



Centers for Disease
Control and Prevention
National Center for
Health Statistics

2021 Laboratory Procedures Manual

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National Health and Nutrition Examination Survey

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1. Overview and Laboratory Team Responsibilities

1.1 Overview

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

The blood collection (venipuncture) procedure consists of (1) administering a questionnaire to screen for medical conditions that will exclude the study participant (SP) from the blood draw; (2) determining fasting status; and (3) performing the blood draw. The phlebotomist also collects one additional blood tube from SPs selected for the volatile organic compounds (VOC) special study on consenting SPs aged 12 years and older, and Liver Genetics on SP's 18 years of age and older. The procedure also includes an additional questionnaire, Pesticide Use Questionnaire (PUQ), as part of the Phlebotomy exam.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 3 years and older to (1) allocate urine into vessels for storage and transport to multiple government and contract laboratories for analysis; and (2) allocate urine into a vessel for future studies.

The purpose of blood processing is to (1) allocate blood (whole blood, plasma, and serum) into vessels for transport to multiple government and contract laboratories for analysis; (2) allocate serum into vessels for future studies; and (3) process serum for environmental testing.

The purpose of performing a CBC on blood specimens is to provide a study of blood cells.

The purpose of urine pregnancy testing is to exclude pregnant women aged 8-59 years from participating in the dual-energy x-ray absorptiometry (DXA), balance, and the liver ultrasound transient elastography (LUTE) sections of the mobile examination center (MEC) exam.

The purpose of conducting the special VOCs study is to collect blood to determine the prevalence of exposures to certain chemicals.

The purpose of collecting the Genetics samples is to use genetic testing in incidences of hepatitis.

1.2 The Laboratory Team

Each laboratory team includes three certified clinical laboratory scientists (CLSs) or medical laboratory technicians (MLTs) who have experience in all aspects of laboratory practice, and a certified phlebotomist who has experience in venipuncture.

The chief medical technologist is a senior member of the team. In conjunction with the MEC Manager, they are responsible for overseeing the day to day technical activities of the laboratory staff on the MEC, as well as assisting with scheduling, quality control (QC), equipment calibration, and maintenance. The chief medical technologist performs the same duties as the other laboratory staff members.

1.3 Tasks

The phlebotomist's primary tasks include conducting the venipuncture; assisting the laboratory personnel as needed; managing the phlebotomy component inventory; performing MEC equipment QC activities and recording the results; printing laboratory labels; labeling blood processing racks; and assisting with the weekly and End of Stand shipping processes when needed. The CLSs' and MLTs' tasks include printing labels and labeling vessels, performing CBCs, conducting urine tests, processing blood and urine, performing MEC equipment QC activities and recording the results, and shipping specimens to contract laboratories. On a routine basis, the laboratory personnel assist the phlebotomist as needed and manage the laboratory component inventory.

1.4 Organization of the Laboratory

The laboratory consists of two areas—the phlebotomy room and the laboratory area (labeling and shipping area, biological sample processing, and hematology/pregnancy testing/urine processing). The phlebotomy room and laboratory area are located in trailer 4. Figures 1-1 and 1-2 illustrate the laboratory layout and phlebotomy room layout, respectively.

Figure 1-1. Laboratory layout

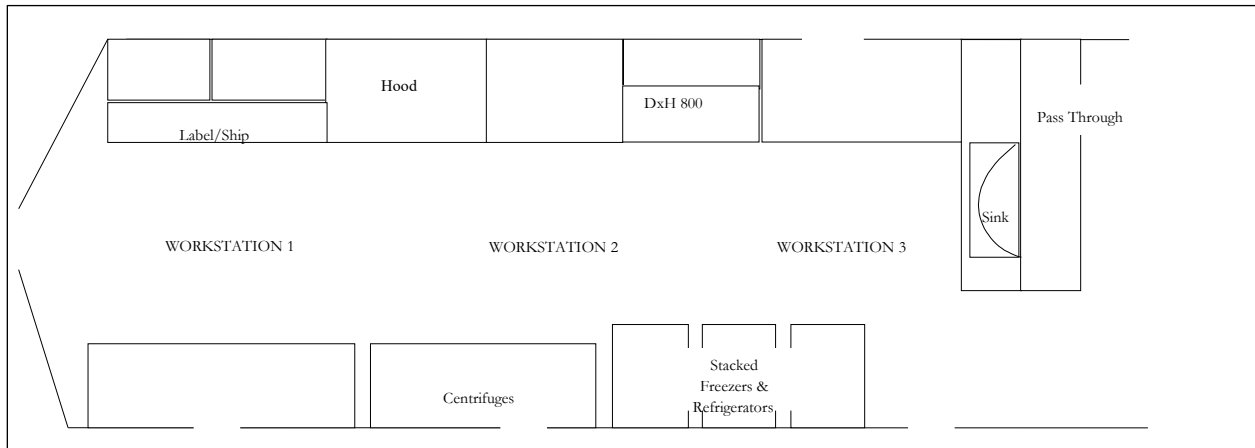
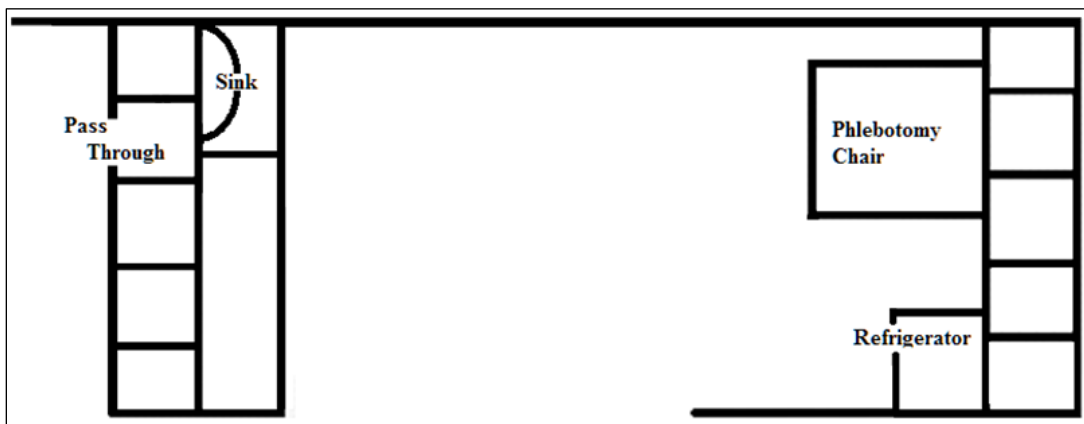


Figure 1-2. Phlebotomy room layout



The phlebotomist performs the phlebotomy examination in the phlebotomy room.

Laboratory Area Floor Plan

The laboratory area contains three workstations designated as workstations 1, 2, and 3. Printing labels, labeling vessels for each SP's blood-processing rack, and shipping activities occur at workstation 1. Blood processing and storage occur at workstation 2. Urine collection, urine processing and storage, pregnancy testing, running CBCs, genetics blood processing, VOC blood processing, glycohemoglobin processing, and routine QC activities occur at workstation 3.

1.5 Tasks—Phlebotomy Room

- Set up supplies and record received dates on the received date label for new supplies, and check expiration dates of all consumable supplies used in phlebotomy;
- Complete the phlebotomy examination, including conducting the venipuncture interview, administering the fasting questionnaire, the Pesticide Use Questionnaire (PUQ), the Volatile Toxicant Questionnaire (VTQ) for selected SP's, and performing the venipuncture;
- Label and transfer all blood tubes to the laboratory area;
- Disinfect all the counters and blood draw chair at the end of each session, as needed when soiled with blood or other body fluids, or between every SP as outlined in the NHANES COVID-19 Mitigation Protocols document during the COVID-19 pandemic;
- Take and record the QC readings;
- Maintain the appearance of the venipuncture area and the equipment;
- Monitor the inventory and restock supplies;
- Conduct the start and end of stand inventory counts;
- Send temperature sensitive supplies back to the warehouse at the end of each stand;
- Clean and stock the phlebotomy room, including the equipment, at the start and end of each stand;
- Assist in printing laboratory labels, and label and assemble blood-processing racks; and
- Assist the laboratory staff when they pack the shippers.

1.6 Tasks—Lab Workstation 1

- Print blood and urine vessel labels;
- Pre-label the vials for each SP's blood-processing rack;
- Generate container IDs at the start of stand;
- Assign a container ID label to one container for each vessel;
- When shipping, close all open containers, create airbills, and assign containers to shippers;

- Print shipping manifests;
- Prepare blood (whole blood, serum, and plasma) and urine samples for shipping;
- Pack, label, and ship shippers;
- Open all new containers after shipping;
- Prepare Class 9 labels for the next stand;
- Prepare return shipping packets at the start of the stand;
- Maintain the appearance of the label/ship area and the equipment;
- Monitor inventory and restock supplies;
- Assist the phlebotomist with venipuncture;
- Conduct start and end of stand inventory counts;
- Clean the laboratory at the start and end of each stand; and
- Disinfect between every appointment block as outlined in the NHANES COVID-19 Mitigation Protocols document during the COVID-19 pandemic.

1.7 Tasks—Lab Workstation 2

- Stock blood processing and storage supplies;
- Receive blood specimens;
- Select the correct pre-labeled rack and age-appropriate template;
- Set the red-top blood tubes aside to clot;
- Pipette whole blood into separate 2-ml cryovials from the 3-ml, 4-ml, 7-ml lavender tube for vessel 1 (lead/cad/Hg), vessel 5 (mercury), vessel 235 (BChE), vessel 3 (RBC folate);
- Centrifuge and pipette the plasma from the 7-ml lavender tube and transfer to vessel 109 (TFA);
- Perform cell washing on the remaining cells from the 7-ml lavender for vessels 88 (acrylonitrile), 221 (RBC folate forms), and 222 (RBC fatty acids);
- Make the dilutions for RBC folate, folate forms, and serum folate vessels;

- Transfer the 3-ml or 4-ml lavender tube to the workstation 3 technologists for hematology if needed;
- Centrifuge the 2-ml gray tube;
- Pipette the plasma from the 2-ml gray tube into a 2-ml cryovial for vessel 9 (glucose);
- Centrifuge the red-top tubes;
- Pool the serum from the 7-ml, 10-ml, and 15-ml red-top tubes for each SP and mix well;
- Aliquot serum into separate 2- or 5-ml cryovials for the serum vessels according to the age-specific protocols;
- Make dilutions for serum folate (vessel 110);
- Enter all blood processing results;
- Refrigerate or freeze the processed vessels;
- Check contents of blood storage boxes (containers) using the content container verification module at the end of each session;
- Disinfect all the counters and the laminar flow hood at the beginning and end of each appointment block, when the area becomes soiled with blood or other body fluids, or follow the guidance as outlined in the NHANES COVID-19 Mitigation Protocols during the COVID-19 pandemic;
- Maintain the appearance of the blood processing area and the equipment;
- Monitor the inventory and restock supplies;
- Conduct the start and end of stand inventory counts;
- Clean the laboratory at the start and end of each stand; and
- Assist in printing laboratory labels and label and assemble blood-processing racks.

1.8 Tasks—Lab Workstation 3

- Perform start of stand, start of session, end of session, weekly, and end of stand QC checks on laboratory equipment and record results;
- Prepare the 1 percent and 7 percent ascorbic acid solutions daily;
- Enter the ascorbic acid into Daily QC;
- Stock supplies for urine processing, hematology, and pregnancy;
- Verify and accept the urine volume and record the urine collection results;
- Run the pregnancy test controls;
- Perform startup procedures, run QC materials on the Coulter® DxH 800, and record the successful performance of 6C QC in the Session QC tab of the ISIS application;
- Run specimens from one of the 4-ml EDTA tubes on the Coulter® DxH 800 and enter results;
- Label the second EDTA tube with the label for vessel 4 (glycohem) and refrigerate;
- Process and refrigerate VOC blood (vessel 54) tube;
- Process and refrigerate genetics blood (vessel 119) tube;
- Conduct the pregnancy test and enter results;
- Label urine vessels and aliquot into 2- or 5-ml cryovials, Five-O 5-ml cryovial, or 10-ml VWR screw cap tubes according to the processing protocol;
- Enter the urine processing results;
- Store the urine vessels;
- Check contents of urine, genetic samples, and VOC samples using the content container verification module at the end of each session;
- Disinfect all the counters and the lab sink at the beginning and/or end of each session appointment block, or when the area becomes soiled with blood or other body fluids, or follow the guidance as outlined in the NHANES COVID-19 Mitigation Protocols during the COVID-19 pandemic. Maintain the appearance of the urine processing/hematology area and the equipment;
- Monitor the inventory and restock supplies;

- Return temperature-sensitive supplies to the warehouse at the end of each stand;
- Discard temperature-sensitive supplies that are not sent back to the warehouse at the end of each stand;
- Conduct the start and end of stand inventory counts;
- Clean the laboratory at the start and end of each stand; and
- Assist in printing laboratory labels and label and assemble blood-processing racks.

1.9 Cross Training

Cross training the laboratory staff and the phlebotomist increases an individual's skills and provides scheduling flexibility and a safety net during staff absences. The primary phlebotomist helps the laboratory team with shipping and set up and tear down. CLSs and MLTs trained in phlebotomy (backup phlebotomists) work in phlebotomy on a routine basis to ensure competency and proficiency. The basic underlying assumption is that the blood draw must **never** be compromised. When a backup phlebotomist is working in phlebotomy, the primary phlebotomist must be available to step in and complete the blood draw until the backup phlebotomist is proficient in the phlebotomy protocols.

2. Laboratory Information Systems (ISIS) Functionality

2.1 Laboratory-Specific Functionality

While mobile examination center (MEC) applications are custom built for each specific component, they share a common design. This commonality provides all component applications the same “look and feel,” which minimizes reorienting staff who rotate from component to component. A complete ISIS overview and these features and characteristics are described in the *MEC Operations Manual, Chapter 2*. The laboratory application has additional functionality that has been developed to accommodate and facilitate processing specimens and reporting results, as described in this chapter.

2.2 Laboratory Heads-Up Display

The laboratory heads-up display presents the sample persons (SPs) scheduled into the session, the modules for which they are eligible, and their current process status. Use the heads-up display to access modules.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
214268	214268	SC	P	M	11	PERSAUD, JUSTIN 2	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
290160	290160	BE	P	F	16	HOYA, MARY	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
483445	483445	BE	P	M	15	HOYA, SON J	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
491168	491168	BE	P	F	40	HOYA, JANE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
711860	711860	SC	P	M	45	HOYA, JOHN A	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
913751	913751	SC	P	F	9	JONES, MICAYLA 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=Scheduled, LI=Logged-in, CI=Checked-in, BE=Being examined, EX=Exited), Appointment Type (P=primary, G=guest, VIP=VIP guest, D=dry run), Gender (M=male, F=female), Age, and Name (last, first.).

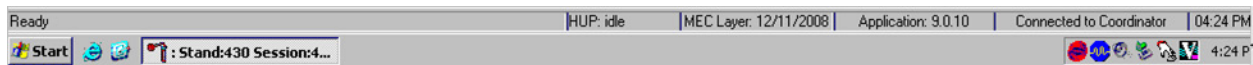
The heads-up display provides the Process Status for the following modules: UC (urine collection), U (urine processing), P (pregnancy testing), CBC (complete blood count), B (blood processing), and PC (packed cell or vessels 88, 221, and 222 processing). The SP is ineligible for a module when the process status appears as a dot. The SP is eligible for a module, but the collection is not complete when the process status is ○. The SP is eligible for a module and the collection has been completed 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 process status for blood processing (B) and the CBC will not enable (◯) until at least one blood tube has been recorded as collected in the phlebotomy component. The process status is ○ for urine processing (U), and pregnancy testing (P), until the SP's urine is marked as collected in the UC module. Once these samples are collected, the process status changes from ○ to ◯. The process status regularly updates and changes after each result is saved.

The active SP's information is contained in a rectangular box on the heads-up display. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.

2.3 Laboratory Task Bar

Monitor the activity in the laboratory task bar, which is located on the bottom of the screen.



The laboratory task bar displays the following information:

- The status of the refresh routine such as when the labels are printing or the data is updating;
- The status of the heads-up display such as when it is “idle”;

- The current version of the MEC layout;
- The current version of the application;
- The status of the connection to the coordinator; and
- The current time.

2.4 Menu Bar Options

Each MEC application has tailored menu options to support the specific examination. The menu options below list all available options. Options are grayed (inverted) or not present when they are not available for a specific subsystem.

2.4.1 File Menu Options

	Status	Type	Gender	Age	Name	Process Status								
						UC	U	P	CB	B	PC			
	SC	P	M	11	PERSAUD, JUSTIN 2	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	
	BE	P	F	16	HOYA, MARY	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	
483445	483445	BE	P	M	15	HOYA, SON J	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
491168	491168	BE	P	F	40	HOYA, JANE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
711860	711860	SC	P	M	45	HOYA, JOHN A	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
913751	913751	SC	P	F	9	JONES, MICAYLA 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-

Asterisks (*) denote menu options common to all MEC examination components.

*File	
*Open (Ctrl+O)	Opens a new, partial, or not done SP exam; the SP must be assigned by the coordinator if the application is not in standalone mode.
*Close	This option is grayed out and not applicable.
*Print	Prints the current examination screen or report.
*Delete	This option is grayed out and not applicable.
*Exit	Exits the application.

2.4.2 Utilities Menu Options

File View **Utilities** Quality Control Reports Modules Shipping Window Help

SP ID	Name	Process Status							
		UC	U	P	CB	B	PC		
214268	PERSAUD, JUSTIN 2	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
290160	HOYA, MARY	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
483445	HOYA, SON J	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
491168	HOYA, JANE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
645451	PERSAUD, MICAYLA 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
711860	HOYA, JOHN A	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
781732	PERSAUD, JUSTIN 1	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
913751	JONES, MICAYLA 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-

*Utilities	
*Exam Pause	This option is grayed out and not applicable.
*Observation	Submits an observation to the physician/clinician for possible referral.
IC Exclusions	This option is grayed out in the laboratory application and is not applicable. Posts an exclusion record for those SPs who do not want HIV or STD tests performed, or samples stored for future research; this utility is available only for coordinator, physician/clinician, and phlebotomy. A complete description of this functionality is described in Section 2.5.
*Send Message (Ctrl+M)	Opens a dialog box to send messages to the coordinator.
*UFO Sighting	Opens the Unusual Field Occurrence utility to document unusual equipment, SP, protocol, trailer, or supply issues.
Set Session	Allows the laboratory medical technologist to change the current session in the laboratory application. A complete description of this functionality is described in Section 2.6.
English (Ctrl+E)	This option is grayed out in the laboratory application and is not applicable. Toggle option to set exam language to English.
Spanish (Ctrl+S)	This option is grayed out in the laboratory application and is not applicable. Toggle option to set exam language to Spanish.
*Toolbars	Configures placement of toolbars.
*System Configuration	Displays the configuration and version of lab application.

2.4.3 Quality Control Menu

SP ID	Sample	Name	Process Status					
			UC	U	P	CB	B	PC
214268	214268	PERSAUD, JUSTIN 2	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
290160	290160	HOYA, MARY	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
483445	483445	HOYA, SON J	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
491168	491168	HOYA, JANE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
645451	645451	PERSAUD, MICAYLA 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
711860	711860	HOYA, JOHN A	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
781732	781732	PERSAUD, JUSTIN 1	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
913751	913751	JONES, MICAYLA 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*Quality Control	
Quality Control	Opens Quality Control for Start of Stand, End of Stand, Session, Daily, Weekly, and NCHS QC.
Pregnancy QC	Opens pregnancy quality control window.

Modules	
Hematology	Opens the laboratory hematology module. A complete description of this functionality is described in Section 6.19.2.

2.4.6 Shipping

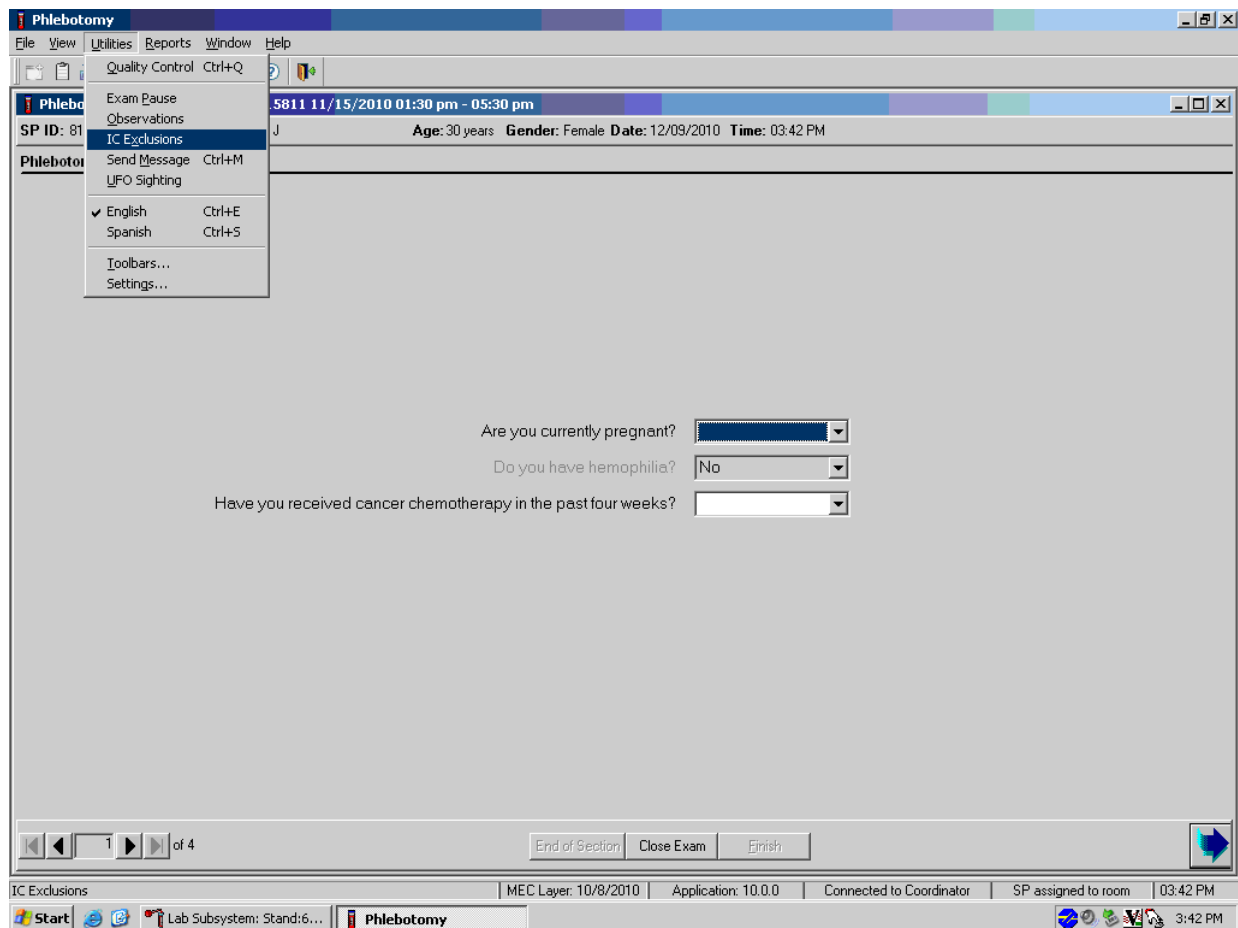
SP ID	Sample ID	Status	Type	Gender	Age	Access Status
214268	214268	SC	P	M	11	P CB B PC
290160	290160	BE	P	F	16	● ○ ○ ○ - -
483445	483445	BE	P	M	15	- ○ ○ ○ - -
491168	491168	BE	P	F	40	HOYA, JANE ○ ○ ○ ○ ○ ○ - -
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1 ○ ○ ○ ○ ○ ○ - -
711860	711860	SC	P	M	45	HOYA, JOHN A ○ ○ - ○ ○ ○ - -
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1 ○ ○ - ○ ○ ○ - -
913751	913751	SC	P	F	9	JONES, MICAYLA 2 ○ ○ ○ ○ ○ ○ - -

Shipping	
Print New Container Labels	Allows the clinical laboratory scientist or medical laboratory technologist to print labels for containers. A complete description of this functionality is in Section 8.4.
Container Map	Allows the clinical laboratory scientist or medical laboratory technologist to view a list of all containers with a graphic representation of the samples assigned to that container. A complete description of this functionality is in Section 2.7.
Close Containers	Allows the clinical laboratory scientist or medical laboratory technologist to “close” active containers that have been previously opened. A complete description of this functionality is in Section 8.5.
Assign Containers to Shippers	Allows the clinical laboratory scientist or medical laboratory technologist to assign or associate a closed container with a FedEx airbill number. A complete description of this functionality is in Section 8.8.
Trash Containers	Allows the clinical laboratory scientist or medical laboratory technologist to delete container label numbers in the database for labels that are damaged. A complete description of this functionality is in Section 8.6.
Shipping Manifest	Allows the clinical laboratory scientist or medical laboratory technologist to print hard-copy manifests and electronically send email files to the contract laboratories. A complete description of this functionality is in Section 8.9.
Container Content Verification	Allows the clinical laboratory scientist or medical laboratory technologist to view a list of containers with a graphic representation of that container. The tech uses the barcode gun to scan in the contents of that container to verify that the specimen is in the correct position. See page 2-14 for a complete description.

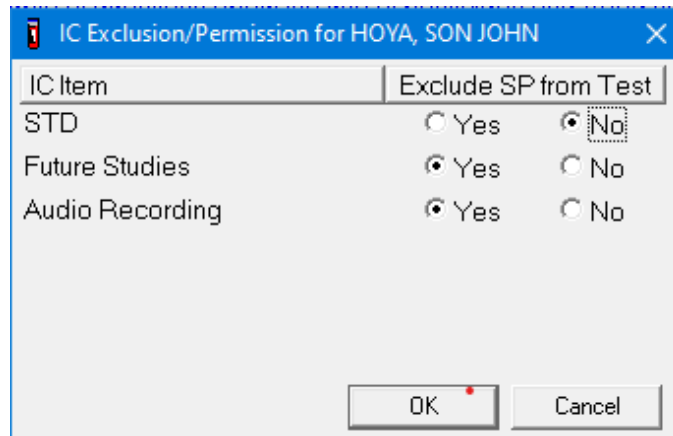
2.5 Informed Consent (IC) Exclusions

If at any time during the phlebotomy or physician exam, the SP indicates that they do not want their biological specimens tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, trichomonas, and *Mycoplasma genitalium*), or future studies, then the staff enters this information using the IC Exclusions module.

To access the IC (informed consent) Exclusions module, direct the mouse arrow to Utilities in the menu bar, left-click, drag the arrow to IC Exclusions, and left-click.



The IC Exclusions window displays all the specific exclusion item tests or groups of tests for which the SP is eligible and the status for each exclusion item.



Record each item as directed by the SP. To mark each item, 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.

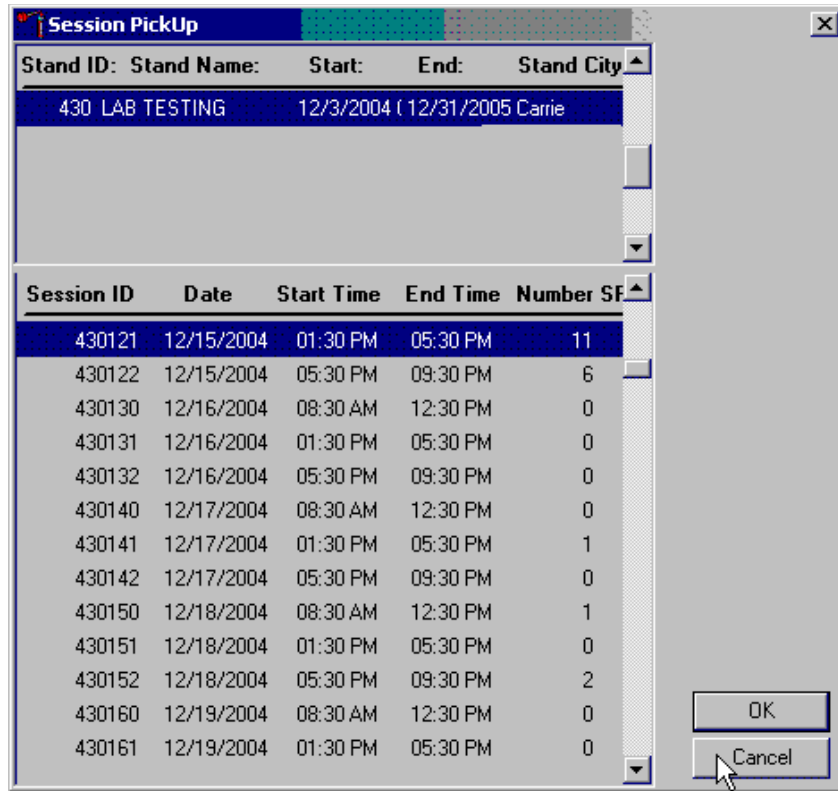
2.6 Set Session Utility

Sign on to the computer terminal. Open the laboratory application. If the laboratory is conducting a MEC session, the heads-up display will default to the current session. Use the Set Session utility to access past or future sessions.

To access the Set Session utility, direct the mouse arrow to Utilities and left-click. Drag the arrow to Set Session and left-click.



The Session Pickup list displays. Select the correct session from the pick list.



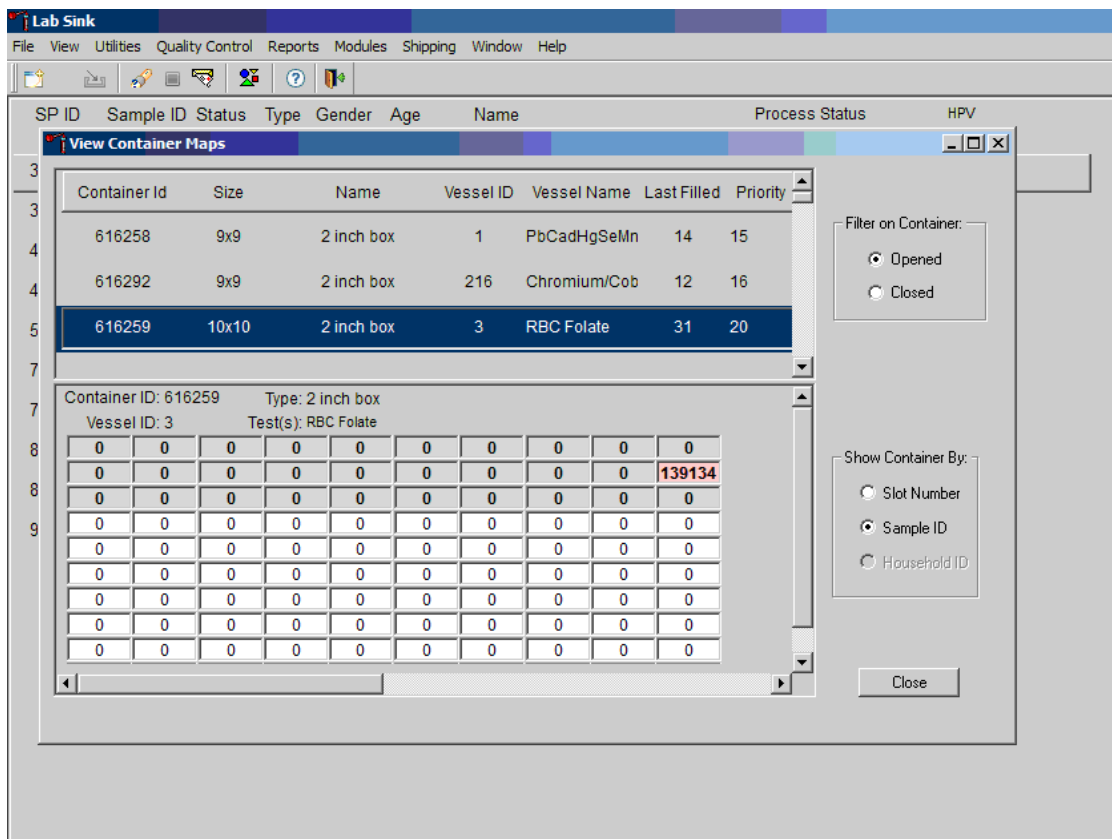
The Session Pickup window displays. The current stand is displayed in the top section of the window. Use the lower vertical scroll bar to view all sessions. Use the mouse to select the desired session. To proceed, hit the OK button or press Enter. To cancel and return to the previous session, click the Cancel button.

After selecting a session from the Session Pickup list and selecting OK, the laboratory heads-up screen displays.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
214268	214268	SC	P	M	11	PERSAUD, JUSTIN 2	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
290160	290160	BE	P	F	16	HOYA, MARY	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
483445	483445	BE	P	M	15	HOYA, SON J	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
491168	491168	BE	P	F	40	HOYA, JANE	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
711860	711860	SC	P	M	45	HOYA, JOHN A	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
913751	913751	SC	P	F	9	JONES, MICAYLA 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-

2.7 Container Map

Check the slot assignment of all containers at the end of each session. Access the Container Map report under the Reports or Shipping menu.



Use Container Mapping to verify the contents of each container.

- Use as a reference for determining the position of each vessel within a container.
- If “Opened” under “Filter on Container” is selected, then all open containers will display.
- If “Sample ID” under “Show Container By” is selected, then sample IDs will display in the assigned slot in the graphical representation of the container.
- Container IDs may be selected by mouse or by using the up and down keys.
- 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.

To exit the Container Map report, click the Close button.

2.8 Container Content Verification

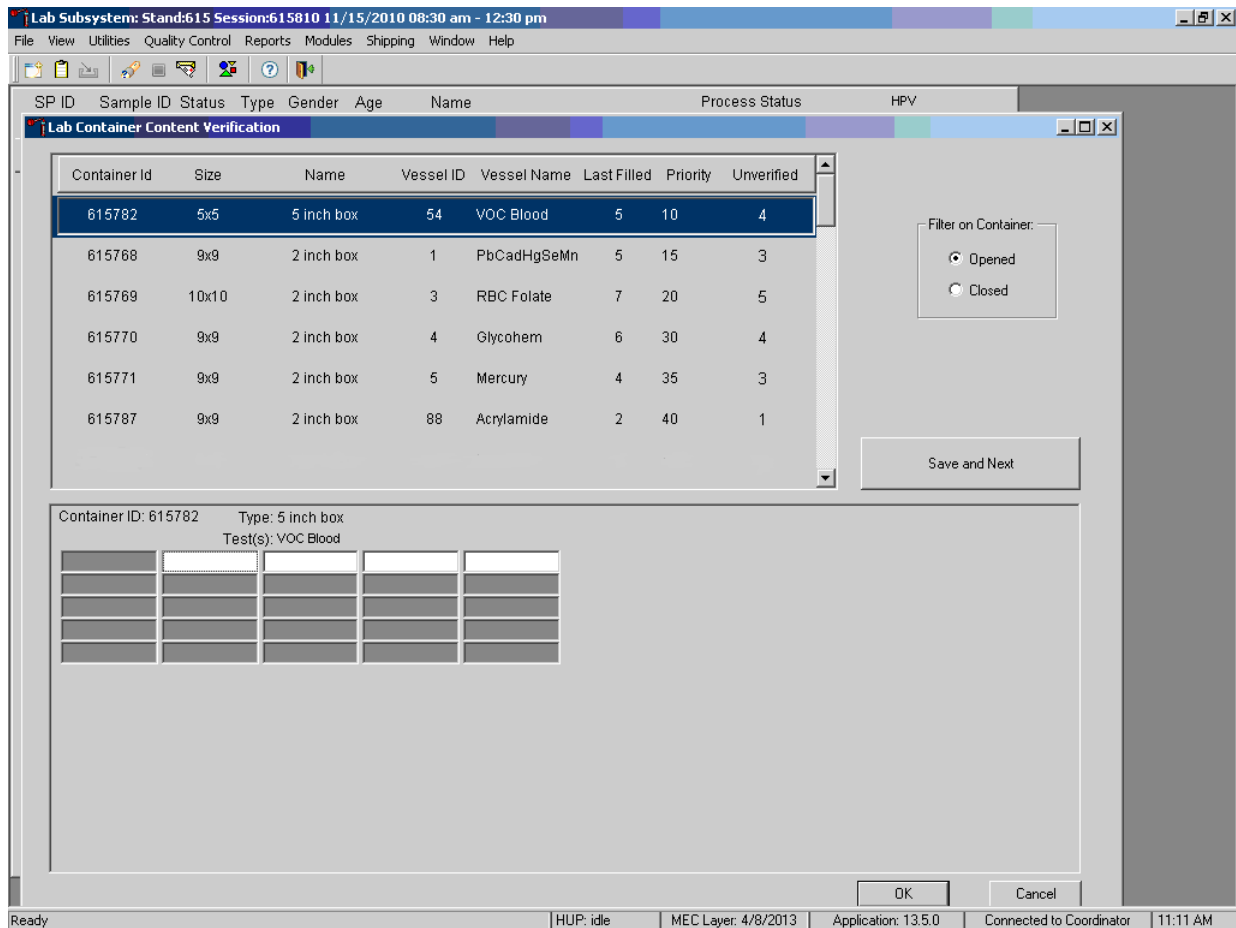
- Use Container Content Verification to verify the contents of each container.
- Access to container verification is located under the shipping tab from the lab's heads-up display.
- Perform container verification after each session.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the system.
- Mark the specimens that have been checked by placing a mark unique to each medical technologist in the center of the vial cap. When subsequently checking the Container Content Verification system for this container, begin checking the first specimen after the unique mark.

The screenshot shows a software interface with a 'Shipping' menu open. The menu options are: Print New Container Labels, Container Map, Close Containers, Assign Containers to Shippers, Trash Containers, Shipping Manifest, and Container Content Verification. The background table has columns for SP ID, Sample ID, Status, Type, Gender, Age, and a 'Process Status' section with sub-columns P, CB, B, and PC. The table contains several rows of data, including container IDs like 214268, 290160, 483445, 491168, 645451, 711860, 781732, and 913751, along with names like HOYA, JANE and PERSAUD, MICAYLA 1.

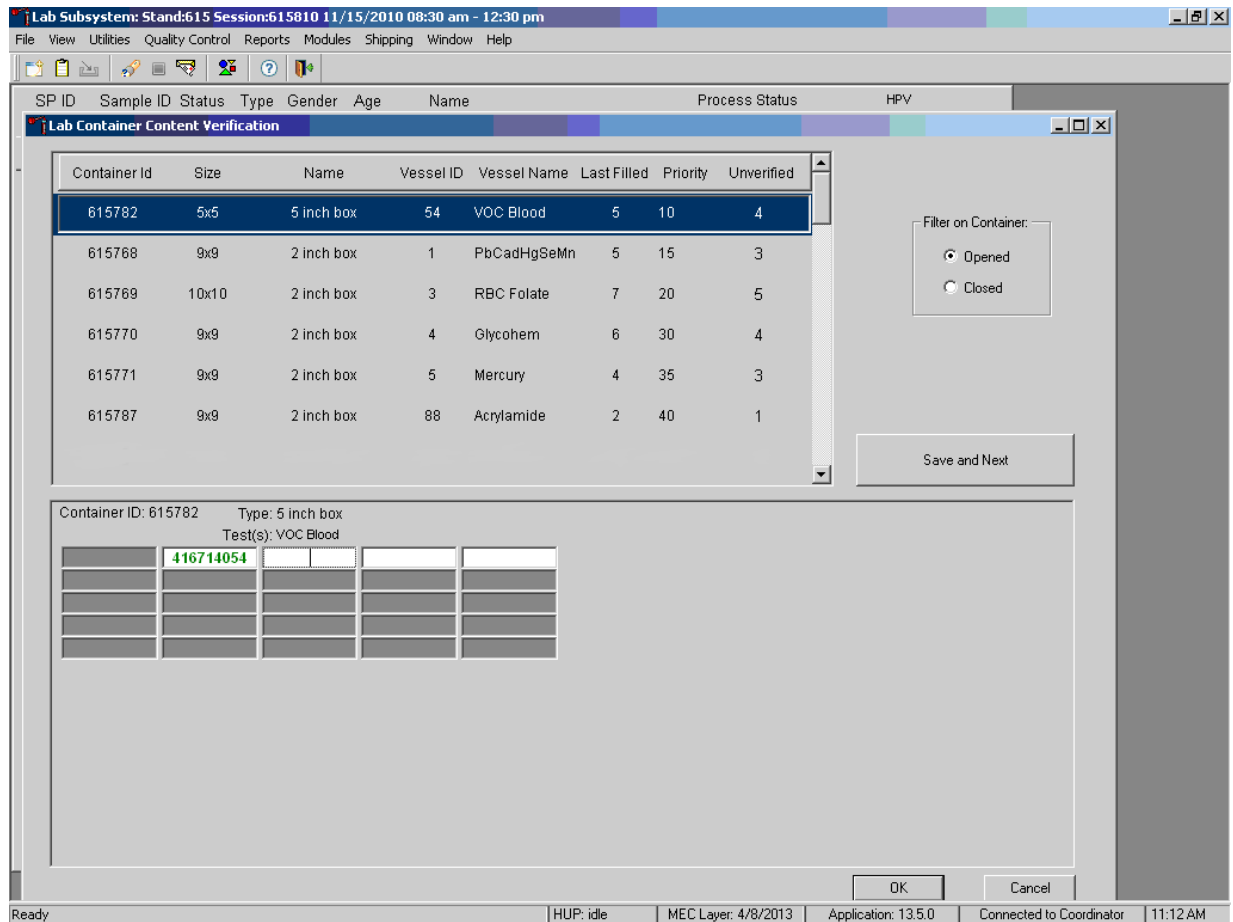
SP ID	Sample ID	Status	Type	Gender	Age		Process Status				
						P	CB	B	PC		
214268	214268	SC	P	M	11		-	○	○	○	-
290160	290160	BE	P	F	16		●	○	○	○	-
483445	483445	BE	P	M	15		-	○	○	○	-
491168	491168	BE	P	F	40	HOYA, JANE	○	○	○	○	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	○	○	○	○	-
711860	711860	SC	P	M	45	HOYA, JOHN A	○	○	-	○	○
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	○	○	-	○	○
913751	913751	SC	P	F	9	JONES, MICAYLA 2	○	○	○	○	-

The container content verification includes the container ID, container size, name of container, vessel ID, vessel name, last filled slot #, vessel priority number, and the number of unverified vessels remaining.

- There is an indicator for opened or closed filters on containers.
- Save and Next button saves your work and opens the container that is next in the list.
- To save your work and exit the application, use the OK button.
- To cancel your current work and exit the application, use the Cancel button.

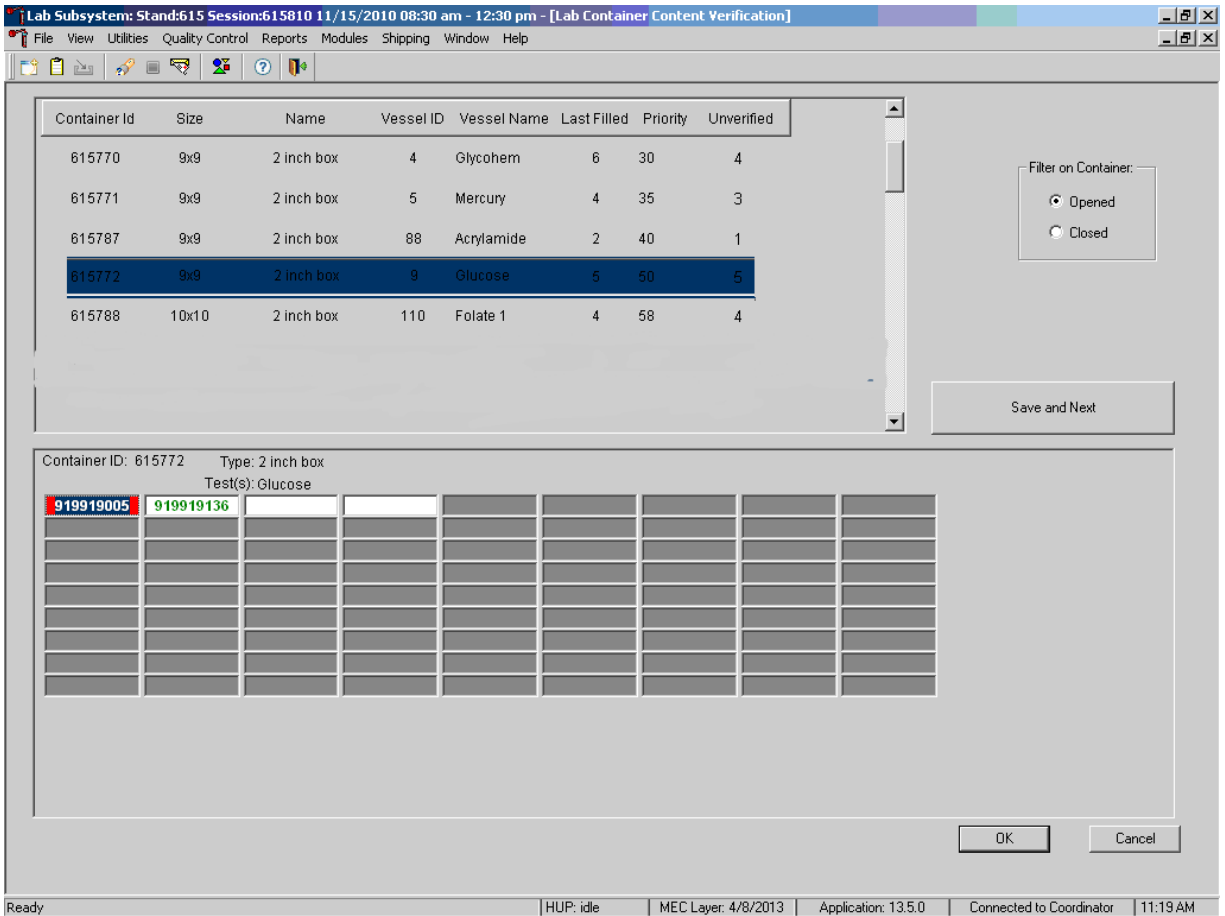


To use the container content verification application, remove a container from the freezer; using the barcode gun, scan the Sample ID or the Astro ID of the first vessel to be verified. If correct vessel is scanned in, the sample ID will be displayed in green.

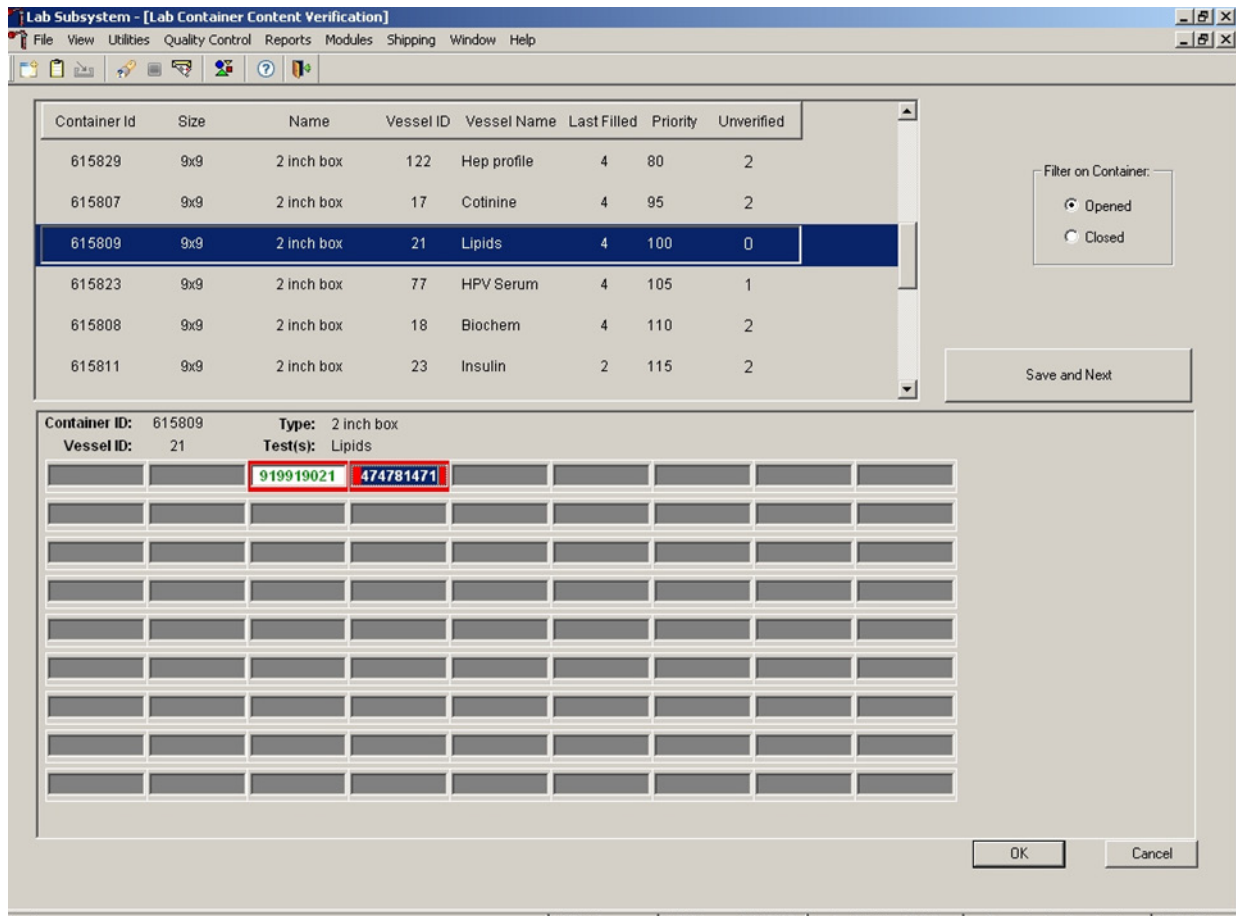


If incorrect vessel is scanned, the following will happen:

- The sample # will be highlighted in blue; this allows the user to rescan the correct vessel without deleting the incorrect #.
- A pop-up box will be displayed, indicating the correct contents of that slot.

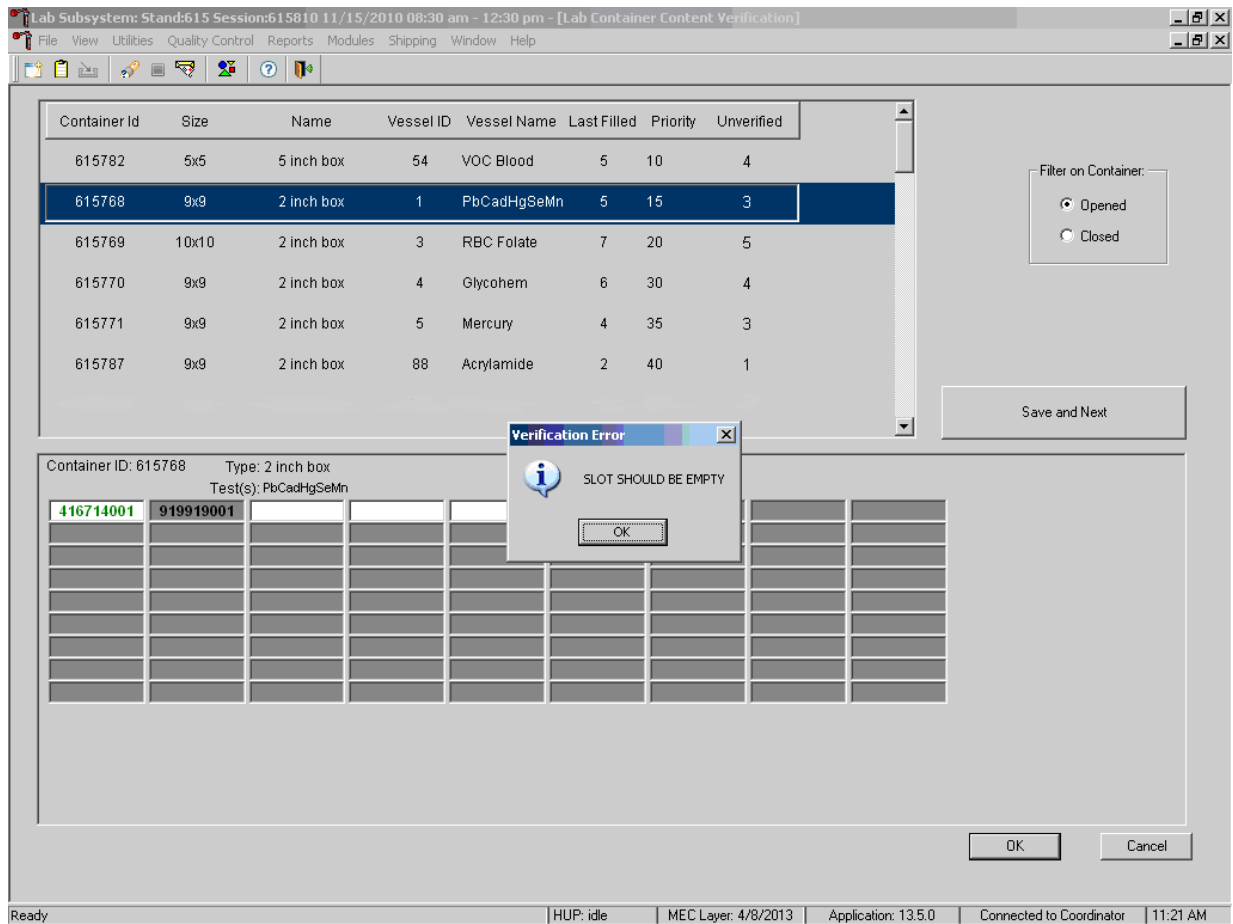


The following screenshot shows a vessel that requires a red cap insert and a vessel that is incorrectly scanned in side-by-side. The red cap insert is identified with a red outline around the box of the vessel, whereas the incorrect specimen number is highlighted in blue with red shading underneath.



If you encounter an empty slot:

- You must tab off that slot to the next available slot to continue.
- This serves as verification for the empty slot.
- If you scan a vessel in a slot that should be empty, a pop-up box will appear to indicate the slot should be empty.
 - Hit OK to verify message.
 - Tab to next slot.



To save your verification, you must hit the Save and Next button or OK button. If you hit the Cancel button, your last scanned vessel will not be saved.

- The enter key is the same as hitting the OK button on the pop-up boxes and on the Verification screen.
 - It will save your work and exit you from the Verification screen.

2.9 Subsample Preview

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

SP ID	Sample ID	Status	Type	Process Status					
				UC	U	P	CB	B	PC
214268	214268	SC	P	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-
290160	290160	BE	P	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
483445	483445	BE	P	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-
491168	491168	BE	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
645451	645451	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
711860	711860	SC	P	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-
781732	781732	BE	P	<input checked="" type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-
913751	913751	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-

Access the Subsample Preview report under Reports in the menu bar.

Review the Subsample Preview report.

Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
4109982	229013	FONTANA2, FREDDIE	F	41	1	Volatile Organic Compounds (VC
					1	Persistent Pesticide and Dioxins
					1	Heavy Metals
					1	Urine Phytoestrogens
					1	Speciated Arsenic
					1	Persistent Pesticides 2
					1	Urine Mercury/Iodine
					1	OMRON / Mercury
					1	Household Water
					1	RBC Folate 1/3
					1	Vitamin B6/Folate 1/3
					1	PAH HB adducts

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This report contains the appointment ID, SP ID, person name, gender, age, appointment 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 scroll bar. To print a copy of the report, direct the mouse arrow to the Print button and left-click. To exit and close the report, click the Close button.

2.10 Informed Consent Status

Access the Informed Consent Status report to view SPs and the status of the informed consent result for various tests and/or groups of tests.

The screenshot shows a software application window with a menu bar and a data table. The 'Reports' menu is open, showing options like 'Show Results', 'Room Log', 'Session Preview', 'Subsample Preview', 'Partial Sp Session', and 'Informed Consent Status'. The table below displays a list of SPs with columns for SP ID, Sample ID, Status, Type, and a 'Process Status' section with sub-columns UC, U, P, CB, B, and PC. Each cell in the Process Status section contains a radio button, with some being checked.

SP ID	Sample ID	Status	Type	Process Status						
				UC	U	P	CB	B	PC	
214268	214268	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
290160	290160	BE	P	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
483445	483445	BE	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
491168	491168	BE	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
645451	645451	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
711860	711860	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
781732	781732	BE	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
913751	913751	SC	P	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Access the Informed Consent Status report under the Reports menu in the menu bar.

Review the SPs scheduled into the current session and the status of their informed consent by using the Informed Consent Status report.

Consent Report for Session 617027

Sp Id	HIV	STD	HPV Swab Permission	Genetic Testing	Future Studies
913751	-	-	-	-	-
781732	-	N	-	-	Y
645451	-	-	-	-	-
214268	-	-	-	-	-
290160	-	N	-	-	Y
483445	-	N	-	-	Y
491168	N	N	N	N	Y
711860	-	-	-	-	-

Y = SP Excluded
 N = SP Not Excluded
 - = Not Applicable

The consent report lists all SPs scheduled in the current session, their appointment and SP IDs, and the exclusion status for the following tests or groups of tests:

- HIV (vessel 22 – serum);
- STD (vessel 24 – HSV);
- Future research (32-39 – serum, 52 and 139 – urine); and
- The status is “Y” or “Yes” if the SP is excluded, and “N” if the SP is not excluded.

2.11 Access a Processing Module

Select the correct SP and access the module of interest. Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.

For example, if the SP ID is incorrect in the SP Logon window, a warning message box displays, indicating the problem and giving remedial instructions. To remove the warning message box, click the OK button.

2.12.1 “Not Filled” Requires a Comment

Data cannot be saved until all vessels marked as “Filled–No” are assigned a comment.



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, click the OK button.

2.12.2 Labels Must Be Printed in Advance

If labels have not been printed in advance, all SPs will be displayed in red. A pop-up box will appear with Label Action Required.

Specimen processing cannot occur unless labels have been printed in advance. Reprint the labels for all SPs or an individual SP in a session. See Chapter 8 for detailed instructions on the Lab Print Application.

2.13 Coulter and Urine Scale Icons

Coulter

This is the NHANES Coulter[®] Monitor. It must be open and running at the start of each session. This icon stores all DxH[™] 800 runs in the ISIS database. Open the icon by double-clicking on the Coulter icon on the desktop. The Coulter icon looks like this:



Note the red icon in the lower-left corner of the system tray.



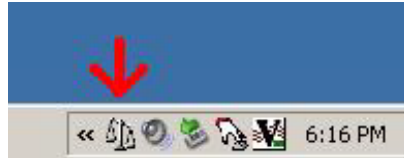
Note: If there is an interface problem with the database and the Coulter application, the Hematology module does not need to be open before running SP samples on the DxH 800. The SP's CBC results can be transmitted to the database at a later time after the interfaces between the database and the DxH 800 are restored.

Urine Scale

Ensure that computer workstation 1 (Urine/Sink) is turned on and a technician is logged in to the laboratory application. Open the Urine Scale application by double-clicking on the Urine Scale icon on the desktop. The Urine Scale icon looks like this:



The Urine Scale application icon will appear in the system tray, similar to the Coulter application. This application captures data from the scale and logs it into the database. The Urine Scale application must be opened and in the system tray to capture any urine collection readings from the scale.



3. Venipuncture

3.1 Introduction

The blood collection procedure consists of administering a questionnaire to screen for conditions that exclude the participant from the blood draw, administering the Pesticide Use Questionnaire (PUQ), determining fasting status, and performing a blood draw. The phlebotomist also administers the Volatile Toxicant Questionnaire (VTQ), and collects one additional blood tube from study participants (SPs) selected for the VOC (volatile organic compounds) study.

The phlebotomist conducts an interview to screen SPs for use of pesticides by first administering the PUQs, and then asking about any conditions that may exclude them from the blood draw due to safety reasons. The phlebotomist also administers a fasting questionnaire to determine fasting compliance. The VTQ questions are then used to screen the SPs for the use of volatile toxicants to determine survey eligibility. The venipuncture protocol is dependent on the SP's age, appointment type, whether they are foreign born, and session time. Exhibits 3-1 and 3-2 illustrate the various venipuncture protocols. These protocols indicate the types and numbers of tubes in priority order for each age group and person type. The Venipuncture Protocol chart that is located in the phlebotomy room and the laboratory also illustrates this information and is updated as the protocols change. It is extremely important to perform the venipuncture protocol as described for each SP. Document any comments to describe differences between the actual tubes drawn and the established protocol (i.e., alternative protocol or missed tubes). After the results of the blood draw are entered, labels automatically print for the blood tubes. The phlebotomist immediately labels collected tubes in the presence of the SP and places them through the pass-through window to the laboratory. All SPs are offered juice and cookies immediately after their blood draw to be consumed after completion of the Liver Ultrasound Transient Elastography component, if eligible. Then the phlebotomist escorts the SP to their next component and introduces the next examiner. If the examiner is not present in the component, the phlebotomist is required to wait with the SP until the examiner arrives, or escort the SP back to the reception area to wait with the coordinator.

Exhibit 3-1. Venipuncture protocol — primary

Tube	Age in years				
	1 – 2	3 – 5 ⁵	6 – 11	12 – 19	20+
3 mL lavender	1	2			
4 mL lavender			1	2	2
6 mL royal blue			1	1	1
6 mL lavender ³				1	1
2 mL gray (morning sessions only)				1	1
7 mL red	1	2	2	1	
15 mL red ^{0,2,6}				5	5
10 mL red ⁵			2		
7 mL gray (12+) ¹				1	1

⁰ SPs selected for inclusion in the Dioxin and Perfluorinated samples One third 0,3,7,10

¹ SPs selected for inclusion in the VOC subsample One half 1,2,4,5,10,11

² SPs selected for inclusion in the BFR subsamples One third 4,6,8,9

³ Guest Profiles include: CBC and for 12+ Biochem Panel. Genetic testing for SPs 18+

⁴ SPs selected for inclusion in the Dioxin/BFR and Perfluor subsample One third (0,3,7,10) (12+)

⁵ SPs included in Thyroid full sample (3-5)

⁶ SPs selected for inclusion in the Thyroid and Serum Terpenes subsample One third (1,2,5,11) (12+)

If the veins of an SP appear too fragile to accommodate the size of the large red-top tubes, substitute smaller red-top tubes as an alternative protocol. Exhibit 3-2, Alternative venipuncture protocol—primary, illustrates the alternative size and number of tubes in boldface with the original tube protocol in parentheses. When the alternative protocol is substituted for the original protocol, a comment must be recorded. This protocol constitutes a deviation from the established standard; it should be used only in rare circumstances.

Exhibit 3-2. Alternative venipuncture protocol — primary

Tube	Age in years		
	3-5	6-11	12+
3 mL red	5	2	
7 mL red	(2)	5 (2)	5 (1)
15 mL red			
10 mL red		(2)	4
15 mL red			(5)

Note: Alternative venipuncture protocol tubes are shown in boldface; regular protocol tubes are shown in parentheses.

3.2 Equipment and Supplies

The phlebotomy room contains a phlebotomy chair, sink, data terminal, Dymo direct thermal label printer, refrigerator, and cabinets. Exhibit 3-3 illustrates the floor plan for the phlebotomy room.

Exhibit 3-3. Floor plan for phlebotomy room



The equipment and supplies used in venipuncture are listed in Exhibit 3-4.

Exhibit 3-4. Equipment and supplies – phlebotomy

Consumable supplies	
BD Hemogard Vacutainer® 3 mL EDTA	Alcohol wipe
BD Hemogard 4 mL EDTA	
Greiner-Bio Vacutainer® 6 mL EDTA	Nonsterile, powder-free, nonlatex gloves – extra small, small, medium, large
BD 6 mL EDTA Royal Blue Top Tube	Disposable lab coats (M, L)
BD Hemogard Vacutainer® 2 mL gray	Co-Flex NL cohesive bandage
Covidien 7 mL red	Adhesive bandage – Coverlet
Covidien 15 mL red	Venolite disposable covers
BD Vacutainer® 10 mL red	Transpore tape
BD Vacutainer® 7 mL gray (VOC)	Cartoon stickers
Nipro 19-gauge x 3/4" butterfly needles	Pillow and disposable pillow cover
Nipro Luer adapter for use with the 19-gauge	Squeeze ball
Saf-T EZ® set	
BD 21-gauge x 3/4" butterfly needles	Juice (apple/orange/mixed berry) and animal crackers
Nipro 23-gauge with adapter	List of reportable tests (handout) English and Spanish
BD Vacutainer® needle holder – single use	Labels for Dymo printer
Air sickness bag	Bio-Hazard Sharps container 5 quart
Heel warmer	Batteries, AA
Sani-Cloth	Batteries, AAA
Purell hand soap	
Stretch disposable tourniquet	
Magic Marker – Ultra Fine Sharpie – Black	
Emergency blanket	
VeinLite EMS	
Nonconsumable supplies	
Solar wall thermometer	Tube racks
Plastic supply baskets	Sharps container wall holder
	Phlebotomy Photostory
	Buzzy
Emergency supplies	
Obtain from lab	
Hand cream	Facial tissue
	Bleach bottle

For each SP, the phlebotomist routinely requires the following materials:

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

3.3 Overview

The coordinator uses the coordinator system to track each SP throughout the examination process within the mobile examination center (MEC). This includes the SP's arrival, their location during the session, and their exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC to determine if all the appropriate examinations are complete. The MEC coordinator monitors the exam component status using responses from examination stations.

It is critical to assign SPs aged 12 years and older to phlebotomy as soon as possible at the start of a session block, especially the morning session blocks, as we ask the participants to fast for at least 8 hours. The coordinator gives each SP a hard-copy verification form as part of the check-in process. For SPs aged 12 years and older who are examined during a morning session, the form includes the question, "Did you eat or drink anything, other than plain water, after 11:30 p.m. last night?" The SP records "Yes" or "No" in a checkbox and the coordinator enters this information into the coordinator application. The coordinator application then highlights (hot pink) the names of SPs who responded "Yes" since they have not met the 8-hour fast requirement. The coordinator uses the highlighted names to aid in prioritizing SPs for the phlebotomy component; SPs who are not highlighted are assigned to phlebotomy before SPs whose names are highlighted.

Each SP receives a barcoded ID bracelet upon arrival at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP's ID number in barcode and eye-readable format. The phlebotomist "wands" the bracelet barcode with a barcode 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 and typing the numbers using the keyboard.

Phlebotomy Seating Options. The UMF 8678 phlebotomy chair (Exhibit 3-5) features an electric motor for up and down patient positioning, three positions—upright, recline, and full recline—and fully adjustable padded armrests that recline as the patient reclines. The chair includes both hand-operated and foot-operated controls to recline the chair with a touch of a button. To recline the chair, push the bottom button on the controller. The foot support will rise and the armrests will recline with the chair.

Exhibit 3-5. UMF 8678 phlebotomy chair



For the blood draw, the seating options are dependent on the weight of the SP and chair model. The chair weight restriction for the UMF 8678 chair model is 375 lbs. If the phlebotomist estimates that the weight of the SP is less than 375 lbs and the SP will fit comfortably in the phlebotomy chair, then ask the SP to sit in the chair. If the SP exceeds the capacity of the chair, use a chair from the staff lounge to comfortably and safely seat the SP. If the SP feels faint and is sitting in the electronic chair, recline the chair either before or during the blood draw as needed.

Seating SPs with disabilities if unable to sit in the phlebotomy chair:

- Roll wheelchairs completely into the room and engage wheel brakes. Walkers and canes can be set aside and out of the way to avoid a potential trip hazard.

Starting Phlebotomy Component:

- Access the phlebotomy application and open the phlebotomy exam. Log the SP in to phlebotomy as described in Section 3.6.

3.4 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 of the questions the SP poses about the venipuncture procedure. In addition, the phlebotomist must convey the importance of cooperation in the venipuncture component of the examination.

The phlebotomist must be prepared 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, the phlebotomist will know the following information about the procedures used for the study:

3.4.1 Rationale

Although the SP has provided much useful information in the 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 more than 250 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. Three different sizes of butterfly needles are available so that the most appropriate size can be selected to ensure the least discomfort for each SP.

