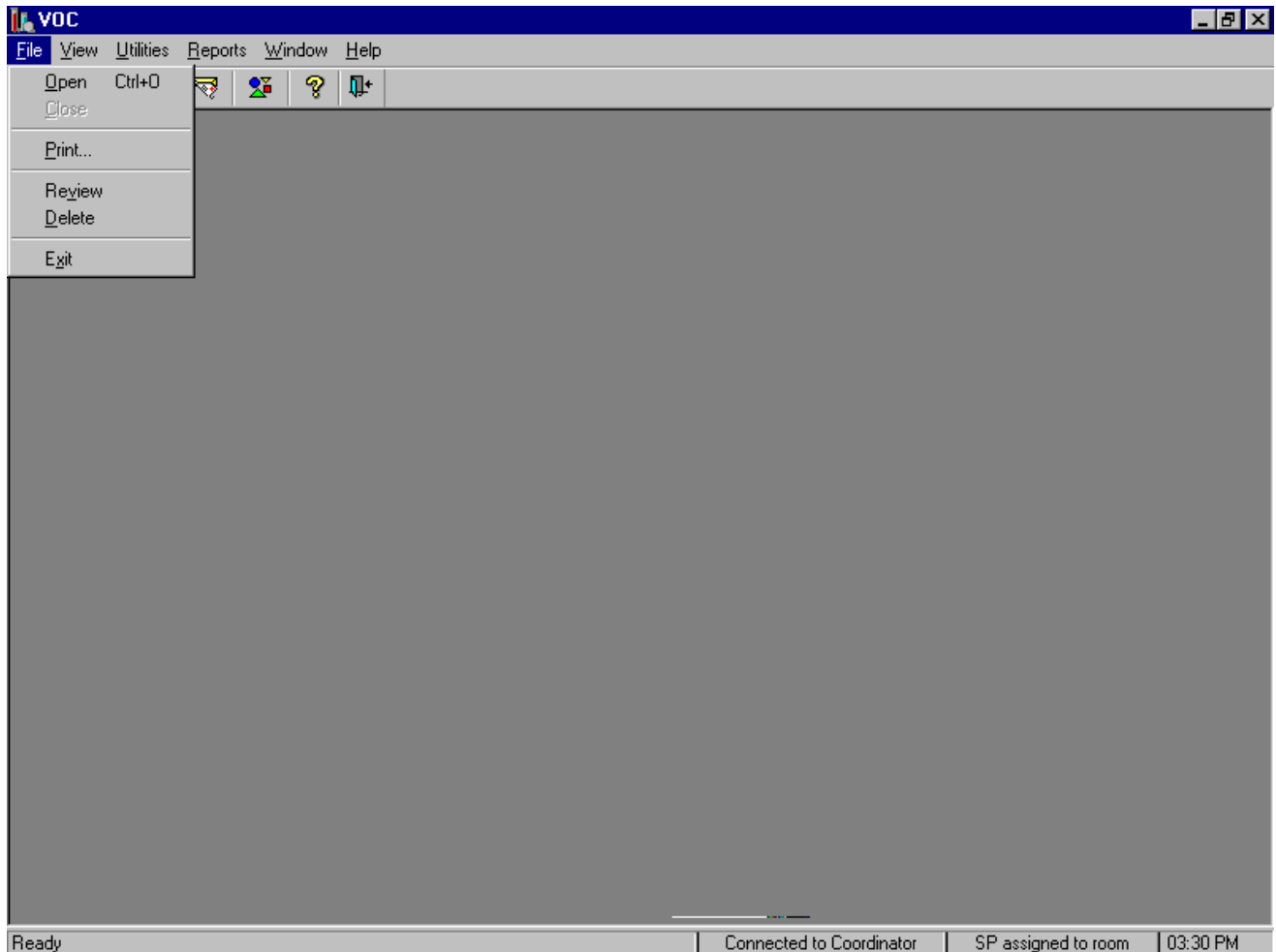
A.5.1 Open the Exam and Log the Primary VOC SP into the Component

Open the VOC application.



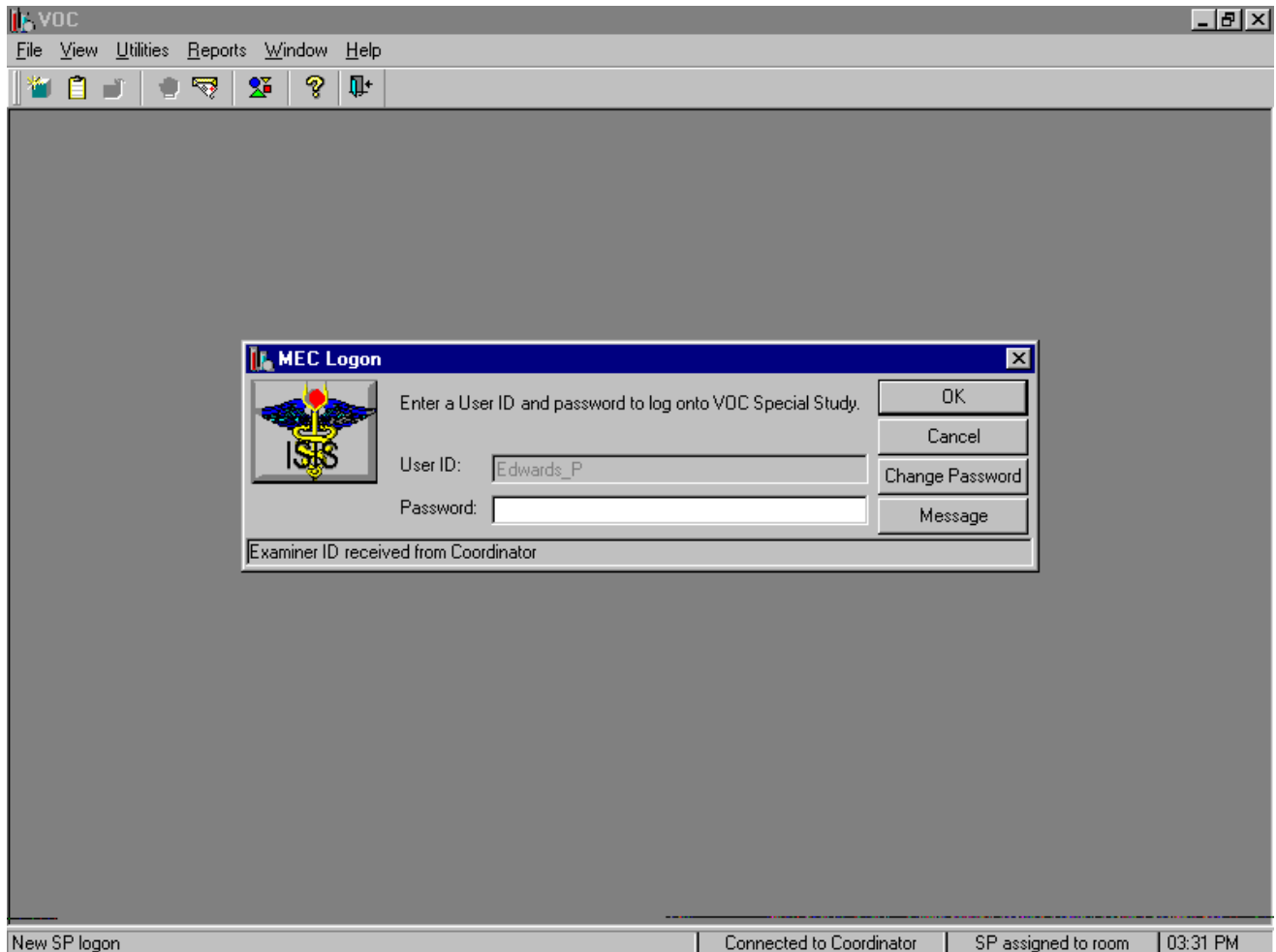
To open the VOC application, use the mouse to direct the mouse arrow to the VOC icon on the desktop and double click.

The VOC application opens. Access or open a primary VOC return examination.



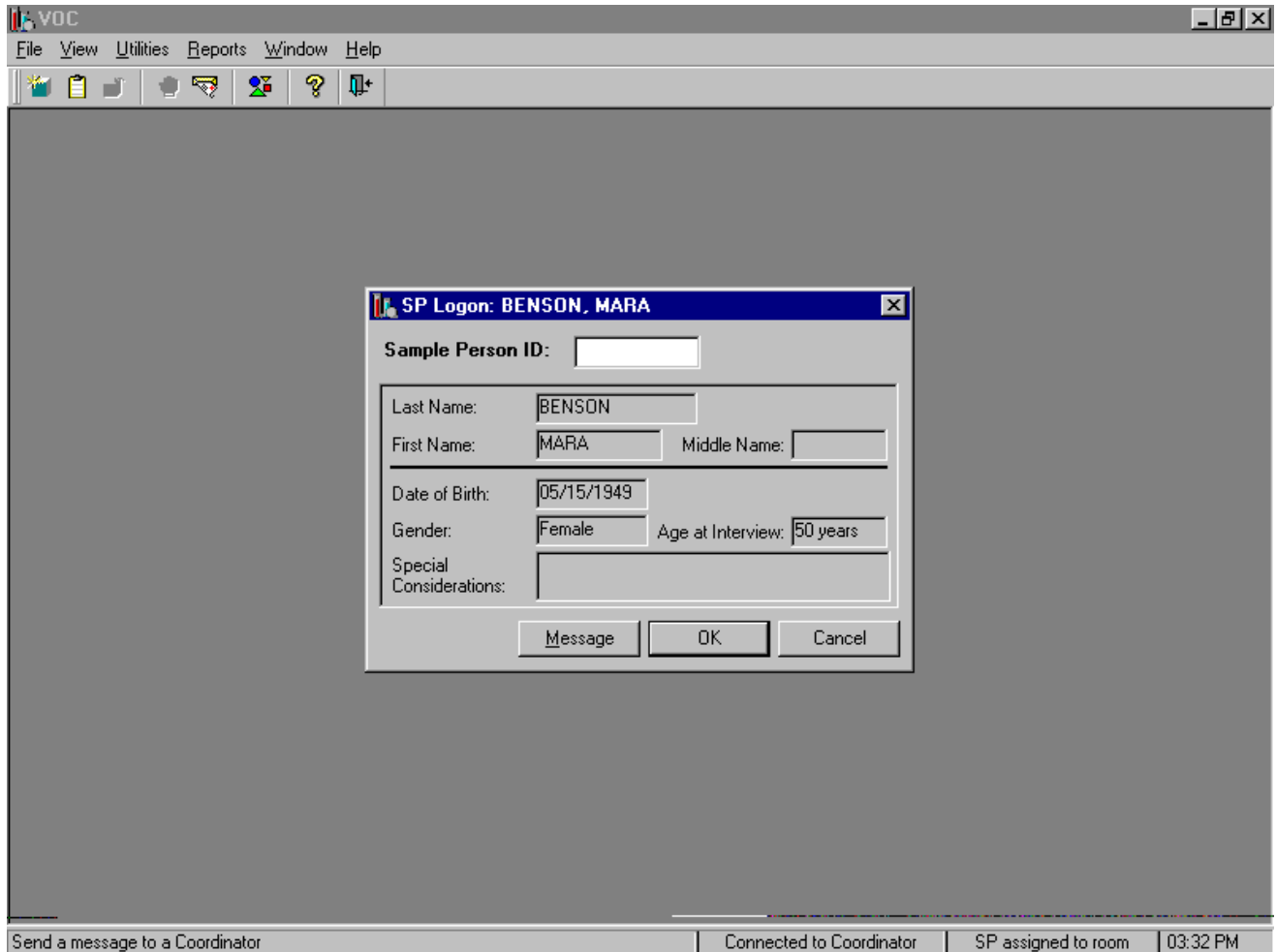
To open a VOC return examination for a primary VOC SP, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Open} and left click, or type [Alt] [F] [O] or [Ctrl] [O].

Log onto the VOC application.



The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this window without entering a password, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the **Message** button and left click.

The SP Logon window displays.



The SP Logon window displays for the primary SP assigned to the component. To log the primary SP into the component either read the SP ID from the primary SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue to log the SP into the exam. Verify the information.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. A modal dialog box titled "SP Logon: BENSON, MARA" is open, displaying the following information:

Sample Person ID:	946144		
Last Name:	BENSON		
First Name:	MARA	Middle Name:	
Date of Birth:	05/15/1949		
Gender:	Female	Age at Interview:	50 years
Special Considerations:			

At the bottom of the dialog are three buttons: Message, OK, and Cancel.

The status bar at the bottom of the main window displays: "Apply changes and close window" | "Connected to Coordinator" | "SP assigned to room" | "03:33 PM"

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

To move forward to the primary VOC sample collection window, press [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the SP Login process, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

A.5.2 The Primary SP VOC Blood Collection - Phlebotomist

CDC prescreens the gray-top tubes used for the VOC protocol for this study. The following is the procedure for preparing the 7-mL gray Vacutainer® VOC blood collection tubes and a statement of their purpose. Dr. David Ashley at the CDC provided this procedure.

Procedure for preparing the 7-mL gray Vacutainer® Tubes

- Because of the volatile organic compounds present in commercial Vacutainers® with rubber stoppers, it is necessary to decontaminate the tubes before blood collection. CDC laboratory personnel carry out this decontamination procedure. The vacuum is released and the glass tube with anticoagulant and the stopper are placed in a vacuum oven. These materials are then decontaminated under vacuum at 70° C for 2 weeks. The Vacutainers® are reassembled and tested for lack of contamination. A vacuum is reapplied to each Vacutainer® and they are sterilized in a Gamma-ray sterilizer to kill any microbiological organisms that may have entered the tubes.
- This procedure is absolutely necessary to acquiring a volatile organic compound measurement that is a true measure of an individual's internal dose level of VOCs.

Since the date on the Vacutainer® is a guarantee that the vacuum is reliable, this date has no reference to the current materials sent from CDC to NCHS. The laboratory at CDC will ensure that the Vacutainers® sent to the NHANES staff have been prepared on a date within the time frame necessary for their use.

Proceed to the first primary SP's VOC window, "VOC Sample Collection."

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm". Below the header bar is a status bar with the text "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM". The main area of the window is titled "VOC Sample Collection" and contains the following fields:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 0 of 2 (with up-down arrow controls)
- Exposure badge collected: [dropdown menu]
- Water sample collected?: [dropdown menu]
- Comment: [text input field]
- Other specify [text input field]

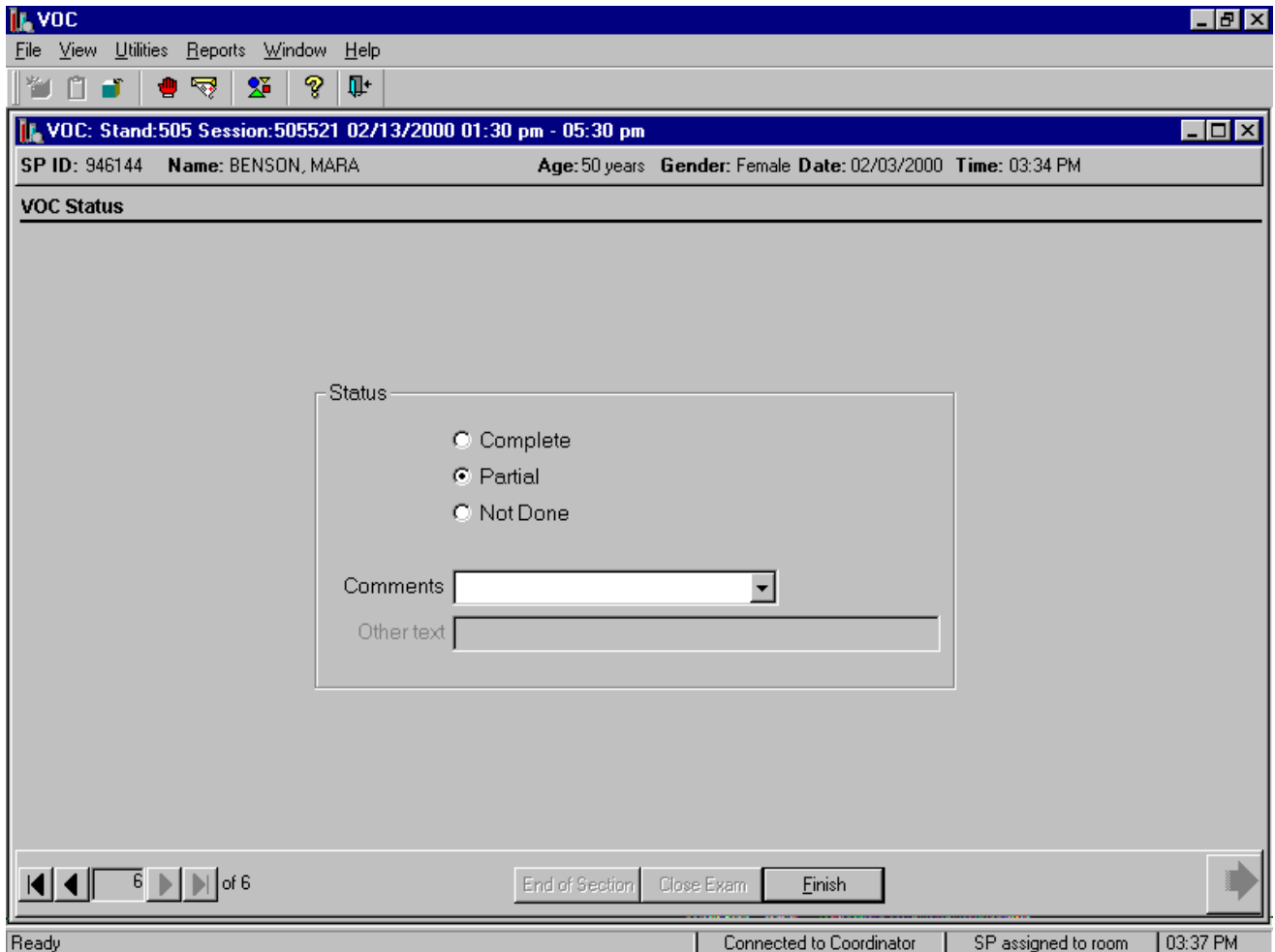
At the bottom of the window, there is a navigation bar with left and right arrow buttons, a page indicator "1 of 6", and three buttons: "End of Section", "Close Exam", and "Finish". A blue arrow icon is also present in the bottom right corner. The Windows taskbar at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "03:34 PM".

The window displays the appropriate venipuncture protocol for returning primary VOC SPs. Draw two 7-mL gray top tubes using procedures described in Chapter 4.

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes by placing the bar coded label on the tube. Pass the blood tubes through the window to the laboratory.

The slide navigation bar provides a means to move forward and back through an examination. To move forward to the last window in the exam, use the mouse to direct the mouse arrow to the black right arrow with the line on the right side on the navigation bar and left click.

Review the examination status.



Use comment codes to explain partial and not done status codes. Exams are partial if one or more of the blood tubes, the water, or the badge are collected and not done is none of these specimens are collected.

A.5.3 The Primary SP's VOC Badge and Water Collection – MEC Interviewers and TB Readers

The MEC interviewer or the TB reader collects the primary VOC SP's badge and water sample and administers the questionnaire.

Record collection of the primary VOC SP's exposure badge.

The screenshot displays the 'VOC' software interface. At the top, there is a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main window title is 'VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm'. Below the title bar, a status bar shows 'SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM'. The main content area is titled 'VOC Sample Collection' and contains the following fields:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: [dropdown menu]
- Water sample collected? [Yes/No dropdown menu]
- Comment: [text box]
- Other specify [text box]

At the bottom of the form, there is a navigation bar with 'End of Section', 'Close Exam', and 'Finish' buttons. The status bar at the very bottom shows 'Ready', 'Connected to Coordinator', 'SP assigned to room', and '03:37 PM'.

To record yes or no type [Y/y] for “Yes,” or [N/n] for “No.” Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes” or “No” and left click. In the MEC, the labels generate automatically on the printer in the phlebotomy room for “Yes” responses.

Reassemble the badge. Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.

Record collection of the water sample.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM

VOC Sample Collection

Sample ID: 372425

Number of 7 ml gray (VOC) tubes collected: 2 of 2

Exposure badge collected: Yes

Water sample collected? Yes/No

Comment: _____

Other specify _____

1 of 6

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 03:39 PM

Record collection of the primary VOC SP's water vessel. To record yes or no type [Y/y] for "Yes," or [N/n] for "No." Alternatively to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. In the MEC, a label prints automatically in the phlebotomy room for "Yes" responses.

If the water collection response is “No,” the Comment text box highlights.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM

VOC Sample Collection

Sample ID: 372425

Number of 7 ml gray (VOC) tubes collected: 2 of 2

Exposure badge collected: Yes

Water sample collected? No

Comment:

Other specify

- SP did not return the water
- Broken
- Other

1 of 6

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 03:39 PM

To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the mouse arrow to select or highlight the most appropriate choice and left click. Alternatively to select a code, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, then use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and, when the correct choice is highlighted, left click. If “Other” is chosen, type a short explanation in the “Other specify” text box. To proceed to the VOC questionnaire, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click.

Label and store or transport the specimens.

A.6 The Return Visit Second Exam SPs

MEC examinees are recruited to return for a second MEC exam. The coordinator asks examinees as they exit the MEC if they would be willing to return for a dietary day 2 interview, a second exam, or both. Only examinees who had their blood drawn, had most components completed, and agree to have phlebotomy again will be recruited for a second exam.

Approximately 16-20 second exams are performed at each stand for quality control purposes. The field office determines if the examinee is eligible for a second exam. Some examinees may not be eligible because of participation in other components such as DIMES and the mental health CATI. Second exams may be scheduled beginning 1 week after the primary exam, and will generally be scheduled towards the end of a stand schedule when exam sessions are lighter. In the event of a conflict in obtaining a primary MEC exam component or a second exam component, the primary MEC exam component should always be given preference.

The coordinator application also identifies second exam SPs who are returning to the MEC and assigns the second exam SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the second exam SP into the phlebotomy exam, and performs venipuncture to collect the second exam venipuncture protocol tubes, which includes two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer administers a unique second exam VOC questionnaire.

A.6.1 Open the Phlebotomy Application and Log the Second Exam VOC SP into the Phlebotomy Component

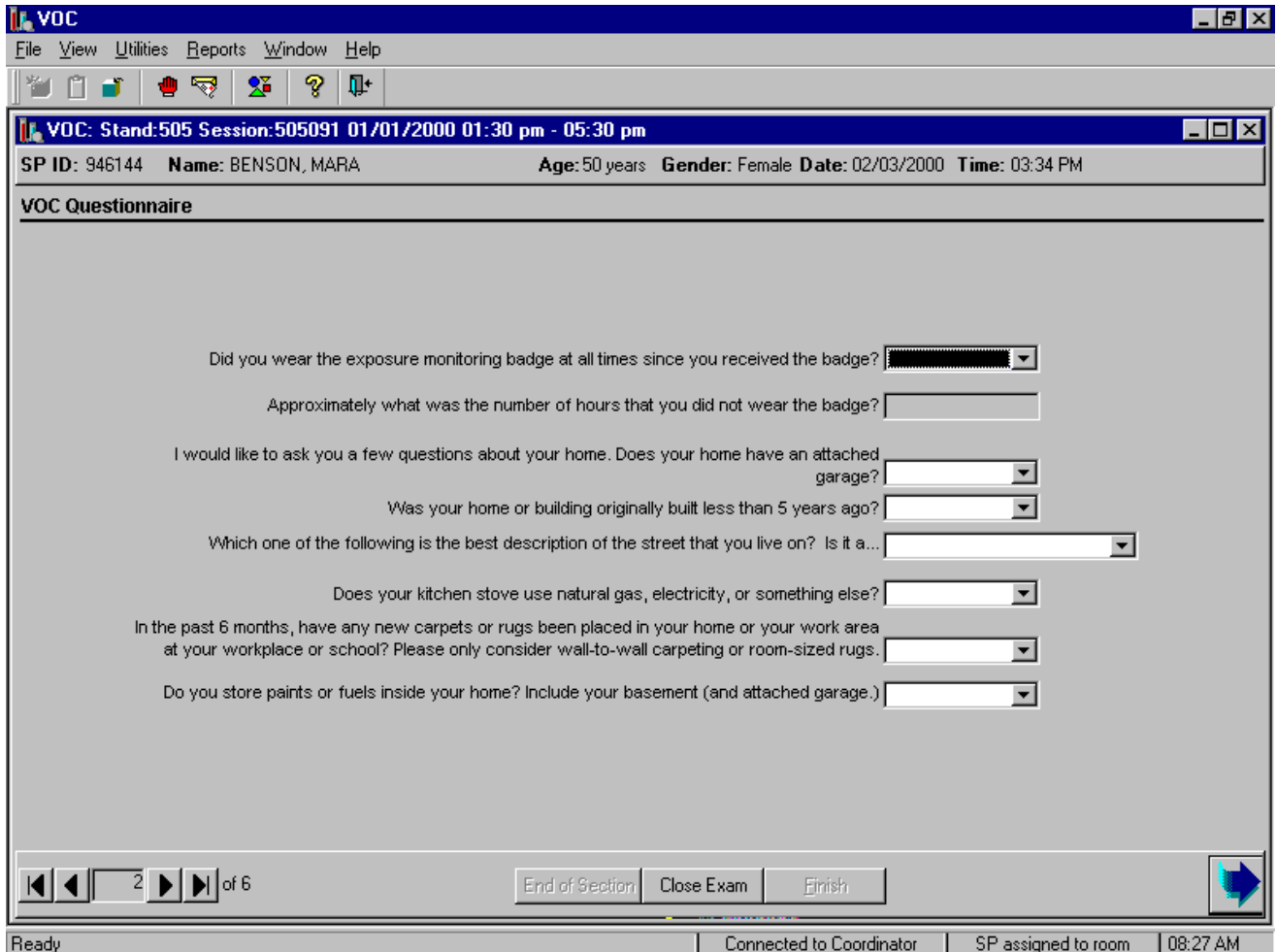
Open the Phlebotomy application.

- To open the phlebotomy application, use the mouse to direct the mouse arrow to the phlebotomy icon on the desktop and double click.

Log onto the Phlebotomy application.

- The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this window without entering a password, use the mouse to direct the mouse arrow

Begin to administer the primary SP's VOC questionnaire. Ask each question exactly as presented on the window.



Did you wear the exposure monitoring badge at all times since you received the badge? [Yes, No]

<p>This initial question determines the length of time the primary SP actually wore the badge since the time they left the MEC and returned for their MEC appointment.</p>	<p>“At all times” means that the primary SP wore the badge from the time they left the MEC to the present time. This includes time spent sleeping, bathing, and showering. Select “Yes,” if they wore the badge the entire time, “No” if they wore the badge less than the entire time. If “No” is selected, the next text box is enabled.</p>
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**If no: Approximately what was the number of hours that you did not wear the badge?
[Number of hours]**

<p>This question documents the actual number of hours that the primary SP did not wear the badge between the time they received the badge and the time they returned to their MEC appointment.</p>	<p>Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round <30 minutes down to nearest whole number, if >30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the SP's best estimate.</p>
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Q1: I would like to ask you a few questions about your home. Does your home have an attached garage? [Yes, No, Refused, Don't know]

<p>Q1: This question refers to the primary residence where the primary SP spent the last 46-76 hours and specifically refers to whether or not the home has a garage and if it does, is it attached.</p>	<p>Home refers to the building where the primary SP lives. This can be a mobile trailer, apartment, townhouse, single, or multiple family building. An attached garage refers to a building or wing of a building in which a car is parked that is also attached or connected as a part to the home. Select "Yes," if the home has an attached garage, "No" if it does not; "Refused" if the primary SP refuses to answer the questions; and "Don't know" if the primary SP is unsure.</p>
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Q2: Was your home or building originally built less than 5 years ago? [Yes, No, Refused, Don't know]

<p>Q2: This question asks the age of the primary SPs home or primary residence.</p>	<p>Ask the primary SP to state the age of their home or when they believe their home was built. If the home was built less than 5 years ago, select "Yes." If the home is older than 5 years, select "No." If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know or cannot estimate the age of their home select "Don't know."</p>
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Q3: Which one of the following is the best description of the street that you live on? Is it a [Rural or country road, Dead-end residential street, Through residential street, Commercial street, Major highway, Refused, Don't know]

<p>Q3: This question asks the primary SPs to describe the street on which their house or primary residence is located.</p>	<p>Ask the primary SP to decide which of the choices best describe the street on which their home is located. Rural or country refers to country as opposed to urban or suburban. This includes farming and agriculture areas. Dead-end residential refers to a street in a suburban or small area that does not go through to another street. Through residential describes a street in a suburb, city, or small town that does go through to another street. A commercial street is a street that has commercial businesses located on it. A major highway is any state-designated highway or Federal interstate highway. Select the primary SP's response. If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know select "Don't know."</p>
--	--

Q4: Does your kitchen stove use natural gas, electricity, or something else? [Natural gas, Electricity, Something else, Refused, Don't know]

<p>Q4: This question asks the primary SP to describe the energy source for their kitchen stove.</p>	<p>Ask the primary SP to decide if the source of power or energy for their kitchen stove is one of the choices. Natural gas refers to propane and other natural gases used as fuel. Electricity refers to electric current used or regarded as a source of power. "Something else" refers to any other known energy source other than natural gas or electricity such as a wood stove or coal furnace. Select the primary SP's response. If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know select "Don't know."</p>
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Q5: In the last 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? [Yes, No, Refused, Don't know]

<p>Q5: This question asks the primary SP to decide if the carpets or rugs in any of the three environments are new within the last 6 months.</p>	<p>If the carpets or rugs in any of these three environments are less than 6 months old select "Yes." If the carpets or rugs are older than 6 months select "No." If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know or cannot estimate the age of their carpets and rugs select "Don't know."</p>
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Q6: Do you store paints or fuels inside your home? Include your basement (and attached garage.) [Yes, No, Refused, Don't know]

<p>Q6: This question asks the primary SP to decide if they currently have any paints or fuels stored inside their home. Include the basement and attached garage if the primary SP reports having an attached garage.</p>	<p>Include areas of the home like the basement and attached garage. Do not include separate storage facilities like barns or sheds on the same property. Include all paints, both indoor and outdoor, and fuels like propane or butane. Do not include wood or coal. If the primary SP indicates they store paint or fuels in any of these locations select "Yes." If the primary SP reports they do not store these items in these locations select "No." If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know select "Don't know."</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM

VOC Questionnaire

Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge 50 hours ago up until this appointment.

During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping.

Were any windows open in your home?

About how many hours did you spend indoors at work or at school?

About how many hours did you spend outdoors?

Did you pump gas into a car or other motor vehicle yourself?

3 of 6

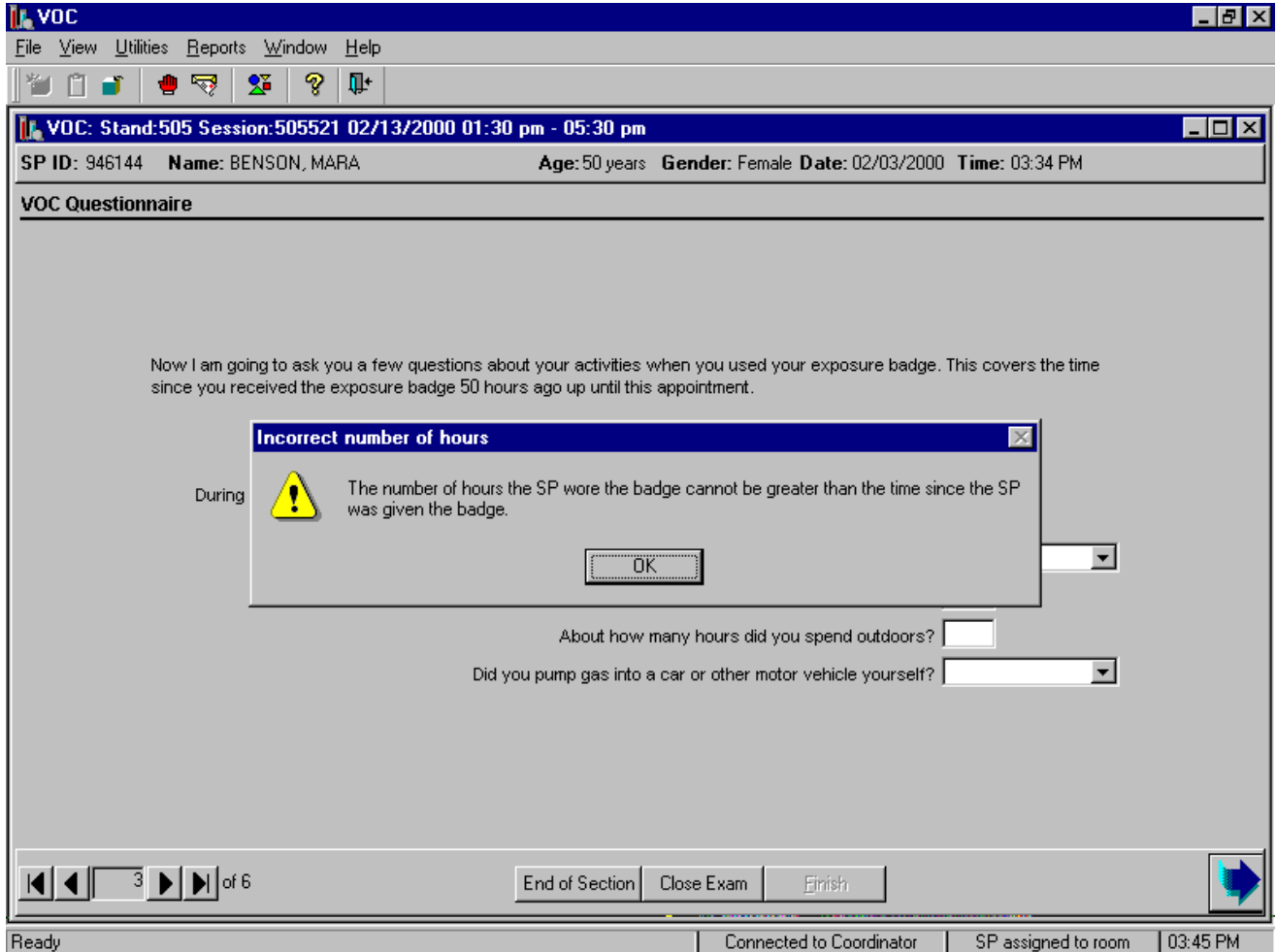
End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 03:45 PM

The number of hours since the initial MEC appointment displays. The beginning time is based on the time the primary VOC SP checked out of the MEC.

Read the script to the primary SP. “Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge (number of hours inserted here) hours ago up until this appointment.” Encourage the primary SP to refer to the activity log to assist in the calculations.

The total number of hours reported in Q7 through Q10 must not total more than the number of hours since the badge was issued.



An error message text box displays if the number of hours reported in questions Q7, Q9, and Q10 exceed the total number of hours since the badge was issued. Review the reported information with the primary VOC SP and probe to clarify any responses. Correct any responses so that the number hours reported in questions Q7, Q9, and Q10 are less than the total number of hours. To remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

Q7: During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping. [Number of hours]

<p>Q7: This question asks the primary SP to report the total number of hours spent in their home during the time they used the exposure badge.</p>	<p>Type the number of whole hours the primary SP reports they spent indoors in their home while using the exposure badge. Record answers to two digits. If the answer is 0 type "00." Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round <30 minutes down to nearest whole number, if >30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP's best estimate.</p>
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Q8: Were any windows open in your home? [Yes, No, Refused, Don't know]

<p>Q8: This question asks the primary SP to report if any windows were open in their home during the time that they used the exposure badge.</p>	<p>Include open doors, e.g., sliding doors to patios and house doors with screens. If the primary SP reports that any windows were open, select "Yes." If no windows were open, select "No." If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know or recall select "Don't know."</p>
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Q9: About how many hours did you spend indoors at work or school? [Number of hours]

<p>Q9: This question asks the primary SP to report the total number of hours spent indoors at work or school during the time they used the exposure badge.</p>	<p>Type the number of hours the primary SP reports they spent indoors in their home while using the exposure badge. Record answers to two digits. If the answer is 0, type “00.” Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round <30 minutes down to nearest whole number, if >30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP’s best estimate.</p>
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Q10: About how many hours did you spend outdoors? [Number of hours]

<p>Q10: This question asks the primary SP to report the total number of hours spent outdoors during the time they used the exposure badge.</p>	<p>Type the number of hours the primary SP reports they spent outdoors while using the exposure badge. Record answers to two digits. If the answer is 0, type “00.” Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round <30 minutes down to nearest whole number, if >30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP’s best estimate.</p>
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Q11: Did you pump gas into a car or other motor vehicle yourself? [Yes, No, Refused, Don't know]

<p>Q11: This question asks the primary SP to report if they pumped gas into a car or other motor vehicle during the time that they used the exposure badge.</p>	<p>Include any grade of gas but do not include natural gas. Include pumping gas into a container, such as a lawn mower container. Do not record "Yes" if the primary SP reports being a passenger in a car into which gas was pumped. If the primary SP reports actually pumping gas into any car or motor vehicle, select "Yes." If the primary SP reports they did not pump gas into a car or other motor vehicle, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know if they pumped gas into any car or other motor vehicle, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

to the button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the button and left click.

The Message Center window identifies the SP assigned to phlebotomy.

- A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component displays. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the button and left click, or select [Enter].

Open the phlebotomy exam.

- To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F], [O], or [Ctrl] [O].

The SP Logon window displays.

- The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the button and left click.

Verify the information.

- Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

A.6.2 The Second Exam VOC Blood Collection - Phlebotomist

Conduct the phlebotomy interview, administer the fasting questionnaire, perform the venipuncture, and review the exam section status.

The Phlebotomy application opens. Access or open a second exam phlebotomy examination.

Q13: Did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week? [Yes, No, Refused, Don't know]

<p>Q13: This question asks the primary SP to report if they visited a dry cleaning shop or wore clothes that had been dry cleaned within the last week.</p>	<p>The cleaning process cleans clothing with chemical solvents having little or no water. Determine if the primary SP visited a dry cleaning shop during the time they used the exposure badge or if they wore clothes that had been dry-cleaned within the last week or 7 days. If the primary SP meets either criterion, select "Yes." If the primary SP reports that they were not at a dry cleaners and have not worn clothes dry-cleaned within the last week, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot remember if they were at a dry cleaning shop or wore clothes dry cleaned within the last week, select "Don't know."</p>
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Q14: Did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors? [Yes, No, Refused, Don't know]

<p>Q14: This question asks the primary SP to report if they have spent 10 or more minutes near wood-burning fires either indoors or outdoors during the time they used the exposure badge.</p>	<p>Include wood-burning devices such as wood stoves, fireplaces and outdoor pits or fires. If the primary SP meets any of these criteria, select "Yes." If the primary SP reports that they have not been around any of these sources of wood fires, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall if they spent any time near wood burning fires while using the exposure badge, select "Don't know."</p>
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Q15: Did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe? [Yes, No, Refused, Don't know]

<p>Q15: This question asks the primary SP to report if they have spent 10 or more minutes near any person who was smoking cigarettes, cigars, or a pipe during the time they used the exposure badge.</p>	<p>Include any brand of cigarette, any size of cigar, or any style of pipe. If the primary SP meets any of these criteria, select "Yes." If the primary SP reports that they have not been around any of these sources of smoke, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall if they spent any time near someone who was smoking these forms of tobacco while using the exposure badge, select "Don't know."</p>
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Q16: Even though you did not use the badge when taking a hot shower, did you take a hot shower for five minutes or longer during this time period? [Yes, No, Refused, Don't know]

<p>Q16: This question asks the primary SP to report if they took a hot shower of at least 5 minutes during the time they used the exposure badge.</p>	<p>Determine if the primary SP took a hot shower for at least 5 minutes. If the primary SP reports taking a hot shower for a total of at least 5 minutes, select "Yes." If the primary SP reports taking a cold or warm shower or a hot shower for less than 5 minutes, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall taking a hot shower for at least 5 minutes, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "VOC: Stand:505 Session:505130 01/05/2000 08:30 am - 12:30 pm". Underneath the header bar, a status bar displays "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM". The main content area is titled "VOC Sample Collection" and contains the following text: "During the time you used the exposure badge, did you breathe fumes from or use any of the following? (Check all that apply)". Below this text is a list of items, each with a dropdown menu: Paints, Mothballs, moth crystals, or mothflakes, Household disinfectant or degreasing cleaners, Furniture polish, Hairspray, Fingernail polish or fingernail polish remover, Diesel fuel or kerosene, Gasoline, Paint thinner, brush cleaner, or furniture stripper, Air fresheners or room deodorizers, Drycleaning fluid or spot remover, and Glues or adhesives used for hobbies or crafts. At the bottom of the list are two checkboxes: "Refused" and "Don't Know". The bottom of the window features a navigation bar with left and right arrow buttons, a page indicator "5 of 6", and buttons for "End of Section", "Close Exam", and "Finish". A blue arrow icon is located in the bottom right corner of the window. The Windows taskbar at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:56 AM".