Amount. Phlebotomists draw the following amount of blood:

- 1-2 years primary SP, 10 mL (0.3 ounces), 0.7 tablespoons;
- 3-5 years primary SP, 20 mL (0.7 ounces), 1.4 tablespoons;
- 6-11 years primary SP, 45 mL (1.5 ounces), 3.0 tablespoons;
- 12-19 years primary SP, 112 mL (3.8 ounces), 7.6 tablespoons;
- 20+ years primary SP, 112 mL (3.8 ounces), 7.6 tablespoons;
- Guests (1-11 years), 3 mL (0.1 ounces), 0.2 tablespoons;
- Guests (12+ years), 6 mL (0.2 ounces), 0.4 tablespoons;
- Dry Run Odd, 32 mL (1.1 ounces), 2.2 tablespoons; and
- Dry Run Even, 28 mL (0.9 ounces), 1.9 tablespoons.

An average adult male has 12 pints of blood and an average adult 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 maximum volume drawn with an NHANES phlebotomy amounts to slightly more than 25 percent (128 mL) of the amount drawn 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 sterile, one-time use, and disposable. There is absolutely no possibility of the SPs being infected by any blood-borne disease, such as hepatitis or HIV, due to participation in the venipuncture component of the NHANES exam.

Cooperation. Gaining the cooperation of an 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 HIV.
- Be aware of body image; a positive body image shows confidence and helps instill trust with the SP. Maintain a tidy appearance, erect posture, and a smile.
- Speak face to face with the SP and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that they are 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.

3.4.2 Refusal Conversion

The phlebotomy component maintains the highest priority among MEC examinations. All staff members performing phlebotomy are required to take the Phlebotomy Refusal Conversion Training contained in Westat’s Learning Management System.

Codes

The field office and interviewing teams use “Special Consideration” codes to describe SPs with special needs and/or reservations about the phlebotomy procedure to the MEC staff. The codes are part of the special consideration section of the MEC Appointment Schedule in the coordinator application. The phlebotomist prints the Session Preview Report for each session and notes CB/NB codes under the Special Considerations column. All codes should be given special consideration and understood to be situational.

- If an SP expressed no reservations or concerns about phlebotomy during the home interview, then no code appeared and no special action was needed from MEC staff.
- **CB** – represents “Convert Blood”—this means that the SP has expressed concern or fear about the blood draw, but did not indicate that they intend to refuse having blood drawn. If an SP is coded CB, phlebotomy remains a priority exam and the SP should be sent to the phlebotomy room as soon as possible in the session.
- **NB** – represents “No Blood”—this means the SP indicated during the home interview that they intended to refuse the blood draw. When an SP has a NB code, the coordinator may send the SP to phlebotomy either (1) after all other SPs have completed phlebotomy or (2) after the SP has completed the exams in the profile. The coordinator should use the following script to simply explain that “We need to send you to the exam room; we can scan your ID band barcode into the system.”

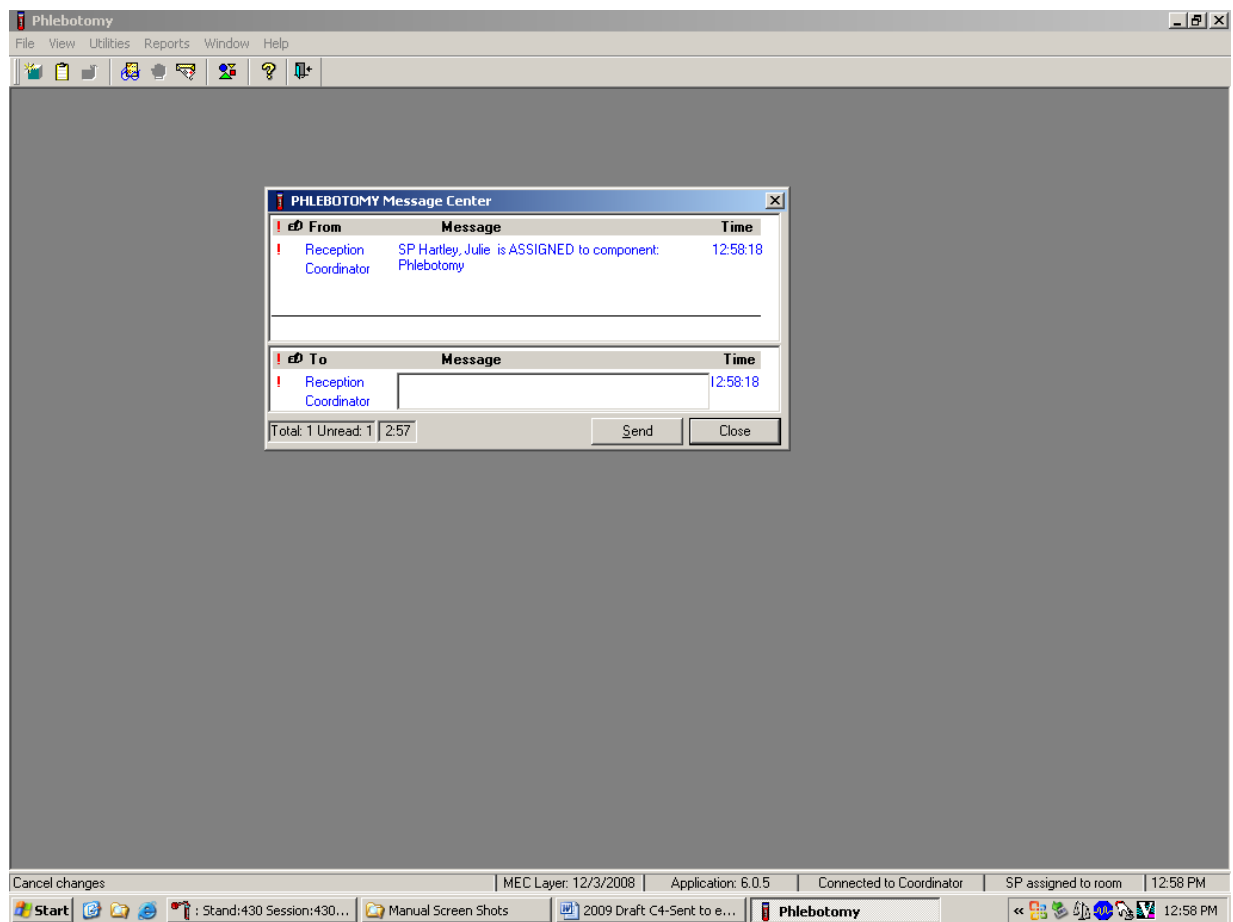
The MEC manager and coordinator should work in collaboration with the phlebotomist in assigning the NB-coded SPs; the phlebotomist is trained in refusal conversion techniques and is responsible for the overall response rate for this component. At all times, the coordinator and MEC manager must use their judgment in assigning SPs with NB to phlebotomy. If the SP is vehemently adamant about not giving blood, there is no reason to provoke the SP by sending them to the phlebotomy room. In this instance, the coordinator will mark the phlebotomy component as a refusal.

3.5 Performing the Venipuncture on SPs Who Do Not Speak English

When the phlebotomist must administer the venipuncture procedure to an 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. Refer to the MEC Operations manual for detailed instructions on the interpreter module.

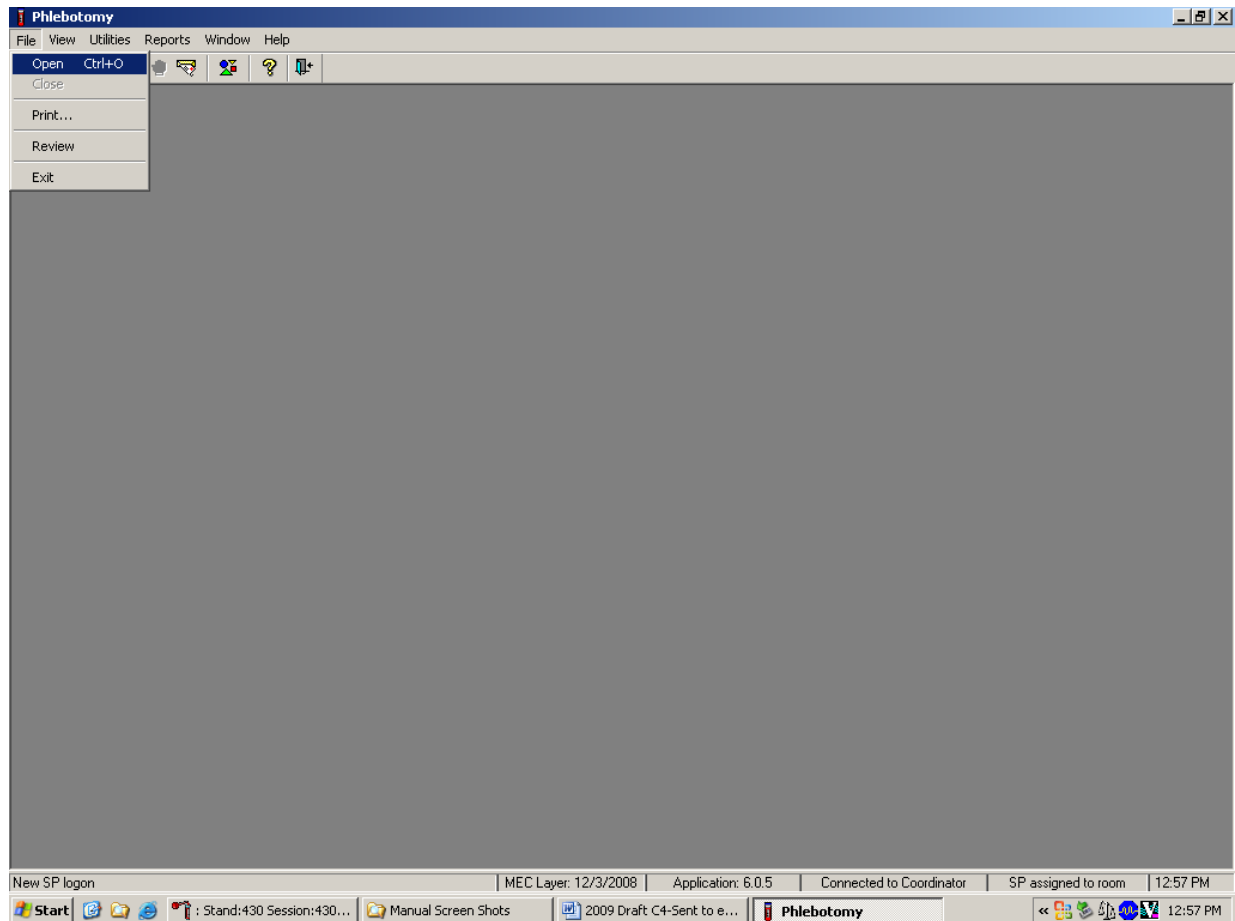
3.6 Open the Exam and Log the SP in to the Exam

Open and log on to the Phlebotomy application. The message center window identifies the SP assigned to Phlebotomy.



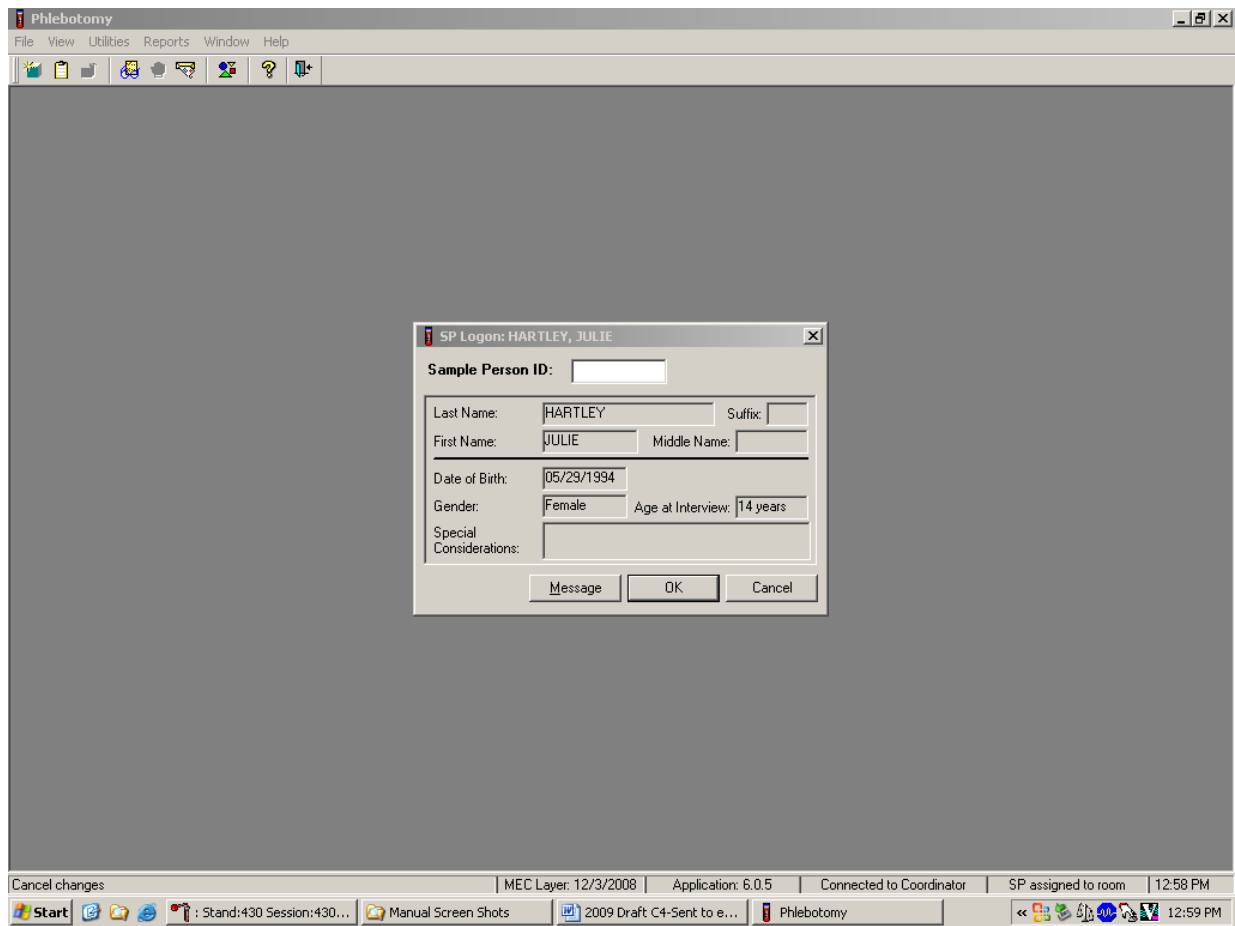
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component. To enter an optional text message and, to send the message to the coordinator, direct the mouse arrow to the Send button and left-click. To exit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

Open the Phlebotomy exam.

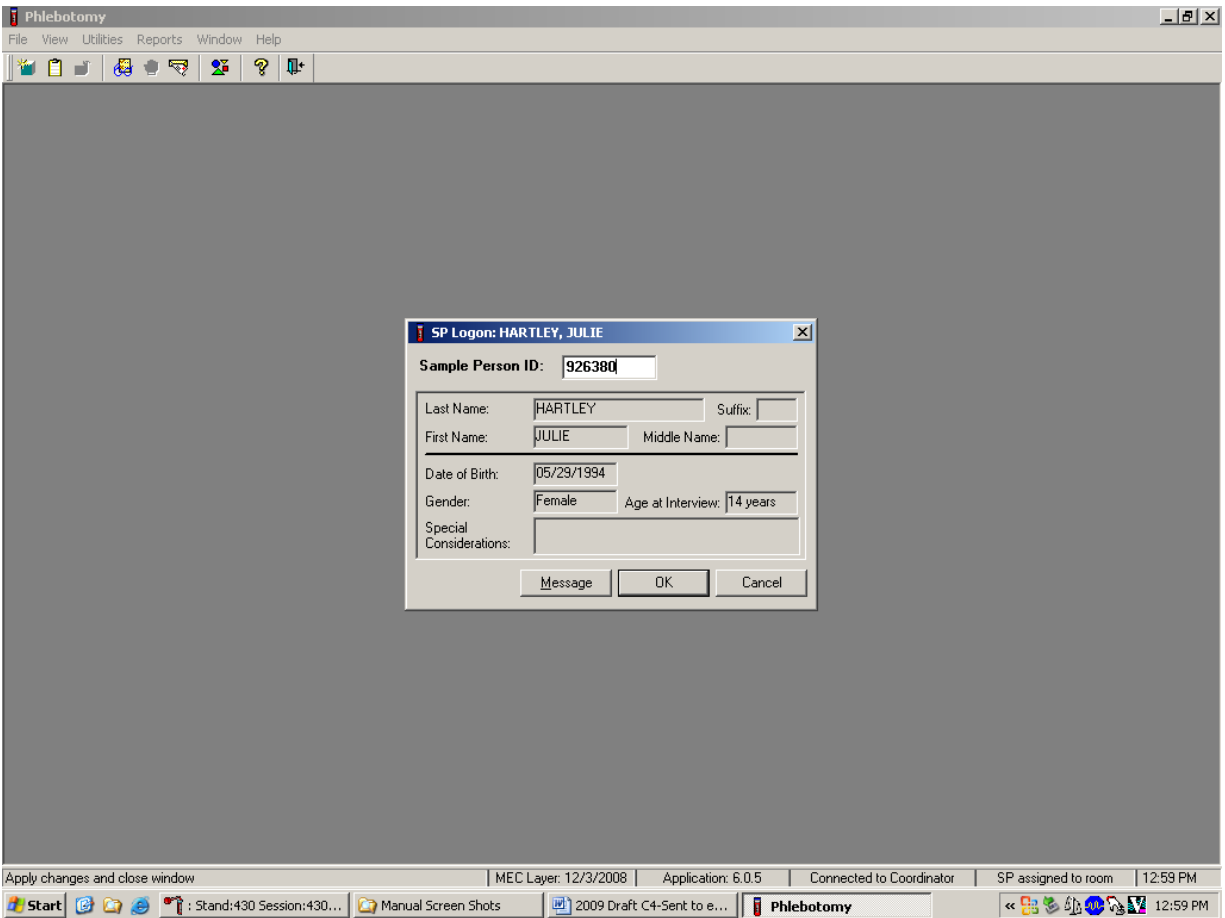


To open an exam, move the mouse to File in the menu bar, then click on Open.

The SP Logon window displays for the SP assigned to the component.



Log the SP in to the component.



To log the SP in to the component, use the barcode wand to scan the bracelet barcode. Otherwise, the phlebotomist can read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box. To continue, press Enter or direct the mouse arrow to the OK button and left-click. To cancel the Logon process and remove the window, direct the mouse arrow to the Cancel button and left-click.

Verify all information that appears in 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.

3.7 The Phlebotomy Interview

The Phlebotomy Interview includes two PUQ questions for ages 6 years and older, a shared exclusion pregnancy question for all females aged 12-59 years and 8-11 years if the SP has reported

starting her menses, plus, two safety exclusion questions. There are only two reasons to exclude an SP from venipuncture—hemophilia, and having received cancer chemotherapy within the past 4 weeks. The phlebotomist will administer the interview (and fasting questionnaire) directly to SPs over the age of 12, or will administer the interview questions (and fasting questionnaire) to the SP's parent or guardian for SPs under age 12. For SPs 1-15 years of age, the safety questions, hemophilia and cancer chemotherapy, will be asked in Proxy and should be filled in when the SP arrives in phlebotomy. If not, ask the safety questions to the parent for SPs under 15 years of age.

Additionally, the Pesticide Use Questionnaire will be asked in Proxy to parents of SPs aged 6 to 17 years. If these are not filled in when the SP is in Phlebotomy, ask the parents if the SPs are between 6 and 17 years of age.

Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly as written (**verbatim**) and record the responses.

The pesticide use questions are:

1. In the **past 7 days**, were any chemical products used in {your/their} home to control fleas, roaches, ants, termites, or other insects? The responses for this question are: “Yes,” “No,” “Refused,” or “Don’t Know.”
2. In the **past 7 days**, were any chemical products used in {your/their} lawn or garden to kill weeds? The responses for this question are: “Yes,” “No,” “Refused,” or “Don’t Know.” If the SP does not have a lawn or garden, code the response as “No.”

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm

SP ID: 373531 Name: BROWN, HARRY Age: 15 years Gender: Male Date: 02/09/2021 Time: 10:25 AM

PUQ Question

[I am going to ask you a couple of questions about the use of pesticides and weed killers in your home, yard, and garden.](#)

In the past 7 days, were any chemical products used in Harry home to control fleas, roaches, ants, termites, or other insects?

In the past 7 days, were any chemical products used in Harry lawn or garden to kill weeds?

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
 SP ID: 105917 Name: BROWN, SARA Age: 33 years Gender: Female Date: 02/09/2021 Time: 10:35 AM

Phlebotomy Interview

I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.

Are you currently pregnant? No

Do you have hemophilia? No

Have you received cancer chemotherapy in the past four weeks?

3.7.1 Pregnancy Shared Exclusion Question

For female SPs aged 12-59 years, the shared exclusion pregnancy questions are enabled and are asked during the MEC examination in the first examination. Additionally, female SPs aged 8 to 11 years who self-report as having started menses are also asked the pregnancy exclusion question. Each question is asked only once, even when the question is relevant for more than one component. Some examinations, like phlebotomy, do not require all the shared exclusions to be asked. In this situation, there may be some questions answered in one examination and then disabled in the remaining examinations. Shared exclusion questions are component specific. Answers provided during previous components appear on the screen for the next examiner to see, but the text box for data entry is disabled. Only shared exclusion questions relevant to the age and component that have not been answered are enabled. Example: If the SP goes to the clinician component before phlebotomy, the questions about “pregnancy” and “how many weeks” would be asked by the clinician. The “pregnancy” question would be disabled in the phlebotomy component.

- If the SP is a male, a female less than 12 years, or a female older than 60 years, the shared exclusion pregnancy questions will not be displayed, unless a younger female (8- to 11-years-old) has self-reported that her menses has started.
- If the SP is a female aged 12-59 years, the first shared exclusion pregnancy question is displayed and enabled.

Read the introductory statement, then read and record the response to the shared exclusion question.

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
SP ID: 888737 Name: BROWN, MARY Age: 22 years Gender: Female Date: 02/09/2021 Time: 11:00 AM

Phlebotomy Interview

I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.

Are you currently pregnant?

Do you have hemophilia?

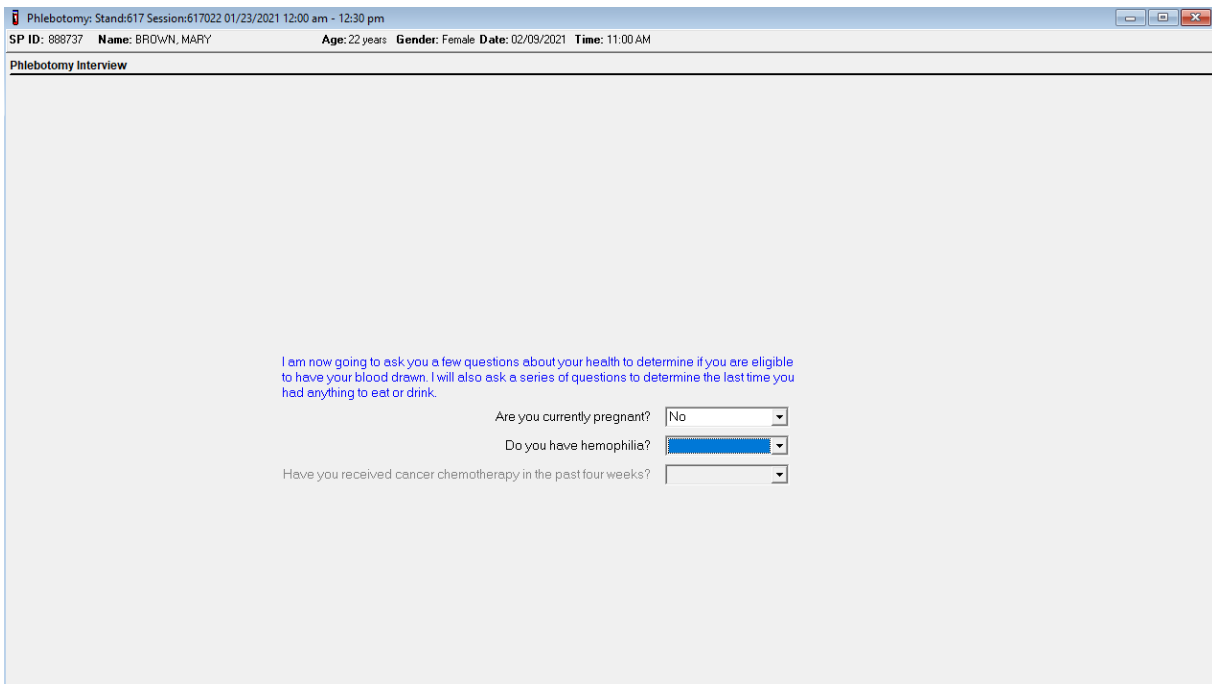
Have you received cancer chemotherapy in the past four weeks?

Yes
No
Don't Know

Record the response by typing [Y] for “Yes,” [N] for “No,” or [D] for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, and drag the mouse arrow to “Yes,” “No,” or “Don’t know” and left-click. Press Tab to move to the next text box.

If the response to the question “Are you currently pregnant?” is “Yes,” the SP is excluded from Liver Ultrasound Transient Elastography, and DEXA (Body Composition) due to pregnancy status. At the coordinator application, the component status for Liver Ultrasound Transient Elastography and DEXA defaults to “Not Done” with the comment “Blocked: Not Done [SP pregnant].”

Ask the next two phlebotomy safety exclusion questions.



If the answer to the shared pregnancy exclusion question is “No” or “Don’t know,” press Tab to proceed to the first safety exclusion question, “Do you have hemophilia?” If the SP answers “Don’t know,” to the pregnancy exclusion question, they will not go through the DEXA or Liver Ultrasound exams.

3.7.2 Safety Exclusion Questions

Continue to 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 normally. If an 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 the SP back to the coordinator or to the next component as directed by the Message Center.</p>
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Record the exact response.

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
SP ID: 888737 Name: BROWN, MARY Age: 22 years Gender: Female Date: 02/09/2021 Time: 11:00 AM

Phlebotomy Interview

I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.

Are you currently pregnant? No

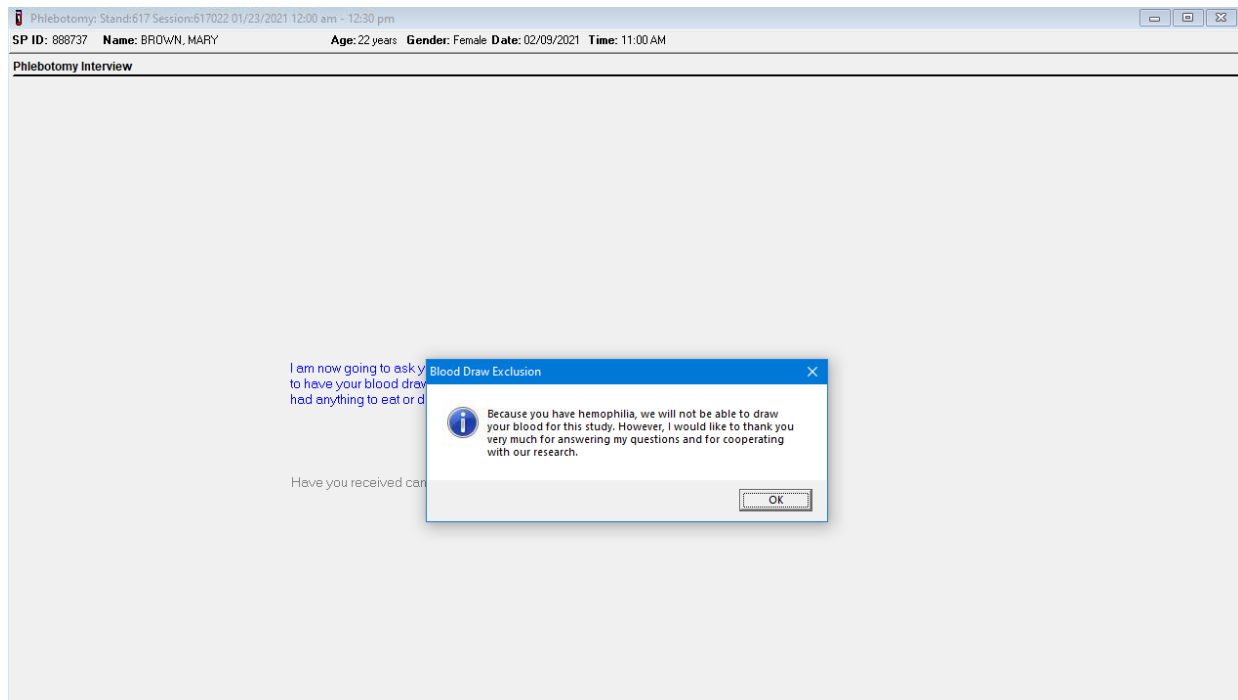
Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

Yes
No
Refused
Don't Know

Record the response by typing [Y] for “Yes,” [N] for “No,” [R] if they refuse, or [D] for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, 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,” direct the mouse arrow to the bright blue right arrow in the bottom-right corner of the screen and left-click or press Enter.

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.

If the SP is excluded from the phlebotomy component due to hemophilia, an informational Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.

To remove the Exclusion message text box, move the mouse to the OK button and left-click, or press Enter.

Verify the status.

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
 SP ID: 888737 Name: BROWN, MARY Age: 22 years Gender: Female Date: 02/09/2021 Time: 11:00 AM

Phlebotomy Status

Status

Complete
 Partial
 Not Done

Comments

Other text

SPs excluded because of hemophilia are automatically coded by the application as a status of “Not Done” with a comment of “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the SP has not been excluded because of hemophilia, continue the phlebotomy interview by asking the second question displayed on the screen, “Have you received cancer chemotherapy in the past 4 weeks?”

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
 SP ID: 487626 Name: BROWN, BARB Age: 25 years Gender: Female Date: 02/09/2021 Time: 11:39 AM

Phlebotomy Interview

I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.

Are you currently pregnant?

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

Yes

No

Refused

Don't Know

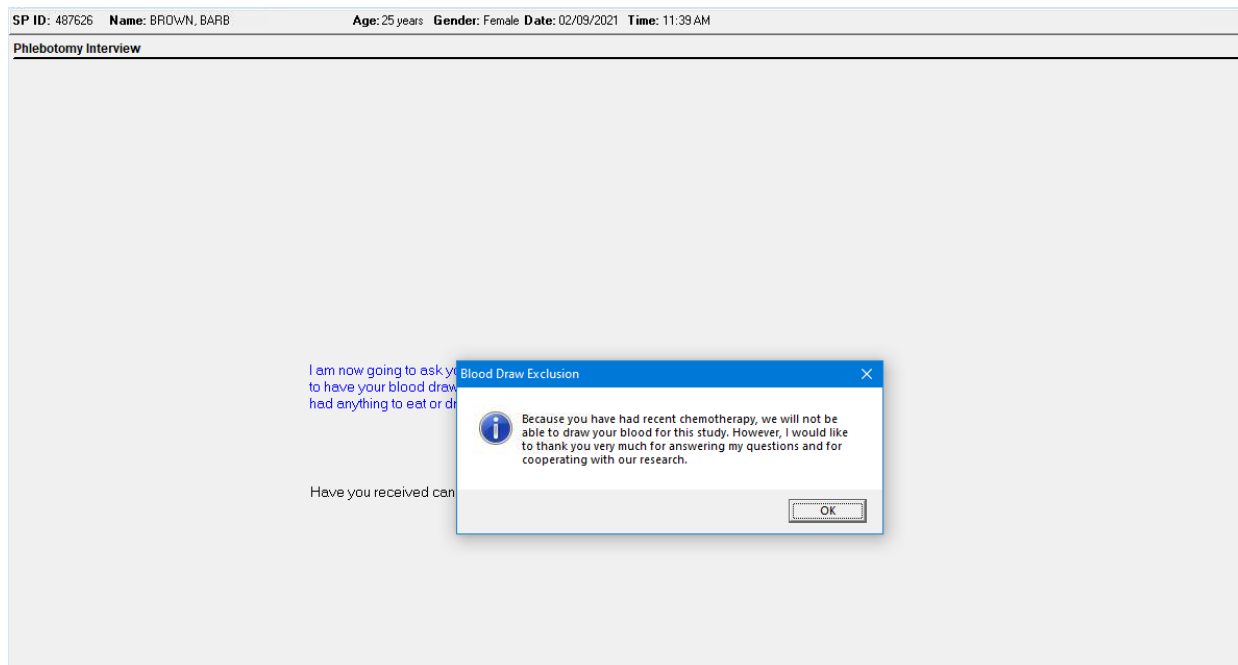
Q2. Have you received cancer chemotherapy in the past 4 weeks?

Q2. This question asks whether the SP has received cancer chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.

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 script in the box to the SP and escort them back to the coordinator or to the next component as directed by the Message Center.

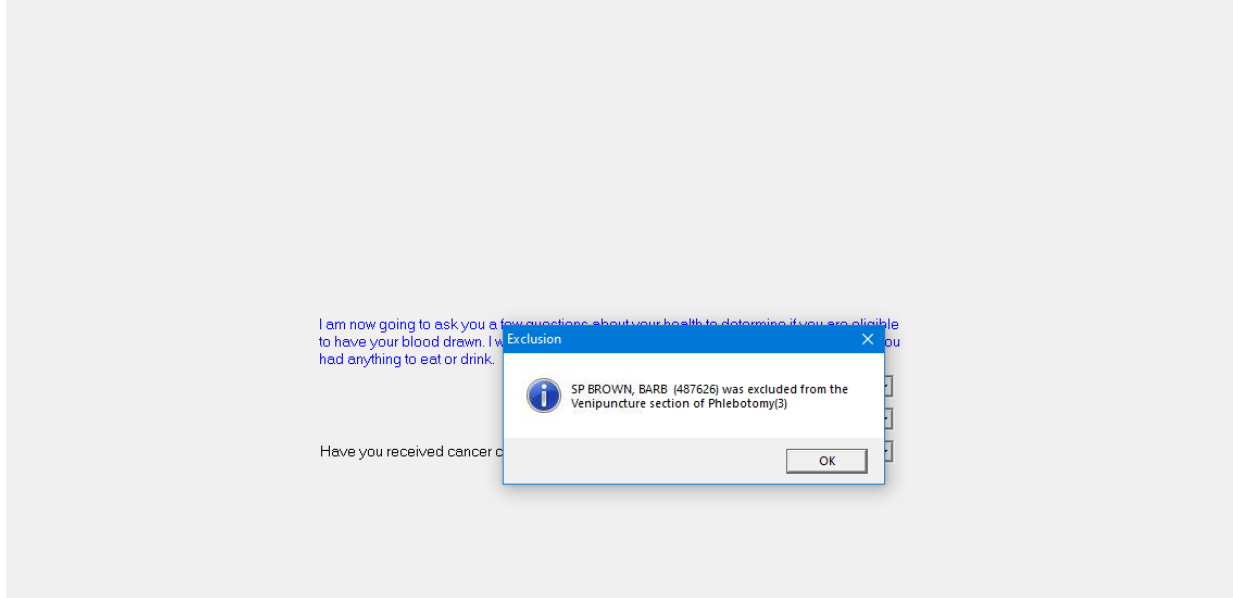
Record the response by typing Y for “Yes,” N for “No,” R if they refuse, or D for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t know” and left-click. If the response is “Yes,” “Refused,” or “Don’t know,” direct the mouse arrow to the bright blue right arrow in the bottom-right corner of the screen and left-click. If the SP answers “Don’t know” to the cancer chemotherapy question, they will be excluded from the blood collection.

If the SP is excluded from the phlebotomy component because of chemotherapy, an informational Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.



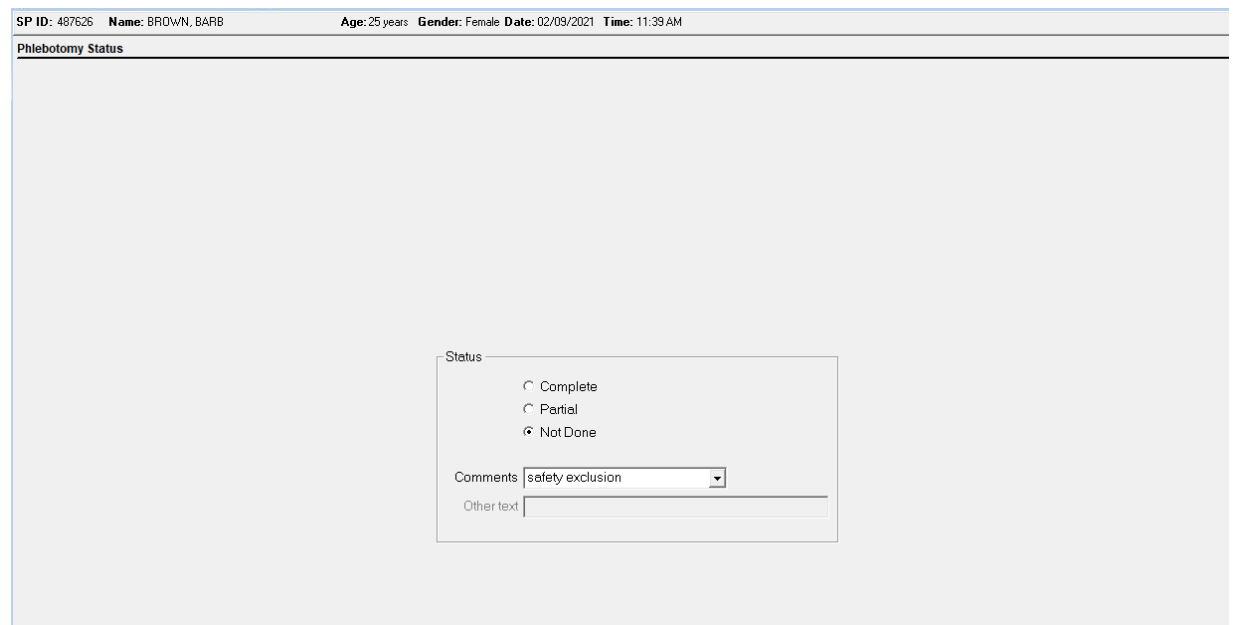
Read the script to the SP. To remove the Blood Draw Exclusion message box, direct the mouse arrow to the OK button and left-click.

Phlebotomy Interview



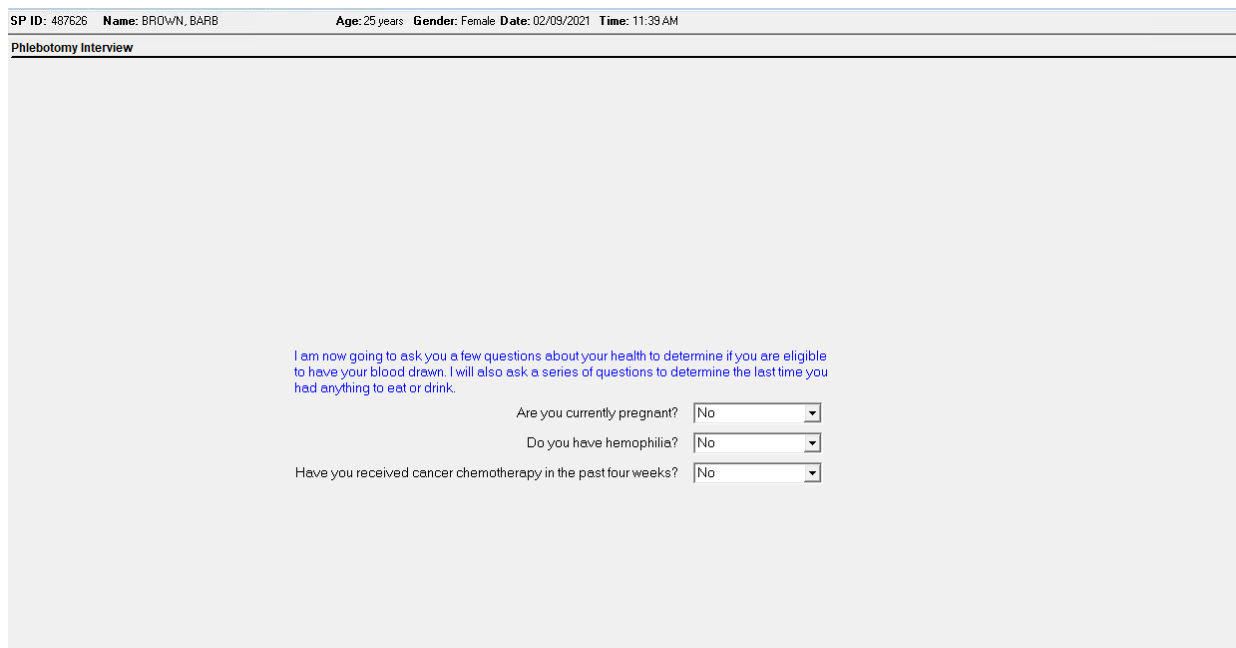
To remove the Exclusion message text box, move the mouse to the OK button and click, or press Enter. To progress to the Component Status screen, direct the mouse arrow to the bright blue arrow in the bottom-right corner and left-click, or press Enter.

Review the status.



SPs excluded because of chemotherapy are automatically coded by the application as a status of “Not Done” with a comment of “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the response to both exclusion questions is “No,” continue to the next screen.



SP ID: 487626 Name: BROWN, BARB Age: 25 years Gender: Female Date: 02/09/2021 Time: 11:39 AM

Phlebotomy Interview

I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.

Are you currently pregnant? No

Do you have hemophilia? No

Have you received cancer chemotherapy in the past four weeks? No

To progress to the Fasting Questionnaire screen, direct the mouse arrow to the bright blue arrow in the bottom-right corner and left-click, or press Enter.

3.8 Administering the Fasting Questionnaire

Fasting status is critical to many of the laboratory analytes, and fasting data is required for correct interpretation of laboratory results. No primary SPs aged 1-11 years or SPs assigned to afternoon or evening blocks are asked to fast. All other primary SPs aged 12 years and older appointed to a morning block are asked to fast for 8 hours; this includes diabetics. These SPs are given the highest priority, so the venipuncture can be completed as soon as possible after the SPs check into the MEC, where they will be offered juice and cookies to be consumed after completion of the Liver Ultrasound Transient Elastography component, if eligible.

The phlebotomist administers the fasting questionnaire to all SPs, and the application calculates and displays the fasting time in number of hours and minutes. The phlebotomist then performs the venipuncture.

The overall objective is to perform phlebotomy on all eligible SPs. The coordinator must base the decision to assign an 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 an SP insists on leaving the MEC before they have been assigned to phlebotomy. It is always preferable to perform the venipuncture on this SP before they leave the MEC. The coordinator and MEC manager can provide the best overall assessment of the status of a particular SP.

SPs may opt to return to the MEC to complete exams that were missed or to complete exams that were begun but not finished. These SPs are designated as “Partial” SPs. When the SP returns to the phlebotomy component, ask and record the fasting questions a second time so that the data is accurate. If the SP returns to the MEC to complete the phlebotomy component at an alternate date, the Field Office, Lab Component Lead, and the ISIS team must work together to reset the phlebotomy component so the phlebotomy interview can be administered a second time to capture changes in the data that may have occurred between the initial and follow-up visit (i.e., fasting status).

Read the text exactly as written and record the time and response options.

Q1. When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet’N Low, NutraSweet, Equal, or Splenda.

Q1. This question elicits the last time the SP ate or drank anything and determines fasting time.

SPs are allowed to consume diet soda, black coffee, or tea with artificial sweeteners like Sweet’N Low, NutraSweet, Equal, or Splenda since these have no effect on study analytes. Do not include flavored waters.

Enter the response.

Enter the date.

SP ID: 627401 Name: ZHOU, BOB S Age: 37 years Gender: Male Date: 02/09/2021 Time: 11:50 AM

Fasting Questionnaire

When was the last time you include diet soda or black NutraSweet, Equal, or Splenda? Do not N Low. 09:00 PM //

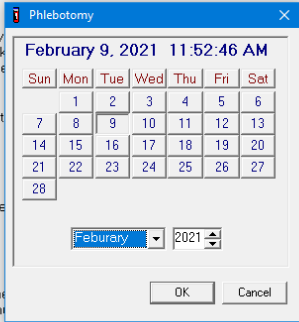
Coffee or tea with Have you had any of the following since

Gum, breath mints, lozenges

Dietary supplements

Fasting Time:
The SP will meet their 8 hour fast at (### AM/PM). Do you want to delay the blood collection?

Hours Minutes



Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and press Tab, or use the calendar to enter the date. To access the calendar, select **[F2]**. To select the correct month, 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, direct the mouse arrow to the correct day on the displayed month and left-click. To correct the year, 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, direct the mouse arrow to the OK button and left-click, or press Enter. To exit the calendar function, 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.

SP ID: 627401 Name: ZHOU, BOB S Age: 37 years Gender: Male Date: 02/09/2021 Time: 11:50 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:00 PM 02/08/2021

Have you had any of the following since yesterday at 9:00 PM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] Yes No

Alcohol, such as beer, wine, or liquor? Yes No

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? Yes No

Antacids, laxatives, or anti-diarrheals? Yes No

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes No

Fasting Time: 14 Hours 54 Minutes

The SP will meet their 8 hour fast at {### AM/PM}. Do you want to delay the blood collection? Yes No

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 artificial sweeteners is unacceptable. Include all milk products such as half-and-half, light cream, nonfat milk, and all other nondairy creamers like Cremora or Coffee-Mate. If "Yes"...correct fasting time.
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. If "Yes"...correct fasting time.
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?	Do not include sugar-free gum and mints in this category. If the answer is "Yes"... correct fasting 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. 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. 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, 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 press Tab to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 AM or [P/p] for times between noon and 11:59 PM and press Tab. Alternatively, to select AM or PM, 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 press Tab, or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, 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, direct the mouse arrow to the correct day on the displayed month and left-click. To correct the year, 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, direct the mouse arrow to the OK button and left-click, or press Enter. To exit the calendar function, direct the mouse arrow to the Cancel button and left-click.

Example of Changing the SP’s Fasting Time

When administering the questions in the questionnaire, there will be instances that trigger the SP’s memory, and the phlebotomist will need to go back and change the fasting time.

SP ID: 627401 Name: ZHOU, BOB S Age: 37 years Gender: Male Date: 02/09/2021 Time: 11:50 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:00 PM 02/09/2021

Have you had any of the following since yesterday at 9:00 PM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] Yes No

Alcohol, such as beer, wine, or liquor? Yes No

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? Yes No

Antacids, laxatives, or anti-diarrheals? Yes No

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes No

Fasting Time 14 Hours 54 Minutes

The SP will meet their 8 hour fast at (### AM/PM). Do you want to delay the blood collection? Yes No

For the SP who had coffee with cream and sugar, this response should be changed to the time they drank the coffee with cream and sugar.

The **first question determines the SP's fasting time**, and the next 5 questions are to help trigger the SP's memory.

Reason to adjust the fasting time:

- If the SP says “Yes” to the coffee with cream or sugar – change the time in the 1st question to reflect this.
- If the SP had alcohol – change the time in the first question to reflect this.
- If the SP has had gum, breath mints, lozenges or cough drops (unless they were sugar free) – change the time in the first question to reflect this.

Review the data in the Fasting Questionnaire.

SP ID: 627401	Name: ZHOU, BOB S	Age: 37 years	Gender: Male	Date: 02/09/2021	Time: 11:50 AM
Fasting Questionnaire					
When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda.					
09:00 PM 02/08/2021					
Have you had any of the following since yesterday at 9:00 PM?					
Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] No : / /					
Alcohol, such as beer, wine, or liquor? No : / /					
Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? No : / /					
Antacids, laxatives, or anti-diarrheals? No : / /					
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes 08:00 AM 02/09/2021					
<i>Fasting Time:</i> 14 Hours 54 Minutes					
The SP will meet their 8 hour fast at {### AM/PM}. Do you want to delay the blood collection?					

To progress to the next screen, direct the mouse arrow to the bright blue arrow in the bottom-right corner and left-click, or press Enter.

SPs Not Meeting 8-Hour Fast – Morning Appointments Only

If an SP during the morning appointment block does not meet their 8-hour fast, a message will appear at the bottom of the fasting screen stating, “the SP will meet their 8 hour fast at xx:xx AM/PM. Do you want to delay the blood collection?” If the SP has just started the exam and the

time to meet the fast is within a 2-hour window, select “yes” in the block and explain to the SP that they have not met the required fasting time yet, so they will complete their other exams and will return to phlebotomy after the other components are completed. If the time to meet the fast is outside of the appointment block, ask the SP if they are willing to wait until they have met the fasting time. If they are not willing to wait, select “no” and continue with the blood collection. If they agree to wait, contact the coordinator and MEC manager to coordinate a place for the SP to wait for the blood draw once they have completed all of the other components. Select “yes” in the block and escort the SP to the next component as directed by the coordinator. For those SP’s who have not met the 8-hour fast, the coordinator screen turns yellow and will turn back to green when the 8-hour fasting requirement has been met. The coordinator will assign the SP to phlebotomy when that time has been met.

SP ID: 627401 Name: ZHUU, BUB S Age: 37 years Gender: Male Date: 02/09/2021 Time: 11:50 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 05:30 AM 02/09/2021

Have you had any of the following since today at 5:30 AM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] No : / /

Alcohol, such as beer, wine, or liquor? No : / /

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? No : / /

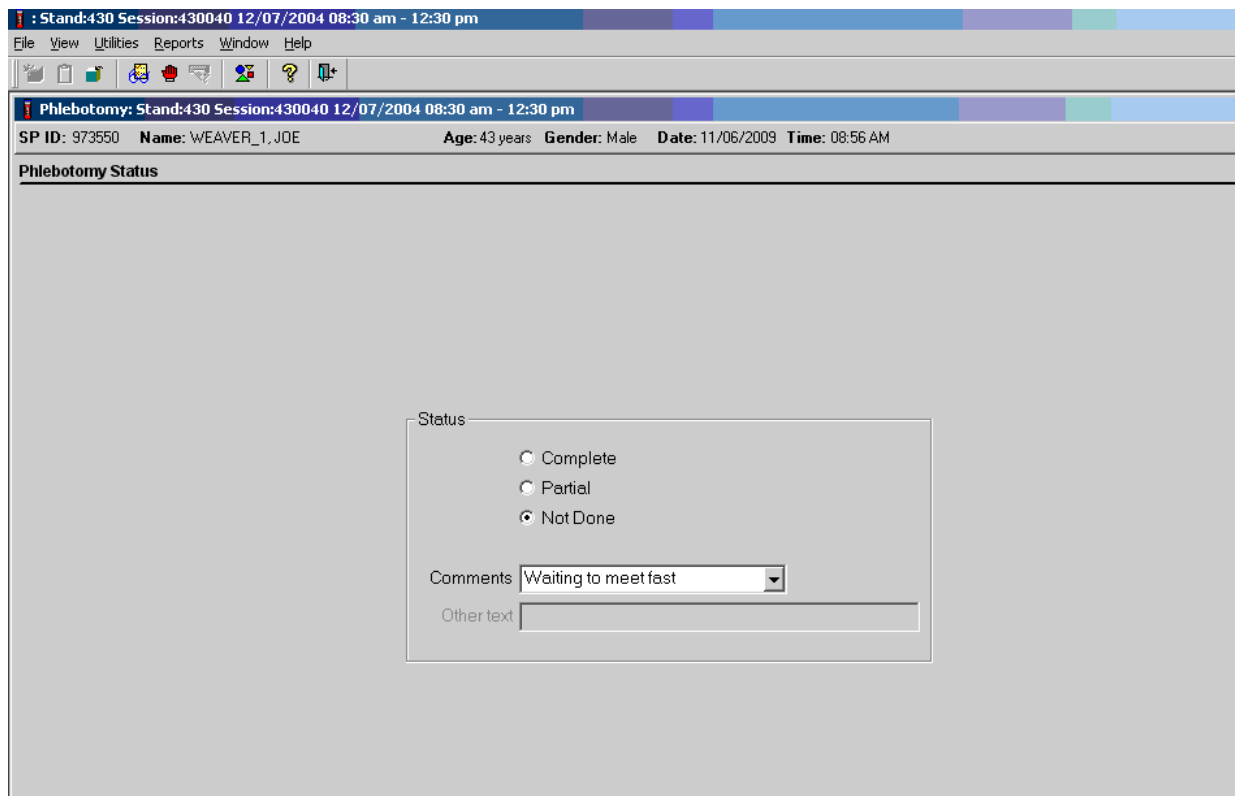
Antacids, laxatives, or anti-diarrheals? No : / /

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes 08:00 AM 02/09/2021

Fasting Time: 6 Hours 37 Minutes

The SP will meet their 8 hour fast at (### AM/PM). Do you want to delay the blood collection? Yes
No

The Phlebotomy Status screen will automatically default to Not Done with a comment of “Waiting to meet fast.”



If the SP will not meet the 8-hour fast during the session, they are prompted to have their blood drawn without waiting for the 8-hour fast. If the 8-hour fast will not be met by the end of the appointment block, the application will allow the blood to be drawn in the phlebotomy exam.

Note: The system does not indicate if the SP is leaving early. The blood should be drawn if the SP hasn't met their 8-hour fast and needs to leave the MEC.

3.9 Venipuncture Procedures

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins in the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side (top) of the hand on the left arm/hand and then the right arm/hand. Be aware of SPs on dialysis who may have fistulas in both arms located in the antecubital space and forearms, and switch to a hand draw with permission from the SP.

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 NHANES venipuncture protocol as displayed in ISIS.

The exact quantity of blood drawn into each tube varies slightly with altitude, ambient temperature, and venous pressure.

1. Completely fill tubes with additives to ensure proper ratio of blood to additive.
2. Thoroughly mix the lavender tubes (3, 4, and 6 mL), 6 mL royal blue, 2 mL and 7 mL gray-top tubes immediately after drawing the blood.
Note: Mix the 7 mL gray (VOC) tube 30 times immediately after filling.
3. Visually check the bottom and around the stopper of the 7 mL gray-top tube to ensure all the powder has been dissolved. Remix as needed.
4. Label all the blood tubes and place them in the pass-through window to the laboratory.

Use Vacutainer tubes at room temperature. Protect tubes from extreme temperatures and store in a cool place. Note the expiration date printed on Vacutainer tubes. Do not use expired tubes unless they are the only tubes available and 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 any expired tubes in a Unusual Field Occurrence (UFO).

Two venipuncture attempts are permitted by the phlebotomist with the SP’s verbal consent or with the parent’s consent if an SP is a child or an infant. After two attempts, one of the lab techs may attempt the venipuncture if given permission from the SP and or guardian if a child or an infant.

If an SP faints or becomes ill, causing termination of the procedure without collecting all of the blood, repeat the procedure with the SP’s consent after the SP has recovered.

3.9.1 Preparation of the Puncture Site

It is extremely important that the anticipated puncture site is thoroughly cleaned and all necessary equipment, including needles and tubes, is 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. **Do not touch a SP or any samples without applying gloves.**
- Place appropriate blood collection tubes in a test tube rack in the draw order outlined in the venipuncture protocol as displayed in ISIS. If an SP exhibits nervousness, block the tubes from their view, if possible.
- Instruct the SP to sit in the phlebotomy chair. **Never** attempt a venipuncture on a standing SP. Having the SP sit helps guard against any injury that might result if the SP faints. Place the SP in a supine position if it is impossible for them to sit upright during the procedure. Instruct the SP to extend their arm palm up and straight at the elbow. If the SP is a child or infant, have a clinical laboratory scientist hold the SP in the proper position.
- Position the SP's arm on the armrest or a pillow so that the veins are readily accessible and you are 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. Change the pillowcase after use.
- Inspect the arm.
- 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 techniques if the veins do not distend quickly.
 1. Warm the antecubital area with a heat pack.
 2. Tap the area lightly 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.
 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 scrubbing back and forth motion. Do not cross over an area that has already been cleansed.
- Wait for the cleansed area to dry. 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 19-, 21-, or 23-gauge butterfly depending on the condition of the SP's veins. The 19-gauge butterfly should be suitable for most SPs. If the SP's veins appear fragile or small, use a 21- or 23-gauge butterfly.

3.9.2 Venipuncture Technique for the Nipro (19-, 21-, and 23-Gauge)

- Prepare the blood collection set. Obtain one blood collection set and one luer adapter. Open the blood collection package and inspect the unit. Open the cover by twisting the two ends at the seal. Push the male luer adapter firmly and securely into the female end of the needle assembly. Attach a tube holder onto the adapter.
- Ask the SP to make a fist. Do not have the SP pump their fist since this action may alter certain results.
- Fix the vein about 1 inch below the proposed point of entry by pulling the skin taut with the thumb of your less dominant hand.
- 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.
- Remove the needle cover. Grasp the wings and push the needle firmly and deliberately into the vein. Do not grasp the translucent needle shield to insert. 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 secured with Co-flex over the puncture site. Switch to the other arm using a new needle.
- 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.

- As the Vacutainer tube is filling, transfer the tube holder to the non-dominant hand, leaving the dominant hand free to pick up and change the tubes.
- Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
- Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive.
- When VOC tubes are collected:
 - Fill each tube with 7 mLs of blood.
 - Keep the tube on the needle for 2-3 seconds once the tube appears to be completely filled to ensure the correct volume is drawn.
 - Immediately after collection, invert the tubes 30 times to ensure the powder is mixed into the blood. Avoid vigorous shaking as this may cause aberrant results.
- When Genetics tubes are collected:
 - Fill each tube with 6 mLs of blood.
 - Keep the tube on the needle for 2-3 seconds once the tube appears to be completely filled to ensure the correct volume is drawn.
 - Immediately after collection, invert the tube several times to ensure the anticoagulant is mixed into the blood. Avoid vigorous shaking as this may cause aberrant results.
- 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. Loosen the tourniquet when the last tube begins filling, and remove it as the last tube fills.
- Fill tubes in the proper order, according to the NHANES protocol listed in ISIS.
- When the last tube has filled, first remove the tourniquet, and then 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. To activate the shielding mechanism, either grab the tubing and hold the needle guard at the end closest to the tubing and pull the tubing until the needle guard locks in place, or hold the needle guard at the end closest to the tubing, grab the wings and slide the wings back until the needle guard locks in place.
- 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.

3.9.3 Concluding the Venipuncture

- Place all used needles in a sharps container and dispose of all visibly contaminated waste in a biohazard container.
- Check the venipuncture site for clotting.
- Apply a CoFlex dressing over the gauze pad. Do not ask the SP to bend their arm at the elbow to hold the gauze in place because this may cause a bruise to form at the venipuncture site. Instruct the SP to remove the bandage no less than **45 minutes** from the completion of the procedure and if bleeding has stopped. Also, suggest that the SP sit quietly for a few minutes. If bleeding continues, have SP raise their arm above their head and continue to keep direct pressure on the site for 2 minutes or more.
- **Continue wearing gloves until the tubes have been labeled and passed to the laboratory.**
- Corresponding computer-generated barcode labels print automatically, after the phlebotomist enters the quantity of tubes drawn.
 - Label the 7 mL gray-top tube with the label containing the title VOC Blood, a barcode plus Sample ID – XXXXXX054, and a second barcode plus Astro ID. Place the barcode label on the 7 mL gray top tube so the lot number and expiration date of the tube is visible.
 - Label the 6 mL lavender-top tube with the label containing the title Genetics, a barcode plus Sample ID – XXXXXX119, and a second barcode plus Astro ID.
 - Label one of the two 4 mL lavender-top tubes with the label containing the title Glycohem, a barcode plus Sample ID – XXXXXX004, and a second barcode plus Astro ID.

- Label all other tubes with barcoded labels with the barcode vertical on the tube. The time prints on the label.



- Administer the VTQ to SPs selected to have the VOC 7 mL gray-top tube collected. See Exhibit 3-10 for the questions.
- Place the rack containing the blood collection tubes in the pass-through window located over the sink.
- Offer the SP refreshments. Ask them to not eat/drink the refreshments until after the completion of the LUTE exam. Explain to them once they are given a yellow band that they can eat/drink the refreshments.
- Report any adverse reaction to the venipuncture to the clinician immediately, and document the event by using the automated UFO utility.
- Escort the SP back to the next scheduled exam or the coordinator.
- If blood has spilled on the phlebotomy chair, wash the area with a 10 percent solution of bleach and water, then prepare the workstation for the next SP. Routinely disinfect the phlebotomy chair with Sani-Wipes to disinfect after each SP.
- Follow the COVID-19 Mitigation Protocol and clean the room completely after each SP. Always wear gloves when cleaning the room.

3.10 Pediatric Venipuncture

Pediatric venipuncture requires special techniques. Because you 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 the parent/guardian and/or a clinical laboratory scientist. 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 colorful Coflex bandages, stickers, and a snack when finished.

Preschoolers, age 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 word “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 Coflex bandages, stickers, and a snack. Try using distractions, such as using the instruction cards, distraction cards, applying the Buzzy above the venipuncture site, pointing to wall stickers, 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 clinical laboratory scientist 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 mock demonstrations, on you or the parent, whenever possible. Having the child help during the procedure distracts the child as well as letting them have

some control. Be sure to reinforce how big a help they were after the draw. Give the child realistic choices, such as which arm to choose. Try using distractions, such as using distraction cards and applying the Buzzy above the venipuncture site. You may need to consider having a clinical laboratory scientist assist with some children even at this stage. Colorful Coflex bandages, stickers, and snacks continue to be important.

Although adolescents aged 12 to 18 years 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 them that the best technique is being used. It is very important that the adolescent maintain control of the situation; therefore, give them some choices, as well as allowing them to help if offered. Be very clear about rules, such as remaining motionless, but do not restrain the adolescent.

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. Assess the size of the vein and use the appropriate needle size for a successful venipuncture. For difficult to find veins, use the Veinlite as described in Section 3.12 to locate a suitable vein and reassure the SP and the parent. Follow the general guidelines in Section 3.9 for performing venipunctures.

3.10.1 Age Specific Care and Phlebotomy

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB

What's Up with this "Age Specific Care?"

- The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) requires that all healthcare staff annually meet competency expectations in performing Age Specific Care.
- An interpretation of the standards and their intent relates to all staff members who assess, treat, and manage, or who work in areas that have direct impact on, patients in age-specific populations.
- Managers are being challenged to make sure their phlebotomists are not only proficient at phlebotomy, but proficient with all age groups.

Phlebotomy Applications

- Basic knowledge of human growth and development.
- Age specific interpersonal skills.
 - Psychological needs;
 - Social needs; and
 - Appropriate tone of voice, eye contact, and active listening skills.
 - Technical expertise – physical skills;
 - Talking points developed by the National Center for Health Statistics;
 - Photostory color sheets developed by the National Center for Health Statistics; and
 - Other age-appropriate distraction tools (Buzzy, distraction cards, and wall stickers).

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Age-Specific Groups

- Neonate/Infant 0-11 months;
- Toddler 1-3 years;
- Pre-School 4-5 years;
- School Age 5-12 years;
- Adolescent 13-18 years;
- Young Adult 19-35 years;
- Adulthood 36-65 years; and
- Late Adult 65+ years.

Neonate/Infant Psychosocial Needs

- Total dependence on parents/adults.
- Older infant has fear of strangers and separation from parent.
- Parent may hold child and provide comfort.
- Pacify with bottle/pacifier or distract with toys.
- Primary interaction will be with parent.
 - Introduce yourself.
 - Gentle, comforting tone of voice.
 - Compassionate expression and body language.
- Clearly explain the procedure.
- Older infants – talk slowly and make eye contact.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Neonate/Infant – Fears/Safety

- Try not to separate from parent unless absolutely necessary.
- Do not perform venipunctures on infants less than 6 months of age unless absolutely necessary (only applicable to Infant Blood Pilot).
- For heel sticks, follow recommended procedures to the letter (not applicable to NHANES).
- Collect minimum amount of blood necessary.

Toddler 1-3 Years Psychosocial Needs

- Try not to separate from parent unless absolutely necessary.
- Parent may assist by holding, explaining to, and comforting the child.
- Approach in friendly, cheerful, and empathetic manner.
- Speak before you touch, use child's name.
- Explain procedure in soothing tone using age-appropriate terms; children this age fear pain.
- Emphasize cooperation.
- Praise child during procedure.
- Encourage parent to praise child after procedure.

Toddler 1-3 Years – Fears/Safety

- Childproof area, no supplies in reach.
- Be prepared, have all supplies needed to avoid delay.
- NEVER say "This will not hurt"; rather, use age-appropriate terms, and it's OK for them to say "ouch."
- Distract with a toy or other object.
- If appropriate, keep child informed on how much longer it will be.
- Adhesive bandages may not be appropriate, child may swallow and choke.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Pre-School 4-5 Years Psychosocial Needs

- Parent may be present to provide emotional support and to assist in obtaining child's cooperation.
- Approach in friendly, cheerful, and empathetic manner. Use child's name.
- Explain procedure in soothing tone using age-appropriate terms. Children this age fear pain.
- NEVER say "This will not hurt"; rather, use age-appropriate terms, and it's OK for them to say "ouch."
- Keep child informed on how much longer it will be.
- Praise for bravery, say "Thank you."

Pre-School 4-5 Years – Fears/Safety

- Childproof collection area.
- Children this age fear pain.
- Avoid delays, have all equipment.
- Assemble equipment out of child's eyesight.
- Use your best judgment whether to encourage child to look away.
- Involve child in after care by allowing selection of adhesive bandage and sticker.

School Age 6-12 Years – Psychosocial Needs

- Increased language skills and self-control.
- Move from security-seeking behavior toward independence.
- Try not to embarrass the child.
- Must communicate with them as an individual using age-appropriate words and appropriate eye contact.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

- May want parent to hold hand.
- Explain the procedure and why blood is needed.
- Be prepared to answer questions.

School Age 6-12 Years – Fears/Safety

- Younger ages fear pain, older ages may “act” brave.
- Younger ages may need distraction such as a toy or other object.
- Explain use of equipment, if appropriate.
- Reassure the patient during the procedure.
- Let them know how much longer.
- Explain the importance of maintaining pressure after completion of procedure.

Adolescent 13-18 Years Psychosocial Needs

- Maintain privacy.
- Concerned with the present more than the future.
- Conscious of appearance.
- Actively involved in anything concerning the body.
- Engage in behaviors to establish they are an adult.
 - May be hypersensitive or non-interactive.
 - May act hostile to hide fear.
 - Important to assess the patient and use appropriate interpersonal skills.
- Take extra time for explanations and or preparation.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Adolescent 13-18 Years – Fears/Safety

- Embarrassed to show fear.
- Adolescent male has greater potential for fainting.
 - Periodically check for pre-syncope signs.
 - Be aware of sudden silence in a previously talkative patient or extremely talkative after previously silent.
- Keep up a running conversation to distract the patient.
- Stress importance of post-phlebotomy care.

Young Adult 19-35 Years Psychosocial Needs

- Reflect on interests, goals, and aspirations for the future.
- Focused on preservation and maintenance of health.
- May work and play too hard and sacrifice sleep, nutrition, and exercise.
- May experience anxiety, stress, and depression related to work, marriage, parenting, and social expectations.
- More involved with healthcare decisions, may ask questions putting you “on the spot.”
- Communicate in a professional manner.
 - Explain why you cannot answer certain questions.
 - Do not patronize or talk down to the patient.
 - Clearly and honestly explain the procedure.
- Avoid negative body language.
- Eye contact is critical; promotes sense of trust but be aware of cultural differences.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Young Adult 19-35 Years – Fears/Safety

- Can possess same fears as pediatric patient.
- Confidence and professionalism are essential to set patient at ease.
- Be aware of signs of syncope, especially in fasting or GTT patients.
- Stress importance of post-phlebotomy care.

Adulthood 36-65 Years Psychosocial Needs

- Generativity vs stagnation.
- Prepares for empty nest.
- Adapts to aging process.
- Older, wiser, and more likely to be at peace with society and self.
- Health problems may require prescription drugs.
- Interpersonal skills the same as the young adult.

Adulthood 36-65 Years – Fears/Safety

- Rarely fearful of the procedure.
- Stress post-phlebotomy site care **ESPECIALLY** for patients on anti-coagulant therapy.
- Site should always be checked before patient leaves.

Late Adult 65+ Years Psychosocial Needs

- Aging process continues.
- Reduced attention span and memory.
- Experiences anxiety over loss, isolation, and changes.
- Reflects on their life and comes to accept death.
- Due to loneliness may take more of your time.
- Challenges due to neurological and physical disabilities.

Exhibit 3-6. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Late Adult 65+ Years – Fears/Safety

- “Normal” older adults not a problem.
- Patients with physical or neurological problems can present very challenging problems.
- Ask for assistance if limbs must be manipulated or held still.
- Take GREAT care to select your equipment.
- Provide exceptional aftercare to prevent bruising.
- Adhesive bandages MAY NOT be appropriate for elderly patients with “paper thin” skin.

Summary

- Define the age specific categories.
- Create study materials based on your institution’s unique patient population.
- Define competencies.
- Conduct annual assessments, observation, written test, or combination.
- Develop remediation plan.
- Research and revise annually.

3.11 Hand Venipuncture

It is acceptable to use dorsal hand veins as the venipuncture site. This site should be used only if the antecubital veins are unsuitable, such as when the antecubital area is edematous, burned, or scarred, there are casts on both arms, or the veins are thrombosed.

- With **gloved hand**, select a vein that is palpable, by lightly brushing a finger across the back of the hand as it is palpated. This helps select the best vein and determines its direction. Palpate even when the vein is visible.
- Use a 21-gauge or 23-gauge butterfly blood collection set, depending on the condition of the SP’s veins.
- Follow the venipuncture technique described in Section 3.9.3 to draw the blood.

3.12 Veinlite EMS

Supplies

- Two AA alkaline batteries; and
- Disposable plastic covers.

The TransLite Veinlite EMS is a hand-held battery powered transillumination device for finding veins and assisting in vein access. It uses side-transillumination, which enables the VeinLite EMS to uniformly illuminate a small region of skin and subcutaneous tissue, anywhere on the body, without any areas of shadow.

- Place the Veinlite EMS inside the disposable plastic cover. Check the cover to make sure it is intact.
- Wipe the area of the plastic cover coming in contact with the SP with an alcohol prep pad.
- Turn off any overhead fluorescent lights as these may interfere with transillumination. Low power, nonfluorescent side lighting may be used.
- Visually locate the region of the skin you wish to examine for veins and then place the Veinlite EMS over it, with the LEDs facing down toward the skin (Exhibit 3-7).
- Apply gentle pressure to the Veinlite EMS to ensure it is in contact with the skin.
- Depress the orange button to switch on the LEDs.
- To access a vein while viewing with the Veinlite EMS, place the Veinlite EMS so the opening in the circle of the LEDs faces away from the heart. Apply gentle pressure on the Veinlite EMS to hold the vein. Pull back slightly on the Veinlite EMS to stretch the skin and provide a taut surface for the venipuncture (Exhibit 3-8).
- When suitable vein is located, continue with the phlebotomy procedure.
- Discard the disposable plastic cover after each SP, and switch off the Veinlite EMS when it is not in use.

Exhibit 3-7. Position of Veinlite EMS while looking for a vein



Exhibit 3-8. Position of Veinlite EMS while accessing a vein



Caution. Do not look at the LEDs when they are switched on or shine the light from the LEDs into anyone's eyes.

Cleaning. Wipe the device, after each use, with a Sani-Cloth or alcohol prep pad. Do not immerse the device in liquid.

3.13 Buzzy®

Supplies

- Two AAA alkaline batteries; and
- Disposable, plastic, infection control covers.

Buzzy uses natural “gate control” pain relief by confusing the body’s own nerves, thereby dulling or eliminating sharp pain. In the same way that rubbing a bumped elbow helps stop the hurt, Buzzy controls sharp pain. The premise is that when nerves receive non-painful signals such as vibration or cold, the brain closes the gate on pain signals.

Switch on to activate Buzzy®’s vibration, then place Buzzy® and ice wings proximal to the lab draw or IV area. Do not place directly on site of access. The rounded bottom end of Buzzy® should be 3-5cm above the site. Turn Buzzy® on and leave in place and vibrating throughout access.

Immediately prep area and perform the venipuncture as usual.

3.14 Recording the Results of the Venipuncture Procedure

The Venipuncture screen displays the tube protocol for the SP. The blood tubes are listed in the order they should be drawn.

Phlebotomy: Stand:617 Session:617022 01/23/2021 12:00 am - 12:30 pm
SP ID: 373531 Name: BROWN, HARRY Age: 15 years Gender: Male Date: 02/09/2021 Time: 10:25 AM

Venipuncture

4 ml lavender 0 of 3
7 ml lavender 0 of 1
2 ml gray 0 of 1
15 ml red 0 of 5

Obtained all
373531

Comment: []

Each SP’s profile is dependent on their age, appointment type, selection for inclusion into randomly selected subsamples, the session time, and the testing that is being performed for the subsample the SP is assigned to.

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.

SP ID: 627401 Name: ZHOU, BOB S Age: 37 years Gender: Male Date: 02/09/2021 Time: 11:50 AM

Venipuncture

4 ml lavender	<input type="text" value="3"/>	of 3	<input checked="" type="checkbox"/> Obtained all 627401
7 ml lavender	<input type="text" value="1"/>	of 1	
6 ml lavender	<input type="text" value="1"/>	of 1	
2 ml gray	<input type="text" value="1"/>	of 1	
15 ml red	<input type="text" value="3"/>	of 3	
7 ml gray	<input type="text" value="1"/>	of 1	
Comment: <input type="text"/>			

To record all tubes as filled or obtained, move the mouse to the “Obtained all” checkbox and 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, 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.

Venipuncture

4 ml lavender	<input type="text" value="0"/>	of 3	
7 ml lavender	<input type="text" value="0"/>	of 1	
6 ml lavender	<input type="text" value="1"/>	of 1	<input type="checkbox"/> Obtained all
2 ml gray	<input type="text" value="1"/>	of 1	627401
15 ml red	<input type="text" value="0"/>	of 3	
7 ml gray	<input type="text" value="0"/>	of 1	

Comment:

To record either “Alternative Protocol Used” or “SP in Supine Position” comments in the Comment text box, move the mouse to the arrow on the drop-down list, left-click, drag the mouse arrow to the desired choice, and left-click. Alternatively, type [A] for “Alternative Protocol Used” or [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, direct the mouse arrow to the bright blue arrow in the bottom-right corner and left-click, or press Enter when this blue arrow is highlighted.

To reprint the Dymo labels, move forward one screen and then back to the original screen using the navigation arrows. A Print Labels informational text box displays. It is also possible to reprint labels in the review mode.

To reprint the labels, direct the mouse arrow to the arrow on the “Yes” button, and left-click. To remove the Print Labels informational text box without reprinting the labels, direct the mouse arrow to the “No” button and left-click.

3.15 Venipuncture Status

Verify the venipuncture status.

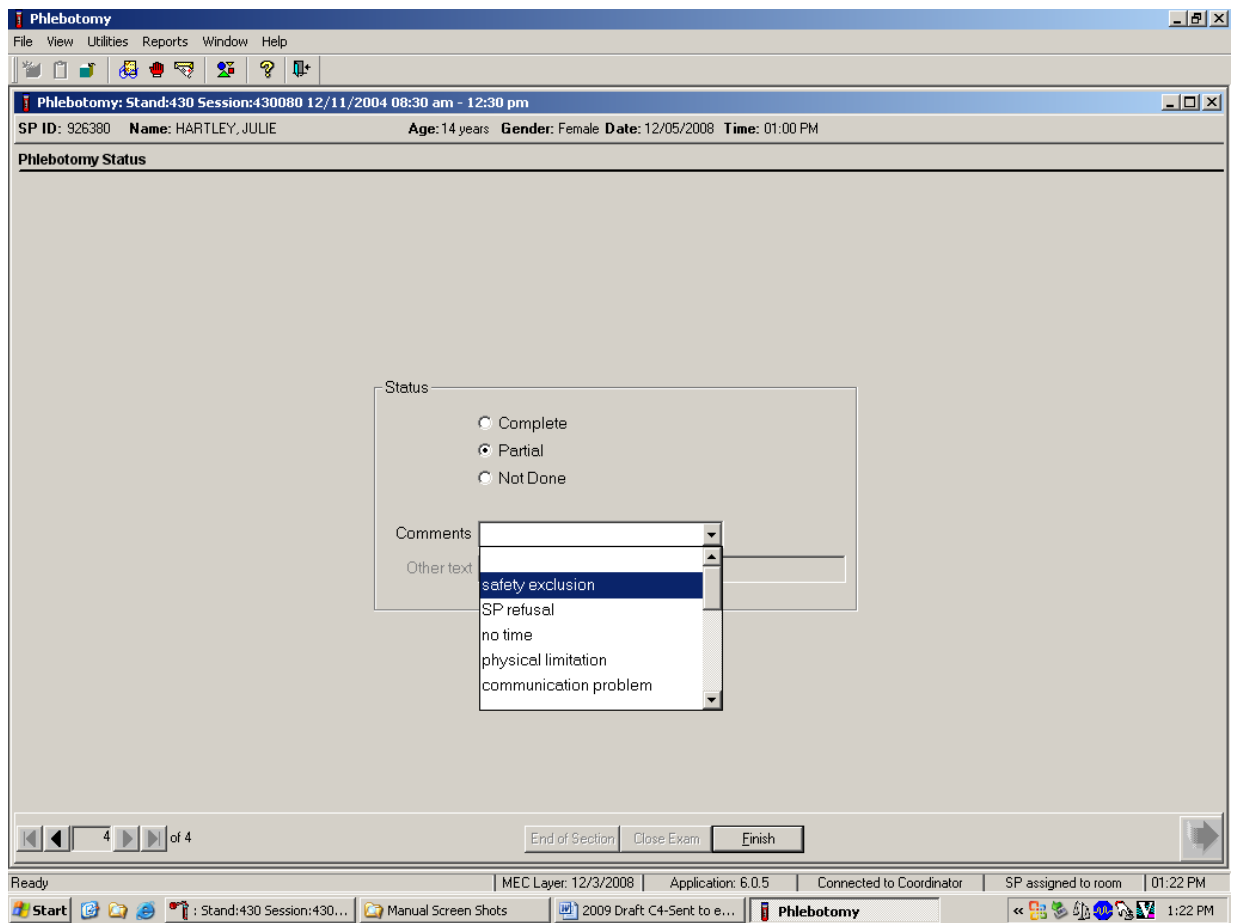
The screenshot shows the Phlebotomy software interface. The title bar reads "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title is "Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm". The patient information is displayed as "SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM". The "Phlebotomy Status" section contains a form with the following fields:

- Status: Complete, Partial, Not Done
- Comments:
- Other text:

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar shows "Ready", "MEC Layer: 12/3/2008", "Application: 6.0.5", "Connected to Coordinator", "SP assigned to room", and "01:21 PM". The taskbar at the bottom shows the Start button, several open applications, and the system clock at 1:21 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 Comments text box, 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.

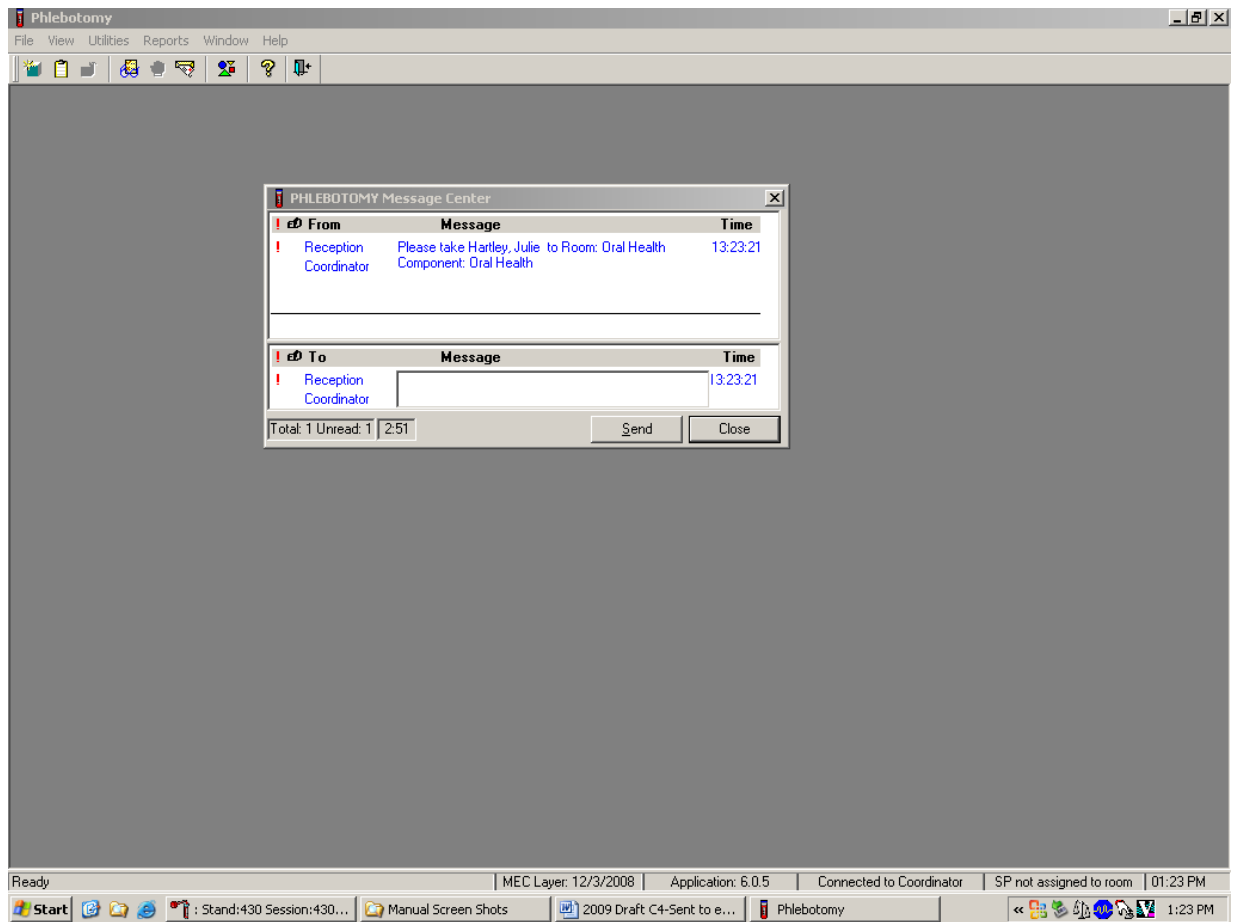
Exhibit 3-9 presents the comment codes for partial or not done venipuncture.

Exhibit 3-9. Comment codes for partial and not done venipunctures

Comment code	Use when
Safety exclusion	This is reserved for positive responses to the hemophilia and cancer chemotherapy exclusion questions and it is automatically coded by the application.
SP refusal	The SP refuses to have their blood collected. This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. All SPs will be sent to phlebotomy to have their arm band barcode scanned and coded. If the SP refuses after starting the blood draw, the phlebotomist codes the exam as a refusal. Use this comment to code partial exams when the SP refuses after one tube has been drawn, or the blood flow stops after one tube but before all tubes have been successfully drawn.
No time	Not applicable.
Physical limitation	Not applicable.
Communication problem	Not applicable.
Equipment failure	Not applicable.
SP ill/emergency	Not applicable.
Interrupted	Not applicable.
Error (technician/software/supply)	Use this comment to code Partial and Not Done exams when there are phlebotomist errors, or software or supply issues.
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.
No suitable vein	Use this comment to code exams as Not Done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, there is a rash over the entire area, or the blood draw was started but there was no blood in the tubing.
Vein collapsed	Use this comment to code exams as Partial when one or more tubes are successfully drawn but blood flow stops before all tubes are drawn or when the vein collapses.
SP not feeling well	Use this comment to code Not Done or Partial when the SP is about to faint or the SP became ill and the test could not be performed on the SP.
Fainting episode	Use this comment to code Not Done or Partial when the SP faints and the test could not be performed on the SP.
Language barrier	Use this if SP is unable to understand English and an interpreter is not available.

When finished, direct the mouse arrow to the bright blue arrow in the bottom-right corner and left-click to exit or press Enter when this blue arrow is highlighted.

Escort the SP to the location indicated in the Message Center text box.



Review the instructions in the Message Center text box and follow the directions.

3.16 Repeat Blood Draw

In rare circumstances, a result from the complete blood count may be an extreme value that would be considered a “panic” value in clinical practice. An example is severe thrombocytopenia. The clinician may repeat the complete blood count if the participant reports no history of nosebleeds or prolonged bleeding and the clinician verifies that the site of the first venipuncture clotted normally. The second complete blood count will overwrite the first results in ISIS and will be used for reporting and referrals.

Problem Identification

Rare occurrences of critical CBC results, particularly low platelet counts, have been observed that resulted in a medical referral for the clinicians on the MEC. While the clinical laboratory scientists and clinician may suspect laboratory instrument error or blood collection affecting reported results, it is not standard practice to repeat the test with a new blood specimen from a second phlebotomy. There is nothing in the phlebotomy, laboratory, and clinician protocols that requires a second blood draw on an SP when critical results are obtained. This is only done at the clinician's request.

Recommended Action

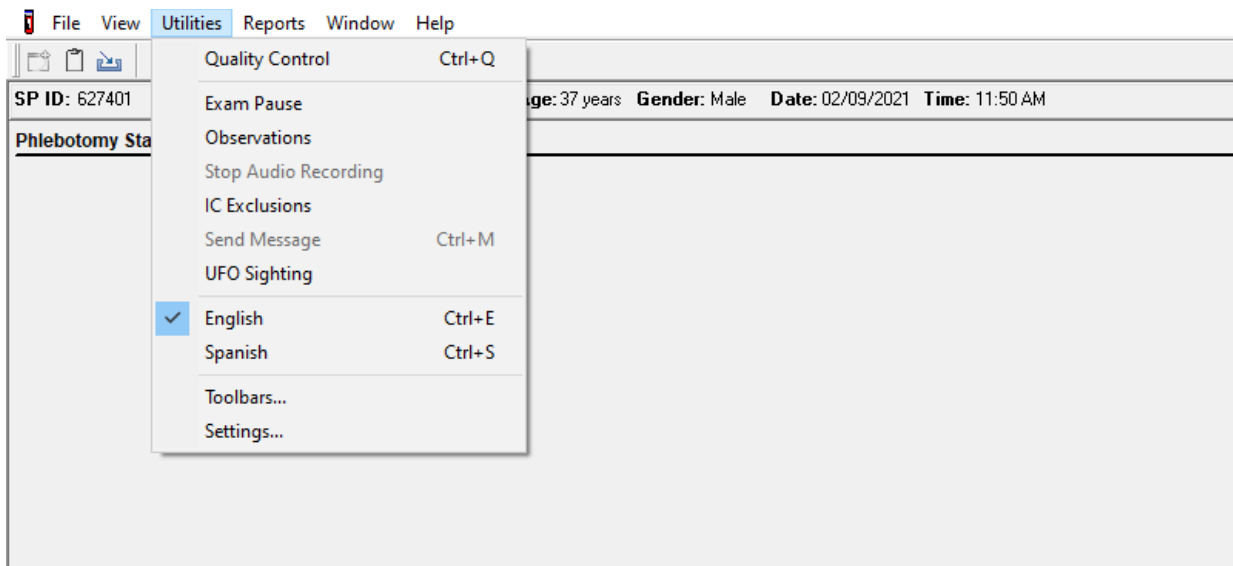
If the clinician feels a repeat blood count is needed, then they have the discretion to discuss this with the SP and have the phlebotomist draw a 3 mL EDTA tube for a repeat CBC if the SP agrees. Prior to a second phlebotomy, the clinician should visually inspect the site of the first venipuncture to rule out prolonged bleeding. If the puncture site looks normal, a second phlebotomy can be requested. The SP always has the right to refuse the blood draw.

After the clinician reviews the findings with the SP, and the SP agrees to a repeat CBC phlebotomy:

- The clinician should consult with the MEC manager, the phlebotomist, and chief clinical laboratory scientist to arrange to have the blood drawn at the next earliest opportunity.
- This additional blood draw will not be supported by the laboratory and phlebotomy applications.
- As long as the SP has not checked out of the MEC or if the Report of Findings has not been printed, the lab application will allow the clinical laboratory scientist to overwrite the existing CBC data with the new data and the new data will become the final result of record.
- The clinician will document this event under observations in the clinician application.

3.17 Phlebotomy Quality Control

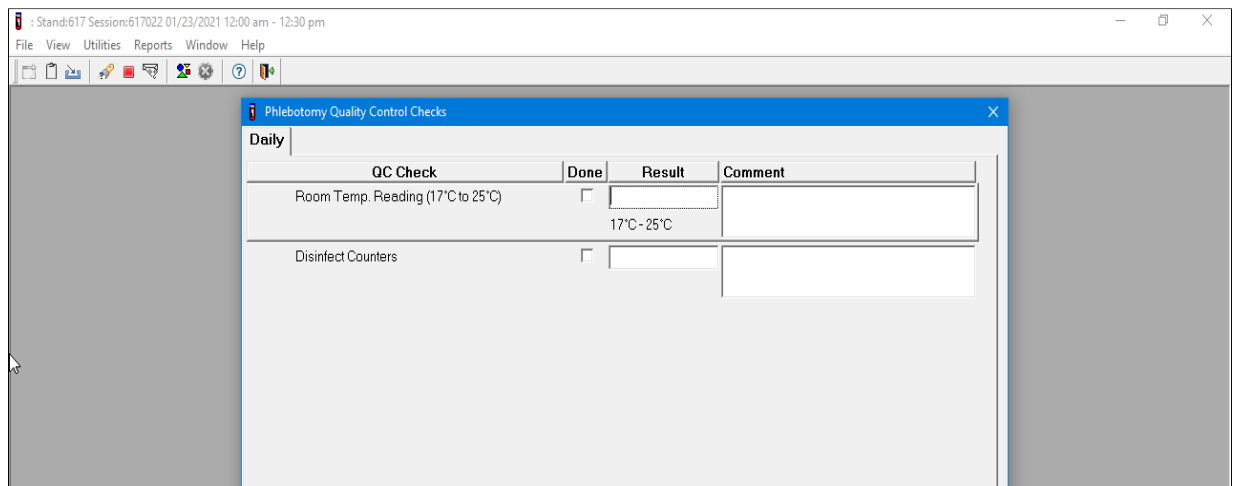
Perform phlebotomy quality control at the start of the first session block **even if there are no SPs scheduled in any of the session blocks**. Using the End of Session tab, record the room temperature reading and indicate that the counters were disinfected.



To access the phlebotomy Quality Control module, direct the mouse arrow to Utilities in the menu bar, left-click, drag the arrow to Quality Control, and left-click.

3.17.1 Daily Quality Control

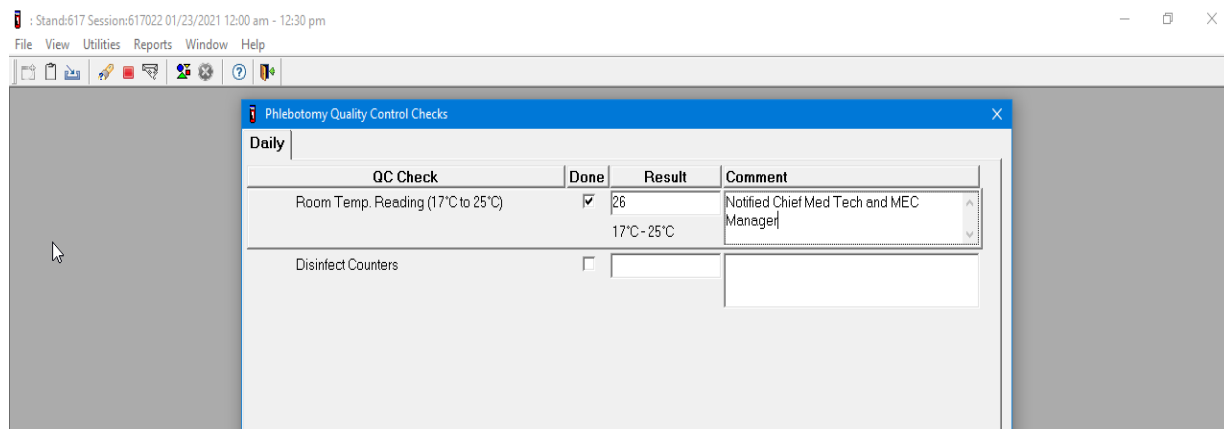
Record the daily quality control activities at the start of the first session. Mark each “Done” checkbox with a check mark. The comment section is left blank unless the temperature is out of the accepted range of 17-25°C. A comment must be entered in the comments field describing the issue and resolution of the issue.



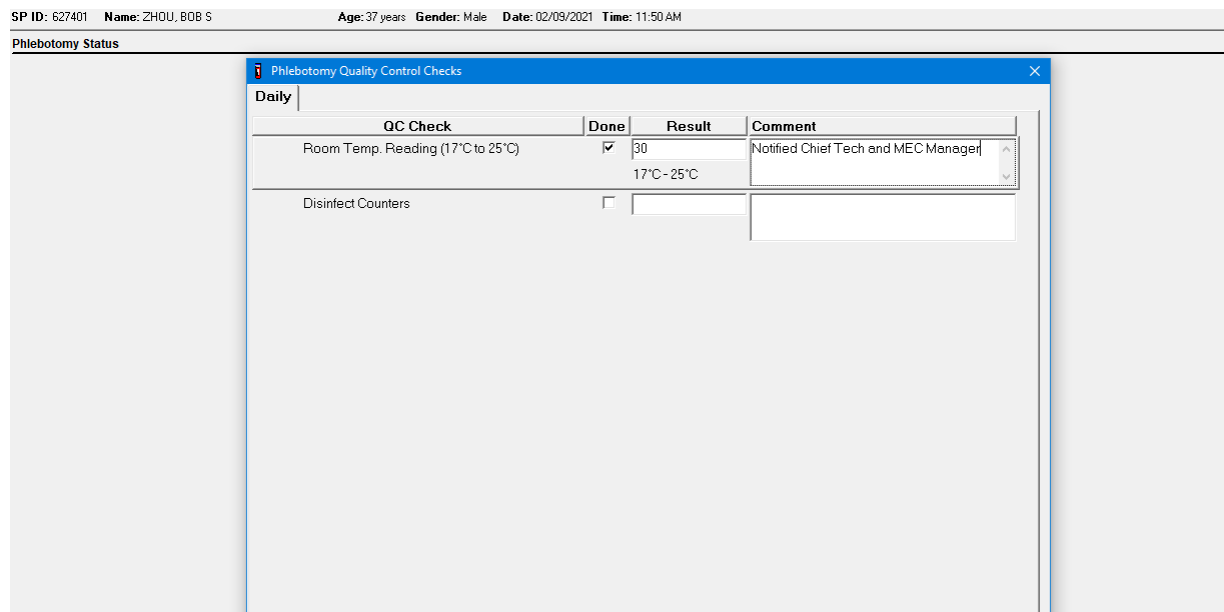
To record a check mark in the “Room Temp. Reading” checkbox, direct the mouse arrow to the checkbox in the Done column and left-click, and then press Tab to move to the Result text box.

Enter the temperature in the Result text box and press 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. Press Tab to move to the next Quality Control item.

Continue entering the Quality Control checks.



To record a check mark in the “Disinfect Counters” checkbox, direct the mouse arrow to the checkbox and left-click, and then press 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.



3.18 Red Cross Procedures for Handling Fainting (Syncope)

“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 their head at the level of their 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;
7. Possible disturbance of vision; and
8. Touching hand to face, neck, or head.

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.
- Elevate feet above the heart.
- Cool the back of the neck with a refrigerated ice pack.

Provide a disposable airsickness bag if the SP vomits, and either roll the SP onto their side or turn the SP's head to the side.

- Maintain an open airway.
- **Do not** pour water over the SP's face because of the danger of aspiration; instead, provide a cool wet cloth to the forehead.
- **Do not** give any liquid unless the SP has revived.
- Examine the SP to determine if they have suffered injury from falling.

- Seek medical assistance from the MEC clinician if symptoms are long lasting or extreme. Do not leave the SP. Call for assistance. Observe the SP carefully afterward because fainting might be a brief episode in the development of a serious underlying illness.¹ Make every effort to make the SP as comfortable as possible. Offer water, juice, and cookies, if necessary, despite the possibility of breaking the SP's fast early.

3.19 How to Deal with System Failure

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibits 3-10 and 3-11). Complete a Phlebotomy worksheet for each SP while conducting the exam. Enter the results after the system is operational.

Exhibit 3-10. Phlebotomy worksheet – English Primary

PESTICIDE USE QUESTIONNAIRE, PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, PROTOCOL PRIMARY SP, AND VOLATILE TOXICANT QUESTIONNAIRE

SP ID _____

Pesticide use questionnaire	Responses <u>Yes, No, Refused, Don't know</u>
Q1. In the past 7 days, were any chemical products used in {your/their} home to control fleas, roaches, ants, termites, or other insects?	
Q2. In the past 7 days, were any chemical products used in {your/their} lawn or garden to kill weeds?	
Phlebotomy interview	Responses <u>Yes, No, Refused, Don't know</u>
I am now going to ask you a few questions about your health to determine if you are eligible to have your blood drawn. I will also ask a series of questions to determine the last time you had anything to eat or drink.	
Are you currently pregnant? (Females aged 12-59, or 8-11 if menstruating)	
Do you have hemophilia?	
Have you received cancer chemotherapy in the past 4 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 or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda.	
Confirmation Question: Q2. Have you had any of the following since {insert time from Q1 here}?	Responses <u>Yes, No</u>
Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]	If Yes, record time and date

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 3-10. Phlebotomy worksheet – English Primary (continued)

Pesticide use questionnaire		Responses <u>Yes, No, Refused, Don't know</u> Pesticide use questionnaire	
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.]			
Primary SP protocol		# Filled	Not filled
3 mL lavender (1 age 1-2 and 2 age 3-5)			
4 mL lavender (1 age 6-11, and 2 age 40+ AM session blocks)			
6 mL royal blue (1 age 6+)			
6 mL lavender (1 age 12+ foreign born)			
2 mL gray (morning only 1 age 12+)			
7 mL red (1 age 1-2, 2 age 3-11, and 1 age 12+)			
15 mL red (3 age 12+)			
10 mL red (2 age 6-11)			
15 mL red (5 age 12+ if eligible for Persistent Pesticides, Perfluorinated, and BFR subsamples)			
7 mL gray (1 age 12+ if eligible for VOC subsample)			
Volatile toxicant questionnaire (If vessel 54 was collected)		Responses <u>Yes, No, Refused, Don't know</u>	
First, I would like to ask you a few questions about {your/SP's} home.			
Q1. Is the source of water for {your/their} home from a private well?			
Q2. {Do you/Do they} currently use moth balls, moth crystals or toilet bowl deodorizers inside {your/their} home?			
Q3. In the last three days, did {you/they} inhale smoke from any source for 10 or more minutes?			
Q4. When did {you/they} last spend 10 or more minutes inhaling smoke? (Responses: TODAY, YESTERDAY, MORE THAN 2 DAYS, REFUSED, DON'T KNOW)			
Now I am going to ask you a few questions about {your/SP's} activities over the last 48 hours. This means today or yesterday.			
Q5. In the last 48 hours, did {you/they} pump gas into a car or other motor vehicle {yourself/themself}?			
Q6. How long ago, in hours, did {you/they} pump gas into a car or other motor vehicle {yourself/themself}? (Response: 1-48 hours)			
Q7. In the last 48 hours, did {you/they} use dry cleaning solvents, visit a dry cleaning shop, or wear clothes that had been dry cleaned within the last week?			
Q8. How long ago, in hours, has it been since {you/they} used dry cleaning solvents, visited a dry cleaning shop, or wore clothes that had been dry cleaned within the last week?			
Q9. In the last 48 hours, did {you/they} take a hot shower or bath for 5 minutes or longer?			
Q10. How long ago, in hours, has it been since {your/SP's} last shower or hot bath? (Response: 1-48 hours)			
Q11. In the last 48 hours, did {you/they} breathe fumes from freshly painted indoor surfaces, paints, paint thinner, or varnish?			
Q12. How long ago, in hours, has it been since {you/they} breathed fumes from freshly painted indoor surfaces, paints, paint thinner, or varnish? (Response: 1-48 hours)			
Comments:			

Exhibit 3-11. Phlebotomy worksheet – Spanish Primary

PESTICIDE USE QUESTIONNAIRE, PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, PROTOCOL PRIMARY SP, AND VOLATILE TOXICANT QUESTIONNAIRE

SP ID _____

Pesticide use questionnaire		Responses Yes, No, Refused, Don't know	
Q1. En los últimos 7 días, ¿se usó algún producto químico en {su hogar/el hogar de {él(M)/ella(F)} para controlar las pulgas, cucarachas, hormigas, termitas u otros insectos?			
Q2. En los últimos 7 días, ¿se usó algún producto químico en {su jardín o césped/el jardín o césped de {él(M)/ella(F)} para matar las malas hierbas/la maleza?			
Phlebotomy interview		Responses Yes, No, Refused, Don't know	
¿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 tomó alguna cosa aparte de agua sola? No incluya soda de dieta o café o té solo endulzado con endulzadoras artificiales como Sweet'N Low, NutraSweet, Equal o Splenda.			
Confirmation Question:		Responses	If Yes, record time and date
Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}?		Yes, No	
¿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		# Filled	Not filled
3 mL lavender (1 age 1-2 and 2 age 3-5)			
7 mL lavender (1 age 6+)			
5 mL lavender (1 age 12+)			
2 mL gray (morning only 1 age 12+)			
7 mL royal blue tops (1 age 6+)			
3 mL red (2 age 1-2)			
7 mL red (2 age 3-5, 1 age 6+)			
15 mL red (2 age 12+)			
10 mL red (1 age 6-11)			
15 mL red (3 age 12+ if eligible for Persistent Pesticides, Perfluorinated, and BFR subsamples)			
7 mL gray (1 age 12+ if eligible for VOC subsample)			

Exhibit 3-11. Phlebotomy worksheet – Spanish Primary (continued)

Volatile toxicant questionnaire (If vessel 54 was collected)	Responses Yes, No, Refused, Don't know
Q1. ¿Es la fuente de agua para {su hogar/el hogar de él/ella} de un pozo privado?	
Q2. Actualmente, ¿usa {usted/él/ella} bolas o cristales de naftalina para las polillas o desodorante para la taza del (inodoro/excusado/wáter) dentro de su hogar? Algunos desodorantes para el (inodoro/excusado/wáter) se cuelgan en la orilla de la taza, otros, como desodorantes en barras y gelatinas, se ponen en el tanque o se cuelgan dentro de la pared del tanque. Algunas marcas conocidas son Bully, 2000 Flushes, Vanish, X-14, Ty-D-Bol, Toilet Duck, Clorox, Lime-A-Way, y Sno Bol.	
Q3. En los últimos tres días, ¿respiró {usted/ella/él} cualquier tipo de humo por 10 o más minutos? El humo que se respira incluye humo de fogatas, chimeneas, marihuana y productos de tabaco como cigarrillos, puros y pipas.	
Q4. ¿Cuándo fue la última vez que {usted/ella/él} respiró humo por 10 o más minutos??	
Q5. Ahora le voy a hacer algunas preguntas acerca de las actividades que {usted/SP} hizo en las últimas 48 horas, es decir hoy o ayer.	
Q6. En las últimas 48 horas, ¿le echó gasolina {usted mismo/él mismo (MPR)/ella misma (FPR)} a un carro u otro vehículo de motor?	
Q7. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} {mismo/mismo/misma} le echó gasolina a un carro o a otro vehículo de motor?	
Q8. En las últimas 48 horas, ¿usó usted disolventes para lavado en seco, visitó {usted/él/ella} una (limpiaduría/tintorería/lavandería) de lavado en seco o usó ropa que había sido lavada en seco dentro de la última semana?	
Q9. ¿Cuánto tiempo hace, en horas, que {usted/ella/él} usó disolventes para lavado en seco, visitó una (limpiaduría/tintorería/lavandería) de lavado en seco o usó ropa que había sido lavada en seco dentro de la última semana?	
Q10. ¿Hace cuánto tiempo, en horas, fue que se duchó o se dio un baño caliente {usted/SP}?	
Q11. En las últimas 48 horas, ¿aspiró {usted/él/ella} gases de lugares interiores recién pintados, de pinturas, de disolvente de pintura o de barniz?	
Q12. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} aspiró los gases de lugares interiores recién pintados, de pinturas, de disolvente de pintura o de barniz? (Response: 1-48hours)	
Comments:	

The following four screenshots document the English text and official Spanish translations for the phlebotomy component:

- Phlebotomy Interview – English,
- Phlebotomy Interview – Spanish,
- Fasting Questionnaire – English, and
- Fasting Questionnaire – Spanish.

Phlebotomy Interview – English

Phlebotomy Interview

Are you currently pregnant? No

Do you have hemophilia? No

Have you received cancer chemotherapy in the past four weeks? No

Phlebotomy Interview – Spanish

Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 312716 Name: HAMILTON, BARBARA Age: 48 years Gender: Female Date: 12/09/2008 Time: 12:58 PM

Phlebotomy Interview

¿Está usted actualmente embarazada? No

¿Tiene hemofilia? No

¿Ha recibido tratamiento de quimioterapia para el cáncer en las cuatro semanas pasadas? No

Fasting Questionnaire – English

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 306325 Name: KAIGA, NEWTON Age: 13 years Gender: Male Date: 12/09/2008 Time: 12:54 PM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 09:30 PM 12/08/2008

Have you had any of the following since yesterday at 9:30 PM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] No : //

Alcohol, such as beer, wine, or liquor? No : //

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? No : //

Antacids, laxatives, or anti-diarrheals? No : //

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] No : //

Fasting 15 Hours 26 Minutes

Fasting Questionnaire – Spanish

Phlebotomy
File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm

SP ID: 306325 Name: KAIGA, NEWTON Age: 13 years Gender: Male Date: 12/09/2008 Time: 12:54 PM

Fasting Questionnaire

¿Cuándo fue la última vez que comió o tomó alguna cosa aparte de agua sola? No incluya soda de dieta o café o té solo endulzado con endulzadores artificiales como Sweet'N Low, NutraSweet, Equal o Splenda. 09:30 PM 12/08/2008

Ha tomado o comido algo de lo siguiente ¿desde ayer a las 9:30 de la tarde?

¿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? No : //

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

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

Fasting 15 Hours 27 Minutes

End of Section Close Exam Finish

References

Kirven, D.R. (2003). Age-specific techniques in phlebotomy competency. *Advance for Medical Laboratory Professionals*, 14(6):11-17. Retrieved from https://www.cdc.gov/nchs/data/nhanes/nhanes_13_14/2013_MEC_Laboratory_Procedures_Manual.pdf.

University of Texas Medical Branch (UTMB), Clinical Pathology Services. (2009). *Phlebotomy Age Specific Competencies* [training document]. Galveston, Texas: Author. Retrieved from http://www.utmb.edu/pcs/images/pcsvcs_137741.pdf.

4. Urine Specimen Collection and Processing

4.1 Introduction

The purpose of urine collection and processing is to collect sufficient urine from participants aged 3 years and older to be able to (1) perform a pregnancy test on selected females aged 8 to 11 years and all females aged 12 to 59 years to exclude pregnant participants from other components that could put the participant at risk; (2) aliquot urine into vessels for storage and transport to multiple government and contract laboratories for analysis; and (3) aliquot urine into a vessel for future studies.

Collect a urine specimen from all study participants (SPs) aged 3 years and older. The volume of urine required to complete each SP's protocol is displayed in the Urine Collection module. Place the urine container on the Mettler Toledo scale and then scan the barcode on the label. The weight is converted to volume and transmitted to the Urine Collection module in the Integrated Survey Information System (ISIS). Visually compare the volume in the urine container to the volume displayed in the Urine Collection screen. Accept the weight. Perform the pregnancy test if indicated, process the urine according to protocol, and store the vessels.

The mobile examination center (MEC) coordinator instructs each SP aged 6 years and older to provide a urine sample as soon as possible when they enter the MEC. Ideally, this sample would be collected at the same time that the SP changes into the exam outfit. If the SP cannot provide a urine sample at that time, the coordinator offers the SP a glass of water and asks the SP to provide a sample as soon as possible. The SP is instructed to collect a complete void by emptying the bladder into the urine collection cup. The coordinator, assistant coordinator, or any MEC staff member is responsible for transporting the urine specimen to the laboratory.

MEC staff explain the following instructions to the SP before urine collection:

- Wash your hands with soap and water.
- Take the cap off the cup.
- Urinate directly into the cup until it is full or until you have finished urinating.
- **DO NOT OVERFILL THE CUP.**

- The inside of the cup and cap should not touch or come into contact with any part of your body, clothing, or external surfaces.
- Recap the collection cup and seal tightly.
- Place the filled urine cup on the top of the toilet tank lid.
- Please remember to wash your hands.

The MEC health technologists, clinician, or MEC managers will introduce urine collection for 3- to 5-year-olds to the parent or guardian, who will help the child collect the urine. Detailed instruction will be provided by the MEC staff, who will also transport the specimen to the laboratory.

- The MEC staff will prep the toilet for the 3- to 5-year-olds.
- The MEC staff will place the urine collection container on the toilet's porcelain rim and lower the toilet seat for the SP.
- The MEC staff will explain not to touch the inside of the container, not to put toilet paper inside the collection container, and to have the parent/guardian hold the child over the collection container.
- The MEC staff will also instruct the parent/guardian to gently place the lid on the container and leave it on the toilet when they are finished.
- The MEC staff will transport the specimen to the laboratory.

If an elderly SP, disabled person, or obese female wishes to use the same collection container that is used for the 3- to 5-year-olds in place of the urine cup, the request will be accommodated along with the appropriate instruction for its use. An adjustment for the container tare weight will need to be made at the time the urine volume is recorded.

4.2 Equipment and Supplies

For a list of the equipment and supplies needed for urine collection, urine processing, and storage see Exhibits 4-1 and 4-2 below.

Exhibit 4-1. Urine collection equipment

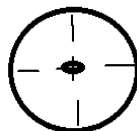
Blue scale carrying case	Mettler Toledo PL602E Scale Cone protector Weigh pan One Troemner 100-g weight (start of stand QC) Two Troemner 300-g weights (start of stand QC)
Care Pac M	Cleaning cloth Two gloves Weight transfer tool for 500-g weight Weight transfer forceps for 20-g weight Cleaning brush One Ohaus 500-g weight (daily QC) One Ohaus 20-g weight (daily QC)
Clear acrylic scale cover	
Barcode scanner	

Exhibit 4-2. Urine collection supplies – urine processing and storage

2-ml cryovial sterile	Cardboard box, 2.0-inch with 9 x 9 grid
5-ml cryovial sterile; Five-O screwcap	Cardboard box, 5.25" x 5.25" with foam insert
5-ml cryovial sterile	Cardboard box, 3.0-inch with 9 x 9 grid
10-mL Vial CryoPro VWR screwcap – WITH ADDITIVE (Urine/Mercury)	Cardboard box, 3.0-inch with 5 x 5 grid – White
3.5-ml Starstedt Transfer pipette	Cube rack – 4-way flipper rack
Bench Kote paper	Kimwipes Nonsterile, powder-free, gloves—small, medium, large Sani-Cloth Plus

4.3 Using the Scale for Urine Collection

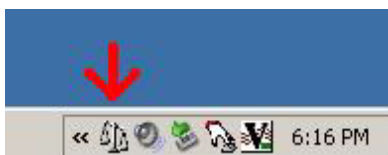
The Mettler Toledo scale is located in the clean laboratory area near workstation 3. Check to make sure the scale’s weighing pan is free of any objects or debris. Turn on the Mettler Toledo scale by pressing the “On” button. After the display briefly lights up all segments, the LED will display “0.0 g.” This indicates that the scale is ready to weigh samples. The scale should be used only when set to measure in grams. Cover the scale with the clear acrylic scale cover until a sample is available for weighing. The scale must be leveled before using it for reporting results and performing QC. The leveling bubble is located in the right rear corner of the scale. The bubble must be leveled so that it sits in the center of the window. See diagram below.



Ensure that computer workstation 3 (Urine/Sink) is turned on and a technician is logged in to the Laboratory application. Open the Urine Scale application by double-clicking on the Urine Scale icon on the desktop. The Urine Scale icon looks like this:



The Urine Scale application icon will appear in the system tray, similar to the Coulter application. This application captures data from the scale and logs it into the database. The Urine Scale application must be opened and in the system tray to capture any urine collection readings from the scale.



If the LED reads “MT Green,” the scale is in sleep mode. Touching the scale pan, placing a urine container on the scale pan, or clicking on the scale icon will bring the scale to a ready state.

To obtain accurate weighing results, the balance must be calibrated to match the gravitational acceleration at its location. Calibration is necessary before the balance is used for the first time and at the start of each stand. The balance should be on for 60 minutes before calibrating. To calibrate the balance, press and hold the <<cal>> key down until “CAL” appears in the display. Release the key. The required calibration weight will flash in the display. Place the required calibration weight in the center of the pan. The balance will automatically calibrate and “0.00 g” will flash, indicating that the weight can be removed. The calibration is completed when “CAL done” appears in the display. When the balance is back in weighing mode and ready for operation, “0.00” will display.

If the urine collection cup appears to contain < 1 ml, do NOT weigh the cup; see Section 4.5.1.

Place the urine collection cup on the Mettler Toledo scale. Cover the scale with the clear box cover to protect the scale from draft. Look at the scale’s LED display. In the bottom left corner of the

display, the stability detector “o” will appear briefly. Once the stability indicator goes away, the weight result is valid. Scan the barcode on the cup using the barcode scanner next to the scale.



Look at the scale’s LED screen to ensure that the SP ID displays. Checking for the SP ID display on the LED screen is verification that the collection was recorded in the database.

Note: The LED display does not show the first digit of the SP ID.

4.4 Document Urine Collection

Once a urine sample has been scanned in, the urine collection (UC) circle on the heads-up screen for that SP will turn either to a solid blue ●, to indicate that the quantity is sufficient, or to a blue bullseye ⊙, for quantity not sufficient (QNS).

For SPs aged 6 years or older, the label on the urine container reads CC1, which indicates collection cup 1 or the 500-ml cup. For SPs aged 3-5 years, the label on the urine container will read CC2, which indicates collection cup 2.



Verification of Urine Collection

To verify a urine sample, locate the correct SP ID and Name on the Lab Subsystem display; the row will have a blue UC circle. The blue color indicates that there is a urine sample in the laboratory ready to be verified by the laboratory technician.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
214268	214268	SC	P	M	11	PERSAUD, JUSTIN 2	○	○	-	○	○	○	-	-
290160	290160	BE	P	F	16	HOYA, MARY	●	○	●	○	○	○	-	-
483445	483445	BE	P	M	15	HOYA, SON J	●	○	-	○	○	○	-	-
491168	491168	BE	P	F	40	HOYA, JANE	○	○	○	○	○	○	-	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	○	○	○	○	○	○	-	-
711860	711860	SC	P	M	45	HOYA, JOHN A	○	○	-	○	○	○	-	-
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	○	○	-	○	○	○	-	-
913751	913751	SC	P	F	9	JONES, MICAYLA 2	○	○	○	○	○	○	-	-

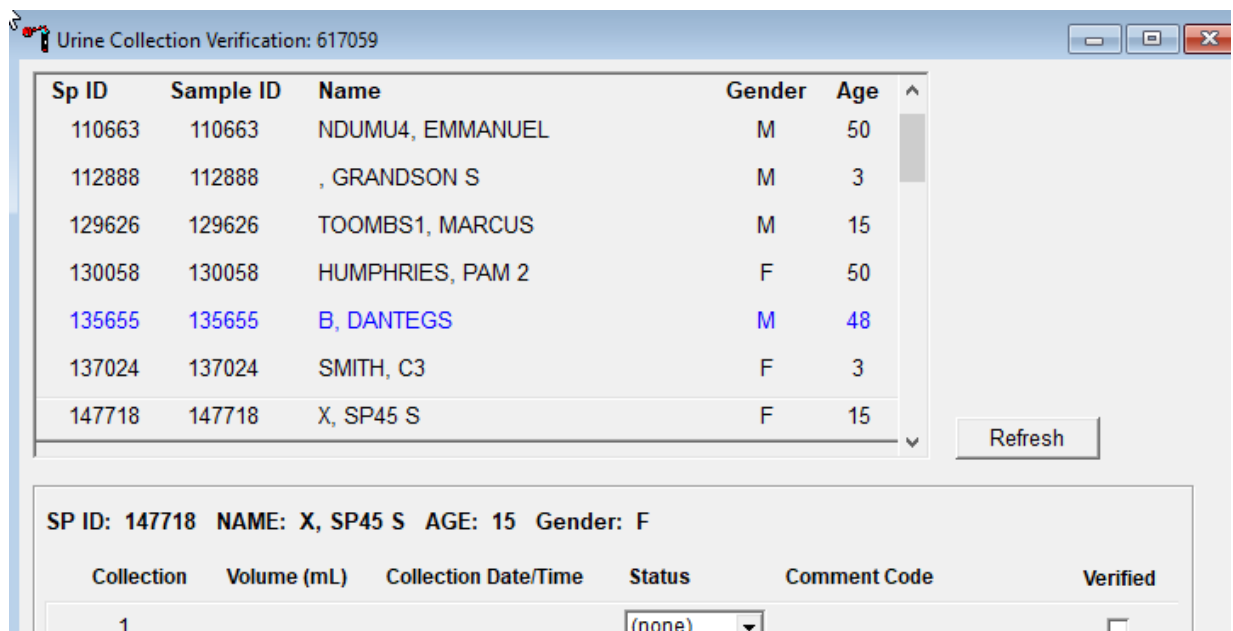
1. Select an SP with a blue UC circle and access the Urine Collection module. Right-click on the blue circle under the UC column on the heads-up screen to access the Urine Collection module.
2. Left-click on “Urine Collection” on the module pop-up menu. The Urine Collection Verification screen will open.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
214268	214268	SC	P	M	11	PERSAUD, JUSTIN 2	○	○	-	○	○	○	-	-
290160	290160	BE	P	F	16	HOYA, MARY	●	○	●	○	○	○	-	-
483445	483445	BE	P	M	15	HOYA, SON J	●	○	-	○	○	○	-	-
491168	491168	BE	P	F	40	HOYA, JANE	○	○	○	○	○	○	-	-
645451	645451	SC	P	F	10	PERSAUD, MICAYLA 1	○	○	○	○	○	○	-	-
711860	711860	SC	P	M	45	HOYA, JOHN A	○	○	-	○	○	○	-	-
781732	781732	BE	P	M	12	PERSAUD, JUSTIN 1	○	○	-	○	○	○	-	-
913751	913751	SC	P	F	9	JONES, MICAYLA 2	○	○	○	○	○	○	-	-

- Urine Processing
- Blood Processing
- Packed Cell Processing
- Female HPV Processing
- Male HPV Processing
- Urine Collection
- Pregnancy Testing
- Hematology >
- Refresh

The urine collection verification window displays an upper and lower section. The top of the urine collection window contains:

- Columns for the SP ID, person name (last, first), gender, and age;
 - Rows for checked-in SPs are indicated (in black);
 - SPs who have not checked into the MEC session (in gray); and
 - SPs who have a urine collection ready for verification display (in blue).
3. Use the scroll bar to view all SPs scheduled into the session.



4. Left-click on the row for the SP ID (blue text) to be verified. The lower half of the screen displays the following information:
- A. Collection attempt;
 - B. Volume (whole mL);
 - C. Collection date and time;
 - D. Status of the urine;
 - E. Comment code;
 - F. Verification check box; and
 - G. Total collected amount (sum in mL of all urine collections).

If the SP has submitted a urine collection that has been weighed and scanned into the database, the volume, collection status, and collection date and time will automatically display in the lower portion of the Urine Collection screen. If the collection did not meet the minimum requirement for the protocol, the system will automatically select “QNS” with the comment code “quantity not sufficient.” A QNS result immediately notifies the coordinator to prompt for an additional urine collection. A second instance of urine collection for the first QNS sample or a third instance of urine collection for the second QNS sample will appear below the current sample for SPs aged 6 years or older. For SPs aged 3-5 years, if the first instance of urine collection is QNS, a second instance will appear. If the quantity of urine collection does meet the requirement of the urine protocol, the system will automatically select “Yes” and no additional collections will appear.

Evaluate the quantity of urine received in the laboratory.

Sp ID	Sample ID	Name	Gender	Age
110663	110663	NDUMU4, EMMANUEL	M	50
112888	112888	, GRANDSON S	M	3
129626	129626	TOOMBS1, MARCUS	M	15
130058	130058	HUMPHRIES, PAM 2	F	50
135655	135655	B, DANTEGS	M	48
137024	137024	SMITH, C3	F	3
147718	147718	X, SP45 S	F	15

SP ID: 147718 NAME: X, SP45 S AGE: 15 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	15	03/10/2021 10:00 AM	QNS	quantity not sufficient	<input type="checkbox"/>
2			(none)		<input type="checkbox"/>

Total Collected: 15
Total Required: 27

The Application Estimates that 1 g of Urine is Equal to 1 mL of Urine and Records the Weight of the Urine in Whole Numbers Following Standard Rounding Procedures. The application will automatically assign the comment code “quantity not sufficient” (QNS) for all urine collections that are calculated to be QNS. The application uses the total collected volume and compares it to the total required volume to determine the QNS status. The laboratory technologist may also manually assign a QNS status to all samples that are deemed QNS during the verification process.

A QNS result automatically turns the laboratory progress bar yellow on the Coordinator screen. This yellow progress bar alerts the coordinator, who then asks SPs aged 6 years or older to provide an additional urine specimen and asks the parent/guardian of the 3- to 5-year-olds if the child could drink additional water or juice so that another urine collection attempt might be possible before the participant leaves the MEC.

4.4.1 Quantity Not Sufficient (QNS) Urines

When there is a delay in processing urine due to a QNS status, place the sample in the refrigerator so it can be pooled and processed with any additional urine from the SP.

If the SP has voided <1.0 ml, the laboratory will ask the coordinator for a re-collection of Urine Collection (UC) 1. Do not record any results for this urine instance. Manually enter the urine weight as described below. Discard this sample and wait for a new UC 1. An exception is when a female SP requiring a pregnancy test provides <1 ml. In this instance the SP’s UC1 must be entered manually.

- On the urine collection screen:
 - The lowest volume that can be entered in the urine collection screen is 1 mL, so the urine weight will be left blank.
 - Enter the collection date and time.
 - Select “QNS” as the status and select the comment, “<1 mL of Urine.”
 - Click the verify button.

In a situation where there is a pregnancy test needed, the first collection, although less than 1 mL, will be counted as a collection because the pregnancy test needs to be performed and the collection

needs to be recorded in the urine collection module to perform the pregnancy test. Enter the urine weight and collection date and time as described above. The next urine collection in this instance will be UC2.

When additional urine is obtained or collected and it is enough to fill the SP's profile, pool the urine into the most recently collected cup (the cup with the highest urine collection instance number on the cup label), mix, 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. If the second urine sample is a full cup, mix equal parts of the first and second collections to fill the vessels in the profile.

Urine Collection Verification: 617059

Sp ID	Sample ID	Name	Gender	Age
110663	110663	NDUMU4, EMMANUEL	M	50
112888	112888	, GRANDSON S	M	3
129626	129626	TOOMBS1, MARCUS	M	15
130058	130058	HUMPHRIES, PAM 2	F	50
135655	135655	B, DANTEGS	M	48
137024	137024	SMITH, C3	F	3
147718	147718	X, SP45 S	F	15

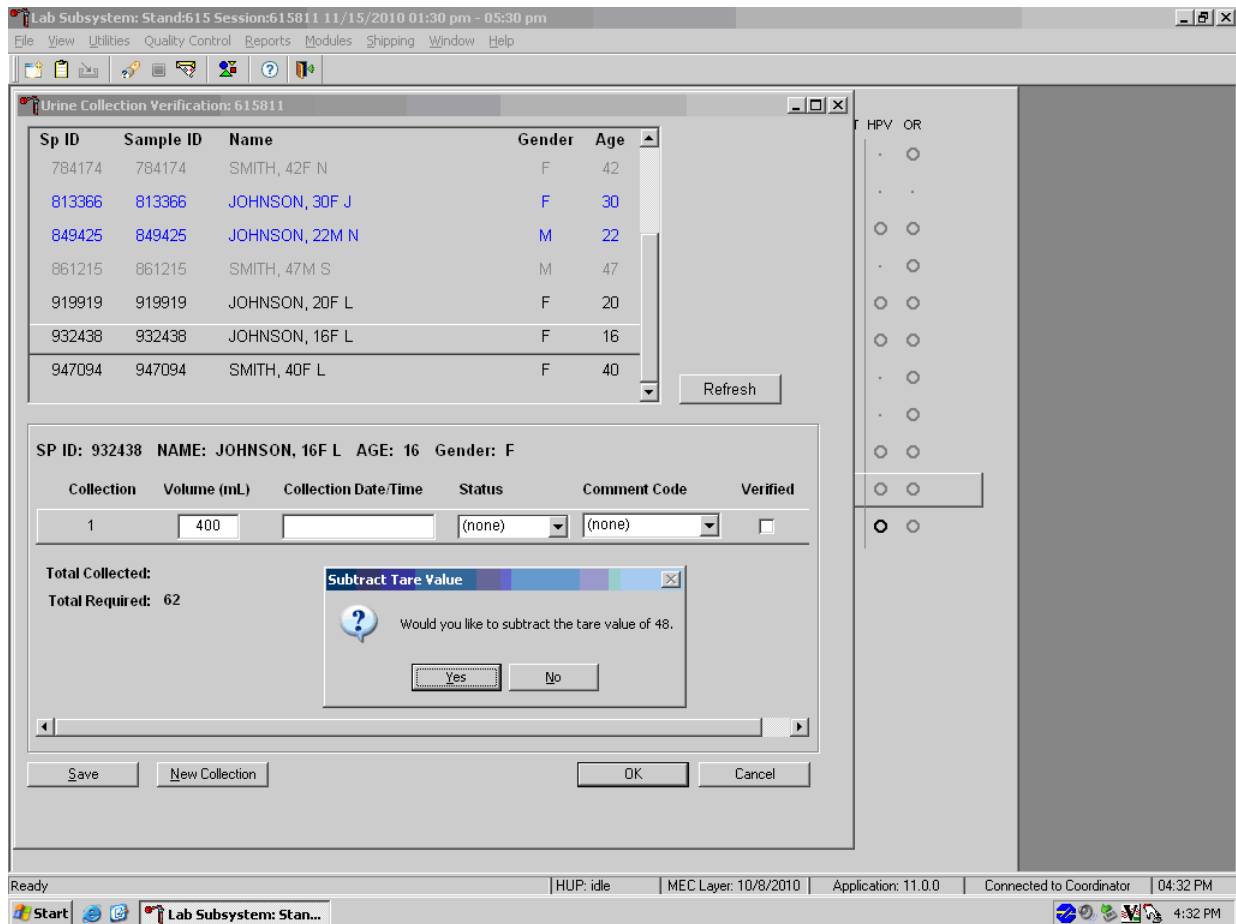
Refresh

SP ID: 147718 NAME: X, SP45 S AGE: 15 Gender: F

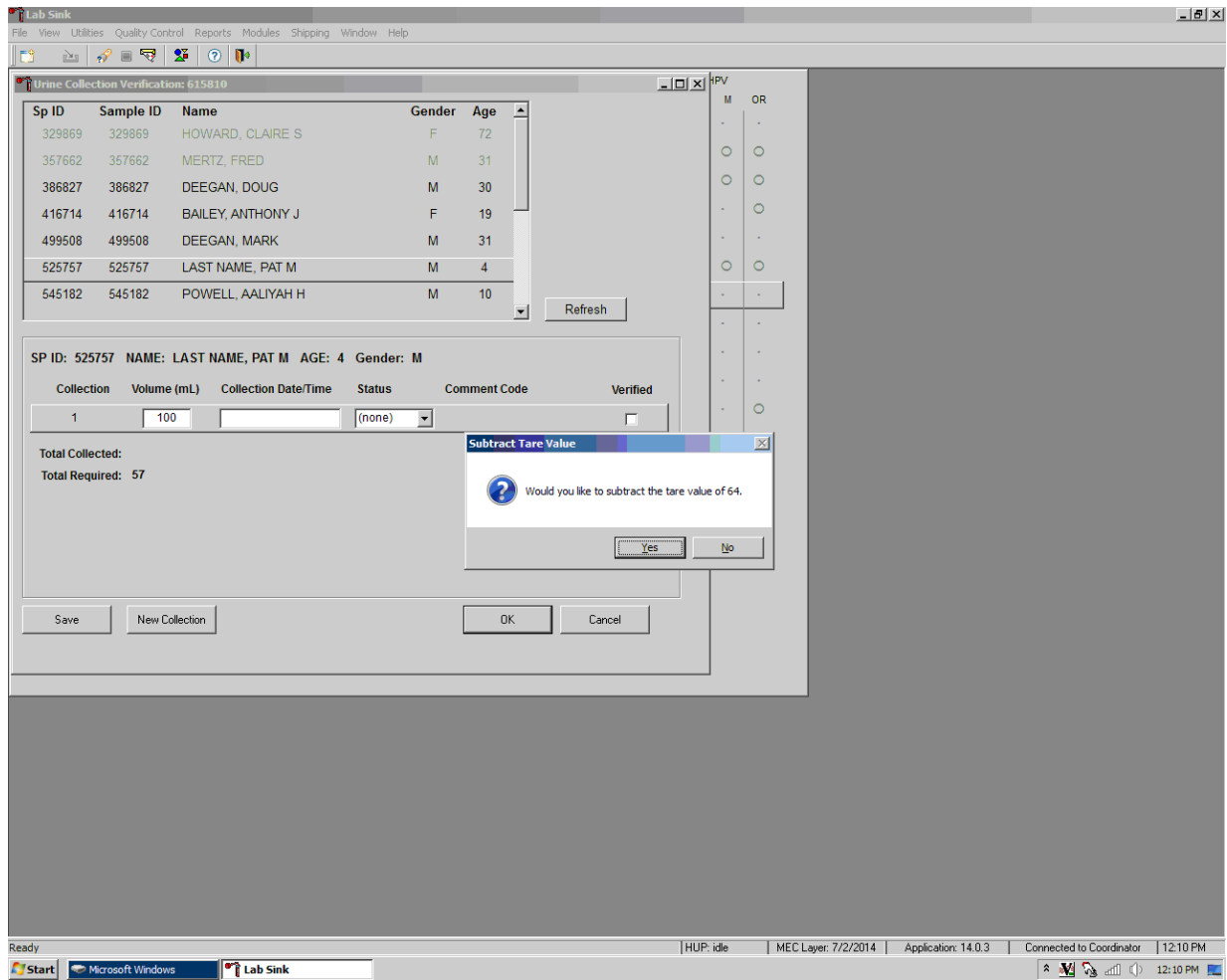
Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	15	03/10/2021 10:00 AM	QNS	quantity not sufficient	<input type="checkbox"/>
2			(none)	quantity not sufficient	<input type="checkbox"/>

Total Collected: 15
Total Required: 27

Save New Collection OK Cancel



For SPs 6 years or older, press the Tab key to move to the Collection Date/Time field. The application will ask “Would you like to subtract the tare value of?” Select Yes. Enter the date and time of the specimen collection. The tare weight for empty collection containers for 3- to 5-year-old SPs is 64.



Press the Tab key to continue on to the Status field. Record urine collections that exceed the scale as “Yes.” To mark the urine collection status, direct the mouse arrow to the drop-down list, click to display the different status, and select Yes by clicking once on Yes with the mouse arrow. Use the Tab key to proceed on to the Comment Code field.

Urine Collection Verification: 430420

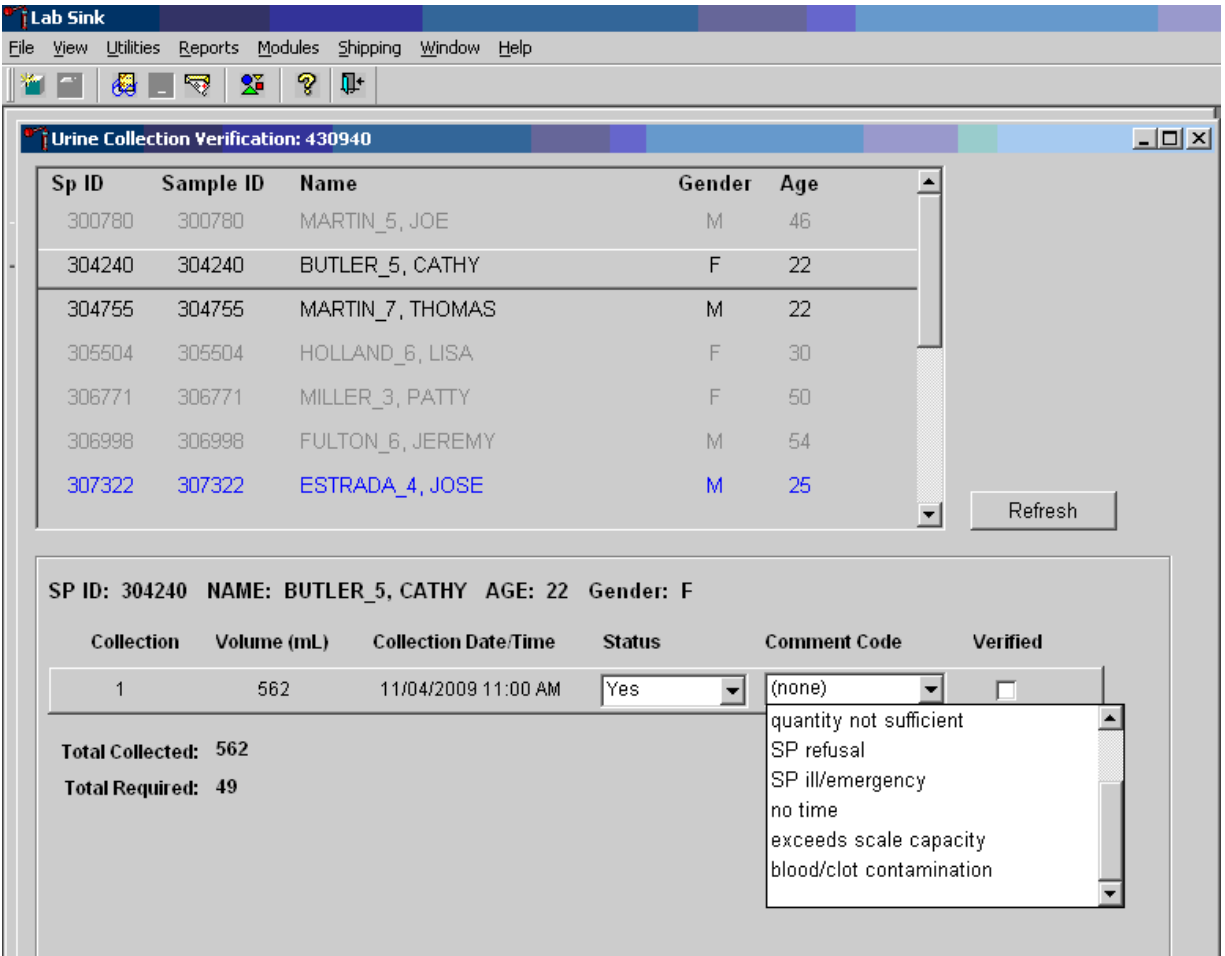
Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 220901 NAME: RUSSELL_2, JACK AGE: 25 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	556	12/19/2008 03:30 PM	Yes	(none)	<input type="checkbox"/>

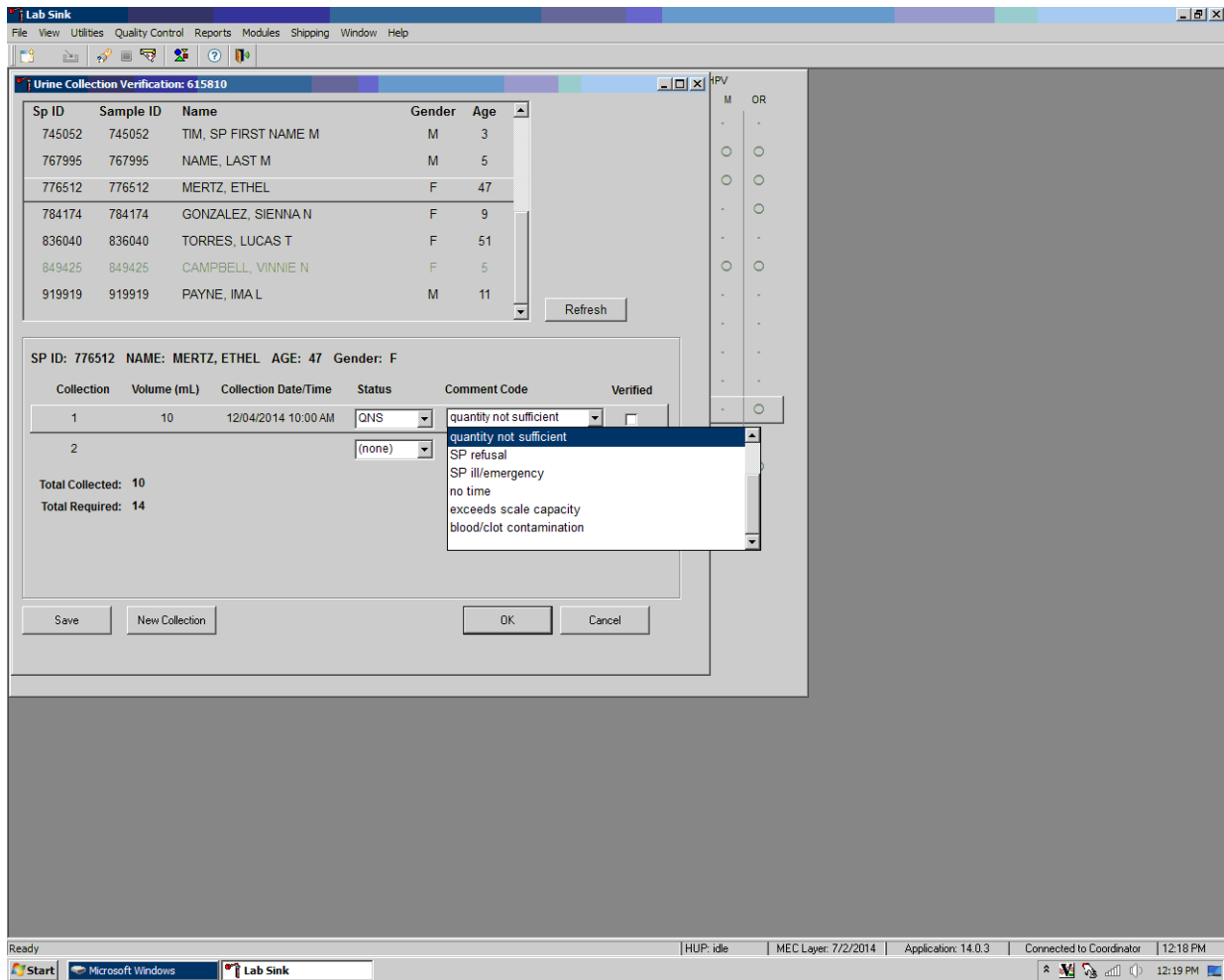
Total Collected: 556
Total Required: 55

Save New Collection OK Cancel



To record a comment, direct the mouse arrow to the drop-down list, click to display the Comment Codes, and select “exceeds scale capacity” from the drop-down list. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and left-click when the correct choice is highlighted.