Continue to enter responses for each item. If the bright blue arrow in the navigation bar or [Enter] is inadvertently selected, an error message text box displays. Review the text and, to remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

Q17: During the time you used the exposure badge, did you breathe fumes from any of the following? [Yes, No, Refused, Don't know]

<p>Q17: This question asks the primary SP to report if they breathed fumes from a variety of sources during the time that they used the exposure badge.</p>	<p>Individually determine if the primary SP breathed fumes from each source. Record each answer. If the primary SP reports breathing fumes from an item while using the exposure badge, select "Yes." If the primary SP reports s/he did not breath fumes while using the exposure badge, select "No." If at any point during the interview the primary SP refuses to answer any further questions, select the "Refused" square. If the primary SP does not know or cannot recall breathing fumes while using the exposure badge, select "Don't know" or if the primary SP reports they do not know the answer to all the remaining choices, select the "Don't know" square. Select the bright blue arrow to proceed to the last window.</p>
<p>Paints</p>	<p>Include all interior and exterior paints, spray paints used in arts and crafts, and oil-based artist paints.</p>
<p>Mothballs, moth crystals, or mothflakes</p>	<p>Mothballs are composed of a ball of camphor or naphthalene. They are used for protection of clothes from moths.</p>
<p>Household disinfectant or degreasing cleaners</p>	<p>Consider all disinfectants including Lysol® and PineSol®.</p>
<p>Furniture polish</p>	<p>Consider Pledge®, Liquid Gold, and lemon polish and all other brands of furniture polish.</p>
<p>Hairspray</p>	<p>Consider all brands of hairspray.</p>
<p>Fingernail polish or fingernail polish remover</p>	<p>Nail polish and nail polish remover contains acetone.</p>
<p>Diesel fuel or kerosene</p>	<p>Diesel fuel is a crude oil. Kerosene is a hydrocarbon oil, chiefly of the methane series, used for burning in lamps. It is also called coal oil.</p>
<p>Gasoline</p>	<p>Gasoline is a distillate of crude petroleum.</p>

Paint thinner, brush cleaner, or furniture stripper	These items contain turpentine.
Air fresheners or room deodorizers	Consider all spray types of air fresheners such as Airwick®, Glade®, and Lysol® and include the type that affixes to a wall or toilet or stands upright in a dispenser.
Dry-cleaning fluid or spot remover	Consider all spot removers like K2R.
Glues or adhesives used for hobbies or crafts	Glue is a viscid cement or adhesive preparation and is usually an impure gelatin derived from boiling certain animal substances. Hobby glue contains a significant amount of toluene.

To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Verify the status for the primary VOC exam.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM

VOC Questionnaire

Status

Complete

Partial

Not Done

Comments

Other text

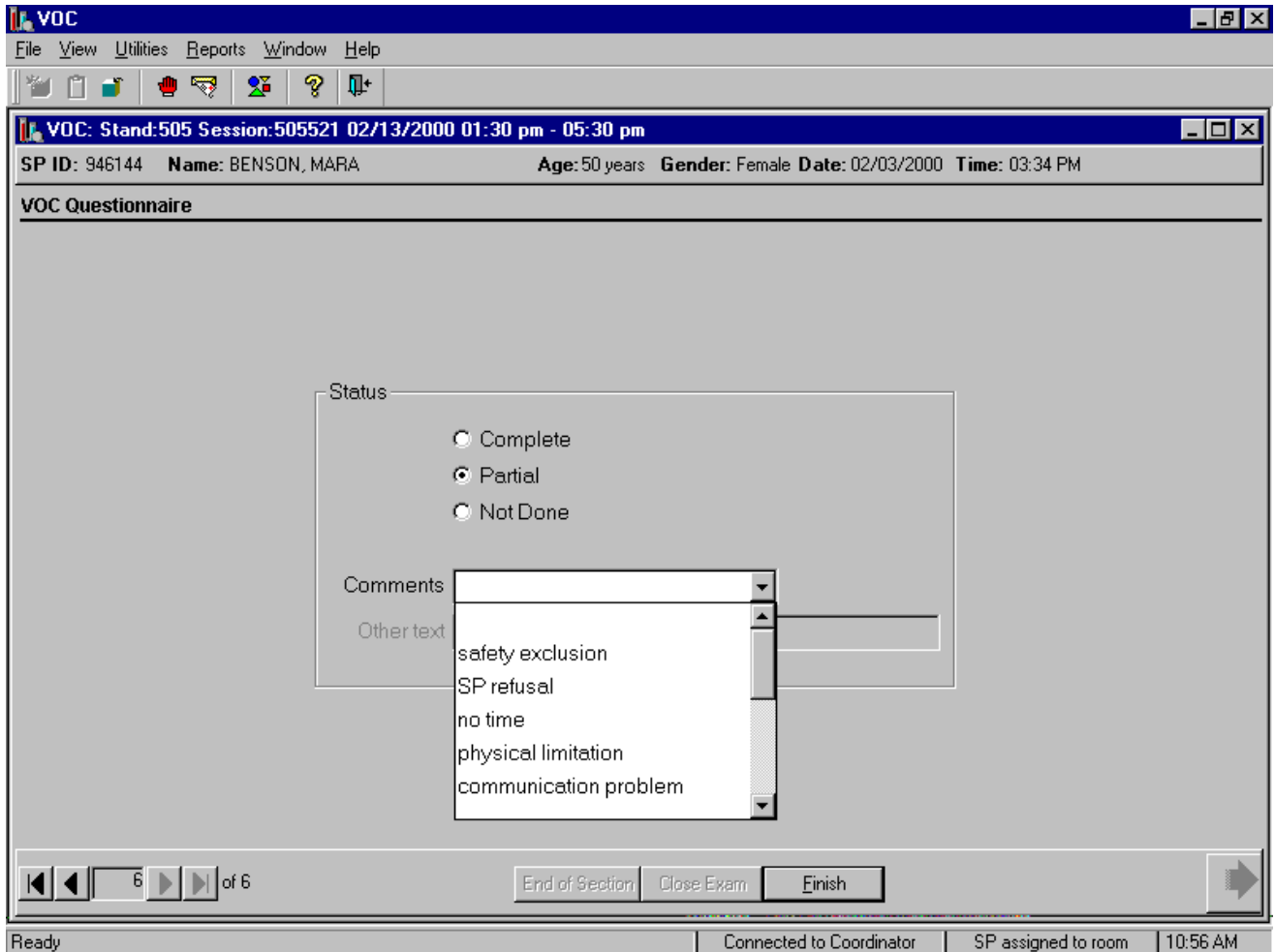
6 of 6

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:56 AM

Comment codes are used to explain partial and not done status codes. Exams are partial if any of the blood tubes, water, or badge are collected and not done is none of the specimens are collected.

Choose and enter the appropriate comment code when the examination status is partial or not done.



To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice and left click. Alternatively to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If “Other, specify” is chosen, type a short explanation in the “Other text” text box.

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	This is SP initiated nonresponse due to refusal. The primary SP refuses the component for any reason other than an illness or emergency. If the primary SP refuses in the reception area, the coordinator can code the exam. If the primary SP refuses after starting the exam, the examiner will code the exam.
no time	Not applicable
physical limitation	The venipuncture is unsuccessful.
communication problem	The primary SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable
SP ill/emergency	The primary SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	Not applicable
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the VOC examination, use the mouse to direct the mouse arrow to the Finish button in the navigation bar and left click or press [Enter] when the Finish button is highlighted. If the SP is in the MEC, escort them back to the coordinator.

A.6 The Return Visit Second Exam SPs

MEC examinees are recruited to return for a second MEC exam. The coordinator asks examinees as they exit the MEC if they would be willing to return for a dietary day 2 interview, a second exam, or both. Only examinees who had their blood drawn, had most components completed, and agree to have phlebotomy again will be recruited for a second exam.

Approximately 16-20 second exams are performed at each stand for quality control purposes. The field office determines if the examinee is eligible for a second exam. Some examinees may not be eligible because of participation in other components such as DIMES and the mental health CATI. Second exams may be scheduled beginning 1 week after the primary exam, and will generally be scheduled towards the end of a stand schedule when exam sessions are lighter. In the event of a conflict in obtaining a primary MEC exam component or a second exam component, the primary MEC exam component should always be given preference.

The coordinator application also identifies second exam SPs who are returning to the MEC and assigns the second exam SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the second exam SP into the phlebotomy exam, and performs venipuncture to collect the second exam venipuncture protocol tubes, which includes two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer administers a unique second exam VOC questionnaire.

A.6.1 Open the Phlebotomy Application and Log the Second Exam VOC SP into the Phlebotomy Component

Open the Phlebotomy application.

- To open the phlebotomy application, use the mouse to direct the mouse arrow to the phlebotomy icon on the desktop and double click.

Log onto the Phlebotomy application.

- The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this window without entering a password, use the mouse to direct the mouse arrow

to the button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the button and left click.

The Message Center window identifies the SP assigned to phlebotomy.

- A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component displays. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the button and left click, or select [Enter].

Open the phlebotomy exam.

- To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F], [O], or [Ctrl] [O].

The SP Logon window displays.

- The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the button and left click.

Verify the information.

- Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

A.6.2 The Second Exam VOC Blood Collection - Phlebotomist

Conduct the phlebotomy interview, administer the fasting questionnaire, perform the venipuncture, and review the exam section status.

The Phlebotomy application opens. Access or open a second exam phlebotomy examination.

- To open a phlebotomy exam for a second exam, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Open} and left click, or type [F] [O] or [Ctrl] [O].

Conduct the phlebotomy interview. Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly and record the responses.

- Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “Refused,” or “Don’t Know,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the window and left click.

Administer the fasting questionnaire.

- Read the text exactly and record the time. Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to “AM” or “PM” and left click.
- Type in the date using the keyboard’s numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the button and left click.

- Continue administering the questionnaire. Verify the initial time response by asking the remaining questions.

The window displays the appropriate venipuncture protocol for returning second exam SPs. Only second exam SPs age 20-59 are eligible for the two additional VOC blood tubes. Complete the second exam venipuncture procedure (Exhibit A-5) using procedures described in Chapter 4.

Exhibit A-5. Venipuncture protocol – second exam

Age in Years	12-19	20-59	60-69
Tube Type – Priority			
5-mL Lavender	2	2	2
3-mL Gray (Morning sessions only)	1	1	1
3-mL Blue (40+)		1	1
15-mL Red	2	2	2
7-mL Gray		2	

Enter the blood draw results.

The screenshot shows a software window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The main window title is "Phlebotomy: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 687219", "Name: SPARKS, TODD", "Age: 30 years", "Gender: Male", "Date: 02/02/2000", and "Time: 10:42 AM". The section is titled "Venipuncture".

There are four rows of blood draw results, each with a spin box and a label:

- 5 ml EDTA: spin box shows 0, label "of 2"
- 3 ml gray: spin box shows 0, label "of 1"
- 15 ml red: spin box shows 0, label "of 2"
- 7 ml gray: spin box shows 0, label "of 2"

To the right of these rows is a checkbox labeled "Obtained all" which is currently unchecked. Below the checkbox is the patient ID "687219".

At the bottom of the main area is a "Comment:" label followed by a text input field.

The bottom navigation bar contains several controls: a set of navigation arrows (back, forward, home, end), a page indicator "3 of 4", and three buttons: "End of Section", "Close Exam", and "Finish". A bright blue arrow icon is located on the far right of the navigation bar.

The system tray at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "10:40 AM".

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes and pass to the laboratory. To collectively mark all tubes as collected, use the mouse to direct the mouse arrow to the Obtained all check box and left click to insert a check mark or type [B].

To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrows highlighted.

Review the examination status.

The screenshot shows a software window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for home, print, save, undo, redo, help, and refresh. The main content area is titled "Phlebotomy: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 687219 Name: SPARKS, TODD Age: 30 years Gender: Male Date: 02/02/2000 Time: 10:42 AM". The section is titled "Venipuncture Status". A form titled "Status" contains three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below the radio buttons are two text input fields: "Comments" and "Other text". The bottom of the window features a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, along with a slide show indicator showing "4 of 4". The status bar at the very bottom displays "Finish slide show", "Connected to Coordinator", "SP assigned to room", and "10:40 AM".

Use comment codes to explain partial and not done status codes. Exams are partial if one or more of the blood tubes are collected and not done is none of these specimens are collected.

A.6.3 The Second Exam VOC Questionnaire – MEC Interviewers

The MEC interviewer administers the unique second exam VOC questionnaire. Access the VOC application, open a VOC examination, and log the second exam SP into the exam. Verify all information that appears on the SP Logon window. The second exam VOC questionnaire displays on the subsequent windows.

Record the various text and numeric responses by using one of the following two methods.

- Record text responses either by typing the first letter of the choice, or select or highlight the correct choice by using the mouse to direct the mouse arrow to the drop-down list, left click, drag the mouse arrow to the correct choice, and left click when the correct choice is highlighted. Select [TAB] to move to the next question.
- Record numeric responses by using the keyboard's numeric keys to enter the number and select [TAB] to move to the next question.

Begin to administer the second exam VOC questionnaire. Ask each question exactly as presented on the window.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

SP ID: 687219 Name: SPARKS, TODD Age: 30 years Gender: Male Date: 02/02/2000 Time: 11:01 AM

VOC Questionnaire

I would like to ask you a few questions about your home. Does your home have an attached garage?

Was your home or building originally built less than 5 years ago?

Which one of the following is the best description of the street that you live on? Is it a...

Does your kitchen stove use natural gas, electricity, or something else?

In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please only consider wall-to-wall carpeting or room-sized rugs.

Do you store paints or fuels inside your home? Include your basement (and attached garage.)

1 of 4

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:56 AM

Q1: I would like to ask you a few questions about your home. Does your home have an attached garage? [Yes, No, Refused, Don't know]

<p>Q1: This question refers to the primary residence where the second exam SP lives and specifically refers to whether or not the home has a garage and if it does, is it attached.</p>	<p>Home refers to the building where the second exam SP lives. This can be a mobile trailer, apartment, townhouse, single, or multiple family building. An attached garage refers to a building or wing of a building in which a car is parked that is also attached or connected as a part to the home. Select "Yes," if the home has an attached garage, "No" if it does not, "Refused" if the second exam SP refuses to answer the questions, and "Don't know" if the second exam SP is unsure.</p>
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Q2: Was your home or building originally built less than 5 years ago? [Yes, No, Refused, Don't know]

<p>Q2: This question asks the age of the second exam SP's home or primary residence.</p>	<p>Ask the second exam SP to state the age of their home or when they believe their home was built. If the home was built less than 5 years ago, select "Yes." If the home is older than 5 years, select "No." If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know or cannot estimate the age of their home, select "Don't know."</p>
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Q3: Which one of the following is the best description of the street that you live on? Is it a [Rural or country road, Dead-end residential street, Through residential street, Commercial street, Major highway, Refused, Don't know]

<p>Q3: This question asks the second exam SP to describe the street on which their house or primary residence is located.</p>	<p>Ask the second exam SP to decide which of the choices best describes the street on which their home is located. Rural or country refers to country as opposed to urban or suburban. This includes farming and agriculture areas. Dead-end residential refers to a street in a suburban or small area that does not go through to another street. Through residential describes a street in a suburb, city, or small town that does go through to another street. A commercial street is a street that has commercial businesses located on it. A major highway is any state-designated highway or Federal interstate highway. Select the SP response. If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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Q4: Does your kitchen stove use natural gas, electricity, or something else? [Natural gas, Electricity, Something else, Refused, Don't know]

<p>Q4: This question asks the second exam SP to describe the energy source for their kitchen stove.</p>	<p>Ask the second exam SP to decide if the source of power or energy for their kitchen stove is one of the choices. Natural gas refers to propane and other natural gases used as fuel. Electricity refers to electric current used or regarded as a source of power. "Something else" refers to any other known energy source other than natural gas or electricity such as a wood stove or coal furnace. Select the second exam SP's response. If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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Q5: In the last 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? [Yes, No, Refused, Don't know]

<p>Q5: This question asks the second exam SP to decide if the carpets or rugs in any of the three environments are new within the last 6 months.</p>	<p>If the carpets or rugs in any of these three environments are less than 6 months old select "Yes." If the carpets or rugs are older than 6 months select "No." If the second exam SP refuses to answer the question, select "Refused" and if the SP does not know or cannot estimate the age of their carpets and rugs, select "Don't know."</p>
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Q6: Do you store paints or fuels inside your home? Include your basement (and attached garage.) [Yes, No, Refused, Don't know]

<p>Q6: This question asks the second exam SP to decide if they currently have any paints or fuels stored inside their home. Include the basement and attached garage if the second exam SP reports having an attached garage.</p>	<p>Include areas of the home like the basement and attached garage. Do not include separate storage facilities like barns or sheds on the same property. Include all paints, both indoor and outdoor, and fuels like propane or butane. Do not include wood or coal. If the second exam SP indicates they store paint or fuels in any of these locations, select "Yes." If the second exam SP reports they do not store these items in these locations, select "No." If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

SP ID: 687219 Name: SPARKS, TODD Age: 30 years Gender: Male Date: 02/02/2000 Time: 11:01 AM

VOC Questionnaire for Day 2 Exam

Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday.

In the last three days, did you pump gas into a car or other motor vehicle yourself?

In the last three days, did you spend any time at a swimming pool?

In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

In the last three days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors?

In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

In the last three days, did you take a hot shower for five minutes or longer?

2 of 4

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:56 AM

Read the script to the second exam SP. “Now I am going to ask you a few questions about your activities over the last 3 days. This means today, yesterday, or the day before yesterday.”

Q7: In the last three days, did you pump gas into a car or other motor vehicle yourself? [Yes, No, Refused, Don't know]

<p>Q7: This question asks the second exam SP to report if they pumped gas into a car or other motor vehicle during the last 3 days.</p>	<p>Include any grade of gas but do not include natural gas. Include pumping gas into a container, such as a lawn mower container. Do not record "Yes" if the second exam SP reports being a passenger in a car into which gas was pumped. If the second exam SP reports actually pumping gas into any car or motor vehicle, select "Yes." If the second exam SP reports they did not pump gas into a car or other motor vehicle, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know if they pumped gas into any car or other motor vehicle, select "Don't know."</p>
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Q8: During the last three days, did you spend any time at a swimming pool? [Yes, No, Refused, Don't know]

<p>Q8: This question asks the second exam SP to report if they spent any time at a swimming pool during the last 3 days.</p>	<p>Determine if the second exam SP spent time at a swimming pool. The second exam SP did not have to swim in the pool. If the second exam SP reports being at or in a swimming pool, select "Yes." If the second exam SP reports that they were not at a swimming pool, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they were at a swimming pool, select "Don't know."</p>
--	--

Q9: During the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week? [Yes, No, Refused, Don't know]

<p>Q9: This question asks the second exam SP to report if they visited a dry cleaning shop or wore clothes that had been dry cleaned within the last week.</p>	<p>The cleaning process cleans clothing with chemical solvents having little or no water. Determine if the second exam SP visited a dry cleaning shop during the time they used the exposure badge or if they wore clothes that had been dry-cleaned within the last week or 7 days. If the second exam SP meets either criterion, select "Yes." If the second exam SP reports that they were not at a dry cleaners and have not worn clothes dry-cleaned within the last week, select "No." If the second exam SP refuses to answer, select "Refused." If the SP second exam does not know or cannot remember if they were at a dry cleaning shop or wore clothes dry cleaned within the last week, select "Don't know."</p>
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Q10: During the last three days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors? [Yes, No, Refused, Don't know]

<p>Q10: This question asks the second exam SP to report if they have spent 10 or more minutes near wood-burning fires either indoors or outdoors during the last 3 days.</p>	<p>Include wood-burning devices such as wood stoves, fireplaces, and outdoor pits or fires. If the second exam SP meets any of these criteria, select "Yes." If the second exam SP reports that they have not been around any of these sources of wood fires, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they spent any time near wood burning fires while using the exposure badge, select "Don't know."</p>
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Q11: During the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe? [Yes, No, Refused, Don't know]

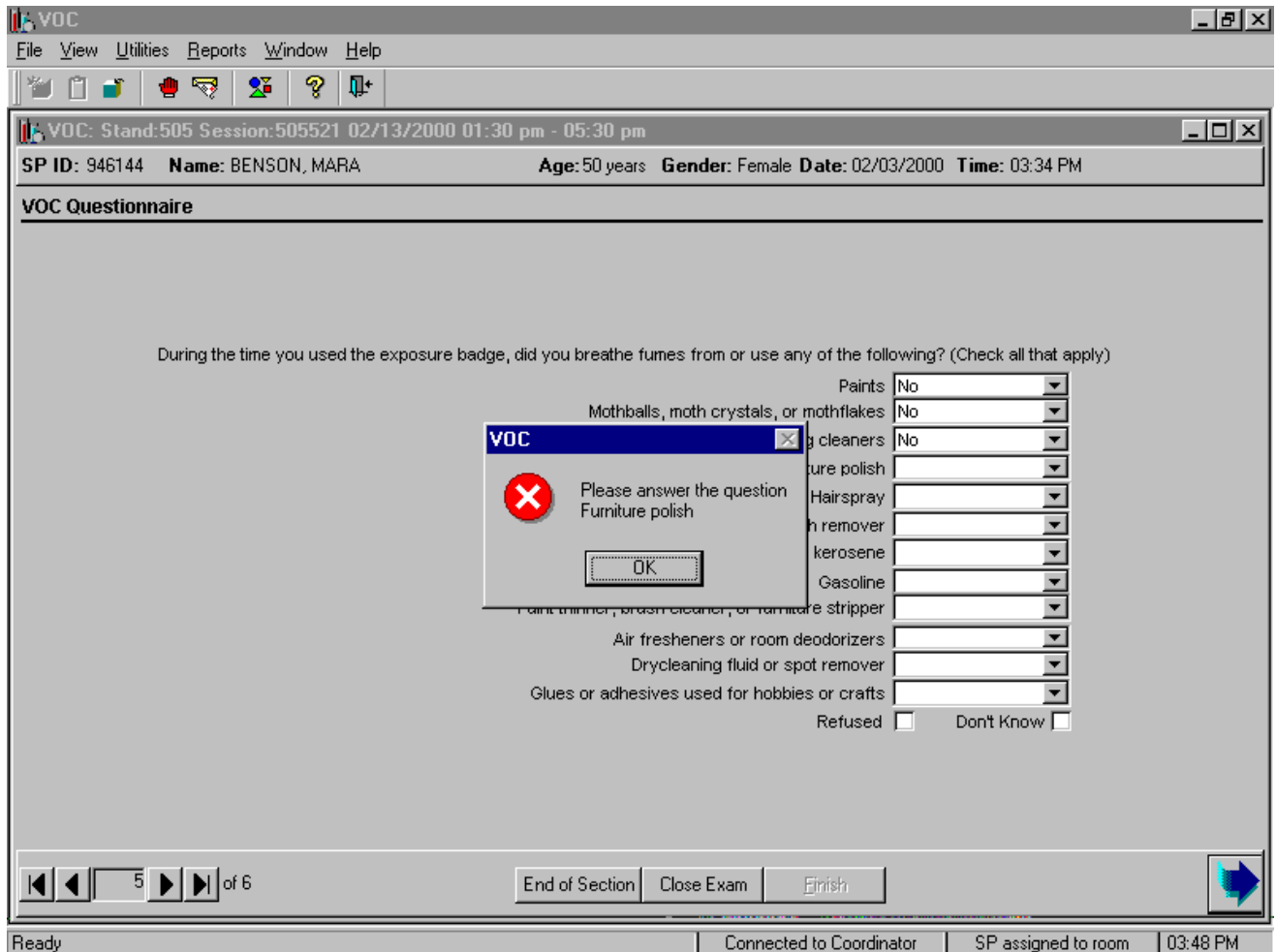
<p>Q11: This question asks the second exam SP to report if they have spent 10 or more minutes near any person who was smoking cigarettes, cigars or a pipe during the last 3 days.</p>	<p>Include any brand of cigarette, any size of cigar, or any style of pipe. If the second exam SP meets any of these criteria, select "Yes." If the second exam SP reports that they have not been around any of these sources of smoke, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they spent any time near someone who was smoking these forms of tobacco while using the exposure badge, select "Don't know."</p>
--	---

Q12: In the last three days, did you take a hot shower for five minutes or longer? [Yes, No, Refused, Don't know]

<p>Q12: This question asks the second exam SP to report if they took a hot shower for at least 5 minutes during the last 3 days.</p>	<p>Determine if the second exam SP took a hot shower for at least 5 minutes. If the second exam SP reports taking a hot shower for a total of at least 5 minutes, select "Yes." If the second exam SP reports taking a cold or warm shower or a hot shower for less than 5 minutes, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall taking a hot shower for at least 5 minutes, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
--	---

To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.



Continue to enter responses for each item. If the bright blue arrow in the navigation bar or [Enter] is inadvertently selected, an error message text box displays. Review the text and, to remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

Q13: In the last three days, did you breathe fumes from any of the following? [Yes, No, Refused, Don't know]

<p>Q13: This question asks the second exam SP to report if they breathed fumes from a variety of sources during the last 3 days.</p>	<p>Individually determine if the second exam SP breathed fumes from each source. Record each answer. If the second exam SP reports breathing fumes from an item while using the exposure badge, select "Yes." If the second exam SP reports s/he did not breath fumes while using the exposure badge, select "No." If at any point during the interview the second exam SP refuses to answer any further questions, select the "Refused" square. If the second exam SP does not know or cannot recall breathing fumes while using the exposure badge, select "Don't know" or if the second exam SP reports they do not know the answer to all the remaining choices, select the "Don't know" square. Select the bright blue arrow to proceed to the last window.</p>
<p>Paints</p>	<p>Include all interior and exterior paints, spray paints used in arts and crafts, and oil-based artist paints.</p>
<p>Mothballs, moth crystals, or mothflakes</p>	<p>Mothballs are composed of a ball of camphor or naphthalene. They are used for protection of clothes from moths.</p>
<p>Household disinfectant or degreasing cleaners</p>	<p>Consider all disinfectants including Lysol® and PineSol®.</p>
<p>Furniture polish</p>	<p>Consider Pledge®, Liquid Gold, and lemon polish and all other brands of furniture polish.</p>
<p>Hairspray</p>	<p>Consider all brands of hairspray.</p>
<p>Fingernail polish or fingernail polish remover</p>	<p>Nail polish and nail polish remover contains acetone.</p>
<p>Diesel fuel or kerosene</p>	<p>Diesel fuel is a crude oil. Kerosene is a hydrocarbon oil, chiefly of the methane series, used for burning in lamps. It is also called coal oil.</p>
<p>Gasoline</p>	<p>Gasoline is a distillate of crude petroleum.</p>

Paint thinner, brush cleaner, or furniture stripper	These items contain turpentine.
Air fresheners or room deodorizers	Consider all spray types of air fresheners such as Airwick®, Glade®, and Lysol® and include the type that affixes to a wall or toilet or stands upright in a dispenser.
Dry-cleaning fluid or spot remover	Consider all spot removers like K2R.
Glues or adhesives used for hobbies or crafts	Glue is a viscid cement or adhesive preparation and is usually an impure gelatin derived from boiling certain animal substances. Hobby glue contains a significant amount of toluene.

To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Verify the status code for the second exam VOC examination.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505521 02/13/2000 01:30 pm - 05:30 pm

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 02/03/2000 Time: 03:34 PM

VOC Questionnaire

Status

Complete

Partial

Not Done

Comments

Other text

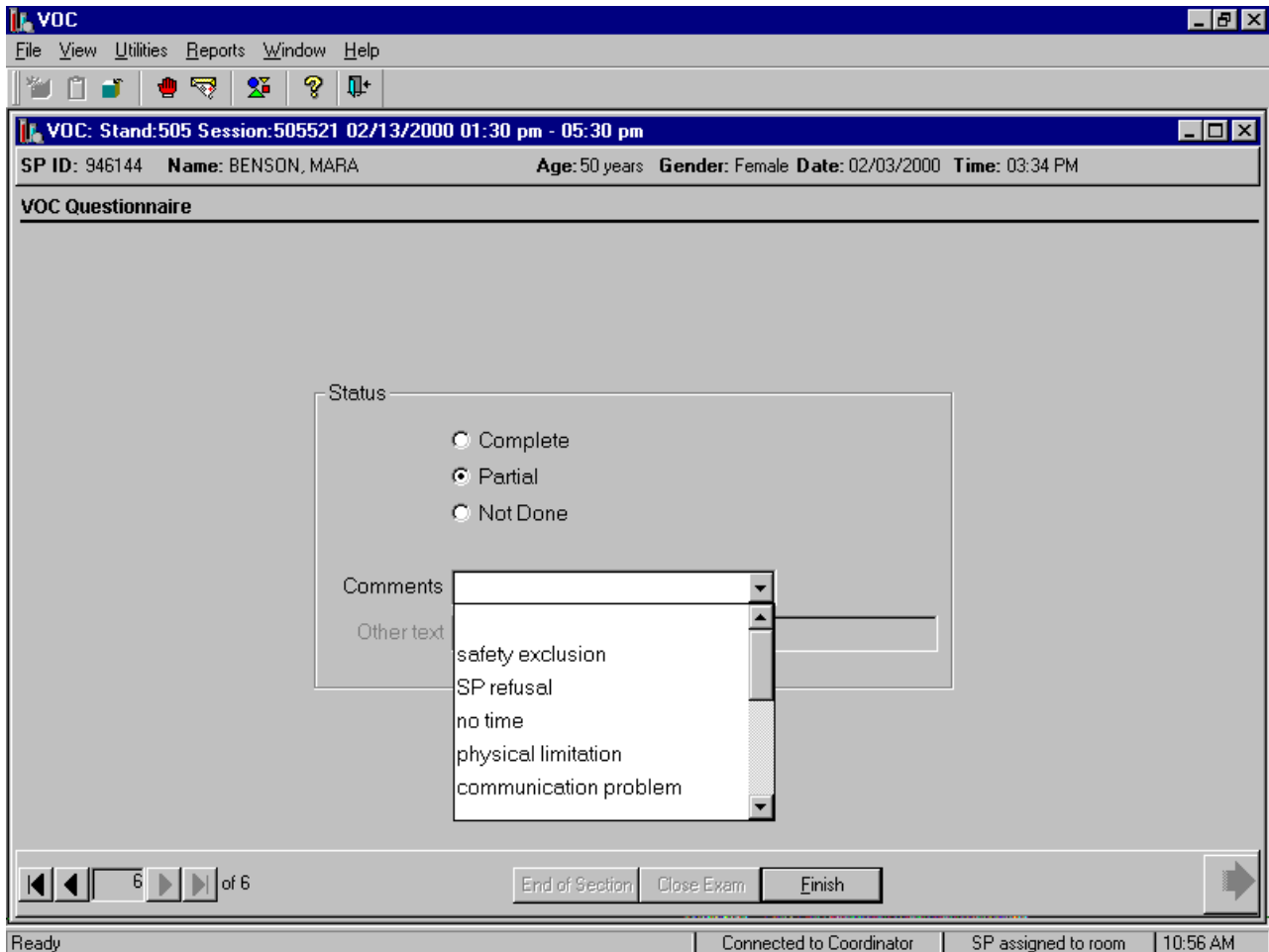
6 of 6

End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:56 AM

Comment codes are used to explain partial and not done status codes.

Choose and enter the appropriate Comment Code when section status is partial or not done.



To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice and left click. Alternatively to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If “Other, specify” is chosen, type a short explanation in the “Other text” text box.

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the

	reception area, the coordinator can code the exam. If the SP refuses after starting the exam, the examiner will code the exam.
no time	Not applicable
physical limitation	The venipuncture is unsuccessful
communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	Not applicable
other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the VOC examination, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted. Escort the SP back to the coordinator.

A.7 Reviewing an Exam

Review a completed exam. Access the Review module.

- To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F], [V]. The Session PickUp list displays.

Select the session.

- The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Select the SP.

- The SP Login window displays. To view a list of previously examined SPs, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.

- The Sample Person ID and Sample Person Name text boxes fill in with the SP ID and SP ID-last name. To continue, use the mouse to direct the mouse arrow to the **Retrieve** button and left click, or select [Enter]. To exit, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue to select the SP.

- Once the **Retrieve** button is selected, the remaining data in the SP Login box fills in. To move forward and to review the exam, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. The phlebotomy exam windows with results are displayed. To progress through the windows, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

After the phlebotomy protocol window is displayed and the bright blue arrow in the bottom right hand corner is selected, a Print Labels message text box displays.

- The Print Labels informational message text box displays the following message; “Data is already present. Do you wish to print labels?” To reprint the labels, use the mouse to direct the mouse arrow to the **Yes** button and left click, or select [Enter]. To decline the opportunity to reprint labels, use the mouse to direct the mouse arrow to the **No** button and left click. The venipuncture status window displays. To finish, select [Enter] or use the mouse to direct the mouse arrow to the **End of Section** button and left click.

A.8 Performing the Venipuncture, and Administering the Primary and Second Exam Questionnaire on SPs Who Do Not Speak English

When the phlebotomist performs the venipuncture procedure on a primary or second exam SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the SP’s language assists the phlebotomist. When the MEC interviewer or TB reader must

administer either the primary or second exam questionnaire to a SP who does not speak English and the MEC interviewer or TB reader does not speak the language of the SP, a translator who does speak the SP's language assists the MEC interviewer or TB reader.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the venipuncture.

Convert the phlebotomy interview and fasting questionnaire text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

SP ID: 687219 Name: SPARKS, TODD Age: 30 years Gender: Male Date: 02/02/2000 Time: 11:01 AM

VOC Questionnaire for Day 2 Exam

Ahora le voy a hacer algunas preguntas acerca de sus actividades durante los últimos tres días. Esto significa hoy, ayer, o antes de ayer.

En los últimos tres días, ¿le echó gasolina usted mismo a un automóvil u otro vehículo automotor?

En los últimos tres días, ¿pasó algún tiempo en una (alberca/piscina)?

En los últimos tres días, ¿visitó una lavandería de lavado en seco o usó ropa que había sido lavada en seco dentro de la última semana?

En los últimos tres días, ¿pasó 10 minutos o más cerca del fuego de una chimenea de leña, una estufa de leña, adentro o afuera del hogar?

En los últimos tres días, ¿pasó 10 minutos o más cerca de una persona que estaba fumando (cigarro/cigarrillo), (puro/cigarro/tabaco), o pipa?

En los últimos tres días, ¿se dio una ducha o baño caliente por cinco minutos o más?

2 of 4

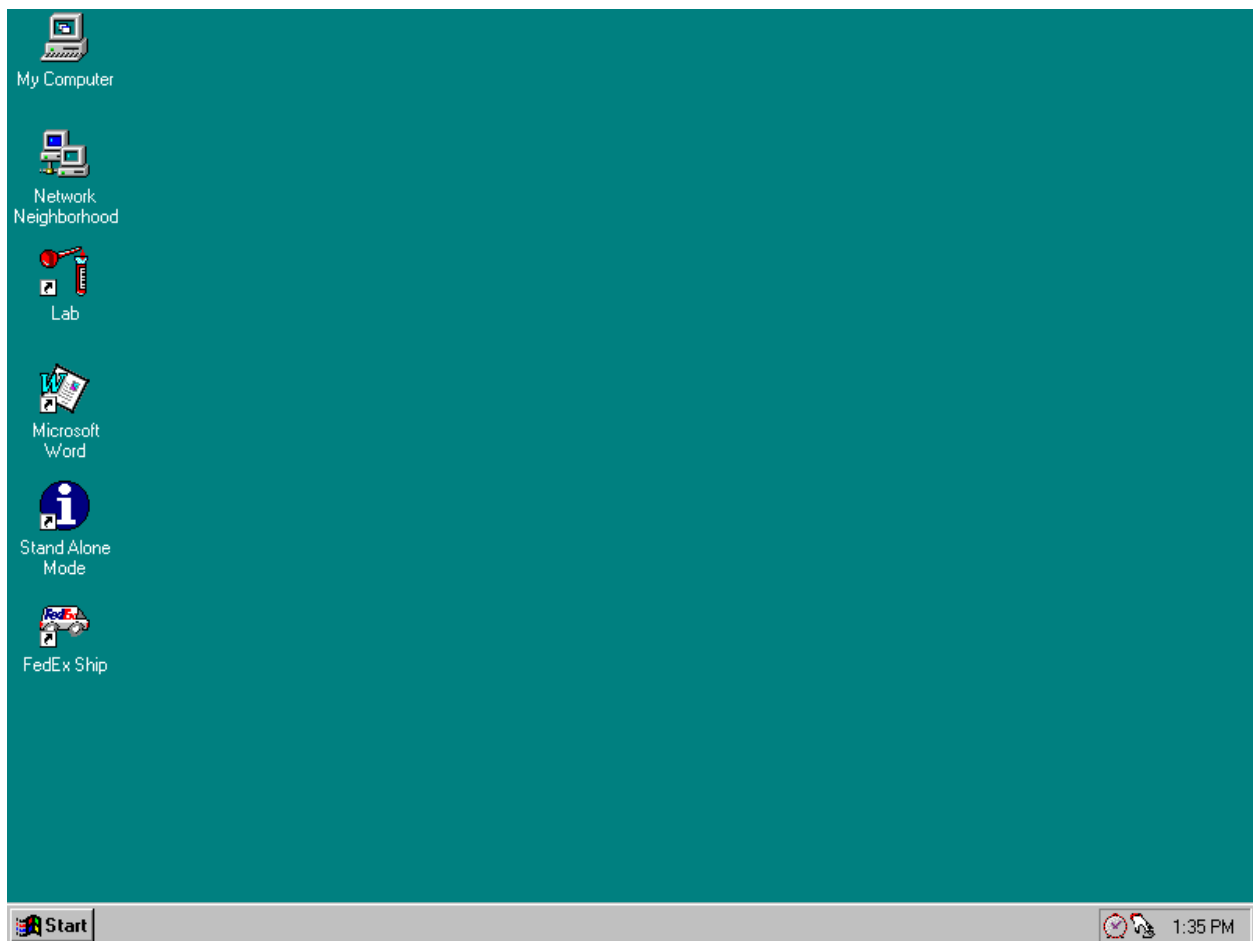
End of Section Close Exam Finish

Ready Connected to Coordinator SP assigned to room 10:56 AM

To view the phlebotomy interview, fasting questions, or questionnaires in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S]. To return the phlebotomy interview, fasting questions, or questionnaire to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E].

A.9 Processing VOC Specimens (Vessels) in the Laboratory

Open the laboratory application, select the correct session, and review the heads-up display.



To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

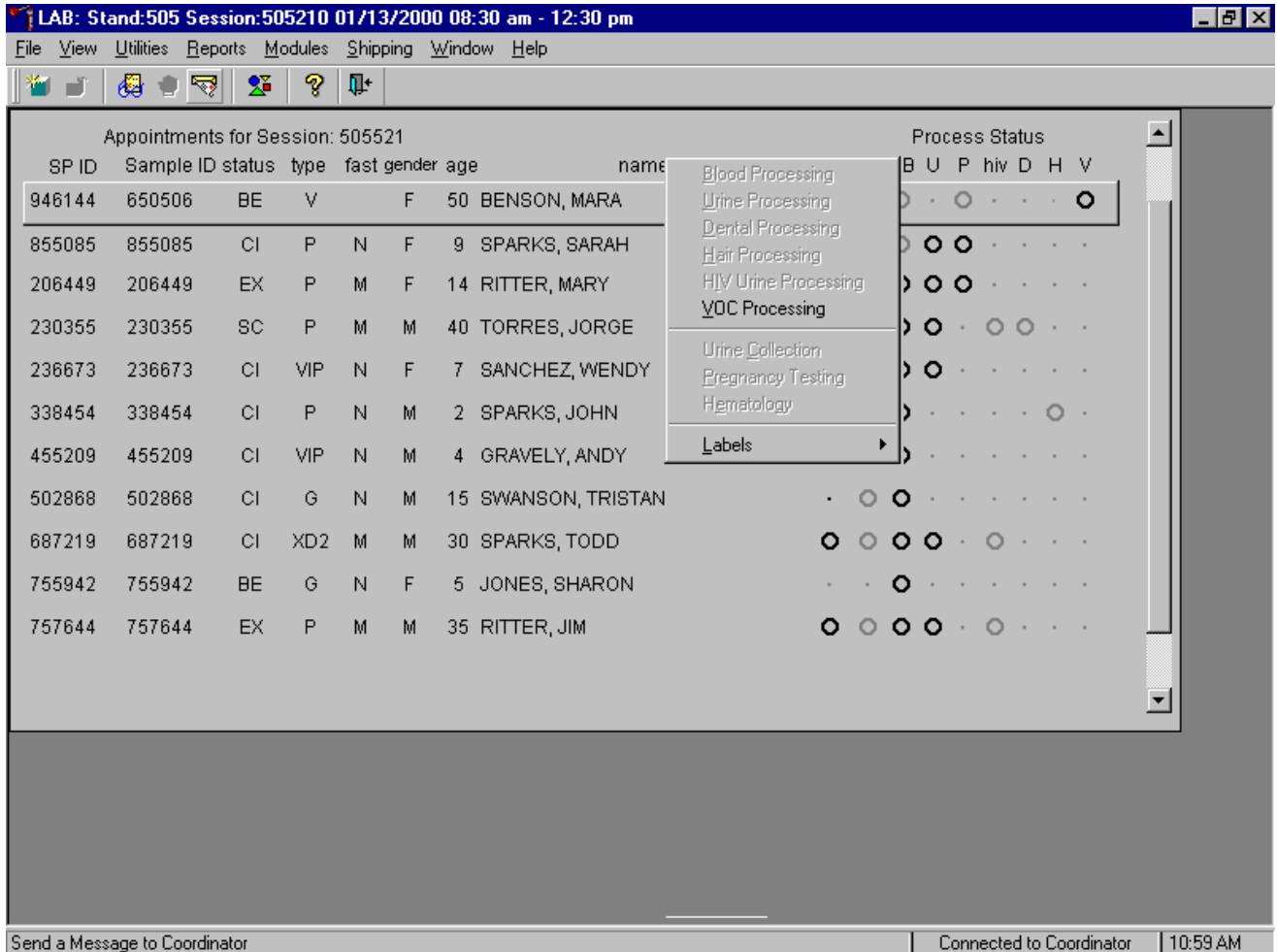
status is ☉. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●. The SP is eligible for a module but the process status is O until the SP's blood, dental saliva, and hair samples are recorded as collected. Once the sample is collected, the process status will change from O to ○.