Visually evaluate the urine sample for blood contamination. If the sample is contaminated with blood, record the “blood/clot contamination” comment for both sufficient and QNS urine collections.



The “blood/clot contamination” comment should supersede the “quantity not sufficient” comment code when blood is present in a QNS specimen. To record a comment, direct the mouse arrow to the drop-down list, click to display the comment codes, and select “blood/clot contamination” from the drop-down list. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and left-click when the correct choice is highlighted.

Record a comment for all insufficient urine collections. The laboratory application will automatically assign the comment code “quantity not sufficient” for all urine collections that are calculated as QNS by the scale application. The laboratory technician may also assign this comment code to all samples that are changed to QNS during the verification process. As mentioned above, the “blood/clot contamination” comment supersedes the “quantity not sufficient” comment code.

Urine Collection Verification: 430420

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 244445 NAME: NELSON_2, JENNY AGE: 36 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	12	12/19/2008 04:13 PM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

Total Collected: 12
Total Required: 56

Save New Collection OK Cancel

The comment codes are shown in Exhibit 4-3.

Exhibit 4-3. Comment codes for urine collection

Comment code	Use when
Communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problems and is unable to complete the test.
SP unable to comply	SP has a physical limitation that prohibits them from producing a urine specimen, or SP is unable to produce urine during the session.
Quantity not sufficient	The quantity of urine is insufficient to process any or all urine vessel(s).
SP refusal	SP refuses to provide urine during the session.
SP ill/emergency	Not applicable.
No time	Not applicable.
Exceeds scale capacity	The weight of the urine exceeds the scale weight capacity of 610 g.
Blood/clot contamination	Blood or clots are present in the urine and may affect the volume capture.

Verify the results of the urine collection. To verify, direct the mouse arrow to the “Verified” check box. Left-click on the check box and a checkmark will appear in the box. Verifying the results will save them to the database.

Urine Collection Verification: 430420

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36

SP ID: 220901 NAME: RUSSELL_2, JACK AGE: 25 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	556	12/19/2008 03:30 PM	Yes	exceeds scale ca	<input checked="" type="checkbox"/>

Total Collected: 556
Total Required: 55

Buttons: Save, New Collection, OK, Cancel

Continue recording and verifying urine collection results as specimens are received in the laboratory. Use the scroll bar to view all SPs in the top part of the Urine Collection screen. SPs who need their urine verified will appear in blue on the top screen.

An SP will be prompted for additional urine only if (1) the total of their urine collection was insufficient to meet the SP’s protocol requirement, and (2) the SP has submitted less than two (ages 3 to 5) or three (ages 6+) collection samples. The Urine Collection screen will display up to

three instances of urine collection for SPs aged 6+ and two instances for SPs aged 3-5 years. Urine collection is complete regardless of the amount of urine collected after the maximum number of attempts.

Sp ID	Sample ID	Name	Gender	Age
220901	220901	RUSSELL_2, JACK	M	25
224633	224633	SMITH_2, TYLER	M	46
238763	238763	WALLACE_3, MILDRED	F	73
240491	240491	WALLACE_3, JILL	F	39
244445	244445	NELSON_2, JENNY	F	36
248212	248212	TAYLOR_2, BEN	M	28
251401	251401	NELSON_3, HOWARD	M	36


SP ID: 244445 NAME: NELSON_2, JENNY AGE: 36 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	12	12/19/2008 04:13 PM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

Total Collected: 12
Total Required: 56

Buttons: Save, New Collection, OK, Cancel

If the urine collection is the first or second collection and the status is QNS, a record for the second and third instances of urine collection will automatically be added by the Laboratory application. Second and third collections will display as empty rows after the last urine collection. The instance number is displayed under the Collection column.

After verifying the urine collection, select “Save” to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

Once a urine collection has been recorded for an SP, the circle on the heads-up screen will turn black (⦿ for QNS or ● for Yes). A black urine collection circle indicates that no additional action needs to be taken on that SP for urine collection at that time.

4.5 Manually Documenting Urine Collection

4.5.1 Manually Document Urine Collection with Barcode Scanning

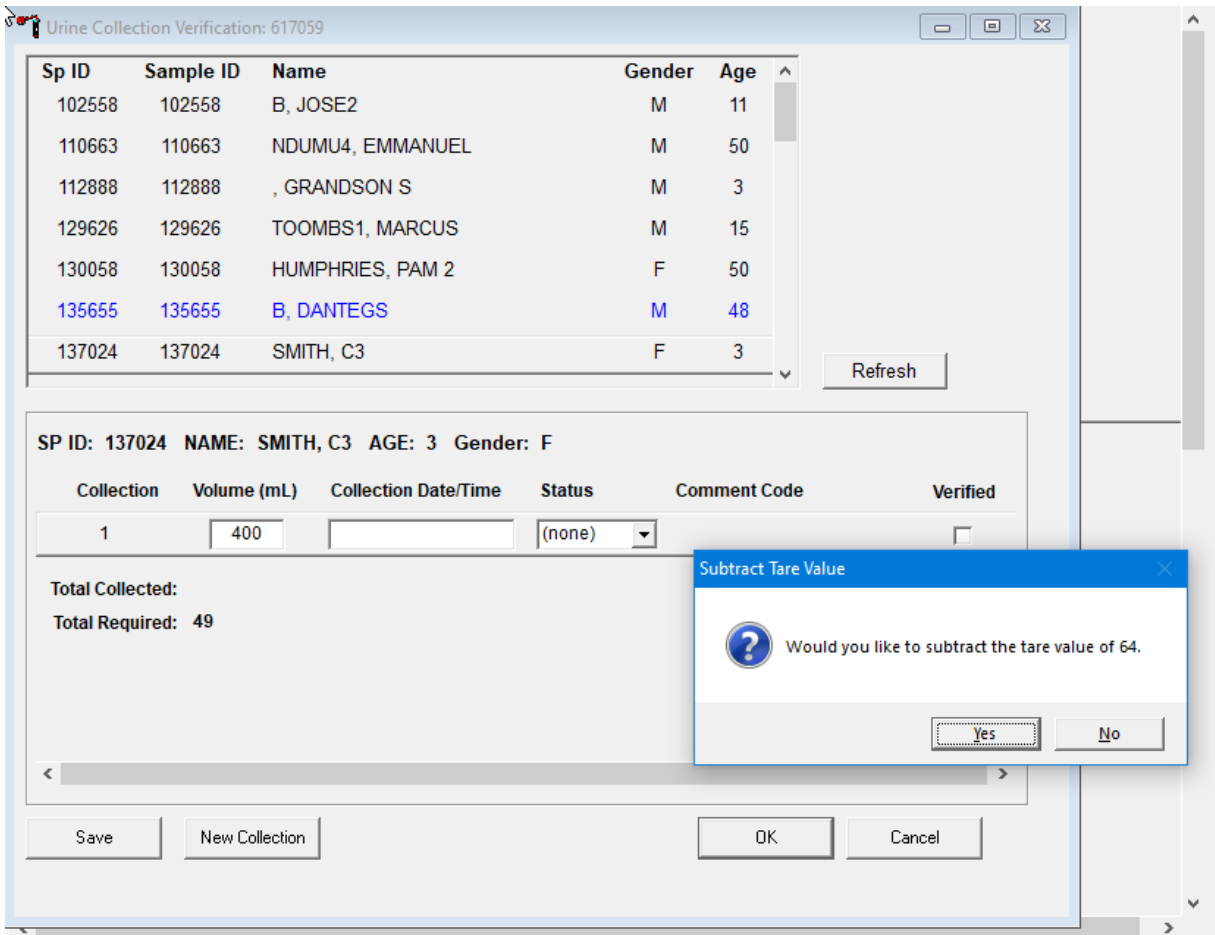
The clinical laboratory scientist can manually record the volume, status, and collection date and time in the Urine Collection module within the laboratory application. Place the urine collection cup on the scale and cover with the clear acrylic scale cover. Scan the barcode on the urine cup.

Note: Use this function when the interface between the scale and the laboratory system is not functioning properly or if there is a change in the tare weight of either the urine collection cups or urine containers for 3- to 5-year-olds. The weights will be entered manually until the new tare weight is programmed in ISIS.

Open the Urine Collection screen from the heads-up as described in Section 2.2. The urine collection window displays. At this point, the technician can modify the volume of the urine and the collection date/time.

To manually adjust the volume (mL), direct the mouse arrow to the text box under the Volume (mL) column. Double-click to open boxes for modification and then click on the text box to enable the cursor in the box. Make changes using the number pad on the keyboard. Once any necessary adjustments have been made, direct the mouse arrow to the box under the Collection Date/Time column or press the Tab key. A prompt will pop up, asking if you would like to subtract the weight of the cup. If the volume of the sample was transmitted from the scale and you have made a manual adjustment to that reading, select “No.”

In the Collection Date/Time box, right-click on the text box to enable the cursor inside the box. Adjust the date and time by entering the date in the format “MMDDYYYY ##:##” using the number pad on the keyboard. Adjust “am/pm” by using the up or down arrow. Once any necessary adjustments have been made, direct the mouse arrow to the box under the Status column or press the Tab key.



Continue to enter the collection date/time, selecting the appropriate urine collection status and a comment code if applicable. Verify the urine collection.

If the urine collection is the first or second collection and is QNS, second and third instances of urine collection may be added by using the “New Collection” button at the bottom of the screen.



Add a second or third collection only if the previous collection was QNS. Enter the second or third urine collection results when the sample is submitted to the MEC laboratory. Do this by typing in the boxes for Volume and Collection Date/Time and then selecting the appropriate urine collection status and a comment code if applicable.

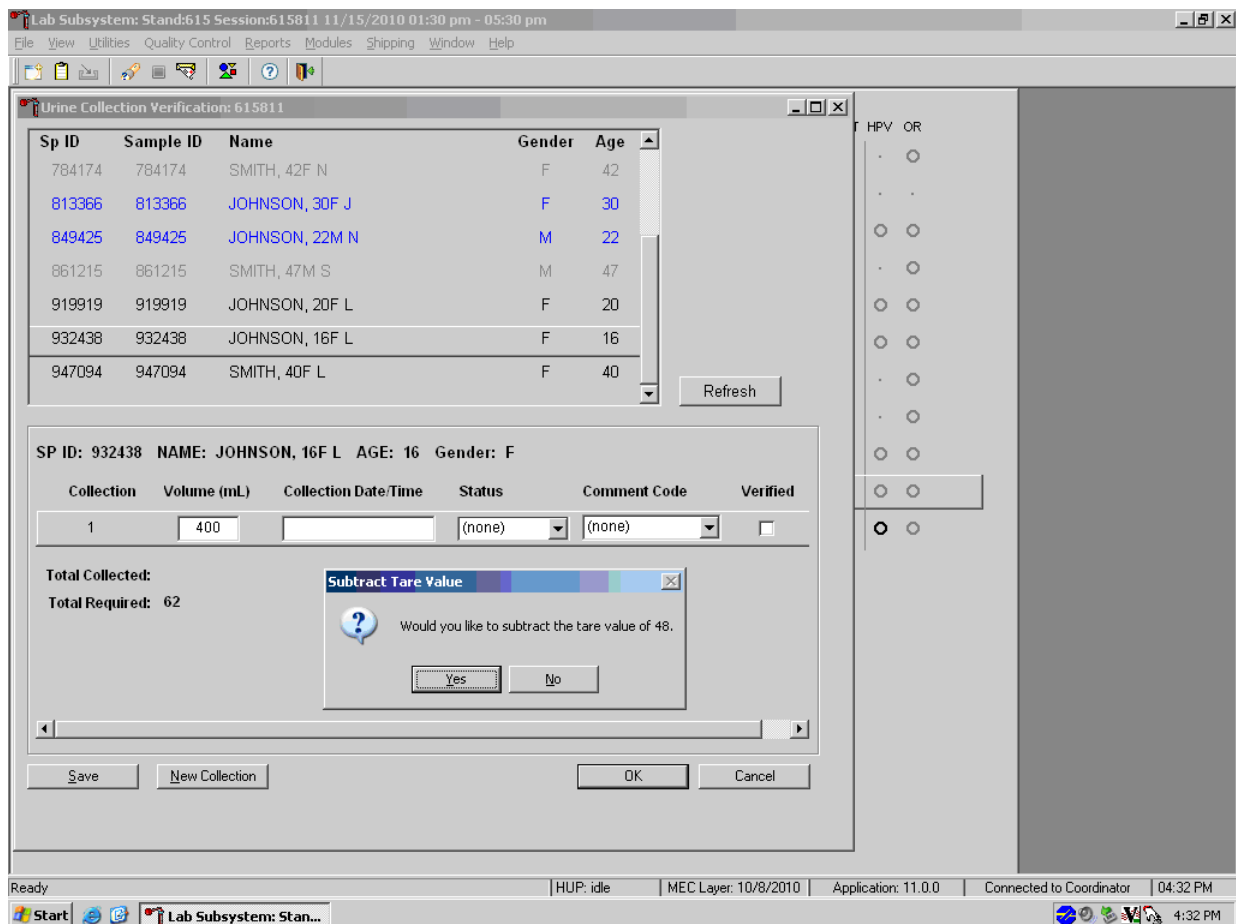
Verify the urine collection and save the changes.

4.5.2 Manually Document Urine Collection Without Barcode Scanning

If the connection between the scale and workstation 3 is down, the clinical laboratory scientist can manually record the volume, status, and collection date and time in the Urine Collection module within the laboratory application. Place the urine collection cup on the scale and cover with the clear acrylic scale cover. Note the weight reading from the LCD.

Open the Urine Collection screen from the heads-up as described in Section 2.2. The urine collection window displays. Double-click in the area underneath Volume or Collection Date/Time to open the boxes where the values can be entered. Enter the urine collection results by typing in the weight reading from the scale's display in the box for volume.

If the next box is selected by pressing the Tab key or using the mouse, a prompt will pop up asking if you would like to subtract the weight of the urine cup from the result entered. Select "Yes."



Continue to enter the urine results as described in Section 4.10. Verify and save the results.

4.5.3 Manually Entering Adults Who Collect in 3- to 5-Year-Old Container

Follow these instructions to manually enter information for adults who use collection container 2:

1. Place the urine on the scale.
2. Document the volume.
3. Subtract 64 g from the volume.
4. Use procedure 4.11 to enter the calculated weight into ISIS.

4.6 Urine Specimen Assays

Process urine specimens using the disposable transfer pipettes 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 primary SPs aged 3 years and older;
- Chlamydia (Chlam), Trichomonas (Trich), and Mycoplasma genitalium (Mgen) on primary SPs 14-39 years old;
- Trichomonas (Trich) and Mycoplasma genitalium (Mgen) on SPs 40-59 years old;
- Speciated Arsenic (Spc Arsenic) on all SPs aged 3-5 years, selected SPs aged 6 years and older;
- Priority Pesticides (Prior Pest) on all SPs aged 3-5 years and selected SPs aged 6 years and older;
- Organophosphates (Organophos) on all SPs aged 3-5 years and selected SPs aged 6 years and older;
- Urine Mercury/Iodine (Urin Merc) on all SPs aged 3-5 years and selected SPs aged 6 years and older;
- Metals on all SPs aged 3-5 years, selected SPs aged 6 years and older;
- Arsenic, Chromium, and Nickel on all SPs 3- to 5-years-old and selected SPs 6 years and older;
- Polyaromatic Hydrocarbons (PAH) on all SPs aged 3-5 years, selected SPs aged 6 years and older;
- Phthalates on all SPs aged 3-5 and selected SPs aged 6 years and older;

- Perchlorate/Thiocyanate on all SPs aged 3-5 and selected SPs aged 6 years and older;
- TSNA/Nicotine Metabolites on all SPs aged 3-5, selected SPs aged 6 years and older;
- Aromatic Diamines (UVOC) on all SPs aged 3-5 and selected SPs aged 6 years and older; and
- Extra urine (Xtra Urine) on SPs aged 3 years and older.

4.7 Urine Specimen Protocols

Exhibit 4-4 summarizes the urine processing protocol for primary SPs. Process urine in priority order with vessel 45 filled first, 46 second, etc.

Exhibit 4-4. NHANES urine processing protocol – primary

Vessel no.	Assay	Age (years)	Sample size (mL)	Vessel
45	Alb/Creat	3+	1	2-mL cryovial
46	Chlam/Trichomonas/Mgen	14-39	2	5-mL Aptima
154	Trichomonas/Mgen	40-59	2	5-mL Aptima
86	Spc Arsenic	3+	2	2-mL cryovial
48	Prior Pest	3+	4.5	5-mL cryovial
49	Organophos	3+	4.5	5-mL cryovial
62	Urin Merc/Iodine	3+	5	10-mL w/presv
50	Metals	3+	4	5-mL cryovial
220	Arsenic/Chromium/Nickel	3+	4	5-mL Five-O cryovial
66	PAH	3+	1.5	2-mL cryovial
67	Phthalates	3+	1.5	2-mL cryovial
102	Perchlorate/Thiocyanate	3+	2	2-mL cryovial
156	TSNA/Nicotine Metabolites	3+	5	5-mL cryovial
218	Aromatic Diamines (UVOC)	3+	2	2-mL cryovial
52	Xtra Urine 1	3+	5	5-mL cryovial
139	Xtra Urine 2	3+	5	5-mL cryovial

4.8 Labeling Urine Processing Vessels

The appropriate barcode labels automatically print for each SP based on the SP's age, sex, appointment type, and subsample selection. The label/ship clinical laboratory scientist at workstation 1 prints the labels as described in Chapter 8. The label/ship clinical laboratory scientist places the urine labels at workstation 3 at the beginning of each session.

Process urine on one SP at a time. Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally and making sure the label wraps onto itself. Arrange vessels so they are filled in priority order.

If the SP does not show up for a session, place the labels in the bag that contains the blood vessels and store in workstation 1 for rescheduling purposes. If the SP cannot comply, discard the urine labels, redact the SP information from the sample cup, and discard.

4.9 Urine Specimen Processing

Follow these steps to process urine samples.

- If there is any delay in processing urine, place the sample in the refrigerator until it can be processed.
- If there are multiple urine cups from the same SP, verify the SP name and ID on each cup. Pool urine samples into the most recently collected cup (i.e., pour CC1 into CC2), cover, and swirl before aliquoting. Discard CC1 after redacting SP personally identifiable information.
- Where indicated, perform the pregnancy test and record results before aliquoting the urine specimen.
- Label all urine aliquot vessels for the SP and arrange them in priority order.

Using the 3.5 mL pipet, aliquot the urine sample for each of these tests using the procedure shown below. Exhibit 4-5 summarizes the urine processing priority order for primary SPs.

Exhibit 4-5. NHANES urine processing priority order

Vessel	Action
45	Aliquot 1 mL of urine for Alb/Creat into a 2-mL vessel
46	Aliquot 2 mL of urine for Chlam/Trich/Mgen (14- to 39-years-old) into a 5-mL Aptima vessel
154	Aliquot 2 mL of urine for Trich/Mgen (40- to 59-years-old) into a 5-mL Aptima vessel
86	Aliquot 2 mL of urine for Spc Arsenic into a 2-mL vessel
48	Using a 5-mL vessel, aliquot 4.5 mL of urine for Prior Pest
49	Using a 5-mL vessel, aliquot 4.5 mL of urine for Organophos

Exhibit 4-5. NHANES urine processing priority order (continued)

Vessel	Action
62	For Urin Merc, <u>use the 3.5 mL disposable transfer pipette to transfer exactly 5 mL of urine into the 10 mL screwcap vessel containing the preservative</u> , close the cap, and mix gently. If the vessel becomes inverted before the urine is aliquoted, tap the bottom of the capped vessel against a hard surface before opening. Then open the cap and pipette 5 mL of urine into the 10 mL vessel. Do not discard the prepared tubes even if the preservative crystallizes. If the preservative crystallizes, add 5 mL of urine with the 3.5 mL <u>disposable transfer pipette</u> and mix extremely well. Do not use these tubes for any other purpose because they contain a preservative. Always store the Urin Merc tubes in an upright position.
50	Aliquot 4 mL of urine for Metals into a 5 mL vessel
220	Aliquot 4 mL of urine for Arsenic/Chromium/Nickel into a Five-0 5 mL vessel
66	Aliquot 1.5 mL of urine for PAH into a 2 mL vessel
67	Aliquot 1.5 mL of urine for Phthalates into a 2 mL vessel
102	Aliquot 2 mL of urine for Perchlorate/Thiocyanate into a 2 mL vessel
156	Aliquot 5 mL of urine for TSNA into a 5 mL vessel
218	Aliquot 2 mL of urine for Aromatic Diamines (UVOC) into a 2 mL vessel
52	Aliquot 5 mL of urine for Xtra Urine 1 into a 5 mL vessel
139	Aliquot 5 mL of urine for Xtra Urine 2 into a 5 mL vessel

If the SP has opted out of Future Studies, the SP will not have vessels 52 or 139 in their profile.

Inform the blood processing technologist that there are no extras on that SP.

Discard any remaining urine specimen at the end of each session after container verification is completed. Pour urine down the drain in the laboratory sink that is connected to the sewer. Flush the sink with water. Discard the urine cup in the regular trash, after marking out the name.

Do not process urine on more than one SP at a time.

4.10 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.

To access the Urine Processing module, direct the mouse arrow to the correct SP, right-click, drag the mouse arrow to the Urine Processing tab, and right-click. Alternatively, use the up and down arrows to move up and down the list until the correct SP is highlighted, right-click, drag the mouse arrow to the Urine Processing tag, and right-click.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						
							UC	U	P	CB	B	PC	
214268	214268	CI	P	M	11	PERSA		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
290160	290160	BE	P	F	16	HOYA,		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
483445	483445	BE	P	M	15	HOYA,		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
491168	491168	BE	P	F	40	HOYA,		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
645451	645451	SC	P	F	10	PERSA		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
711860	711860	SC	P	M	45	HOYA,		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
781732	781732	BE	P	M	12	PERSA		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
913751	913751	SC	P	F	9	JONES, MICAYLA 2		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The SP's urine processing window displays.

UR: 290160

U processing

Tech ID: 1756 Sample ID: 290160 Name: HOYA, MARY Gender: F Age: 16
 SP ID: 290160 Appt Type: Primary Fasting Req: Afternoon/Evening

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat		3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
46	Chl/Trc/Myg		5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
48	Prior Pest		7.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
49	Organophos		7.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
67	Phthalates		4.5	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			

Save OK Cancel

The urine processing window contains the following information for SPs: Tech ID, Sample ID, Name (last, first), Gender, Age, SP ID, Appt (appointment) Type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (U=urine), Vessel Volume, and Vessel Name; Filled (Yes or No) radio buttons; a Comment drop-down box; and a Container ID and Container Slot# column.

To mark an individual urine vessel as collected or Filled—Yes, direct the mouse arrow to the center of 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 and the next open slot number.

To mark an individual urine vessel as not collected or Filled—No, direct the mouse arrow to the center of 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.

UR: 290160
U processing

Tech ID: 1756 Sample ID: 290160 Name: HOYA, MARY Gender: F Age: 16
 SP ID: 290160 Appt Type: Primary Fasting Req: Afternoon/Evening

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat		3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes			
46	Chl/Trc/Myg		5.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes			
48	Prior Pest		7.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
49	Organophos		7.0	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
67	Phthalates		4.5	U	10 ml	WWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			

Buttons: Save, OK, Cancel

To collectively mark all vessels as Filled—Yes, direct the mouse arrow to the Filled button on the top of the radio buttons and left-click, then drag the arrow to Fill All and left-click.

To mark all vessels as Filled—No, direct the mouse arrow to the Filled box and left-click, then drag the mouse arrow to Not Filled All and left-click.

Exhibit 4-6 shows quality control comments and Exhibit 4-7 lists other comment codes that may be used. To enter the quality control comment “blood present,” “contamination – foreign matter,” “contamination – SP touched inside of container,” “possible contamination,” or “room temp >30°C” for a filled vessel, direct the mouse arrow to the drop-down list in the Comments column, left-click to display the choices, drag the mouse arrow to the Blood present tab, and left-click.

Exhibit 4-6. Quality comment codes to use for filled vessels

Comment code	Use when
Blood present	Blood is visible in the specimen.
Contamination, foreign matter	The sample appears to contain any foreign matter.
Contamination, SP touched inside of container	It was reported that the SP or parent/guardian touched the inside of the container during collection.
Possible contamination	The sample appears to be contaminated.
Room temp >30° C	The sample was processed when the room temperature was >30° C.

If a vessel is marked as Filled—No, the comment “quantity not sufficient” is automatically entered. Review the comment for all insufficient urine collections and correct the comment, when necessary.

Exhibit 4-7. Comment codes

Comment code	Use when
Awaiting SP sample	At the end of the session block if the SP hasn't provided another urine sample.
Contamination, foreign matter	The urine sample is contaminated with any materials, such as toilet paper or stool.
Contamination, urine container fell in toilet	The urine container fell in the toilet during or after collection.
Laboratory error	A technologist makes an inadvertent error when processing.
Quantity not sufficient	The amount of urine received in the laboratory is insufficient to fill this vessel.

Continue recording and updating urine collection results as specimens are delivered to the laboratory. 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 the data to the database, direct the mouse arrow to the “Save” button and left-click. To record this action or to save the data to the database and exit the module, direct the mouse arrow to the “OK” button and left-click. To close the window without saving any data in the database, direct the mouse arrow to the “Cancel” button and left-click.

4.11 Second and Third Urine Samples

If the initial urine sample does not meet the minimum volume requirement, hold the initial urine in the refrigerator until enough additional urine is received in the second or third urine collection to meet the minimum requirements to complete the protocol or until the session ends for SPs aged 6+ or the second urine collection for SPs aged 3-5 years. If a subsequent sample collection fulfills the

protocol requirement, pool the initial and subsequent urine samples into the most recently collected specimen cup (if both urine collections pooled together exceed the capacity of the cup, add equal amounts of urine to the cup), update the Urine Collection module, access the Urine Processing module, fill the vessels, and record the results. If the session ends and no additional 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, with the Comment Code “Quantity not sufficient”; and save the results.

4.12 Specimen Storage

Fill the urine vessels, enter the urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 4-8. Check the slot assignment of each urine processing container at the end of each processing session by accessing the content container verification. Verify the contents of each container against the system. Mark the top of the last vessel verified for each session with a mark specific to each individual clinical laboratory scientist.

At the beginning of each stand, generate and print a series of barcoded, numbered labels for storage containers as described in Chapter 8. Use the shipping module to assign a barcode 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.

Exhibit 4-8. Storage and shipping protocol for urine

Lab #	Shipping location		Vessels	Conditions	Frequency	Vessel storage
51	NHANES ARDL	45	Alb/Creat	Frozen	Weekly	9x9 two-inch box
5	CDC/NCID NCHSTD	46	Chlam/Trich/ Mgen	Frozen	Weekly	9x9 three-inch box
5	CDC/NCID NCHSTD	154	Trich/Mgen	Frozen	Weekly	9x9 three-inch box
6	CBR	86	Spc Arsenic	Frozen	Weekly	9x9 two-inch box
6	CDC/NCEH Pesticide Laboratory	48	Prior Pest	Frozen	End of stand or when full	5x5 three-inch box
6	CDC/NCEH Pesticide Laboratory	49	Organophos	Frozen	End of stand or when full	5x5 three-inch box
6	CBR	62	Urin Merc	Frozen	Weekly	5x5 three-inch box
6	CBR	50	Metals	Frozen	Weekly	9x9 three-inch box
6	CBR	220	Arsenic/ Chromium/ Nickel	Frozen	Weekly	5x5 five-inch box with foam insert
6	CBR	66	PAH	Frozen	End of stand or when full	9x9 three-inch box
6	CBR	67	Phthalates	Frozen	End of stand or when full	5x5 three-inch box
6	CBR	102	Perchlorate/ Thiocyanate	Frozen	End of stand or when full	9x9 two-inch box
6	CBR	156	TSNA/Nicotine Metabolites	Frozen	End of stand or when full	9x9 three-inch box
6	CBR	218	Aromatic/ Diamines	Frozen	End of stand or when full	9x9 two-inch box
6	CBR	52	Xtra Urine 1	Frozen	End of stand or when full	9x9 three-inch box
6	CBR	139	Xtra Urine 2	Frozen	End of stand or when full	9x9 three-inch box

4.13 How to Deal with System Failure

If the computer system fails, record results on a preprinted workstation 3 processing worksheet (Exhibit 4-9). Complete a workstation 3 worksheet for each SP after performing the pregnancy test, and while processing the urine specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 4-9. Workstation 3 processing worksheet

URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING

SP ID _____

Result	Urine collected age 3+	Yes ✓	Yes/QNS ✓	No ✓	Comments	Weight of urine collection
Result					Communication problem No time Quantity not sufficient SP ill/emergency SP refusal SP unable to comply	UC1: UC2: UC3:
Result	Pregnancy Test Ages 8-11	Negative ✓	Invalid ✓	Positive ✓	Serum Confirmation Result (Send observation to physician)	
Result	Pregnancy Test Ages 12-59	Negative ✓	Invalid ✓	Positive ✓		

ID	Name	Ages	Sample mL	Sample type	Tube size	Filled ✓	Comments: QNS blood present	Slot #
45	Alb/Creat	3+	1	Urine	2			
46	Chlam/Trich/Mgen	14-39	2	Urine	Aptima			
154	Trich/Mgen	40-59	2	Urine	Aptima			
86	Spc Arsenic	3+	2	Urine	2 mL cryovial			
48	Prior Pest	3+	4.5	Urine	5 mL cryovial			
49	Organophos	3+	4.5	Urine	5 mL cryovial			
62	Urn Merc/Iodine	3+	5	Urine	10 mL screwcap w/presv			
50	Metals	3+	4	Urine	5 mL cryovial			
220	Arsenic/Chromium/Nickel	3+	4	Urine	Five-0 5 mL cryovial			
66	PAH	3+	1.5	Urine	2 mL cryovial			
67	Phthalates	3+	1.5	Urine	2 mL cryovial			
102	Perchlorate/Thiocyanate	3+	2	Urine	2 mL cryovial			
156	TSNA/Nicotine Metabolites	3+	5	Urine	5 mL cryovial			
218	UVOC	3+	2	Urine	2 mL cryovial			
52	Xtra Urine 1	3+	5	Urine	5 mL cryovial			
139	Xtra Urine 2	3+	5	Urine	5 mL cryovial			

5. Urine Pregnancy Test

5.1 Purpose and Principle of the Test

Perform a pregnancy test on females of all appointment types who are aged 12-59 years and girls aged 8-11 years who report, when asked during the interview, that they have experienced their first menstruation. A positive test result excludes pregnant women aged 8-59 years from participating in the dual-energy X-ray absorptiometry (DXA), balance, and liver ultrasound transient elastography (LUTE) components of the MEC exam if they fall into an eligible age category for those components. The test should be performed and the results reported immediately, since these components are not assigned until the results of the pregnancy test are documented in the laboratory information system.

Laboratory tests for pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone that the placenta begins to produce in increasing amounts shortly after fertilization. The ICON[®] 25 hCG (Urine/Serum) test kit is a rapid chromatographic immunoassay for the qualitative detection of hCG in urine or serum to aid in the early detection of pregnancy. Pregnancy tests will be performed solely on urine for NHANES.

In normal pregnancy, hCG can be detected in urine as early as 7-10 days after conception. The hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL (milli-international units per milliliter) by the first missed menstrual period and peaking in the 100,000-200,000 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in urine soon after conception, and its subsequent rapid raise in concentration during early gestational growth, make an excellent marker for the detection of pregnancy.

The ICON[®] 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine samples at the sensitivity of 25 mIU/mL. The test uses a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the ICON[®] 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones human follicle stimulating hormone, human luteinizing hormone, and human thyroid stimulating hormone at high physiological levels.

The assay is conducted by adding urine to the sample well of the test device. The sample migrates via capillary action along the membrane to react with colored conjugate. Positive samples react with the specific antibody-hCG-colored conjugate to form a colored line at the test region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

5.2 Special Safety Precautions

ICON® 25 hCG Test Kit

- This test is for professional *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- The test device should remain in the sealed pouch until use.
- Observe standard guidelines for handling biological hazards.
- Wear gloves while handling specimens. After use, dispose of gloves and other contaminated materials appropriately in a proper container and wash your hands.

Sure-View™ hCG Urine Control Sets

- Sure-View™ hCG urine controls are intended to be used to monitor the performance and accuracy of pregnancy test kits. These controls are for professional use only.
- The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm the validity of the results reported. Testing Sure-View™ hCG Urine Controls will provide assurance that the pregnancy test kit is performing properly.
- Reagents in these kits contain 0.2 percent of 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 buildup. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash skin immediately with plenty of water.
- Do not use the controls beyond the expiration date.

5.3 Computerization: Integrated Survey 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, clinical laboratory scientist ID, and run number are automatically captured; enter the kit lot number and expiration date as well as the urine 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.

5.4 Specimen Collection and Preparation

Collect a urine sample as described in Chapter 4 and perform a urine pregnancy test on females aged 12-59 years and girls aged 8-11 years who report, when asked during the interview, that they have experienced their first menstruation.

If the urine pregnancy test is positive for SP's aged 8-17 years, repeat the pregnancy test a second time. Notify the clinician of the positive results and submit a UFO to notify that the positive pregnancy results were confirmed.

5.5 Reagents and Supplies

5.5.1 Reagents

ICON® 25 hCG Urine/Serum Test Kit

- Product Number 43025 (25)
- Beckman Coulter
4300 N. Harbor Blvd.
Fullerton, CA 92834-3100
<http://www.beckmancoulter.com/pcd>

- Components
 - One test device (25) – Contains anti-hCG particles and anti-hCG coating on the membrane;
 - Disposable sample droppers – plastic pipettes for measuring and dispensing patient samples (packaged together with the test device in a white foil pouch);
 - Zip-closable bag with two extra sample droppers; and
 - Product instructions.
- Storage and stability
 - Store the ICON[®] 25 hCG test kit at 2-25°C (35-77°F). The test device is stable up to the expiration date printed on the sealed pouch. Keep the test device in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. Date and initial the kit when putting it into use.

Sure-Vue™ hCG Control Sets – Urine

- Product Number SA087413-F;
- Fisher Scientific Company; and
- Components.
 - 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 Sure-Vue™ hCG Control Sets directional insert.
 - Low Positive Control: Human urine containing approximately 25 mIU of hCG/mL and 0.2 percent sodium azide as a preservative (1 x 5 mL).
 - High Positive Control: Human urine containing approximately 250 mIU of hCG/mL and 0.2 percent sodium azide as a preservative (1 x 5 mL).
 - Negative Control: Contains 0.2 percent sodium azide as a preservative (1 x 5 mL).
- Storage and stability
 - Store the urine control set at 2-8°C (35-46°F) until the expiration date printed on the label.

5.5.2 Supplies

- Timer

5.6 Assay Procedure

ICON® 25 hCG Test Kit

- Label each test device with the SP ID on a clear section of the test device using a felt tip pen. Label test devices used for quality control as “-” or “+.”
- Use a new transfer dropper for each specimen (**use the ICON® 25 hCG plastic pipette that is in the package with the device** for each individual test).

Sure-View™ hCG Urine Control Sets

- The Sure-View™ urine controls have droppers built into the tip. The use of the control droppers to add control to the device has been validated; **do not** use the ICON® 25 hCG plastic pipette to add controls.
- Allow controls to reach room temperature before testing. The controls are ready to use. No dilution is required.
- The controls are used in place of the specimen and should be tested according to the ICON® 25 hCG test procedure.

Urine Testing Procedure

Perform the test procedure for the ICON® 25 hCG Urine test at room temperature (17-25°C, 63-77°F). Before proceeding, carefully read Section 5.11, titled “Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions.”

- Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer three full drops of urine (approximately 100 µL) to the sample well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the sample well.
- Wait for the red line(s) to appear. Read the results at 3 minutes when testing a urine sample. It is important that the background is clear before the result is read.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period; therefore, do not interpret the result after 3 minutes when testing a urine sample.

5.7 Reportable Range of Results

Report test results as Positive, Negative, or Invalid.

5.8 Quality Control (QC)

Run negative and low positive urine controls containing hCG at concentrations of 0 and 25 mIU/mL, respectively, just prior to or concurrently with the first examinee pregnancy test each exam day, and when putting a new lot into use. The pregnancy QC module contains the following information:

- The session ID number links to the stand number, stand location, and 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 the urine control fills in automatically from the prior QC report. Update or manually enter this information if necessary.
- The Control QC Type is urine.
- Negative Control result.
- Positive Control result.
- Upon a lot change during a stand, test the new lot with low positive and negative controls and update the lot numbers in the Quality Control module.

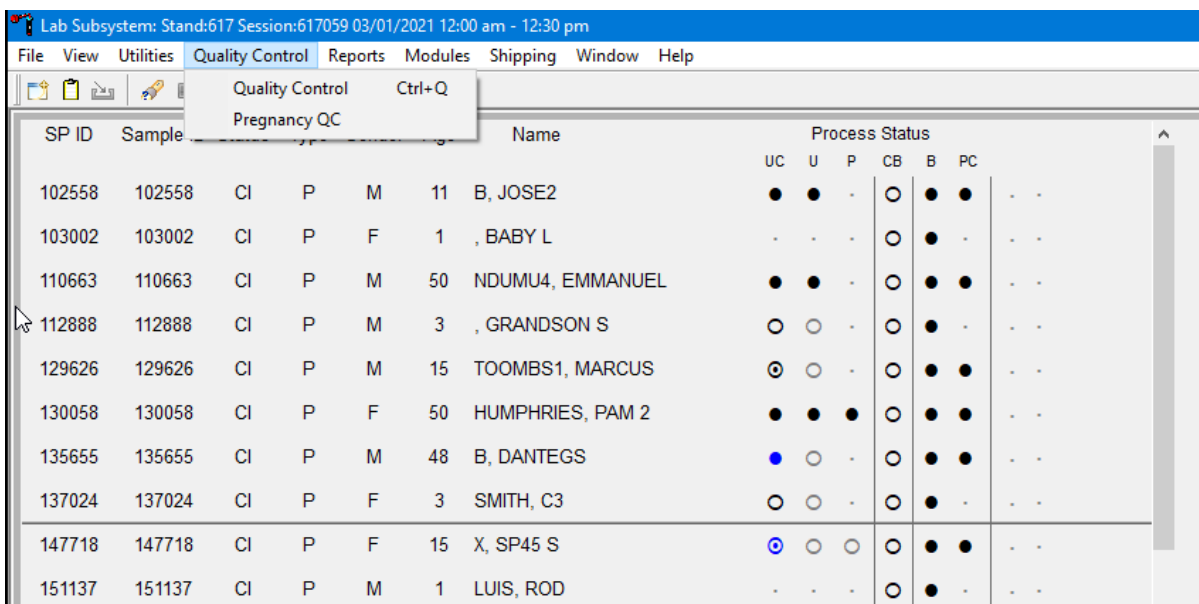
CAP Proficiency Testing

For purposes of this document, proficiency testing is one method of external QC in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 4 months).

Participation in the College of American Pathologists (CAP) proficiency-testing (PT) program is part of the comprehensive QC program. CAP compares the submitted results to established values and issues a report.

CAP sends samples three times a year for qualitative urine hCG. Each urine survey includes five liquid specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the correct CAP form, located on the CAP website, and submit results by the due date indicated on the survey. Send a copy of the CAP result form to the home office at the end of the stand. Do not share or compare CAP PT results with any other laboratory or MEC in operation.

Open the Pregnancy QC module.



To open the pregnancy QC module, direct the mouse arrow to Quality Control in the top menu bar, drag the arrow to Pregnancy QC, and left-click.

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 arrow keys to move up and down the list until the correct SP is highlighted, or direct the mouse arrow to the correct SP, right-click, drag the mouse arrow to Pregnancy Testing, and left-click.

Lab Subsystem: Stand:617 Session:617059 03/01/2021 12:00 am - 12:30 pm

File View Utilities Quality Control Reports Modules Shipping Window Help

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
102558	102558	CI	P	M	11	B, JOSE2	●	●	-	○	●	●	-	-
103002	103002	CI	P	F	1	, BABY L	-	-	-	○	●	-	-	-
110663	110663	CI	P	M	50	NDUMU4, EMMANUEL	●	●	-	○	●	●	-	-
112888	112888	CI	P	M	3	, GRANDSON S	○	○	-	○	●	-	-	-
129626	129626	CI	P	M	15	TOOMBS1, MARCUS	○	○	-	○	●	●	-	-
130058	130058	CI	P	F	50		●	●	●	○	●	●	-	-
135655	135655	CI	P	M	48		●	○	-	○	●	●	-	-
137024	137024	CI	P	F	3		○	○	-	○	●	-	-	-
147718	147718	CI	P	F	15		○	○	○	○	●	●	-	-
151137	151137	CI	P	M	1		-	-	-	○	●	-	-	-
164571	164571	CI	P	F	13		○	○	○	○	●	●	-	-
174973	174973	CI	P	F	59		○	○	○	○	●	●	-	-
175223	175223	CI	P	F	11	GARCIA, SP2_17YEARS G	●	●	●	○	●	●	-	-

Urine Processing
 Blood Processing
 Packed Cell Processing
 Female HPV Processing
 Male HPV Processing
 Urine Collection
 Pregnancy Testing
 Hematology
 Refresh

The Pregnancy QC window displays.

PQ: 410111

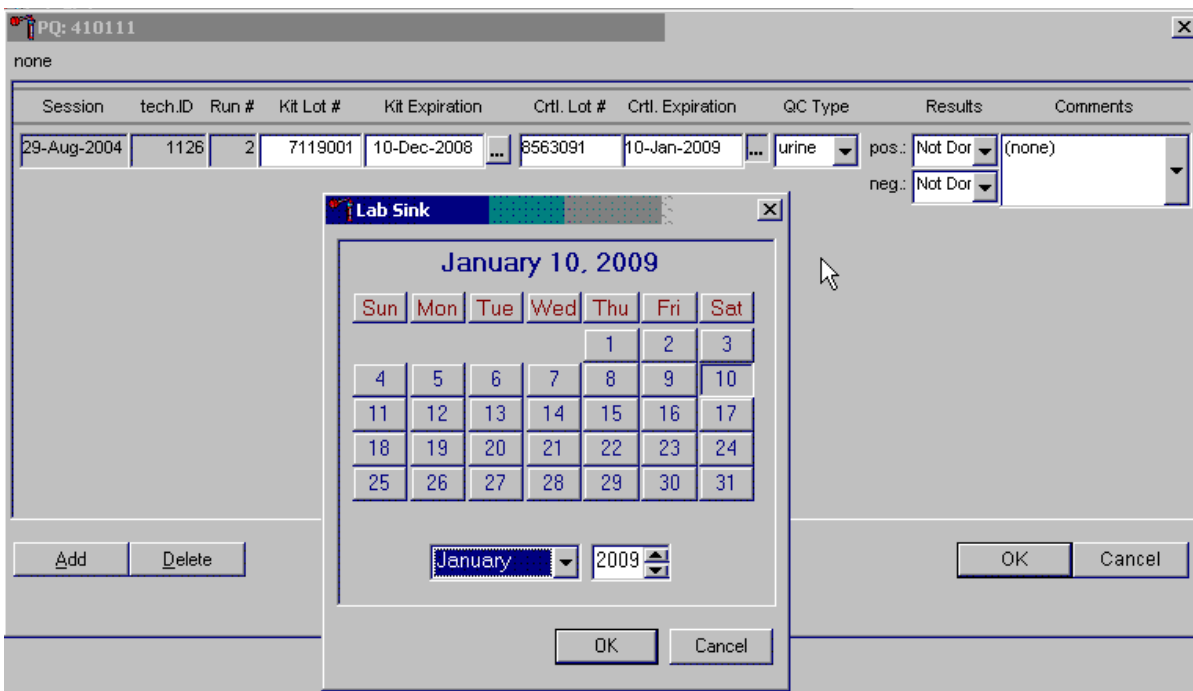
none

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Not Dor neg.: Not Dor	(none)

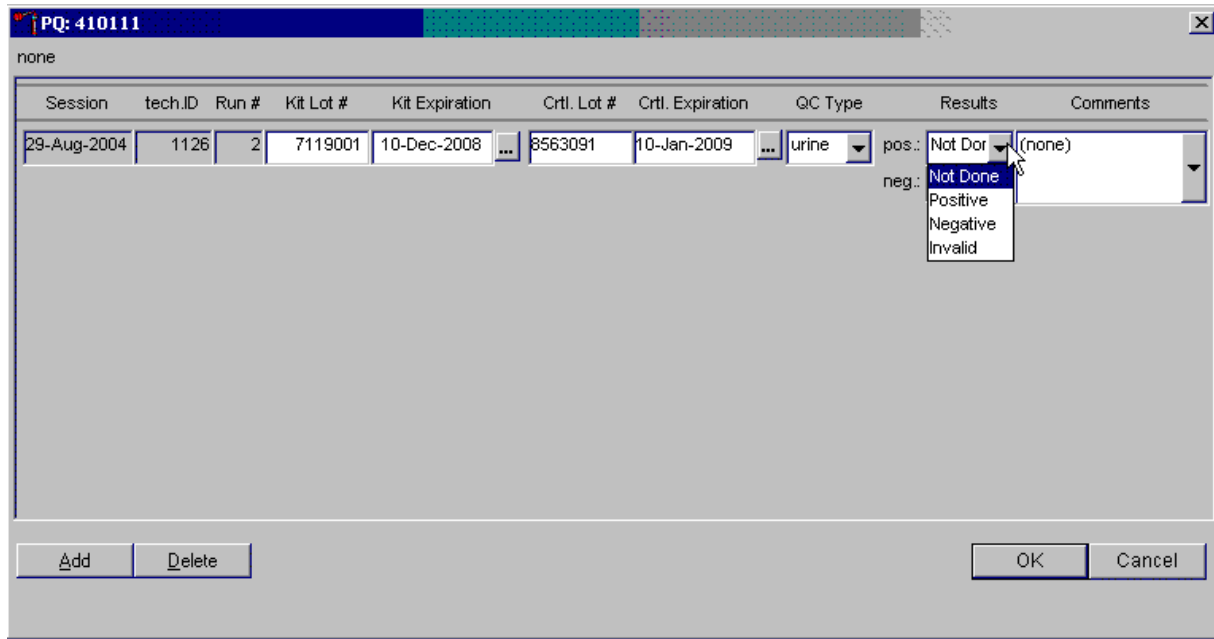
Add Delete OK Cancel

The Pregnancy QC module automatically captures the session date and clinical laboratory scientist 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. Verify the existing kit lot

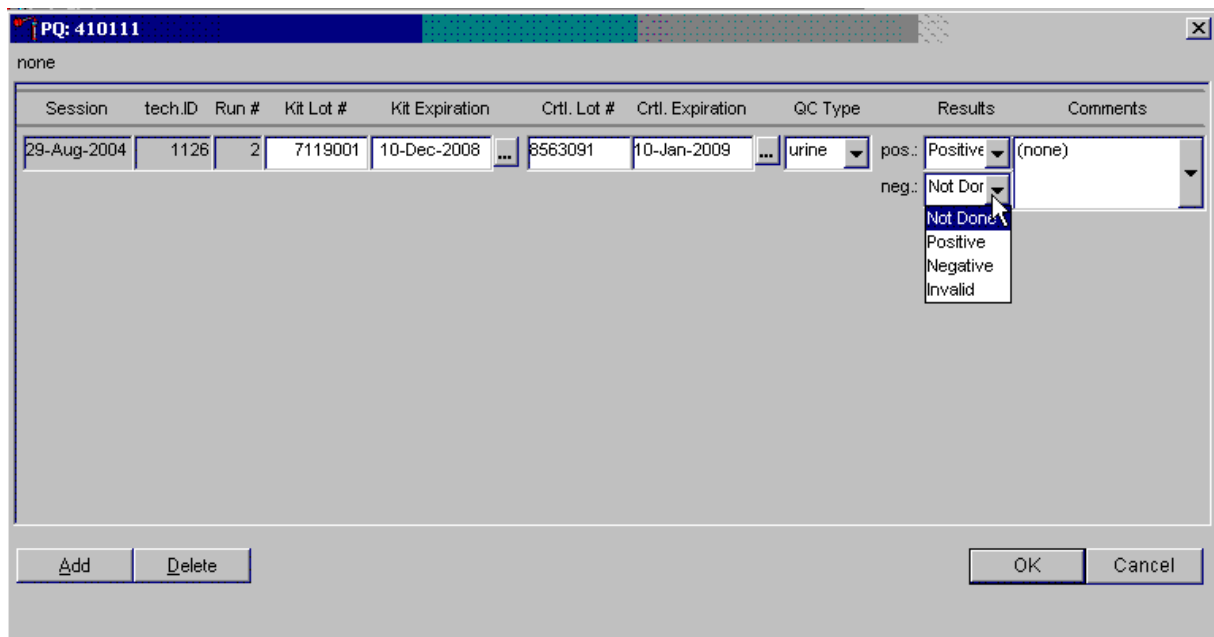
number and expiration date. If the lot number is incorrect, type in the new kit lot number using the keyboard's numeric keys and press the Tab key to progress to the Kit Expiration blank. Use the calendar to correct the Kit Expiration date. If the screen defaults to the current Ctrl lot number, verify 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 press the Tab key to progress to the Ctrl Expiration blank. Use the calendar to correct either the Kit Expiration or Ctrl Expiration date.



To update the Kit or Ctrl Expiration date using the calendar function, type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and press the Tab key or use the calendar to enter the date. To access the calendar, direct the mouse arrow to the ellipsis (...) and left-click. To select the correct month, 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, direct the mouse arrow to the correct day on the displayed month and left-click. To correct the year, direct the mouse arrow to the up/down controls on the spin box and toggle the year up and down. To transfer this date into the text box, direct the mouse arrow to the OK button and left-click. To exit the calendar function, direct the mouse arrow to the Cancel button and left-click.



To enter a result in the positive result text box, type [P/p] for Positive, or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid, and press the Tab key. Alternatively, direct the mouse arrow to the drop-down list; drag the mouse arrow to Positive, and left-click.



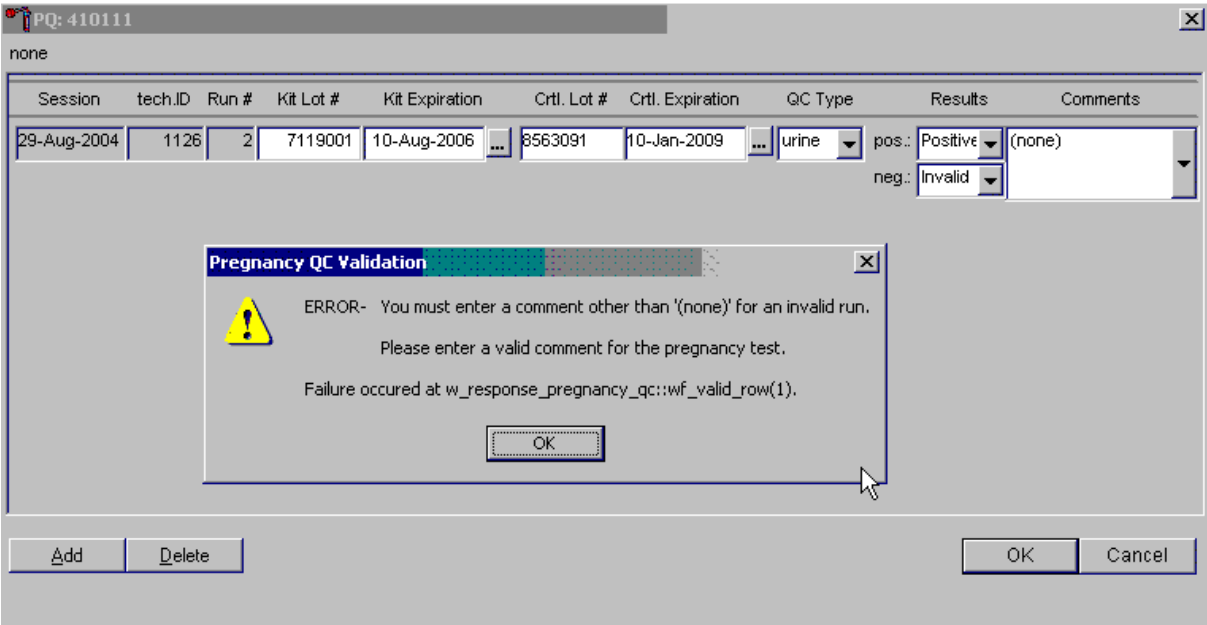
To enter a result in the negative result text box, type [N/n] for Negative or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid and press the Tab

key. Alternatively, direct the mouse arrow to the drop-down list; drag the mouse arrow to Negative, and left-click.

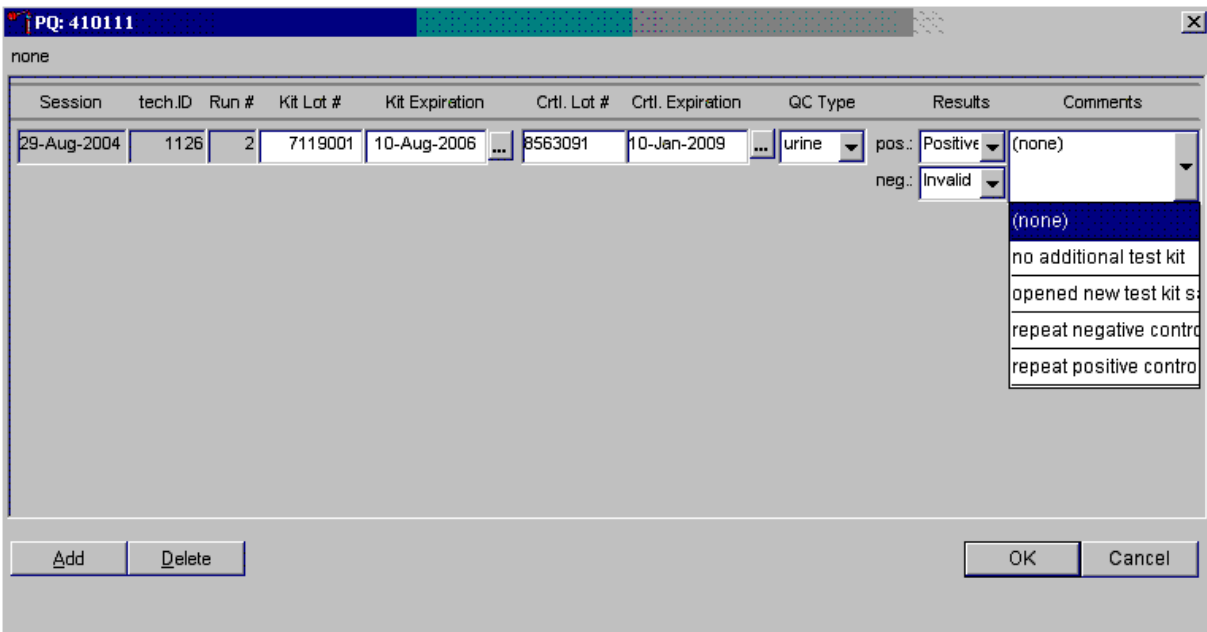
Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Positive neg.: Negative	(none)

If the positive and negative controls demonstrate the expected result, direct the mouse arrow to the OK button and left-click to save the results and proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, 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, direct the mouse arrow to the Delete button and left-click.

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, direct the mouse arrow to the OK button and left-click or press Enter.



To enter a comment for any result that is inconsistent with expected results, enter the appropriate comment in the Comments column by directing the mouse arrow to the drop-down list, left-clicking to display the choices, dragging the mouse arrow to the most appropriate choice, and left-clicking 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: 410111" with a close button in the top right corner. Below the title bar, the text "none" is displayed. 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. A single record is visible with the following data: Session: 29-Aug-2004, tech.ID: 1126, Run #: 2, Kit Lot #: 7119001, Kit Expiration: 10-Aug-2006, Ctrl. Lot #: 8563091, Ctrl. Expiration: 10-Jan-2009, QC Type: urine, pos.: Positive, neg.: Invalid, and Comments: repeat negative control. Below the table are buttons for "Add", "Delete", "OK", and "Cancel".

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Invalid	repeat negative control

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

The screenshot shows the same software window "PQ: 410111" with the text "none" below the title bar. The table now contains two records. The first record is identical to the one in the previous screenshot. The second record has the following data: Session: 29-Aug-2004, tech.ID: 1126, Run #: 3, Kit Lot #: 7119001, Kit Expiration: 10-Aug-2006, Ctrl. Lot #: 8563091, Ctrl. Expiration: 10-Jan-2009, QC Type: urine, pos.: Positive, neg.: Negative, and Comments: (none). The "Add" and "Delete" buttons are visible below the table, along with "OK" and "Cancel" buttons at the bottom right.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Invalid	repeat negative control
29-Aug-2004	1126	3	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Negative	(none)

To 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, direct the mouse arrow to the Add button and left-click. Record

the new results. If this resolves the inconsistency, direct the mouse arrow to the OK button and left-click to save these results and 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.

Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	01-Jul-2006	678454	18-Nov-2008	urine	pos.: Positive neg.: Negative	(none)
29-Aug-2004	1126	3	7119001	01-Jul-2006	789612	26-Dec-2008	serum	pos.: Not Done neg.: Not Done	(none)

Add a new test line each time a control is run during a session. To add a new QC test line, direct the mouse arrow to the Add button and left-click. The QC type defaults to “Urine.” Correct the control lot number and expiration date.

5.9 Interpretation of Results and Remedial Action

ICON® 25 hCG Test

Exhibits 5-1 through 5-4 depict, respectively, the ICON® 25 test device, a positive result, a negative result, and an invalid result.

Exhibit 5-1. ICON® 25 test device

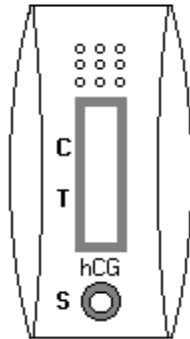
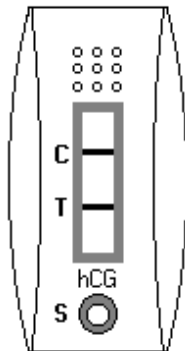
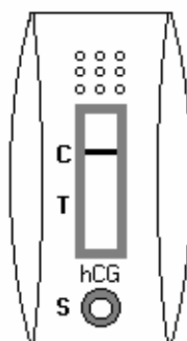


Exhibit 5-2. Positive result



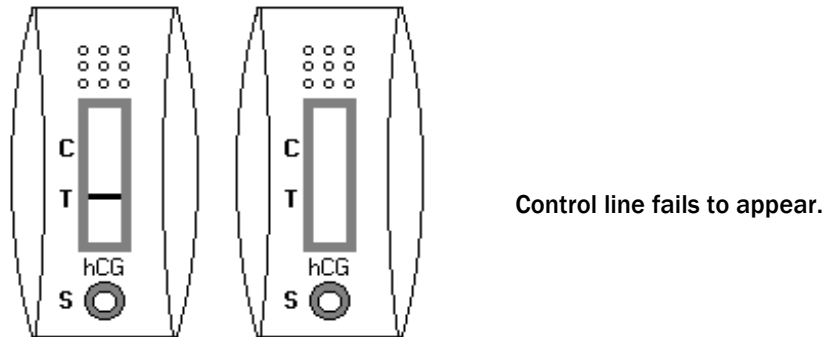
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

Exhibit 5-3. Negative result



One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

Exhibit 5-4. Invalid result



Positive Result. A specimen that produces two distinct red lines is positive for the presence of hCG. One line should be in the control region (C) and another line should be in the test region (T).

Negative Result. A specimen that produces a red line in the control region (C) and no apparent red or pink line in the test region (T) is negative for the presence of hCG.

Invalid Result (any of the following). For the test to be valid, a red line must appear in the control region (C). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and immediately contact the Lab Component Lead.

If an invalid test result occurs repeatedly, or if you need technical assistance, contact the Technical Support Department at Beckman Coulter.

Sure-Vue™ hCG Urine Control Sets

Positive Result. The 25 mIU/mL hCG positive urine controls should produce positive results.

Negative Result. The negative urine control should produce a negative result.

5.10 Record Results

Use the heads-up display and the Pregnancy Testing module to enter the results of the ICON[®] 25 hCG test kit pregnancy test for each SP. Note that the first urine collection must be marked as verified for the Pregnancy Testing module to enable on the heads-up display and on the right-click menu.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
102558	102558	CI	P	M	11	B, JOSE2	●	●	-	○	●	●	-	-
103002	103002	CI	P	F	1	, BABY L	-	-	-	○	●	-	-	-
110663	110663	CI	P	M	50	NDUMU4, EMMANUEL	●	●	-	○	●	●	-	-
112888	112888	CI	P	M	3	, GRANDSON S	○	○	-	○	●	-	-	-
129626	129626	CI	P	M	15	TOOMBS1, MARCUS	○	○	-	○	●	●	-	-
130058	130058	CI	P	F	50		●	●	●	○	●	●	-	-
135655	135655	CI	P	M	48		●	○	-	○	●	●	-	-
137024	137024	CI	P	F	3		○	○	-	○	●	-	-	-
147718	147718	CI	P	F	15		○	○	○	○	●	●	-	-
151137	151137	CI	P	M	1		-	-	-	○	●	-	-	-
164571	164571	CI	P	F	13		○	○	○	○	●	●	-	-
174973	174973	CI	P	F	59		○	○	○	○	●	●	-	-
175223	175223	CI	P	F	11	GARCIA, SP2_17YEARS G	●	●	●	○	●	●	-	-

To access the Pregnancy Testing module, direct the mouse arrow to the correct SP, right-click, drag the mouse arrow to Pregnancy Testing, and left-click. 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.

The Pregnancy Testing window displays.

SP ID	Person Name	Gender	Age	Test Results
215591	PATEL, PAVARTI	F	59	(none)
900081	ABBOTT, HANNAH	F	49	(none)

The text is black for SPs who have urine collection results recorded as “Yes” or “Yes/QNS.” The text is gray for SPs who do not have urine collection results recorded. The window lists the SP ID, Person Name, Gender, and Age and includes a Test Results column (text box).

SP ID	Person Name	Gender	Age	Test Results
215591	PATEL, PAVARTI	F	59	(none)
900081	ABBOTT, HANNAH	F	49	(none)

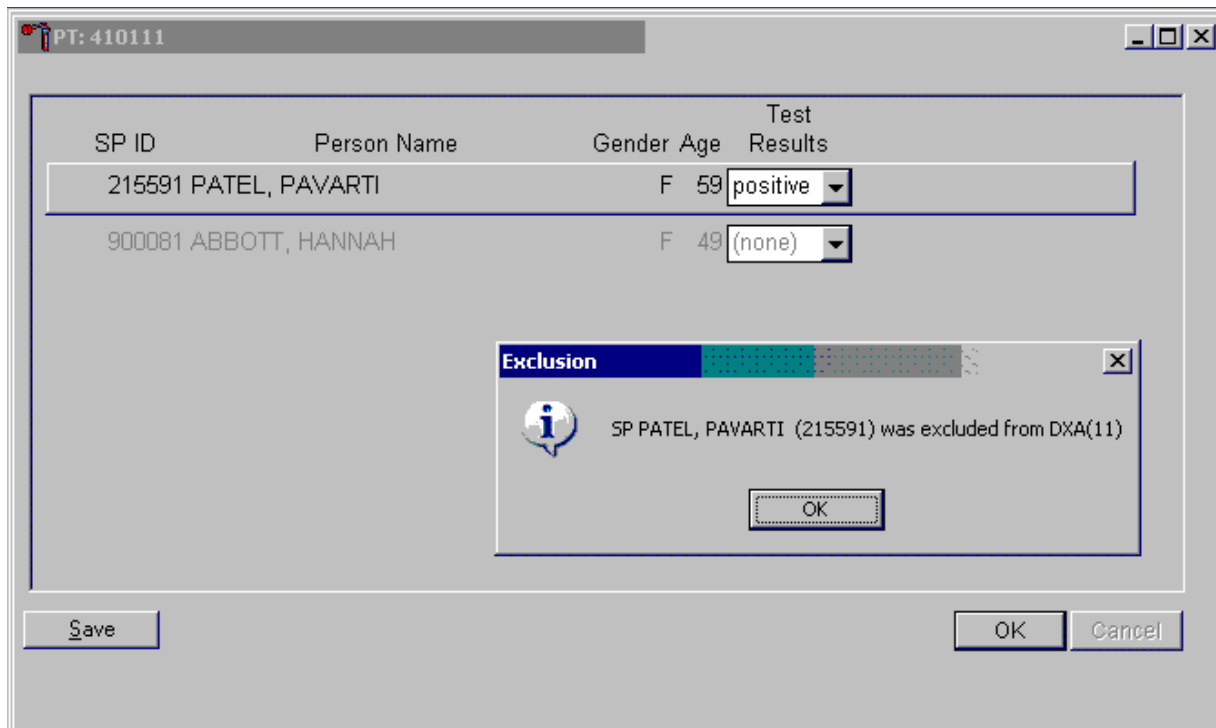
Buttons: Save, OK, Cancel

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. Enter [N/n] for “not done” when the test was not performed. Alternatively, to record a result, 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, direct the mouse arrow to the Save button and left-click. To update the results and exit the window, direct the mouse arrow to the OK button and left-click or select Enter. To exit the module without saving any result, direct the mouse arrow to the Cancel button and left-click.

Continue performing pregnancy tests and recording the results. Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, direct the mouse arrow to the Save button and left-click. To update the results and exit the window, direct the mouse arrow to the OK button and left-click or select Enter. To exit the module without saving any result, direct the mouse arrow to the Cancel button and left-click.

A series of message boxes displays to inform you that an SP has been excluded (blocked).

As each positive result is saved to the database, a blocking message displays.



To close the informational message box, direct the mouse arrow to the OK button and left-click, or select Enter.

5.10.1 Partial Exams Requiring Repeat Pregnancy Testing

When SPs return a second day for completion of an exam (e.g., the DXA machine was down for a session), they must submit another urine sample to confirm a negative pregnancy test on the day of the partial exam. In these cases a second urine pregnancy test will appear on the heads up for the repeat visit. Laboratory staff will perform the urine pregnancy test, then send a message to the coordinator to appropriately assign the SP to pertinent component exams. Should the result of the second visit pregnancy test be positive, a UFO will be submitted in addition to notifying the clinician and the coordinator. The SP will not be assigned to any component where this is an exclusion.

5.11 Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

Read the following procedural notes to ensure the best results with the ICON® 25 hCG test kit.

ICON® 25 hCG Test

- **Dispensing Specimen.** Do not reuse a test device or use a test device for multiple patient samples or controls, as this will produce inaccurate results.
- **Color Intensity.** The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.
- **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 10 test devices be run in one batch.
- **Specimens Containing Particulate Matter.** Urine samples exhibiting visible precipitates should be allowed to settle to obtain a clear sample for testing.
- **Very dilute urine samples,** as indicated by a low specific gravity, may not contain representative levels of hCG.
- **False negative results** may occur when the levels of hCG are below the sensitivity level of the test.
- **Very low levels of hCG** (less than 50 mIU/mL) are present in urine samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed.
- **A number of conditions** other than pregnancy—including trophoblastic disease and certain nontrophoblastic neoplasms, including testicular tumors, prostate cancer, breast cancer, and lung cancer—cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
- **This Test Provides A Presumptive Diagnosis for Pregnancy.** A clinician should make a confirmed pregnancy diagnosis only after all clinical and laboratory findings have been evaluated.
- **Negative Results are Expected in Healthy Nonpregnant Women and Healthy Men.** Healthy pregnant women have hCG in their urine samples. The amount of hCG

will vary greatly with gestational age and between individuals. 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. 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 ICON® 25 hCG test** has a stated sensitivity of 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Sure-View™ hCG Urine Control Sets

These controls are formulated for use as QC specimens in the reagent verification of pregnancy test kits.

Accuracy, Sensitivity, and Specificity: ICON® 25 hCG Test

Accuracy. A multicenter clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine/serum membrane hCG test. The urine study included 159 samples, and both tests identified 88 negative and 71 positive results. The results demonstrated a 100 percent overall agreement (for an accuracy of >99%) of the ICON® 25 hCG test with the other urine/serum membrane hCG test, as shown in Exhibit 5-5.

Exhibit 5-5. Comparison of hCG tests

Kit	Possible result	Commercially available test	
		Positive	Negative
ICON® 25 hCG Urine	Positive	71	0
	Negative	0	88

Sensitivity. The ICON® 25 hCG test detects hCG at concentrations of 25 mIU hCG/mL or greater. The test has been standardized to the World Health Organization Third International Standard. The addition of 300 mIU/mL of luteinizing hormone, 1,000 mIU/mL of follicle stimulating hormone, and 1,000 mIU/mL of thyroid stimulating hormone to negative (0 mIU/mL hCG) urine/serum specimens and to positive (25 mIU/mL hCG) urine/serum specimens did not exhibit cross-reactivity in the assay.

Specificity. The following potentially interfering substances were added to hCG negative and positive samples, as shown in Exhibit 5-6. None of the substances at the concentrations tested interfered in the test.

Exhibit 5-6. Interfering substances

Substance added	Concentration (mg/dl unless noted)
Acetaminophen	20
Acetone	1,000
Acetylsalicylic Acid	20
Acetoacetic Acid	2,000
Ampicillin	20
Ascorbic Acid	20
Atropine	20
Albumin	2,000
B-Hydroxybutyrate salt	2,000
Benzoylcegonine	10
Bilirubin	20
Brompheniramine	20
Caffeine	20
Cannabinol	10
Clomiphene	100
Cocaine	10
Codeine	10
Cholesterol	500
Creatine	20
Dextromethorphan	20
DMSO	5 percent
EDTA	80
Ephedrine	20
Ethanol	1 percent
Estriol	2
Estrone 3-sulfate	10
Gentisic acid	20
Glucose	2000
Hemoglobin	1,000
Heroin	1
Ibuprofen	20
Methadone	10
Methamphetamine	10
Methanol	10 percent
Morphine	0.6
Oxalic acid	40
Phenothiazine	20
Phenylpropanolamine	20
Pregnanediol	2
Salicylic acid	20
Tetracycline	20
Triglycerides	1,200
Theophylline	20
Urea	2,000

Sure-View™ hCG Urine Controls

These controls have been designed to produce correct results in pregnancy test kits. These controls have been tested with the ICON® 25 hCG test and were found to produce satisfactory results.

5.12 Reference Ranges

Not applicable.

5.13 Action Limits

Not applicable.

5.14 Specimen Storage and Handling During Testing

A urine sample must be collected in a clean and dry container. Urine samples exhibiting visible precipitates should be allowed to settle to obtain a clear sample for testing.

5.15 Alternative Method for Performing the Test or Storing Specimens if the Test System Fails

There is no alternative method for testing.

5.16 Test Results Reporting System Protocol for Reporting Action Limits

Not applicable.

5.17 Specimen Accountability and Tracking

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

5.18 Quality Control Summary Statistics and Graphs

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

5.19 Further Reading

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6. Complete Blood Count

6.1 Introduction

A complete blood count (CBC) with automated differential is performed in duplicate on all study participants (SPs) aged 1 year and older. The CBC is performed on the Coulter® DxH 800 analyzer using the SP's EDTA blood tubes, which are obtained via the phlebotomy component.

Note: Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 3- or 4-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.

There are three Coulter DxH 800 analyzers, one for each mobile examination center (MEC). The serial numbers and system IDs are represented in Table 6-1.

Table 6-1. Coulter DxH 800 analyzers serial numbers and system IDs

DxH 800 location	Serial number	System ID	IQAP ID
MEC 1	AU36520	3770768	32979-1-B3
MEC 2	AU32459	3702621	32979-1-B2
MEC 3	AU23263	3348667	32979-1-B1

6.2 Purpose and Principle of Test

The Coulter DxH 800 analyzer is a quantitative, automated hematology analyzer for in-vitro diagnostic use in screening patient populations in clinical laboratories. The UniCel DxH 800 Analyzer provides the following: CBC, Leukocyte 5-Part Differential (Diff), Reticulocyte (Retic), and Nucleated Red Blood Cell (NRBC) on whole blood.

Note: The NHANES study does not use the reticulocyte data, and the NRBC is used only for calculating a corrected white blood cell count.

The Coulter DxH 800 analyzer measures the following parameters:

WBC	White Blood Cell count
UWBC	Uncorrected White Blood Cell count
RBC	Red Blood Cell count (for Whole Blood and Body Fluids)

Hgb	Hemoglobin
Hct	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Cell Distribution Width
RDW-SD	Red Cell Distribution Width-Standard Deviation (SD)
PLT	Platelet count
MPV	Mean Platelet Volume
NE	Neutrophil percent
LY	Lymphocyte percent
MO	Monocyte percent
EO	Eosinophil percent
BA	Basophil percent
NE#	Neutrophil absolute number
LY#	Lymphocyte absolute number
MO#	Monocyte absolute number
EO#	Eosinophil absolute number
BA#	Basophil absolute number
NRBC	Nucleated Red Blood Cell percent
NRBC#	Nucleated Red Blood Cell absolute number
RET	Reticulocyte percent
RET#	Reticulocyte absolute number
MRV	Mean Reticulocyte Volume
IRF	Immature Reticulocyte Fraction
TNC	Total Nucleated Cell (Body Fluids)

6.2.1 Coulter Method

In 1956, Wallace Coulter described the Coulter Principle as follows: A suspension of blood cells is passed through a small orifice simultaneously with an electric current. The individual blood cells passing through the orifice introduce an impedance change in the orifice determined by the size of the cell.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell passes through the aperture, it momentarily increases the resistance of the electrical path between the submerged electrodes on either side of the aperture. This causes a measurable electronic pulse. For purposes of counting, the vacuum used to pull the diluted suspension of cells through the aperture must be at a regulated volume. The number of recorded pulses indicates particle count, and the size of the electrical pulse is proportional to the cell volume. In addition, the system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count, which reduces the odds of statistical error approximately 10 times.

6.2.2 VCSn Technology

Historically, Beckman Coulter analyzers housed a flow cell in a Triple Transducer Module (TTM), which was first introduced commercially in the 1980s. The TTM flow cell was the location for detection of the processed samples. The TTM produced three measurement signals—volume, conductivity, and light scatter.

The DxH 800 system replaces the TTM with the Multi-Transducer Module (MTM), which measures additional multiple angles of light scatter, a major improvement over the single light scatter measured by the TTM. All Diff, NRBC, and Retic analysis occurs in the Volume Conductivity and Scatter properties module. The VCSn module is responsible for controlled sample preparation and delivery of the prepared sample to the flow cell for analysis of the WBC differential, reticulocyte, and NRBC. The VCSn module includes the Air Mix and Temperature Control (AMTC) and the MTM.

In the flow cell, low-frequency direct current measures volume, while high-frequency (RF) current senses cellular internal content through measuring changes in conductivity.

The MTM uses a flow cell to pass particles through a sensing zone, one particle at a time, and a diode laser to illuminate the particles. The illuminated particles both scatter and absorb a portion of the incident light. Sensors strategically placed around the flow cell collect the scattered light of interest. An additional sensor placed in the laser path measures the amount of light removed due to light scatter and absorption. This measurement is called axial light loss.

6.2.3 Dataplot Development

The technician performs a series of operations on the stored digital raw values received from the flow cell to identify populations and calculate the frequency of cells within each population. The system produces the dataplot displays for visual representation of the differential, NRBC membership (types of cells), and density (concentration).

The DxH 800 system algorithm uses tools designed for finding optimal separation between overlapping clusters of data.

The algorithm can:

- Adapt to unusual population shifts and overlaps;
- Define highly irregular separation;
- Make subsequent analysis of the identified regions; and
- Correct deficiencies in separation.

In the dataplots, different colors represent different memberships. Shades of colors represent density: dark colors for low density and bright colors for high density, as shown in the following listing (see Section 6.19.4 for examples):

NRBC analysis		Diff analysis	
NRBC	Red	Lymphocyte	Blue
Other*	Green	Monocyte	Green
WBC	Blue	Neutrophil	Purple
		Eosinophil	Orange
		Basophil	White
		Non-White Cell	Red

* Others include RBC debris, PLT debris, etc.

6.2.4 Parameter Measurement, Derivation, and Calculation

Exhibit 6-1 lists each reportable parameter and the method used to obtain the results. A description of the method is also included.

Exhibit 6-1. Reportable parameters and analysis methods

Parameter (reporting units in US-1 format)	Method	Description
WBC	Coulter Principle	White Blood Cell Count or Leukocyte Count <ul style="list-style-type: none"> • Measure directly, multiplied by the calibration factor. • Corrected for interference if necessary. If no correction is required, then $WBC = UWBC$. • $WBC = N \times 10^3 \text{ cells}/\mu\text{L}$.
UWBC	Coulter Principle	Uncorrected White Blood Cell <ul style="list-style-type: none"> • Measure directly, multiplied by the calibration factor. • $UWBC = N \times 10^3 \text{ cells}/\mu\text{L}$.
RBC	Coulter Principle	Red Blood Cell Count or Erythrocyte Count <ul style="list-style-type: none"> • Measure directly, multiplied by the calibration factor. • Corrected for very high white count if necessary. • $RBC = N \times 10^6 \text{ cells}/\mu\text{L}$.
Hgb	Photometric Measurement	Hemoglobin or Hemoglobin Concentration <ul style="list-style-type: none"> • Transmittance of light at 525 nm through a lysed WBC solution in the Hgb cuvette, compared to the transmittance of the same light through a reagent blank. The system converts this ratio to the Hgb value using a calibration factor. • Weight (mass) of Hgb determined from the degree of absorbance found through photo current transmittance expressed in g/dl. • Corrected for WBC interference. • $Hgb \text{ (g/dl)} = [\text{constant} \times \log^{10} (\text{Reference \%T}/\text{Sample \%T})]$.
Hct	Calculated	Hematocrit <ul style="list-style-type: none"> • The relative volume of packed erythrocytes to whole blood. • $Hct (\%) = RBC \times MCVV^{10}$.
MCV	Derived from RBC Histogram	Mean Corpuscular Volume <ul style="list-style-type: none"> • The average volume of individual erythrocytes derived from the RBC histogram. • The system multiplies the number of RBC in each channel by the size of the RBC in that channel. The products of each channel between 36 and 360 femtoliters (fL) are added. This sum is divided by the total number of RBC between 36 and 360 fL. The analyzer then multiplies by a calibration factor. • Corrected for WBC interference. • Expressed in fL.

The DxH 800 system includes a Specimen Processing Module (SPM), a Pneumatic Supply Module (PSM), and a system manager (SM), precisely integrated to provide process control, data consolidation, and cassette or single-tube delivery of specimens.

6.3 Components of DxH 800

6.3.1 The Specimen Processing Module

The SPM is made up of the following functional modules:

- **Specimen Transport Module (STM).** The STM automatically transports specimens, delivering closed-vial and open-vial specimens, which accommodates a wide range of specimen tubes. The STM supports the following:
 - Operator loading and unloading of specimens;
 - Transport and queuing of specimens;
 - Mixing and presentation of specimens; and
 - A magnetic transport system to move cassettes containing specimens.
- **Sample Aspiration Module (SAM).** The SAM aspirates from capped specimen tubes (presented via cassette or single-tube presentation) or open vials (single-tube presentation). Body fluids are presented via single-tube, while whole bloods can be presented in either presentation mode. The identification and integrity of samples are verified prior to delivery and transfer to the analytical modules within the system. The SAM design provides for two methods of sample delivery: sample segmentation and sample dispensing. In sample segmentation, aspirated sample is transferred through the Blood Sample Valve where it is segmented for whole blood CBC and body fluid. In sample dispensing, whole blood sample segments are dispensed via the aspiration probe into the mixing chambers on the AMTC for the WBC differential and NRBC analyses.
- **VCSn Module.** The VCSn module provides the physical processing elements necessary for the differential and NRBC sample preparation and subsequent measurement. This module includes the Distribution Valve (DV), AMTC module, MTM and their associated electronics and fluidics. Samples prepared at the AMTC are delivered to the MTM where the sample detection occurs.
- **CBC Assembly.** The CBC Assembly provides the physical processing elements necessary for CBC sample conditioning (combining of reagents and the sample segment, mixing, and incubation) and measurement via the aperture bath assemblies, the Hgb assembly, and the electrical signal conditioning circuits.
- **Common Services Consist of the Electronic Supply Module, Pneumatic Services, and Reagent Services (Supply and Distribution).** Common services provide and monitor electronic power and supplies, and monitor the reagent and waste levels as well as the pressure and vacuum.

6.3.2 The System Manager

The DxH 800 SM is responsible for the following:

- Controlling processes, such as analytic and diagnostic procedures;
- Producing test results; and
- Managing data, such as test ordering, result, review and release, quality control, LIS interface, logging, and report generation.

The SM includes an LCD flat panel monitor with touchscreen capability, a computer with a CD/DVD RW drive running Microsoft Windows operating system, the DxH 800 software, a standard keyboard, and an optical mouse.

6.3.3 Pneumatic Supply Module

The PSM supplies vacuum and pressure to the SPM.

6.4 Special Safety Precautions

All specimens may be potentially positive for infectious agents, including HIV and Hepatitis B and C viruses. Observe standard precautions and any additional personal protective equipment requirements in place. **It is mandatory to wear gloves and a lab coat when handling all human blood products and Coulter controls.** Dispose of all biological samples in a biohazard container and wipe down all work surfaces with an approved disinfectant at the end of each appointment block. Clean all spills immediately and with an approved disinfectant. For additional requirements during the COVID-19 pandemic, refer to the NHANES COVID-19 Mitigation Protocols. Certain troubleshooting procedures on the Coulter require the use of a 5 percent – 6 percent bleach solution. The MEC supply of bleach is an 8.25 percent solution. To make 20 mL of a 5 percent – 6 percent bleach solution using the 8.25 percent bleach, add 5.5 mL of DiH²O to 14.5 mL of the 8.25 percent bleach solution.

The MEC Working Safely with Hazardous Chemicals manual contains all Coulter safety data sheets (SDS).

6.5 Digital Interface with the Integrated Survey Information System (ISIS)

The DxH 800 SM transmits individual SP results to the MEC automated ISIS system. All SP results are reviewed at the DxH 800 SM monitor.

The ISIS hematology module in the laboratory application automatically receives the results, or results are transmitted manually to the hematology module. The laboratory application evaluates the data for completeness and accuracy. The final decision to accept or reject a result is the responsibility of the clinical laboratory scientist.

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

6.6 Specimen Collection and Preparation

6.6.1 Specimen Collection

- The phlebotomist collects a 3- or 4-ml K₂ EDTA (ethylene diamine-tetracetic acid) tube, used for a CBC on all SPs aged 1 year and older, following the established venipuncture protocol and procedures. (A 1%–2% dilution effect occurs in this liquid EDTA tube.)
- Sample volume is 165µL of whole blood in the closed-vial mode or the single tube presentation mode. The minimum sample volume per tube in the closed-vial mode is 1-ml with the proper proportion of blood to anticoagulant.

6.6.2 Specimen Preparation

For SPs 1–2 years old, the K₂ EDTA blood sample is shared between blood processing and hematology. The shared EDTA blood tube is processed by the clinical laboratory scientist working in the blood specimen-processing workstation first by taking off whole blood required for various tests in the SP's profile, including the metal tests. This prevents any potential metal contamination from the Coulter needle. The clinical laboratory scientist working in the blood specimen-processing workstation places the specimen on a rocker until the clinical laboratory technologist working in the

hematology workstation can perform the CBC. The CBC should be run as soon as possible; there is no requirement to wait any length of time between drawing the blood and running the CBC.

- There is a dedicated tube drawn for the CBC on SPs aged 3 years and older.

6.7 Procedure for Microscopic Examination

Not applicable. Do not prepare differential microscopic slides.

6.7.1 Reagents and Supplies

DxH reagents, including storage and handling requirements, are listed below.

- Coulter DxH diluent (store at 2–40°C)
 - Coulter DxH diluent is shipped in ready-to-use containers.
 - Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
 - Coulter DxH diluent is a cyanide-free, isotonic-buffered saline solution.
 - Coulter DxH diluent dilutes the specimen, is used for rinsing SPM components between sample analyses, and provides a sheath stream to transport the specimen through the flow cell.
- Coulter DxH Lyse reagent (store at 2–40°C)
 - Coulter DxH Lyse reagent is shipped in ready-to-use containers.
 - Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
 - Coulter DxH Lyse is a cyanide-free, CBC lytic reagent that lyses red blood cells for the white blood cell count and works in conjunction with Coulter DxH diluent to generate a stable hemoglobin measurement.
 - Coulter DxH Cell Lyse is also used to lyse the red blood cells and discriminates nucleated red blood cells from white blood cells.

- Coulter DxH Diff Pack (store at 2–25°C)
 - Coulter DxH Diff Pack is shipped in ready-to-use containers.
 - Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
 - The Coulter DxH Diff Pack consists of the Erythrolyse Lytic reagent and StabiLyse Preservative reagent.
 - The Erythrolyse Lytic reagent is a cyanide-free lytic reagent that dilutes the blood sample and lyses red blood cells in preparation for white blood cell measurement in the flow cell.
 - The StabiLyse Preservative reagent neutralizes the Diff lytic reagent and preserves the white blood cells for measurement in the flow cell. Together, Erythrolyse and StabiLyse provide the five-part differential.
- Coulter DxH cleaner (store at 2–25°C)
 - Coulter DxH cleaner is shipped in ready-to-use containers.
 - Opened containers are stable for 3 months. Do not use this product beyond the expiration date.
 - DxH cleaner is a cyanide-free, aldehyde-free cleaning agent that degrades residual materials so that they may be flushed from the system with diluent.

Note: If any Coulter DxH reagent has been partially or completely frozen, allow the product to warm to room temperature. Mix product by gentle inversion prior to placement on the instrument.

DxH controls, including storage and handling requirements, are listed below:

- Coulter 6C cell control (store at 2–8°C)
 - The Coulter 6C cell control is an integrated control that enables monitoring of system performance and calibration status for all directly measured and calculated CBC, Diff, and NRBC parameters. Instructions for use are as follows:
 - Remove 6C cell control vials from refrigerator and warm at ambient temperature for 10 to 15 minutes.
 - Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll between the palms of the hands eight times. Then gently invert the tube eight times. Repeat.

- Run the controls in the cassette presentation on the instrument.
- Return the control tubes to the refrigerator within 30 minutes.
- The Coulter LIN-X Linearity control (store at 2–8°C) is recommended for verification of the reportable range and linearity, and for calibration assessment of the WBC, RBC, HGB, and PLT parameters.
 - When analyzing LIN-X Linearity Controls patient flags will occur. These flags should be ignored if a numerical result is obtained. When voteout (- - - -), incomplete computation (.....) or over range (+++++) flags occur, the sample should be repeated. Some levels may generate a non-blood (N) flag. DO NOT ignore System messages (R).
 - Remove Coulter Lin-X cell control vials from refrigerator and warm at ambient temperature for 15 minutes.
 - Ensure there is sufficient reagent to complete the analysis.
 - Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll between the palms of the hands eight times. Then gently invert the tube eight times. Repeat mixing procedure three times. Temporarily disable the NRBC module.
 - Run the Lin-X cell controls in consecutive order beginning with Level 0 and ending with Level 11. Run controls in cassette presentation on the instrument.
 - Level 11 is used to clean the system. The values for this level are not recorded.
- How to run linearity in the MEC:
 - Run each level under a separate repeatability—this is useful since it will calculate the mean for that level of Lin-X.
 - Print out the summary report for each level of Lin-X.
 - Write the level number on the top of each summary report.
 - Document all values on the Coulter Lin-X Control Worksheet. Do not forget to record the kit lot number on the worksheet. This number is different from the lot number for each of the tubes.
 - Send worksheet, package insert, and summary reports in the end of stand box to the Lab Component Lead at the home office in Rockville, MD.

- Coulter Latron CP-X control (store at 2–30°C) is recommended for the verification of the system calibration status of the VCSn parameters. Coulter Latron CP-X control checks the alignment of the laser and the flow cell on the DxH 800.
 - Perform daily checks prior to running Latron control.
 - Gently mix Latron CP-X control by inversion five to eight times. Avoid foaming.
 - Run the controls in the cassette presentation on the instrument.
- Coulter S-CAL[®] Calibrator is traceable to reference methods and recommended for determining adjustment factors to ensure accurate SPM measurements of directly measured CBC parameters. Calibrator results should be monitored with Coulter 6C cell control.
 - Remove S-CAL from the refrigerator and warm at ambient temperature for 15 minutes.
 - Roll the tube slowly between the palms of the hands eight times in an upright position.
 - Invert the tube and slowly roll between the palms of the hands eight times. Then gently invert the tube eight times. Repeat.
 - Inspect the tube contents to determine if all cells have been uniformly distributed. Repeat the mixing procedure if contents have not been uniformly distributed.
 - Complete entire procedure within 1 hour.

6.7.2 DxH 800 Supplies

- 3-ml K₂ EDTA BD Hemogard Vacutainer[®] tube;
- 4-ml K₂ EDTA BD Hemogard Vacutainer[®] tube;
- Tube rocker;
- Bleach, 8.25 percent sodium hypochlorite;
- Bottled deionized water;
- Plastic squirt bottle;
- Cotton gauze pads;
- Three-hole paper punch;

- Notebook;
- Flashlight;
- Precision screwdriver set; and
- CD-RW.

6.8 Shutdown of DxH 800 System

The DxH 800 SPM, SM, and monitor are connected to an uninterruptible power supply. In the event of a power outage at your facility, the components will continue to operate for a short time so that you can shut down the system. The printer is connected to the back-up power supply. Shut down the SM as follows:



- Shut down the operating system by using the routine Windows application.
- Power off the computer. Powering off the computer also powers off the monitor. You do not need to power off the monitor separately. The computer does not need to be shut down on a routine basis. Power off the computer only when circumstances deem it necessary.

6.8.1 Daily Shutdown

Beckman Coulter recommends that the SPM remain in cleaner for at least 30 minutes every 24 hours. If the SPM has power and is in Shutdown but the pneumatics are off, automatic cycling occurs every 24 hours to prevent flow cell and sample line clogging.

- Shutdown can be initiated manually or automatically.
- Shutdown removes diluent from the UniCel DxH 800 and replaces it with cleaner.
- At the end of the time with cleaner, the cleaner is replaced with diluent. Then, the compressor automatically shuts off.

6.8.2 Shutdown at the Mobile Examination Center

- Shutdown will be set automatically.
 - Select Calendar icon on top of DxH monitor screen.
- From the Daily Checks screen, select the Shutdown button to display the Manual Shutdown dialog box.
 - Select Autoconfiguration at the bottom of the screen.
 - Select Configure Shutdown.
 - Check Enable Automatic Shutdown: Fill in hour **07**, Min **00**.
 - Daily.Coulter.
 - Make sure each of the 7 days is checked.
 - Time in cleaner **0** Hour(s) **30** Minutes.
 - Select OK.
- Daily Checks (formerly known as StartUp) (Menu>QA>Daily Checks) are programmed to immediately follow the StartUp.
 - Select Autoconfiguration at the bottom of the screen.
 - Select Configure Daily Checks.
 - Check Enable Automatic Daily Checks.
 - Choose radio button Perform Daily Checks after Shutdown.
 - Select OK.
- Latron CP-X control should be run immediately following daily checks.

6.8.3 Cancel Automatic Shutdown

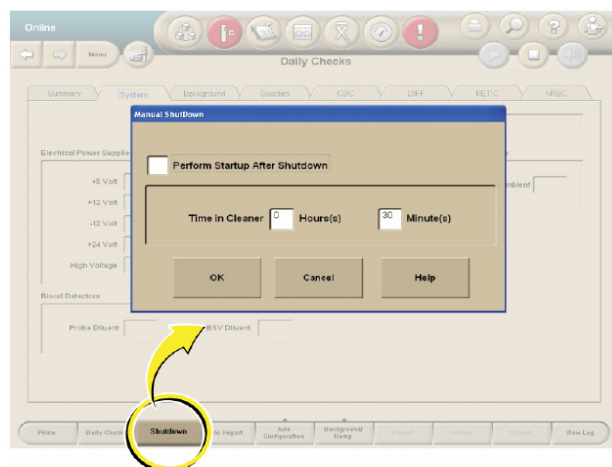
At certain times, automatic shutdown will have to be cancelled. To cancel automatic shutdown:

- From the Daily Checks screen, select Auto Configuration.
- Select Configure Shutdown.
- Remove the checkmark from the Enable Automatic Shutdown box.

To perform a manual shutdown when Auto Configuration is disabled, see the information that follows (Section 6.8.4).

6.8.4 Manual Shutdown of DxH Units

- From the Daily Checks screen, select the Shutdown button to display the Manual Shutdown dialog box.



- Select the Perform Startup After Shutdown check box to automatically begin Daily Checks after shutdown.
- Type in Time in Cleaner 0 Hours and 30 Minutes check boxes to determine the time in cleaner.
- Select OK to begin shutdown or Cancel to exit the pop-up window without starting shutdown.

6.9 Log On as User

Logging on to the SM:



- Type your user name.
- Type your password. If you forgot it, ask one of the senior techs to reset it for you.

6.9.1 Entering New Operator

- Select Menu button in the upper-left corner of the DxH 800 screen.
- Then select **Setup** button.
- Select **Operators and Roles** button.
- Select **New Operator** button, enter all information. HINT: Do not enter the password you want to use; the first time you sign on you will be asked to change your password. Under operators access you need to select Level 3 to do all tasks on the DxH 800.

6.10 Run Daily Checks

- Select the Daily Checks button (Calendar icon) from the top of any screen to display the Daily Checks Summary screen with results of the most recent Daily Checks.
- Obtain printout of Daily Checks from printer, initial as “Reviewed by” and place in Hematology Log Book.
- If Daily Checks passed all criteria, run Latron Control.
- Running Daily Checks manually if Automatic Daily Check failed:
 - Select the Daily Checks button (Calendar icon) from the top of any screen to display the Daily Checks Summary screen with results of the most recent Daily Checks.
 - Select the Daily Checks button at the bottom of the screen. A DxH 800 dialog box displays the following:

“Are you sure you want to start a Daily Checks procedure?” Press OK to continue.

Select OK to run Daily Checks or select Cancel.

6.10.1 Daily Checks Screen

- The results of Daily Checks display on eight tabbed views: Summary (default view), System, Background, Supplies, CBC, Diff, Retic, and NRBC.
- When Daily Checks pass, the Daily Checks icon is neutral. Select the individual tabs to view those results.

If any of the Daily Checks do not pass, the following occurs:

- The Daily Checks icon is red.
- The problematic result is backlit in red on the Summary tab.
- The tab that contains the problematic result has a red indicator.
- If there are any failures, you must Review Daily Checks (Event Logs>General tab) to proceed with further analysis.
- The Daily Checks must pass or be reviewed in order to run specimens.
- From any tab on the Daily Checks screen, select the Review button on the local navigation bar to indicate that the Daily Checks results have been reviewed.

Note: If Daily Checks pass, the Review button is disabled.

- You have to review only results that are questionable.
- Document on the Troubleshooting Log any action taken to troubleshoot the Daily Checks failure.

6.10.2 Additional Tasks From the Daily Checks Screen

- Select the Histogram button at the right of the screen on the Diff, Retic, or NRBC tabs to display the VCSn Ramp Tests Histogram screen.

Note: The VCSn Ramp Tests Histogram screen is not for routine use; however, you may at some time be asked to access this screen when on the phone with a Beckman Coulter representative.

- Prime the SPM.
- Prime provides a method to remove cleaner in case an error occurred during a shutdown cycle.
- Select the Prime button at the bottom of the Daily Checks screen to prime the SPM.
- A DxH 800 dialog box will display the following message: “You have requested to perform a Prime Cycle.”
- Select OK to continue or Cancel.

6.11 Quality Control

- Quality control is the routine monitoring of performance and service using commercial or patient controls.
- Controls have known characteristics when run on a given system and are analyzed periodically in the same manner that patient specimens are analyzed.
- The results of analyzed controls are then compared to the known characteristics using statistical methods.
- This comparison allows changes in the SPM performance to be detected.
- You can then take some action if the changes detected are significant.

6.11.1 Frequency of Performing Quality Control

- Beckman Coulter 6C cell control will be run at the beginning (8:30 am before SPs are processed), mid-point (1:30 pm), and at the end of each session (either 6:30 pm or 9:30 pm depending on the schedule). The time of the first run of the day of the 6C control QC performance is set to follow the preprogrammed Daily Checks of the analyzers and after the Latron run. After the QC has successfully passed and all parameters are within limits, the Start of Session QC tab must be updated to reflect successful performance of Beckman Coulter 6C controls.
 - According to the manufacturer, each tube can be aspirated from 18 times within 16 days. The clinical laboratory scientist in WS 3 will record each time the QC vial is aspirated using the Coulter 6C Cell Control Open Vial Stability Monitoring Log (Exhibit 6-2). The clinical laboratory scientist in WS 3 will record why the QC was analyzed (QC run completed AM/PM/EVE, Precision Check, Concurrent Lot Testing, or Troubleshooting) and their initials each time the control or controls are analyzed. The header of the document will also be completed with pertinent information. The document will be housed on the WS 3 computer until completed and then sent to the Laboratory Component Lead as part of the end-of-stand QC.
 1. The same tray of the current lot number in use of 6C controls should be used until one or more levels of the QC have been analyzed the maximum number of times (18 occurrences in 16 days). Once one or more levels of the QC have been injected the maximum number of times, the *entire tray should be discarded* and a new tray should be used.
 2. If the 6C controls do not pass at the end of the session, troubleshooting will be performed. Once the QC passes, the CBC's for the session will be repeated. The results of the repeated CBCs will be sent to the Laboratory Component Lead for precision analysis and consultation with the Laboratory Director for a determination of notification of SPs with results not meeting the precision calculations.

Note: The clinical laboratory scientist in WS 3 must be very careful not to use all of the sample from any of the SP's for the session as primes.

Samples from a previous session should be used whenever possible.

Exhibit 6-2. Coulter 6C cell control open vial stability monitoring log

COULTER 6C CELL CONTROL OPEN VIAL STABILITY MONITORING LOG*																					
STAND #		STAND LOCATION						MEC #													
TEAM #		COULTER SYSTEM ID																			
LOT #		BOX EXP. DATE						BOX OPEN DATE													
*Coulter 6C Cell Control has an open vial stability of 18 events over 16 days																					
		EVENTS		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
P A C K # 1	Set # 1	Level 1	Run																		
	Open Date:		Initials																		
	Set # 1	Level 2	Run																		
	Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
P A C K # 2	Set # 2	Level 1	Run																		
	Open Date:		Initials																		
	Set # 2	Level 2	Run																		
	Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
P A C K # 3	Set # 3	Level 1	Run																		
	Open Date:		Initials																		
	Set # 3	Level 2	Run																		
	Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
P A C K # 4	Set # 4	Level 1	Run																		
	Open Date:		Initials																		
	Set # 4	Level 2	Run																		
	Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
RUN																					
✓A	QC Run Completed AM																				
✓P	QC Run Completed PM																				
✓E	QC Run Completed EVE																				
P	Precision Check																				
CT	Concurrent Lot Testing																				
T	Troubleshooting																				
When one or more levels reaches 18 events, discard all 3 levels. Open a new set of QC to run start of session QC.																					

- Beckman Coulter 6C cell control is run in the cassette mode on the DxH analyzers.
- Beckman Coulter Latron CP-X control is run once each 24 hours following Daily Checks on the instrument and is run in the cassette mode on the DxH analyzers.
- Beckman Coulter Lin-X will be run once per year or at high elevation stands.
- Calibration with S-CAL will be performed at the start of every stand or when recommended to troubleshoot a problem.

6.11.2 Setting Up a Control File

- Entering 6C cell control lot numbers and expiration dates.
- Menu>QA>QC>More Options>QC Setup>New Control from Barcode>*Scan the 6C Cell Insert Barcode*>Select ALL & Auto Transmit>Select OK.

6.11.3 Setting Up a Latron Control File

- Entering Latron control lot numbers and expiration dates.

Menu>QA>QC>More Options>QC Setup>New Control from Barcode>*Scan the Latron Insert Barcode*>Select ALL & Auto Transmit>Select OK.

6.11.4 Establishing Means and Standard Deviations (SDs) for Quality Control Material

- To be effective and evidence based, quality control ranges should be:
 - Developed using performance, bias, and precision of the test method;
 - Specific to the Coulter DxH 800, control level, and individual parameter; and
 - Designed to identify issues with the Coulter DxH 800.
- Manufacturer-assigned values should be used as a guide. Actual values for the mean and SD must be established by repeated testing on the instrument in the MEC where the data/information will be implemented. The mean should fall within the range published by the control manufacturer. Coulter's Hematology Interlaboratory Quality Assurance Program (IQAP) provides useful measures of the means and SDs observed in other laboratories using the Coulter DxH 800.
- At the start of a stand, use the manufacturer control published mean and SD until 20 runs have been performed on the control. After the 20 runs are completed, follow the steps below to establish the instrument-specific mean and SD for each level of the control.
- Procedure for establishing means and standard deviation (SD) requirements:
 - Analyze the new control a minimum of 20 times across multiple days. Testing conditions should mimic routine testing as closely as possible.

- View the mean and SD of the parameters using the QC menu on the DXH 800. Reviewing the Levey-Jennings plots for each of the parameters may identify drifts or shifts in the results over time, or a highly deviant result (see 6.11.10 for Levey-Jennings graph information). If no pronounced drifts, shifts, or outliers are seen, use the 20 data points to establish the mean and SD for the instrument (see Exhibit 6-3 for examples). Since the MEC laboratory runs multiple controls per day, the long-term SD may be underestimated and will need to be monitored.
- This mean should be within the range stated on the control assay sheet and is considered the established target value.
- Incorporate the SD range around the established target value and monitor throughout the dating of the product. Long-term sources of variability in the SD include different reagent bottles or lots, preventive maintenance, component replacement, and environmental factors.
- The mean and SD measurements should be monitored and updated once sufficient data is collected.
- When using the Coulter 6C assigned value or an instrument-specific mean, the instrument is considered well maintained and operating correctly if: (1) greater than or equal to 95 percent of the QC values fall within the EXPECTED RANGE of the Coulter assigned values, (2) QC values do not trend outside of the EXPECTED RANGE, and (3) control results with system messages and review flags, R, can be accepted except for the specific system event messages that indicate a hardware parameter is out of limit for some item such as voltage, temperature, or pressure.
- It is important to re-evaluate the criteria after a full lot of data has been compiled, and continue to evaluate on an ongoing basis to ensure that the control ranges are appropriate.

6.11.5 To Change the Mean and Standard Deviation (SD) on the Coulter

- Enter the QC menu selecting Data View.
- On the bottom of the screen, select More Options.
- Select QC Setup.
- Select Edit Control.
- Select Parameters.
- Edit the values needed and select Save.

- When given the option, select “Do not delete all runs.”
- **Changes to means and SDs or calibration factors should only be made after consultation with the Laboratory Component Lead (Technical Consultant).**

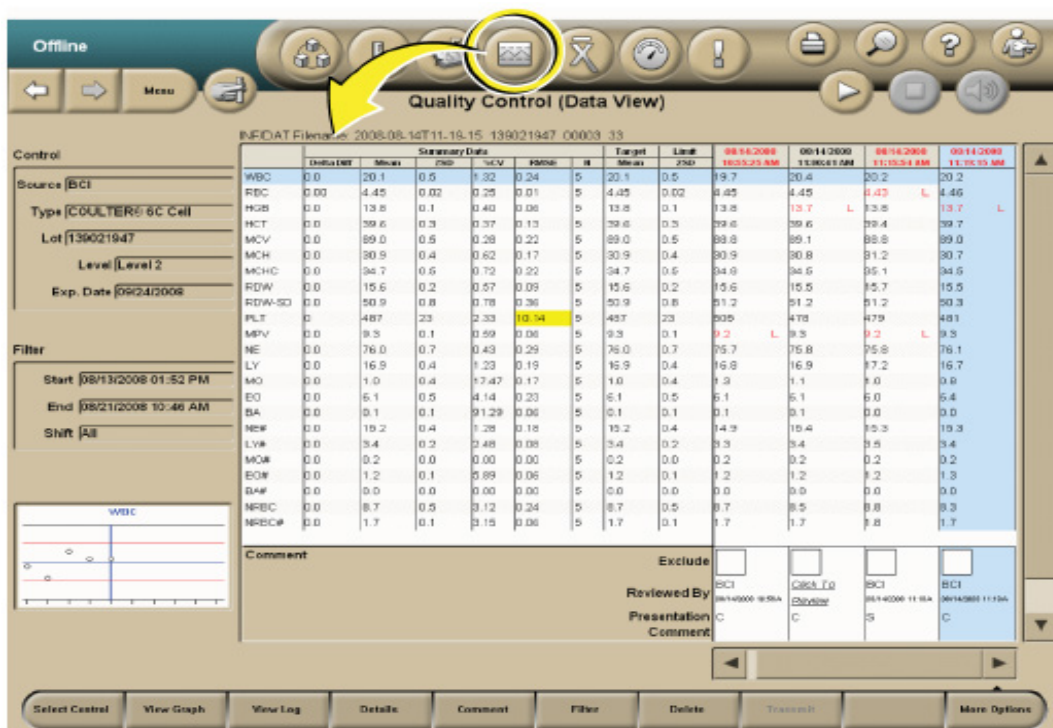
6.11.6 What to do When a Control is Out of Range

- When a commercial control is out of range:
 - Ensure that the control material was mixed properly. If not, mix it according to the package insert.
 - Verify that the control was identified properly. If using a barcode reader, ensure that the barcode labels are clean and positioned correctly. If entering the ID manually, ensure that you typed the correct information.
 - Verify that the assigned setup information (assigned values and expected ranges) matches either the control package insert or your labs’ established values. If they do not, contact a senior technologist to change the control’s information to match.
 - If the problems above are ruled out, rerun the control to ensure that the problem was not a statistical outlier.
 - Ensure that the control material was not contaminated by running another vial or level of control.
 - Ensure that there are no errors during the cycle. If necessary, call Beckman Coulter for help in resolution.
 - Exclude the results on any out-of-range control by checking the Exclude box when reviewing that control.
 - Document action taken in the comment tab on the Coulter screen of affected control and the Troubleshooting Log.
- When Latron QC is out:
 - Ensure that the control setup information (assigned values and expected ranges) matches the package insert. If it does not, change the control information to match the package insert, then rerun the control.
 - Ensure that the Latron control is not contaminated, is properly mixed, is not expired, and you have a sufficient volume of sample.

- If necessary, use a new vial of control. Be sure to mix it according to the directions listed above.
- Ensure that the flow cell is clear by performing the flush flow cell procedure.
- Rerun the control. If the control is still outside the expected ranges, call Beckman Coulter.
- Document action taken in the Comment tab on the Coulter screen of Latron Control and in the Troubleshooting Log.
- Check the Exclude box on any Latron results that are out of range.

6.11.7 Viewing Control Files – Data View (Menu>QA>QC)

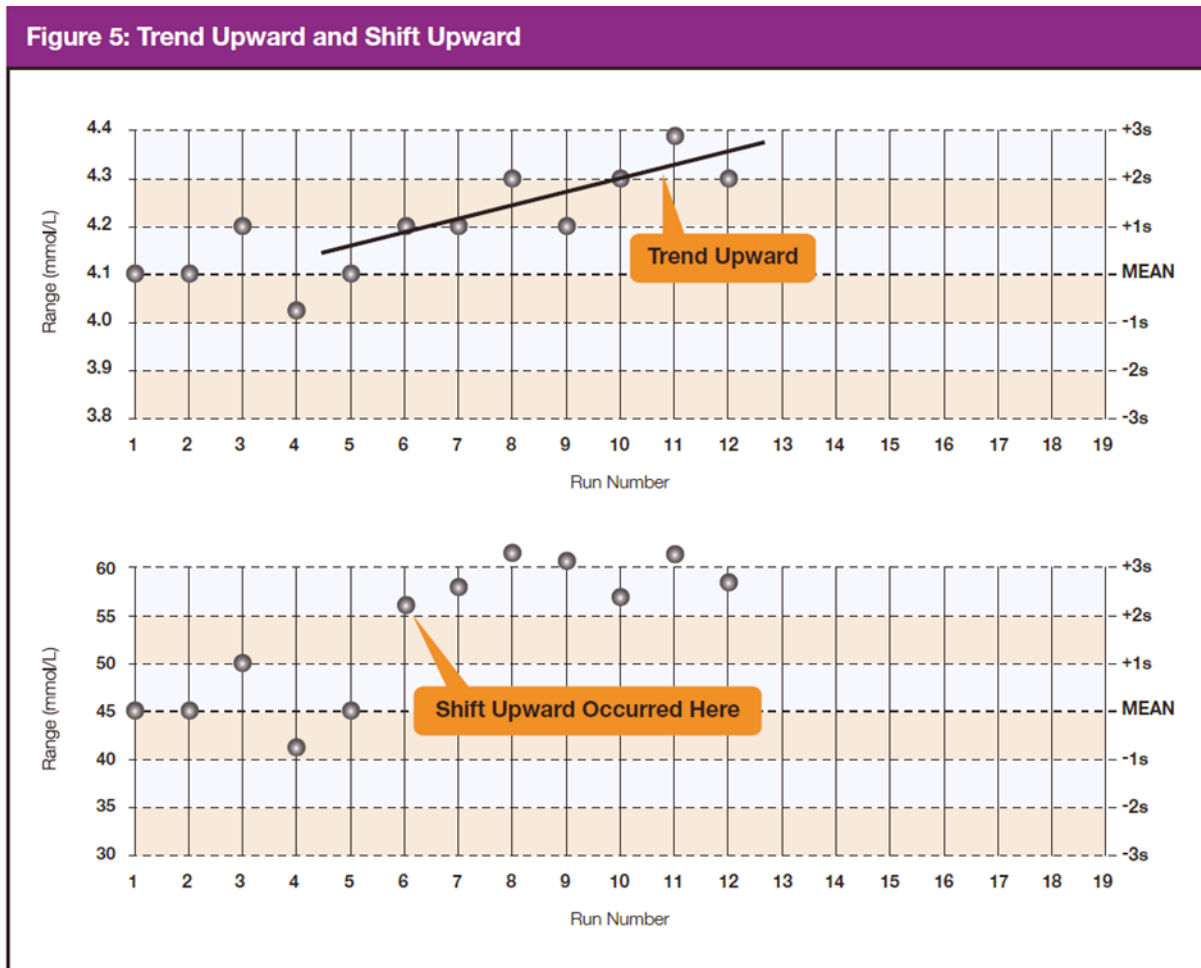
- To view control files on the Quality Control (Data View) screen, select the QC Status icon at the top of any screen.



- The Quality Control (Data View) screen displays the most recently analyzed control lot with the most recently analyzed run selected by default.
- If controls have not been reviewed, a dialog box displays a list of them.
- Out of control data as well as the date and time are displayed in red text.

- The Quality Control (Data View) screen includes summary data, configuration data, a filter section, QC run data, run status, and one thumbnail Levy-Jennings graph for the selected parameter (row).
- The chief clinical laboratory scientist will review QC on a weekly basis looking for any outlier results using the Westgard rules listed below. See examples of trends and shifts in QC data (Exhibit 6-3).

Exhibit 6-3. Examples of trends and shifts in QC data



Exhibits 6-4 through 6-8 present the Westgard rules as mentioned earlier.

Exhibit 6-4. Westgard Rule 1_{2s}

Rule 1_{2s}. A single control measurement exceeds 2 standard deviations (SD) of control limits either above or below the mean. This rule is used as a warning rule to trigger careful inspection of the control data.

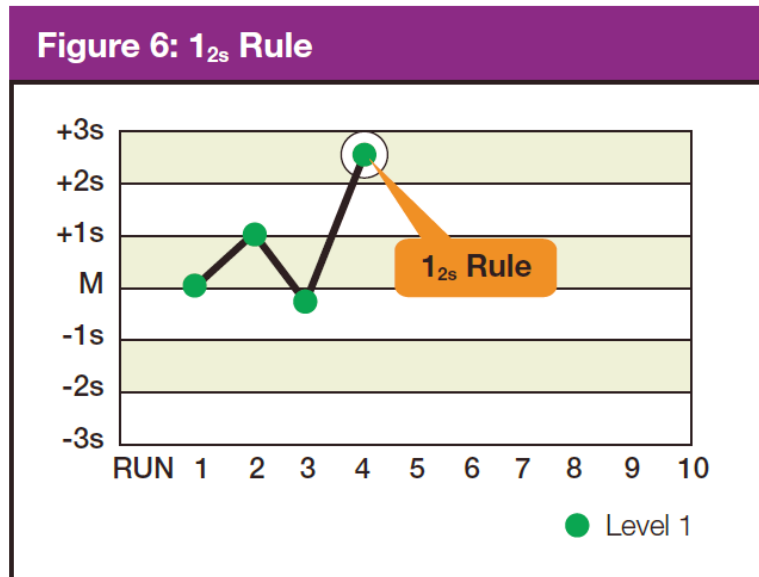


Exhibit 6-5. Westgard Rule 1_{3s}

Rule 1_{3s}. Identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC outside ± 3 SD violates this rule. A run is rejected when a single control measurement exceeds the mean ± 3 control limits.

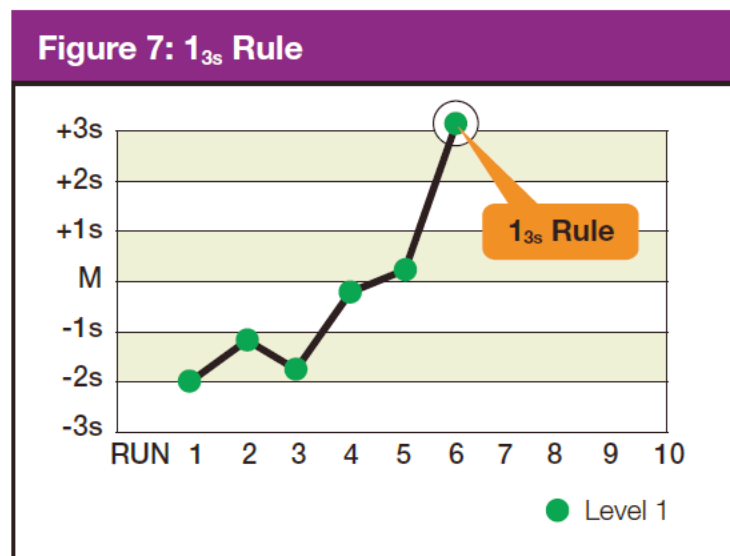


Exhibit 6-6. Westgard Rule 2_{2s}

Rule 2_{2s}. There are two rejection criteria for this rule: two consecutive QC results that are greater than 2 SD that are on the same side of the mean. Violation within the run indicates that systematic error is present and that it potentially affects the entire analytical curve. Violation across the run indicates that only a single portion of the analytical curve is affected by the error. The control run is rejected when two consecutive control measurements are greater than 2 SDs of control limits on the same side of mean within or across the run, with this rule.

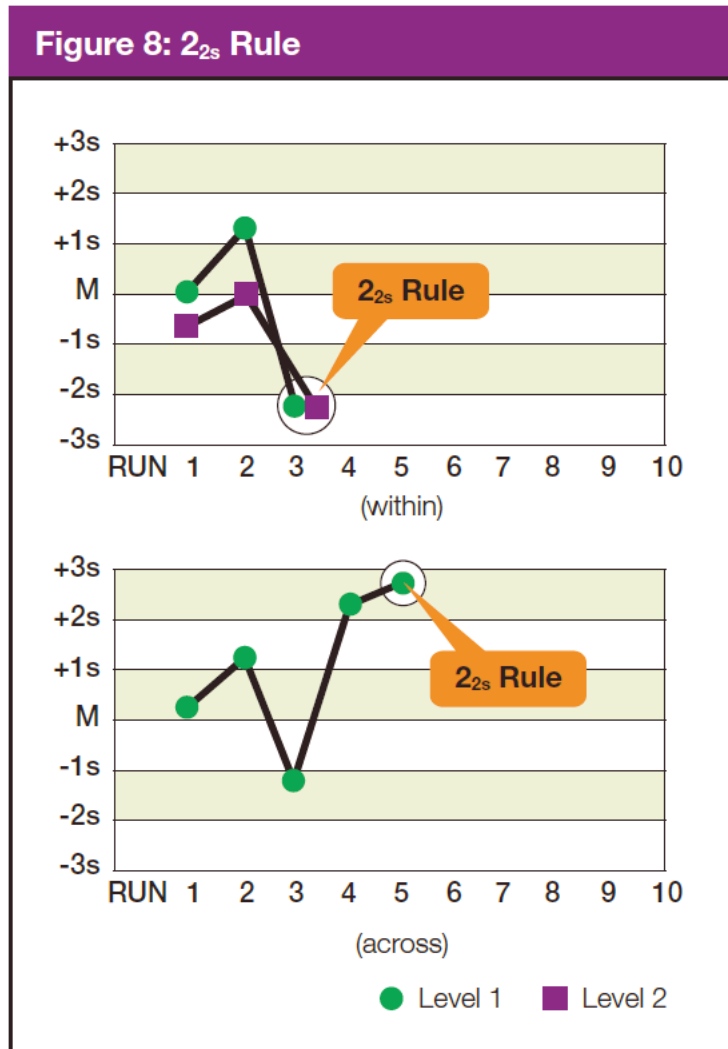
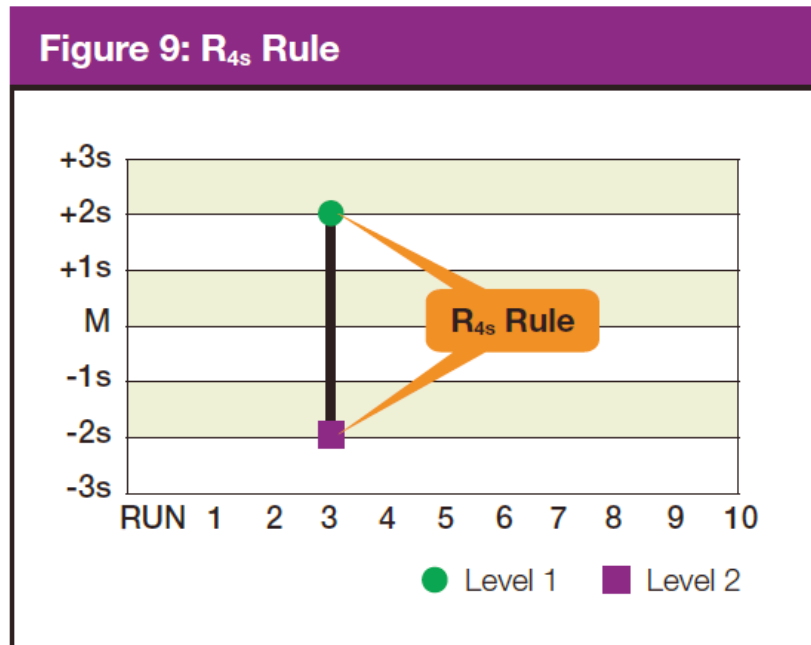


Exhibit 6-7. Westgard Rule_{4s}

Rule_{4s}. This rule rejects a run if there is at least a 4 SD difference between control values within a single run. For example, Level 1 control is + 2.9 SD above the mean and Level 2 is -1.4 SD below the mean. The total difference between the two control levels is greater than 4 SD. This rule identifies random error and is applied only within the current run.



Note: Violation of any of the following rules does not necessarily require rejection of the **analytical** run. These violations typically identify smaller systematic error or analytical bias that is not often clinically significant or relevant. Analytical bias may be eliminated by performing calibration or instrument maintenance.

Exhibit 6-8. Westgard Rule 4_{1s}

Rule 4_{1s}. This rule is violated with the fourth consecutive control measurement exceeding 1 SD on the same side of the mean. Troubleshooting action includes calling the Coulter hotline to see if other labs are reporting a bias with the same lot number of control. Perform any suggested diagnostic action or recalibrate if suggested by Coulter.

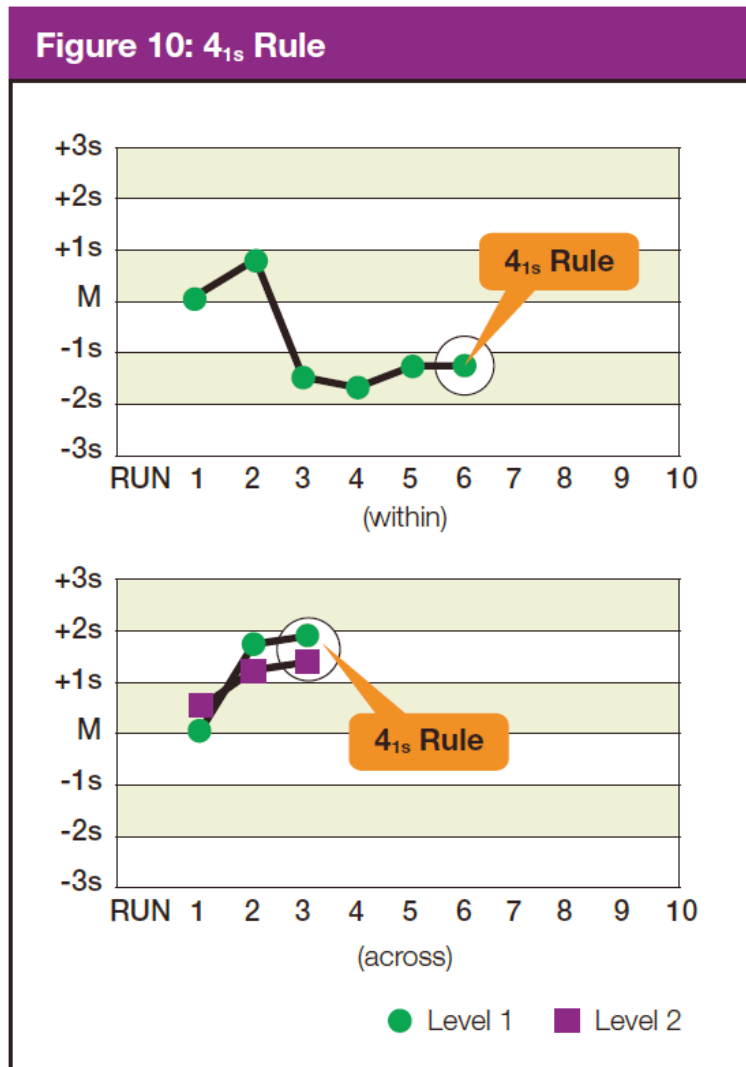



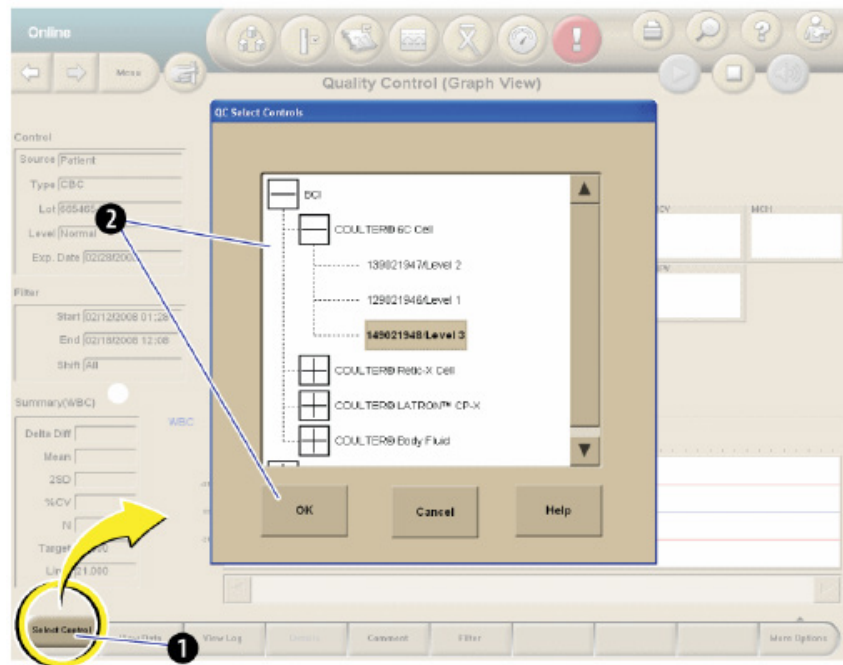
Table 6-2 lists the components seen on the QC Data View screen.

Table 6-2. Components on the QC data view screen

Component	Description
Delta Diff	The difference between the calculated mean and the assigned target of the parameter within the specified filter. Note: If the Extended QC is enabled and if Extended QC limits have been configured, and the equation below is greater than (absolute Delta Diff/BCI Target Value) x 100, and is greater than the Systematic Error limit, the Delta Diff will be highlighted in yellow for that parameter if N>=2 and N<15 or in red if N>=15. If the parameter's target is not applicable, N/A displays in this field.
Mean	The calculated mean of the included points within the specified filter.
25D	The calculated SD of the included points within the specified filter.
PercentCV	The calculated Coefficient of Variation of the included points within the specified filter. Note: If the Extended QC is enabled and Extended QC limits have been configured and the CV value is greater than the Random Error limit, the Percent CV will be highlighted in yellow for that parameter if N>=2 and N<15, or in red if N>=15.
RMSE	Root Mean Square Error (RMSE) displays when Extended QC is enabled. The RMSE is a Single Measurement Error. If the value exceeds the Single Measurement Error limit, the RMSE value will be highlighted in yellow for that parameter if N>=2 and N<15. The value is highlighted in red if N>=15. If the parameter's target is not applicable, NA displays in this field.
N	The number of included points within the specified filter.
Target	The assigned target of the parameter being used in your lab at the time of the control analysis. The target used by Extended QC will be based on what has been configured for traditional QC (either assigned or Mean to Target values).
(Assigned or Mean)	If Beckman Coulter or manually entered targets are used, the label below this heading reads "Assigned." If means are used, the label below the heading reads "Means." If the parameter's target is not applicable, NA displays in this field.
Limit	The traditional expected limit of the parameter in use in your lab at the time of the control analysis.
(Manual, 2SD, or Lab)	If assigned limits are used, the label below this heading reads "Manual." If SDs or Lab Limits are used, the label below this heading reads "2SD" or "Lab," respectively.
Date/Time	The date and time of the control analysis.
Exclude	Allows you to exclude the results of that run from the control statistics calculations.
Reviewed By	Displays one of the following: <ul style="list-style-type: none"> • If the run has not yet been reviewed: A Click to Review link, which allows you to review the run. • If the run has been reviewed: The reviewer's user name and the review date and time.
Presentation	Displays the method of presentation for each run in the control file. <ul style="list-style-type: none"> • C = Cassette Presentation • S = Single-tube Presentation
Comment	A comment icon  displays in this column if any comments have been added.
Ref. RBC	If the control type is a RETIC only, a Ref. RBC heading and numeric value display on the left side of the screen under the Summary Data columns. If the control is RETIC only and the Reference RBC Target and Limit are not set, No Value will display in the Ref. RBC field.

6.11.8 Selecting a Control

- From the Quality Control (Data View) screen or the Quality Control (Graph View) screen, select the Select Control button on the local navigation bar to display the QC Select Controls dialog box.



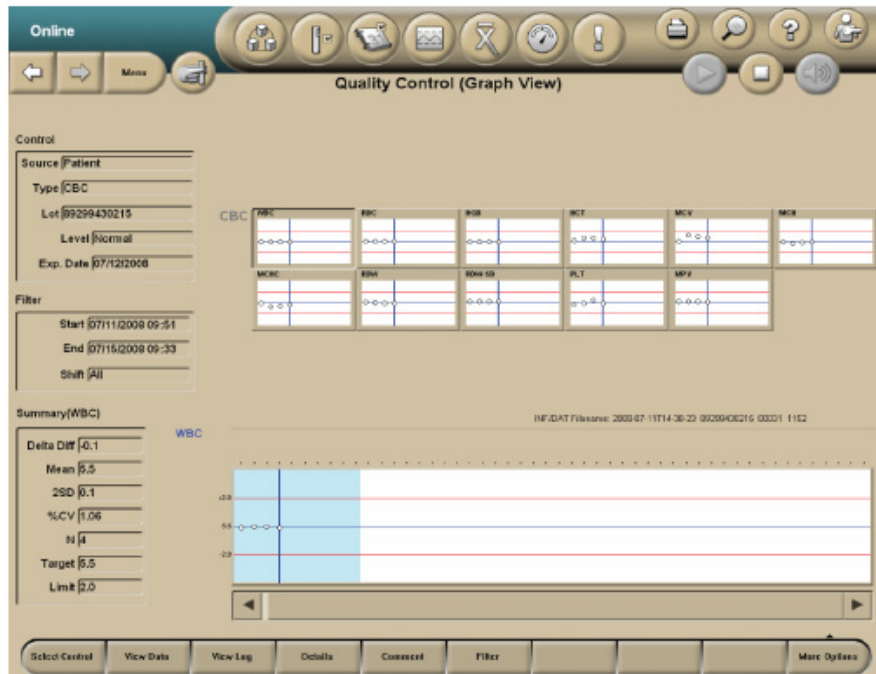
- Highlight the desired control and select OK.
- Exclude and rerun any control that is out of range. Document action taken to correct QC under comments on the Coulter screen in the affected control.

6.11.9 Viewing Control Files Graphically (Menu>QA>QC>View Graph)

From the Quality Control (Data View) screen, select the View Graph button OR select a parameter (row) and double-click the thumbnail Levey-Jennings graph.

The Quality Control (Graph View) screen displays the following:

- Up to 31 thumbnail Levey-Jennings graphs, one graph per parameter;
- An expanded Levey-Jennings graph for the selected parameter data; and
- Summary data for the selected parameter.



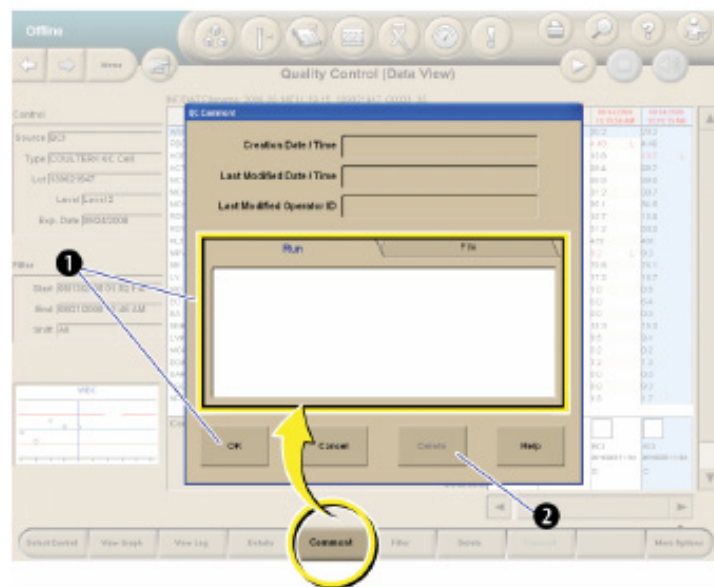
6.11.10 Using and Interpreting the Levey-Jennings Graphs

- The top half of the Quality Control (Graph View) screen displays all parameters associated with controls.
 - Levey-Jennings graphs display the latest run points for all parameters.
 - Each graph displays up to 10 points, and these change to reflect the scrolling of the expanded graph.
 - The points shown in the blue-shaded window of the expanded graph reflect those shown in the thumbnail graphs.
- The point cursor on the thumbnail graphs is synchronized with the selected run within the data grid and the point cursor in the expanded graph.
- If you select a thumbnail graph, it will be displayed in the expanded graph section on the lower half of the screen.
- Any thumbnail graph's border displays red if it contains a QC Out point.
 - Once all runs in a graph are reviewed, its border will return to normal color, but the QC Out point will remain red in the graph.
 - If the results violate the extended QC Single Measurement Error, the point will be yellow.

- The expanded Levey-Jennings graph at the bottom of the Quality Control (Graph View) screen displays all of the results for a selected parameter in the control file.
 - The blue-shaded window on the expanded graph, which contains up to 10 points and the point cursor, determines the points and cursor displayed in the thumbnail graphs.
- The point cursor is a blue vertical line on the graph that reflects the date selected in the Data View.
 - The cursor can be moved left or right by using the scroll bar or by selecting either the data points on the graph or the control run analysis Date/Times in the Data View table.
 - If the cursor moves to a point outside the window, the window shifts so that the new point displays in the window as the furthest right or left point.

6.11.11 Add, Modify, or Delete Comments to QC Results

- From the Quality Control (Data View) or the Quality Control (Graph View) screen, select the Comment button to display the QC Comment dialog box.

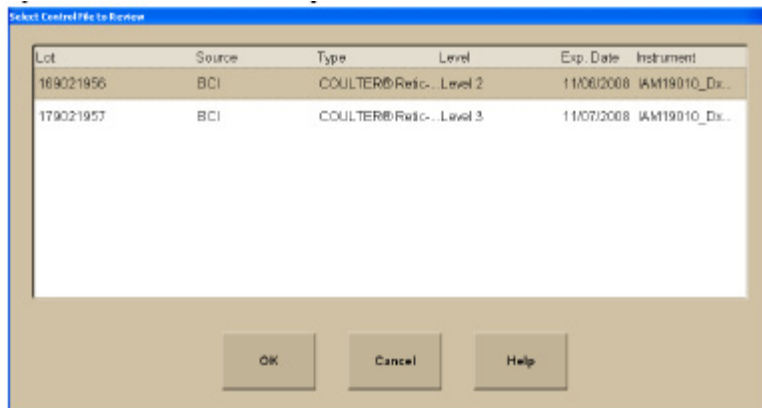


- The Creation Date/Time, Modified Date/Time, and Last Modified Operator ID will not be populated until the entry of the comment has been completed.
- To add or modify a comment on a control run, select the Run tab, type in the text box, and select OK.