Table A-1 illustrates the VOC processing and storage protocol.

Table A-1. VOC processing and storage protocol

Vessel No	Assay	Age in years	Sample size mL	Collection Type	Vessel Storage
54	VOC Blood	20-59	7	7-mL Gray top	1 x 5 foam mailer
55	VOC Blood	20-59	7	7-mL Gray top	1 x 5 foam mailer
56	VOC Water	20-59	10	10-mL Glass	1 x 3 foam mailer
57	VOC Badge	20-59	48 hour	Badge	12 x 12 Plastic bag

Access the VOC processing module.



To access the VOC processing module, use the mouse to direct the mouse arrow to the correct SP and right click, drag the mouse arrow to {VOC Processing} and right click or type [V]. Alternatively to access the VOC processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {VOC Processing} and left click or type [V].

The VOC processing window displays.

Appointments for Session: 505521 Process Status

VOC: 650506

94 none

94

20

23

23

33

45

50

66

75

75

85

Tech ID: 1226	Sample ID: 650506	Name: BENSON, MARA		Gender: F	Age: 50				
	SP ID: 946144	SubSample: 3		Fasting_Req:					
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled		Container ID	Slot#
54	VOC Blood	7	VW	7 ml	gray top	<input type="radio"/> Yes	<input type="radio"/> No		
55	VOC Blood	7	VW	7 ml	gray top	<input type="radio"/> Yes	<input type="radio"/> No		
56	VOC Water	10	H2	10 ml	glass vial	<input type="radio"/> Yes	<input type="radio"/> No		
57	VOC Badge	48	EB	1 badge	badge	<input type="radio"/> Yes	<input type="radio"/> No		

Save OK Cancel

Ready Connected to Coordinator 04:02 PM

Compare the Sample ID on the window to the bar code label on the vessels.

Mark each vessel as filled, yes or no.

The screenshot shows a software window titled 'LAB' with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main window is titled 'Appointments for Session: 505521' and contains a sub-window for 'VOC: 650506'. The sub-window displays patient information: Tech ID: 1226, Sample ID: 650506, Name: BENSON, MARA, Gender: F, Age: 50, SP ID: 946144, SubSample: 3, and Fasting_Req: . Below this is a table of vessels with columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled (Yes/No radio buttons), and Container ID/Slot#.

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
54	VOC Blood	7	VW	7 ml	gray top	<input checked="" type="radio"/> Yes <input type="radio"/> No	0305444	1
55	VOC Blood	7	VW	7 ml	gray top	<input checked="" type="radio"/> Yes <input type="radio"/> No	0305445	1
56	VOC Water	10	H2	10 ml	glass vial	<input type="radio"/> Yes <input type="radio"/> No		
57	VOC Badge	48	EB	1 badge	badge	<input type="radio"/> Yes <input type="radio"/> No		

At the bottom of the sub-window are buttons for 'Save', 'OK', and 'Cancel'. The status bar at the bottom of the main window shows 'Ready', 'Connected to Coordinator', and '04:02 PM'.

To individually mark each vessel as filled or not filled, use the mouse to direct the mouse arrow to the Yes or No radio button for a specific vessel ID (or test), and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container. Store each vessel in the correct slot in the correct container. To record these actions or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S]. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Review the heads-up display.

LAB: Stand:505 Session:505210 01/13/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

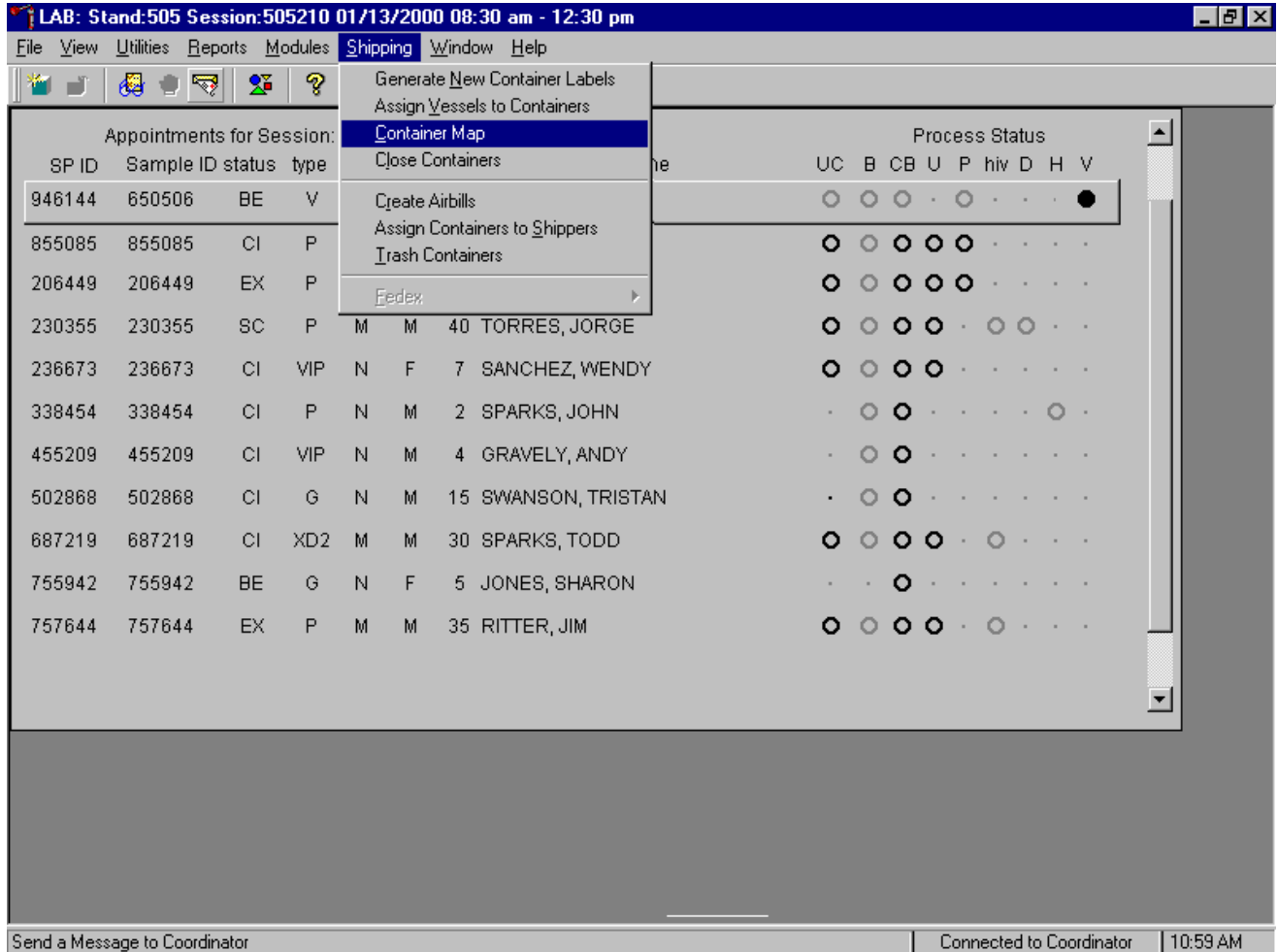
Appointments for Session: 505521

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status									
								UC	B	CB	U	P	hiv	D	H	V	
946144	650506	BE	V		F	50	BENSON, MARA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
855085	855085	CI	P	N	F	9	SPARKS, SARAH	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
206449	206449	EX	P	M	F	14	RITTER, MARY	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
230355	230355	SC	P	M	M	40	TORRES, JORGE	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
236673	236673	CI	VIP	N	F	7	SANCHEZ, WENDY	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
338454	338454	CI	P	N	M	2	SPARKS, JOHN	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
455209	455209	CI	VIP	N	M	4	GRAVELY, ANDY	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
502868	502868	CI	G	N	M	15	SWANSON, TRISTAN	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
687219	687219	CI	XD2	M	M	30	SPARKS, TODD	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
755942	755942	BE	G	N	F	5	JONES, SHARON	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
757644	757644	EX	P	M	M	35	RITTER, JIM	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Send a Message to Coordinator | Connected to Coordinator | 10:59 AM

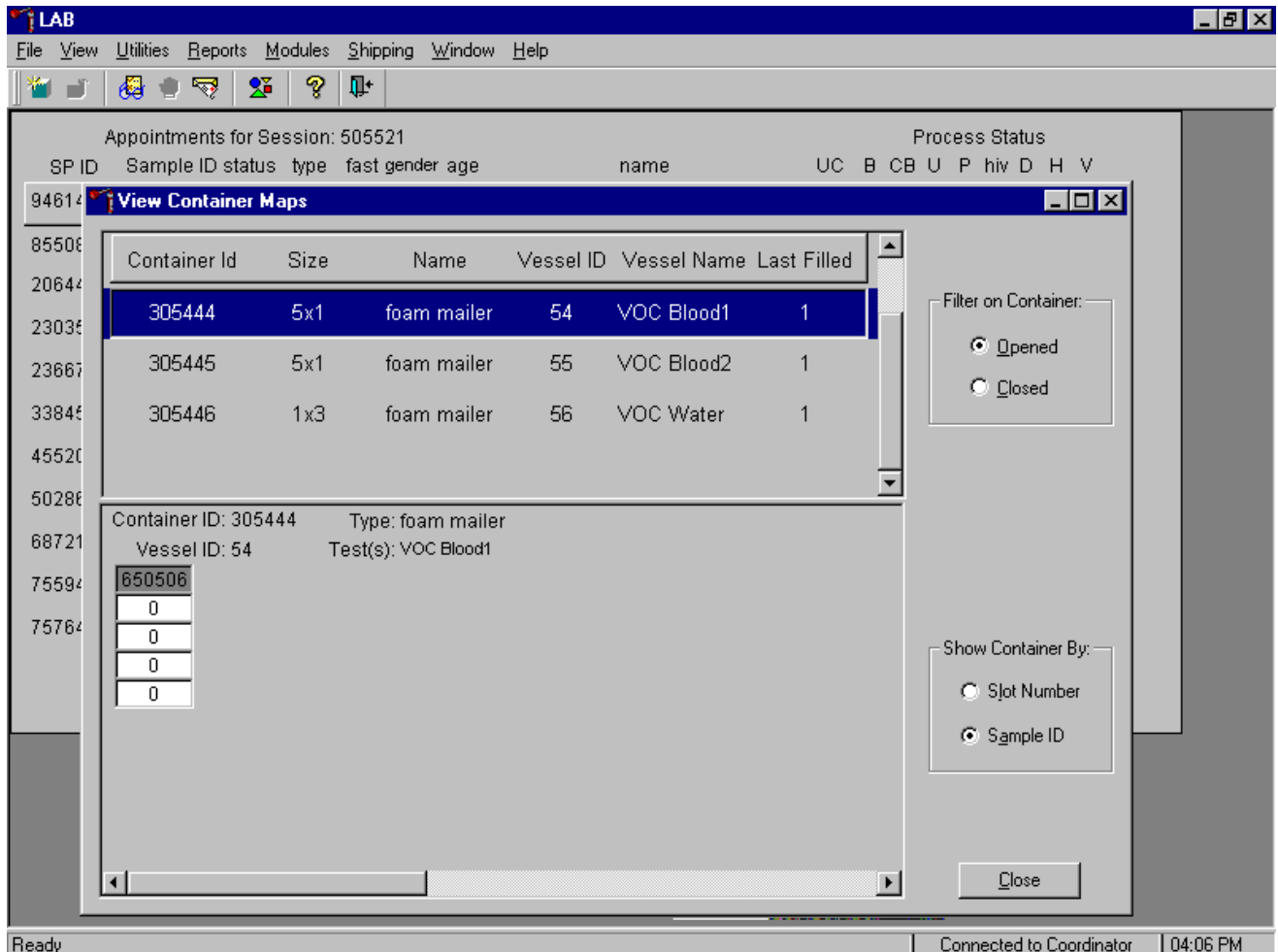
Verify that the heads-up display is updating correctly.

Check the slot assignment of containers associated with vessels 54-57, at the end of each session.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping}, drag the arrow to {Container Map} and left click or type [Alt] [S], [C].

Verify the contents of each container against the container map.



- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to “Opened” and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to “Sample ID” and left click.
- Highlight or select the container ID for vessel 54 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 54.
- To sort on Container ID, Size, Name, Vessel ID, Vessel Name, or Last Filled, use the mouse to direct the mouse arrow to any column title and right click. To reverse the order, use the mouse to direct the mouse arrow to the column title and right click.

- Verify the container ID on the box against the container ID listed on the window and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for vessels 55, 56, and 57.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

A. 10 Quality Control

The are four types of weekly VOC quality control (QC): repeat participant, field monitoring, positive controls, and office air monitoring. Conduct one of each QC type weekly according to the following schedule. The phlebotomist is responsible for the repeat participant, the laboratory is responsible for the positive control, and the MEC interviewers are responsible for the field monitoring and the room air monitoring.

A.10.1 Week 1 – Repeat Participant

The phlebotomist recruits two primary SPs who is asked to wear two badges for the entire 46-76 hours, one on each side of the lapel. The primary SP returns to the MEC 46-76 hours later. The phlebotomist collects two tubes of blood, both badges, one water sample, and administers the VOC questionnaire. Labels print on the Intermec printer in the phlebotomy room and all specimens are delivered to the laboratory. The laboratory processes the samples using the heads-up window (identical to dry run samples since the duplicate badge is blinded to the analysis laboratory.) Only primary SPs who are eligible for MEC return appointments are eligible to be recruited as the repeat participant.

Recruit two SPs per stand as repeat participants.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a sub-header: "Phlebotomy: Stand:505 Session:505070 12/30/1999 08:30 am - 12:30 pm". A status bar displays: "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 01:52 PM". The main content area is titled "VOC Introduction" and contains the following form fields:

- Will you participate in this special study? Yes (dropdown menu)
- Airbadge Number: 946144 (text input)
- Airbadge Lot No: 64422 (text input)
- Expiration Date: 10/31/2004 (text input)
- Repeat Participant (button)

At the bottom of the form, there are navigation controls: "1 of 3" (page indicator), "End of Section", "Close Exam", "Finish" (buttons), and a blue arrow icon.

System status bar at the bottom: Ready | Connected to Coordinator | SP assigned to room | 01:52 PM

Enter the initial recruitment response, record the airbadge number, airbadge lot number, and expiration date in a manner identical to routine VOC SPs. Assess the SPs return appointment date and time and their willingness to participate. If the SP is eligible to return to the MEC and appears interested, ask if they would be willing to wear two badges, one on each side of their lapel.

Access the repeat participant QC function.

The screenshot shows the Phlebotomy software interface. The title bar reads "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for navigation and actions. The main window title is "Phlebotomy: Stand:505 Session:505070 12/30/1999 08:30 am - 12:30 pm". Below this, a status bar displays "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 01:52 PM". The main content area is titled "VOC Introduction" and contains a form with the following fields: "Will you participate in this special study?" with a dropdown menu set to "Yes", "Airbadge Number:" with the value "946144", "Airbadge Lot No:" with the value "64422", and "Expiration Date:" with the value "10/31/2004". A "Repeat Participant" button is located to the right of these fields. At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:52 PM".

To access the repeat participant QC function, use the mouse to direct the mouse arrow to the **Repeat Participant** button and left click. A second set of response boxes appears.

Enter the information for the second badge.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "Phlebotomy: Stand:505 Session:505070 12/30/1999 08:30 am - 12:30 pm". Below the header bar is a status bar with the text "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 01:52 PM". The main area is titled "VOC Introduction" and contains a form with the following fields:

Will you participate in this special study?	Yes		
Airbadge Number:	535881	535881	
Airbadge Lot No:	64422	64422	
Expiration Date:	10/31/2004	10/31/2004	Cancel

At the bottom of the form, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "01:54 PM".

Enter the information for the second badge including the airbadge number, airbadge lot number, and expiration date in a manner identical to all routine primary VOC SPs. If the SP changes their decision, use the mouse to direct the mouse arrow to the **Cancel** button and left click. The second set of response boxes disappears and the **Repeat Participant** button becomes bold or active again. Continue to recruit two primary SPs as repeat participants. Once the second primary SP is recruited, the **Repeat Participant** button disappears. Continue the routine recruitment process by scheduling the return appointment, verifying the examination status, and escorting the primary SP back to the coordinator. The MEC interviewer attaches both badges to the primary SP as the SP exits the MEC.

The repeat participant returns to the MEC for their return appointment.

The screenshot shows the VOC application window. The title bar reads "VOC". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below this, a header displays "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields:
Sample ID: 372425
Number of 7 ml gray (VOC) tubes collected: 0 of 2 (with up/down arrows)
Exposure badge collected: [dropdown menu]
Water sample collected?: [dropdown menu]
Comment: [text input field]
Other specify [text input field]
A "Repeat Participant" button is located to the right of the exposure badge field. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish", along with a blue arrow icon. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:16 PM".

Log the repeat participant into the VOC application. The window displays the appropriate venipuncture protocol. Draw two 7-mL gray top tubes using procedures described in Chapter 4.

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes by placing the bar coded label on the tube. Pass the blood tubes through the window to the laboratory.

Record collection of the repeat participant's first exposure badge.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Underneath the header bar, participant information is displayed: "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields and controls:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes (dropdown menu)
- Water sample collected? (dropdown menu)
- Comment: (text input field)
- Other specify (text input field)
- Repeat Participant (button)

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow button. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:17 PM".

To record yes or no type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. In the MEC the labels generate automatically on the printer in the phlebotomy room for "Yes" responses.

Reassemble the badge. Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.

Record collection of the repeat participant's water vessel.

The screenshot shows the VOC software interface. The title bar reads "VOC". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below this, a status bar displays "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes
- Water sample collected?: Yes (dropdown menu is open showing "Yes" and "No" options)
- Comment: [text input field]
- Other specify: [text input field]

Buttons include "Repeat Participant", "End of Section", "Close Exam", and "Finish". A navigation bar at the bottom shows "1 of 6" and a blue arrow icon. The system tray at the bottom indicates "Ready", "Connected to Coordinator", "SP assigned to room", and "02:17 PM".

Record collection of the repeat participant's water vessel. To record yes or no, type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. A label prints for "Yes" responses.

Record collection of the second (repeat) exposure badge.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below the header bar is a status bar with the text "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields and buttons:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes (dropdown menu)
- Water sample collected? Yes (dropdown menu)
- Comment: (text box)
- Other specify (text box)
- Repeat Participant (button)

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow button. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:19 PM".

To record collection of the second (repeat) exposure badge, use the mouse to direct the mouse arrow to the **Repeat Participant** button and left click. A second response text box displays next to the original text box.

Continue recording collection of the second (repeat) exposure badge.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar is a header bar with the text "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below the header bar is a status bar with the text "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields and controls:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes (dropdown menu)
- Water sample collected? Yes (dropdown menu)
- Comment: (text input field)
- Other specify (text input field)
- Repeat Participant (button)

At the bottom of the window, there is a navigation bar with the text "1 of 6" and buttons for "End of Section", "Close Exam", and "Finish". The system tray at the bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:19 PM".

To record yes or no, type [Y/y] for “Yes,” or [N/n] for “No.” Alternatively to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes” or “No” and left click. Labels generate automatically on the printer for “Yes” responses.

A second unique sample ID is assigned to the second badge.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below this, a header bar displays "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/09/2000 Time: 08:24 AM". The main area is titled "VOC Sample Collection" and contains the following fields and controls:

- Sample ID: 372425
- Sample ID: 376097
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes Yes (with a "Repeat Participant" button)
- Water sample collected? Yes
- Comment: [text input field]
- Other specify [text input field]

At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status bar showing "Ready", "Connected to Coordinator", "SP assigned to room", and "08:29 AM".

Note that there are two sample IDs, one for each badge. Reassemble and label the exposure monitoring badges.

- Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.
- Label one exposure badge with one set of labels and the second exposure badge with the second set of labels; each label set contains unique numbers. Label both sides of the exposure badge and the outside of the canister with the labels. Return the exposure badge

sections to the canister and replace the canister plastic lid. Label the glass water sample vessel vertically with bar coded labels. The badges and water are ready for transport to the laboratory.

Administer the VOC questionnaire, verify the status of the examination, and escort the SP back to the coordinator.

Process the repeat participant's samples in the laboratory in a manner identical to dry run vessels.

LAB: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

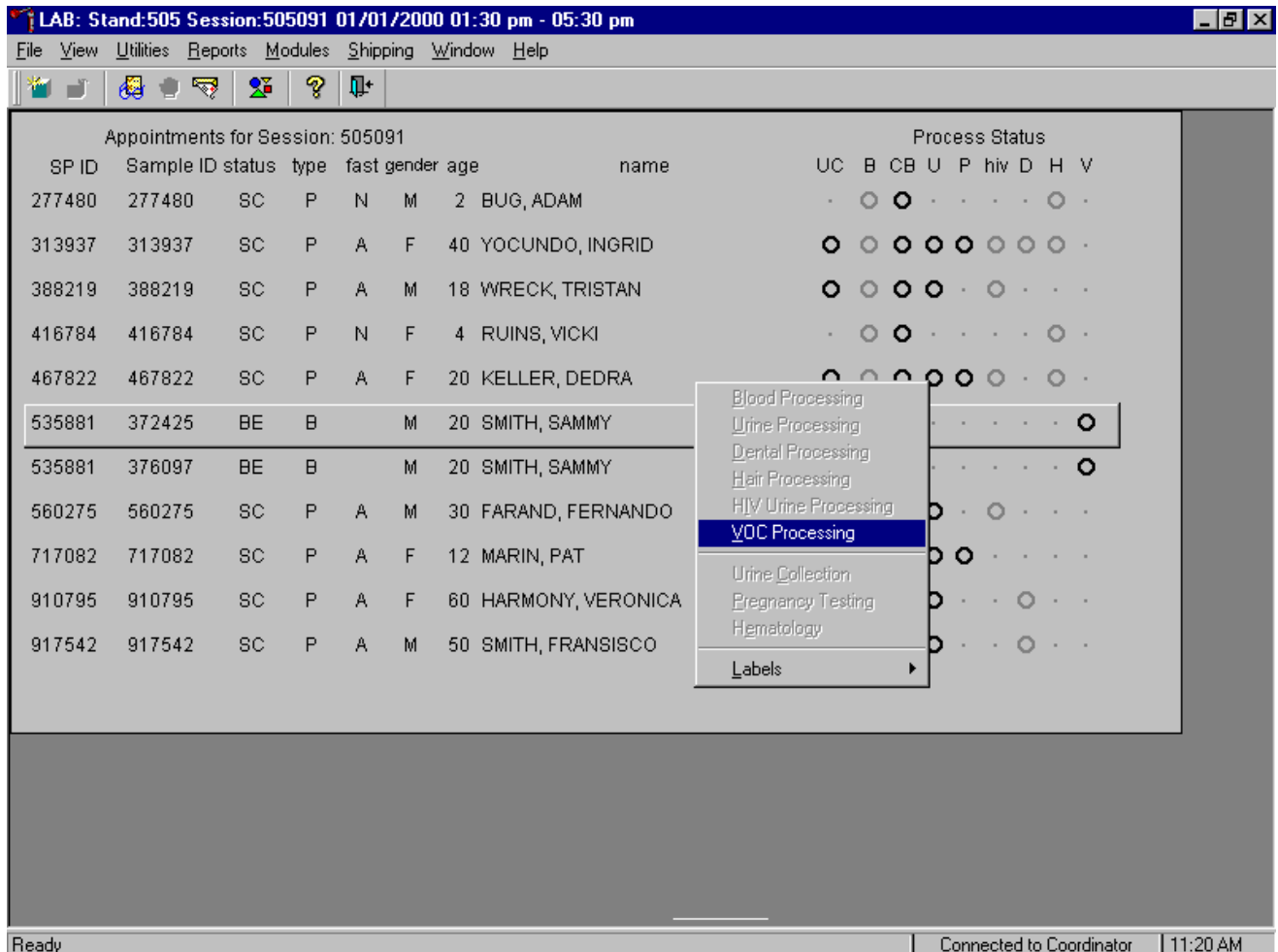
Appointments for Session: 505091

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status									
								UC	B	CB	U	P	hiv	D	H	V	
277480	277480	SC	P	N	M	2	BUG, ADAM	-	○	●	-	-	-	-	-	○	-
313937	313937	SC	P	A	F	40	YOCUNDO, INGRID	○	○	○	○	○	○	○	○	○	-
388219	388219	SC	P	A	M	18	WRECK, TRISTAN	○	○	○	○	-	○	-	-	-	-
416784	416784	SC	P	N	F	4	RUINS, VICKI	-	○	○	-	-	-	-	-	○	-
467822	467822	SC	P	A	F	20	KELLER, DEDRA	○	○	○	○	○	○	-	○	-	-
535881	372425	BE	B		M	20	SMITH, SAMMY	-	○	○	-	-	-	-	-	-	○
535881	376097	BE	B		M	20	SMITH, SAMMY	-	○	○	-	-	-	-	-	-	○
560275	560275	SC	P	A	M	30	FARAND, FERNANDO	○	○	○	○	-	○	-	-	-	-
717082	717082	SC	P	A	F	12	MARIN, PAT	○	○	○	○	○	-	-	-	-	-
910795	910795	SC	P	A	F	60	HARMONY, VERONICA	○	○	○	○	-	-	○	-	-	-
917542	917542	SC	P	A	M	50	SMITH, FRANSISCO	○	○	○	○	-	-	○	-	-	-

Ready | Connected to Coordinator | 11:17 AM

Locate the repeat participant on the laboratory heads-up display. Note that the SP is listed twice; one record is linked to the SP's blood, badge, and water samples and the second record is linked to the second badge. Each record is assigned unique sample IDs.

Select the correct SP and access the VOC Processing module.



To access the VOC Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {VOC Processing} and right click or type [V]. Alternatively to access the VOC processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {VOC Processing}, and right click or type [V].

The SP's VOC processing screen displays.

LAB: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505091 Process Status

VOC: 372425

2: none

3: Tech ID:1226 Sample ID: 372425 Name: SMITH, SAMMY Gender: M Age: 20

3: SP ID: 535881 SubSample:4 Fasting_Req:

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
54	VOC Blood	7	VW	7 ml	gray top	<input type="radio"/> Yes <input type="radio"/> No		
55	VOC Blood	7	VW	7 ml	gray top	<input type="radio"/> Yes <input type="radio"/> No		
56	VOC Water	10	H2	10 ml	glass vial	<input type="radio"/> Yes <input type="radio"/> No		
57	VOC Badge	48	EB	1 badge	badge	<input type="radio"/> Yes <input type="radio"/> No		

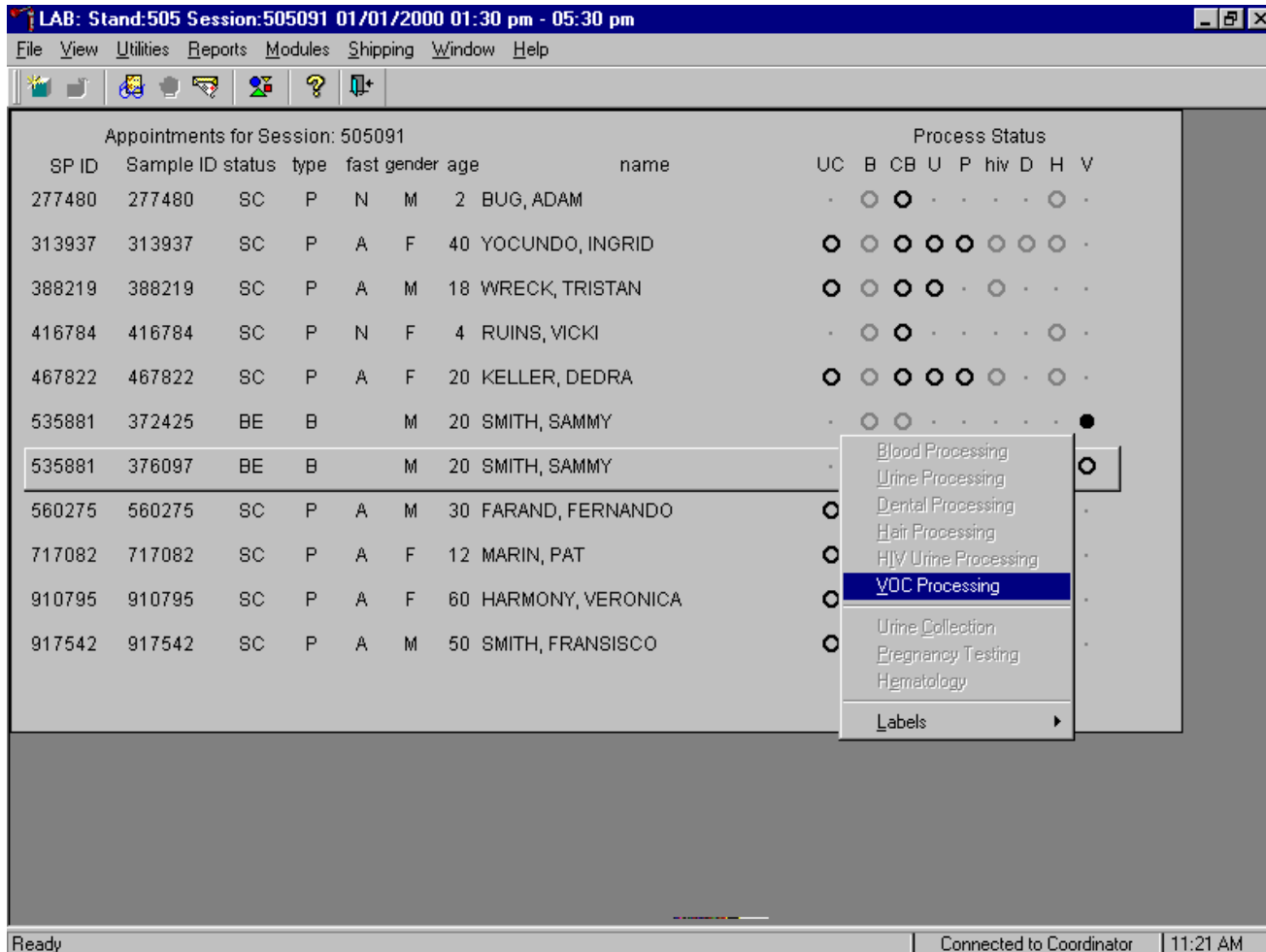
Save OK Cancel

Ready Connected to Coordinator 11:20 AM

The VOC processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample (4=VOC), Fasting_Req, columns for Vessel ID (54-57), Test Name, Sample Volume, Type (whole blood, H2, EB), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled yes and no and Radio buttons. Record VOC-processing results for the SP. Individually mark each vessel as Filled - "Yes" or Filled - "No." To mark an individual VOC vessel as collected or Filled - "Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As each vessel is marked as Filled - "Yes," it is automatically assigned to a slot in an existing (open) container. To mark an individual blood vessel as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the

Save button and left click or type [S]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Record the processing results for the second badge.



To access the VOC Processing module for the second badge, use the mouse to direct the mouse arrow to the SP's second line, right click, drag the mouse arrow to {VOC Processing} and right click or type [V]. Alternatively to access the VOC processing module for this SP, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {VOC Processing}, and right click or type [V].

The SP's second VOC processing screen displays.

Appointments for Session: 505091

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V	Process Status	
2774	VOC: 376097																	
3139	none																	

Tech ID: 1226 **Sample ID: 376097** **Name: SMITH, SAMMY** **Gender: M** **Age: 20**
SP ID: 535881 **SubSample: 4** **Fasting_Req:**

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
57	VOC Badge	48	EB	1 badge	badge	<input type="radio"/> Yes <input type="radio"/> No		

Buttons: Save, OK, Cancel

Status: Ready | Connected to Coordinator | 11:22 AM

Individually mark this vessel as Filled - "Yes" or Filled - "No." To mark this individual VOC vessel as collected or Filled - "Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As each vessel is marked as Filled - "Yes," it is automatically assigned to a slot in an existing (open) container. To mark this individual badge as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

A.10.2 Weeks 2 and 4 - Field Monitoring

MEC interview - Perform this QC during the first day of the second and fourth workweek. New (unopened and unexposed) badges are shipped to the MEC at the beginning of each stand. Open one canister in the phlebotomy room, immediately separate the front and back sections of the badge, immediately cap the front and back sections, and put both sections back into the canister. Snap the lid onto the canister. Write the current date, time, and “field monitoring” on the top of the canister. Allow the canister to remain in the phlebotomy room for 48 hours. After 48 hours, collect the canister, write the collection date and time on the top of the canister, and deliver it to the laboratory. In the laboratory, print labels for the field monitoring using the VOC QC Label module. Retrieve the start and end date and time from the top of the canister and record this information in the VOC QC Label module. Record the sample type as “field monitoring.” Process the field monitoring using the VOC QC module. Label the badge, immediately store in the refrigerator, and ship with routine samples.

A.10.3 Week 5 - Office Air Monitoring

MEC interview – Perform this QC during the first day of the fifth workweek. New (unopened and unexposed) badges are shipped to the MEC at the beginning of each stand. Open one canister in the area where the SPs clothes are stored and place or clip the badge in a space where it will not be disturbed or disrupted. Write the current date and time on the top of the canister. Collect the canister 46-76 hours later. Separate the front and back sections of the badge, immediately cap the front and back sections, and put both sections back into the canister. Snap the lid onto the canister. Write the data, time and “office air” on the top of the canister. Deliver the canister immediately to the laboratory. In the laboratory, print labels for the office air monitor using the VOC QC Label module. Retrieve the start and end date and time from the top of the canister and record this information in the VOC QC Label module. Record the sample type as “office air monitoring.” Process the office air monitor badge using the VOC QC module. Label the badge, immediately store in the refrigerator, and ship with routine samples.

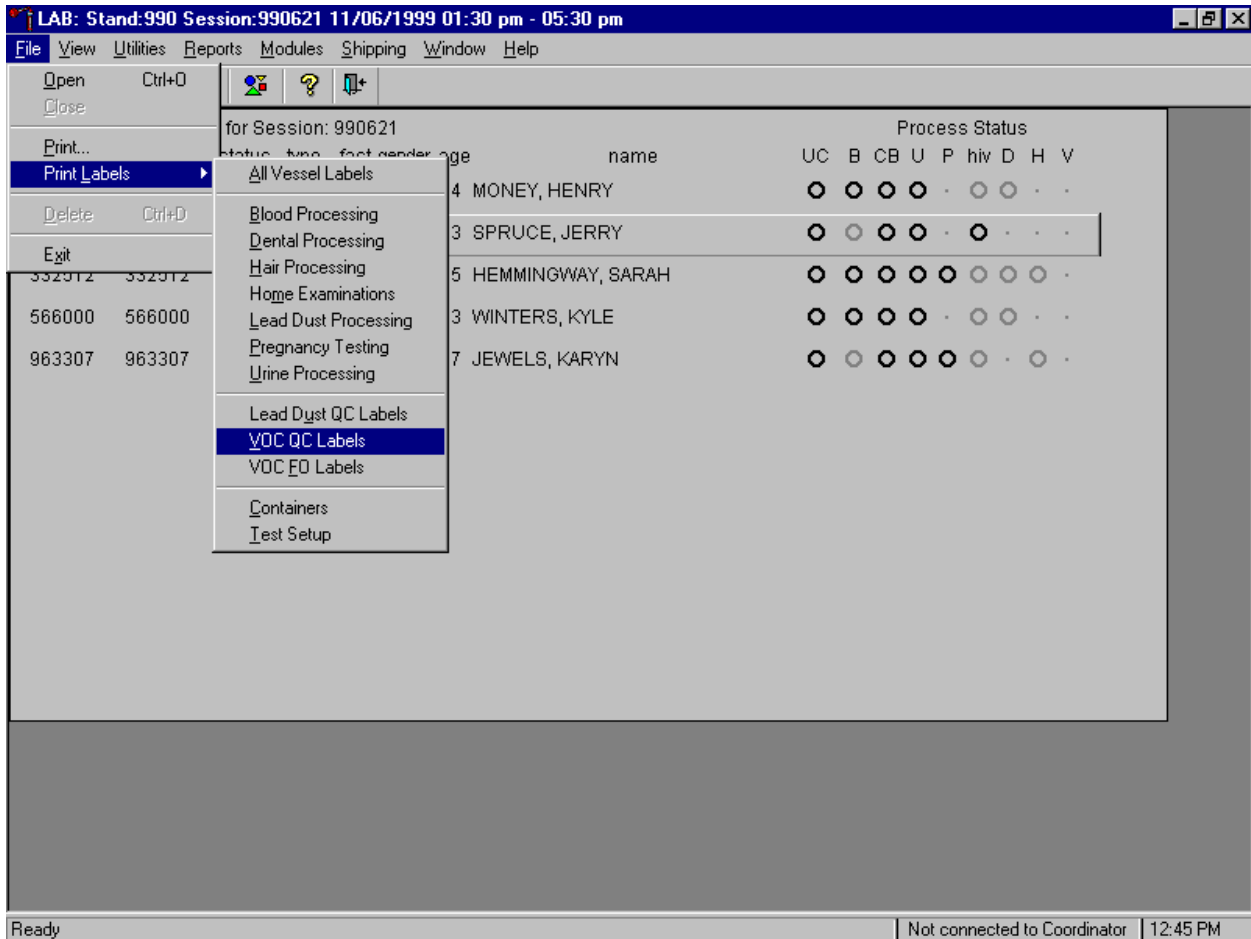
A.10.4 Week 3 - Positive Control

Laboratory – One positive control is received at the MEC at the beginning of the first week of each stand. Initially process the positive control using the Print VOC QC Labels module. Record the start and end date and time as the current date and time. Record the sample type as “positive control.” Document

collection using the VOC QC module; place the labeled canister in the laboratory refrigerator, and ship with routine badges.