- To add or modify a comment on a control file, select the File tab, type in the text box, and select OK.
- To delete a comment, select the Delete button.

6.11.12 View Control Files Under Error Conditions

- Under Error conditions, the Quality Control Status icon at the top of the screen is red.
- If more than one lot triggered an error condition, the Select Control File to Review dialog box displays.
- All lots that are OUT are displayed on the dialog box.
- To review a specific log, select the lot and select the OK button.



6.12 Sample Analysis

6.12.1 Status

- The SPM must be online to run samples.
- You can view the status of the SPM in the Status Mode area at the upper-left corner of any screen, except the Home screen.



6.12.2 Cassette Presentation

- Ensure that the SPM is set up for the appropriate test for your workflow.
- Ensure that specimens have been collected and stored properly.
- Load the specimens into the cassettes. Narrow tubes with small internal diameters will require manual premixing prior to analysis to ensure proper cell and plasma distribution and to avoid possible erroneous results. Premix these tubes before placing them in the cassette and then analyze the cassette by placing it in the Stat position of the input buffer.
- Place the cassettes in the input buffer to the right of the SPM. The SPM automatically begins cycling the cassettes.
- After the SPM cycles the samples, review the sample results at the SM. To avoid serious injury, do not place your hand through the cassette presentation opening on the SPM.

6.12.3 Single-Tube Presentation

- Ensure that your specimens have been collected and stored properly.



The screenshot shows a software window titled "Single-tube Presentation". The interface is divided into several sections:

- Default Test:** Contains two dropdown menus. "Specimen Type" is set to "Whole Blood" and "Test" is set to "CBC". A speaker icon is located to the right of these menus.
- Specimen Identifier:** A text input field.
- Patient Name:** A text input field.
- Test Requested:** A text input field.
- DxH Control:** A checkbox.
- Edit Order:** A button.
- Instructions:** A yellow highlighted bar with the text "Scan or Type Specimen Identifier and Press <Enter>".
- Buttons:** A row of four buttons at the bottom: "Dispense Diluent", "Clear", "Exit", and "Help".

- Place the specimen on the barcode reader platform of the single-tube presentation station with the barcode facing the SPM to allow the single-tube presentation barcode reader to scan the specimen label. The barcode may also be scanned with the handheld scanner or the Specimen Accession Number may be typed into the Specimen Identifier field.
- Verify the Specimen Accession Number and test request. Acknowledging the ID that displays on the SM screen indicates that you accept either the barcode label read or the manual entry.
- Thoroughly mix the specimen.
- Place the specimen in the correct single-tube position.
- Do not place a closed tube or a 16-mm diameter tube in the right position of the single-tube presentation station. Doing so could cause incomplete aspiration and an erroneous result.

6.12.4 Handling Alarms

- An audible or visible alarm on the DxH 800 system should be addressed by reviewing the Event Logs on the History Log screen.
 - The Worklist-Custom tab can be used to select from predefined or user-defined filters to set the audible alarms.

6.13 Data Evaluation

6.13.1 Flags

Flags appear to the right of the result:

- For some parameters, flagging occurs as a result of the flagging or editing of other parameters.
- Flags in the following exhibit are shown in order of placement on screens and printouts, with the highest priority flags at the top within each space.
- A yellow background on the screen indicates that results were above or below a reference range.
- A red background on the screen indicates that results exceeded an action or critical limit or that another flag was present.

- Flags appear in one of four positions to the right of the result.
- The flags are listed in order of priority within each space. It is possible to have flags in each of the four positions.
- Refer to Exhibit 6-9 to interpret DxH flags.

Exhibit 6-9. Interpretation of DxH flags

Flag and position				Description
1	2	3	4	
e				Result calculated from a manually edited parameter.
+				Result above the measuring range.
-				Result below the measuring range.
R				Review the result. Special handling is required for editing a result flagged with R. Any parameter derived from an R-flagged parameter cannot be recalculated until that parameter is edited. R flags may also indicate that a System Message has occurred. Check the message area on the Patient Result screen and the History Log>General table for details.
c	L			Low critical limit exceeded.
c	H			High critical limit exceeded.
a	L			Low action limit exceeded.
a	H			High action limit exceeded.
		H		High reference range limit exceeded.
		L		Low reference range limit exceeded.
			P	Partial aspiration detected during sample analysis.
			N	Non-blood sample detected.
			D	Delta check triggered.

6.13.2 Codes

Codes appear in place of results when the system cannot generate results:

- Codes are also called nonnumeric results.
- Codes in the following table are shown in order of the placement on screens and printouts, with the highest priority flags at the top within each space.

Refer to the following list to interpret DxH codes.

==== Analysis was disabled at the configuration level of the SM (Menu>Setup>System>Analysis).

For example:

IF NRBC is temporarily disabled, any results with an NRBC enumeration in the panel will display ===== in place of the NRBC values. The ===== persists in the database after the analysis has been re-enabled.

xxxxx Although available on a panel, this parameter was not enabled as a Test (Menu>Setup>Reporting>Tests) at the time of analysis; however, after this analysis, the parameter was enabled as a test.

For example:

Sample A was analyzed for a CR panel, but the IRF and MRV were not enabled as Tests.

Later, IRF and MRV were enabled as Tests; therefore, the system will not display the IRF and MRV parameters for CR panel results but, for Sample A, xxxxx displays in place of a value for those parameters.

:::: Flow cell clog was detected.

----- Total voteout occurred. No average histogram will appear for the affected parameter.

Incomplete computation.

May occur in place of calculated parameters because a voteout or over-range occurred for a primary parameter used in the calculation. Occurs when the instrument cover is opened.

+++++ Result exceeds the operating range.

????? Result is outside the range of values that can be formatted for display.

Results were rejected.

6.13.3 Messages

Messages can be results-related or demographic- or status-related:

- Results-related messages:
 - Suspect messages (appear in red) are generated by internal algorithms to convey that a clinical condition may exist with a specimen based on an abnormal cell population or distribution.

Refer to the *Unicel DxH 800 Help Manual* on board the analyzer for a detailed list of all Suspect messages.
 - System messages (appear in green) indicate an event occurrence that may affect the operation of a system, requires operator notification, or entry into a History Log.

The majority of system messages are accompanied by an R (review) flag. Some are accompanied by N or P flags.

Refer to the *Unicel DxH 800 Help Manual* onboard the analyzer for a detailed list of all system messages.
 - Definitive messages (displayed in blue) are displayed for results based on exceed limits configured as part of an individual flagging set.

Definitive messages can be created by copying reference ranges, or by manual entry of your own message definition.

Refer to definitive messages in the setup chapter of the onboard *Unicel DxH System Help Manual*.
- Demographic/status-related messages:
 - Exception messages.
 - If there are any exceptions for a specimen, a comments indicator displays in the System Status Message area below the patient demographics.
 - Select the Additional Data button to view the Exceptions.
 - System status messages indicate that the instrument was operating in some nonstandard state when a specimen was analyzed. These states are usually the result of some user action. They do not indicate that any problem was seen when the specimen was analyzed; instead, they indicate that the system was being operated in a manner in which some problems might not be detected.
 - Lab Action messages are triggered by Decision Rules programmed in the analyzer.

These messages are listed in the Lab Actions area of the Patient Results screen.

6.13.4 All Specimens

- Misleading results can occur if the specimen is not properly collected, stored, or transported. Beckman Coulter recommends that you follow Clinical Laboratory Standards Institute (CLSI) or equivalent procedures to ensure proper specimen collection, storage, and transport. Always follow the manufacturer's recommendations when using micro-collection devices for capillary specimen collection.
- Misleading results can occur if specimens contain clots. Always use good laboratory practices for inspecting specimens for clots and verifying results.
- Misleading results can occur if the specimen is not properly mixed. Always use good laboratory practices to ensure that specimens are appropriately mixed. Do not bypass or circumvent the automated mixing process used on the DxH 800.
- When running a test panel, with NRBC analysis enabled, the information from the analysis is used to supplement interference detection, flagging, and correction.
- **WBC and TNC**
 - NRBCs, giant platelets, platelet clumps, malarial parasites, precipitated elevated proteins, cryoglobulin, microlymphoblasts, very small lymphocytes, fragmented white cells, agglutinated white cells, lyse resistant red cells, unlysed particles greater than 35 fl in size.
 - Elevated WBC counts may have a carryover effect on subsequent leukopenic specimens, within the limits specified by Beckman Coulter. (See the Carryover section in the *Unicel DxH Help Manual* on board the analyzer.)
- **RBC**
 - Very high WBC count, high concentration of very large platelets, auto-agglutination.
 - If hemolysis is occurring in vivo, the instrument RBC may be flagged as low, reflecting the true circulating cells. If, however, the hemolysis is in vitro, the specimen may give falsely low RBC results. Cell counts due to in vitro hemolysis do not represent the number of circulating red blood cells.
- **HGB** – severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing.
- **MCV** – very high WBC count, high concentration of very large platelets, auto-agglutination.
- **RDW** – very high WBC count, high concentration of very large platelets, auto-agglutination.

- **PLT** – giant platelets, platelet clumps, white cell fragments, electronic noise, very small red cells, and red cell fragments.
- **HCT** – known interferences related to RBC and MCV.
- **MCH** – known interferences related to HGB and RBC.
- **MCHC** – known interferences related to HGB, RBC, and MCV.
- **NRBC** – known interferences may be related to the following:
 - Lyse-resistant red cells,
 - Malarial parasites,
 - Very small or multi-population lymphocytes, or
 - Precipitated elevated proteins.
- **Differential**
 - Hypogranular granulocytes, agranular granulocytes, lyse-resistant red cells, very small or multi-population lymphocytes, elevated triglycerides, precipitated elevated proteins.
 - A transient basophilia may be observed in samples that have been exposed to high temperatures (90°F or 32°C). The temporary basophilia should resolve after stabilization at room temperature (72°F or 22°C).

6.14 Laser Safety

The Multi-Transducer Module contains a laser. A laser is a unique light source that exhibits characteristics different from conventional light sources.

The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light. The beam can cause eye damage and instrument damage. There is enough power from the laser to ignite substances placed in the beam path, even at some distance. The beam might also cause damage if contacted indirectly from reflective surfaces (specular reflection). The laser on the DxH 800 is covered by a protective housing.

6.15 Calibration of the DxH 800

The S-CAL calibrator kit determines the adjustment factors for the calibration of the Coulter DxH 800. Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. Calibration is performed in the closed-vial mode at ambient room temperature range (17–25°C, 63–77°F), using S-CAL as an alternative to whole blood.

6.15.1 Perform Calibration

- At the start of each stand, before you begin analyzing samples;
- After you replace any component dealing with dilution preparation, such as the BSV primary measurement, such as an aperture; and
- If your Beckman Coulter representative suggests that you calibrate.

6.15.2 Verify the Calibration of Your Instrument

- 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.

6.15.3 Coulter Pre-Startup Procedure

Supply list: One diluent; one Cell Lyse; one Diff Pak; one cleaner; Latron; and 6C cell controls.

Arrangements for a Beckman Coulter representative to perform the necessary pre-startup procedures on the DxH 800, prior to the arrival of the team to the stand, will be made by the clinical laboratory scientist responsible for that MEC's coulter in advance. These pre-startup procedures for the representative will include:

- Removal of the travel brackets;
- Placement of all reagent lines in the reagents: diluent, Cell Lyse, Diff Pack, and cleaner (No RETICS!!!);
- Power up the analyzer;

- “*Wetting*” the analyzer (full prime of the system); and
- Flow cell adjustment.

A placard will be available for the representative (placed on the right side of the analyzer) with detailed instructions of the tasks that will need to be performed prior to the arrival of the team. The representative will be given the clinical laboratory scientist’s number and email address in the event of any questions concerning the instructions.

6.15.4 Initial DxH 800 Startup

Perform a daily check after the instrument has been “Shutdown for at least 30 minutes.” Select Menu>QA>Daily Checks>Daily Checks>OK.

Draw three 3-ml EDTA tubes from a person with a normal CBC.

Inventory all Coulter reagents – mark with received dates. (Once reagents have been opened, mark with an opened date and tech initials.)

- Log in to the DxH SM

BEFORE DELETING THE PREVIOUS STAND’S DATABASE OR CONTROL FILES, VERIFY WITH THE CHIEF CLINICAL LABORATORY SCIENTIST THAT IT IS OK TO PROCEED WITH THE FOLLOWING INSTRUCTIONS.

- **Delete the database from the previous stand** – Menu>Worklist>Custom>Advanced Search>Insert>Specimen>Analysis Date/Time>Between>Start Date/Time (*Enter MM/DD/YYYY & 24 HR hh:mm:ss that is at least 3 months prior to the current date*) and End Date/Time (*Enter MM/DD/YYYY & 24 HR hh:mm:ss that is 1 day before the current Setup date*)>Select OK>Select Save As (Create a Filter Name – Stand #: the stand you are getting ready to begin)>Search>Delete Order>Select All Test Orders in Current Filter>Select OK>Warning Box Will Appear, Select OK.

- **Delete previously used 6C cell control files** – Menu>QA>QC>More Options>QC Setup>Select Previous (Older) Control File (will be highlighted)>Delete Control>OK.

You can only delete control files one at a time.

- **Enter reagent lot numbers and expiration dates** – Menu>Supplies>Setup>*Scan the Reagent Barcodes*>Select OK.

- **Enter 6C cell control lot numbers and expiration dates** – Menu>QA>QC>More Options>QC Setup>New Control from Barcode>Scan the 6C Cell Insert Barcode>Select ALL & Auto Transmit>Select OK.
- **Enter Latron control lot numbers and expiration dates** – Menu>QA>QC>More Options>QC Setup>New Control from Barcode>Scan the Latron Insert Barcode>Select ALL & Auto Transmit>Select OK.
- **Double click the Coulter icon on the desktop** and verify that the icon is in the taskbar (right corner of the screen).
- **Enter 6C Cell and Latron Control Lot Information into ISIS** – Right-click on the Lab Coulter icon in the taskbar>Select Expected Values>Scan the Insert Barcode>Press Tab Key>Verify ALL Values>Select OK. Perform for both 6C cell and Latron control file inserts.
- Place QC and Latron package inserts in the Coulter binder.

Storage, handling, and stability: Sealed vials are stable through the expiration date when stored at 2-8°C (35-46°F). S-CAL when opened is stable for 1 hour once the calibration procedure has started.

6.15.5 Repeatability, Carryover Check, and Calibration

Repeatability

Supply list: Two 3-ml EDTA tubes filled with normal blood.

Before you can start or restart the carryover process, the SPM must be **offline**.

Ensure that you have enough normal whole blood from a **single donor** for a minimum of 10 cycles, and delete any data on the Repeatability screen before starting a new study.

- Use two 3-ml EDTA tubes (aspiration probe damage can occur if a specimen tube is pierced more than five times).
- Select Menu>QA>Repeatability>Repeatability Setup:
 - Presentation: Cassette;
 - Test Panel: CD;

- Number of Aspirations: 5; and
 - Select OK and follow the screen prompts.
 - Place the two tubes in consecutive positions in a cassette, place the cassette in the input buffer, and select OK on the DxH dialog box to start the cycle.
 - When the cycle has completed, review the results on the Repeatability screen. Use the scroll bar to review all the results. Verify the %CV and the Diff parameters (see limits below). Select Finish.
 - Verify that the coefficient of variation (CV) does not exceed the established repeatability 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) for the **Diff** parameters with these limits:
 - **NE%** ≤ 4.8
 - **LY%** ≤ 4.8
 - **MO%** ≤ 3.2
 - **EO%** ≤ 1.6
 - **BA%** ≤ 1.6
- If any of the results are outside the limits, call Beckman Coulter customer service.
- If all the results are within these parameters: Print>Select “Finish” and proceed with Carryover Check.

Use the %CV line for CBC parameters only and the Diff line for the differential parameters only.

Please see Chapter 1: System Overview – Performance Specifications and Characteristics section in the

Help Menu of the *Unicel DxH 800 Help Manual* for additional information regarding repeatability limits for acceptability (Table 1-1 and Table 1-7).

6.15.6 Carryover

Supply list: One 3-ml EDTA tube filled with normal blood and three empty 3-ml EDTA tubes.

Note: Remove S-CAL from refrigerator to allow time to acclimate to room temperature. Before you can start or restart the carryover process, the SPM must be offline.

- Fill three empty 3-ml Vacutainer EDTA tubes with diluent. Select Single-Tube Presentation icon>Dispense Diluent>Select OK. Place one empty capped EDTA tube in the purple tube holder on the left side of the cradle; *1 ml of diluent is dispensed during this process*. Once completed, “Do you want to dispense more diluent in the same tube?” box will appear>Select No. Remove the filled EDTA tube, and repeat the above steps two more times to fill the two remaining empty EDTA tubes with diluent. Select Exit>“Are you sure you want to exit Single-tube Presentation?”>Select Yes.
- Select Menu>QA>Carryover>Carryover Setup:
 - Presentation: Cassette;
 - Test Panel: CD; and
 - Select OK and follow the screen prompts.
- Select OK to start the carryover procedure.
- Place a cassette in the input buffer with one blood tube followed by three diluent tubes consecutively and select OK to start the carryover procedure.
- When carryover is complete, review the results on the Carryover screen. If any of the carryover results “FAIL,” repeat the procedure.

If the carryover results “FAIL” after the second attempt, call Beckman Coulter customer service.

- If the status of all parameters is “PASS”: Print.

When performing a carryover procedure, the calculated percent carryover and/or background for each parameter is compared to the carryover and background limits for acceptability. See Chapter 1: System Overview – Performance Specifications and Characteristics section in the Help Menu of the *Unicel DxH 800 Help Manual* for additional information regarding carryover and background limits for acceptability (Table 1-12 and Table 1-13).

6.15.7 Calibration

Supply list: One S-CAL calibrator.

Note: Before you can start or restart the calibration procedure, the SPM must be offline.

- Allow S-CAL to warm to ambient (room) temperature for approximately 15 minutes.
- Select Menu >QA>CBC Calibration>Calibration Setup. You will be prompted by a dialog box that states: Existing data will be deleted. Select OK to continue.
 - Number of Aspirations: 11;
 - Presentation: Cassette; and
 - Calibrator Type: BCI.
- Select Upload>*Scan the S-Cal Insert Barcode*>Verify ALL Values>Select OK.
- Mix the S-CAL by hand by rolling 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. When all cells are uniformly distributed, place the calibrator in the cassette.
- Place the cassette in the input buffer and select OK to start calibration procedure.
- Exclude the first run by checking the box beside that run.
- Review the calibration results.
- If all the results are within the specified parameters: Print>Select Finish.
- If results recommend calibration (the boxes at the bottom of the calibration screen are check marked)>Select OK.

The background of the Factor %Diff, %CV, and Difference cells changes color when the presented value is out of the normal range as follows:

- Yellow for Difference indicates that the value is out of range, which means that calibration is recommended.
- Red applies only to the %CV and indicates that the statistical value is NOT within range and the system does NOT allow calibration.

When all results are acceptable, the Edit System Recommendations button at the bottom-right corner of the screen is enabled. This button allows the modification of the calibration recommended

by the system by selecting or deselecting check boxes. Verify the calibration by running controls. Menu>QA>QC>Select Control>*Select the control that you want to view*>Select OK> Select “Reviewed By” to review controls>Print.

Note: Place all printed charts and control inserts into the DxH Logbook.

Below is an image of the NHANES Coulter Monitor icon. It must be open and running at the start of each session. This icon stores all DxH 800 runs in the ISIS database. Double-click on the Coulter icon so that it displays in the lower-right taskbar. Once the icon is displayed, the Coulter and the ISIS Laboratory application are communicating with each other.



6.16 Run Study Participant Samples

Exhibit 6-10 presents a picture of blood tubes.

Exhibit 6-10. Picture of tubes



- Place tube in the cassette and place in the SPM.

- Run all samples in duplicate. The DxH is set to automatically rerun SP samples in duplicate, but not controls.

To set DxH 800 for automatic repeat of each SP sample, use the following sequence of steps:

Menu>Set-up>Flagging/Rules>Rules>Select decision rule workbench tab (upper right)>Add Rules>Rule name: Type 'Repeat' at the *> Specimen Type: use drop-down menu and select whole blood>Rule description: Type automatic repeat if condition RBC<10>Additional test: Check Rerun box in additional test box>OK. Place analyzer offline>Activate Decision Rules tab (middle center tab)>Activate Rule (lower left).

- Run samples in the primary mode.

Check to make sure the printer is working properly. Operate the analyzer with the doors and panels closed. Monitor reagent levels.

6.16.1 Review Data and Transmit

- Review the data. Select Menu>Patient Results.
- Data from the Coulter DxH 800 are automatically transmitted to the ISIS system when the NHANES Coulter monitor icon has been opened on the ISIS screen.
- Use the Worklist screen to sort, retrieve, transmit, and archive data to CD. Transmit data from the Coulter DxH 800 to ISIS as necessary. Save all data to CD at the end of each stand.

6.16.2 Daily Shutdown

See Section 6.8, pages 6-13 to 6-15.

6.16.3 Prolonged Shutdown

- If the instrument is going to be idle for more than 72 hours, as in summer or winter 2-week breaks, adjust the shutdown procedure as follows: Menu>QA>Daily Checks>AutoConfiguration>Configure Shutdown>Uncheck Daily, Check only boxes for every other day (Mon, Wed, Fri, Sun)>OK. Ensure that there is sufficient cleaner and diluent for shutdowns during the break time.

6.16.4 Beginning and End of Stand Operations

- Beginning of stand:
 - Arrange for a Coulter service representative to remove all travel brackets and re-wet the system.
 - Follow procedure for Calibration, Repeatability, and Carryover Check.
- End of stand.
 - Call Coulter Support to have an engineer install the travel brackets and perform the travel shutdown procedure for the DxH 800. Before the engineer performs this service, the following tasks must be completed by the technologist assigned to the Coulter for that stand:
 - Select (QC Icon)>Select Control>Select 6C Cell Control Level 1>Transmit>Select All Runs in Current Control File>Select OK. The Coulter icon on the workstation computer will “flicker” to indicate the transmission of data. Once the flickering has stopped, repeat the same steps beginning with Select Control and transmit QC data for 6C Cell Control Levels 2 and 3, followed by the Latron Control File.
 - Select [QC Icon]>Select Control>Select 6C Cell Control Level 1>Select [Printer Icon]>Change Report Type to Summary Report>Select [Control Lot] and checkmark all Current Stand Controls (Both Latron and 6C Cell Files)>Select [Print] All Runs>Select [Print Options] Data Report and Graphical Report>Select Thumbnails>Select Print.

Clip all the reports together with a binder clip and place them in the end of stand FedEx Box.
 - DISC 1: IQAP

Export IQAP Data. Insert a blank disc into the disc drive. Select Menu>Set-up>Quality Control>IQAP Export>All DxH Control Lots>Multiple Shifts>CD Recorder>Start>Follow screen prompts.

Label the disk IQAP and include Stand # and MEC # and place the disc in the end of stand FedEx box.
 - DISC 2: LOGS

Export Log Data. Insert a blank disc into the disc drive. Select Menu>Logs>Export>Select ALL in (1) Event, (2) Data Summary, (3) Maintenance, and (4) Audit Logs>Select and Enter Date Range (Start of Stand to End of Stand)>Select Start. The disc will automatically eject out of the disc drive upon completion.

Label the disk **Logs** and include **Stand # and MEC #** and place the disc in the end of stand FedEx box.

– DISC 3: DATABASE

Export Patient Log (Database). Insert a blank disc into the drive. Select Menu>Worklist>Custom>Advanced Search>Filter Name (Stand #)>Insert>Specimen>Analysis Date/Time>Between (Start of Stand to End of Stand)>OK>Search>Export>Type CSV>All Results in Current Filter>Destination CD Recorder (G:\)\>Select Start. The disc will automatically eject out of the disc drive upon completion.

Label the disk Database and include Stand # and MEC # and place the disc in the end of stand FedEx box.

Clean the aspiration probe. Select Menu>Maintenance>Clean Aspiration Probe>[Start]. Once procedure has completed, select Finish>[OK].

Clean the BSV, the handheld barcode scanner, and the STM and wipe the analyzer's exterior with lint-free tissue and deionized water.

- Complete the Hematology Maintenance Log and include all of the paperwork from the Hematology Notebook, including Daily Check logs, package inserts, precision checks, and calibration data. This information should be binder-clipped separately into the respective subsections and included in the end of stand FedEx box to the Laboratory Component Specialist at Westat. The box can now be sealed and sent with the rest of the shipment.

Service performed by a Beckman Coulter representative:

- In most cases the Facilities Equipment Specialist will discard all trash and empty reagent boxes after the representative has finished decommissioning the analyzer.
- In most cases the FES will strap down and secure the DxH and computer monitor for the impending travel.

6.17 Coulter Reportable Range of Results

Table 6-3 presents the Coulter reportable range of results.

Table 6-3. Coulter reportable range of results

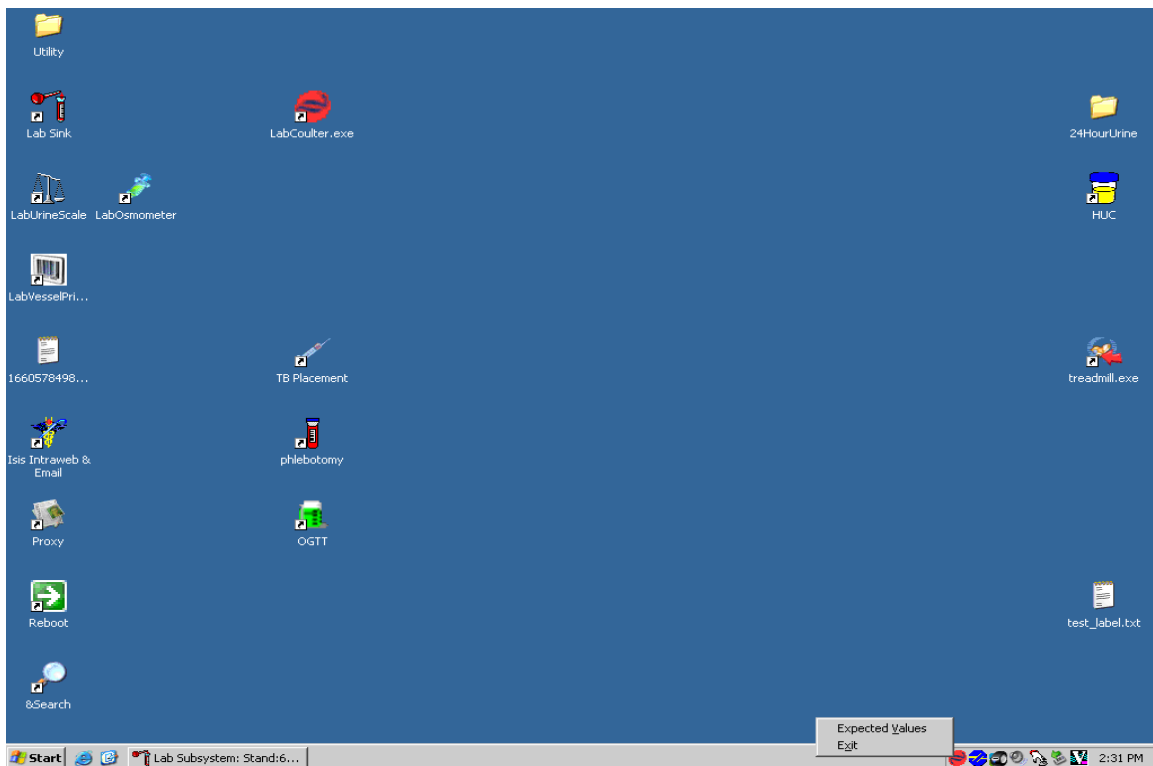
Parameter	Linearity	Limits: The greater of
WBC x 10 ³ cells/μL	0 to 337.7	0.2 or 3.0%
RBC x 10 ⁶ cells/μL	0 to 8.30	0.05 or 2.0%
Hgb g/d	0 to 24.3	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10 ³ cells/μL	0 to 4897	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

6.18 Integrated Survey Information System

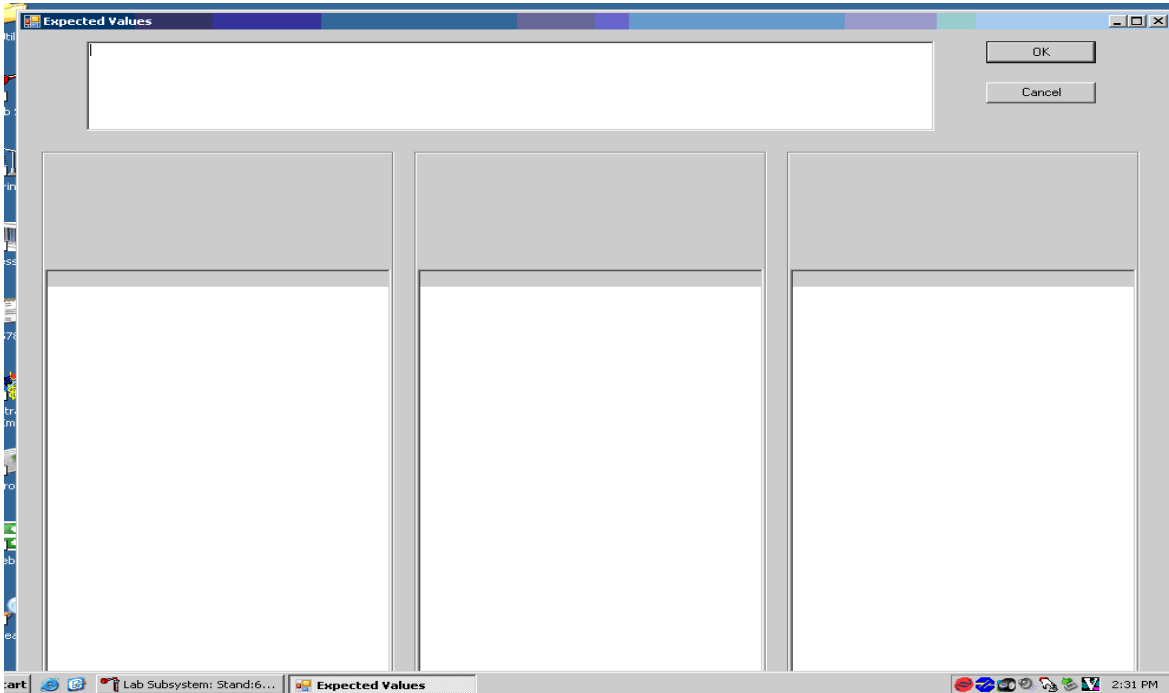
6.18.1 Record 6C Cell and Latron Lot Numbers in Integrated Survey Information System

The Integrated Survey Information System (ISIS) maintains the capability to download all 6C cell and Latron control data. The data are used to monitor quality control results. Upload or enter data for each lot number each time a new lot number is put into use. The ISIS uses the same 6C cell control package insert and Latron package insert as the DxH 800.

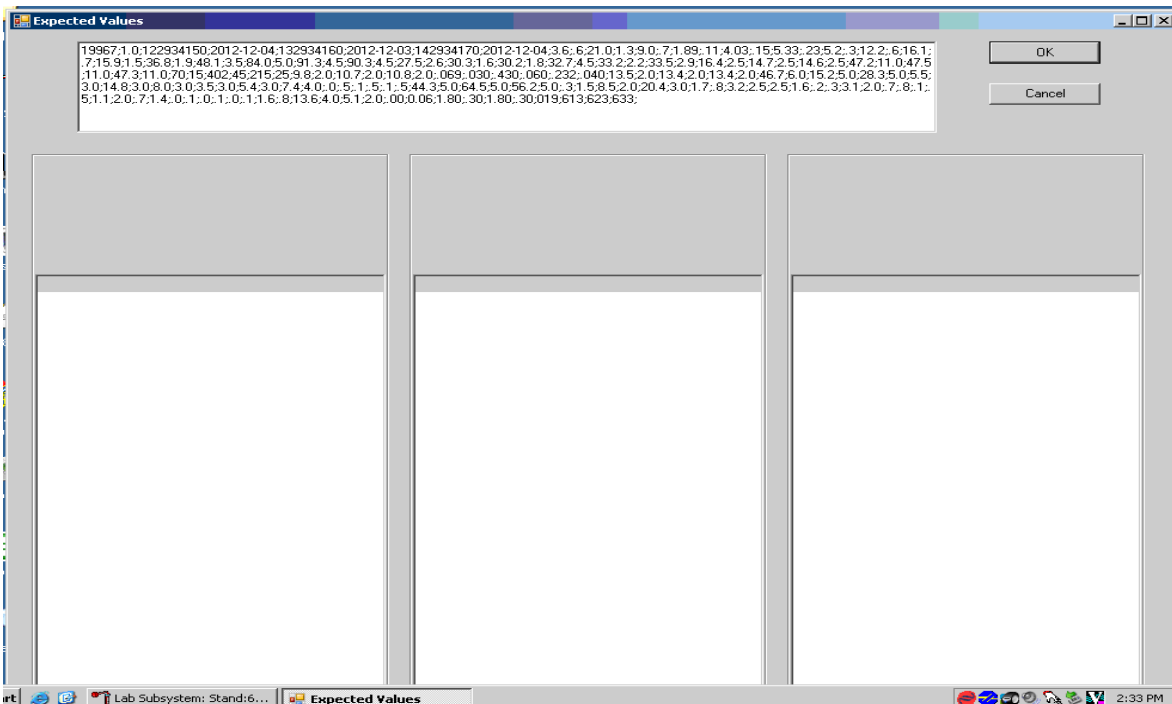
- Access the Coulter QC Lot Info module.
- Right-click on the Coulter icon in the bottom-right corner of window.



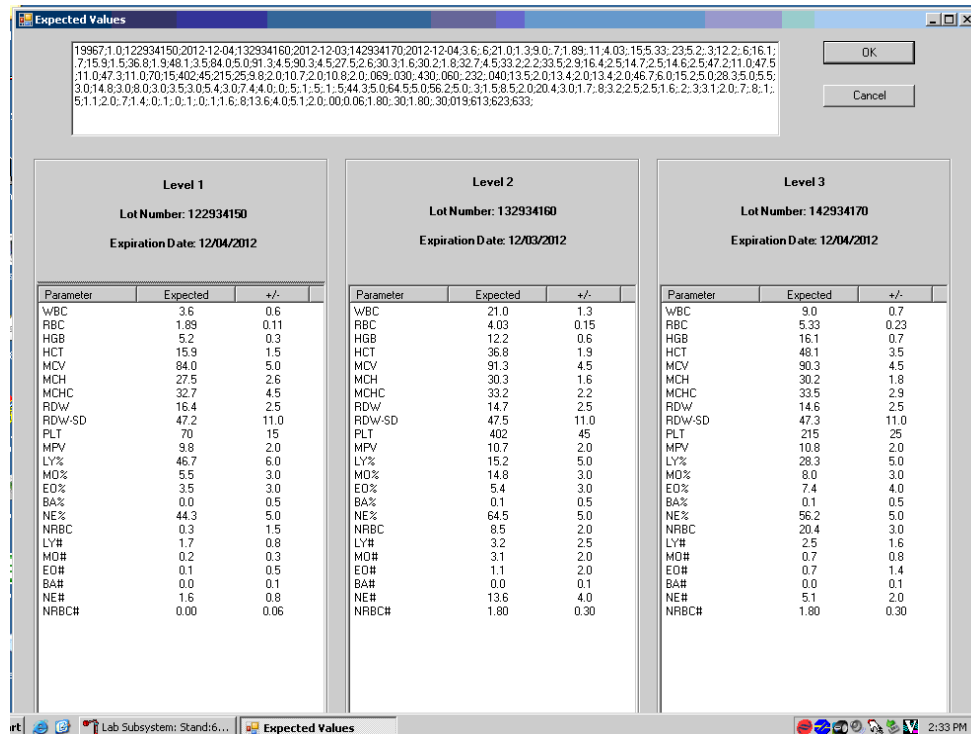
- Click on Expected Values to bring up the Coulter QC Input screen for 6C cell controls and Latron QC.



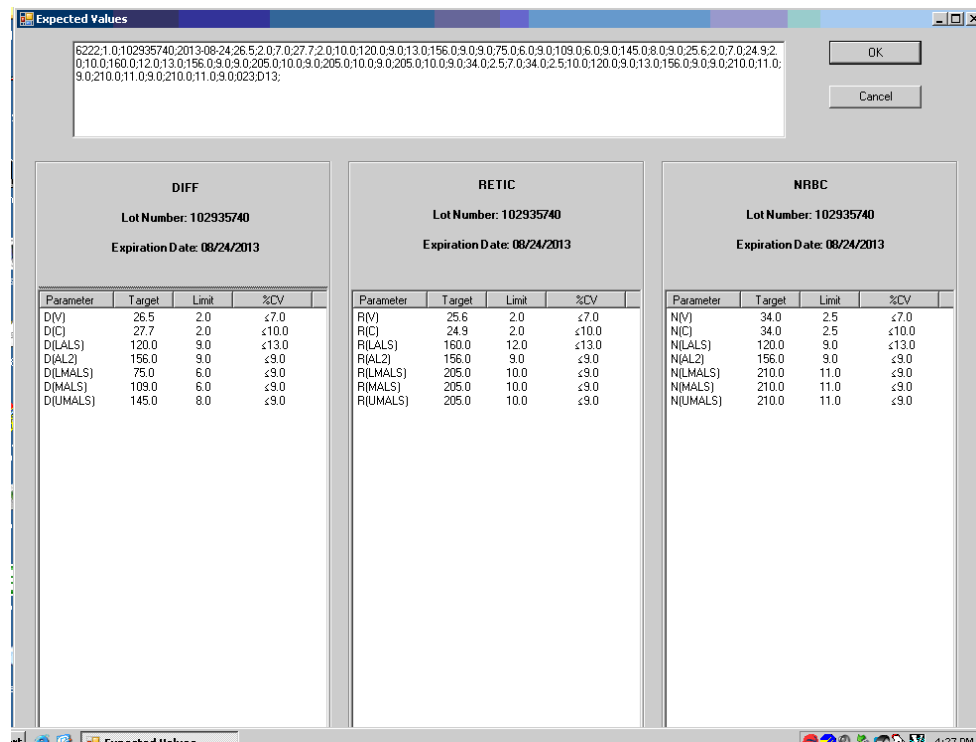
- Make sure cursor is in the top window, scan the barcode on the Coulter package insert, and wait until data fill in the top window.



- Tab to populate the bottom windows for each level of 6C cell control.



- Below is a screenshot depicting Latron QC expected values for Diff, Retic, and NRBC. Check the expected values against the package insert and click OK to save and exit.



6.18.2 Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Coulter's IQAP program. The IQAP program includes saving results of 6C cell controls, transferring them to a CD, and sending them to Beckman Coulter, which compares the results to other laboratories. Beckman Coulter issues a report that contains a statistical analysis to evaluate performance. Perform this procedure at the end of each stand.

The procedure to download IQAP files to CD follows:

- Slide the CD into the drive and gently close CD holder.
- Menu>QA>QC>More options (bottom of screen)>Export.
- Type: CVS.
- Data Selection: All runs in current control file.
- Folder: CD Recorder Radio Button.

Repeat for each of the three levels of QC.

6.18.2.1 Reviewing IQAP Peer Group Means (Chief Techs)

- Use the website <https://qapweb.beckmancoulter.com/qapweb/>.
- Log in.
- Choose the Analyzer (with note that B1 is MEC 3, B2 is MEC 2, B3 is MEC 1).
- Review active pool statistics. **(Note the number of labs in current pool. A small sample size can have a significant effect on data.)**
- Put in lot number of 1st level 6C.
- View report.
- **Note:** Look at Mean and SD (not the assayed value), which is what is on the assay sheet we get. The Mean and SD are the averages for all the labs submitting data for this lot using 800 DXH. The shown SD is 2 SD from the peer mean.
- Select "BACK."

- Use same procedure for remaining lot #.
- Address concerns with the Lab Component Lead if any issues arise.

6.18.3 Proficiency Testing

Evaluation and participation in the College of American Pathologists (CAP) proficiency-testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of five 3-ml whole blood specimens. Follow all CAP instructions 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 log book, and send results to CAP.

After the assigned primary clinical laboratory scientist has tested and recorded results, other clinical laboratory scientists are to perform the testing and record their results without consultation with the primary tech. The secondary clinical laboratory scientist's results will be sent to the Laboratory Component Lead as a record of competency testing.

To make barcode labels:

- Select Utility on desktop.
- Select "Dymo test labels."
- Highlight the label shown:
 - Click on "Properties" in far upper right;
 - Symbology: Choose "code 128 Auto";
 - Data: Barcode delete "Click me" or "0000001" and type in proficiency sample number, i.e., FH6-01;
 - Align: Center;
 - Size: Medium; and
 - Show barcode text: Below.

- Print: Will print on Dymo label maker.
- Repeat for all five samples.
- Exit out and select “No” to “do you want to save?”

To auto print results for proficiency samples:

- Select Menu>Set Up>Reporting>Auto Report.
- Check box “Print Lab Report as Each Analysis is Complete.”
- Back out of setup.
- BE SURE to uncheck box after you have finished running samples and printing results.

Run proficiency samples in cassette (samples will be run twice under current setup and each result will print separately).

- Average results on NHANES Hematology CAP Results worksheet.
- Select Computer>MECSTAFF>Lab.
- Save as KitName-KitNumber_YYYY-MMDD_MEC#_Tech Initials_ P (for primary) or S (for secondary operator).
- Enter results on CAP paperwork.
- Enter results in CAP site on computer using your own personal CAP login:
 - Log in to the CAP site with individual account info;
 - Click on the e-lab solutions suite;
 - On the right side of the screen, click on the “Request access to laboratory data” link;
 - The screen will open that will ask you to enter the CAP number; and
 - Enter 6910001.

Have another tech proof your computer entry before submitting. Take a picture of your worksheet as a copy of your work and print for your records. Place your worksheet with indication of kit number, primary or secondary operator, your name and date in the Hematology log book to forward to the Laboratory Component Lead at end of stand, and also email the primary copy to the lead.

Record completion on your annual CAP survey Check Sheet. Indicate if you were primary or secondary operator.

6.18.4 Linearity for WBC, RBC, Hgb, and Plt Parameters

Lin-X™ (PN 628029) – The Lin-X linearity control verifies the reportable range of Coulter hematology system parameters for WBC, RBC, Hgb, and Plt.

Run the Lin-X survey material:

- At installation;
- At least yearly; and
- Whenever experiencing an altitude change of 1 mile or more between stands.

Principle – Lin-X linearity controls are human blood components from which repeated measurements verify the reportable range of Coulter hematology systems. Controls contain 12 vials, ranging from 0-12. Lin-X verifies the ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Coulter system calibrates with S-CAL calibrator.

6.19 Interpretation of Results and Remedial Action

6.19.1 Sample Person Hemoglobin and Hematocrit Review and Remedial Actions

Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin. If an “H&H Does Not Match Flag” is displayed on both runs of an SP, repeat the run. Report out of range results if all runs are similarly flagged. Delete all but two of the runs before averaging.

6.19.2 SP Parameter Value Review and Remedial Actions

1. Access the Hematology module or reject a clotted blood tube

Open the Hematology module.

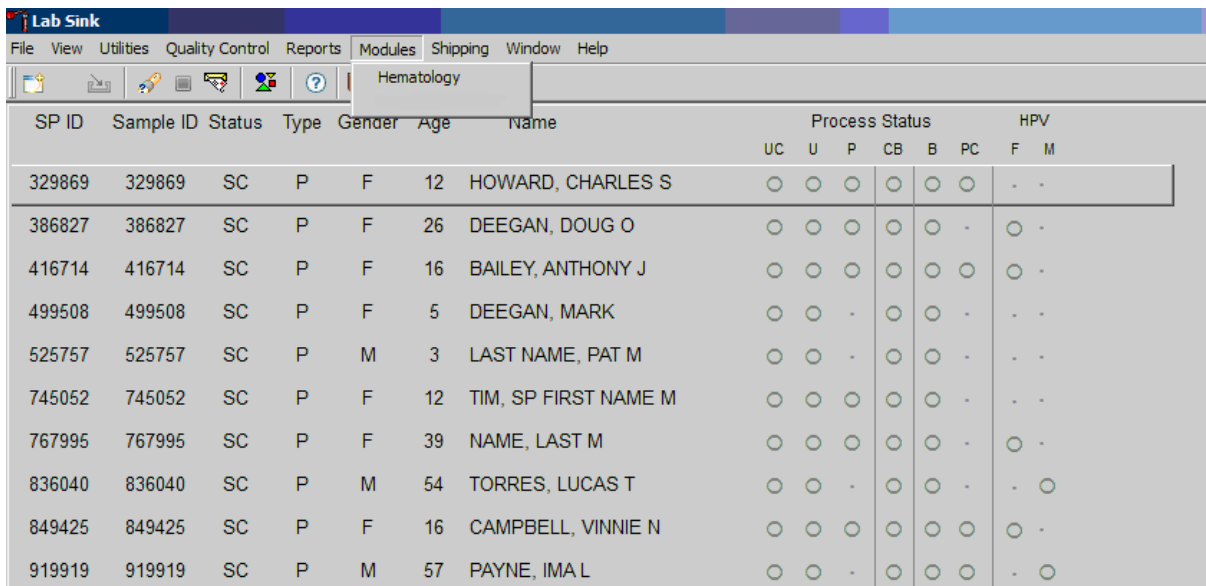
The Hematology module does not need to be open before running SP samples on the DxH 800. Note the red icon in the lower-right corner of the system tray.



This is the NHANES Coulter Monitor icon. It must be open and running at the start of each session. This icon stores all DxH 800 runs in the ISIS database. Double-click on the Coulter icon on the desktop to open the application.

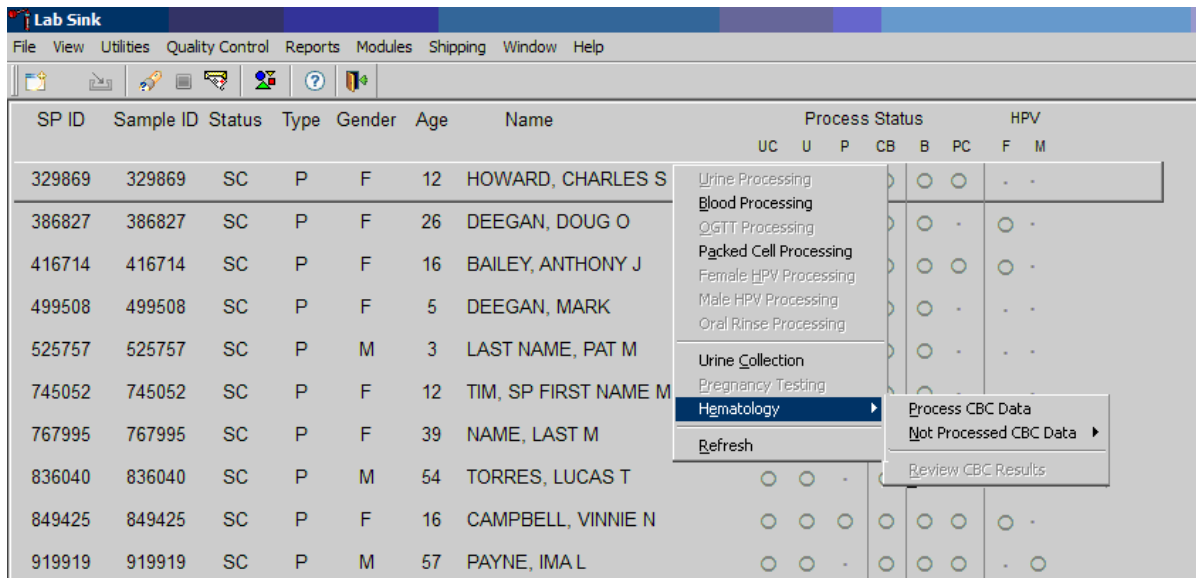


Open the Hematology module: Direct the mouse arrow to Modules, in the top menu bar, left-click, drag the mouse arrow to Hematology, and right-click.



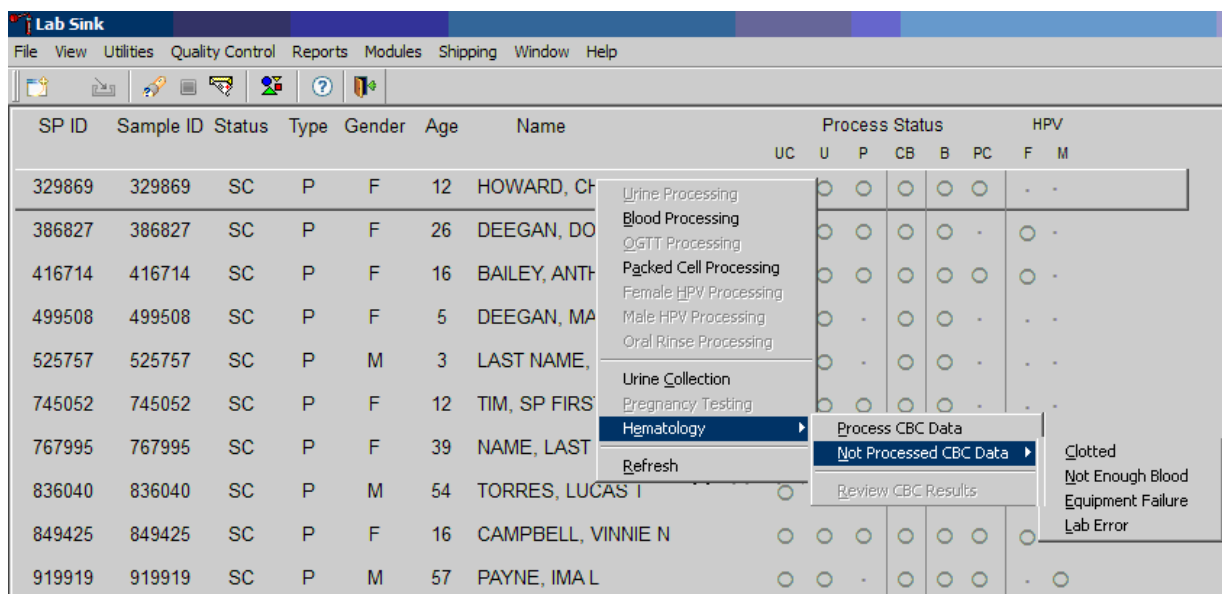
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						HPV	
							UC	U	P	CB	B	PC	F	M
329869	329869	SC	P	F	12	HOWARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC	P	F	26	DEEGAN, DOUG O	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
416714	416714	SC	P	F	16	BAILEY, ANTHONY J	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
499508	499508	SC	P	F	5	DEEGAN, MARK	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
525757	525757	SC	P	M	3	LAST NAME, PAT M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
745052	745052	SC	P	F	12	TIM, SP FIRST NAME M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
767995	767995	SC	P	F	39	NAME, LAST M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
836040	836040	SC	P	M	54	TORRES, LUCAS T	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>
849425	849425	SC	P	F	16	CAMPBELL, VINNIE N	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
919919	919919	SC	P	M	57	PAYNE, IMA L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>

Alternatively, open the Hematology module from the heads-up display.



To access the Hematology module, direct the mouse arrow to any SP, right-click, drag the mouse arrow to Hematology, then to Process CBC Data, and right-click. Alternatively, use the arrow keys to move up and down the list until a particular SP is highlighted, right-click, drag the mouse arrow to Hematology then to Process CBC Data, and right-click.

Either open the module or reject the specimen and add a reason or comment for every CB record where blood was drawn in phlebotomy AND there are no CBC results.



Open the module (Process CBC Data) or record why the CBC is not being run (Not Processed CBC Data). Select or record a comment for every CBC that is not run. To complete opening or accessing the Hematology module, direct the mouse arrow to Process CBC Data and right-click. To record why a CBC is not being run, direct the mouse arrow to the exact SP's line on the heads-up display, right-click, drag the mouse arrow to Not Processed CBC Data, and drag the mouse arrow to the correct reason and right-click.

A pop-up window will display. Confirm the selection.

The screenshot shows the Lab Sink software interface. At the top is a menu bar with 'File', 'View', 'Utilities', 'Quality Control', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main area contains a table with the following columns: SP ID, Sample ID, Status, Type, Gender, Age, Name, Process Status (UC, U, P, CB, B, PC), and HPV (F, M). The table lists several patient records. A pop-up dialog box titled 'CBC Data Not Processed' is overlaid on the table. The dialog box contains a question: 'Would you like to mark sample id 416714 as clotted?' and two buttons: 'Yes' and 'No'.

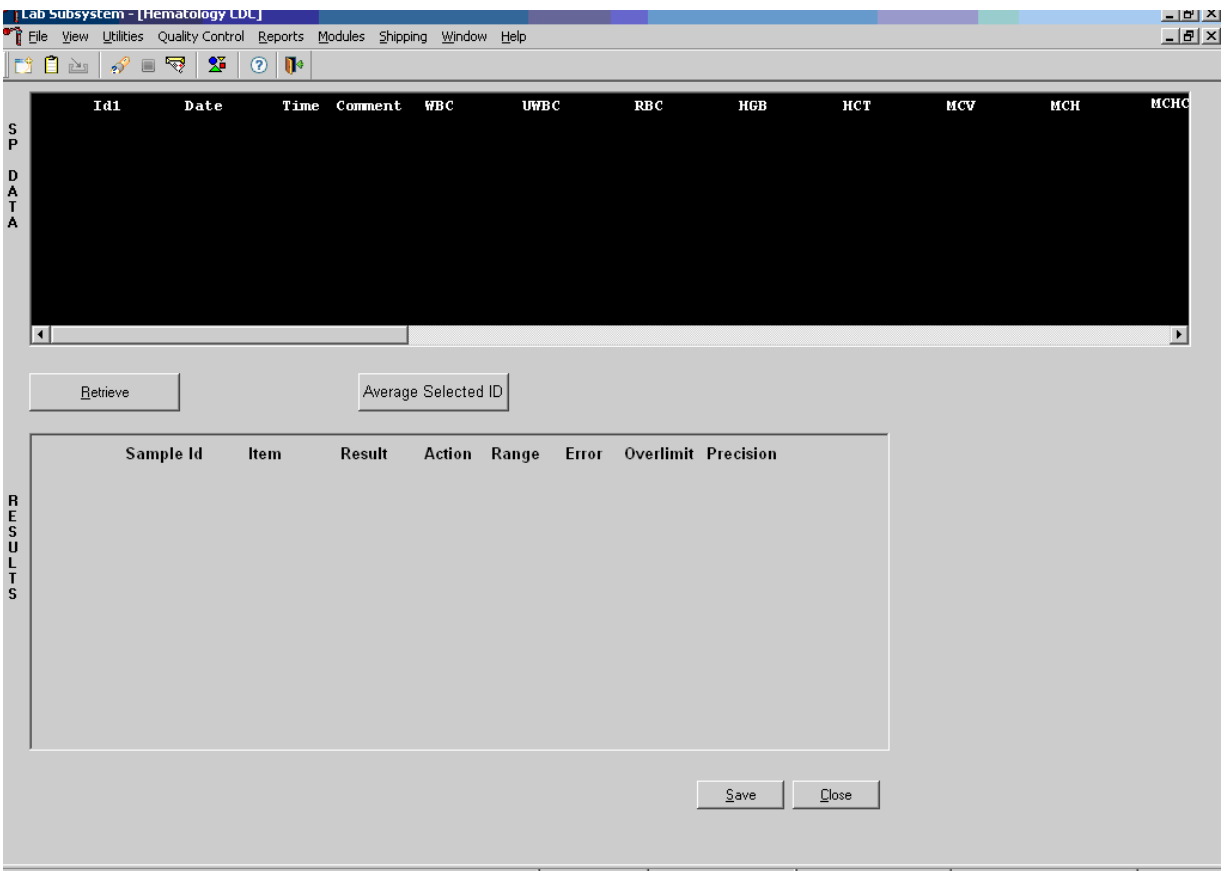
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						HPV	
							UC	U	P	CB	B	PC	F	M
329869	329869	SC	P	F	12	HOWARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
386827	386827	SC	P	F	26	DEEGAN, DOUG O	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
416714	416714	SC	P	F	16	BAILEY, ANTHONY J	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
499508	499508	SC	P	F	5		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
525757	525757	SC	P	M	3		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
745052	745052	SC	P	F	12		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
767995	767995	SC	P	F	39		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
836040	836040	SC	P	M	54	TORRES, LUCAS T	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
849425	849425	SC	P	F	16	CAMPBELL, VINNIE N	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
919919	919919	SC	P	M	57	PAYNE, IMA L	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

A CBC Data Not Processed message text box displays that asks, “Would you like to mark sample ID XXXXXX as Clotted/Not Enough Blood/Equipment Failure/Lab Error?” To record a “Yes” response, direct the mouse arrow to the Yes button and left-click, type [Y], or press Enter. To record a “No” response, direct the mouse arrow to the No button and left-click, or type [N]. If a “Yes” response is recorded, the comment is saved to the database. If a “No” response is recorded, no comment is saved to the database. If the record is marked with the selection in the database, the heads-up display updates to complete (the CB circle fills in black).

2. Hematology module overview

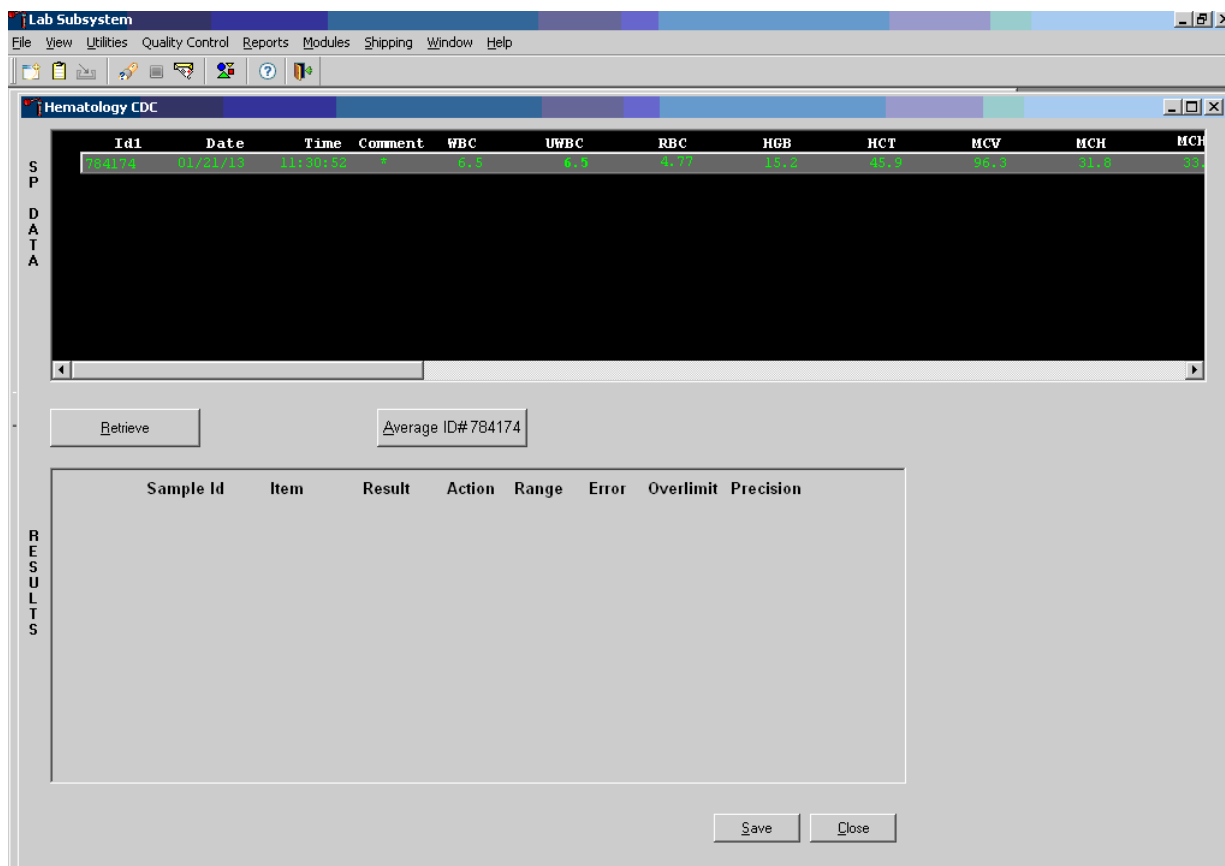
The CBC results are not automatically populated in the Hematology module. Use the Retrieve button to send the results from ISIS to the Hematology module. Select “Retrieve” after each run.

Make sure the Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



After data is retrieved, it displays 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 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 they are retrieved.



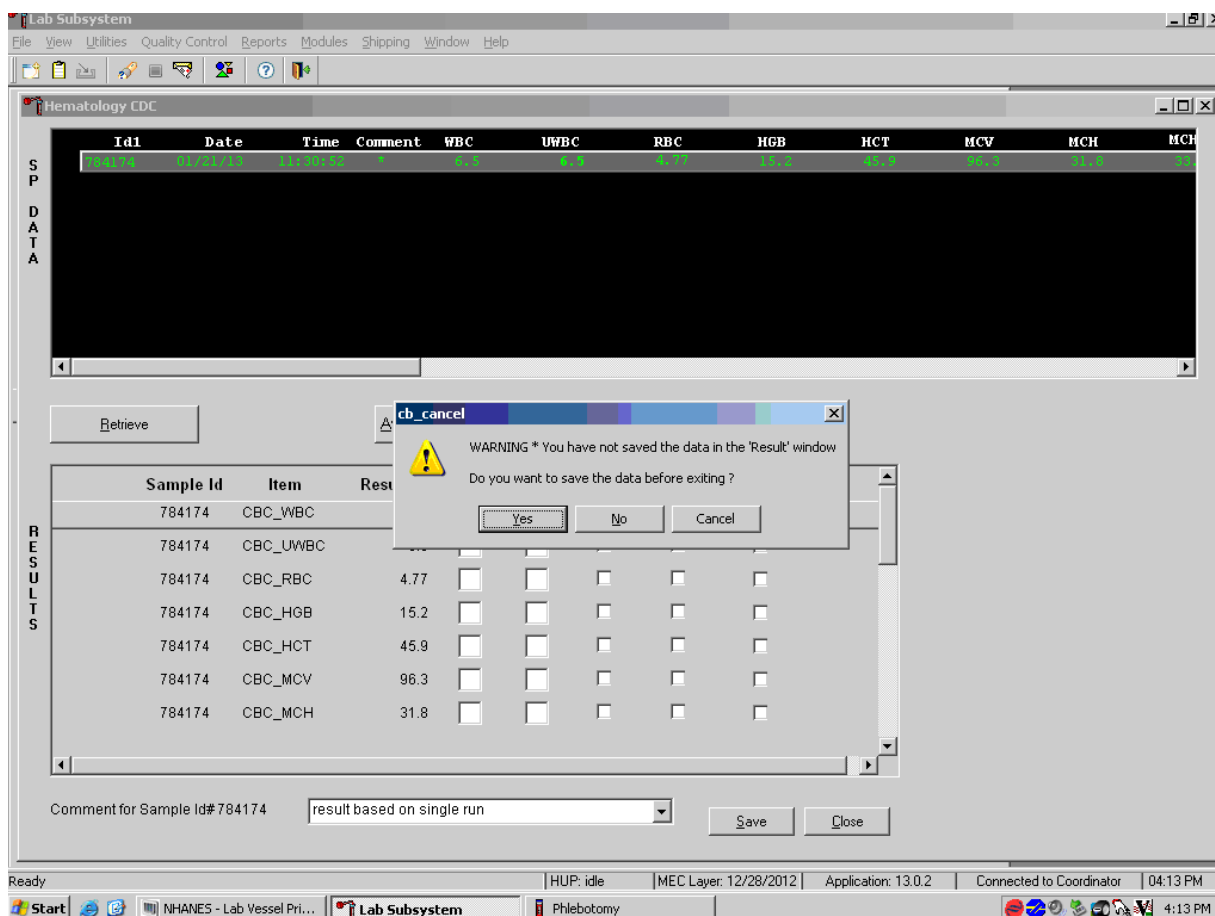
To view SP data for all parameters, direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, direct the mouse arrow to the small scroll arrows on the left and right edges of the horizontal scroll bar, and left-click.

Hematology Results Section Overview. 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 four 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 over limit, or for those that exceed precision limits. An “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, 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, 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, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Cancel button and left-click.

A warning text box displays if the Close button is selected before the results have been saved.

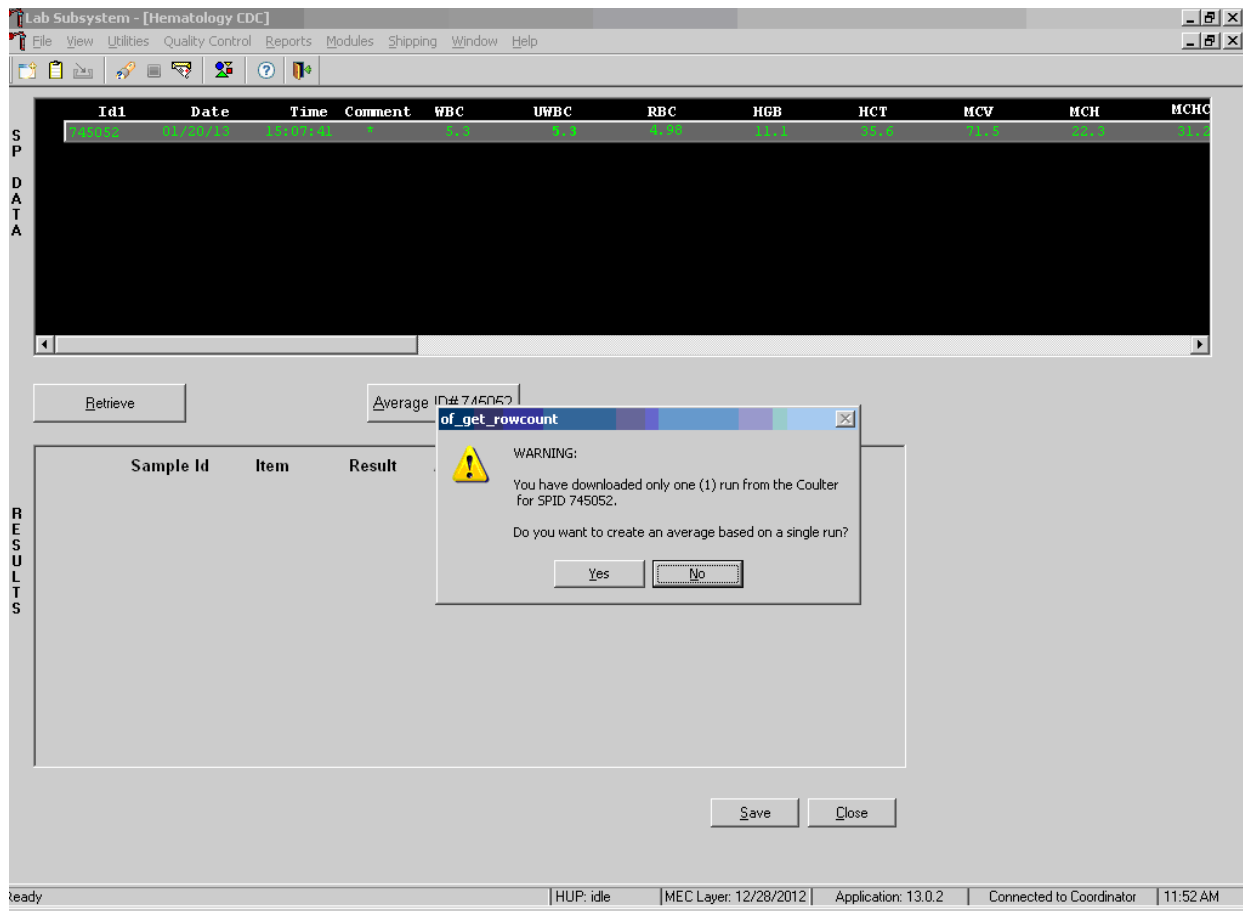


If the Close button is selected before the results are saved to the database, a warning message text box displays that states, “WARNING * You have not saved the data in the ‘Result’ window” and asks, “Do you want to save the data before exiting?” To record a “Yes” response, direct the mouse arrow to the Yes button and left-click, type [Y], or press Enter. To record a “No” response, direct the mouse arrow to the No button and left-click, or type [N]. To cancel the action, 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 are erased. A Cancel response returns the screen to its previous state.