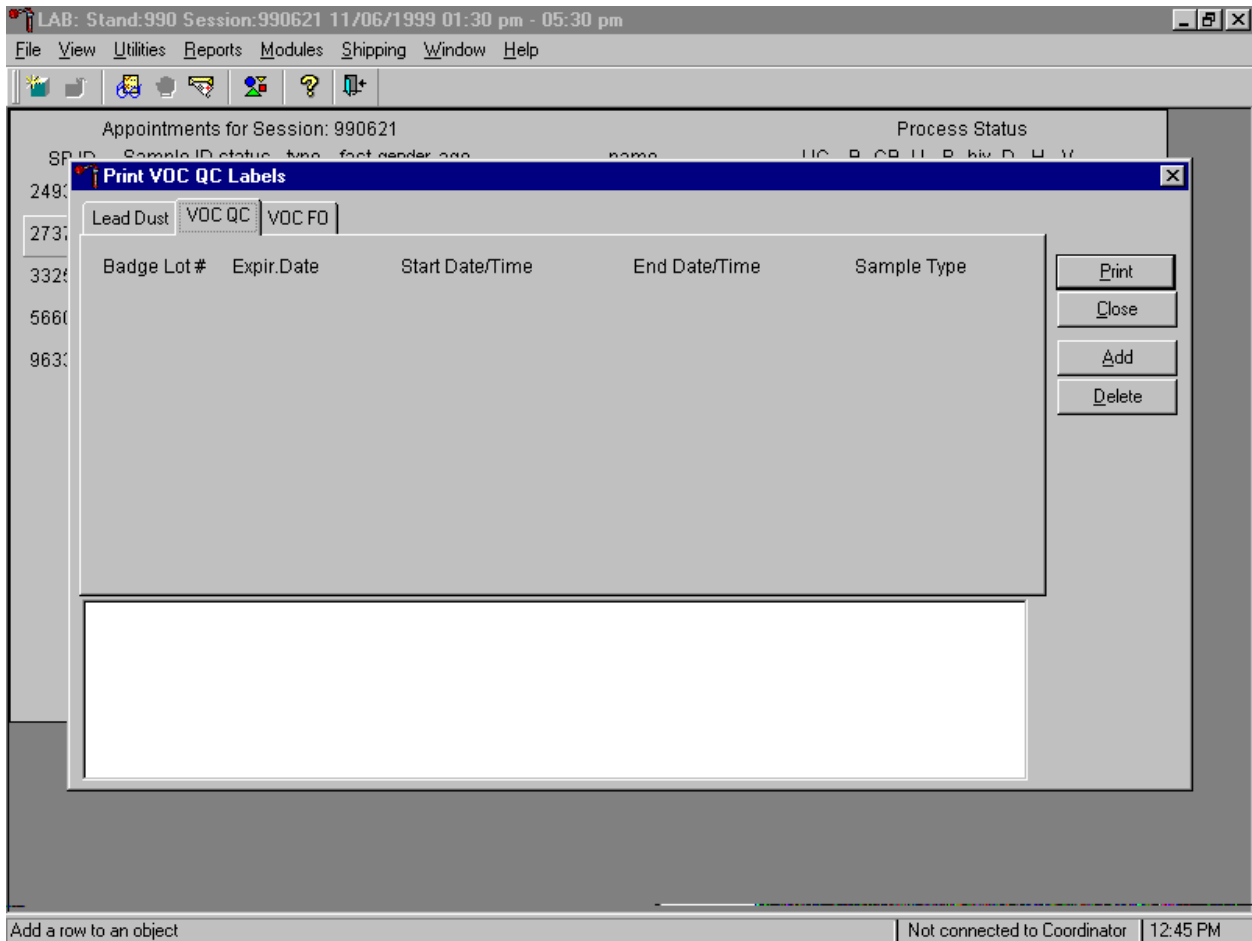
A.10.5 Processing QC Specimens (Vessels) in the Laboratory

Access the VOC QC Label functions.



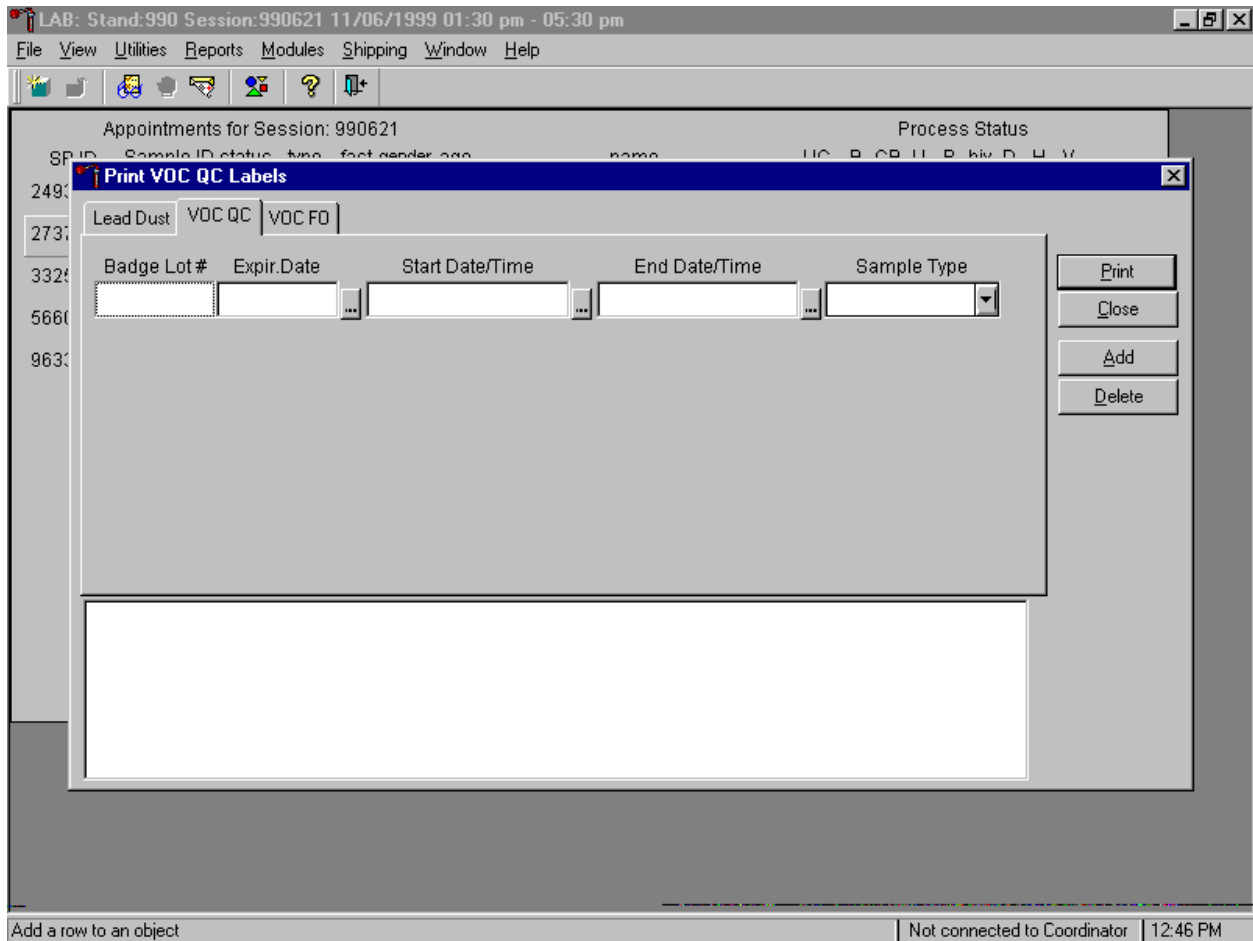
To access the VOC QC label function, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Print Labels}, then to {Print VOC QC labels}, and left click or type [Alt] [F] [L] [V].

The Print VOC QC Labels window displays.



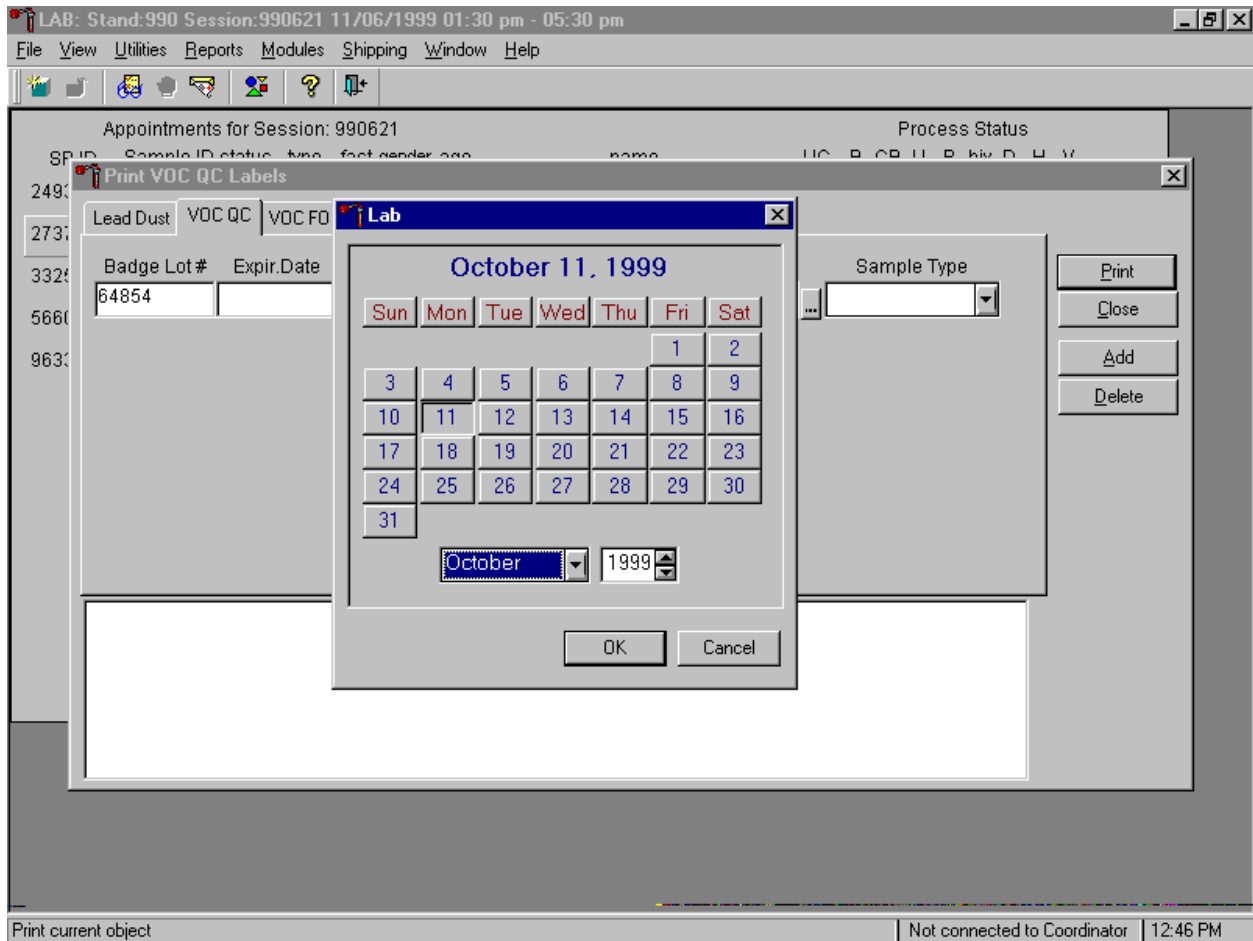
Use this module to print three types of QC labels: positive control, field monitoring, and office air monitoring. To print labels for VOC QC badges, use the mouse to direct the mouse arrow to the VOC QC file header and left click.

Continue to print labels for the VOC QC badges.



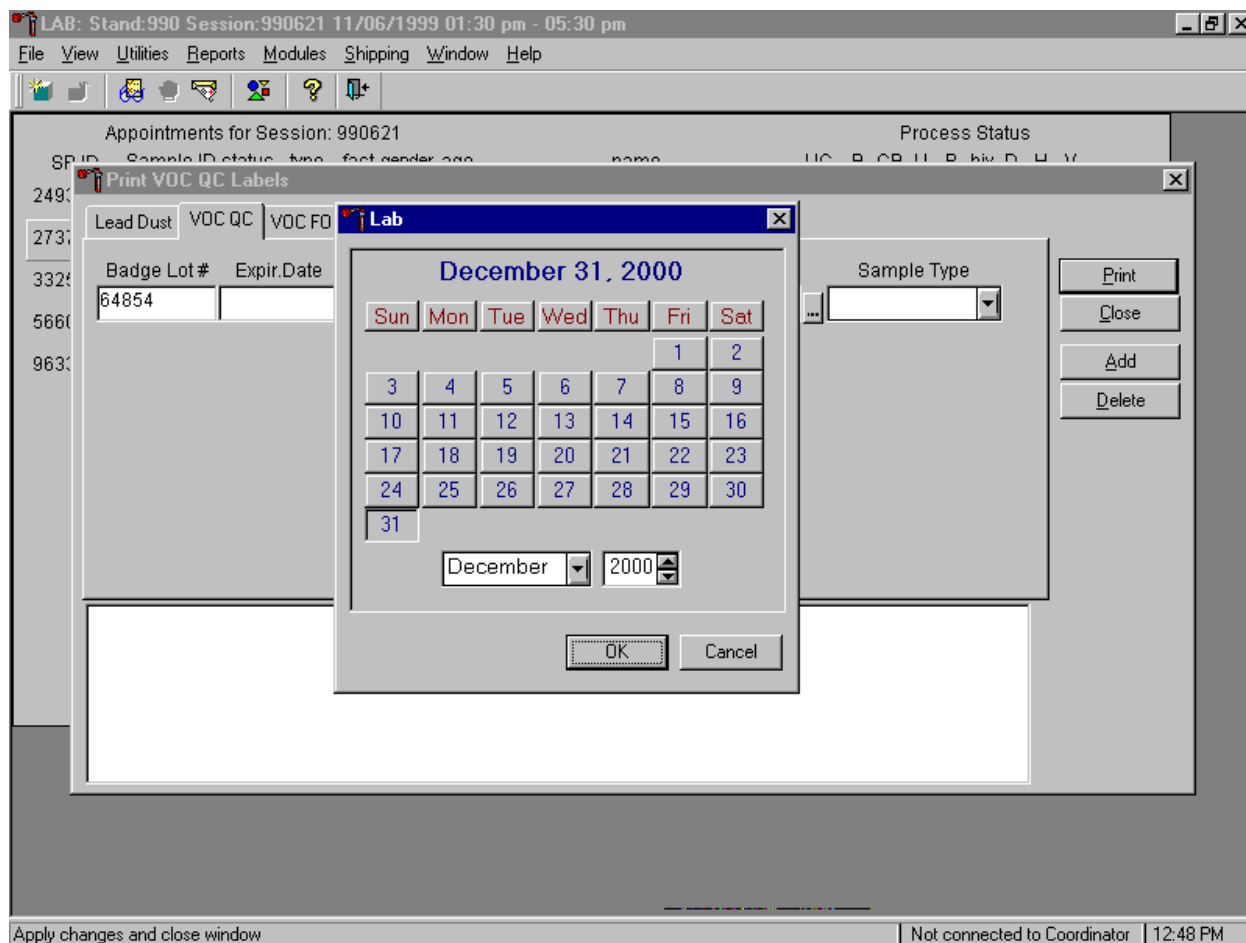
To continue the process, use the mouse to direct the mouse arrow to the **Add** button and left click or type [A]. One line is added to the VOC QC file.

Continue to print labels for the VOC QC badges.



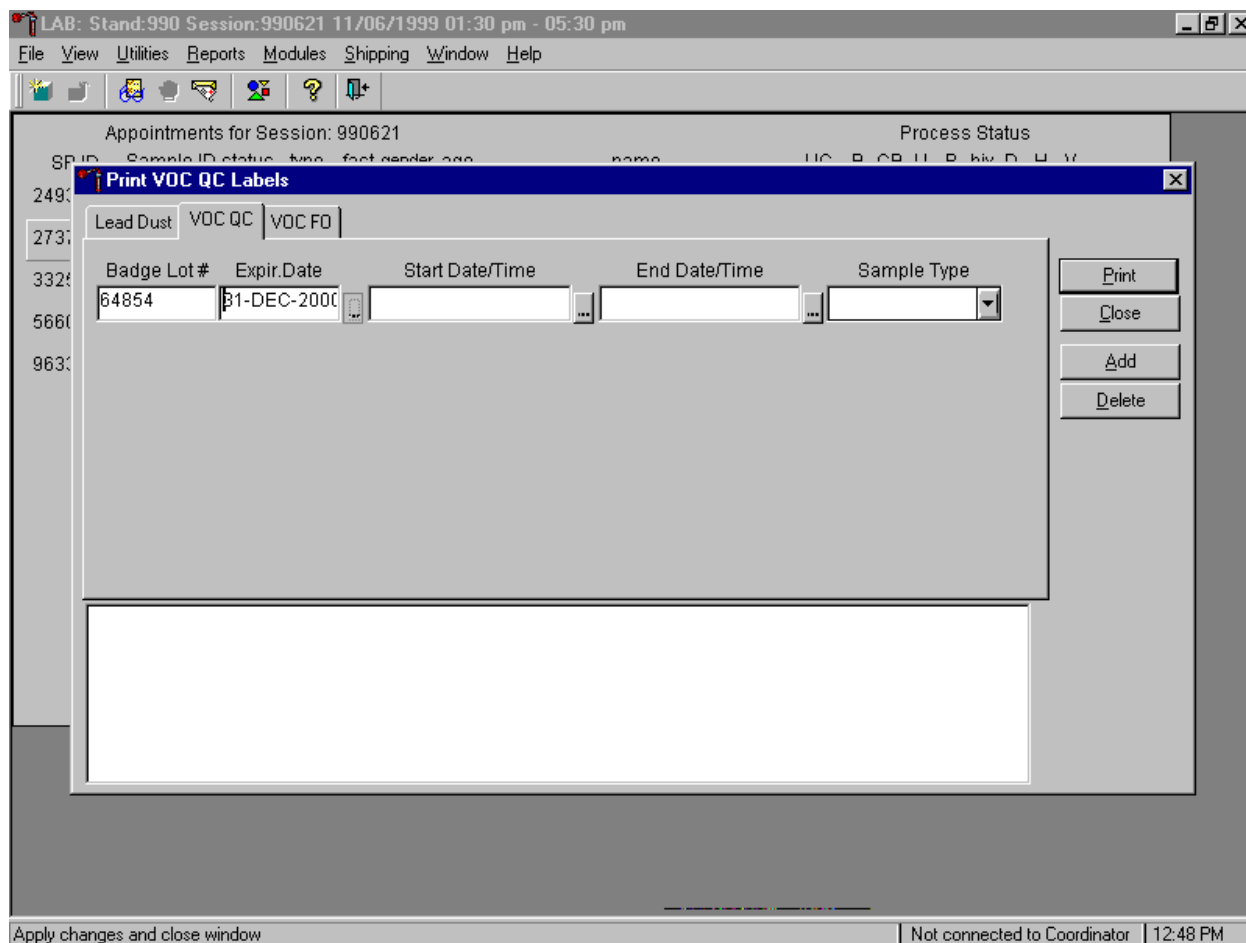
To continue the print QC label process, type the lot number located on the bottom of the canister into the badge lot # response text box and select [TAB] to move to the next text box. Enter the badge expiration date by using the calendar. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the Expire date text box and left click. The lab calendar displays.

Continue to print labels for the VOC QC badges.



For field monitoring and office air monitoring QC, enter the hand written start and end dates and times. For the positive control, enter the current date and time as the start and end date and time. Enter the date by using the calendar. Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

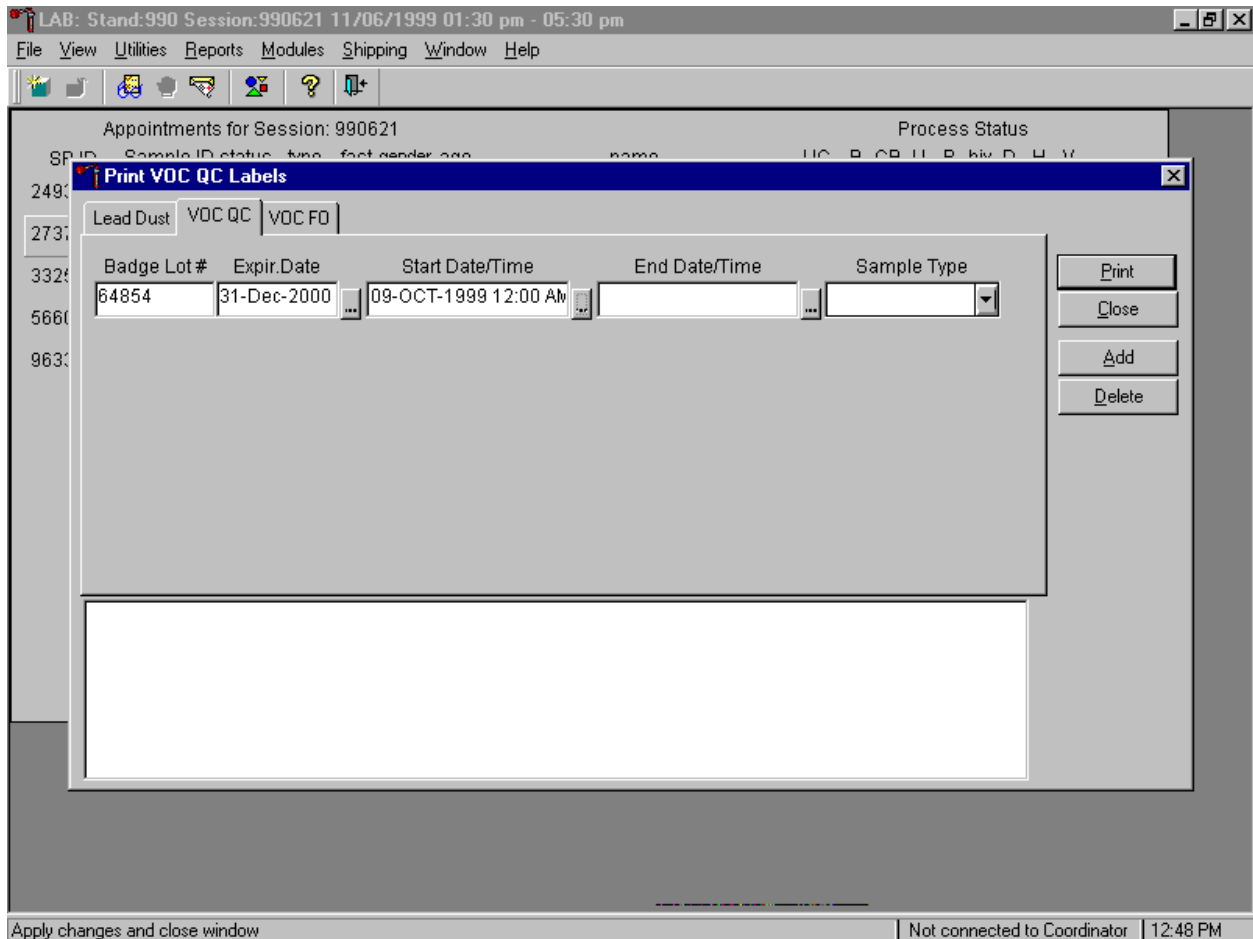
Enter the beginning exposure date and time into the Start Date/Time text box.



The date and time format is dd-mmm-yyyy xx:xxAM or dd-mmm-yyyy xx:xxPM. Use the calendar to enter the exposure date and manually correct the hours. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the Start Date/Time text box and left click. The lab calendar displays. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the **Cancel** button and left click. The calendar time defaults to 12:00AM. To correct the exposure start time, use the mouse to direct the cursor to the insertion point in the Start

Date/Time text box and begin to type the hours, minutes, and AM or PM using the keyboard. Alternatively, type in the date and time using the character and numeric keys and the dd-mmm-yyyy xx:xxAM or dd-mmm-yyyy xx:xxPM format and select [Tab].

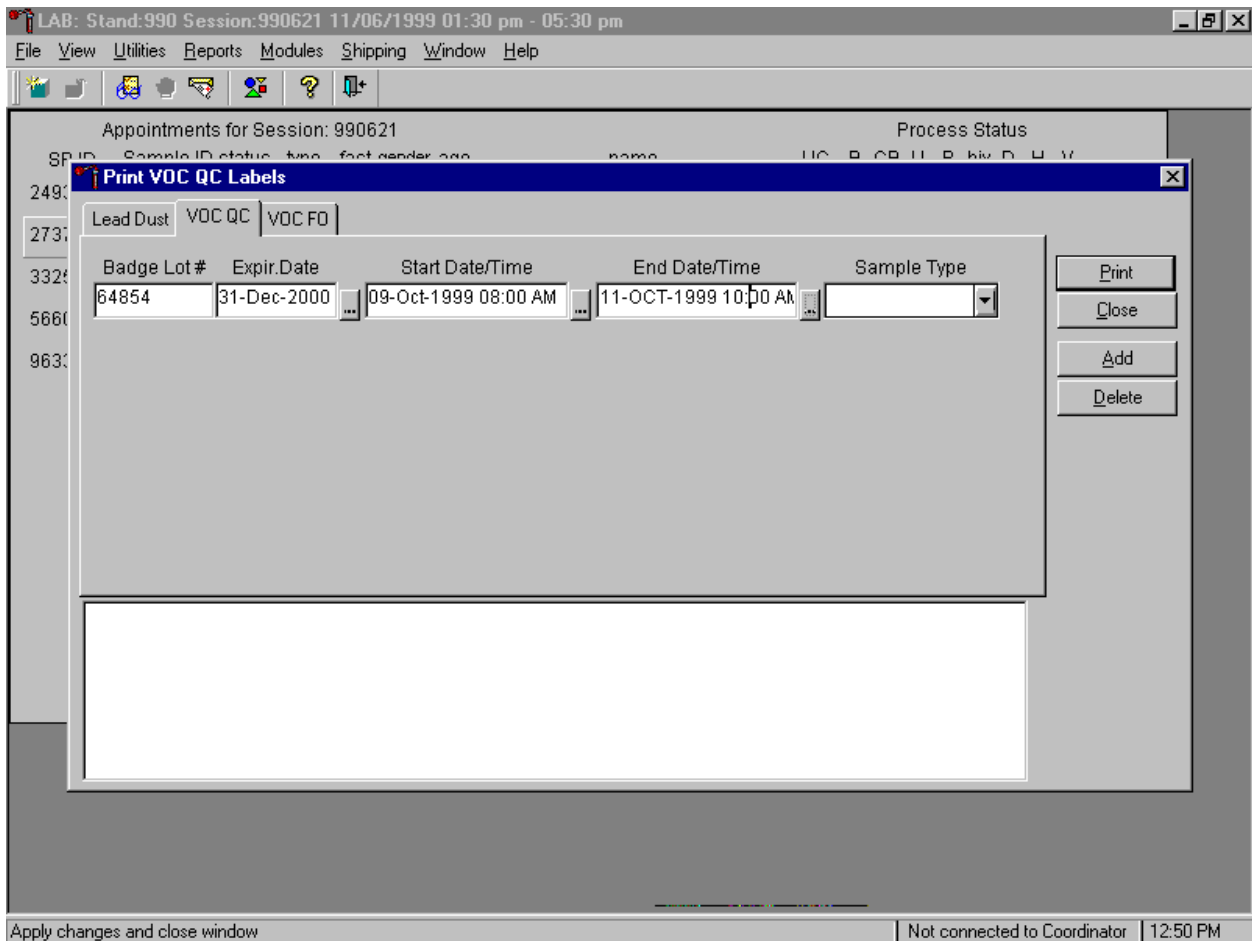
Enter the end exposure date and time into the End Date/Time text box.



The date and time format is dd-mm-yyyy xx:xxAM or dd-mm-yyyy xx:xxPM. Use the calendar to enter the exposure date and manually correct the hours. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the End Date/Time text box and left click. The lab calendar displays. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box

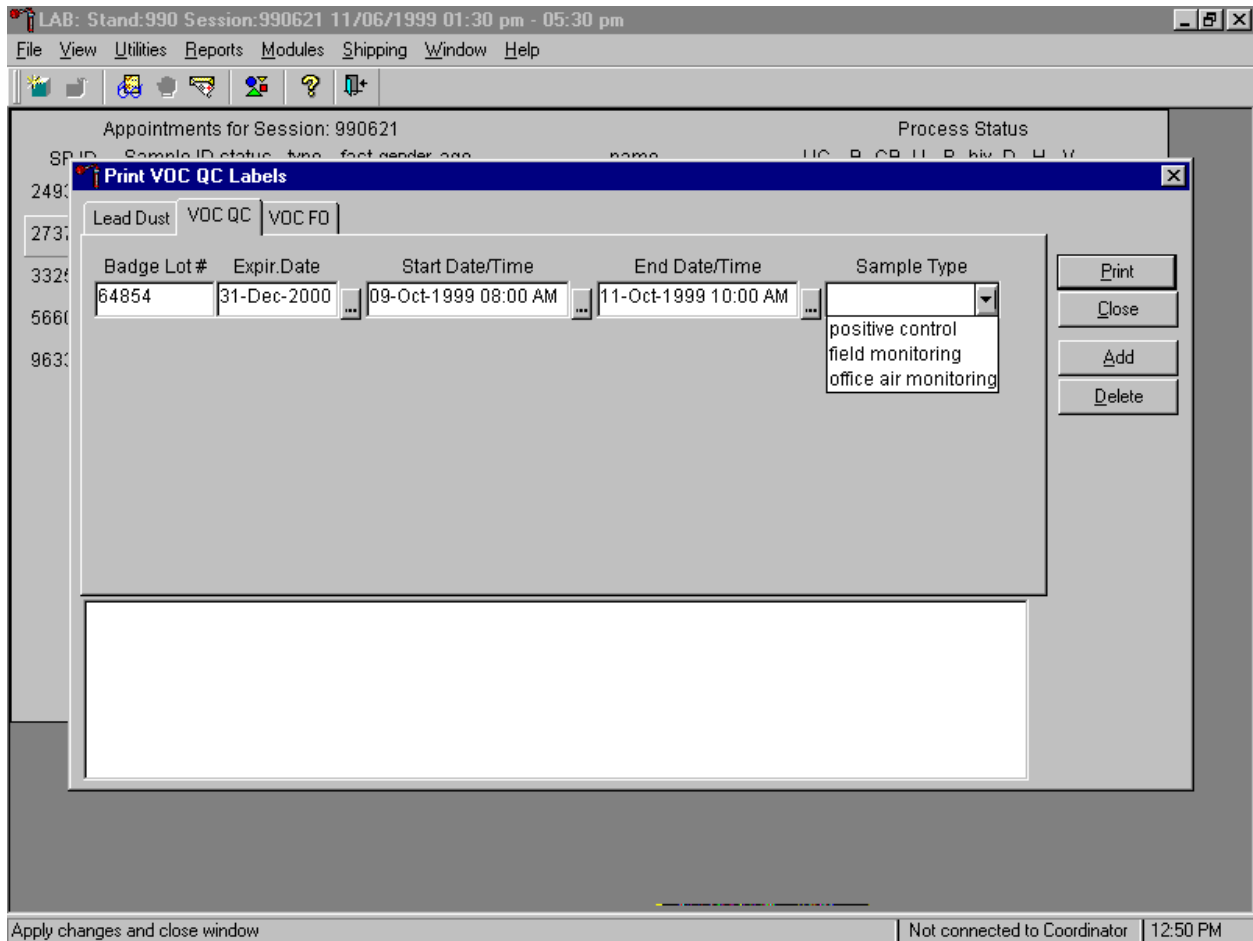
and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the **Cancel** button and left click. The calendar time defaults to 12:00AM. To correct the exposure start time, use the mouse to direct the cursor to the insertion point in the End Date/Time text box and begin to type the hours, minutes, and AM or PM using the keyboard. Alternatively, type in the date and time using the character and numeric keys and the dd-mm-yyyy xx:xxAM or dd-mm-yyyy xx:xxPM format and select [Tab].

Continue to print labels for the VOC QC badges.



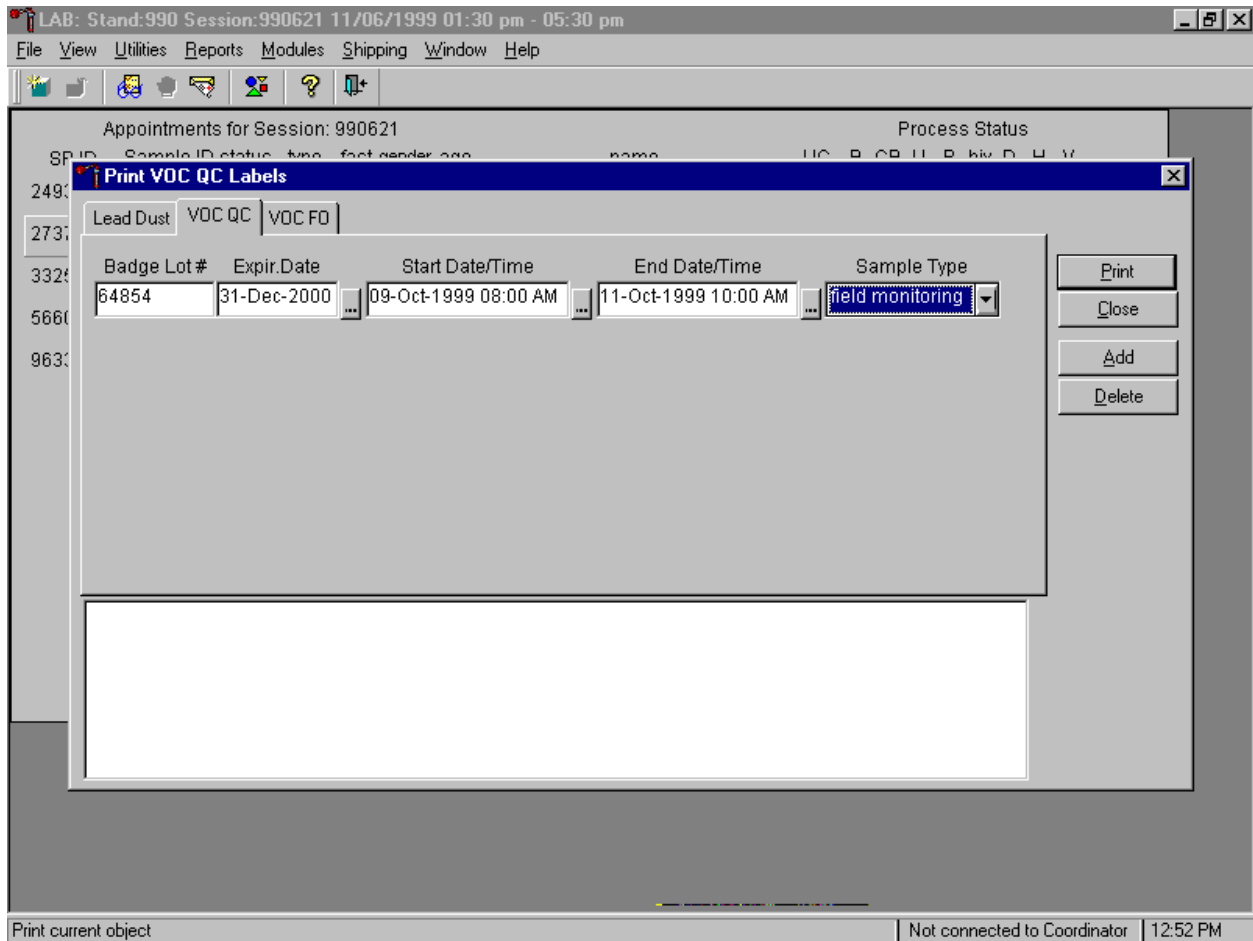
Verify and review the start and end exposure date and times displayed in the window. Compare these dates and times to the start and end date and time documented on the canister.

Select the type of VOC QC sample.



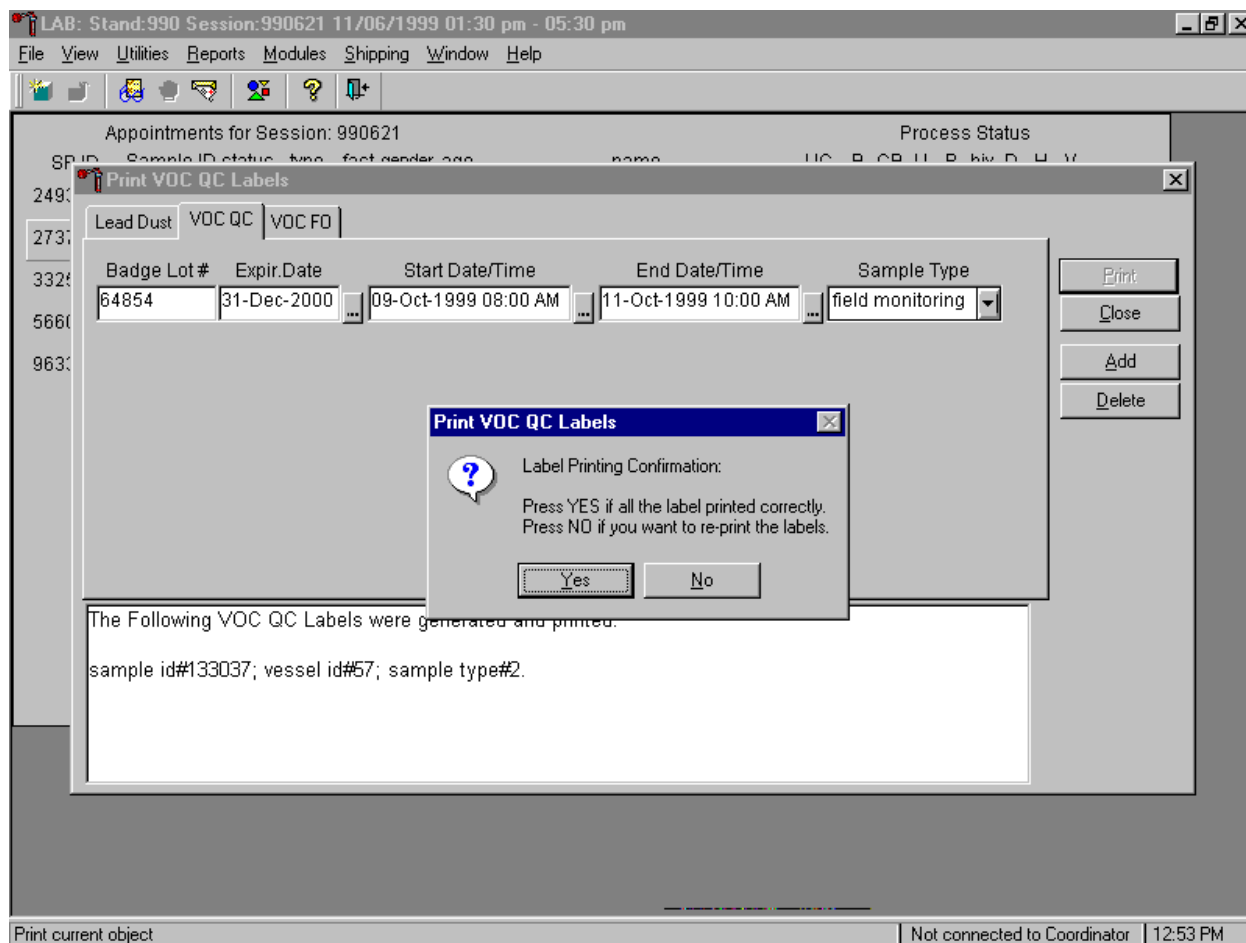
To select the VOC QC sample type, use the mouse to direct the mouse arrow to the drop-down list, left click, drag the arrow to the correct choice and left click.

Continue to print labels for the VOC QC badges.



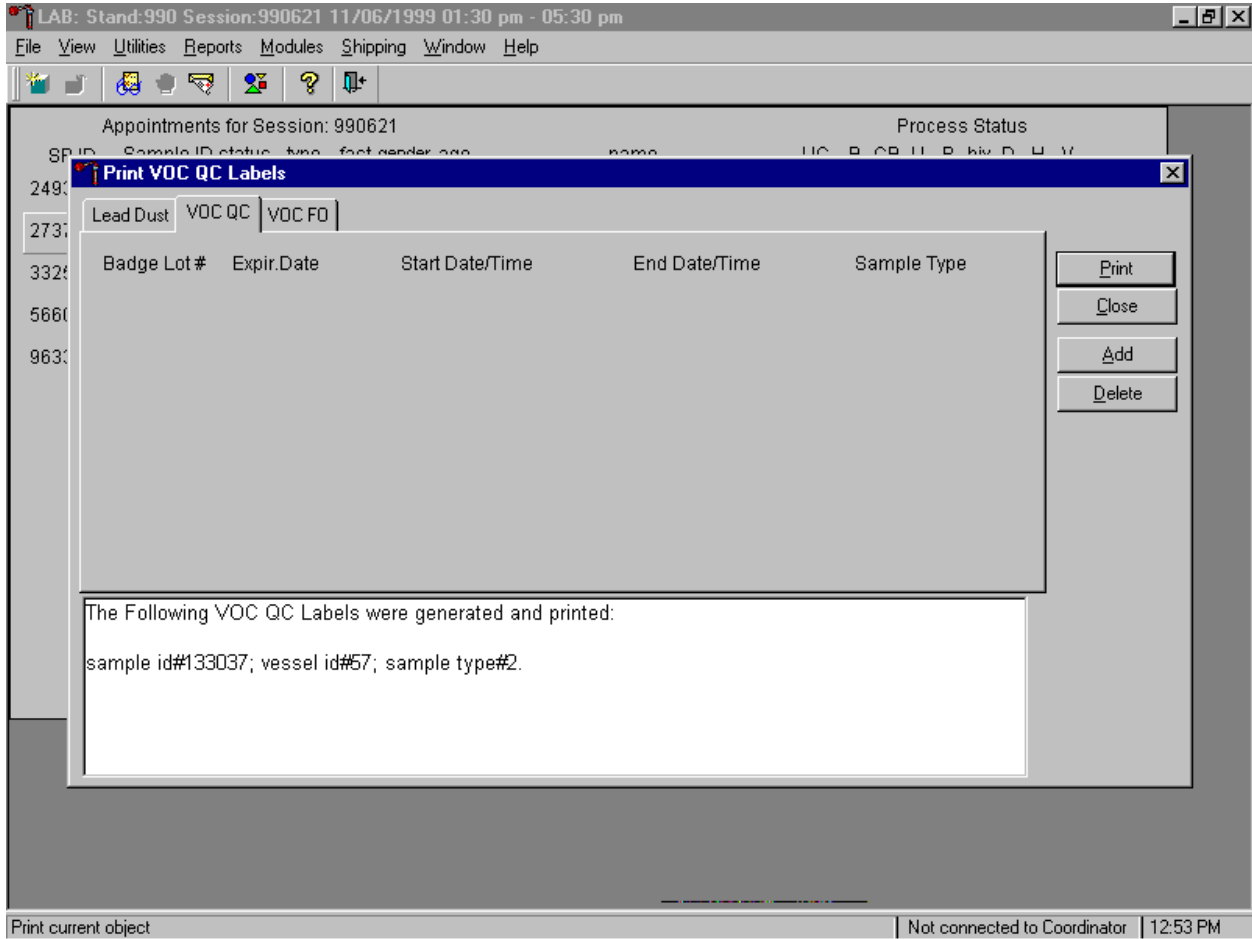
The sample type, positive control, field monitoring, or office air monitoring, displays in the sample type text box. Verify the accuracy of the information in the Print VOC QC Labels window. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click or type [P]. Labels print on the printer in the label/ship area of the laboratory. To close the window without saving any information to the database and to exit the VOC QC label module, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [C]. To add an additional VOC QC line, use the mouse to direct the mouse arrow to the **Add** button and left click, or type [A]. To delete the information in the window, use the mouse to direct the mouse arrow to the **Delete** button and left click, or type [D].