3. Running samples when only one run is possible

Save results where only one run was possible.



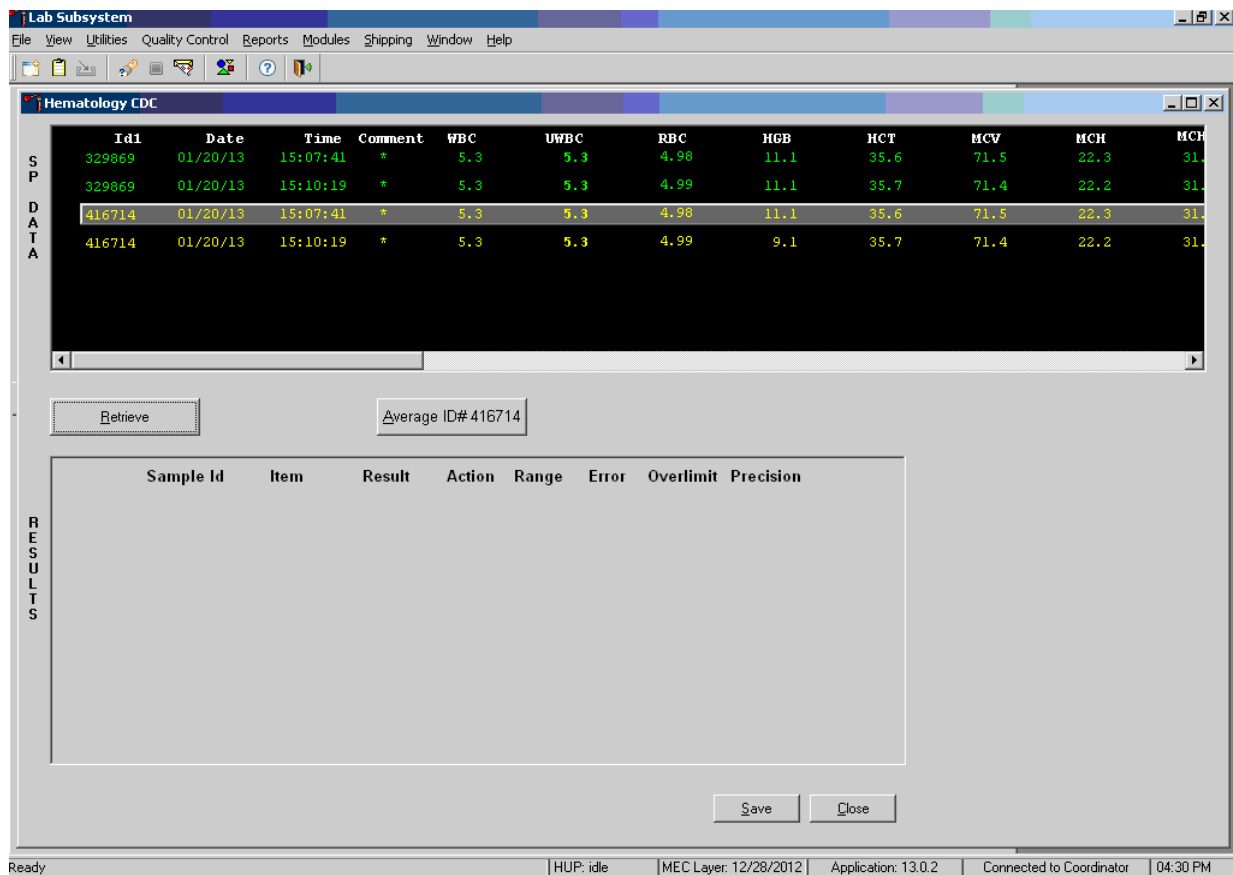
Run Samples in Duplicate Whenever Possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, direct the mouse arrow to the Average Selected ID box and left-click. A warning message text box displays that states, “You have downloaded only one (1) run from the Coulter for SPID XXXXXX” and asks, “Do you want to create an average based on a single run?” To record a “Yes” response, direct the mouse arrow to the Yes button and left-click or type [Y/y]. To record a “No” response, 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.

For results where only one run was possible, the Comment box at the bottom of the window defaults to “result based on single run.”

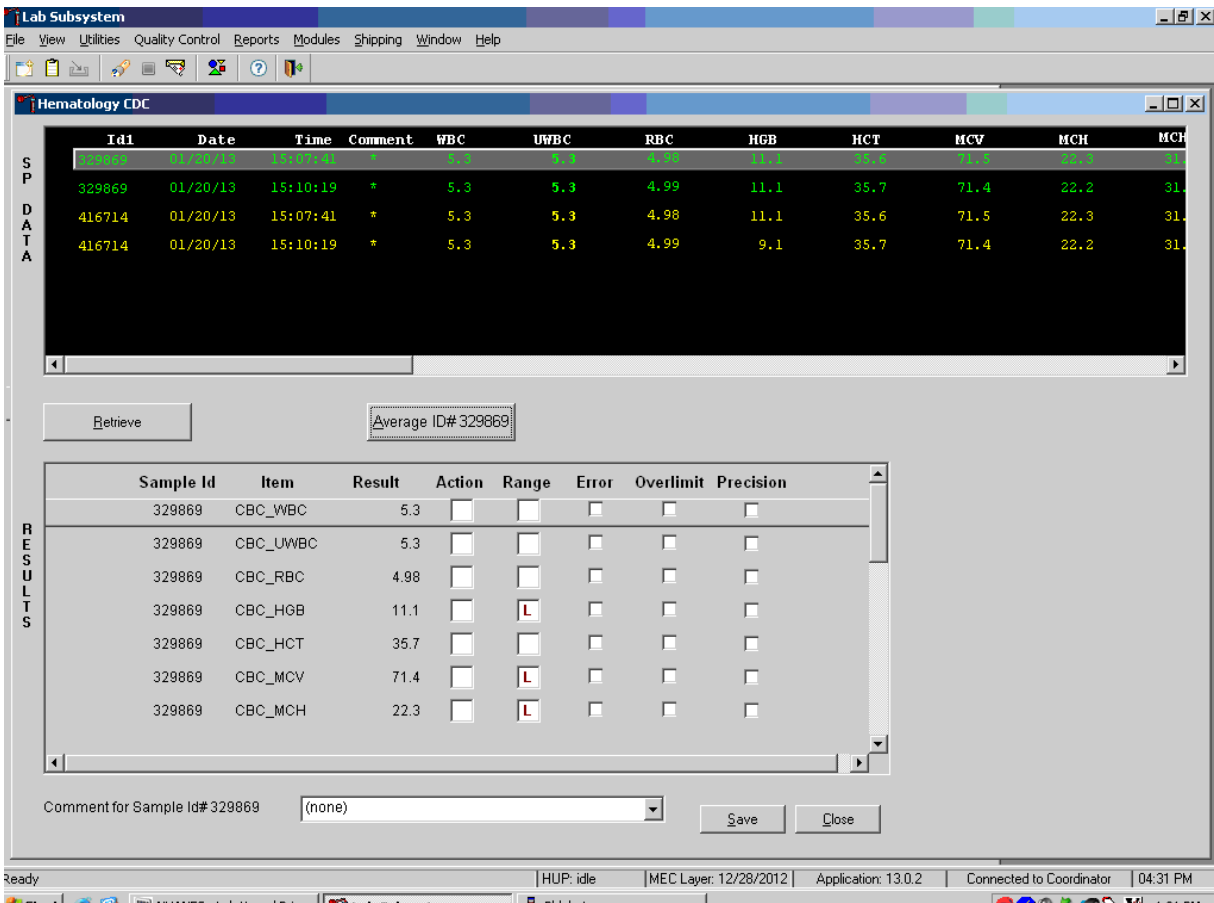
4. Running samples in duplicate

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, direct the mouse arrow to Average ID#XXXXXX button and left-click.

Results display in the lower section of the window.

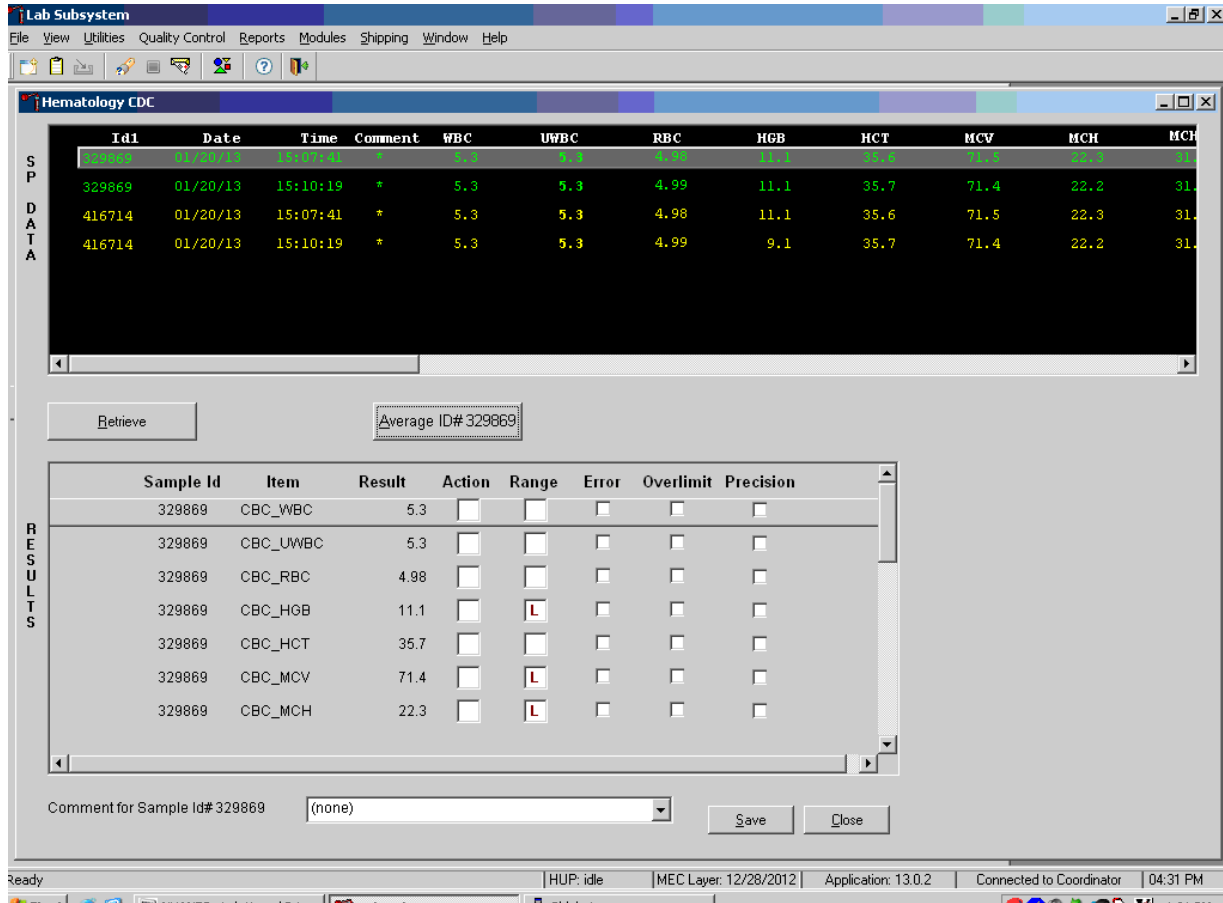


The differences between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if they are within the following CDC-established precision limits (Table 6-4).

Table 6-4. CDC precision limits

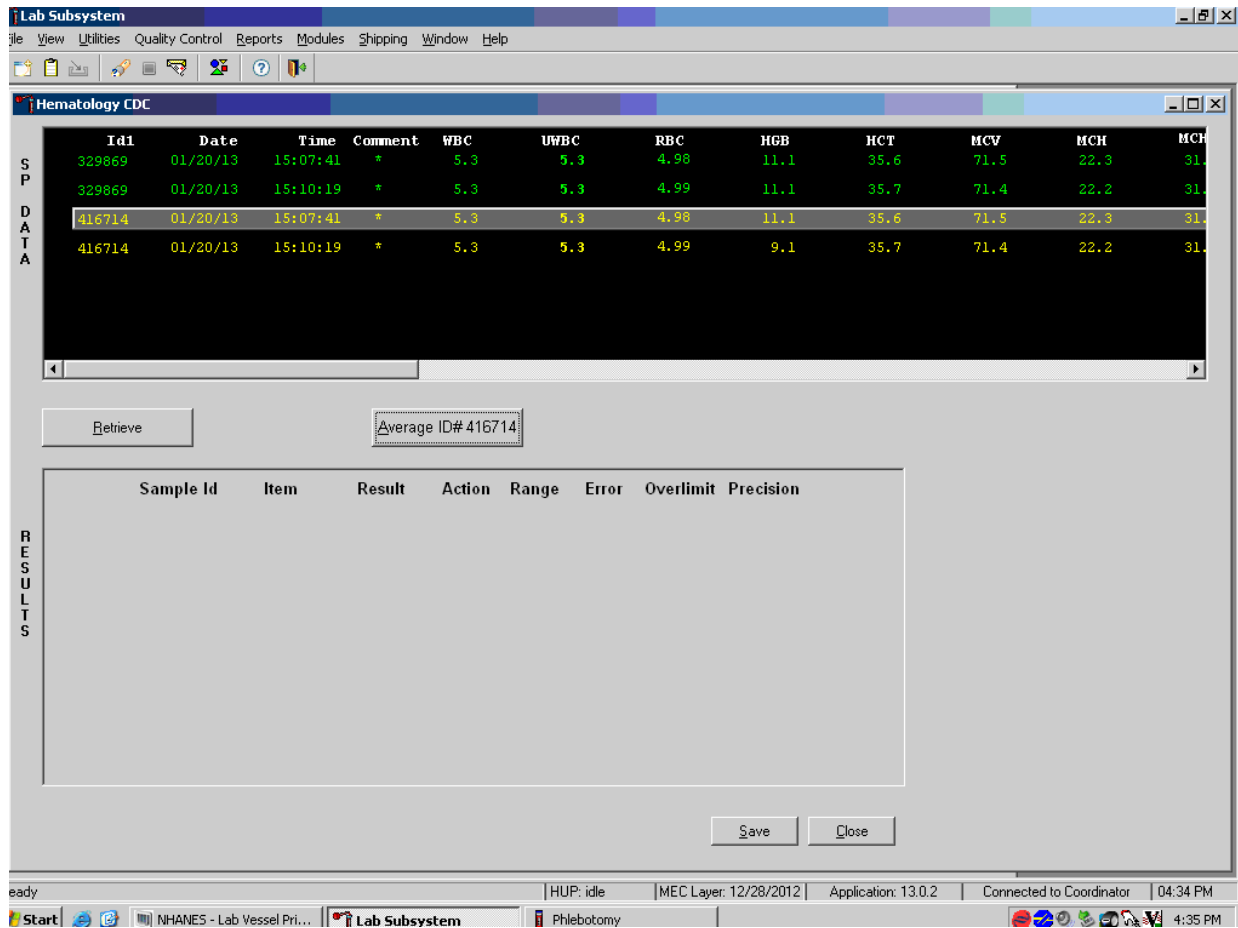
Test	Precision limits
WBC	$\pm 0.4 \times 10^3$
RBC	$\pm 0.1 \times 10^6$
Hgb	± 0.4 g/dl
MCV	± 2.2 fL
Plt	$\pm 23 \times 10^3$
NE#	$\pm 0.4 \times 10^3$
LY#	$\pm 0.2 \times 10^3$
MO#	$\pm 0.2 \times 10^3$
EO#	$\pm 0.2 \times 10^3$
BA#	$\pm 0.2 \times 10^3$

If RBC parameters are out of range, evaluate the data for 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.



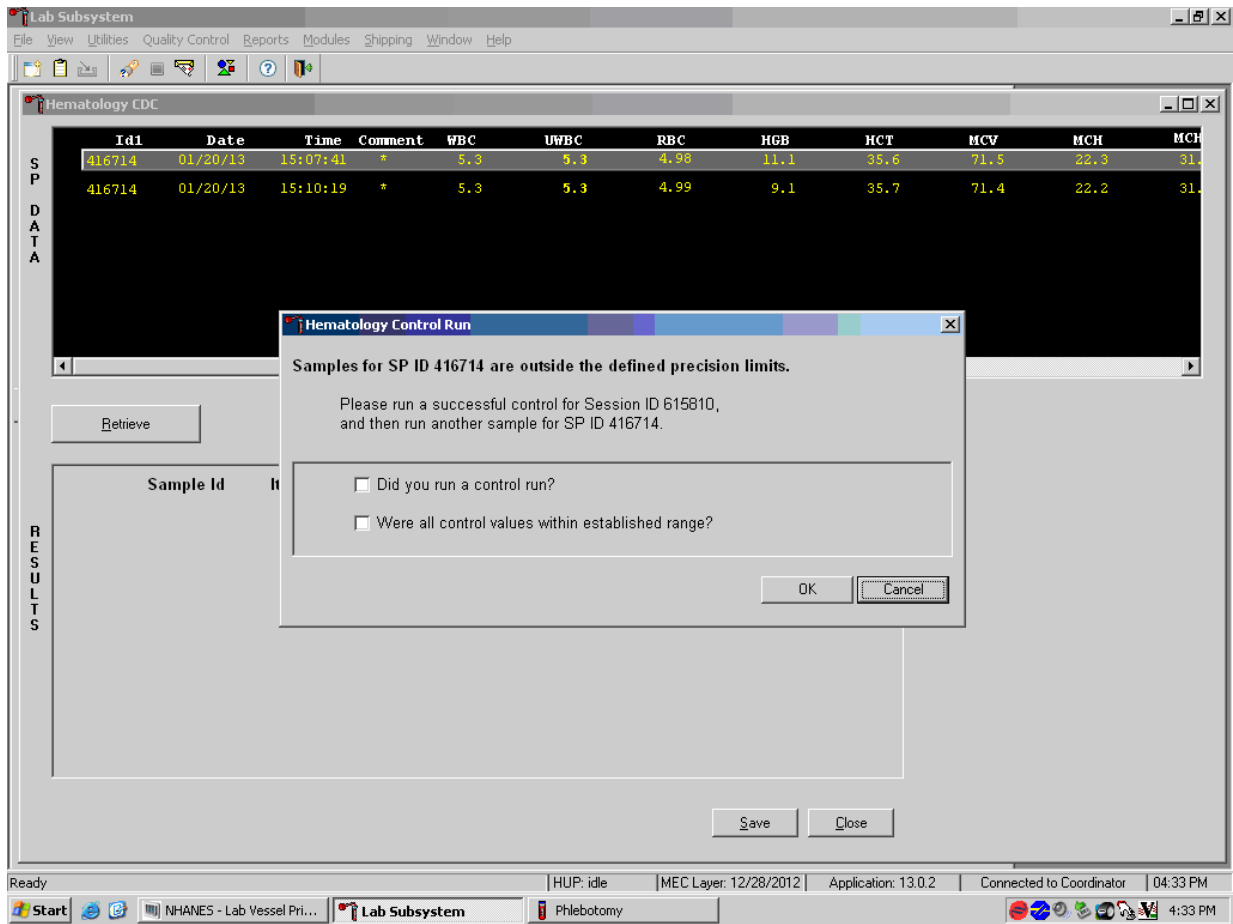
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and “H” or “L” action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click.

Average, evaluate, and rerun specimens that exceed precision limits.



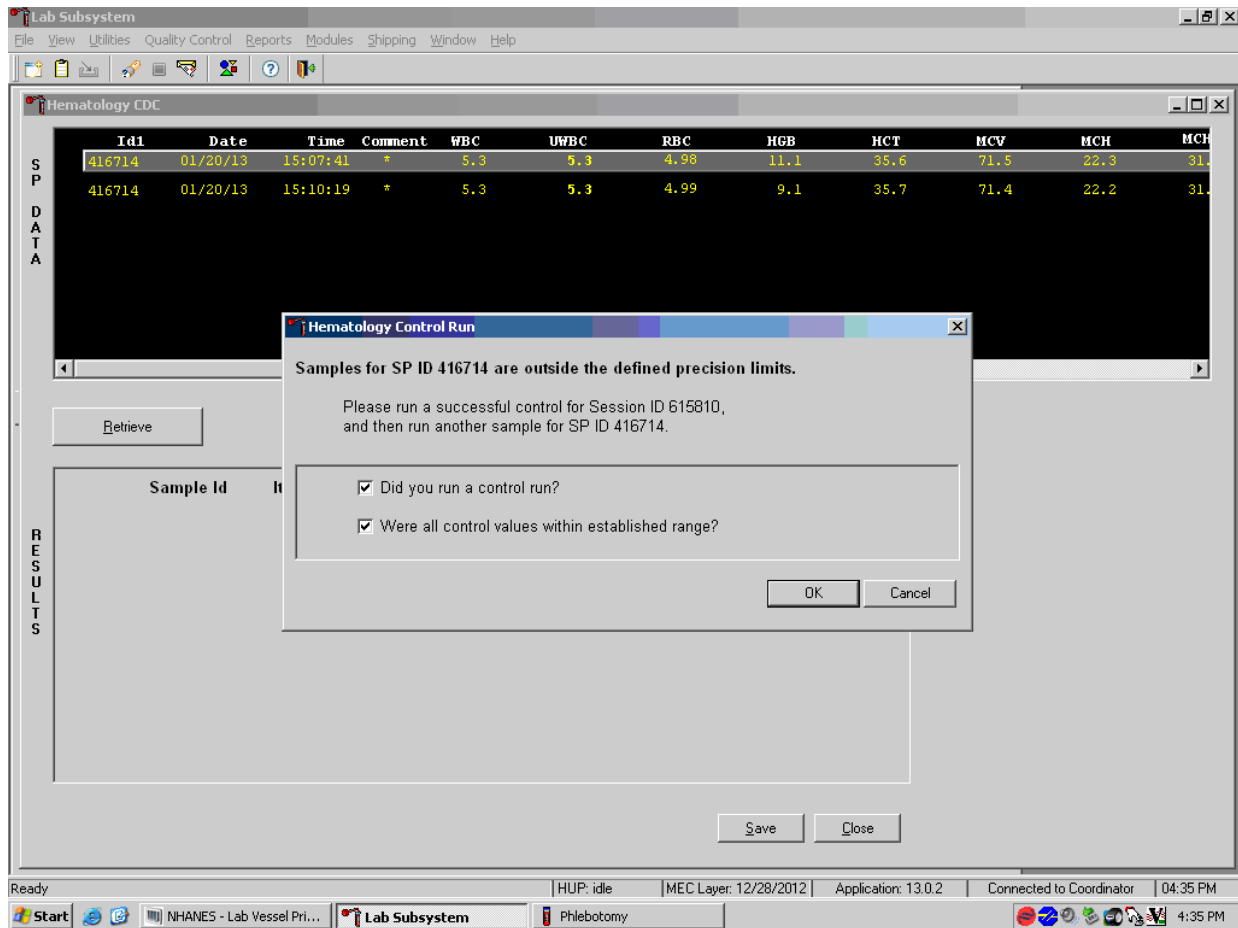
Average the two results by using the mouse to direct the mouse arrow to the Average ID#XXXXXX button and left-click. If, at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate it to determine if all control values fall within the control's established range.

If any parameter exceeds its precision limit, the Hematology Control Run window displays.



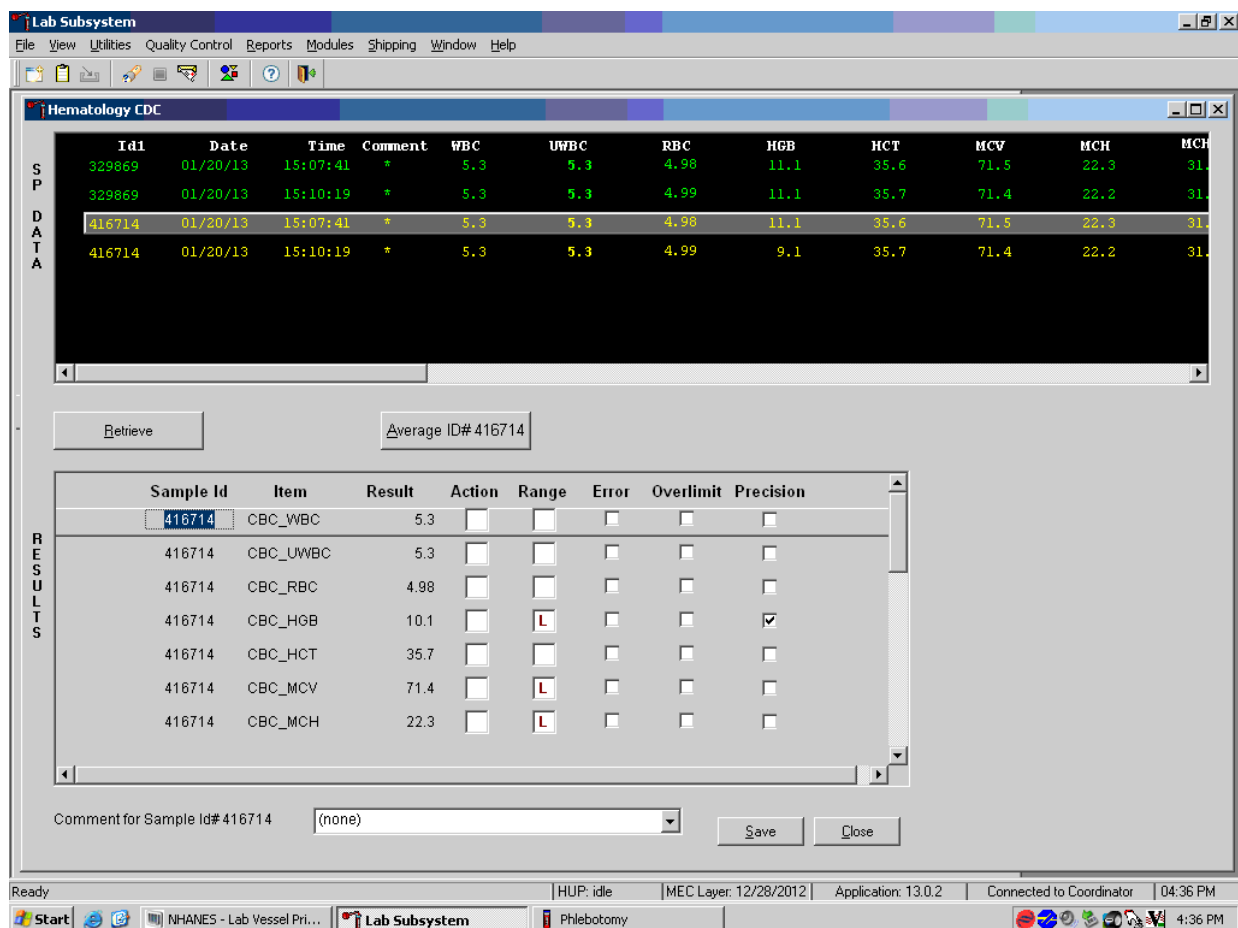
The Hematology Control Run window indicates that the “Samples for SP ID XXXXXX are outside the defined precision limits.” It instructs the technologist to “Please run a successful control for Session ID XXXXXX, and then run another sample for SP ID XXXXXX.” If it has been more than 30 minutes since running the sessions QC (all three levels of 6C cell control), run any one level of 6C 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, direct the mouse arrow to each of the two check boxes and left-click to record the checkmarks.

Save the responses to the check box questions.



To save these responses to the database, direct the mouse arrow to the OK button and left-click or type Enter. To exit the Hematology Control Run window without saving the responses, 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.



Evaluate each parameter for error, overlimit, and precision checkmarks, and “H” or “L” action limit, reference range flags, and comment in the above screen. 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 again (total of four runs, since the instrument is set to run all samples in duplicate), delete the run that caused the precision error. Save one run and comment based on a single run. (In the above example, delete the second run for SP 416714 and save the first run.) To save the results to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click. Run one level of QC when precision limits are exceeded, before re-running the sample in duplicate. Remember to fill out the 6C spreadsheet to account for the extra run of that level of control.

Run the specimen again when any precision limit is exceeded or if one run has a comment and the second run does not.

The screenshot shows the 'Lab Subsystem' interface with the 'Hematology CDC' window open. The 'SP DATA' section displays a table of test results for sample ID 784174. The 'RESULTS' section shows a table of individual test results for the same sample ID.

SP DATA	Id1	Date	Time	Comment	WBC	UWBC	RBC	HGB	HCT	MCV	MCH
	745052	11/19/12	22:33:48	*	5.8	5.8	4.85	14.8	44.0	90.8	30.6
	745052	11/19/12	22:43:53	*	5.6	5.6	4.84	14.7	44.0	90.9	30.3
	767995	01/20/13	15:07:41	*	5.3	5.3	4.98	11.1	35.6	71.5	22.3
	767995	01/20/13	15:10:19	*	5.3	5.3	4.99	11.1	35.7	71.4	22.2
	784174	01/21/13	10:14:12	*	7.0	7.0	4.73	15.0	45.5	96.3	31.6
	784174	01/21/13	11:28:46	*	6.7	6.7	4.81	15.0	45.9	95.5	31.3
	784174	01/21/13	11:30:52	*	6.5	6.5	4.77	15.2	45.9	96.3	31.8

Below the SP DATA table, there is a 'Retrieve' button and a text field containing 'Average ID#784174'.

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
	784174	CBC_WBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_UWBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_RBC	4.76	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_HGB	15.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_HCT	45.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_MCV	96.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Run the blood sample again. Two additional results will be displayed. Whenever a sample is run more than once, all results in the SP Data section are displayed. Scroll through the top of the SP data window and determine which of the two runs match the best. Delete the two outlier runs, which could be the run that caused the precision error or the run that does not/does have a comment, and re-average the two remaining runs.

Lab Subsystem: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm

File View Utilities Quality Control Reports Modules Shipping Window Help

Hematology CDC

SP	DATA	Id1	Date	Time	Comment	WBC	UWBC	RBC	HGB	HCT	MCV	MCH
		530009	11/09/12	14:50:06	*	5.1	5.6	3.96	13.0	37.6	95.1	32.8
		709532	12/08/12	09:18:14	*	4.0	5.0	4.99	15.5	44.2	88.6	31.1
		709532	12/08/12	09:20:57	*	4.0	5.0	4.93	15.5	43.7	88.6	31.4
		721160	11/09/12	14:48:06	*	4.5	5.0	3.96	13.0	37.6	95.1	32.8
		721160	11/09/12	14:50:06	*	4.5	5.0	3.96	13.0	37.6	95.1	32.8
		748968	12/08/12	09:18:14	*	4.0	5.0	4.99	15.5	44.2	88.6	31.1
		748968	12/08/12	09:20:57	*	4.0	5.0	4.93	15.5	43.7	88.6	31.4

Retrieve Average ID# 748968

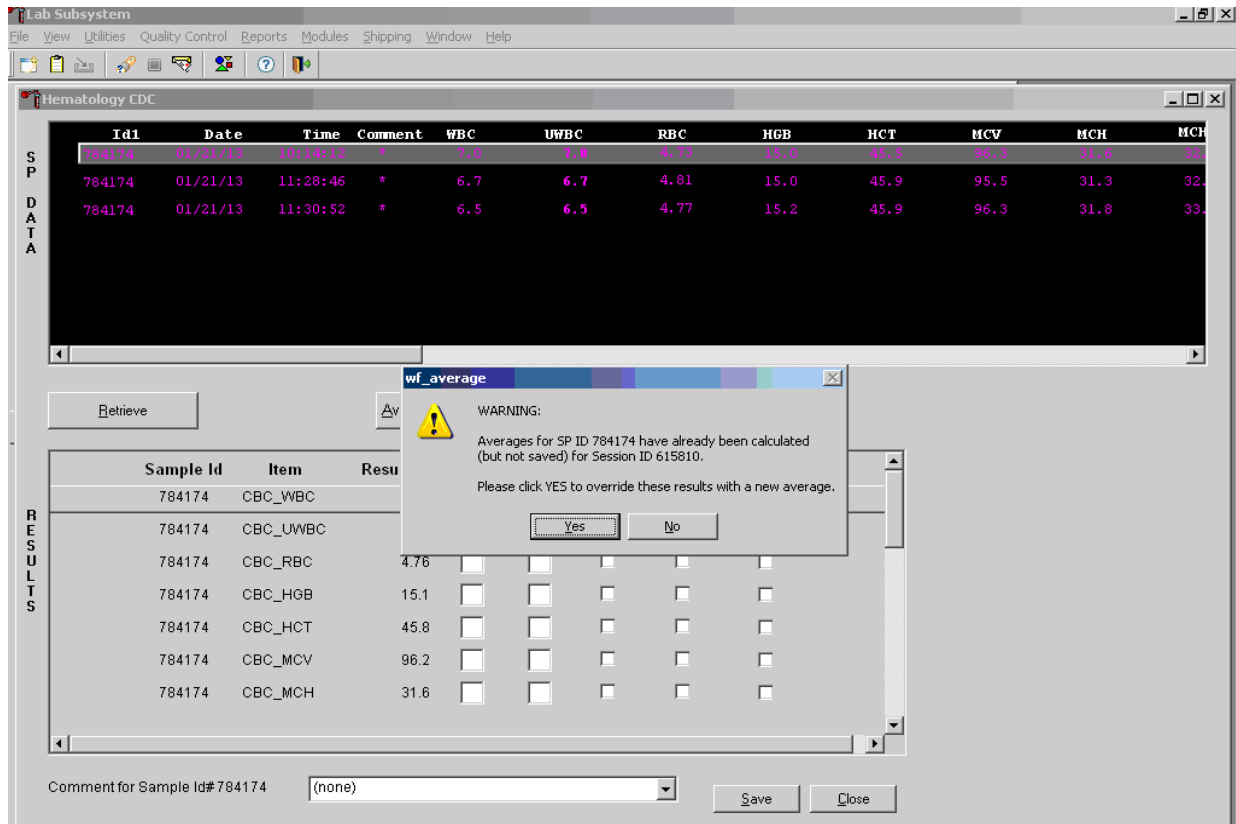
RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision

Save Close

ready | HUP: idle | MEC Layer: 12/28/2012 | Application: 13.0.0 | Not connected to Coordinator | 02:04 PM

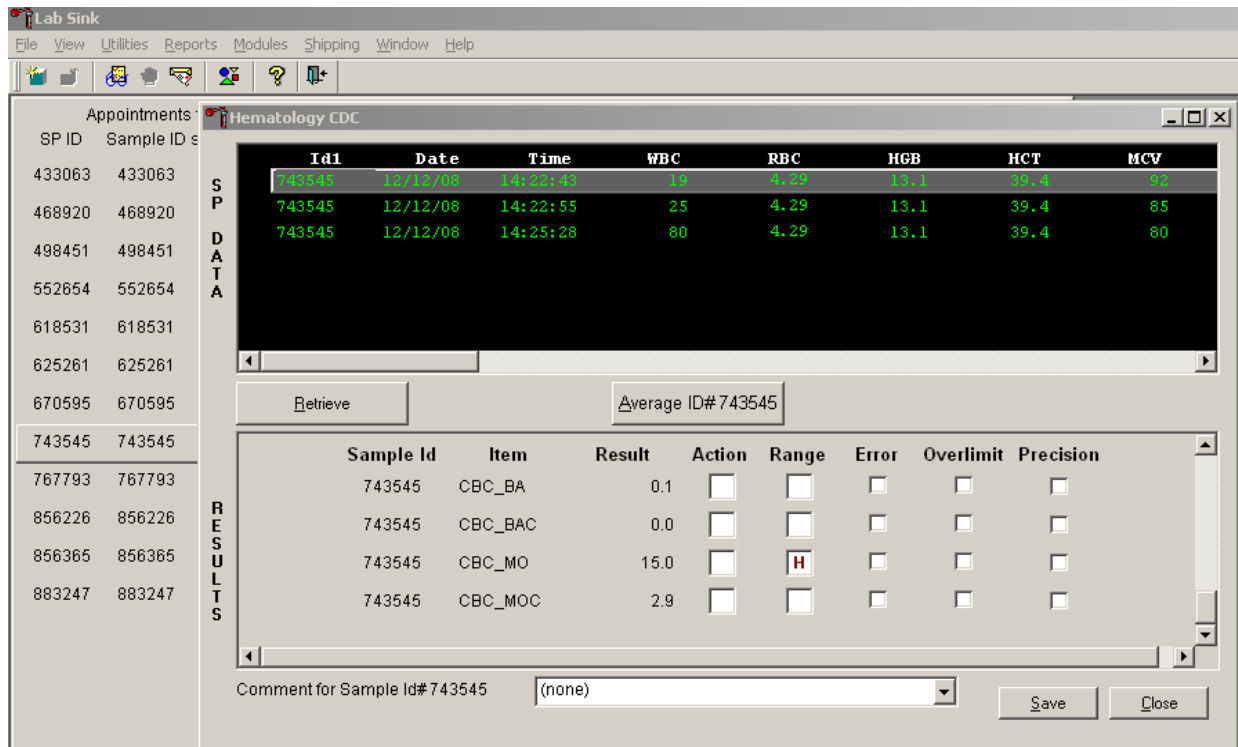
After clearing the outlier runs, re-average the two remaining runs and analyze the results.

Override the current averaged results with a new average.



Whenever a sample has previously been averaged, and a new average is calculated, a warning message text box displays stating, “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, direct the mouse arrow to the Yes button and left-click, or press Enter. To exit or return to the previous screen containing the previous averages, direct the mouse arrow to the No button and left-click.

Evaluate the new results.



If all parameters of the two remaining runs 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, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click.

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 four times.

Lab Subsystem

File View Utilities Quality Control Reports Modules Shipping Window Help

Hematology CDC

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Id1	Date	Time	Comment	WBC	UWBC	RBC	HGB	HCT	MCV	MCH
745052	11/19/12	22:33:48	*	5.8	5.8	4.85	14.8	44.0	90.8	30.6
745052	11/19/12	22:43:53	*	5.6	5.6	4.84	14.7	44.0	90.9	30.3
767995	01/20/13	15:07:41	*	5.3	5.3	4.98	11.1	35.6	71.5	22.3
767995	01/20/13	15:10:19	*	5.3	5.3	4.99	11.1	35.7	71.4	22.2
784174	01/21/13	10:14:12	*	7.0	7.0	4.73	15.0	45.5	96.3	31.6
784174	01/21/13	11:28:46	*	6.7	6.7	4.81	15.0	45.9	95.5	31.3
784174	01/21/13	11:30:52	*	6.5	6.5	4.77	15.2	45.9	96.3	31.8

Retrieve Average ID# 784174

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Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
784174	CBC_WBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_UWBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_RBC	4.76	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_HGB	15.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_HCT	45.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_MCV	96.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
784174	CBC_MCH	31.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 784174 (none) Save Close

Ready HUP: idle MEC Layer: 1/30/2013 Application: 13.0.3 Connected to Coordinator 03:46 PM

5. Attaching comments to the results

Enter a comment for any run where results were repeated and confirmed, the equipment failed, or there was a laboratory error.

The screenshot shows the Lab Sink software interface. The main window displays Hematology CDC results for sample ID 743545. A dropdown menu is open, showing options for attaching comments to the results.

Appointment Data:

SP ID	Sample ID
433063	433063
468920	468920
498451	498451
552654	552654
618531	618531
625261	625261
670595	670595
743545	743545
767793	767793
856226	856226
856365	856365
883247	883247

Hematology CDC Results:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
743545	12/12/08	14:22:47	15	4.29	13.1	39.4	85
743545	12/12/08	14:22:55	25	4.29	13.1	39.4	85
743545	12/12/08	14:25:28	80	4.29	13.1	39.4	80

Results Table:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_BA	0.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_BAC	0.0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MO	15.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MOC	2.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 743545:

- (none)
- (none)
- results repeated and confirmed
- laboratory error
- result based on single run

Buttons: Retrieve, Average ID# 743545, Save, Close

System tray: Ready | HUP: idle | MEC Layer: 12/11/2008 | Application: 9.0.0 | Connected to Coordinator | 02:28 PM

The screenshot displays the 'Lab Subsystem' interface for Hematology CDC. The top window shows a list of samples with the following data:

Id1	Date	Time	Comment	WBC	UWBC	RBC	HGB	HCT	MCV	MCH
745052	11/19/12	22:33:48	*	5.8	5.8	4.85	14.8	44.0	90.8	30.6
745052	11/19/12	22:43:53	*	5.6	5.6	4.84	14.7	44.0	90.9	30.3
767995	01/20/13	15:07:41	*	5.3	5.3	4.98	11.1	35.6	71.5	22.3
767995	01/20/13	15:10:19	*	5.3	5.3	4.99	11.1	35.7	71.4	22.2
784174	01/21/13	10:14:12	*	7.0	7.0	4.73	15.0	45.5	96.3	31.6
784174	01/21/13	11:28:46	*	6.7	6.7	4.81	15.0	45.9	95.5	31.3
784174	01/21/13	11:30:52	*	6.5	6.5	4.77	15.2	45.9	96.3	31.8

The bottom window shows the 'RESULTS' table for sample 784174:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
784174	CBC_WBC	6.9					
784174	CBC_UWBC	6.9					
784174	CBC_RBC	4.76					
784174	CBC_HGB	15.1					
784174	CBC_HCT	45.8					
784174	CBC_MCV	(none)					
784174	CBC_MCH	(none)					

A dropdown menu is open over the 'Action' column for sample 784174, showing the following options:

- (none)
- results repeated and confirmed
- laboratory error
- result based on single run
- (none)

The 'Comment for Sample Id# 784174' box is currently empty.

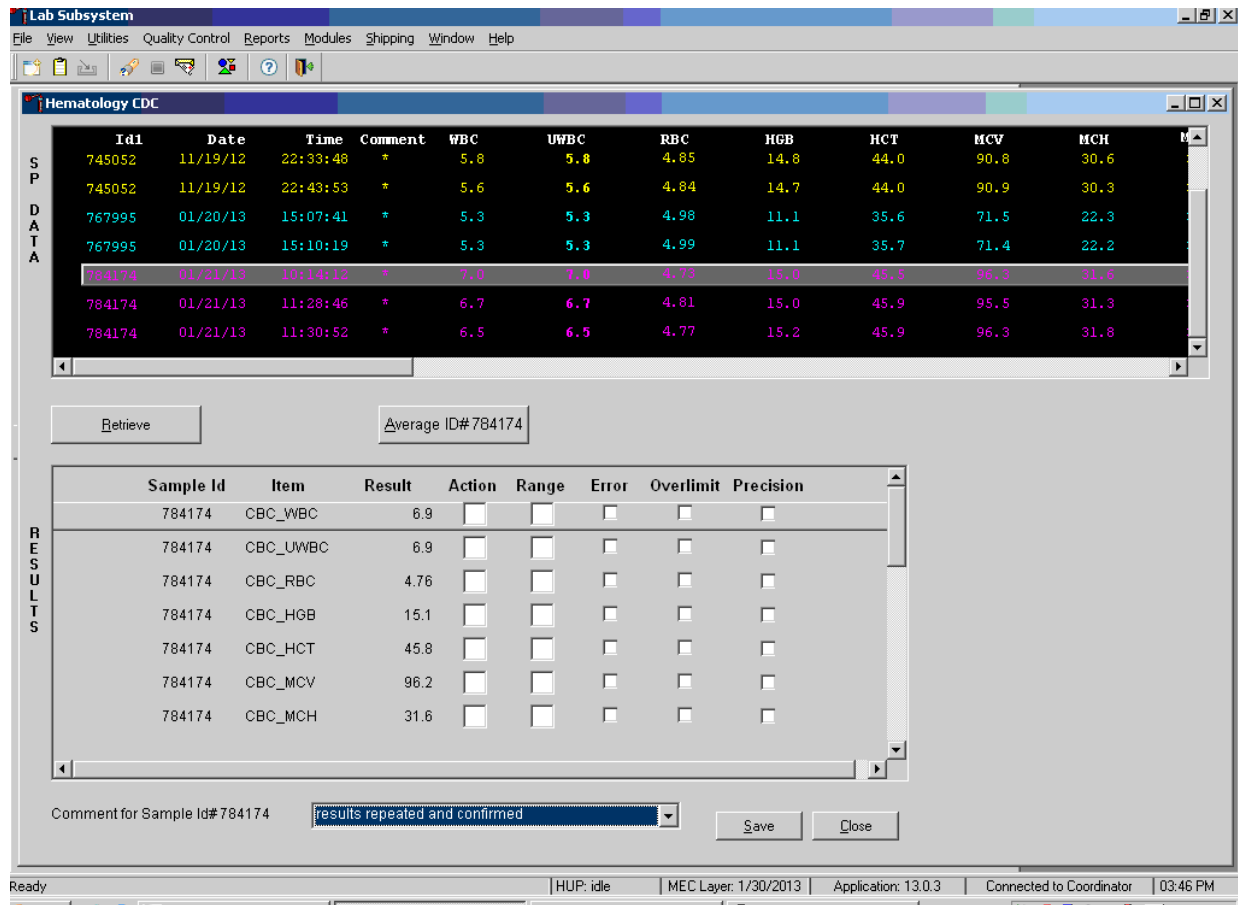
To attach a comment to the results in the database, direct the mouse arrow to the drop-down list on the Comment box, left-click to display the codes, drag the mouse arrow to the most appropriate choice, and left-click. Alternatively, to record a comment, direct the mouse arrow to the drop-down list on 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.

Exhibit 6-11 presents the comments for the samples and when they are to be used.

Exhibit 6-11. List of comments to be used

Comment	Use when
Results repeated and confirmed	Any parameter exceeded an action, range, or precision limit and the specimen (blood tube) was run more than once.
Laboratory error	There was a technologist error.
Result based on single run	The quantity of specimen is insufficient to run it more than once.
Equipment failure	The Coulter malfunctioned.
No diff results/diff vote out	The Coulter does not report parameter results for any part of the differential or the instrument reported a voteout for any of the differential parameters.
Clotted	The blood is clotted.
Not enough blood	There is insufficient blood to perform at least one complete aspiration.

Save the result after attaching a comment.



Save the averaged result and update the comment by using the mouse to direct the mouse arrow to the Save button and left-click. To exit without saving any data to the database, direct the mouse arrow to the Close button and left-click.

6. Using alternative data manipulation choices

Retain data for multiple SPs in the SP Data section of the window.

The screenshot shows the 'Lab Subsystem' interface with the 'Hematology CDC' window open. The 'SP DATA' section displays a table of sample data with columns: Id#, Date, Time, Comment, WBC, UWBC, RBC, HGB, HCT, MCV, and MCH. The data is color-coded by SP ID: 745052 (yellow), 767995 (green), and 784174 (magenta). The '784174' row is highlighted. Below this table is a 'Retrieve' button and a text field containing 'Average ID#784174'. The 'RESULTS' section shows a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The results for SP 784174 are listed. At the bottom, there is a 'Comment for Sample Id#784174' dropdown menu with the text 'results repeated and confirmed', and 'Save' and 'Close' buttons.

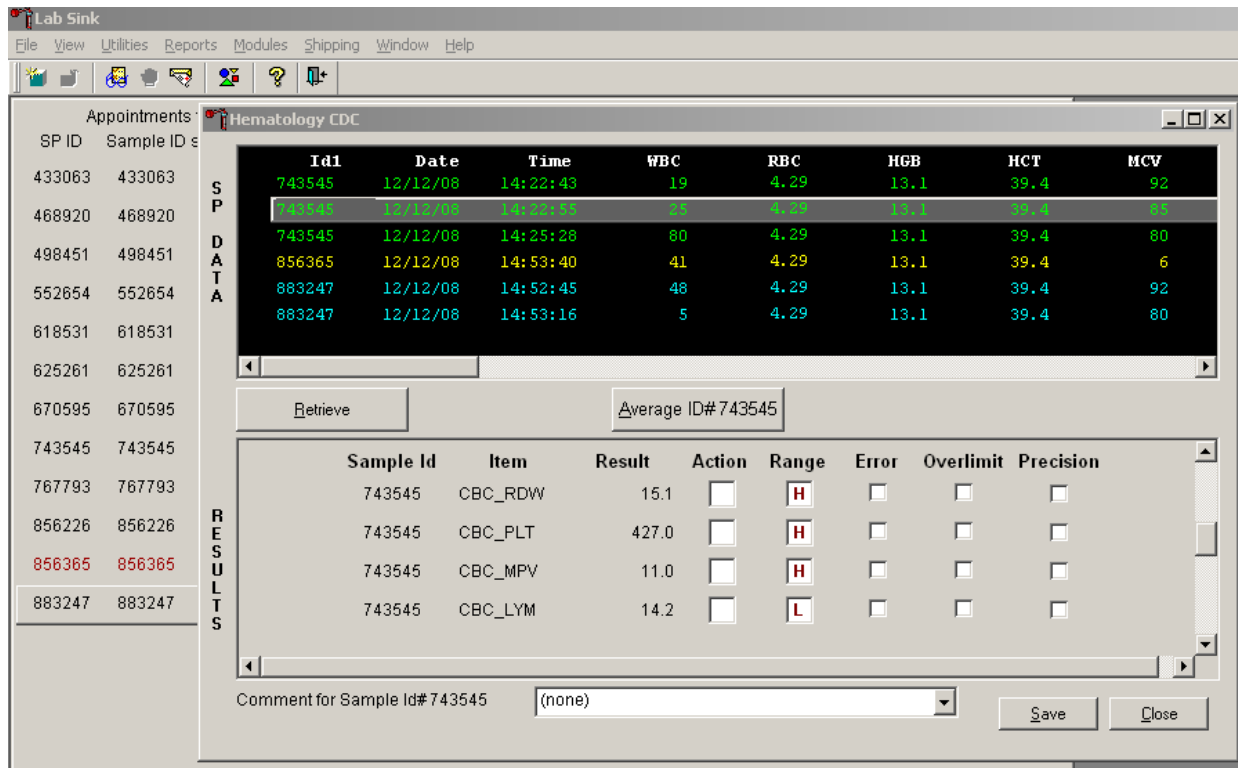
SP DATA	Id#	Date	Time	Comment	WBC	UWBC	RBC	HGB	HCT	MCV	MCH
	745052	11/19/12	22:33:48	*	5.8	5.8	4.85	14.8	44.0	90.8	30.6
	745052	11/19/12	22:43:53	*	5.6	5.6	4.84	14.7	44.0	90.9	30.3
	767995	01/20/13	15:07:41	*	5.3	5.3	4.98	11.1	35.6	71.5	22.3
	767995	01/20/13	15:10:19	*	5.3	5.3	4.99	11.1	35.7	71.4	22.2
	784174	01/21/13	10:14:12	*	7.0	7.0	4.73	15.0	45.5	96.3	31.6
	784174	01/21/13	11:28:46	*	6.7	6.7	4.81	15.0	45.9	95.5	31.3
	784174	01/21/13	11:30:52	*	6.5	6.5	4.77	15.2	45.9	96.3	31.8

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
	784174	CBC_WBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_UWBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_RBC	4.76	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_HGB	15.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_HCT	45.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_MCV	96.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_MCH	31.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id#784174: results repeated and confirmed

In general, run one SP in duplicate through the Coulter, retrieve the data, 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, direct the mouse arrow to the row containing the correct SP ID and left-click.

Average the results for one SP at a time.



Evaluate each parameter for error, over limit, 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, direct the mouse arrow to the Save button and left-click. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click. If there are any precision checkmarks, run a 6C cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

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.

Lab Sink

File View Utilities Reports Modules Shipping Window Help

Appointments

SP ID Sample ID

433063 433063

468920 468920

498451 498451

552654 552654

618531 618531

625261 625261

670595 670595

743545 743545

767793 767793

856226 856226

856365 856365

883247 883247

S
P
D
A
T
A

RESULTS

Hematology CDC

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
743545	12/12/08	14:22:43	19	4.29	13.1	39.4	92
743545	12/12/08	14:22:55	25	4.29	13.1	39.4	85
743545	12/12/08	14:25:28	80	4.29	13.1	39.4	80
856365	12/12/08	14:27:40	41	4.29	13.1	39.4	6
883247	12/12/08	14:45:45	48	4.29	13.1	39.4	92
883247	12/12/08	14:48:16	5	4.29	13.1	39.4	80

Retrieve

Average ID# 856365

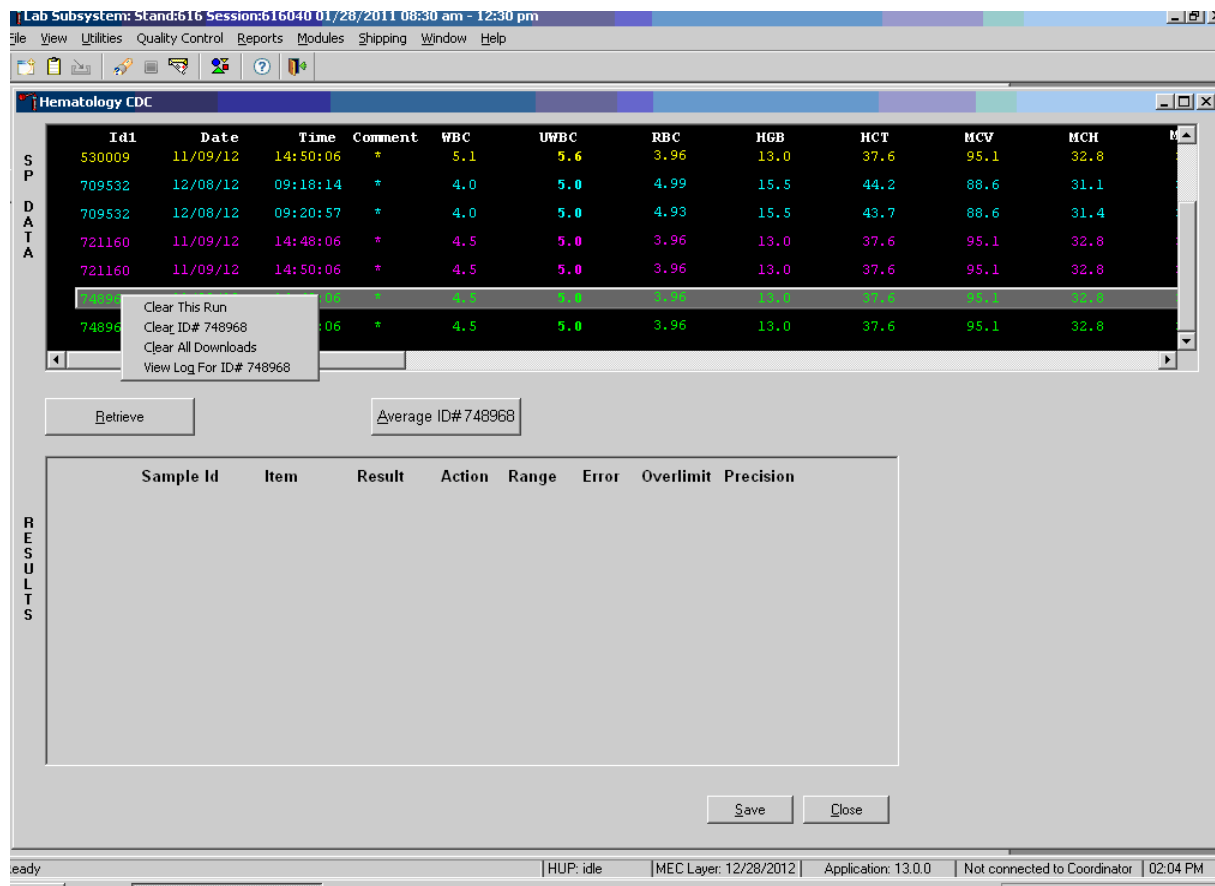
Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_RDW	15.1	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_PLT	427.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_MPV	11.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_LYM	14.2	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 743545 (none)

Save Close

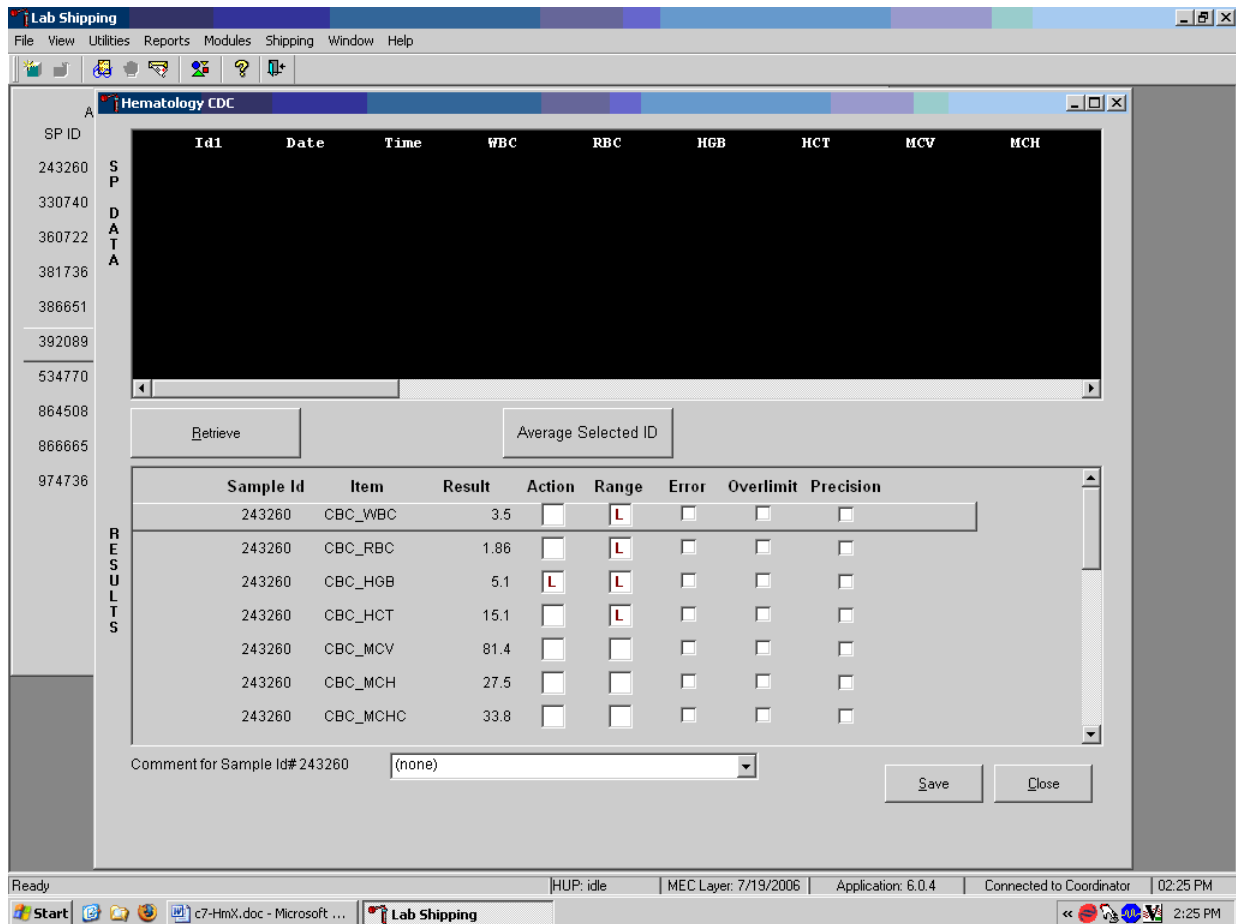
Ready | HUP: idle | MEC Layer: 12/11/2008 | Application: 9.0.0 | Connected to Coordinator | 02:56 PM

Start | Manual Screen Shots (No...) | 2009 Draft: C7.doc - Micr... | Lab Sink | Phlebotomy | 2:56 PM



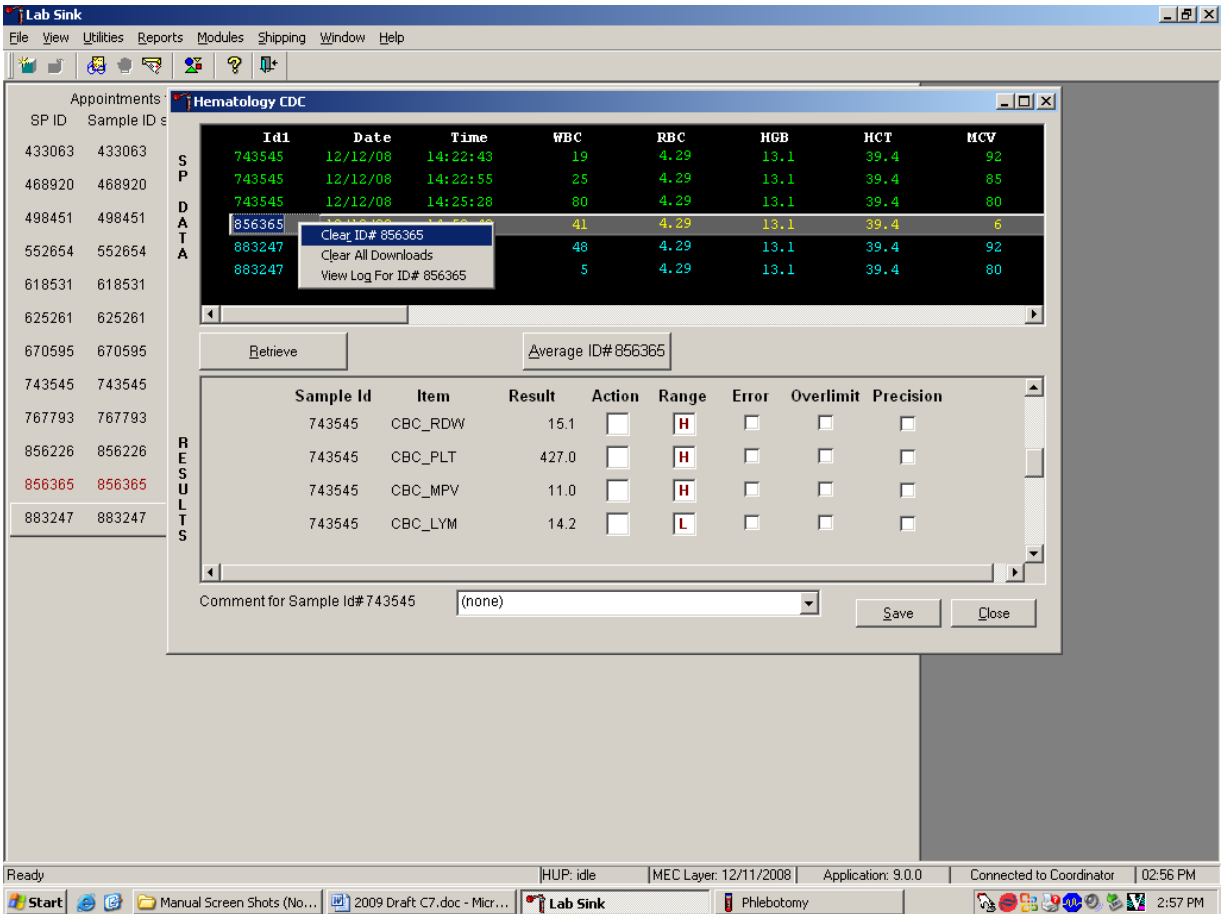
To clear all downloads from the SP Data section, direct the mouse arrow to any row in the SP Data section and right-click to display the alternative data manipulation choices. To select “Clear All Downloads,” drag the mouse arrow to the Clear All Downloads choice and left-click.

Release the mouse button to clear all downloads.



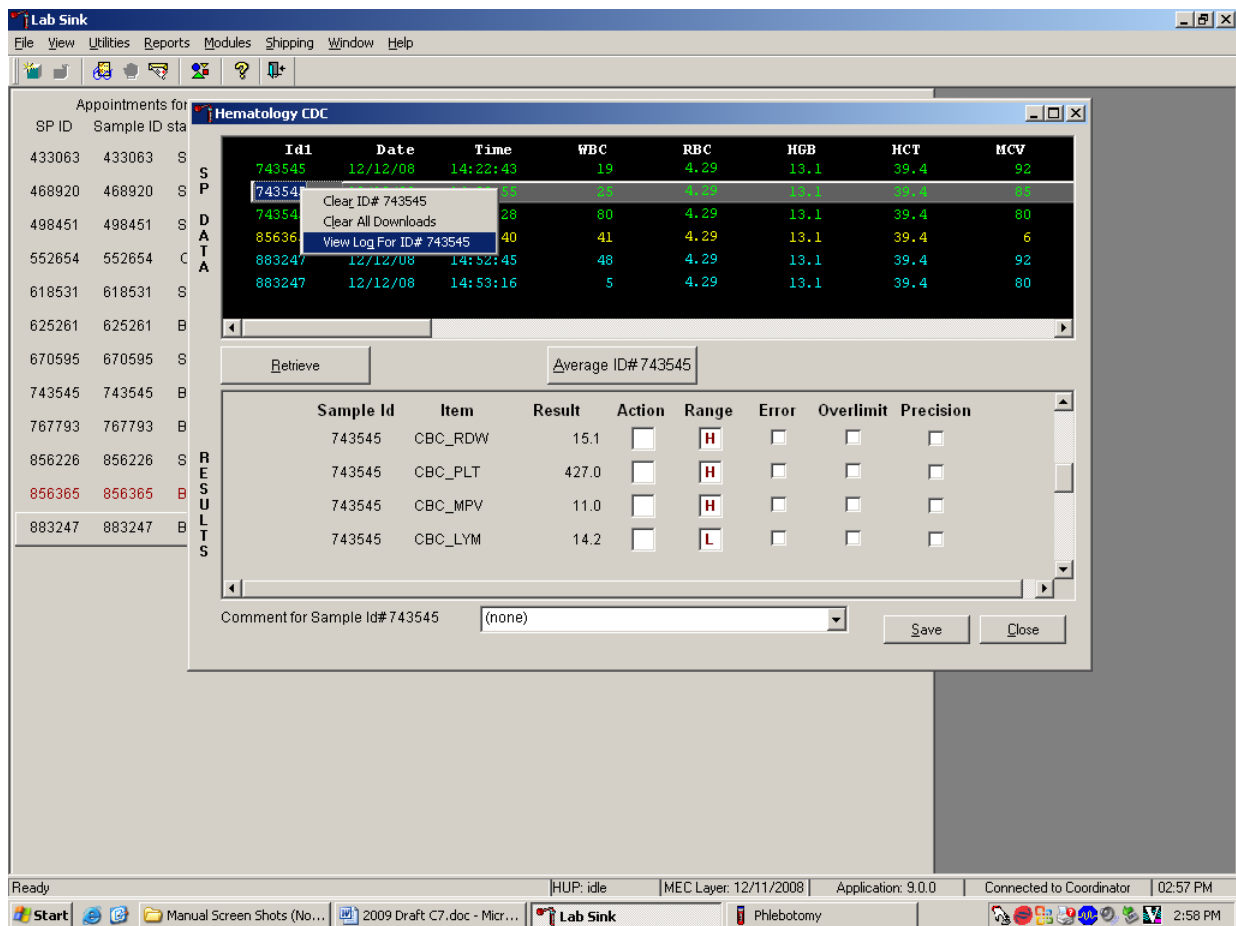
All data in the SP Data section are erased, but any averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the Hematology module, direct the mouse arrow to the Close button and left-click.