Confirm that the labels printed correctly before continuing.



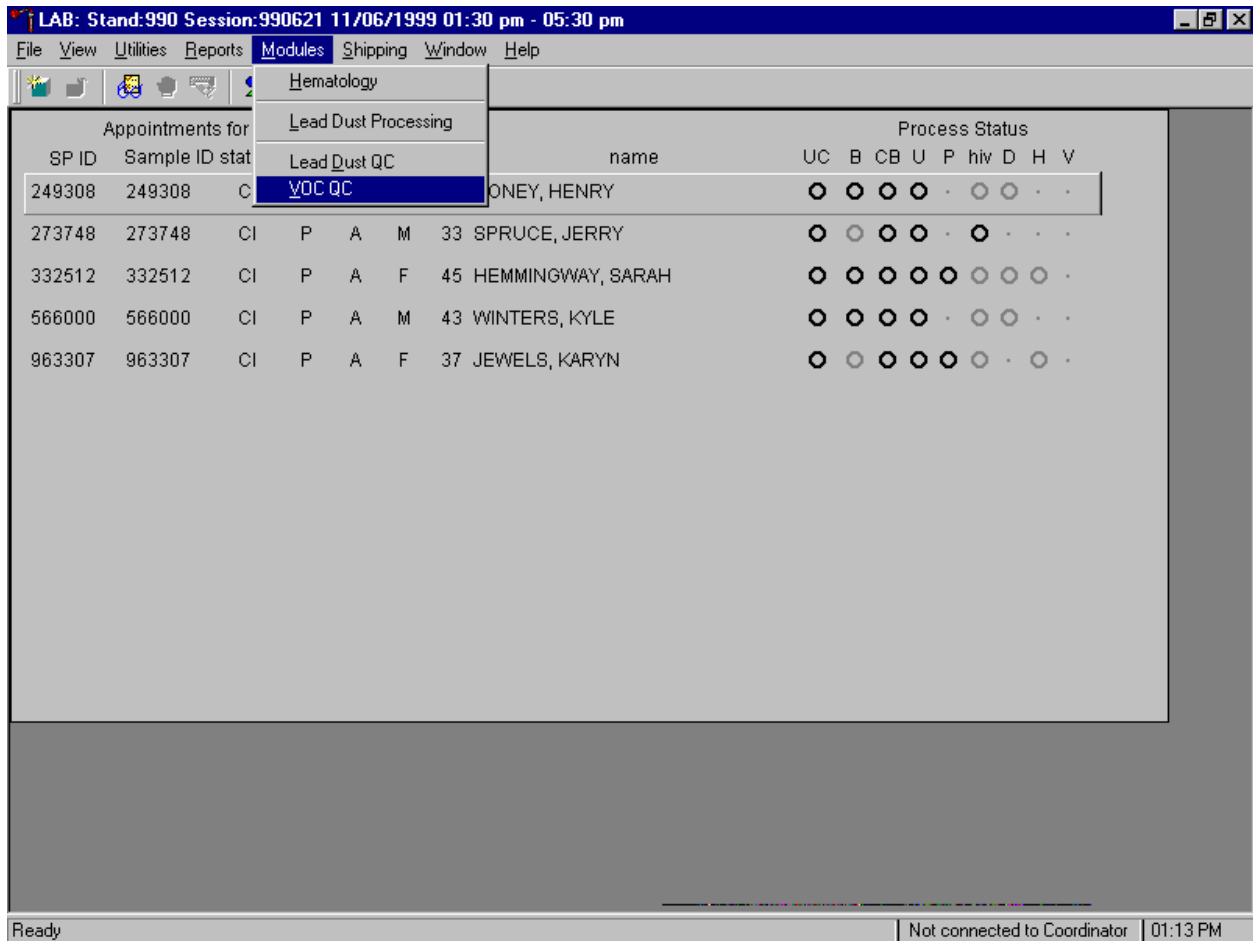
The Print VOC QC Labels message text window displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to **Yes** button and left click or type [Y] or select [Enter]. If any of the labels did not print correctly and/or to reprint the labels, use the mouse to direct the mouse arrow to the **No** button and left click or type [N]. All data is erased from the window once a response is recorded to this question.

Verify the information contained in the lower white section of the Print VOC QC labels window.



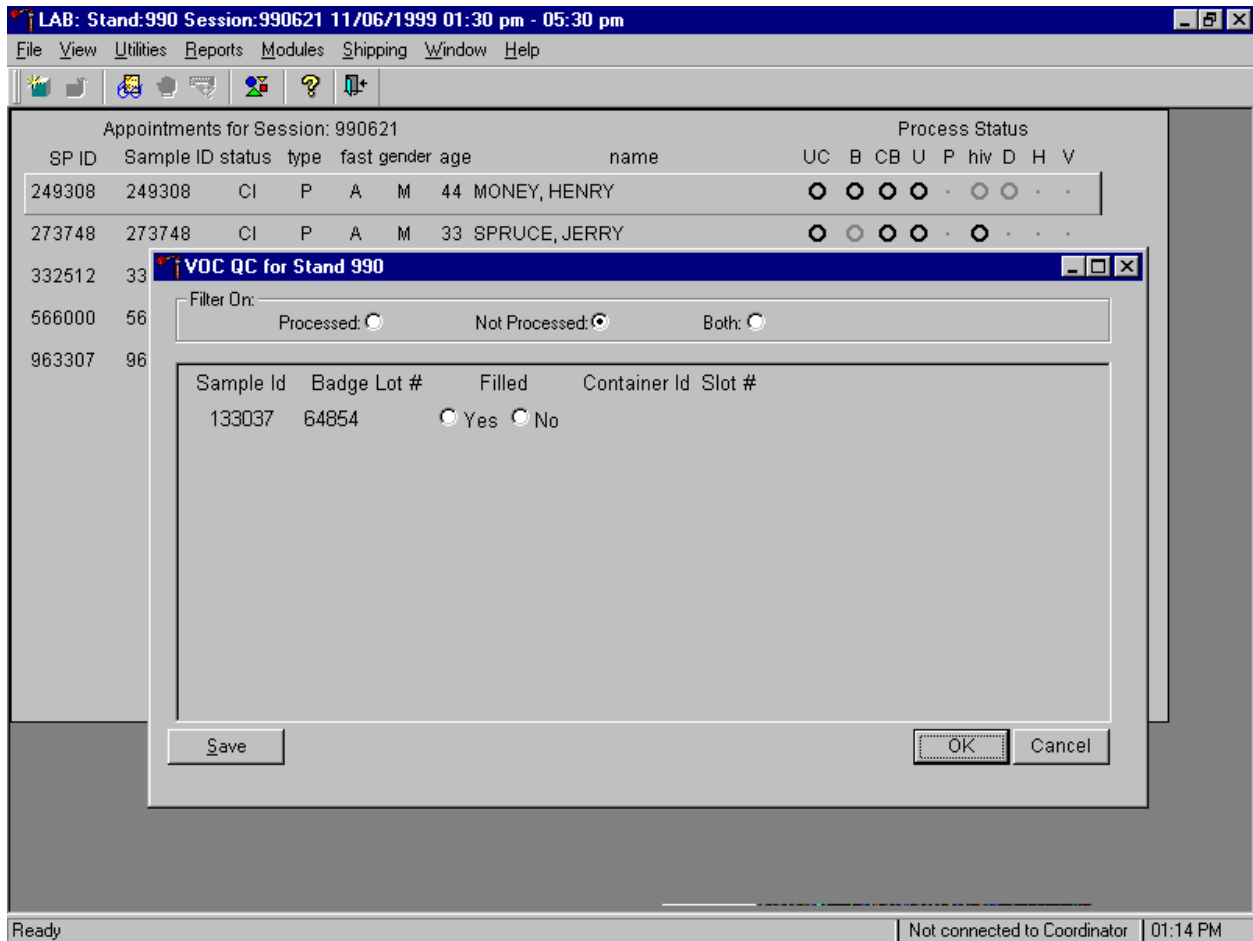
The lower white section of the Print VOC QC Labels window displays the sample ID #, vessel ID #, and sample type #.

Access the VOC QC module to process the QC specimens.



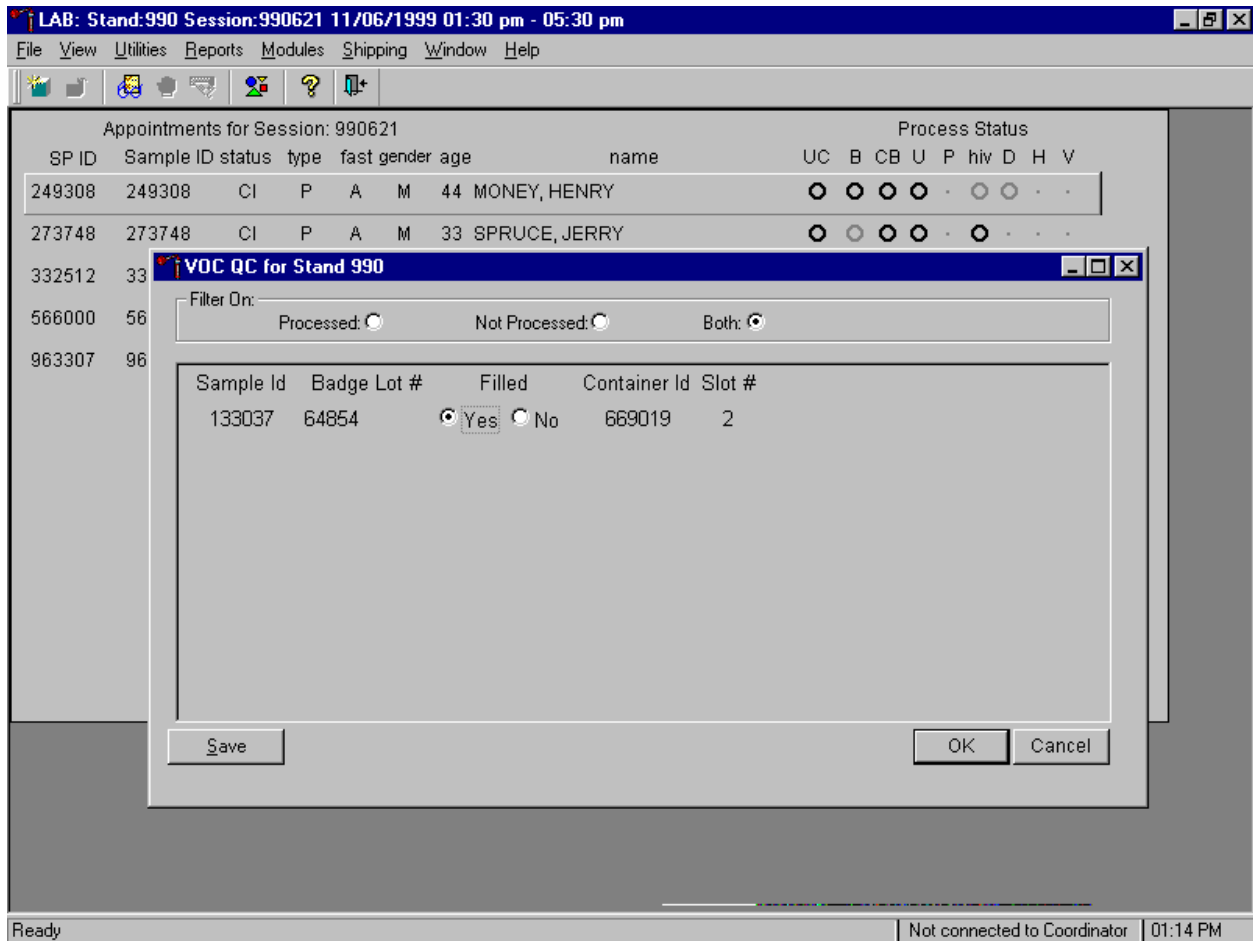
To access the VOC QC module, use the mouse to direct the mouse arrow to {Modules} in the menu bar, right click, drag the arrow to {VOC QC} and left click or type [Alt] [M] [V].

The VOC QC processing window displays.



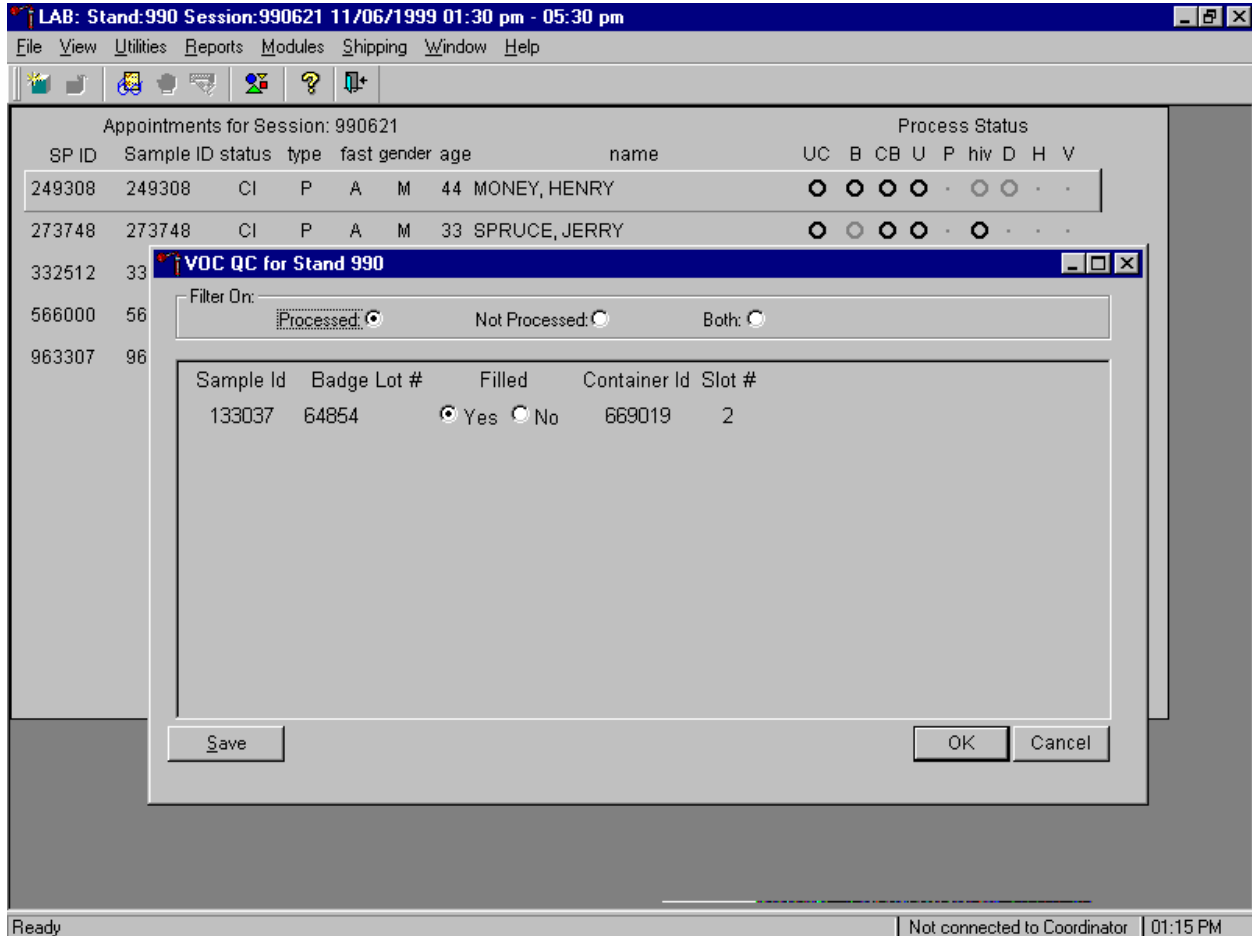
The VOC QC for Stand XXX window displays. Filter on “Processed” to view previously processed vessels, “Not Processed” to view current unprocessed vessels, or “Both” to view previously processed and unprocessed vessels. Verify that the correct filter is selected. Select the “Not Processed” filter to mark vessels as collected and to assign these vessels to containers. The VOC QC window contains the following data items: Sample ID, Badge Lot #, Filled – Yes, Filled - No, Container ID, and Slot #.

Mark the VOC QC badge as collected or Filled – “Yes.”



Compare the Sample ID on the window to the bar code label on the vessels. To mark the badge as collected or Filled – “Yes,” use the mouse to direct the mouse arrow to the Filled “yes” radio button and left click.

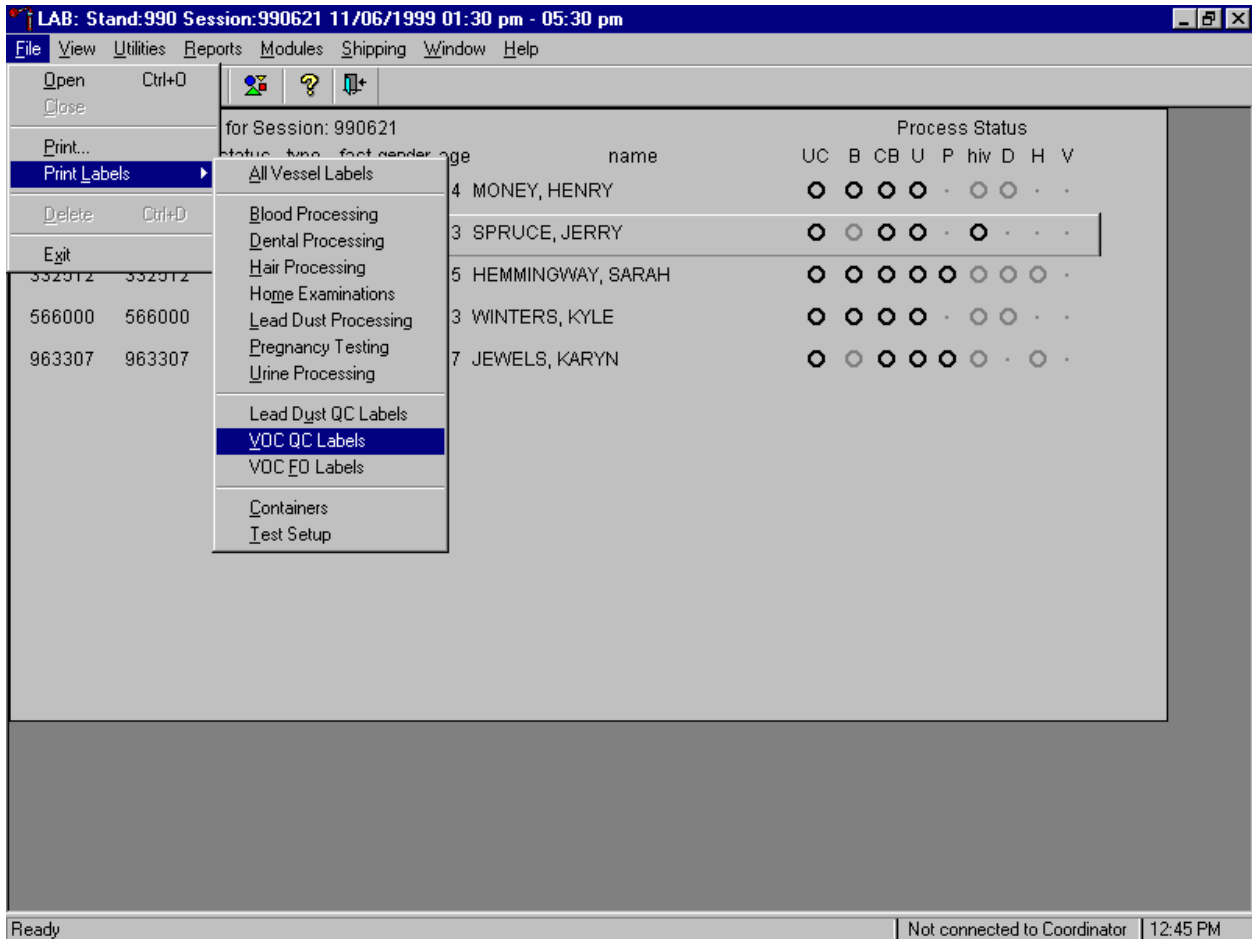
As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **S**ave button and left click or type [S]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click or select [Enter]. To cancel this action and to exit the module, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

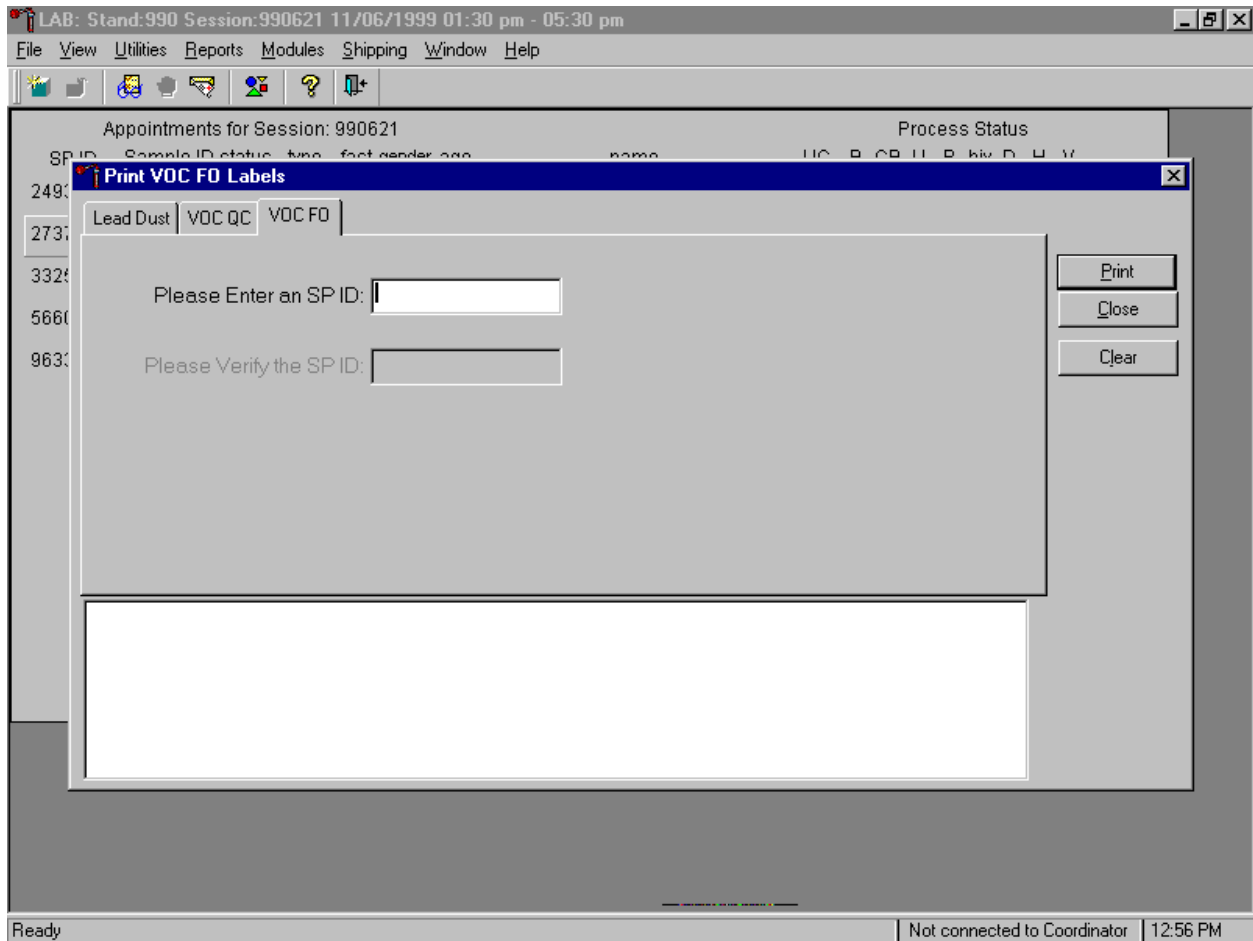
A. 11 Process Vessels Collected in the Field Office

Begin processing vessels collected in the field office by printing vessel labels.



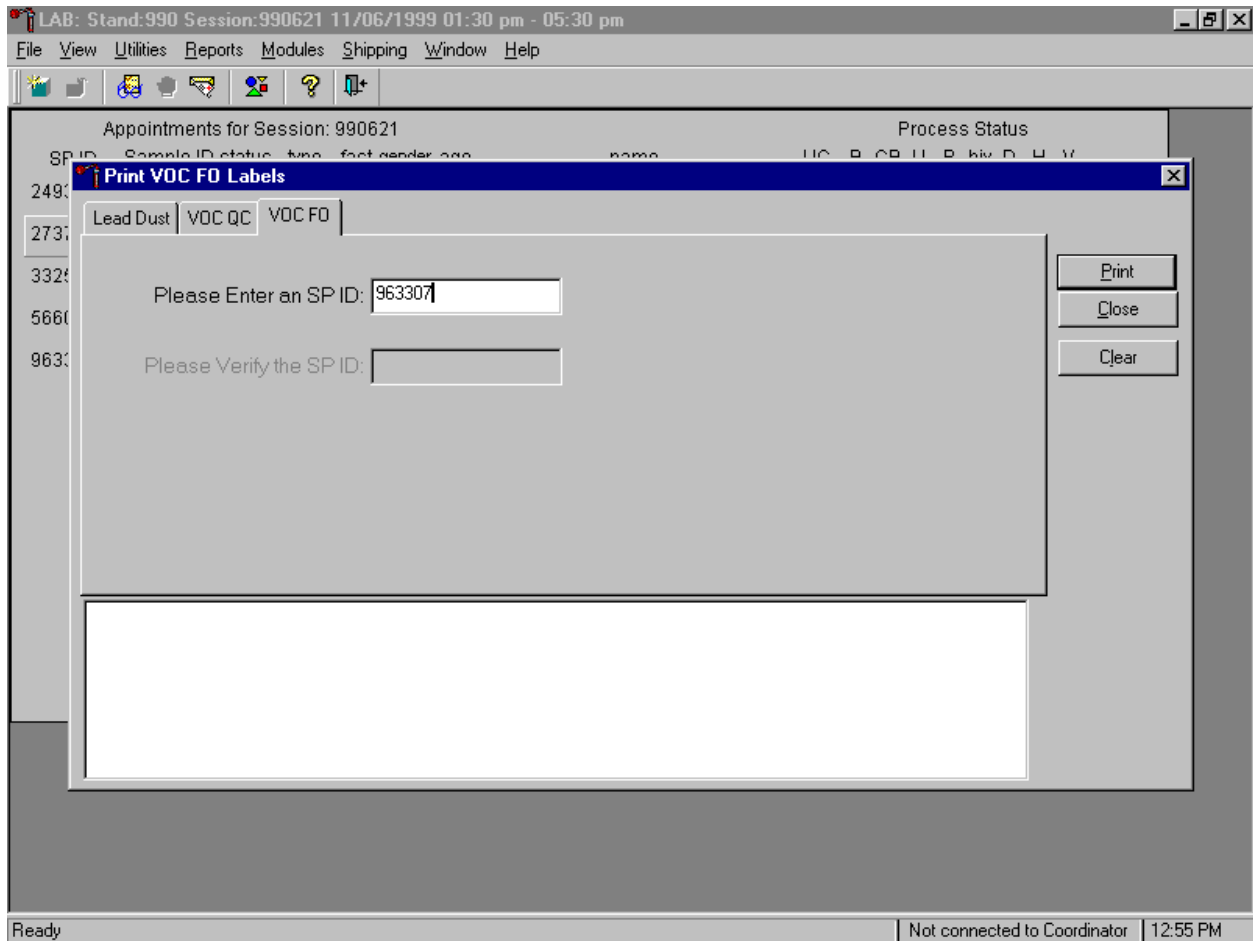
To access the VOC FO label function, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Print Labels}, then to {Print VOC FO labels}, and left click or type [Alt] [F] [L], [F].

The Print VOC FO Labels window displays.



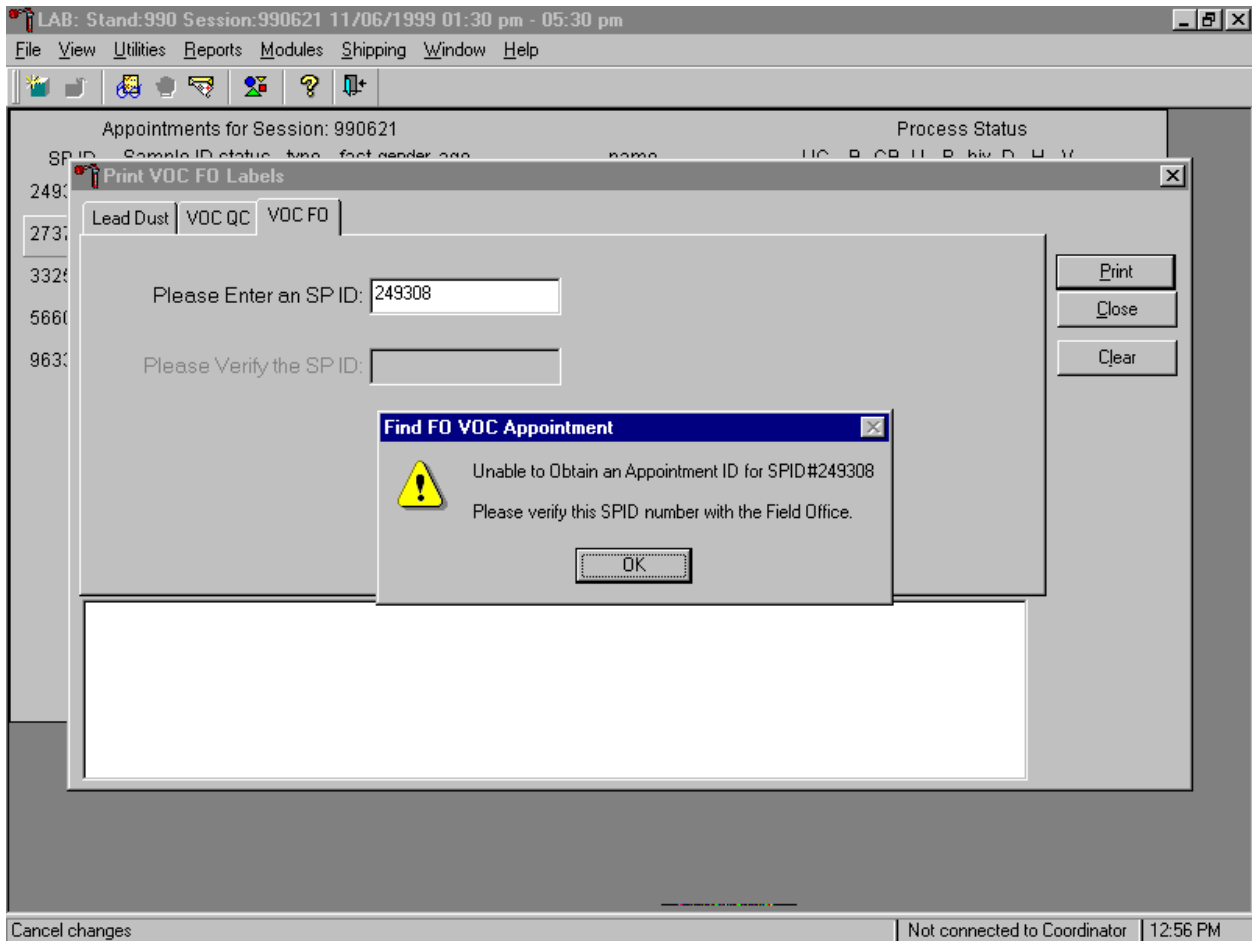
To print labels for VOC FO badges, use the mouse to direct the mouse arrow to the VOC FO file header and left click.

Enter the SP ID for the correct SP.



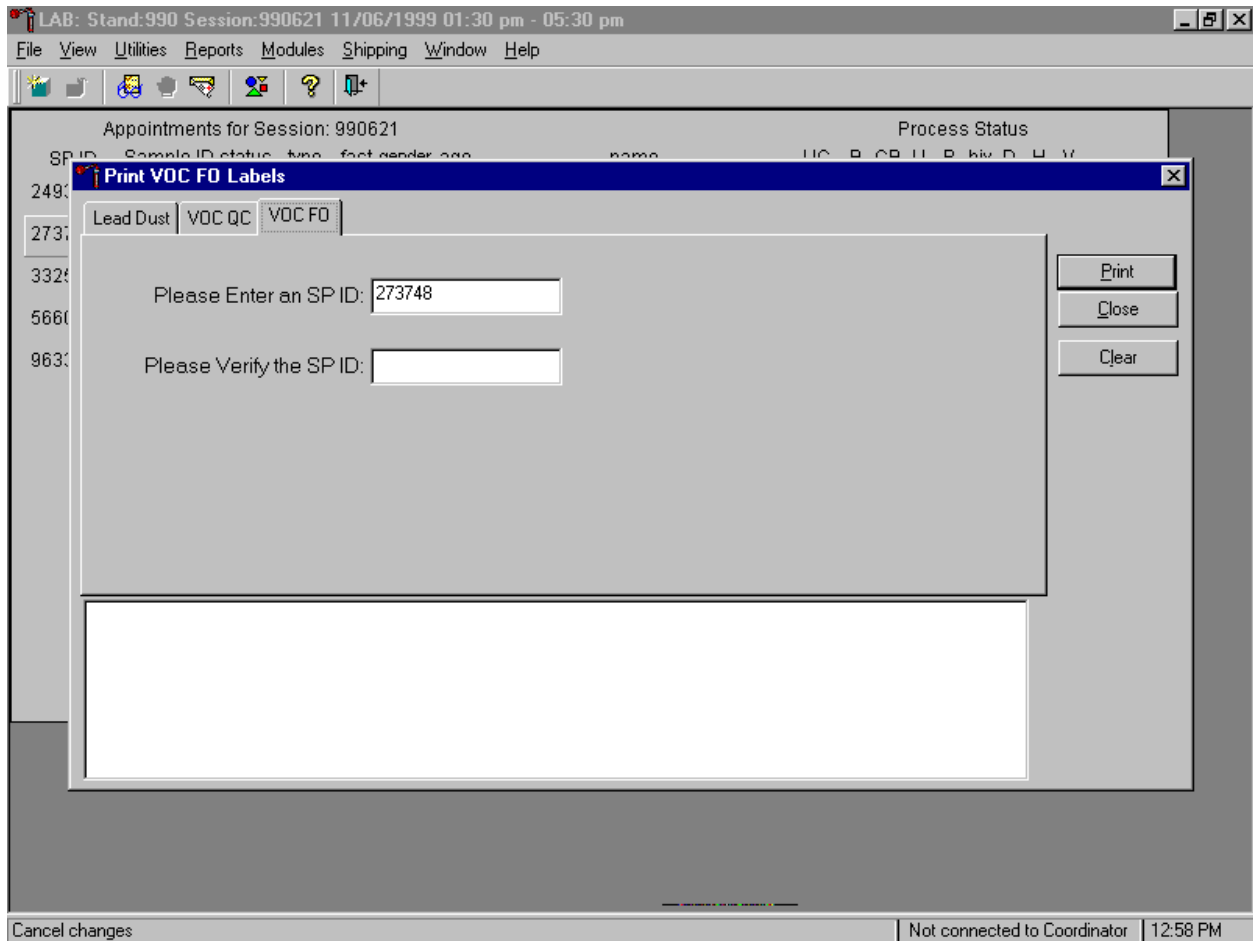
Examine the handwritten SP ID number on the zip closable bag. Type this number into the Please Enter an SP ID: text box using the keyboard numeric keys.

If the SP ID is entered incorrectly, a warning message text box displays.



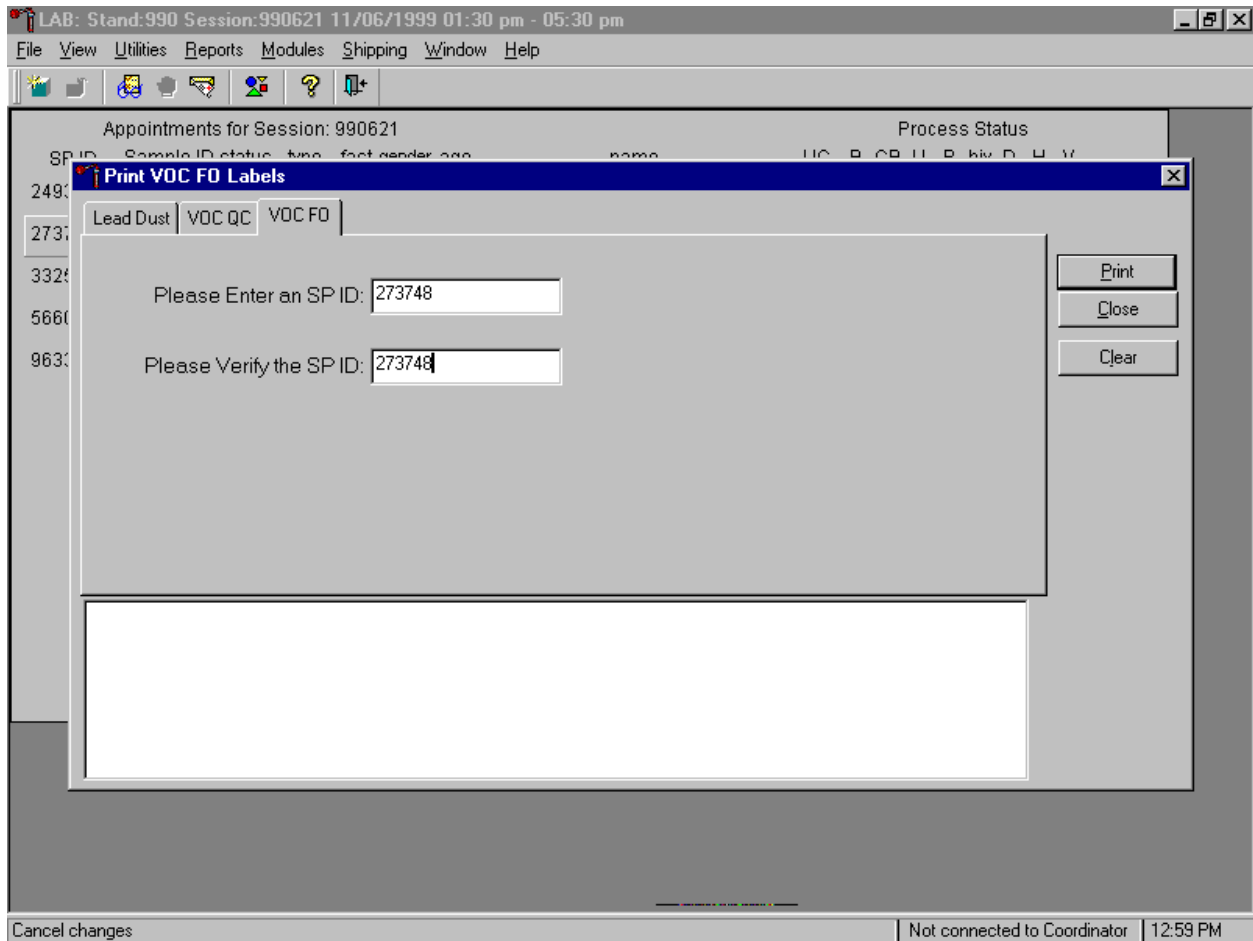
This data entry field contains strict limitations. Only SPs who are eligible for a VOC appointment are recognized. Verify that the number was correctly entered. If the number is incorrect, contact the field office to reconcile the discrepancy. To remove the message, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter].

Verify the SP ID.



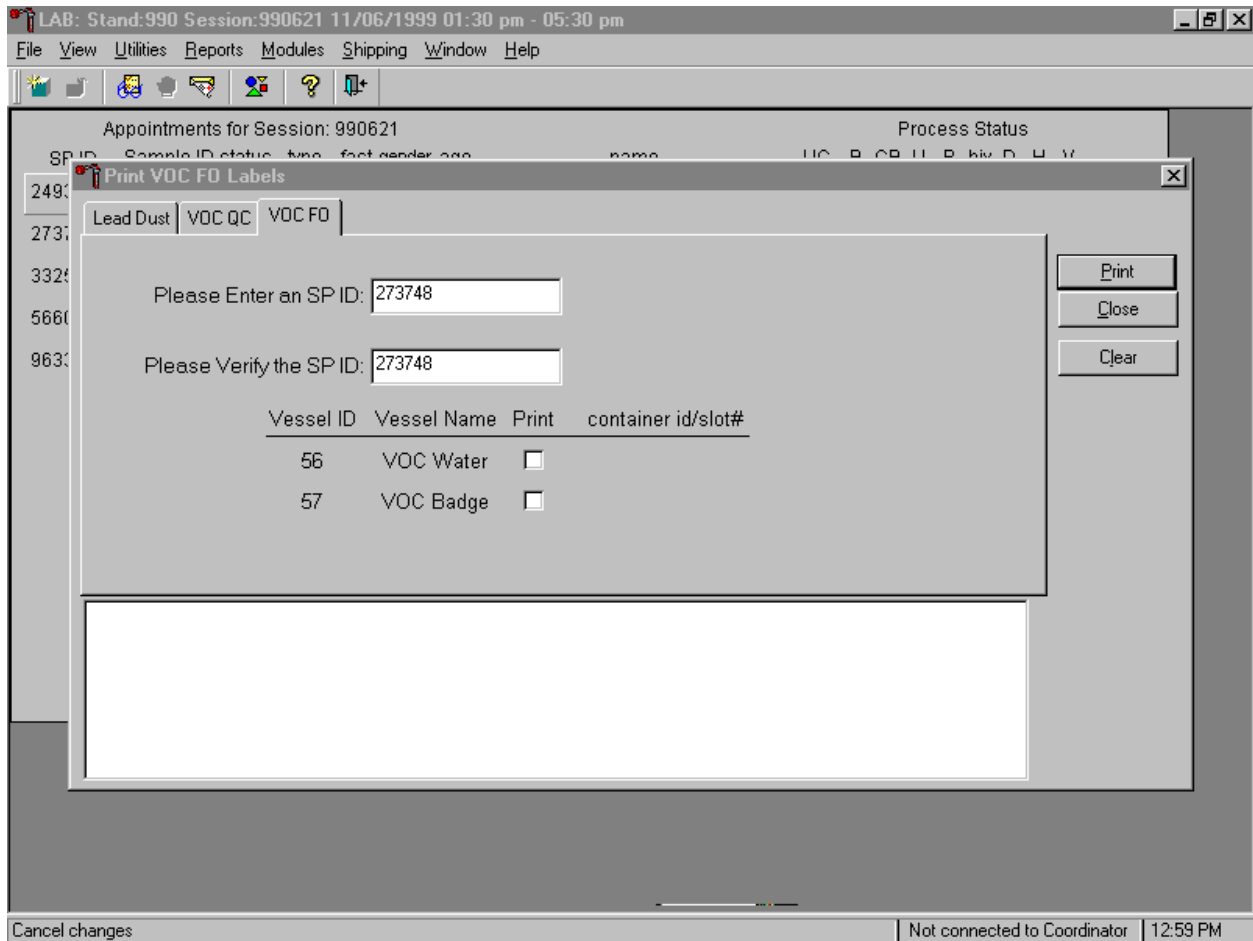
If the SP ID number is recognized, a second Please Verify the SP ID: text box displays.

Enter the SP ID number a second time.



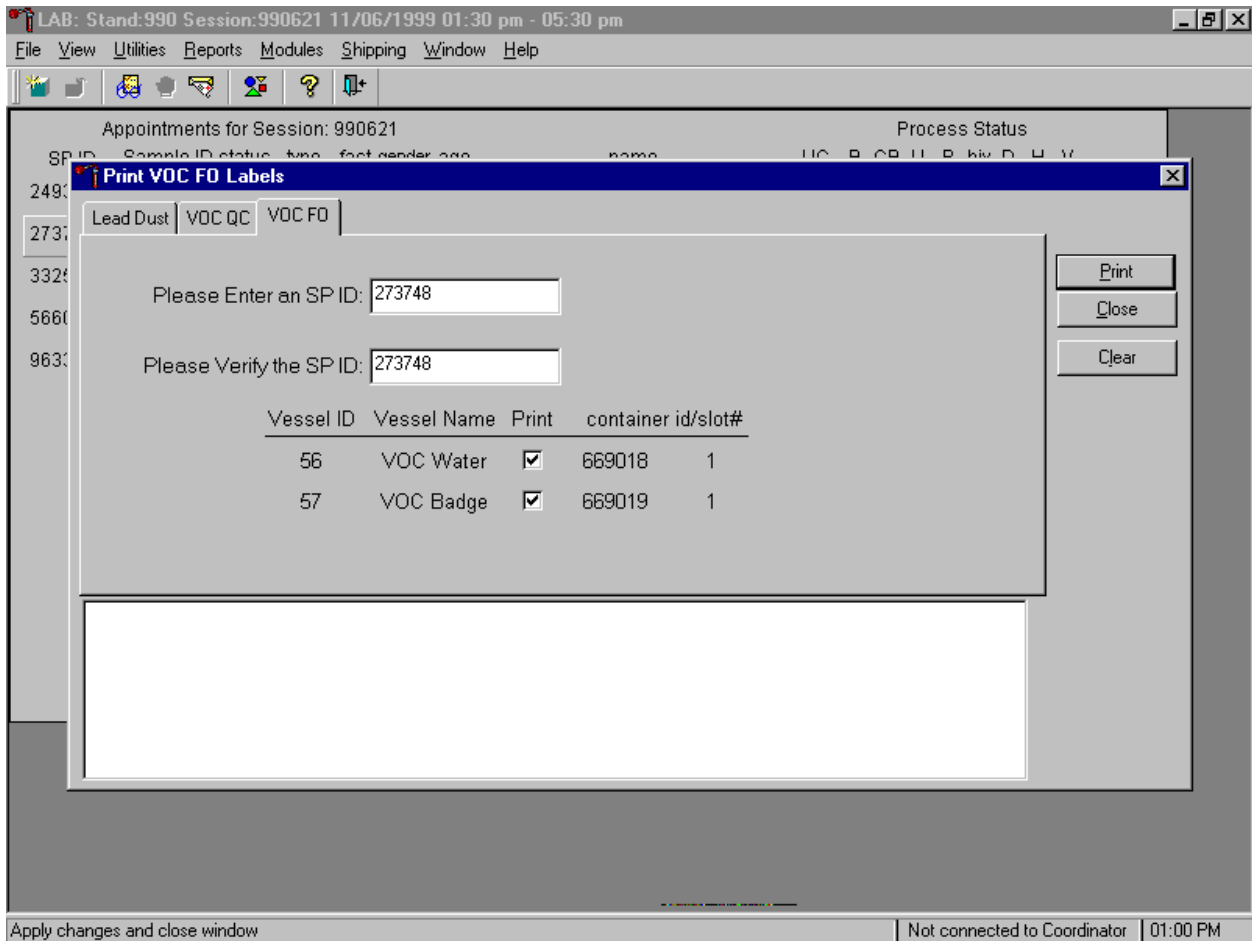
Type the SP ID number into the Please Verify the SP ID: text box using the keyboard numeric keys.

Mark the vessels as collected or filled.



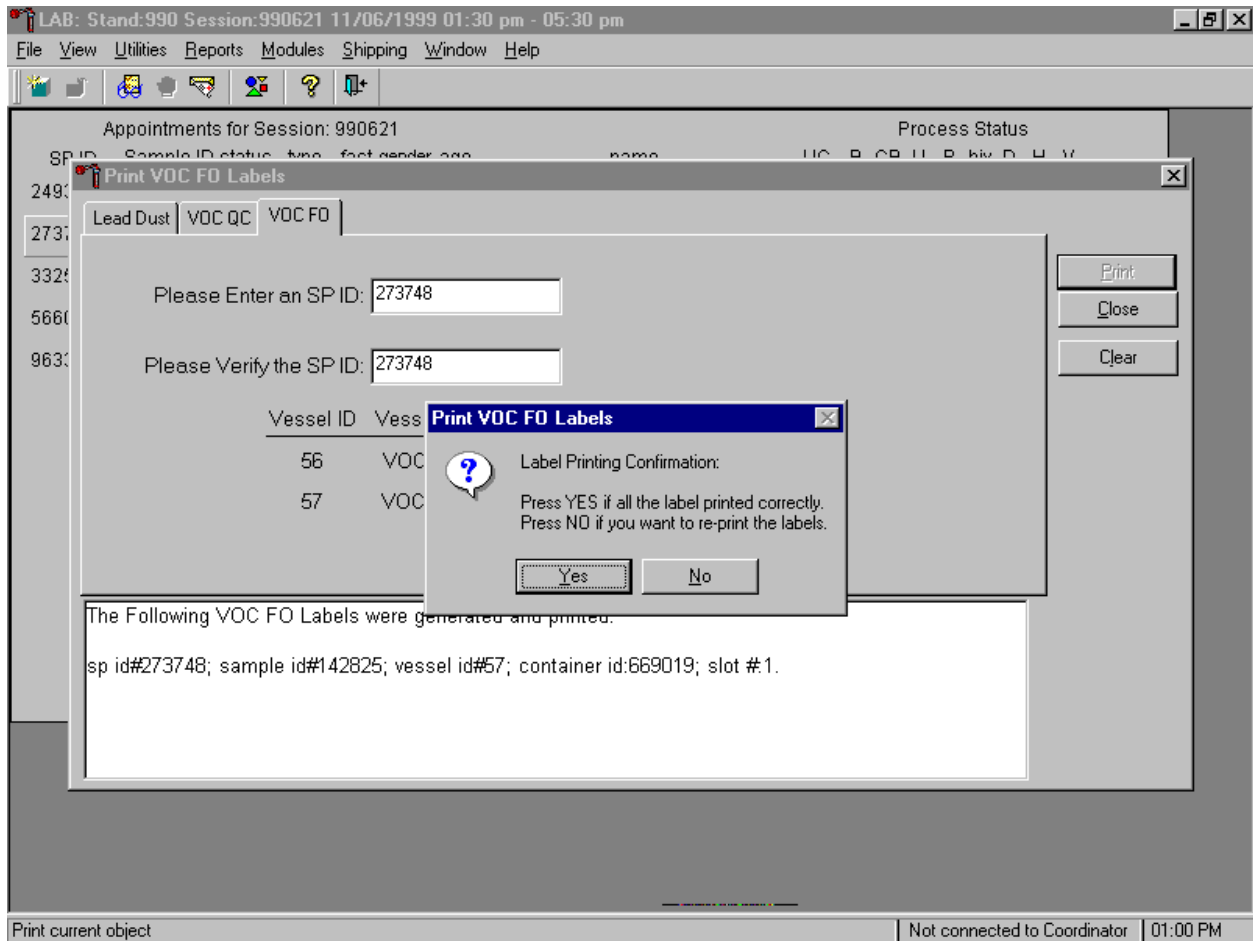
If the data contained in the two SP ID boxes match, the VOC FO vessels for that SP display in the lower section of the window.

Mark the vessels and print the labels.



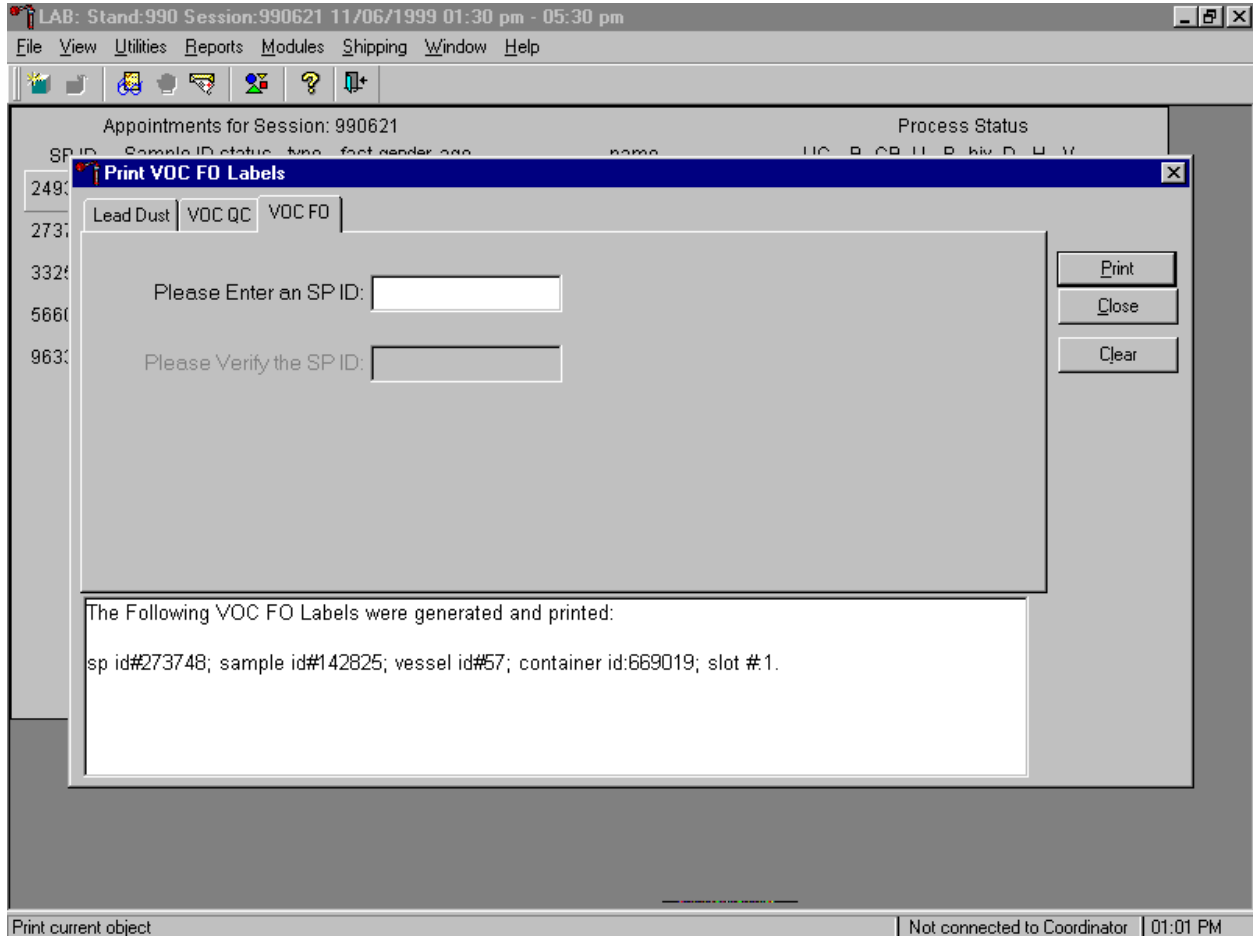
To mark the VOC water and badge vessels as collected or filled, use the mouse to direct the mouse arrow to the print check boxes and left click on the checkbox to insert a checkmark. To print the VOC FO vessel labels, use the mouse to direct the mouse arrow to the **Print** button and left click or type [P]. To clear the entry, use the mouse to direct the mouse arrow to the **Clear** button and left click or type [L]. As each vessel is marked as “Filled - Yes,” it is automatically assigned to a slot in an existing (open) container.

Verify that the labels printed correctly.



The Print VOC FO Labels message text box displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to **Yes** button and left click or type [Y], or select [Enter]. If any of the labels did not print correctly and/or to reprint the labels, use the mouse to direct the mouse arrow to the **No** button and left click or type [N]. All data is erased from the window once a response is recorded to this question.

Verify the information contained in the lower white section of the Print VOC FO labels window and store the vessels.



To close the window, use the mouse to direct the mouse arrow to the **Close** button and left click.

A. 12 Shipping VOC Specimens

Ship VOC blood, badges, and water vessels to two contract laboratories in double-sided Styrofoam and corrugated cardboard shippers or hard sided coolers using wet ice (refrigerant packs). Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit A-6, the Shipping Protocol, illustrates the specifications for the shipment of biological specimens to each of the two contract laboratories.

Exhibit A-6. Shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
VOC				
CDC/Air Toxicant Branch	VOC Blood	Refrigerated	1 x 5 foam mailer	Weekly
CDC/Air Toxicant Branch	VOC Blood	Refrigerated	1 x 5 foam mailer	Weekly
CDC/Air Toxicant Branch	VOC Water	Refrigerated	1 x 3 foam mailer	Weekly
Clayton Laboratories	VOC Badge	Refrigerated	12 x 12 plastic bag	Weekly

The integrity of laboratory specimens, including the VOC vessels, is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contact laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient refrigerant packs, and sending specimens FedEx priority overnight.

The shipping technologist is primarily responsible for packing and shipping the specimens to all laboratories on a designated day. As necessary, other medical technologists, the phlebotomist, and the home examiner assist in performing each of the steps listed below to complete the shipping procedures.

- On the day before a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software.
- On the morning of a shipping day, close all containers, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers and hard sided coolers from the compartments under the MEC.
- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of refrigerant packs as appropriate.
- Place the appropriate paper manifest and the FedEx return airbill in a 12 x 12 plastic bag and place the plastic bag on the Styrofoam lid of shipper and place the lid on shipper.
- Label each shipper with the appropriate FedEx label and warning labels.

When the contract laboratory personnel receive the shippers and/or hard-sided coolers, they unpack the specimens and return the shippers, coolers, and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

Follow the instructions in Chapter 9, Sections 9.8 to create the two airbills; create one for airbill for CDC/Air Toxicant Branch and a second airbill for Clayton Laboratory. Follow instructions in section 9.10 to close containers for vessels 54, 55, 56 and 57. Follow instructions in Section 9.11 to assign the airbills to the shippers. Vessels 54, 55 and 56 are assigned to the same shipper. Vessel 57 is assigned to the airbill associated with Clayton Laboratories.

Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed in Chapter 9, Section 9.12 to prepare the paper manifest and to send the electronic file.

All of these shipments require reusable refrigerant packs to keep specimens cold but not frozen during transit. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.)

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. The Federal regulations include the use of the following items:

- A watertight primary receptacle e.g., sealed cryovial, sealed Vacutainer®, and sealed Falcon tubes;
- A watertight secondary packaging e.g., a sealed plastic storage bag;
- Sufficient absorbent material between the primary receptacle and the secondary receptacle to absorb the entire contents of all primary receptacles;
- Individually wrapped glass primary receptacles if multiple receptacles are placed in a secondary packaging; this ensures that contact between them is prevented; and
- A sturdy outside packaging constructed of corrugated fiberboard.

Store the blood and water vessels in foam 1 x 5 or 1 x 3 mailers. Secure the top of the mailer to the bottom with a rubber band. Place the mailer in a plastic bag, add one absorbent paper, and seal the bag. Store the VOC canisters (badges) in a 5 inch tall empty box in the refrigerator. When ready to pack,

transfer canisters to a 12 x 12 zip plastic bag. Exhibit 7 illustrates the contract laboratory addresses for the VOC Laboratories.

Exhibit A-7. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number E-mail address
CDC/Air Toxicant Branch 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341	VOC Blood #1 VOC Blood #2 VOC Water	Refrigerated	Dr. Ben Blount 770-488-7962
Clayton Laboratories 22345 Roethel Drive Novi, MI 48375	VOC Badge	Refrigerated	Dr. Paul Epstein 248-344-1770

These shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 20 refrigerant packs in the freezers at all times, replacing as necessary.

Pack Medium Shipping Container for CDC/Air Toxicant Branch:

- Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.
- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper;
- Place the sealed mailers (vessels 54, 55 and 56) on top of the refrigerant pack;
- Pack the sides with crumbled newsprint;
- Add two or three additional refrigerant packs;
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid;
- Seal the shipper;
- Weigh the shipper on the scale or assume that the package weighs 10 pounds; and
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

Pack Medium Shipping Container for Clayton Laboratories:

- Pack the specimen storage bag tightly in the hard-sided cooler to prevent movement;
- Place at least one large or two small frozen refrigerant packs around the sealed bag;
- Fill any remaining space with crumpled newsprint;
- Place the hard-sided cooler inside an empty corrugated shipper;
- Fill any remaining space with crumpled newsprint;
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the hand sided cooler;
- Seal the shipper;
- Weigh the shipper on the scale or assume that the package weighs 10 pounds; and
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing refrigerant packs with a “Refrigerate” label;
- Label shippers containing whole blood, with a “Biohazard” label;
- Complete the section of the FedEx label that requests the weight of the contents of the shipper;
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper;

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first three or four weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last two weeks of the stand.

A.13 The MEC Environment

Maintaining a stable interior environment is critical to many laboratory analytes and processes. Environmental contamination of specimens can result if specimens are exposed to outdoor air and/or contaminants. For this reason, the windows in the MEC should generally be kept closed. This is especially important when actively processing specimens in the laboratory. Smoking outside the MEC should be confined to areas where there are no air intake vents and there is no possibility of second-hand smoke entering the interior of the MEC. Thermostats should be adjusted to maintain a comfortable MEC environment; opening and closing windows to adjust the temperature inside the MEC is not an alternative.

Exceptions to this policy are allowed under certain circumstances. Windows and/or bay doors can be opened when:

- A SP is uncomfortable and requires brief exposure to fresh air.
- The blood-processing technologist is not processing specimens and the laboratory has dry ice inside the MEC.
- The MEC is not in session and the medical technologist is shipping specimens with dry ice.
- The blood-processing technologist is not processing specimens and opening the laboratory bay door is required to provide access to the FedEx courier.
- The blood-processing technologist is not processing specimens and opening the laboratory bay door is required to dispose of biohazardous trash.
- Performing set up and tear down activities. (Before any laboratory processing has occurred at the beginning of a stand and after all laboratory processing is complete at the end of a stand.)

A.14 How to Deal With System Failure

If the computer system fails, conduct the English or Spanish primary or second exam VOC questionnaire using a hard copy document (Appendix A.1-A.4), and note the time and number and type of specimens collected (water, badge, and/or blood). Complete the questionnaire and enter the collection and questionnaire results after the system is operational. These documents are available in the blank forms directory in the MEC and the shared directory in the field office. Contact the Data Manager if with questions about how to access and print these documents.

SP Name _____	Date __ _ - __ _ - __ _ _ _
SP ID __ _ _ _ _ _ _ _	Time __ _ : __ _ AM PM
	TECH ID __ _ _ _

APPENDIX A.1 – VOC QUESTIONNAIRE

Did you wear the exposure monitoring badge at all times since you received the badge?

YES 1
NO 2

If no: Approximately what was the number of hours that you did not wear the badge?

|__|_|
HOURS

If less than 1 hour 0

Q1. I would like to ask you a few questions about your home. Does your home have an attached garage?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q2. Was your home or building originally built less than 5 years ago?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q3. Which one of the following is the best description of the street that you live on? Is it a...

Rural or country road 1
Dead-end residential street 2
Through residential street 3
Commercial street 4
Major highway 5
REFUSED 7
DON'T KNOW 9

Q4. Does your kitchen stove use natural gas, electricity, or something else?

- Natural gas..... 1
- Electricity..... 2
- Something else 3
- REFUSED..... 7
- DON'T KNOW 9

Q5. In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please consider wall-to-wall carpeting or room-sized rugs.

- YES 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW 9

Q6. Do you store paints or fuels inside your home? Include your basement (and attached garage.)

- YES 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW 9

Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge ___ hours ago up until this appointment.

Q7. During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping.

 |_|_|
HOURS

Q8. Were any windows open in your home?

- YES 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW 9

Q9. About how many hours did you spend indoors at work or school?

 |_|_|
HOURS

Q10. About how many hours did you spend outdoors?

 |_|_|
HOURS

Q11. Did you pump gas into a car or other motor vehicle yourself?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q12. Did you spend any time at a swimming pool?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q13. Did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q14. Did you spent 10 or more minutes near a wood-burning fire in a fireplace, wood stove, or outdoors?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q15. Did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q16. Even though you did not use the exposure badge when taking a hot shower, did you take a hot shower for 5 minutes or longer during this time period?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q17. During the time you used the exposure badge, did you breathe fumes from any of the following:

	<u>Yes</u>	<u>No</u>
Paints	1	2
Mothballs, moth crystals, or moth flakes.....	1	2
Household disinfectant or degreasing cleaners.....	1	2
Furniture polish	1	2
Hairspray.....	1	2
Fingernail polish or fingernail polish remover	1	2
Diesel fuel or kerosene	1	2
Gasoline	1	2
Paint thinner, brush cleaner, or furniture stripper	1	2
Air fresheners or room deodorizers	1	2
Dry-cleaning fluid or spot remover	1	2
glues or adhesives used for hobbies or crafts	1	2
REFUSED	7	
DON'T KNOW	9	

SP Name _____	Date __ _ - __ _ - __ _ _ _ _
SP ID __ _ _ _ _ _ _ _ _	Time __ _ : __ _ ^{AM} _{PM}
	TECH ID __ _ _ _

APPENDIX A.2 – SPANISH VOC QUESTIONNAIRE

¿Usó una pequeña caja de monitoreo de exposición todo el tiempo desde que la recibió?

- SI..... 1
NO..... 2

Si no: Aproximadamente, ¿cuál fue la cantidad de horas que usted no usó la pequeña caja?

|_|_|
(cantidad de horas);

0 si es menos de 1 hora HOURS 0

Q1. Quisiera hacerle algunas preguntas acerca de su hogar. ¿Tiene su hogar garaje unido?

- SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW 9

Q2. ¿Fue construido originalmente su hogar o edificio hace menos de 5 años?

- SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW 9

Q3.Cuál de las siguientes es la mejor descripción de la calle en que usted vive? ¿Es ésta un(a)

- Camino rural o del condado..... 1
Calle residencial sin salida..... 2
Calle residencial con salida 3
Calle comercial 4
Autopista principal..... 5
REFUSED..... 7
DON'T KNOW 9

Q4. ¿Funciona la estufa de su cocina con gas natural, electricidad, o alguna otra cosa?

- Natural gas..... 1
- Electricidad 2
- Alguna otra cosa 3
- REFUSED 7
- DON'T KNOW 9

Q5. En los 6 meses pasados, ¿se ha puesto alguna alfombra o tapete nuevo en su hogar, o en su área de trabajo en el lugar en donde trabaja, o en la escuela? Por favor considere solamente el alfombrado de pared a pared o alfombras del tamaño de la habitación

- SI..... 1
- NO..... 2
- REFUSED 7
- DON'T KNOW 9

Q6. ¿Guarda pinturas o combustibles dentro de su hogar? Incluya el sótano (y el garaje unido al hogar).

- SI..... 1
- NO..... 2
- REFUSED 7
- DON'T KNOW 9

Texto

Ahora le voy a hacer algunas preguntas acerca de sus actividades cuando usó su caja de exposición. Esto cubre el tiempo desde que recibió la caja de exposición hace XX horas hasta esta cita.

Q7. Durante el tiempo que usó la caja de exposición, ¿cuántas horas más o menos pasó dentro de la casa? Incluya el tiempo que pasó durmiendo.

|||
Cantidad de horas

Q8. ¿Había alguna ventana abierta en su hogar?

- SI..... 1
- NO..... 2
- REFUSED 7
- DON'T KNOW 9

Q9. ¿Cuántas horas más o menos pasó adentro en el trabajo o en la escuela?

|||
Cantidad de horas

Q10. ¿Cuántas horas más o menos pasó afuera?

□□□
Cantidad de horas

Q11. ¿Le echó gasolina usted mismo a un automóvil u otro vehículo de motor?

SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Q12. ¿Pasó algún tiempo en una (alberca/piscina)?

SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Q13. En la última semana, ¿visitó una lavandería de lavado en seco o usó ropa que había sido limpiada al seco?

SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Q14. ¿Pasó 10 minutos o más cerca del fuego de una chimenea de leña, una estufa de leña, o fuera del hogar?

SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Q15. ¿Pasó 10 minutos o más cerca de una persona que estaba fumando cigarrillo, cigarro, puro, o pipa?

SI..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Q16. Aunque usted no usó la caja de exposición cuando se estaba dando una ducha o baño caliente, ¿se dio una ducha o baño caliente por cinco minutos o más durante este período de tiempo?

SI.....	1
NO.....	2
REFUSED.....	7
DON'T KNOW.....	9

Q17. Durante el tiempo que usó la placa de exposición, ¿aspiró los gases de cualquiera de los artículos siguientes?:

	<u>Yes</u>	<u>No</u>
Pinturas	1	2
Bolas de naftalina para las polillas, cristales para las polillas, o escamas para las polillas.....	1	2
Desinfectantes caseros o limpiadores para sacar la grasa	1	2
Lustre para muebles	1	2
Atomizador de líquido para el pelo	1	2
Esmalte para las uñas o removedor de esmalte para las uñas.....	1	2
Combustible de diesel o querosén.....	1	2
Gasolina	1	2
Líquido para diluir pintura, limpiador de brochas, o removedor de pintura para muebles	1	2
Refrescantes de aire o desodorantes para habitaciones.	1	2
Líquidos para limpiar en seco o removedor de manchas.....	1	2
Gomas o adhesivos usados para pasatiempos o obras manuales (artesanías)	1	2
REFUSED	7	
DON'T KNOW	9	

SP Name _____	Date __ _ - __ _ - __ _ _ _ _
SP ID __ _ _ _ _ _ _ _ _	Time __ _ : __ _ AM PM
	TECH ID __ _ _ _

APPENDIX A.3 – VOC EXPOSURE MONITORING QUESTIONNAIRE: SECOND EXAMINATION

(to be administered by MEC interviewer)

Q1. I would like to ask you a few questions about your home. Does your home have an attached garage?

- YES 1
- NO 2
- REFUSED 7
- DON'T KNOW 9

Q2. Was your home or building originally built less than 5 years ago?

- YES 1
- NO 2
- REFUSED 7
- DON'T KNOW 9

Q3. Which one of the following is the best description of the street that you live on? Is it a:

- Rural or county road 1
- Dead-end residential street..... 2
- Through residential street 3
- Commercial street..... 4
- Major highway 5
- REFUSED 7
- DON'T KNOW 9

Q4. Does your kitchen stove use natural gas, electricity, or something else?

- Natural gas..... 1
- Electricity..... 2
- Something else 3
- REFUSED 7
- DON'T KNOW 9

Q5. In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please only consider wall-to-wall carpeting or room-sized rugs.

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q6. Do you store paints or fuels inside your home? Include your basement (attached garage, if applicable).

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Now I am going to ask you a few questions about your activities over the last 3 days. This means today, yesterday, or the day before yesterday.

Q7. In the last 3 days, did you pump gas into a car or other motor vehicle yourself?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q8. In the last 3 days, did you spend any time at a swimming pool?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q9. In the last 3 days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

YES 1
NO 2
REFUSED 7
DON'T KNOW 9

Q10. In the last 3 days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors?

YES 1
 NO 2
 REFUSED 7
 DON'T KNOW 9

Q11. In the last 3 days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

YES 1
 NO 2
 REFUSED 7
 DON'T KNOW 9

Q12. In the last 3 days, did you take a hot shower for 5 minutes or longer?

YES 1
 NO 2
 REFUSED 7
 DON'T KNOW 9

Q13. In the last 3 days, did you breathe fumes from any of the following:

	<u>YES</u>	<u>NO</u>	<u>DK</u>	
	<u>REFUSED</u>			
a. Paints	1	2	7	9
b. Mothballs, moth crystals, or mothflakes	1	2	7	9
c. Household disinfectant or degreasing cleansers	1	2	7	9
d. Furniture polish.....	1	2	7	9
e. Hair spray	1	2	7	9
f. Fingernail polish or fingernail polish remover	1	2	7	9
g. Diesel fuel or kerosene	1	2	7	9
h. Gasoline	1	2	7	9
i. Paint thinner, brush cleaner, or furniture stripper.....	1	2	7	9
j. Fresheners or room deodorizers.....	1	2	7	9
k. Drycleaning fluid or spot remover	1	2	7	9
l. Glues or adhesives used for hobbies or crafts.....	1	2	7	9

SP Name _____	Date __ __ - __ __ - __ __ __
SP ID __ __ __ __ __	Time __ __ : __ __ ^{AM} _{PM}
	TECH ID __ __ __

**APPENDIX A.4 – SPANISH VOC EXPOSURE MONITORING QUESTIONNAIRE:
SECOND EXAMINATION**
(to be administered by MEC interviewer)

Q1. Quisiera hacerle algunas preguntas acerca de su hogar. ¿Tiene su hogar un garaje unido?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q2. ¿Fue construido originalmente su hogar o edificio hace menos de 5 años?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q3. ¿Cuál de las siguientes es la mejor descripción de la calle en que usted vive? ¿Es ésta un(a):

- Camino rural o del condado..... 1
- Calle residencial sin salida..... 2
- Calle residencial con salida 3
- Calle comercial 4
- Autopista principal..... 5
- REFUSED..... 7
- DON'T KNOW..... 9

Q4. ¿Funciona la estufa de su cocina con gas natural, electricidad, o alguna otra cosa?

- Gas natural 1
- Electricidad 2
- Alguna otra cosa 3
- REFUSED..... 7
- DON'T KNOW..... 9

Q5. En los últimos 6 meses, ¿se ha puesto alguna alfombra o tapete nuevo en su hogar, o en su área de trabajo en el lugar en donde trabaja, o en la escuela? Por favor considere solamente el alfombrado de pared a pared o alfombras del tamaño de la habitación

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q6. ¿Guarda pinturas o combustibles dentro de su hogar? Incluya el sótano (y el garaje unido al hogar, si corresponde).

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Texto

“Ahora le voy a hacer algunas preguntas acerca de sus actividades durante los últimos tres días. Esto significa hoy, ayer, o antes de ayer.”

Q07. En los últimos tres días, ¿le echó gasolina usted mismo a un automóvil u otro vehículo de motor?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q08. En los últimos tres días, ¿pasó algún tiempo en una (alberca/piscina)?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q09. En los últimos tres días, ¿visitó una lavandería de lavado en seco o usó ropa que había sido limpiada al seco dentro de la última semana?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW..... 9

Q10. En los últimos tres días, ¿pasó 10 minutos o más cerca del fuego de una chimenea de leña, una estufa de leña, o fuera del hogar?

SI..... 1
 NO..... 2
 REFUSED..... 7
 DON'T KNOW..... 9

Q11. En los últimos tres días, ¿pasó 10 minutos o más cerca de una persona que estaba fumando (cigarro/cigarrillo), (puro/cigarro/tabaco), o pipa?

SI..... 1
 NO..... 2
 REFUSED..... 7
 DON'T KNOW..... 9

Q12. En los últimos tres días, ¿se dio una ducha o baño caliente por cinco minutos o más?

SI..... 1
 NO..... 2
 REFUSED..... 7
 DON'T KNOW..... 9

Q13. En los últimos tres días, ¿aspiró los gases de cualquiera de los artículos siguientes?:

	<u>Yes</u>	<u>No</u>
Pinturas	1	2
Bolas de naftalina para las polillas, cristales para las polillas, o escamas para las polillas.....	1	2
Desinfectantes caseros o limpiadores para sacar la grasa	1	2
Lustre para muebles	1	2
Atomizador de líquido para el pelo	1	2
Esmalte para las uñas o removedor de esmalte para las uñas.....	1	2
Combustible de diesel o querosén.....	1	2
Gasolina	1	2
Líquido para diluir pintura, limpiador de brochas, o removedor de pintura para muebles	1	2
Refrescantes de aire o desodorantes para habitaciones.	1	2
Líquidos para limpiar en seco o removedor de manchas.....	1	2
Gomas o adhesivos usados para pasatiempos o obras manuales (artesanías)	1	2
REFUSED	7	
DON'T KNOW	9	

Appendix B
International Air Transport Association (IATA)
Dangerous Goods Regulations

APPENDIX B

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS REGULATIONS

B.1 General Provisions

IATA is the International Air Transport Association. It publishes dangerous goods regulations. NHANES falls under these regulations because specimens are packed in dry ice, which is classified as dangerous goods, and shipped via Federal Express which uses air transport.

Dangerous goods are articles or substances which are capable of posing a significant risk to health, safety, or to property when transported by air and which are classified as to the type of hazard. The IATA Dangerous Goods Regulations are applicable to all shippers and agents that offer consignments of dangerous goods to airlines. A shipper must comply fully with these regulations when offering a consignment of dangerous goods to IATA Member airlines, and to airlines participating in IATA interline agreements for cargo. Before offering any package for air transport, the shipper must comply with the following responsibilities.

- ◆ A shipper must provide such information to his employees as will enable them to carry out their responsibilities with regard to the transport of dangerous goods by air.
- ◆ The shipper must ensure that the articles or substances are not prohibited for transport by air.
- ◆ The articles or substances must be properly identified, classified, packed, marked, labeled, and documented in accordance with IATA regulations.
- ◆ Before a consignment of dangerous goods is offered for air transport, all relevant persons involved in its preparation must have received training to enable them to carry out their responsibilities.

Training requirements must include:

- ◆ General familiarization aimed at providing familiarity with IATA general provisions.
- ◆ Function specific training in the requirements applicable to the function for which that person is responsible.

- ◆ Safety training to cover the hazards presented by dangerous goods, safe handling and emergency response procedures.

Training must be provided or verified upon the employment of a person in a position involving the transport of dangerous goods by air. Recurrent training must take place within 24 months of previous training to ensure knowledge is current.

A record of training must be maintained, which must include:

- ◆ The individual's name;
- ◆ The most recent training completion date;
- ◆ A description, copy or reference to training materials used to meet the training requirement;
- ◆ The name and address of the organization providing the training; and
- ◆ A copy of the certification issued when the individual was trained, which shows a test has been completed satisfactorily

B.2 Classifications

Dangerous goods are defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of the three UN packing groups according to provisions of IATA regulations. The nine classes relate to the type of hazard whereas the packing groups relate to the degree of danger within the class.

B.2.1 Class 9 – Miscellaneous Dangerous Goods

Class 9 defines miscellaneous dangerous goods as substances and articles which, during air transport present a danger not covered by other classes. Included in this class is solid carbon dioxide, or dry ice. Dry ice is regulated by packing instruction 904.

B.2.2 List of Dangerous Goods

Dry ice is classified as UN number 1845 and is classified as a Class 9 dangerous good. Shipping packaging must be labeled with a Miscellaneous Class 9 label.

Dry ice is included within Packing Group 3, which is classified as a minor danger. A maximum net quantity per package is 200 kg or 441 lb. A special provision directs that packing tests are not considered necessary.

B.3 General Packing Provisions

Packing group III indicates a minor degree of danger. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and "snow" in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns to skin as a result of direct contact due to its very low temperature (about -79°C). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.

Packing materials must be free of any indication that their integrity has been compromised. Packages must be constructed, closed, and prepared for transport so as to prevent any leakage during air transport which might be caused by temperature, pressure, or by vibration normally occurring in air transport.

Packaging used for solids which may become liquid at temperatures likely to be encountered during air transport must also be capable of containing that substance in the liquid state.

Inner packaging – cushioning material: Inner packaging must be packed, secured, or cushioned so as to prevent their breakage or leakage, and so as to control their movement within the outer packing during normal conditions of transport. Cushioning material must not react dangerously with the contents of the inner packaging.

B.3.1 Packing Instruction 904 (Dry Ice)

Carbon dioxide, solid (dry ice) when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

The net weight of dry ice must be marked on the outside of the package.

Arrangements between the shipper and operator(s) must be made for each shipment; to ensure ventilation, safety procedures are followed. The "Nature and Quantity of Dangerous Goods" box on the Shipper's Declaration must show in sequence:

Proper shipping name (**Dry Ice**);

Class or division number (**9**);

UN number (**UN 1845**) and;

Net quantity per package (**kg**).

B.3.2 Packing Instruction 605 (Diagnostic Specimens)

Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations. The shipper must also ensure that shipments are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to persons or animals during shipment. The packaging must include:

650(a) inner packaging comprising:

- ◆ A leak proof primary receptacle(s) – for diagnostic specimens the maximum quantity must not exceed 500-mL
- ◆ A watertight secondary packaging – the maximum quantity per outer packaging for diagnostic specimens must not exceed 4L
- ◆ An absorbent material – must be placed between the primary and the secondary packaging

If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually and the absorbing material must be sufficient to absorb the entire contents of all primary receptacles.

650(b) outer packaging comprising:

- ◆ An outer packaging of adequate strength for its capacity, weight, and intended use.
- ◆ The primary receptacle or the secondary packaging used for diagnostic specimens must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- ◆ Packages consigned as freight must be at least 100mm (4 inches) in the smallest overall external dimension.
- ◆ An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

Each package and the "Nature and Quantity of Goods" box of the air waybill must show the text "DIAGNOSTIC SPECIMENS" – "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650".

The majority of diagnostic specimens can and must be packaged according to the following guidelines.

- ◆ Substances shipped at ambient temperature or higher.

Primary receptacles include those of glass, metal, or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper, or metal crimp seal must be provided. If screw caps are used these must be reinforced with adhesive tape.
- ◆ Substances shipped refrigerated or frozen (wet ice, prefrozen packs, carbon dioxide, solid [dry ice]):

Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

B.4 Labeling and Marking

All markings must be readily visible, legible, and so placed that they are not covered or obscured by any part of or attachment to the packaging or any other label or marking.

Each package must be marked with each of the following:

- ◆ The proper shipping name of the contents and the corresponding UN numbers;
- ◆ The name and address of the shipper and the consignee;
- ◆ The net weight of dry ice within the package; and
- ◆ "Diagnostic Specimens" and "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650."

The hazard label to be used on packages and overpacks is specified for each substance. All packages must bear the appropriate hazard label. The label identifying the primary hazard of the dangerous goods must bear the class number in the bottom corner of the label. For Class 9 goods (dry ice), the package is required to bear the Class 9 "Miscellaneous" dangerous goods label.

All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. Each label must be affixed on a background of contrasting color or must have a dotted or solid line outer border. The label must not be folded or affixed in such a manner that different parts of the label appear on different faces of the package.

B.5 Documentation

An air waybill must be completed for each consignment of dangerous goods. For each shipment containing dangerous goods the shipper must:

- ◆ Use only the correct form in the correct manner;
- ◆ Complete the form accurately and legibly;

- ◆ Ensure that the form is properly signed when the shipment is presented to the operator for shipment; and
- ◆ Ensure that the shipment has been prepared in accordance with IATA regulations.

Each form must include:

- ◆ Full name and address of the shipper;
- ◆ Full name and address of the consignee;
- ◆ Deletion of "radioactive";
- ◆ Proper shipping name (Dry Ice);
- ◆ Class or division number (9);
- ◆ UN number (UN 1845);
- ◆ Net quantity per package (kg);
- ◆ Response telephone number;
- ◆ Name and title of signatory;
- ◆ Place and date; and
- ◆ Signature.

Reference: IATA Dangerous Goods regulations, 38th Edition, effective January 1, 1997, ISBN 92-9035-863-7

B.6 IATA Regulations Examination

Name _____

Date _____

1. IATA stands for _____
2. Dangerous goods are articles or substances which are capable of posing a significant risk to health, safety or to property when transported by air and which are classified as to the type of hazard.
(T or F)
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
 - ◆ _____
 - ◆ _____
 - ◆ _____
 - ◆ _____
4. What are the three training requirements?
 - ◆ _____
 - ◆ _____
 - ◆ _____
5. How many UN hazard classes are there? _____
6. To what UN hazard class does dry ice belong? _____
7. What is the dry ice UN number? _____
8. To what packing group does dry ice belong? _____
9. Dry ice is used primarily for cooling and can cause severe burns to skin as a result of direct contact due to its very low temperature (about -79°C). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.
(T or F)

10. Is the weight of dry ice required on the outside of the packaging?
(T or F)
11. Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations.
What packing instruction regulates diagnostic specimens? _____
12. List the three inner packaging requirements.
- ◆ _____
 - ◆ _____
 - ◆ _____
13. What special requirement does the absorbing material have?

14. Outer packaging material must be of adequate _____ for its capacity, weight, and intended use.
15. Where is an itemized list of contents is placed?

16. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?

17. Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.
(T or F)
18. All markings must be readily _____, _____ and so placed that they are not obscured by any part or attachment to the packaging or any other label or marking.
19. Each package must be marked with each of the following:
- ◆ _____
 - ◆ _____
 - ◆ _____
 - ◆ _____

20. What hazard label is required for Class 9? _____

21. The shipper is responsible for completing any air waybill for each consignment of dangerous goods. List the four requirements.

- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____

22. Each form must include:

- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____
- ◆ _____

B.7 IATA Regulations Examination (Answer Key)

Name _____

Date _____

1. IATA stands for the International Air Transport Association
2. Dangerous goods are articles or substances which are capable of posing a significant risk to health, safety or to property when transported by air and which are classified as to the type of hazard.
(T or F) True
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
 - ◆ Information to employees as will enable them to carry out their responsibilities.
 - ◆ Ensure that articles or substances are not prohibited for transport by air.
 - ◆ Articles must be properly identified, classified, packed, marked, labeled, and documented.
 - ◆ All persons involved in preparing consignment must have received training.
4. What are the three training requirements?
 - ◆ General familiarization aimed at providing familiarity with IATA general provisions;
 - ◆ Function specific training in the requirements applicable to the function for which that person is responsible; and
 - ◆ Safety training to cover the hazards presented by dangerous goods, safe handling and emergency response procedures.
5. How many UN hazard classes are there? 9 (nine)
6. To what UN hazard class does dry ice belong? Class 9
7. What is the dry ice UN number? UN 1845
8. To what packing group does dry ice belong? Packing group 3
9. Dry ice is used primarily for cooling and can cause severe burns to skin as a result of direct contact due to its very low temperature (about -79° C). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.
(T or F) True
10. Is the weight of dry ice required on the outside of the packaging?

(T or F) True

11. Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations.
12. What packing instruction regulates diagnostic specimens? Packing instruction 650 (Dry Ice)
13. List the three inner packaging requirements.
 - ◆ A leak proof primary receptacle(s) - for diagnostic specimens the maximum quantity must not exceed 500-mL.
 - ◆ A watertight secondary packaging - the maximum quantity per outer packaging for diagnostic specimens must not exceed 4L.
 - ◆ An absorbent material - must be placed between the primary and the secondary packaging.
14. What special requirement does the absorbing material have?
The absorbing material must be sufficient to absorb the entire contents of all primary receptacles.
15. Outer packaging material must be of adequate strength for its capacity, weight, and intended use.
16. Where is an itemized list of contents is placed?
An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
17. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?
glass, metal, or plastic
18. Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.
(T or F) True
19. All markings must be readily visible, legible and so placed that they are not obscured by any part or attachment to the packaging or any other label or marking.
20. Each package must be marked with each of the following:
 - ◆ The proper shipping name of the contents and the corresponding UN numbers;
 - ◆ The name and address of the shipper and the consignee;

- ◆ The net weight of dry ice within the package; and
 - ◆ "Diagnostic Specimens" and "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650."
21. What hazard label is required for Class 9? Class 9 "Miscellaneous"
22. The shipper is responsible for completing any air waybill for each consignment of dangerous goods. List the four requirements.
- ◆ Use only the correct form in the correct manner;
 - ◆ Complete the form accurately and legibly;
 - ◆ Ensure that the form is properly signed when the shipment is presented to the operator for shipment; and
 - ◆ Ensure that the shipment has been prepared in accordance with IATA regulations.
23. Each form must include:
- ◆ Full name and address of the shipper;
 - ◆ Full name and address of the consignee;
 - ◆ Deletion of "radioactive";
 - ◆ Proper shipping name (Dry Ice);
 - ◆ Class or division number (9);
 - ◆ UN number (UN 1845);
 - ◆ Net quantity per package (kg);
 - ◆ Response telephone number;
 - ◆ Name and title of signatory;
 - ◆ Place and date; and
 - ◆ Signature.

WESTAT

Certificate of Test Completion

International Air Transport Association (IATA) Dangerous Goods Regulations

Name _____

Date of Successful Exam _____

Examiner _____

Appendix C
Lead Dust Processing and Quality Control

APPENDIX C

LEAD DUST PROCESSING AND QUALITY CONTROL

C.1 Overview

Field interviewers collect lead dust samples in households with children ages 1-5. Associate a dust sample with a specific SP when it is collected; collect the sample in the room where the SP spends most of their time. There are five possible sample types: floor, floor replicate, windowsill, windowsill replicate, and field blank. Collect both floor and windowsill samples in each eligible home. In 10 percent of homes, collect one replicate sample. This replicate is randomly selected as either a floor or windowsill. In those households chosen for a replicate sample, the interviewer must also collect a field blank.

Each lead dust sample consists of one dust collection wipe in a 50-mL skirted conical tube. Label lead dust samples in the field with preprinted randomly assigned specimen identification numbers. Place samples from each household in a sample storage bag and return to the field office. Store samples at room temperature in a box with a lid to prevent excessive exposure to light. The MEC manager delivers lead dust samples and the corresponding Lead Dust Transmittal form to the MEC weekly. Samples are relabeled, assigned to specific slots in storage containers, and shipped weekly to the analysis laboratory. Send the Lead Dust Transmittal form back to the home office at the end of each stand.

The warehouse maintains a supply of spiked positive controls. At the start of each stand, the warehouse manager sends four spiked positive samples to the MEC. Process one pair of spiked samples; designate one control as a floor sample and designate the second positive control as a window sample. Process this pair of samples at the start of weeks one and three. Print labels for these specimens, process, and insert the relabeled samples into the assigned slot in the storage containers.

C.2 MEC Laboratory Lead Dust Processing

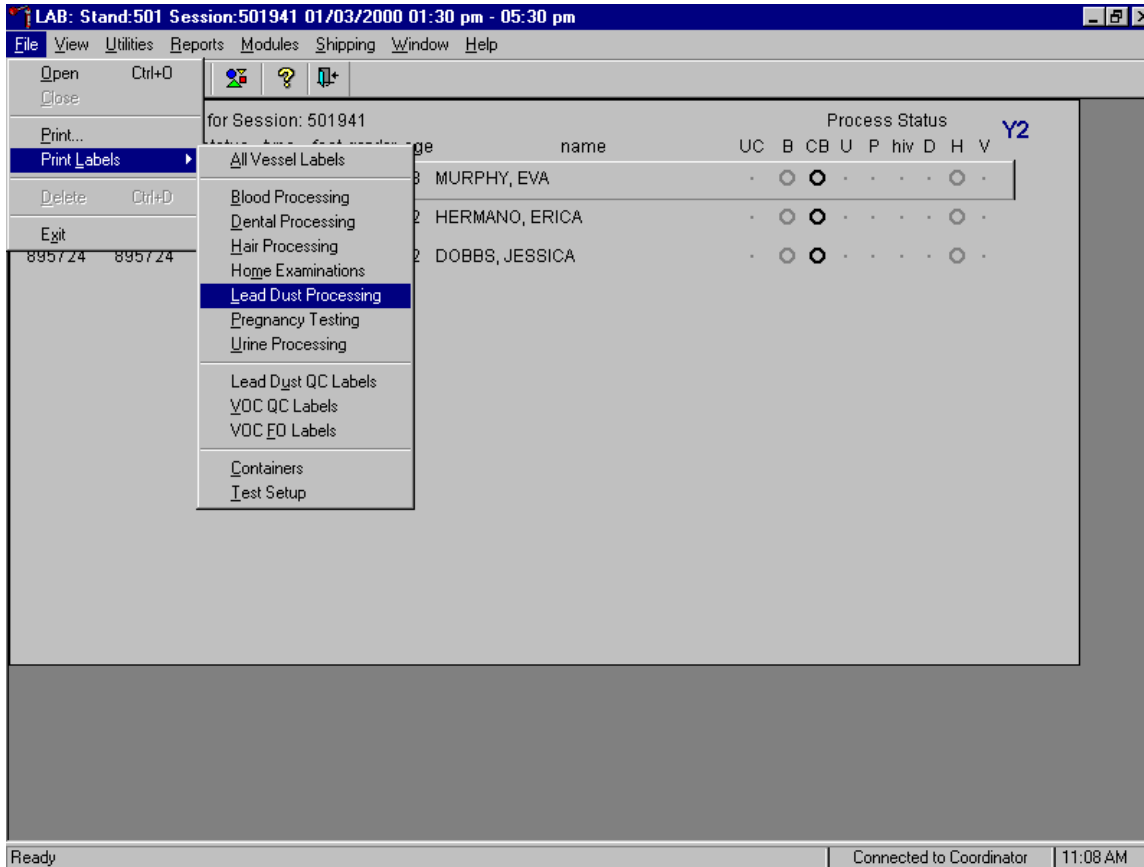
The conical tubes that hold each lead dust sample are labeled in the field with bar-coded labels that contain a preprinted randomly assigned specimen identification number and an indication of the sample

type. Once these tubes reach the MEC, the laboratory staff matches the vessels to the Lead Dust Transmittal form, prints laboratory labels that contain the sample ID associated with each SP and the vessel ID, removes the original field office label, and labels each sample with the new laboratory label. Process the relabeled samples using the Lead Dust Processing module, store the samples at room temperature, and ship weekly. Field blanks are blinded to the analysis laboratory. Label field blanks with “virtual” sample IDs as designated by ISIS.

Laboratory Lead Dust Vessels

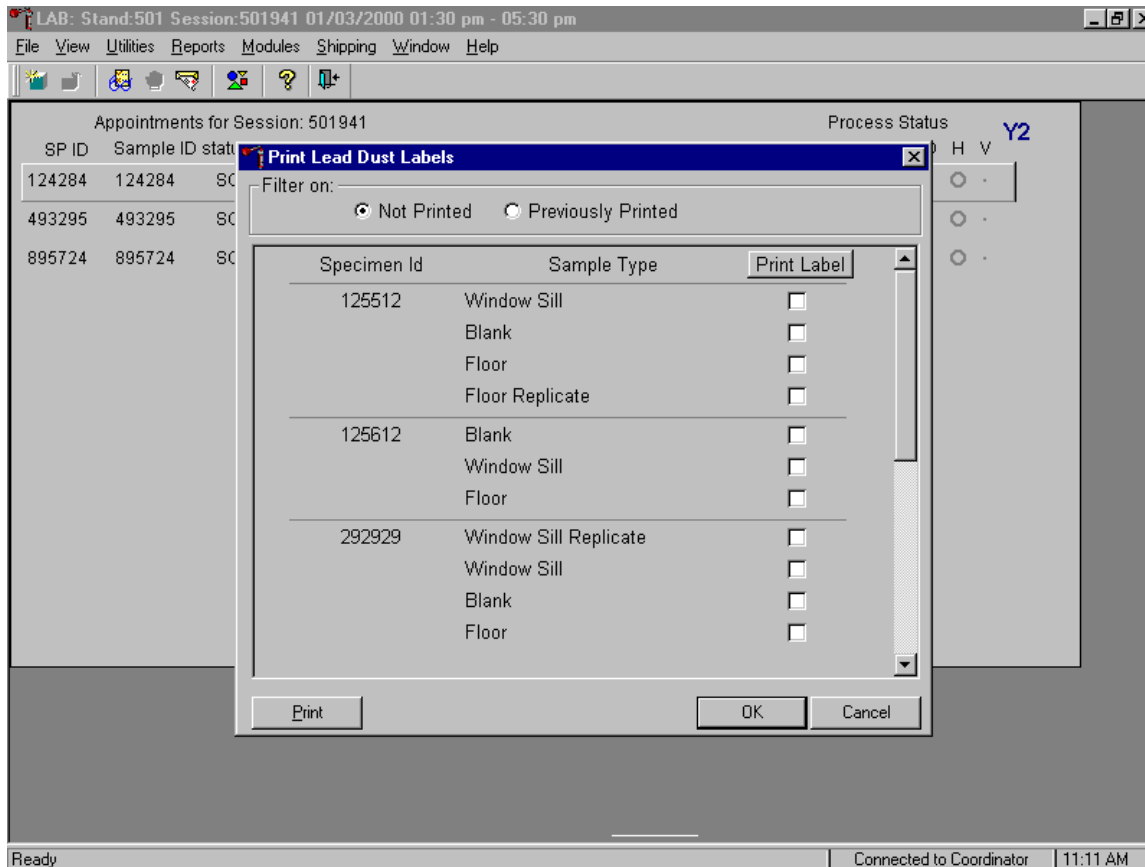
Vessel ID	Test Name	Sample Type	Vessel Type	Vessel Storage
60	Lead Dust Floor	Wipe	50-mL Conical tube	4 x 4 five inch box
61	Lead Dust Windowsill	Wipe	50-mL Conical tube	4 x 4 five inch box

Physically match the vessels listed on the Lead Dust Transmittal form to the actual lead dust samples. If there are discrepancies, contact the field office manager to reconcile the inconsistencies. Print laboratory labels for lead dust samples collected in the home. Access the Lead Dust Processing label module.



To access the Lead Dust Processing label module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, drag the arrow to {Print Labels}, then to {Lead Dust Processing}, and left click or type [Alt] [F], [L], [L].

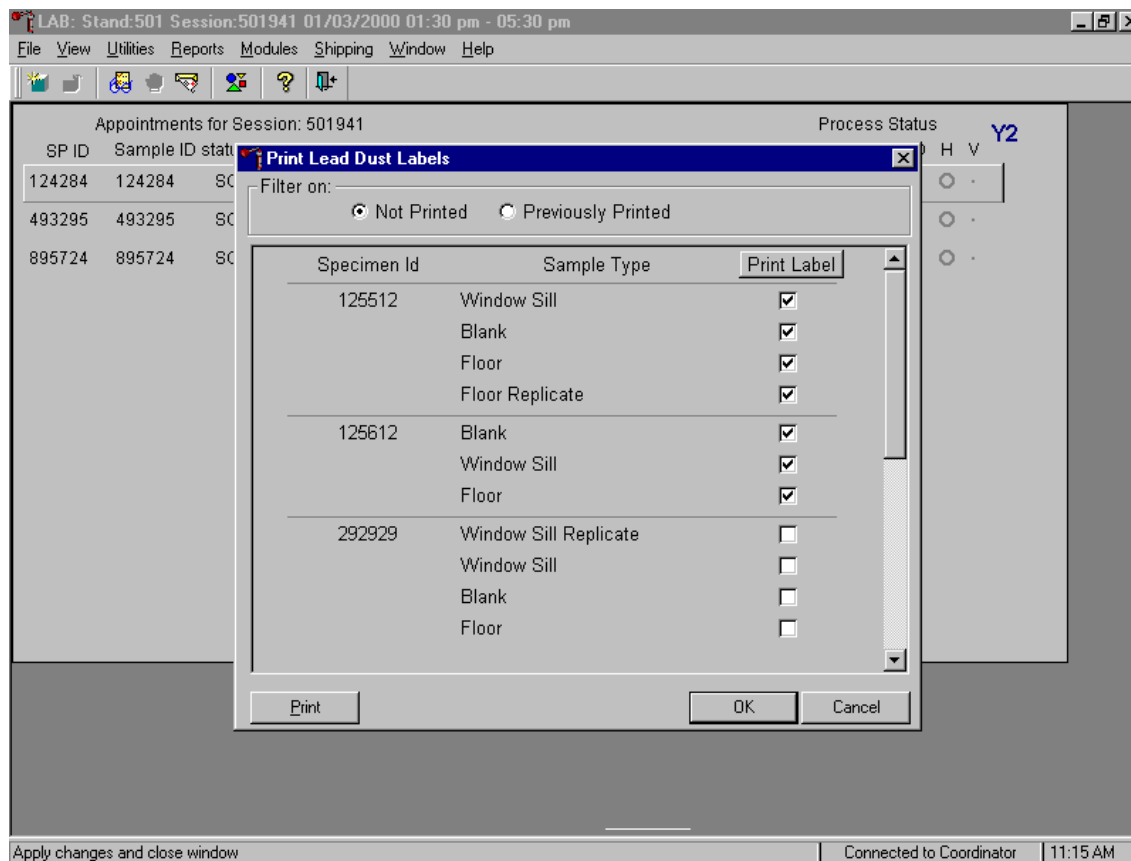
The Print Lead Dust Labels window displays.



The Print Lead Dust Labels window contains a filter that selects or displays samples for which labels have not been printed or samples for which labels have been previously printed, the Specimen ID for each set of samples, the sample types collected, and a check box to mark each sample as requiring a label. Generally, set the filter to Not Printed to view samples that require labels.

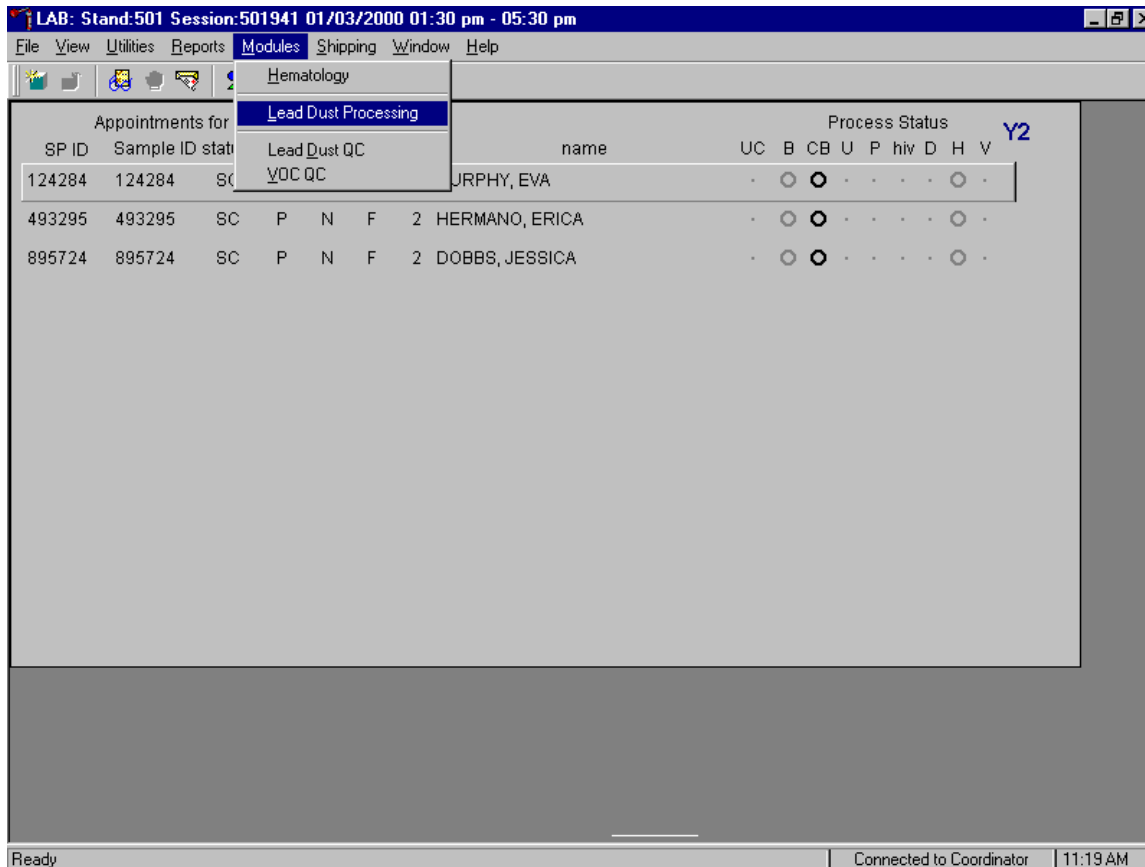
Physically match each sample's specimen ID and sample type to the data displayed in the window. Use the scroll bar to view all Specimen IDs and sample types.

Mark the checkbox for each Specimen ID and sample type.



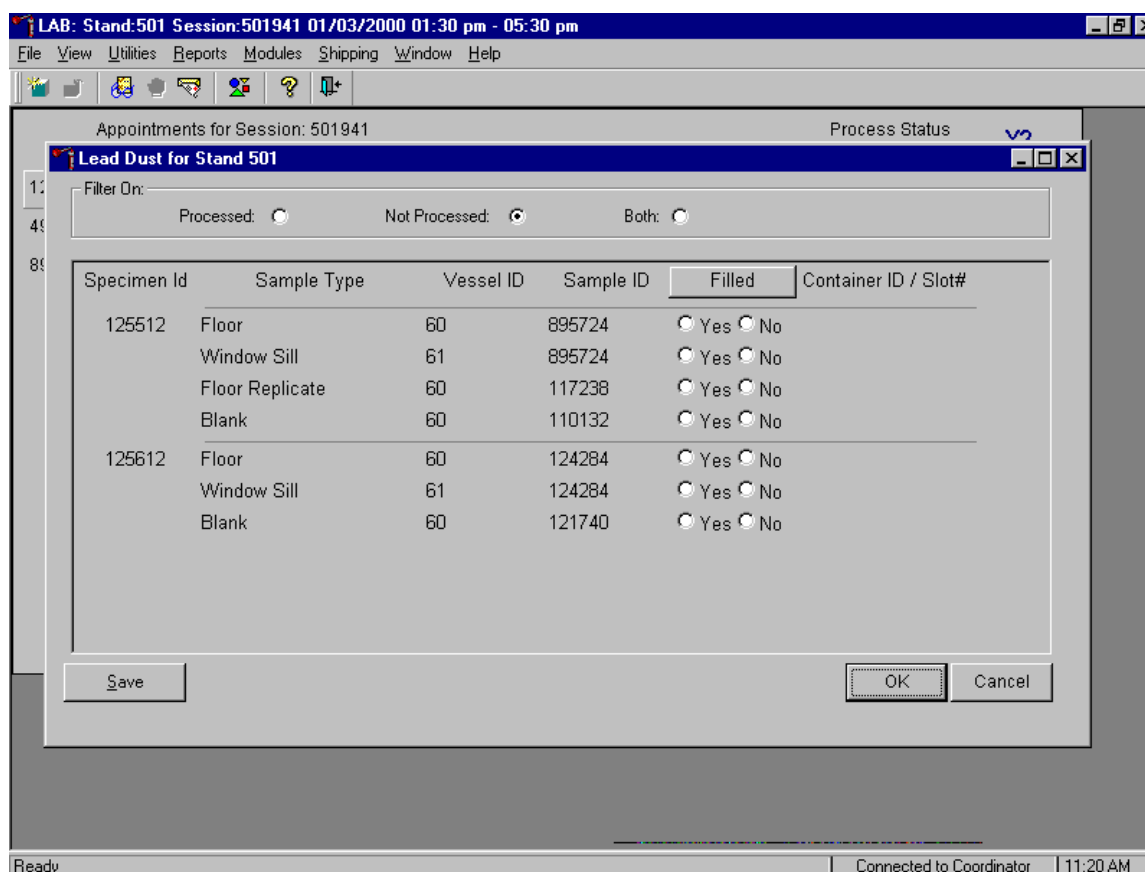
To mark each sample type for each Specimen ID, use the mouse to direct the mouse arrow to each individual checkbox and left click. To mark all Sample Types for all Specimen IDs at one time, use the mouse to direct the mouse arrow to the **Print Label** box at the top of the checkbox column and left click. To remove all checkmarks, use the mouse to direct the mouse arrow to the **Print Label** box and left click a second time. After physically matching all the samples in the window to the samples from the field office and marking the corresponding checkbox, print the labels. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click. Labels print on the Datamax printer. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. Alternatively, to print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click. Labels print on the Datamax printer. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. To close the window without saving any data in the database or printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Process the lead dust samples.



To access the Lead Dust Processing module, use the mouse to direct the mouse arrow to {Modules} in the top menu bar, left click, drag the arrow to {Lead Dust Processing} and left click or type [Alt] [M], [L].

The Lead Dust processing window displays.

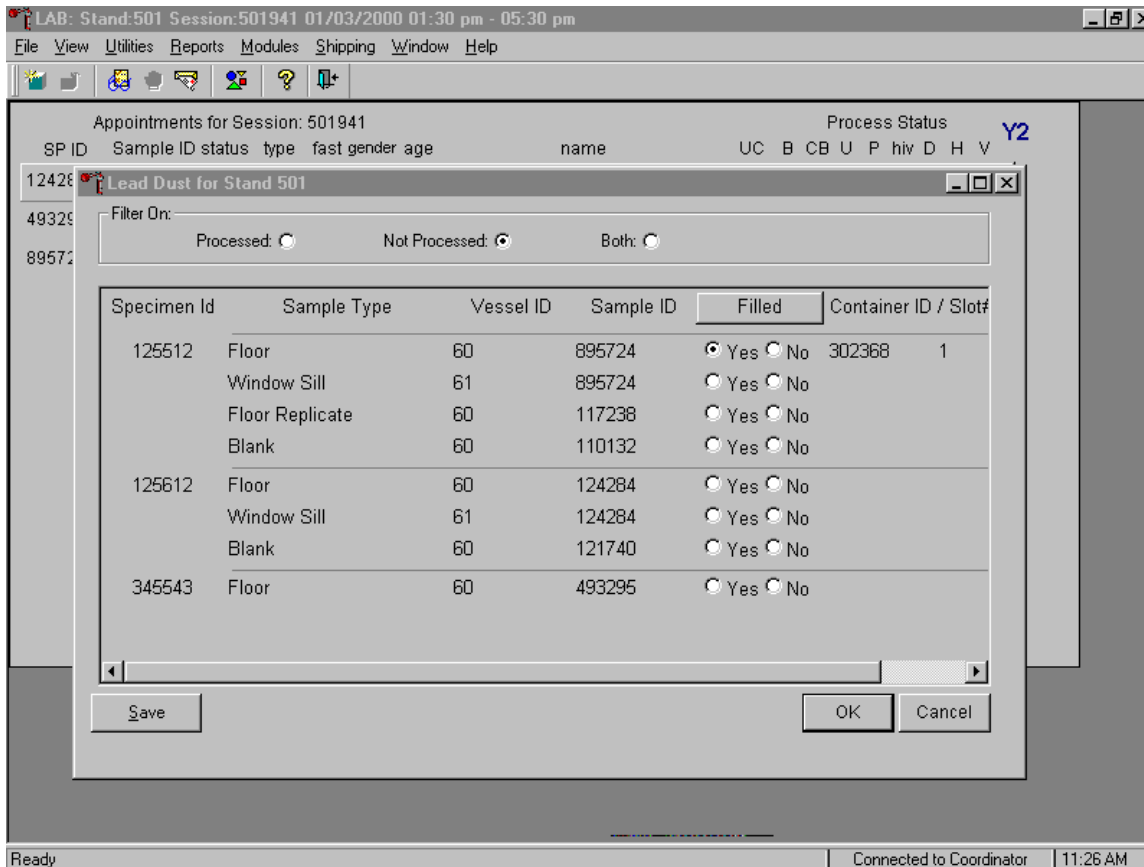


The Lead Dust for Stand XXX window contains a filter that selects or displays processed samples, those samples that have been previously processed; or not processed samples, those samples that have not been previously processed; or both, previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing.

This window contains column titles for Specimen ID, Sample Types, Vessel ID (either 60 or 61), Sample ID, a Filled box, and Container ID/Slot # assignment.

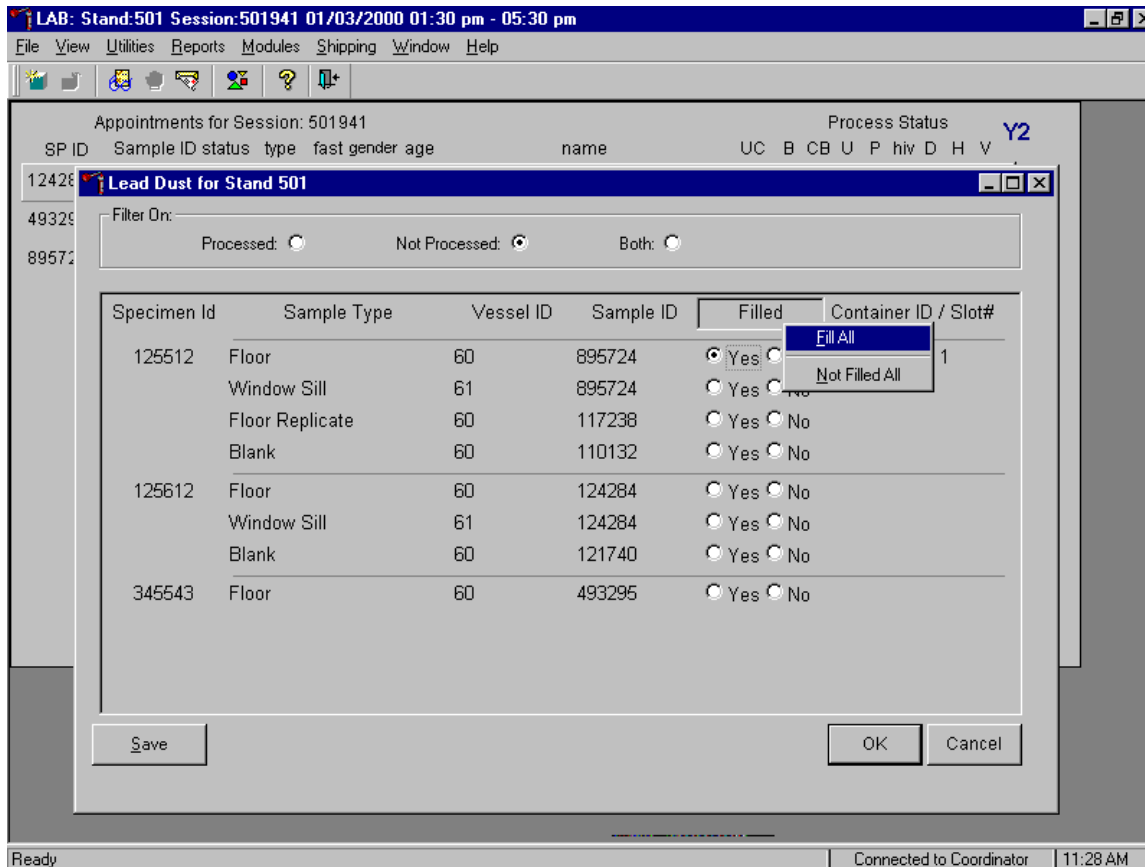
Match the samples to the Datamax laboratory labels. The laboratory label contains the Sample ID concatenated with the vessel ID and includes the text, “W Lead Dust” for windowsill samples or “F Lead Dust” for floor samples. Remove the field office label, relabel each sample with the laboratory label, and mark the vessel as collected or filled.

Individually mark each vessel as filled, yes or no.



To mark individual lead dust vessel as collected or “filled,” use the mouse to direct the mouse arrow to the Filled radio button and left click. As each vessel is marked as “Filled - yes,” it is automatically assigned to a slot in an existing (open) container.

Collectively mark all vessels as filled or not filled.



To collectively mark all vessels as filled, use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click and drag the arrow to Fill All or type [F]. To mark all vessels as Not Filled, use the mouse to direct the mouse arrow to the **Filled** box, left click and drag the arrow to Not Filled All or type [N].

Continue to process all lead dust vessels.

Appointments for Session: 501941 Process Status Y2

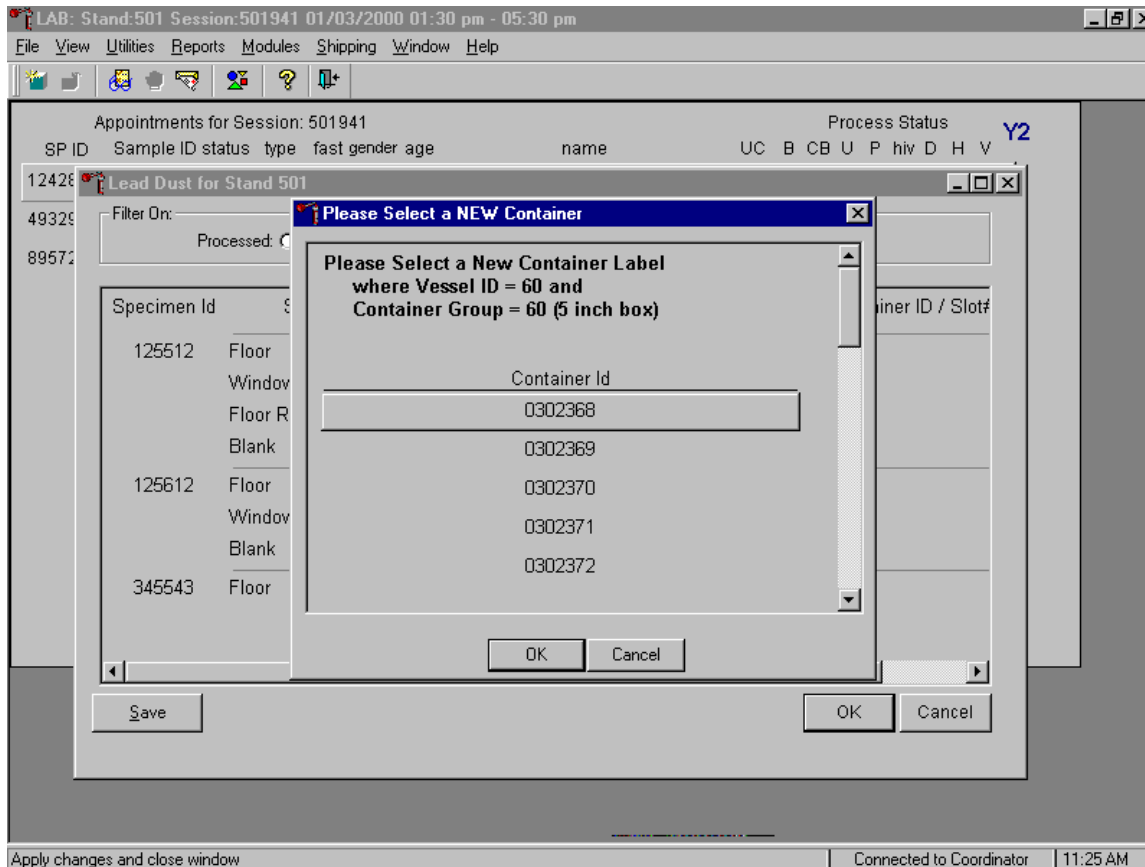
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
12428	Lead Dust for Stand 501															
Filter On:																
Processed: <input type="radio"/> Not Processed: <input checked="" type="radio"/> Both: <input type="radio"/>																
Specimen Id	Sample Type	Vessel ID	Sample ID	Filled		Container ID / Slot#										
125512	Floor	60	895724	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 1										
	Window Sill	61	895724	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 2										
	Floor Replicate	60	117238	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 3										
	Blank	60	110132	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 4										
125612	Floor	60	124284	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 5										
	Window Sill	61	124284	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 6										
	Blank	60	121740	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 7										
345543	Floor	60	493295	<input checked="" type="radio"/> Yes	<input type="radio"/> No	302368 8										

Save OK Cancel

Ready Connected to Coordinator 11:30 AM

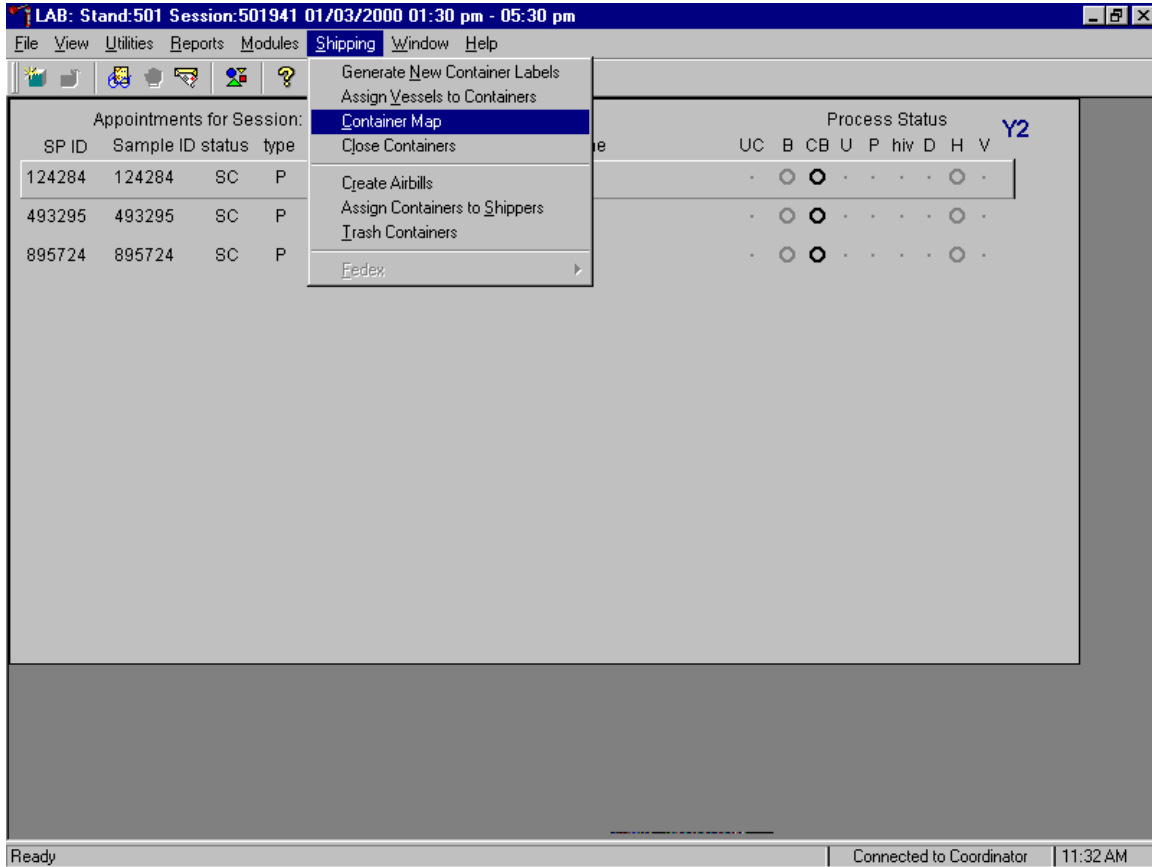
Store each filled vessel in the assigned slot in the designated container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Open a new container when prompted.



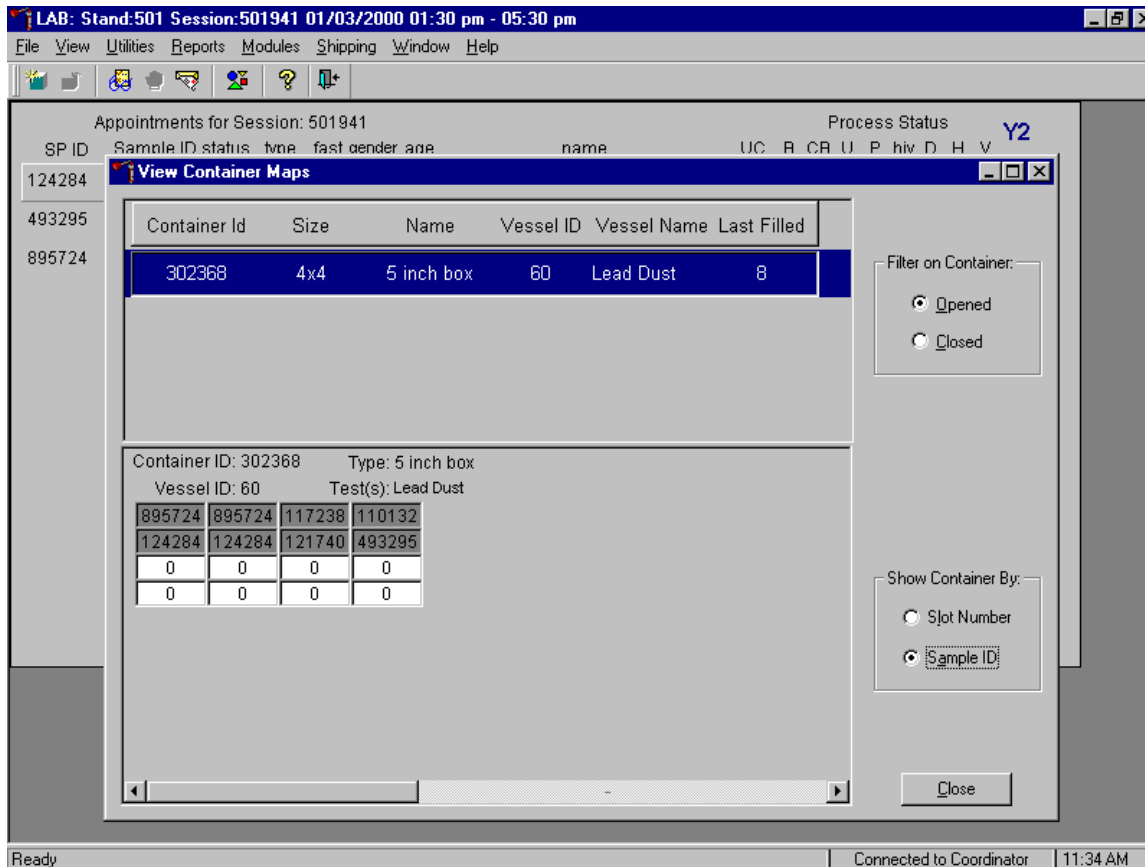
When a container is full an opportunity to open a new container is automatically displayed on the “Please Select a NEW Container” window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Check the slot assignment of the lead dust container at the end of each processing session.
 Access the Container Map report.



To open the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping}, drag the arrow to {Container Map}, and left click or type [Alt] [S], [C].

Verify the contents of each container against the container map.

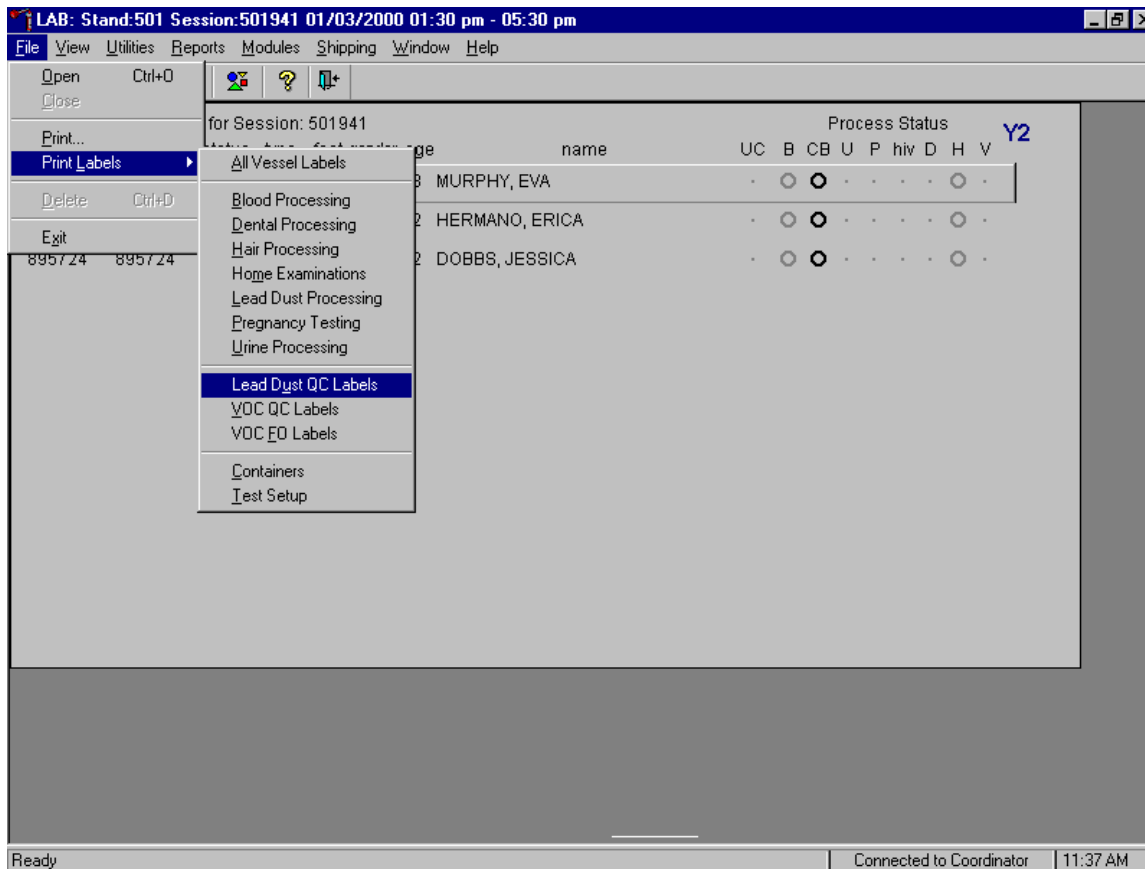


- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to the “Opened” radio button and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to the “Sample ID” radio button and left click.
- Highlight or select the first container ID for vessel 60 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 60.
- To sort on Container ID, Size, Name, Vessel ID, Vessel Name, or Last Filled, use the mouse to direct the mouse arrow to any column title and right click. To reverse the order, use the mouse to direct the mouse arrow to the column title and right click.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.

- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining lead dust vessels.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the **Close** button and left click.

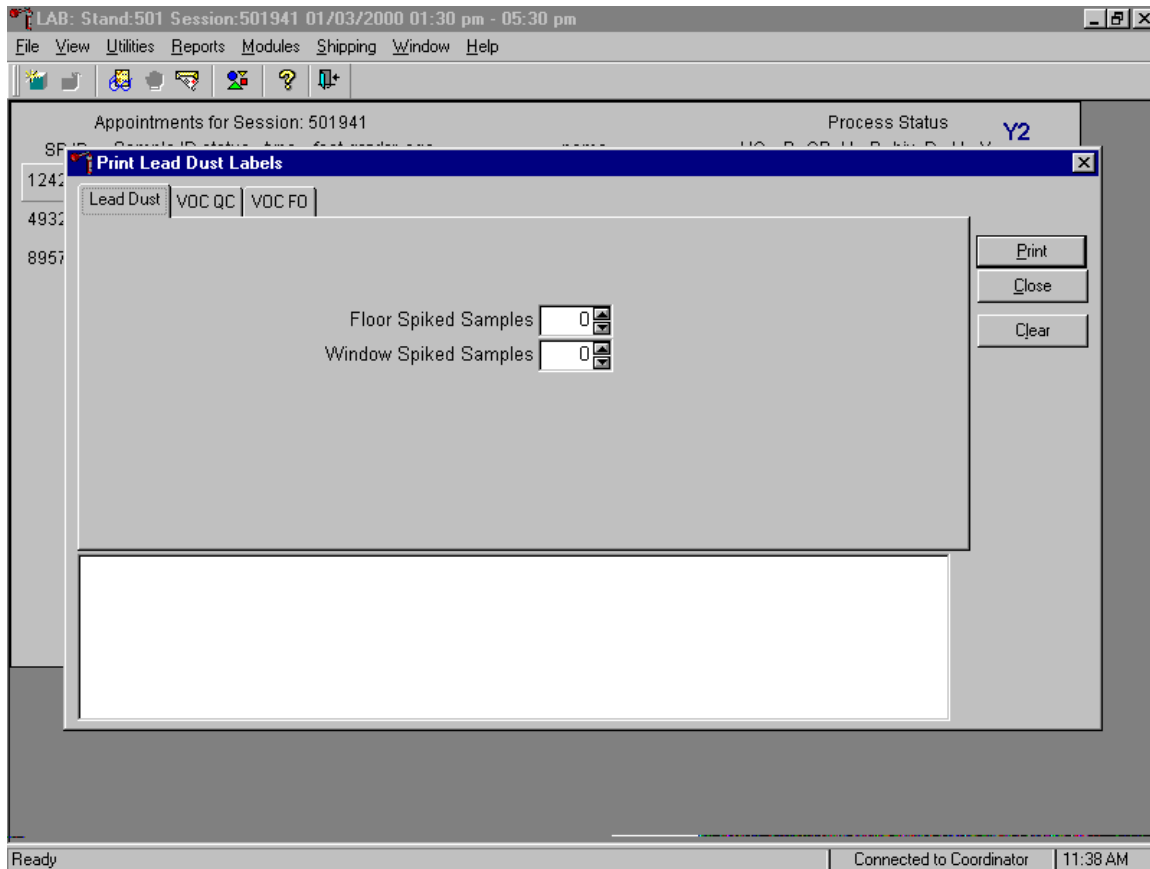
C.3 Lead Dust QC Processing

Print labels for the lead dust QC (positive control) samples. Access the Lead Dust QC Labels module.



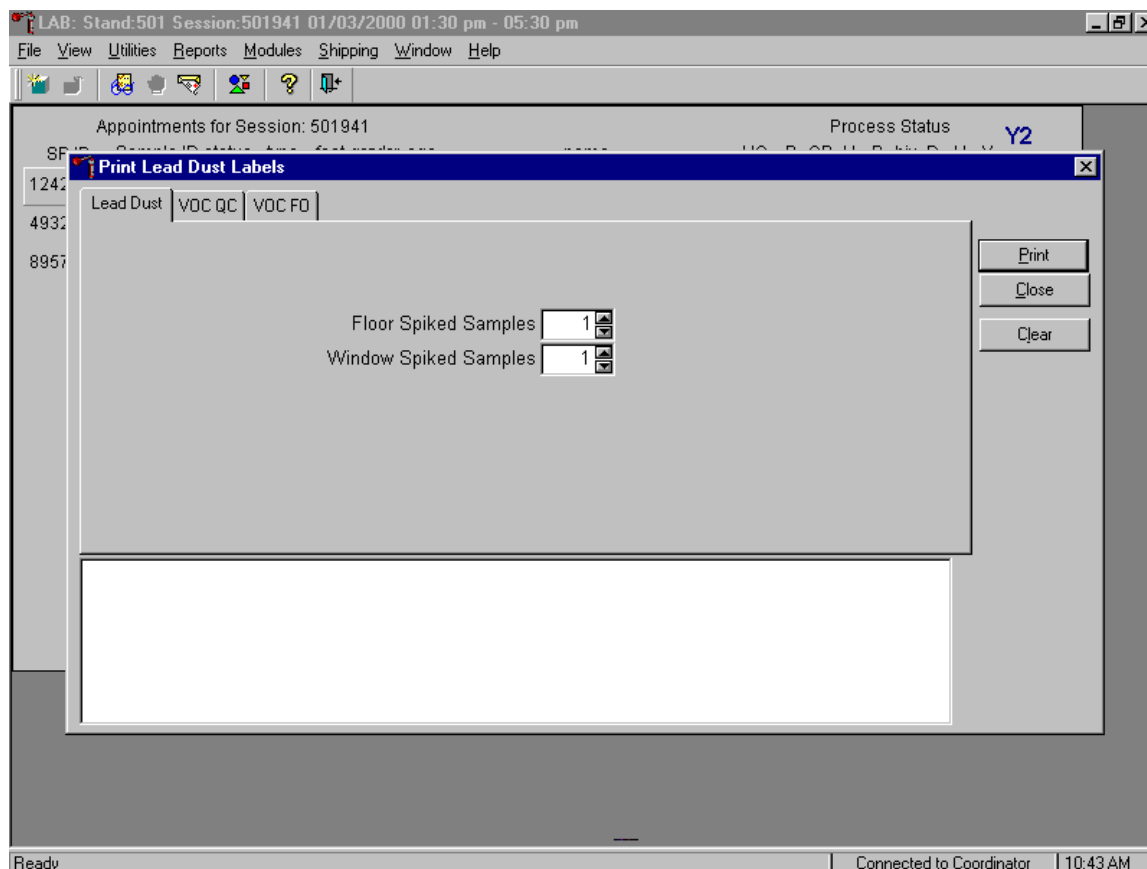
To access the Lead Dust QC Label module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Print Labels}, then to {Lead Dust QC Labels}, and left click or type [Alt] [F], [L], [U].

The Print Lead Dust Labels window displays.



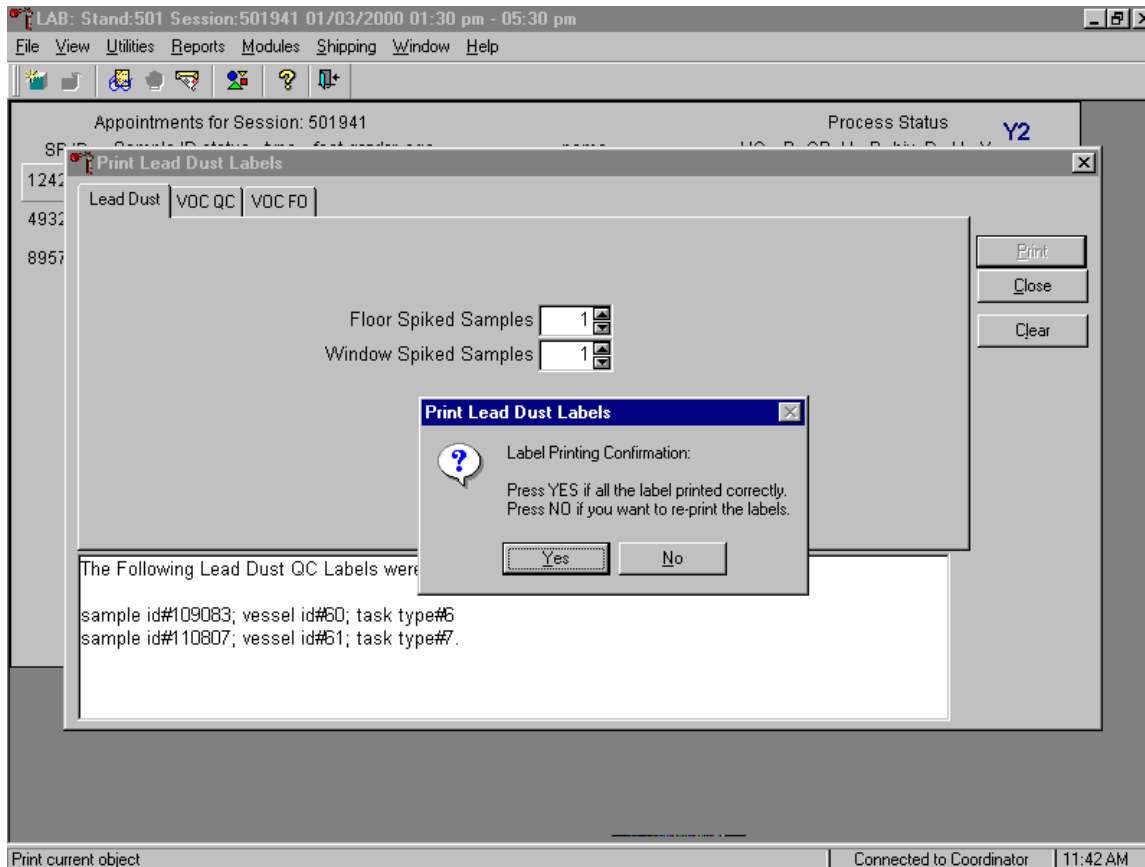
To select the Lead Dust file, use the mouse to direct the mouse arrow to the Lead Dust file header and left click. Use this module to print two types of lead dust QC labels – floor spiked samples and window spiked samples.

Continue the Print Lead Dust Labels process.



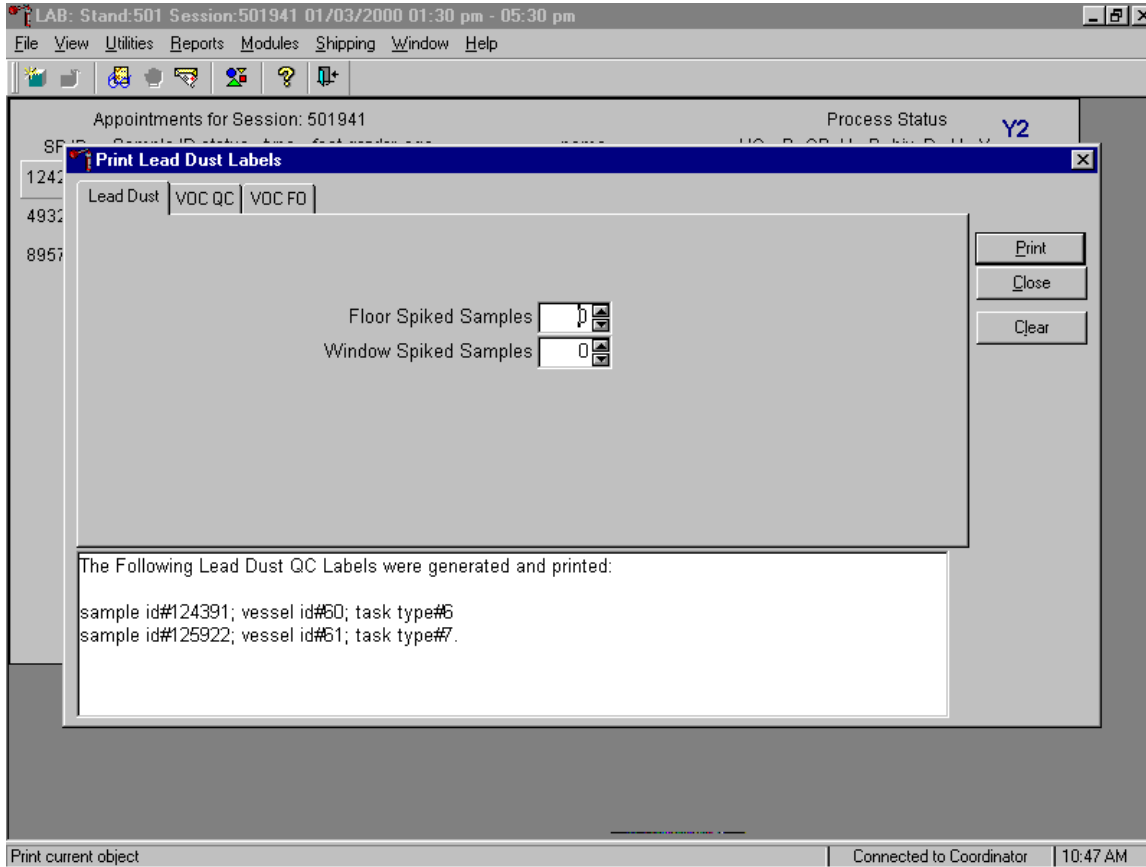
To select the number of floor and window spiked sample labels, use the mouse to direct the mouse arrow to the spin box and toggle the up-down controls until the number “1” is displayed in the text box. Alternatively, insert the cursor inside the Floor Spiked Samples text box, type the number 1, and [Tab] to move to the Window Spiked Samples text box and type the number 1. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click or type [P]. Labels print on the Datamax printer. These labels are indistinguishable from routine vessel labels.

Confirm that the labels printed correctly before continuing.



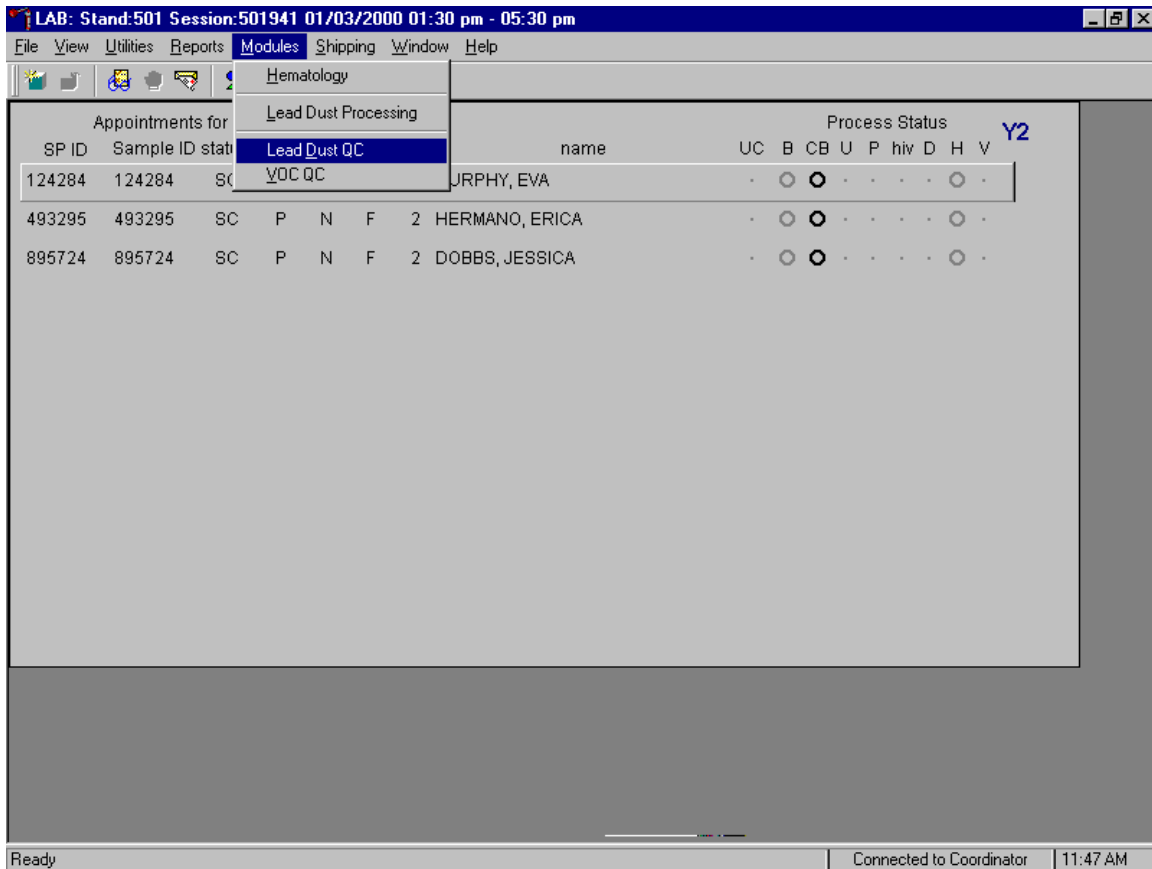
The Print Lead Dust Labels message box displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to the **Yes** button and left click. If any of the labels did not print correctly and/or to re-print the labels, use the mouse to direct the mouse arrow to the **No** button and left click.

Verify the information contained in the lower white section of the Print Lead Dust Labels window.



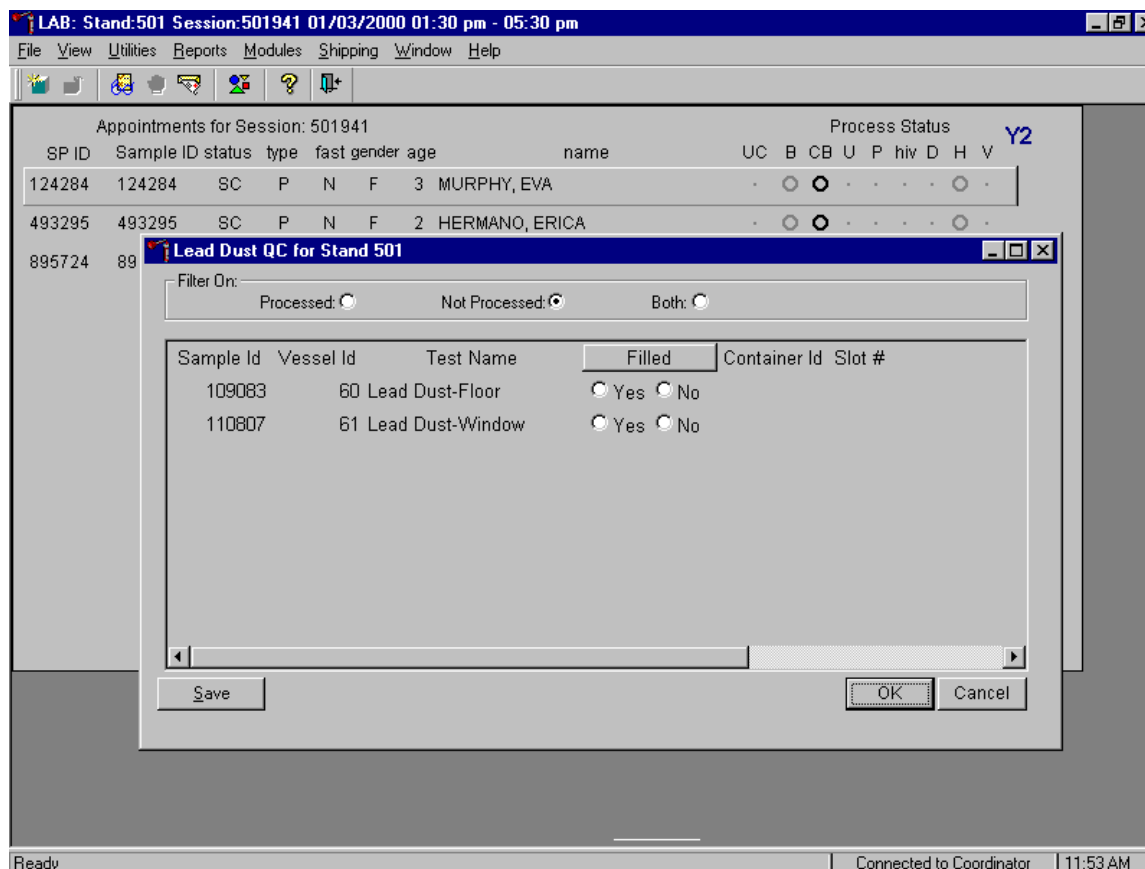
The lower white section of the Print Lead Dust QC Labels window displays the sample ID #, vessel ID # and sample type #. To close the window, use the mouse to direct the mouse arrow to the **Clear** button and left click or type [C].

Access the Lead Dust QC module to process the QC specimens.



To access the Lead Dust QC processing module, use the mouse to direct the mouse arrow to {Modules} in the menu bar, right click, drag the arrow to {Lead Dust QC}, and left click or type [Alt] [M], [U].

The Lead Dust QC processing screen displays.

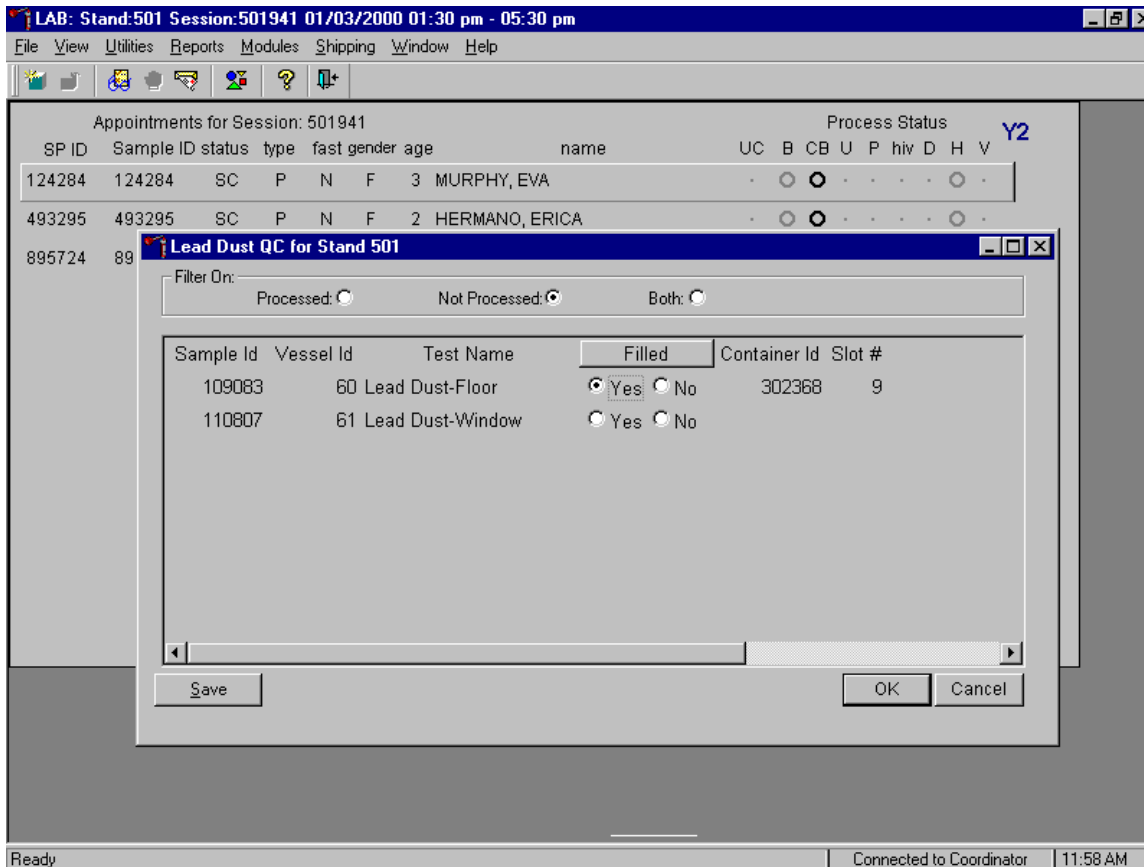


The Lead Dust for Stand XXX window contains a filter that selects or displays processed samples, those samples that have been previously processed; or not processed samples, those samples that have not been previously processed; or both, previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing.

This window contains columns for the Specimen ID, Vessel ID (either 60 or 61), Test Name (either Lead Dust-Floor or Lead Dust-Window), a Filled box (radio button for Yes and No), and Container ID/Slot # assignment.

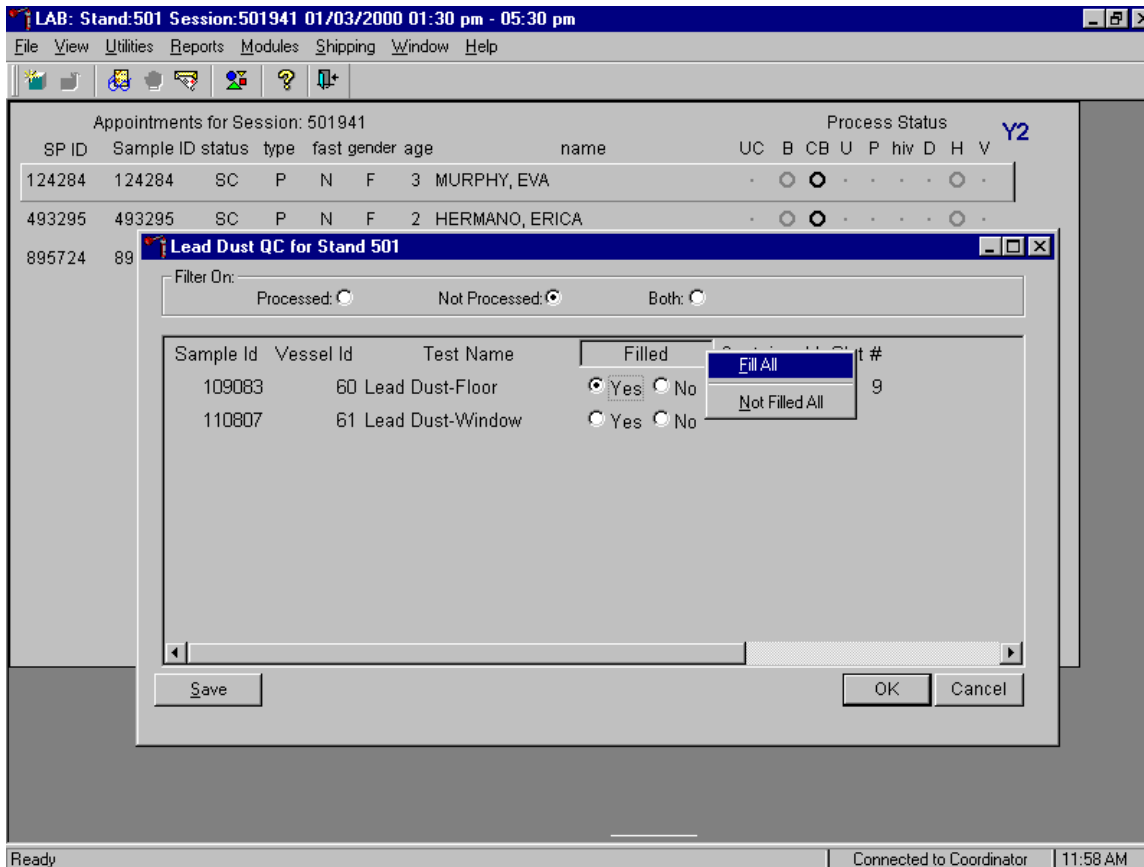
Match the samples to the Datamax labels. Remove the original QC label from the vessel and discard. Place the new laboratory label on the vessel lengthwise.

Mark the lead dust floor and lead dust window QC vessels as collected or “filled.”



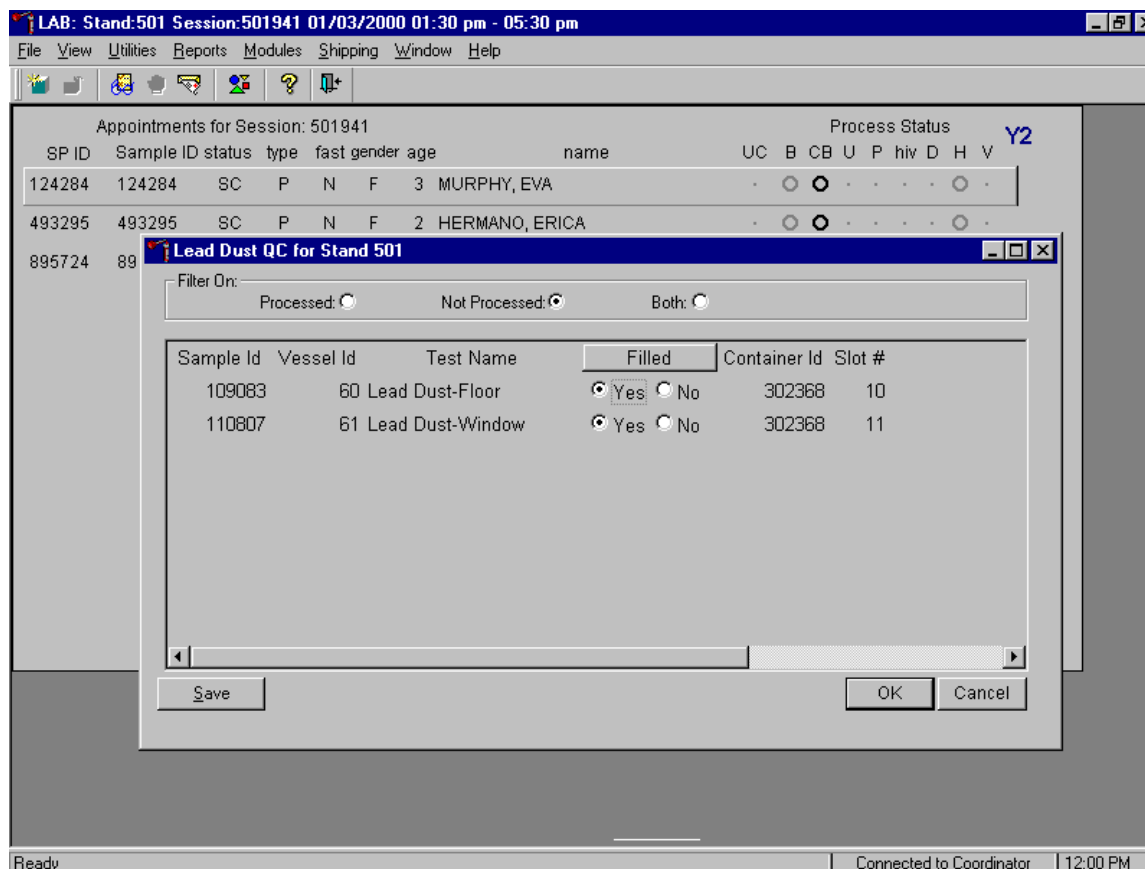
To mark the individual lead dust QC vessel as collected or “filled,” use the mouse to direct the mouse arrow to each Filled radio button and left click. As each vessel is marked as “Filled - yes,” it is automatically assigned to a slot in an existing (open) container.

Collectively mark both vessels as filled or not filled.



To collectively mark both vessels as filled, use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click and drag the arrow to Fill All or type [F]. To mark both vessels as Not Filled, use the mouse to direct the mouse arrow to the **Filled** box, left click and drag the arrow to Not Filled All or type [N].

Store each filled vessel in the assigned slot in the assigned container.



To record this action or to save this data to the database and remove the information from the screen, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without recording any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Only vessels for which labels have been printed are capable of being processed.

The screenshot shows a software window titled "LAB: Stand:501 Session:501941 01/03/2000 01:30 pm - 05:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a table titled "Appointments for Session: 501941". The table has columns for SP ID, Sample ID, status, type, fast, gender, age, name, and Process Status. The Process Status column includes sub-columns for UC, B, CB, U, P, hiv, D, H, V, and Y2. Three rows of data are visible, each with a yellow warning icon in the UC column. A dialog box titled "pfc_preopen" is overlaid on the table, containing a yellow warning icon and the text: "Unable to retrieve Lead Dust QC. Please make sure you have generated Lead Dust QC labels." with an "OK" button.

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V	Y2
124284	124284	SC	P	N	F	3	MURPHY, EVA	-	○	○	-	-	-	-	-	-	○
493295	493295	SC	P	N	F	2	HERMANO, ERICA	-	○	○	-	-	-	-	-	-	○
895724	895724	SC	P	N	F	2	DOBBS, JESSICA	-	○	○	-	-	-	-	-	-	○

Ready | Connected to Coordinator | 12:01 PM

If the Lead Dust QC module is accessed and labels have not been printed, a message text box displays. To remove the text box, use the mouse to direct the mouse arrow to the **OK** button and left click. Access the Lead Dust QC Label module to print the QC labels and then proceed to process the QC samples.

Appendix D
Glossary of Terms

APPENDIX D GLOSSARY OF TERMS

Vessel: Primary sample receptacles. Examples are cryovials, zip-closable bags, jars, Vacutainer® tubes, canisters.

Container: The unit that holds vessels. Examples are 2-, 3-, and 5-inch tall boxes with various dividers, zip-closable bags, and Styrofoam mailers.

Shippers: The unit that holds containers. Examples are insulated Bio-Shippers such as Styrofoam containers inside corrugated outside packaging, hard-sided coolers, and padded envelopes.