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



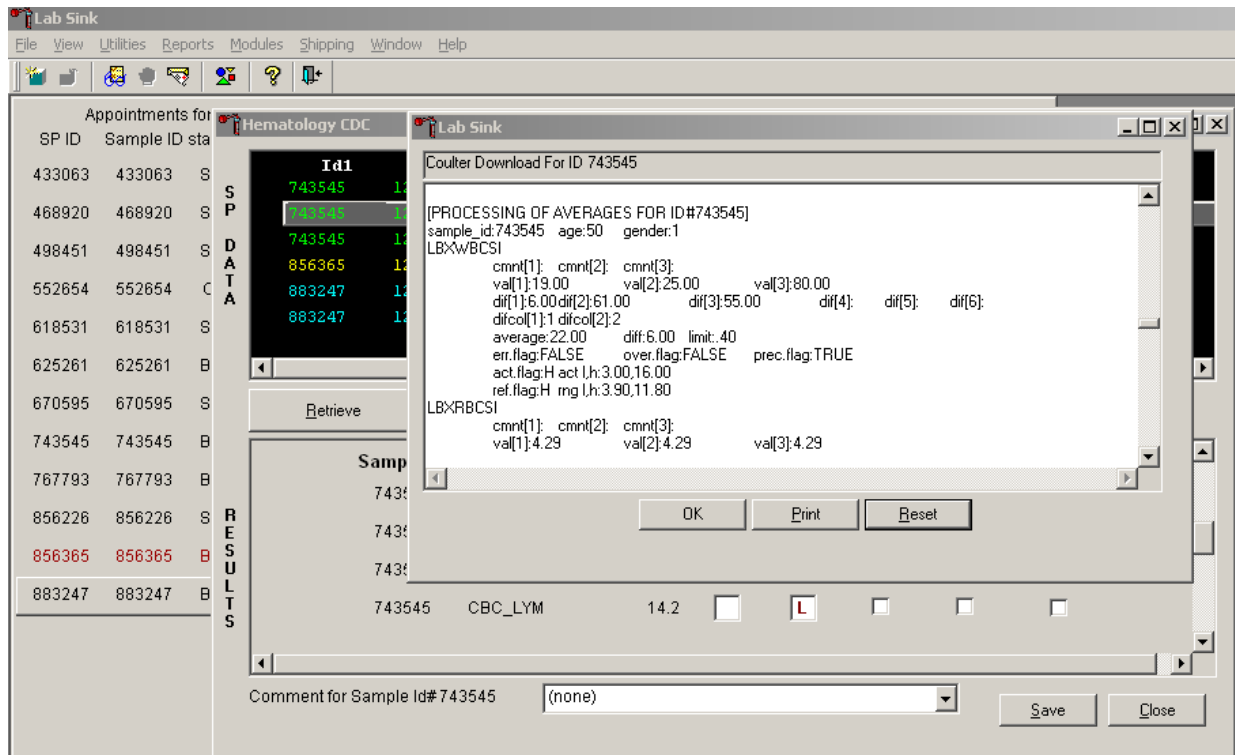
To clear the Coulter downloads for any one SP, direct the mouse arrow to the individual row in the SP Data section, right-click to display the alternative data manipulation choices, drag the mouse arrow to Clear ID#XXXXXX, and right- or left-click. Release the mouse button to clear this download. Retransmit, retrieve, 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, 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 "View Log for IDXXXXXX" 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, 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. To clear the log and close the screen, direct the mouse arrow to the Reset button and left-click, or select Enter.

6.19.3 DxH 800 Suspect Messages

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.

- **Remedial Action.** Rerun the specimen. If the flag is “H&H Does Not Match,” use the SP's EDTA sample from processing station, if available, as a check for proper tube filling. Delete all but two runs if flags are consistent, before averaging and accepting results.

6.19.4 DxH 800 Histogram Interpretations

Exhibit 6-12 presents UniCel DxH 800 Coulter cellular analysis system cell population.

Exhibit 6-12. Cellular analysis images

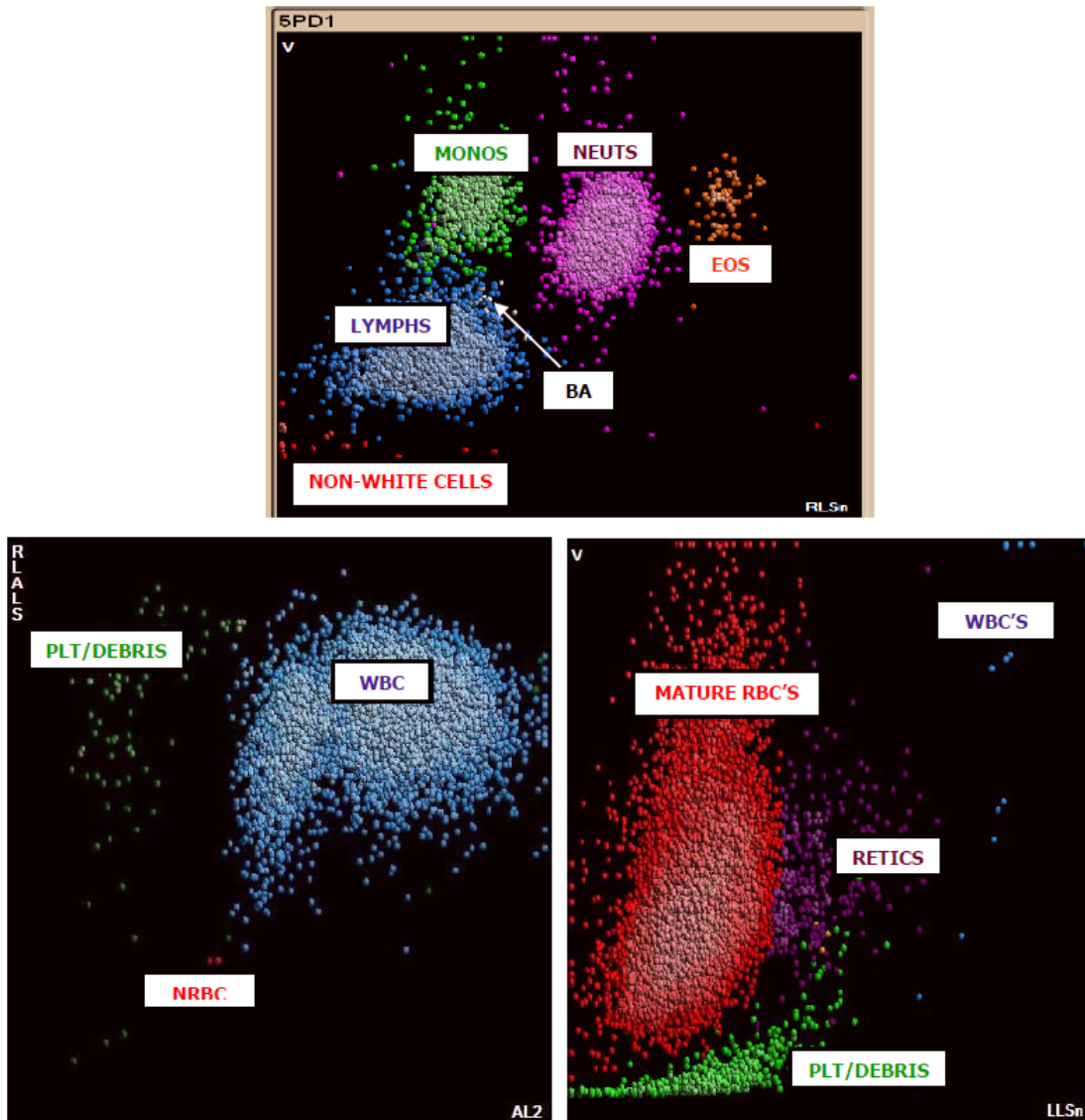


Exhibit 6-13 presents DxH system messages.

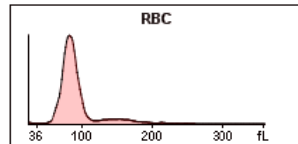
Exhibit 6-13. DxH system messages

All System messages are accompanied by "R" (Review) flags. Exceptions are the System Messages associated with an Aspiration error (P Flag) and the Non-Blood Specimen message (N Flag).

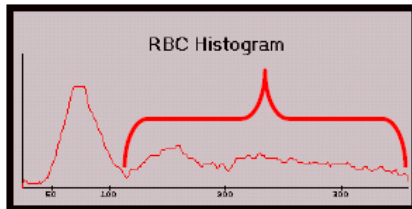
SYSTEM MESSAGE DXH	SYSTEM MESSAGE DXH
WBC	PLT
Abn WBC Pattern	Platelet Clumps
Cellular Inter	PLT Carryover
System Event: WBC	PLT Inter: Debris
WBC Carryover	RBC-PLT Overlap
RBC	System Event: PLT
Abn RBC Pattern	NRBC
System Event: RBC	Abn NRBC Pattern
HGB	AL2 Blank Volt: N
HGB Inter: WBC	DataDisc: N
HGB Blank Shift	High Event Rate: N
System Event: HGB	Low AL2 Events: N
MCV	Low DC Events: N
MCV Inter: PLT	Low Event Rate: N
MCV Inter: WBC	Low Events: N
DIFF	NRBC Inter
Abn Diff Pattern	NRBC-LY Overlap
Aged Sample	System Event: N
Data Disc: D	BF
Excessive Debris: D	Abn TNC Pattern
High Event Rate: D	System Event: TNC
High OP Events: D	TNC Carryover
High RF Events: D	P
Low Event Rate: D	Bubbles
Low Events: D	Carryover
Low OP Events: D	No Aspiration
Low RMALS Events: D	Non-blood Specimen
MO-NE Overlap	Partial Aspiration
NE-EO Overlap	Range Error
System Event: D	Unknown Error
Undefined Pop: D	:::: Code
RETIC	Flow Cell Clog: D
Abn Retic Pattern	Flow Cell Clog: N
AL2 Blank Volt: R	Flow Cell Clog: R
Data Disc: R	
High Event: R	
Low Event: R	
Nucleated Cells	
RET Inter: Debris	
RET Inter: PLT	
RET-RBC Overlap	
System Event: R	

Exhibits 6-14, 6-15, 6-16, and 6-17 respectively present red blood cell histogram examples, white blood cell histogram examples, platelets histogram examples, and an image of better abnormal cell detection.

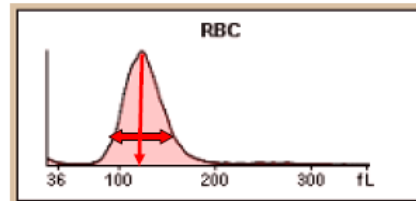
RBC Histogram Examples



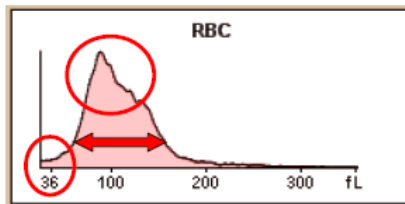
NORMAL



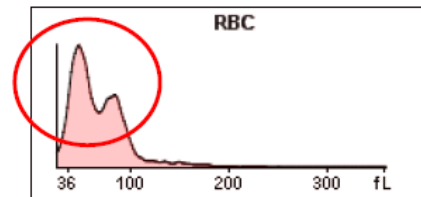
RBC AGGLUTININ



MACROCYTIC, Elevated RDW

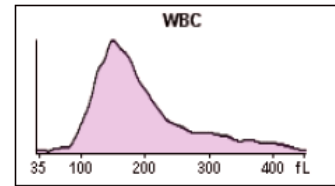
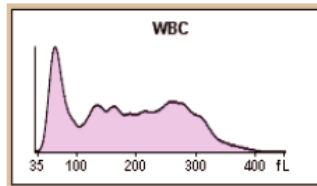
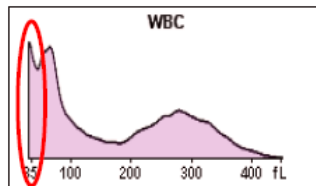
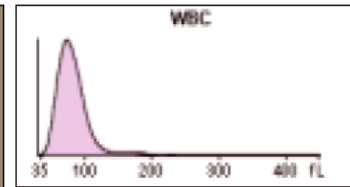
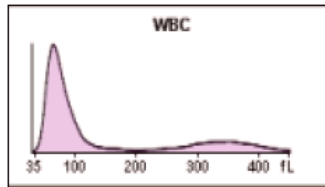
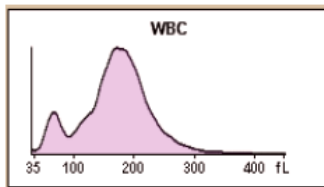
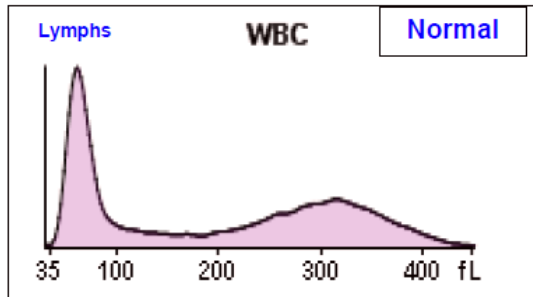


RBC Fragments / DI RBC / Elevated RDW



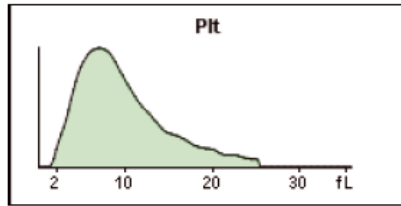
DI RBCs, RBC Frags, Elevated RDW

WBC Histogram Examples

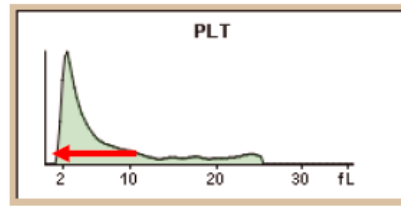


PLT Histogram Examples

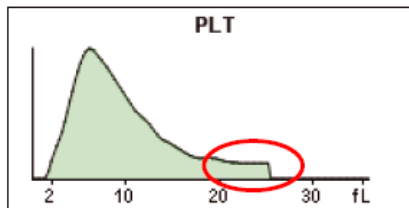
Normal



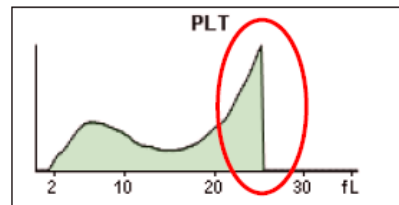
Small Platelets



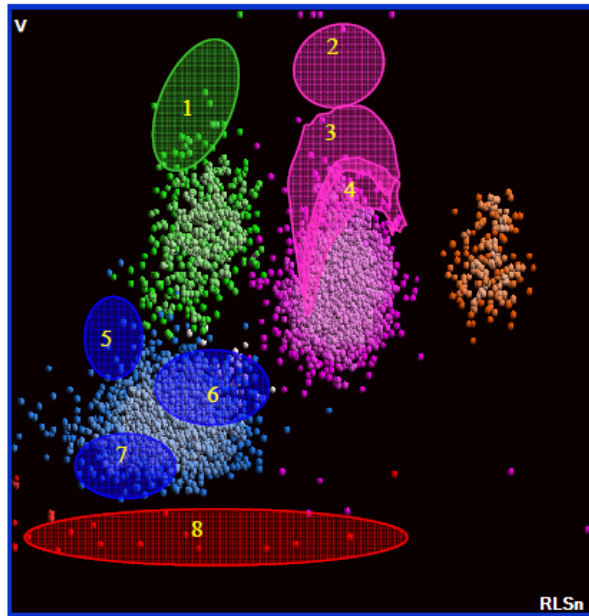
Giant Platelets



RBC/PLT Overlap



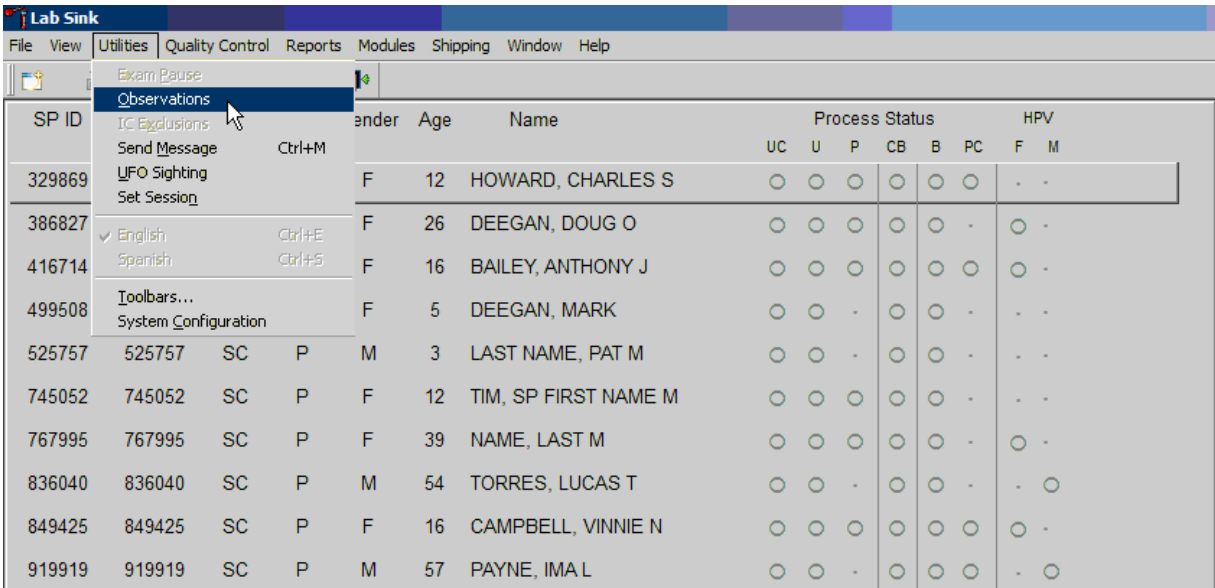
Better Abnormal Cell Detection



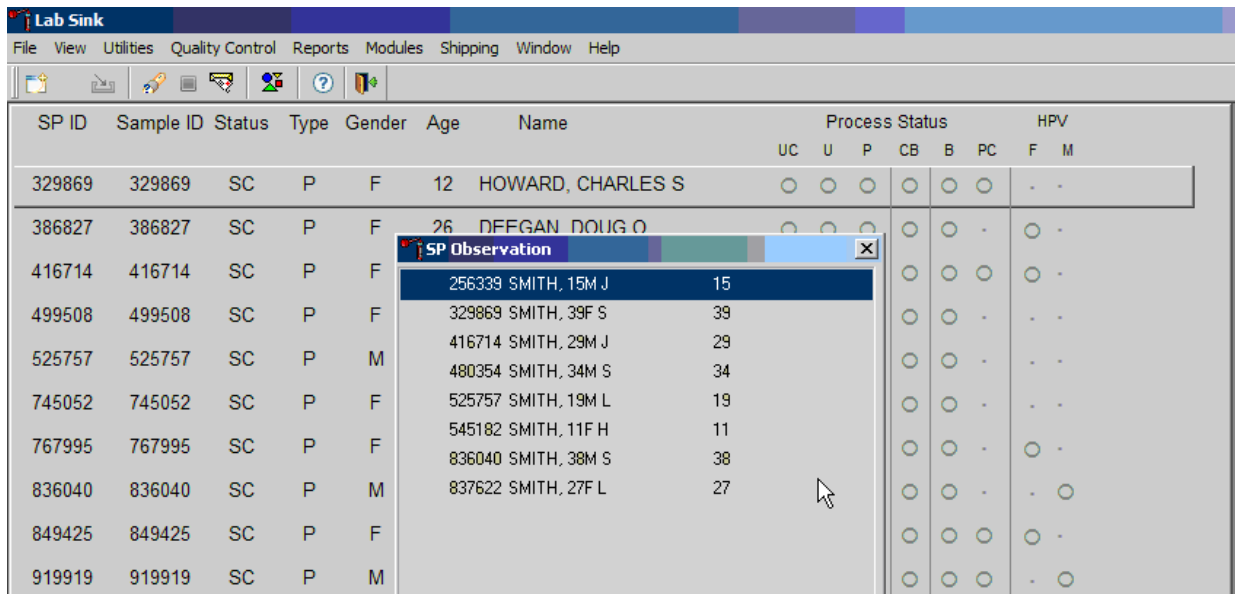
1. MO Blasts
2. NE Blasts
3. Immature Granulocytes
4. Band Neutrophils
5. LY Blasts
6. Variant Lymphocytes
7. Small Lymphs / Low Opacity
8. Non-White Cells

6.19.5 Clinician Review

The MEC clinician reviews and interprets all CBC results. Results outside action limits flash and transmit to the clinician immediately. The clinician determines if referral for the SP for treatment is necessary. The clinical laboratory scientist sends an observation to the clinician whenever a critical or action limit is detected for any CBC parameter.

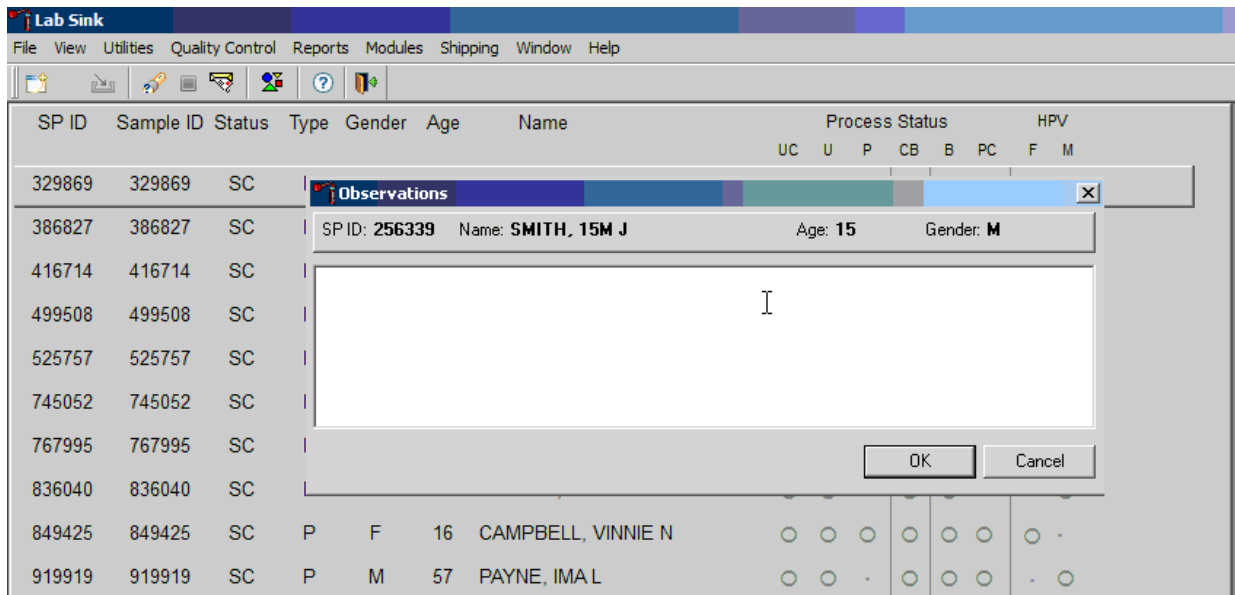


To access the observation function, direct the mouse arrow to Utilities in the menu bar, left-click, drag the mouse arrow to Observations, and left-click. Select or highlight the correct SP.



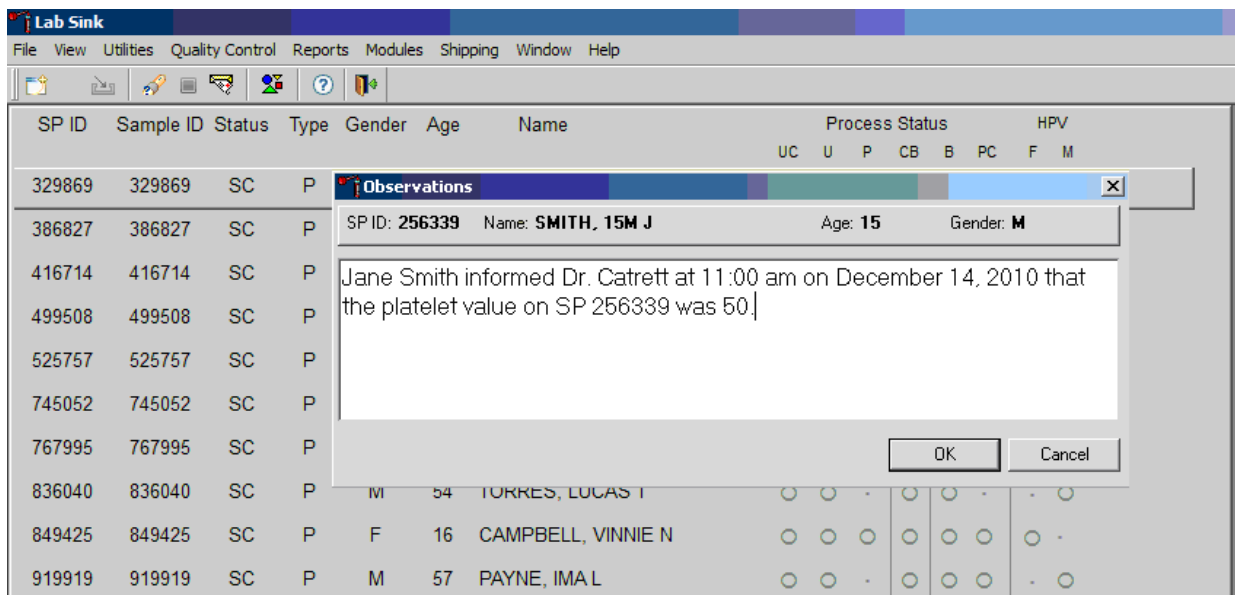
To select or highlight an SP, drag the mouse arrow to the correct SP and left-click or use the keyboard arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, direct the mouse arrow to the OK button and left-click, or select Enter. To cancel these actions and exit the observation function, 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 clinician, 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, direct the mouse arrow to the Cancel button and left-click.

Enter the observation on an SP.



Document the date, time, responsible laboratory individual, person notified, and test results, including the parameter.

6.20 Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

This method limits samples to human whole blood.

6.20.1 Specimen Rejection

Reject clotted specimens and recollect if clinician requests.

6.20.2 Interfering Substances and Conditions

Because the Coulter directly measures RBC, WBC, Hgb, and Diff percent, 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.
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.
- **WBC** – certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, agglutinated WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.
- **RBC** – very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBCs smaller than 36 fL, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.
- **Hgb** – very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing, or anything that increases the turbidity of the sample such as elevated levels of triglycerides.
- **MCV** – very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, or rigid RBCs.
- **RDW** – very high WBC count, high concentration of very large or clumped platelets as in blood anticoagulated with oxalate or heparin, RBCs below the 36-fL threshold, two distinct populations of RBCs, RBC agglutinates, or rigid RBCs.
- **Plt** – very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments, or cellular debris near the lower platelet threshold.
- **MPV** – known factors that interfere with the Plt count and shape of the histogram or known effects of EDTA.
- **Hct** – known factors that interfere with the parameters used for computation: RBC and MCV.
- **MCH** – known factors that interfere with the parameters used for computation: Hgb and RBC.

- **MCHC** – known factors that interfere with the parameters used for computation: Hgb, RBC, and MCV.
- Diff Parameters – known factors that affect the WBC count as listed above or high triglycerides that affect lysing.

6.21 Reference Ranges

Tables 6-5 and 6-6 respectively present reference ranges for blood cell counts for males and females, by age.

Table 6-5. Reference ranges (males)

Age in years	1-5		6-18		19-65		66+	
	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.6	3.6	11.5	3.9	11.8	3.8	12.1
Red cell count (SI)	3.98	5.3	4.14	5.78	4.18	5.86	3.57	5.67
Hemoglobin (g/dl)	10.7	14.2	11.9	16.9	13.1	17.5	11.4	17.1
Hematocrit (%)	32.1	41.7	35.3	49.9	38.7	51.4	33.9	50.9
Mean cell volume (fL)	68.2	88.8	75.6	94.6	79.8	99.1	81.4	102.7
Mean cell hemoglobin (pg)	22.3	30.6	25.0	32.3	26.3	34.0	26.3	35.0
MCHC (g/dl)	32.3	35.6	32.3	35.3	32.3	35.3	32.1	35.1
Red cell distribution width (%)	11.4	15.8	11.4	14.0	11.4	14.5	11.8	16.2
Platelet count (%) SI	212	546	179	439	152	386	124	384
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.1	6.6	10.2
Nucleated red blood cells	0.1	8.3	0	0.6	0	0.6	0	0.6
Lymphocyte percent (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Lymphocyte Absolute	1.0	10.0	0.6	6.2	0.6	5.7	0.5	5.6
Monocyte percent (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14.0
Monocyte Absolute	0.2	2.2	0.2	1.6	0.0	1.6	0.2	1.7
Segmented neutrophils percent (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Segmented Neutrophils Absolute	0.8	9.8	1.1	8.4	1.5	8.8	1.5	9.5
Eosinophils percent (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Eosinophils Absolute	0.0	1.6	0.0	1.3	0.0	1.0	0.0	1.1
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6
Basophils Absolute	0.0	0.4	0.0	0.2	0.0	0.2	0.0	0.2

Table 6-6. Reference ranges (females)

Age in years	1-5		6-18		19-65		66+	
	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.0	3.9	12.2	4.1	12.9	4.0	11.6
Red cell count (SI)	3.96	5.28	3.84	5.24	3.64	5.2	3.51	5.34
Hemoglobin (g/dL)	11.0	14.2	11.2	15.1	10.6	15.6	10.9	15.9
Hematocrit (%)	32.5	41.9	33.5	44.6	32.0	45.9	32.8	47.0
Mean cell volume (fL)	70.2	89.1	74.7	94.9	74.6	98.2	80.3	100.6
Mean cell hemoglobin (pg)	23.3	30.8	24.5	32.6	24.3	33.8	26.4	34.5
MCHC (g/dl)	32.4	35.5	32.3	35.3	32.1	35.3	32.3	35.1
Red cell distribution width (%)	11.3	15.4	11.3	14.8	11.4	16.3	11.6	16.3
Platelet count (%) SI	215	547	190	446	168	441	155	428
Nucleated red blood cell (/100 WBC)	0.1	8.3	0	0.3	0	0.3	0	0.3
Mean platelet volume (fL)	6.1	8.9	6.6	10.0	6.8	10.2	6.7	10.5
Lymphocyte percent (%)	21.6	68.8	17.2	54.7	14.1	47.6	13.7	46.9
Lymphocyte Absolute	0.9	9.6	0.7	6.7	0.6	6.1	0.5	5.4
Monocyte percent (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Monocyte Absolute	0.2	2.0	0.2	1.5	0.2	1.5	0.2	1.5
Segmented neutrophils percent (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Segmented Neutrophils Absolute	0.8	9.7	1.2	9.1	1.6	10.1	1.6	9.1
Eosinophils percent (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Eosinophil Absolute	0.0	1.4	0.0	1.2	0.0	0.9	0.0	0.9
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7
Basophils Absolute	0.0	0.4	0.0	0.2	0.0	0.2	0.0	0.2

Reference ranges for normal values were calculated from the NHANES data set (1999–2004) using 95 percent 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.

6.22 Action Limits

Action limits are a guide to inform the clinician 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 $3 \times 10^3 \mu\text{L}$ or > or = to $16.0 \times 10^3 \mu\text{L}$
- 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) < $50 \times 10^3 \mu\text{L}$ or > $800 \times 10^3 \mu\text{L}$

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; and
- High platelets—risk of thrombosis.

6.23 Specimen Storage and Handling During Testing

Specimen storage:

- Store specimens capped and place on a rocker at room temperature until processed. If specimens are not analyzed during the session due to excessively high room temperature, place all specimens in a biohazard bag and place bag in a cabinet of a cool room. Retrieve from this area when specimens can be run—then mix the specimens well before running.
- Run within 24 hours of drawing.

6.24 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 after thorough mixing.

6.25 Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are brought to the clinician’s attention by sending the clinician an observation and requesting a decision on “course-to-follow.”

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

6.26 Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 6C cell control results for bias and maintain results for the entire study period. Compare all three instruments using the CAP proficiency results.

6.27 Troubleshooting

If the background fails:

- If WBC, RBC, Plt fails—zap apertures, prime sweep flow several times, shutdown as last resort.
- If Differential fails—flush the flow cell.
- If Hgb fails—clean BSV, Prime CBC Module, perform Hgb blank verification, Shutdown.

If the Latron fails:

- D or N(AI2) and/or D or N(Lals) out—unlock DV x 3, flush flow cell x 3.

6.28 Setting Shift Times

From Main Screen>Click on X with Bar over it (top Menu)>XB setup(Bottom screen)>“Shifts” Tab>In “Multiple Shifts” type 08:00:00 in shift one start box>Type in 13:00:00 in Shift 2 box>Type in 23:00:00 in Shift 3 box >The “to” boxes will auto fill >Save.

6.29 Reference

UniCel DxH 800 Coulter Cellular Analysis System Instructions for Use. Beckman Coulter, Inc. Fullerton, CA 92835. www.BeckmanCoulter.com

7. Blood Processing

7.1 Introduction

The purpose of NHANES blood processing is to (1) allocate whole blood into vessels for storage and transport to laboratories across the United States for analysis, (2) allocate serum or plasma into vessels for storage and transport to laboratories across the United States for analysis, and (3) allocate washed packed cells for storage and transport to CDC laboratories for analysis. Serum and plasma samples are stored long-term for future studies.

Blood processing includes centrifuging and storing blood collection tubes; aliquoting whole blood into storage vessels; centrifuging, separating, and aliquoting plasma and serum into storage vessels; performing dilutions; washing and lysing whole blood cells; and storing the specimens in the Mobile Examination Center (MEC) until they are shipped to the testing laboratories for analysis or the biorepository for long-term storage.

Lists of consumable and non-consumable supplies for blood processing can be found in Chapter 11.

7.2 Blood Processing Age-Specific Protocols

Due to the volume of blood needed for testing, the NHANES testing protocol varies by age groups: 1-2, 3-5, 6-11, 12-19, and 20+. Exhibits 7-1 through 7-5 illustrate the blood processing protocols for each primary SP by age group.

Exhibit 7-6 shows the blood processing protocol for guests.

It is extremely important to follow the processing procedures outlined in these protocols and in this manual. **Specimen loss or biased results will occur if the exact procedures are not followed.**

Exhibit 7-1. Blood processing protocol for primary SPs aged 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG/Se/Mn	1-2	0.4	Whole blood	3 mL EDTA	2 mL sterile	
5	Mercury, Ethyl, and Methyl	1-2	0.5	Whole blood	3 mL EDTA	2 mL sterile	
3	RBC Folate	1-2	0.1	Whole blood	3 mL EDTA	2 mL	Dilute with 1 mL AA 1%
236	COVID Serology	1-2	0.6	Serum	7 mL red	2 mL	
110	Folate	1-2	0.7	Serum	7 mL red	2 mL	Dilute with 0.05 mL AA 7%
138	Cytomegalovirus (CMV)	1-2	0.4	Serum	7 mL red	2 mL	
237	EVD68	1-2	0.2	Serum	7 mL red	2 mL	
99	Ferritin/Transferrin Receptor	1-2	0.5	Serum	7 mL red	2 mL	
70	VID	1-2	0.5	Serum	7 mL red	2 mL	
87	Hepatitis ab	2	0.3	Serum	7 mL red	2 mL	Ages 2-5 only
13	CRP	1-2	0.3	Serum	7 mL red	2 mL	

Exhibit 7-2. Blood processing protocol for primary SPs aged 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG/Se/Mn	3-5	0.4	Whole blood	3 mL EDTA	2 mL sterile	
5	Mercury, Ethyl, and Methyl	3-5	0.5	Whole blood	3 mL EDTA	2 mL sterile	
3	RBC Folate	3-5	0.1	Whole blood	3 mL EDTA	2 mL	Dilute with 1 mL AA 1%
109	Transfatty Acids	3-5	0.7	EDTA plasma	3 mL EDTA	2 mL	
110	Folate 1	3-5	0.7	Serum	7 mL red	2 mL	Add 0.05 mL AA 7%
138	Cytomegalovirus (CMV)	3-5	0.4	Serum	7 mL red	2 mL	
237	EVD68	3-5	0.2	Serum	7 mL red	2 mL	
99	Ferritin	3-5	0.5	Serum	7 mL red	2 mL	
70	VID	3-5	0.5	Serum	7 mL red	2 mL	
87	Hepatitis ab	3-5	1.0	Serum	7 mL red	2 mL	Ages 2-5 only
13	CRP	3-5	0.3	Serum	7 mL red	2 mL	
118	Thyroid Panel	3-5	1.0	Serum	7 mL red	2 mL	
239	Sex Steroid Hormone Panel	3-5	0.6	Serum	7 mL red	2 mL	
17	Cotinine	3-5	0.8	Serum	7 mL red	2 mL	
32	Extra Sera1	3-5	0.5	Serum	7 mL red	2 mL	
33	Extra Sera2	3-5	0.5	Serum	7 mL red	2 mL	

Exhibit 7-3. Blood processing protocol for primary SPs aged 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG/Se/Mn	6-11	0.4	Whole blood	4 mL and 6 mL EDTA (blue)	2 mL sterile	
5	Mercury, Ethyl, and Methyl	6-11	0.5	Whole blood	6 mL EDTA (blue)	2 mL sterile	
235	BChe	6-11	1	Whole blood	6 mL EDTA (blue)	2 mL	
3	RBC Folate	6-11	0.1	Whole blood	6 mL EDTA (blue)	2 mL	Dilute with 1 mL AA 1%
88	Acrylonitrile	6-11	1.5	Packed cells	6 mL EDTA (blue)	2 mL	Wash 3 times, 1/3 subsample (1, 2, 5, 11)
221	RBC Folate	6-11	0.1	Packed cells	6 mL EDTA (blue)	2 mL	Wash 3 times, 1 mL 1% AA. Add 0.1 mL diluted RBCs
222	Fatty Acids	6-11	1.6	Packed cells	6 mL EDTA (blue)	2 mL	Wash 3 times
109	Transfatty Acids	6-11	0.7	EDTA plasma	6 mL EDTA (blue)	2 mL	
110	Folate 1	6-11	0.7	Serum	10 mL red and 7 mL red	2 mL	Add 0.05 mL AA 7%
237	EVD68	6-11	0.2	Serum	10 mL red and 7 mL red		
70	VID	3-5	0.7	Serum	10 mL red and 7 mL red	2 mL	
13	CRP	6-11	0.3	Serum	10 mL red and 7 mL red	2 mL	
118	Thyroid Panel	6-11	1.0	Serum	10 mL red and 7 mL red	2 mL	6+ (1, 2, 5, 11)
137	Sex Hormones	6-11	3.5	Serum	10 mL red and 7 mL red	5 mL	Add red cap for females
17	Cotinine	6-11	1.0	Serum	10 mL red and 7 mL red	2 mL	
122	Hep Profile	6-11	1.8	Serum	10 mL red and 7 mL red	2 mL	

Exhibit 7-3. Blood processing protocol for primary SPs aged 6-11 years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
229	Hep Xtra sera	6-11	1.8	Serum	10 mL red and 7 mL red	2 mL	
21	Lipids	6-11	0.5	Serum	10 mL red and 7 mL red	2 mL	
77	HPV-Serum	6-11	0.5	Serum	10 mL red and 7 mL red 10		1/3 subsample 1, 2, 5, 11
240	Serum Terpenes	6-11	1.2	Serum	10 mL red and 7 mL red		
32	Xtra Sera1	6-11	0.5	Serum	10 mL red and 7 mL red	2 mL	
33	Xtra Sera2	6-11	0.5	Serum	10 mL red and 7 mL red	2 mL	

Exhibit 7-4. Blood processing protocol for primary SPs aged 12-19 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG/Se/Mn	12-19	0.4	Whole blood	6 mL EDTA (blue)	2 mL sterile	
5	Mercury, Methyl, and Ethyl	12-19	0.5	Whole blood	6 mL EDTA (blue)	2 mL sterile	
235	BChE	12-19	1	Whole blood	6 mL EDTA (blue)	2 mL	
3	RBC Folate	12-19	0.1	Whole blood	6 mL EDTA (blue)	2 mL	Dilute with 1 mL AA 1%
4	Glycohem	12-19	1	Whole blood	4 mL EDTA	4 mL	Refrigerate
88	Acrylonitrile	12-19	1.5	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times, 1/3 subsample (1, 2, 5, 11)
221	RBC Folate	12-19	0.1	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times, 1 mL 1% AA. Add 0.1 mL diluted RBCs
222	Fatty Acids	12-19	1.6	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times
109	Transfatty Acids	12-19	0.7	EDTA plasma	4 mL and 6 mL EDTA (blue)	2 mL	

Exhibit 7-4. Blood processing protocol for primary SPs aged 12-19 years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
119	Genetics	18-19	6.0	Whole blood	6 mL EDTA (lavender)	5 mL	
9	Glucose	12-19	0.5	NaFl plasma	2 mL gray	2 mL	Morning SPs only
54	VOC Blood	12-19	7.0	Whole blood	7 mL gray	7 mL	1/2 subsample 1, 2, 4, 5, 10, 11
110	Folate1	12-19	0.7	Serum	15 mL red	2 mL	Add 0.05 mL AA 7%
99	Ferritin	12-19	0.7	Serum	15 mL red	2 mL	
70	VID	12-19	0.7	Serum	15 mL red	2 mL	
13	CRP	12-19	0.3	Serum	15 mL red	2 mL	
118	Thyroid Panel	12-19	1.0	Serum	15 mL red	2 mL	6+ (1, 2, 5, 11)
137	Steroid Hormone	12-19	3.5	Serum	15 mL red	5 mL	Add red cap for females
17	Cotinine	12-19	1.8	Serum	15 mL red	2 mL	
122	Hep Profile	12-19	1.8	Serum	15 and 7 mL red	2 mL	
229	Hep Xtra sera	12-19	1.8	Serum	15 mL red	2 mL	
21	Lipids	12-19	1.0	Serum	15 mL red	2 mL	Add cap insert AM, only
18	Biochem	12-19	0.8	Serum	15 mL red	2 mL	
23	Insulin	12-19	0.5	Serum	15 mL red	2 mL	Morning SPs only
77	HPV-Serum	12-19	0.5	Serum	15 mL red	2 mL	
22	HIV	18-19	1.5	Serum	15 mL red	2 mL	18-59 only
24	HSV	14-49	0.2	Serum	15 mL red	2 mL	14-49 only
240	Serum Terpenes	12-19	1.2	Serum	15 mL red	2 mL	1/3 subsample 1, 2, 5, 11
90	Perflour1	12-19	1.5	Serum	15 mL red	2 mL sterile	1/3 subsample 1, 2, 5, 11
29	Dioxin 1	12-19	15.0	Serum	15 mL red	5 mL sterile	1/3 subsample 0, 3, 7, 10
32	Xtra Sera1	12-19	0.5	Serum	15 mL red	2 mL	
33	Xtra Sera2	12-19	0.5	Serum	15 mL red	2 mL	
34	Xtra Sera3	12-19	0.5	Serum	15 mL red	2 mL	
35	Xtra Sera4	12-19	0.5	Serum	15 mL red	2 mL	
36	Xtra Sera5	12-19	0.5	Serum	15 mL red	2 mL	
37	Xtra Sera6	12-19	0.5	Serum	15 mL red	2 mL	

Exhibit 7-5. Blood processing protocol for primary SPs aged 20+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad/HG/Se/Mn	20+	0.4	Whole blood	4 mL and 6 mL EDTA (blue)	2 mL sterile	
5	Mercury, Methyl, and Ethyl	20+	0.5	Whole blood	4 mL and 6 mL EDTA (blue)	2 mL sterile	
235	BChe	20+	1	Whole blood	4 mL and 6 mL EDTA (blue)	2 mL	
3	RBC Folate	20+	0.1	Whole blood	4 mL and 6 mL EDTA (blue)	2 mL	Dilute with 1 mL AA 1%
4	Glycohem	20+	1	Whole blood	4 mL EDTA	2 mL	Refrigerate
88	Acrylonitrile	20+	1.5	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times, 1/3 subsample 1, 2, 5, 11
221	RBC Folate	20+	0.1	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times, 1 mL 1% AA. Add 0.1 mL diluted RBCs
222	Fatty Acids	20+	1.6	Packed cells	4 mL and 6 mL EDTA (blue)	2 mL	Wash 3 times
109	Transfatty Acids	20+	0.7	EDTA plasma	4 mL and 6 mL EDTA (blue)	2 mL	
119	Genetics	20+	6.0	Whole blood	6 mL EDTA	6 mL	
9	Glucose	20+	0.5	NaFI plasma	2 mL gray	2 mL	Morning SPs only
54	VOC Blood	20+	7.0	Whole blood	7 mL gray	7 mL	1/2 subsample 1, 2, 4, 5, 10, 11
110	Folate 1	20+	0.7	Serum	15 mL red	2 mL	Add 0.05 mL AA 7%
99	Ferritin	20+	0.7	Serum	15 mL red	2 mL	
70	VID	20+	0.7	Serum	15 mL red	2 mL	
13	CRP	20+	0.3	Serum	15 mL red	2 mL	
118	Thyroid Panel	20+	1.0	Serum	15 mL red	2 mL	1/3 subsample 1, 2, 5, 11
137	Steroid Hormone	20+	3.5	Serum	15 mL red	5 mL	Add red cap for females
17	Cotinine	20+	1.8	Serum	15 mL red	2 mL	
122	Hep Profile	20+	1.8	Serum	15 mL red	2 mL	

Exhibit 7-5. Blood processing protocol for primary SPs aged 20+ years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
229	Hep Xtra sera	20+	1.8	Serum	15 and 7 mL red	2 mL	
21	Lipids	20+	1.0	Serum	15 mL red	2 mL	Add cap insert AM, only
18	Biochem	20+	0.8	Serum	15 mL red	2 mL	
23	Insulin	20+	0.5	Serum	15 mL red	2 mL	Morning SPs only
77	HPV-Serum	20+	0.5	Serum	15 mL red	2 mL	
22	HIV	20-59	1.5	Serum	15 mL red	2 mL	18-59 only
24	HSV	20-49	0.2	Serum	15 mL red	2 mL	14-49 only
240	Terpenes	20+	1.2	Serum	15 mL red	2 mL	1/3 subsample 1, 2, 5, 11
90	Perflour1	20+	1.5	Serum	15 mL red	5 mL sterile	1/3 subsample 1, 2, 5, 11
29	Dioxin 1	20+	15.0	Serum	15 mL red	5 mL sterile	1/3 subsample 0, 3, 7, 10
32	Xtra Sera1	20+	0.5	Serum	15 mL red	2 mL	
33	Xtra Sera2	20+	0.5	Serum	15 mL red	2 mL	
34	Xtra Sera3	20+	0.5	Serum	15 mL red	2 mL	
35	Xtra Sera4	20+	0.5	Serum	15 mL red	2 mL	
36	Xtra Sera5	20+	0.5	Serum	15 mL red	2 mL	
37	Xtra Sera6	20+	0.5	Serum	15 mL red	2 mL	

Exhibit 7-6. Blood processing protocol for guests aged 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
18	Biochem	12+	0.8	Serum	7 mL red	2 mL

7.3 Labeling Vessels

The phlebotomist and the clinical laboratory scientist assigned to Workstation 1 (WS1) 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 barcode label.

Use the following materials to set up and label blood racks:

- Rack; and
- Age-appropriate processing template.

- Storage vessels of the following sizes:
 - 2.0 mL sterile vessel,
 - 2.0 mL nonsterile vessel,
 - 5.0 mL nonsterile vessel, and
 - 30 mL nonsterile vessel.
- Barcoded SP ID labels, each containing the unique 6-digit SP ID number concatenated with the 3-digit vessel ID.

Prepare one blood processing rack for each SP. The tubes for which each SP is eligible are determined by their sex, appointment type, and inclusion into certain subsamples so that each SP's blood processing rack may be unique. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

Before each session, the clinical laboratory scientist assigned to WS1 distributes the labels, and sets out the blood processing racks. The correct barcode labels automatically print for each SP based on the SP's unique profile.

While the clinical laboratory scientist assigned to WS1 is responsible for labeling the vessels and setting up the blood processing racks, it is the blood processing clinical laboratory scientist'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.

Ensure:

- The SP's ID number on the barcode label;
- The vessel number on the label;
- Yellow dots are applied to the appropriate vessels;
- The adhesion quality of the labels; and
- That specimens are not missing labels or incorrectly labeled.

Save unused vessels:

- If the SP does not show up for the MEC exam at the appointed date and time, it is possible that they will reschedule. Store the SP's labeled vials in the cupboard in workstation 1 until the end of the stand. If the SP has not shown up by the end of the stand, discard the unused vessels. If they refuse phlebotomy during a session, discard vessels from the rack.

7.4 Equipment

7.4.1 Benchtop Centrifuges

See Chapter 10 for centrifuge operation and maintenance.

For plasma and serum—set appropriate time and temperature for each tube as follows:

3 mL or 4 mL EDTA	10 minutes	2-8°C
2 mL gray	10 minutes	2-8°C
3 mL, 7 mL, 10 mL, or 15 mL red	15 minutes	2-8°C

For washed packed cells—set appropriate time and temperature for each tube as follows:

Vessel 88, 221, 222	6 mL EDTA (blue)	10 minutes	2-8°C
Vessel 88, 221, 222	Cell washings	5 minutes	2-8°C

7.4.2 Laminar Flow Biological Safety Cabinet Operating Sequence

- Turn on the cabinet blower and lights, and check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the manometric gauge. 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 as described in the NHANES COVID-19 Mitigation protocols as long as the protocols are in effect, and then according to regular cleaning protocols when no longer necessary.
- 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.

- Wear a long-sleeved laboratory coat and gloves, as well as additional personal protective equipment outlined in the NHANES COVID-19 Mitigation protocols as long as the protocols are in effect. This will minimize the shedding of skin flora into the work area and concurrently protect the clinical laboratory technologist 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 to 3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazard waste as described above.
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

7.5 Blood-Processing Procedures

If centrifugation is required (i.e., red top tubes), centrifuge all blood specimens unopened, then transport to, and 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 release of aerosol 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 1:10 bleach solution. Decontaminate the workstation, including the biological safety hood, using the NHANES COVID-19 Mitigation protocols while in effect, and approved cleaning procedure when no longer needed at the end of the day or immediately when spills occur.

Decontaminate racks by soaking them in a 10 percent bleach solution once a week. The racks will be cleaned after one use and before using again. Decontaminate the templates by wiping with a cleaning agent effective against COVID-19 as long as needed and with approved cleaning techniques when no longer needed. Place on blotter to air dry.

7.5.1 Aliquoting Whole Blood and Serum

Pipette whole blood for vessel 3, washed packed cells for vessel 221, pooled serum, and make dilutions using the Eppendorf Xplorer Plus pipettes. Pipette plasma and remaining whole blood vessels using plastic transfer pipettes.

The MEC laboratory has three Eppendorf Xplorer Plus electronic pipettes: one 5-100 μL (yellow), one 50-1,000 μL (blue), and one 0.2-5 mL (purple). The lab also uses 100 μL and 1,000 μL pipette tips and 5 mL bulk pipette tips. Charge the pipettes in the four-stand charger.

- Use the 5-100 μL pipette (yellow) in the (FIX) mode to aliquot 100 μL of whole blood for RBC Folate – vessel 3. Use this pipette to aliquot 50 μL of 7 percent ascorbic acid solution for Folate 1 – vessel 110. Use this pipette to aliquot 100 μL of diluted washed packed cells for RBC Folate – vessel 221.
- Use the 50-1,000 μL (blue) pipette in the (FIX) mode and set the volume to 1,000 μL . Use this pipette to aliquot the 1 percent ascorbic acid solution for RBC Folate – vessel 3. Use this pipette to aliquot the 1 percent ascorbic acid solution for RBC Folate – vessel 221.
- Use the 0.2 – 5 mL (purple) pipette in the PRG mode. Set the volumes to match the age-specific processing protocols. Set program 1A-1D to match the adult profile for vessels 110-37. Set program 3 to match the child's profile ages 1-2. Set program 4 to match the child's profile ages 3-5. Set program 5A-5B to match the child's profile ages 6-11. Use this pipette to aliquot pooled serum.

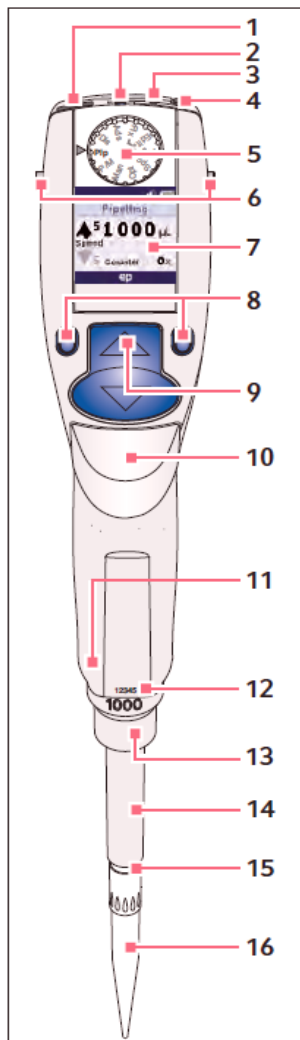
7.5.1.1 General Operation

Display and Keypad

- To switch on: Switch on the ON key (Exhibit 7-7).
- To switch off: Switch off the ON key.

Exhibit 7-7. Illustration of single channel pipette

3.1 Main illustration – single-channel pipette



- 1 USB port**
- 2 On/Off key**
- 3 Reset key**
- 4 Connector socket**
Connects the charging plug of the power supply.
- 5 Selection dial**
Sets the operating mode.
- 6 Charging contacts**
For charging and storage in a series 4880 charger stand or charger carousel.
- 7 Backlit color display**
Switches the display off when it is not in use. The display automatically switches back on when the pipette is moved.
- 8 Softkeys**
The assignment of the respective softkey is shown in the display footer.
- 9 Rocker**
You can either press the rocker up or down. The rocker can either be used to trigger the piston movement or to scroll through the menu and change the values of parameters.
- 10 Ejector**
Moves the ejector sleeve and ejects the pipette tip. After a filled pipette tip has been ejected, the piston returns to the basic position after a slight delay.
- 11 RFID chip**
- 12 Upper part serial number**
- 13 Lower part serial number**
Located under the ejector sleeve.
- 14 Ejector sleeve**
- 15 Spring-loaded tip cone**
The spring-loading action optimizes the force required for attaching and ejecting tips. The spring-loading action is available for all Xplorer pipettes up to 1000 µL.
- 16 Pipette tip**
Only use the pipette with a suitable pipette tip. We recommend epT.I.P.S.

- When unit is on and not in use, it will automatically switch to the standby mode after a period of time. The pipette will automatically switch back on when it is moved.
- To set date and time:
 1. Select Date or Time using the rocker.
 2. Press the Select softkey.
 3. Change the value using the rocker.
 4. Press the Next softkey to change the field.

5. Press the End softkey to end the entry.
6. Change the second parameter in the same manner.
7. Press the End softkey to end the entry.

7.5.1.2 Principle of Operation

The Xplorer Plus pipette is equipped with various operating modes and a primary mode for configuring the pipette. During operation, the piston in the pipettes is moved according to how the rocker is actuated. When you press the rocker up, the piston in the pipette moves up. Liquid is aspirated into the attached pipette tip. When you press the rocker down, the piston in the pipette moves down. The liquid is dispensed into the pipette tip.

Contact Surface on the Head of the Pipette

Both upper surfaces are required for charging the lithium polymer battery. The lower surfaces are the data interfaces for the service department. The contact to the charging adapter or the charging stand cannot be confused with any other contacts.

Acoustic Signals

Certain signals assist the user for different operations:

- Short signal acknowledges that the keypad has been pressed;
- Slightly higher tone indicates that the function for which the key has been pressed cannot be executed;
- Louder tone indicates that the piston movement has ended;
- Louder tone indicates that a specific sequence of steps (e.g., dispensing) has ended; and
- Louder tone indicates an error message.

The acoustic signals are a great help when you are familiarizing yourself with the operating procedure of the Research pro. They can be switched off if required.

7.5.1.3 Programming the Pipettes

PIP Mode

Use this mode for the blue 50-1,000 μL pipette for dispensing 1 percent ascorbic acid. Use for 500, 700, 1,000 μL volumes.

Programming - PIP	
Step 1	Select the pipetting mode PIP. Turn the dial until the PIP choice appears.
Step 2	Press the small blue "EDIT" button on the left.
Step 3	Select the desired volume. If you need to adjust the volume, use the blue toggle to reach desired volume.
Step 4	Set aspiration speed to 8. Hit small blue key to "Next."
Step 5	Set dispensing speed to 8. Hit small blue key to "End."

PRG Mode

Use for dispensing the following volumes: 200, 500, 700, 1,000 μL s from the 50-1,000 μL (blue) pipette. Use for vessel 110 serum and 1 percent ascorbic acid for vessels 3 and 221.

Use for dispensing the following volumes: 50, 100 μL 's from the 5-100 μL (yellow) pipette. Use for vessel 3 whole blood, washed packed cells for vessel 221, and 7 percent ascorbic acid for vessel 110.

Programming - PRG	
Step 1	Select the pipetting mode "EDIT." Turn the dial until the "EDIT" choice appears.
Step 2	Use rocker to highlight "New Program."
Step 3	Press small blue key on left to "Select."
Step 4	Use rocker to name programs (i.e., 200, 500, 700, 1,000). Use rocker to find 1, then hit next, then find 0, next...
Step 5	Hit right small blue key to "Save."
Step 6	Use rocker to highlight "Pipetting."
Step 7	Use small blue key on left to "Edit."
Step 8	Set Volume - use rocker to desired volume. Hit small blue key on left to "Next."
Step 9	Set aspiration speed to 8. Hit small blue key on left to "Next."
Step 10	Set dispensing speed to 8. Hit small right blue key to "Save."
Step 11	Hit small right blue key to "Save."
Step 12	Use rocker to highlight "New Program."
Step 13	For remaining volumes, repeat steps 3-13.

Sequential Dispensing (SD) Mode

Use for the pooled serum profiles of aged 12+ adults, 1- to 2-year-olds, 3- to 5-year-olds, and 6- to 11-year-olds from the 0.2-5 mL (purple) pipette.

Programming – SD	
Step 1	Select the selection dial to “EDIT.”
Step 2	Use the down arrow on the rocker to highlight program.
Step 3	Press the “Select” softkey.
Step 4	Highlight New Program and press the “Select” softkey.
Step 5	You will be prompted to name the program. Use the rocker to select the character and the “Next” softkey to advance to the next space. Name this program “12 Up.”
Step 6	Press the “Save” softkey.
Step 7	Use the rocker to highlight “Sequential Dispensing” operating mode.
Step 8	Press the “Edit” softkey.
Step 9	Use the rocker to change the number of steps to 6.
Step 10	Press the “Next” softkey.
Step 11	Use the rocker to change the volume and assign the necessary volumes to the program. Press “Next” after each volume.
Step 12	Press the “Next” softkey.
Step 13	Press the “Up” arrow on the rocker to change the aspiration speed to 8.
Step 14	Press the “Next” softkey.
Step 15	Press the “Up” arrow on the rocker to change the dispensing speed to 8.
Step 16	Press the “Save” softkey.
Step 17	Press the “Next” softkey and repeat steps 7-16 using the necessary steps and volumes.
Step 18	When complete, press the “Save” softkey to save the program. The program will now appear in the program list.
Step 19	Set the selection dial to “Program” after all editing is complete.
Programming – SD 6- to 11-year-olds	
Step 1	Follow steps 1-4 in the 12 and Up procedure.
Step 2	You will be prompted to name the program. Use the rocker to select the character and the “Next” softkey to advance to the next space. Name this program “6-11.”
Step 3	Follow steps 6-16 in the “12 and Up” programming instructions using the necessary steps and volumes.
Step 4	Press the “Next” softkey and repeat steps 7-16 in the “12 and Up” program using the necessary steps and volumes.
Step 5	When complete, press the “Save” softkey to save the program. The program will now appear in the program list.
Step 6	Set the selection dial to “Program” after all editing is complete.
Programming – SD 3- to 5-year-olds	
Step 1	Follow steps 1-4 in the 12 and Up procedure.
Step 2	You will be prompted to name the program. Use the rocker to select the character and the “Next” softkey to advance to the next space. Name this program “3-5.”
Step 3	Follow steps 6-16 in the “12 and Up” programming instructions using the needed steps and volumes.
Step 4	When complete, press the “Save” softkey to save the program, which will now appear in the program list.
Step 5	Set the selection dial to “Program” after all editing is complete.

Programming – SD 1- to 2-year-olds	
Step 1	Follow steps 1-4 in the 12 and Up procedure.
Step 2	You will be prompted to name the program. Use the rocker to select the character and the “Next” softkey to advance to the next space. Name this program “1-2.”
Step 3	Follow steps 6-16 in the “12 and Up” programming instructions using the needed steps and volumes.
Step 4	Press the “Save” softkey to save the program. The program will now appear in the program list.
Step 5	Set the selection dial to “Program” after all editing is complete.
Programming – SD Extras	
Step 1	Follow steps 1-4 in the 12 and Up procedure.
Step 2	You will be prompted to name the program. Use the rocker to select the character and the “Next” softkey to advance to the next space. Name this program “Extras.”
Step 3	Follow steps 6-16 in the “12 and Up” programming instructions using the following steps and volumes: <ul style="list-style-type: none"> • 8 steps • 0.5, 0.5, 0.5, 0.5, 0.5, 0.5, 0.5, 0.5 mL
Step 4	Set the selection dial to “Program” after all editing is complete.

7.5.1.4 Mode of Operation – Pipetting for 5-100 μ L, 50-1,000 μ L, and 0.2-5 mL Pipettes

If the display of the Xplorer Plus is dark, activate the pipette by pressing the toggle switch (up and down button). If the pipette has not been used for a long period, a motor reset is executed after it has been activated.

- Always pipette in the PRG or FIX mode. Turn dial to PRG or FIX.
- Attach an Eppendorf pipette tip to the Xplorer Plus. The color coded Actuate key corresponds to the color code of the racks for the pipette tips. The dispensing liquid is aspirated into the tip.
- When aspirating liquid, immerse the pipette tip vertically (about 4 mm) into the liquid.
- To wet the pipette tip, immerse the tip vertically, aspirate, and dispense the liquid twice.
- To aspirate the liquid, press the rocker up. Maintain the immersion depth, to ensure no air is aspirated. Slowly pull the pipette tip out of the liquid. Wipe tip against the tube wall to ensure that no outer wetting remains on the pipette tip.
- Press the rocker down to dispense first drop only on the 0.2-5.0 pipettes. Pipette indicates this step needs to be down.
- To dispense the liquid, position the pipette tip at a slight angle against the side of the vessel, press the rocker down to dispense the liquid.
- After dispensing, press the rocker down again to trigger the blow out.

- If more liquid is needed, re-aspirate using same pipette tip and dispense per protocol.
- Discard the pipette tip by pressing the ejector, then attach a new tip and re-aspirate liquid.

For additional information regarding care and maintenance of the pipettes, see Chapter 10.

A complete list of troubleshooting information is included on pages 62-65 of the *Eppendorf Explorer Plus Manual*.

7.5.2 Process the 3 mL, 4 mL, and 7 mL EDTA Tubes

The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation. Use the well-mixed lavender 3 mL (contains K2 EDTA), 4 mL (contains K2 EDTA), and 6 mL (blue) (contains K2 EDTA) for certain whole blood tests. Use the 6 mL (blue) (aged 6+ years) EDTA tubes for washed packed cells.

Please Note: Never use the 6 mL EDTA (blue) tube for CBCs. These tubes cannot be used for CBCs since the coulter is calibrated and precision limits are based on using 4 mL K2 EDTA tubes.

7.5.2.1 Process the 3 mL, 4 mL, and 6 mL EDTA (blue) Tube for Lead/Cad/HG/Se/Mn, RBC Folate, Glycohem, and Mercury

The hematology clinical laboratory scientist runs the CBC on the room temperature 3 mL (aged 1-2 years) EDTA tube after the blood-processing clinical laboratory scientist verifies proper identification and labeling, and processes the tube for the Lead/Cad/HG/Se/Mn, RBC Folate, and Mercury. For ages 3-5 years, two 3 mL EDTA tubes are drawn. One 3 mL EDTA tube will be used for blood processing and one 3 mL EDTA tube will be used for the CBC. For aged 6+ years, a 4 mL and a 7 mL EDTA tube is drawn. The 7 mL EDTA tube should be used for whole blood processing and washed packed cells. If the 7 mL EDTA is not obtained or is clotted, the processing technician should perform blood processing on the 4 mL EDTA tube and then return to the hematology clinical laboratory scientist for the CBC. If there is enough sample left to process the washed packed cells, the processing technician should then proceed with washing the cells. If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad/HG/Se/Mn), vessel 3 (RBC Folate), vessel 4 or vessel 5 (Mercury). If the CBC was inadvertently tested before the whole blood for

vessels 1 (Lead/Cad/HG/Se/Mn), and 5 (Mercury) was pipetted, do not process these two vessels. Add the comment, “laboratory error” to these vessels.

Complete the following process for all SPs. Use the following tubes for the CBC and whole blood protocol:

- Aged 1-2 years
 - Process the 3 mL EDTA tube for all whole blood tests and then run CBC.
- Aged 3-5 years
 - Process the first 3 mL EDTA tube for all whole blood tests.
 - Process the second 3 mL EDTA tube for CBC.
- Aged 6-11 years
 - Process the first 4 and 7 mL tubes for all whole blood tests, and the washed packed cells (vessels 88, 221, and 222).
 - Process the second 4 mL tube for CBC.
- Aged 12-19 years
 - Process the first 4 and 7 mL tubes for all whole blood tests, EDTA plasma sample, and the washed packed cells (vessels 88, 221, and 222).
 - Process the second 4 mL tube for CBC.
- Aged 20+ years
 - Process the first 4 and the 7 mL tubes for all whole blood tests, EDTA plasma sample, and the washed packed cells (vessels 88, 221, and 222).
 - Process the second 4 mL tube for CBC.
- Aged 40+ years
 - Process the first 4 and the 7 mL tubes for all whole blood tests, EDTA plasma sample, and the washed packed cells (vessels 88, 221, and 222).
 - Process the second 4 mL tube for CBC.

The blood-processing clinical laboratory scientist processes the 3, 4, or 7 mL EDTA tube for the whole blood tests.

- Invert the appropriate EDTA tube several times to thoroughly remix contents.
- Pre-wet pipette tip.
- Refrigerate L-ascorbic acid diluent in between session blocks if there is a significant delay between the processing of SP's throughout the day. Discard unused diluent at end of each day.

Vessel 1

- Use 3.5 mL disposable transfer pipette to aliquot 0.4 mL whole blood from the 3, 4, or 6 mL EDTA (blue) tube (dependent upon SP age) into vessel 1 (Lead/Cad/HG/Mn/Se) for primary SPs. Use a sterile 2 mL vessel.

Vessel 5

- Use 3.5 mL disposable transfer pipette to aliquot 0.5 mL whole blood from the 3, 4, or 7 mL EDTA tube (dependent upon SP age) for vessel 5 (Mercury) for primary SPs into a 2 mL sterile vessel.
 - Securely close all vessels to prevent leakage and evaporation.
 - Record results using the Blood Processing module as described in Section 7.6.
 - Store all specimens immediately as outlined in Section 7.7.

Vessel 235

- Use 3.5 mL disposable transfer pipettes to aliquot 1 mL whole blood from the 4 mL EDTA tube for vessel 235 (BChe) for primary SPs 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 7.6.
 - Store all specimens immediately as outlined in Section 7.7.

Vessel 3

- Pre-wet the pipette tips. Use pipette tips and the dedicated 50-1,000 µL (blue) Eppendorf pipette to immediately pipette 1.0 mL of 1 percent ascorbic acid into the 2 mL vessel.
- Use Eppendorf pipette tips and the dedicated 5-100 µL (yellow) Eppendorf pipette to pipette 0.1 mL whole blood from the 3, 4, or 7 mL EDTA tube (dependent upon SP age) into vessel 3 (RBC Folate) for primary SPs into the 2 mL vessel. Mix well.

Vessel 4

- Process and store remaining whole blood, **at least 1 mL**, of one 4 mL EDTA tube (Glycohem).
 - Securely close all tubes to prevent leakage and evaporation.
 - Record results using the Blood Processing module as described in Section 7.6.
 - Store all specimens immediately as outlined in Section 7.7.

7.5.2.2 Process the 7 mL EDTA for Transfatty Acids (Vessel 109) and Washed Packed Cells for Acrylamide (Vessel 88), Folate Forms (Vessel 221), and Fatty Acids (Vessel 222)

Remove whole blood as needed for vessels 1, 5, and 3 (Lead/Cad/HG/Se/Mn; Mercury, Ethyl, and Methyl; BChE; and RBC Folate). Centrifuge the EDTA tube and remove the plasma as described below. Wash the remaining red blood cells (erythrocytes) with sterile saline three times and then add a 1:1 ratio of saline to the washed RBCs to make a homogeneous solution. Invert the tube 8-10 times to create the solution, using special care to not rupture the cells by mixing too hard during the process. Store the saline in the refrigerator and use it cold. Pour saline to be used for the cell washing procedure into a squeeze bottle. Ensure the saline bottle is properly labeled to include the expiration date and who prepared it. It is acceptable to batch the samples as long as the samples and reagents are refrigerated.

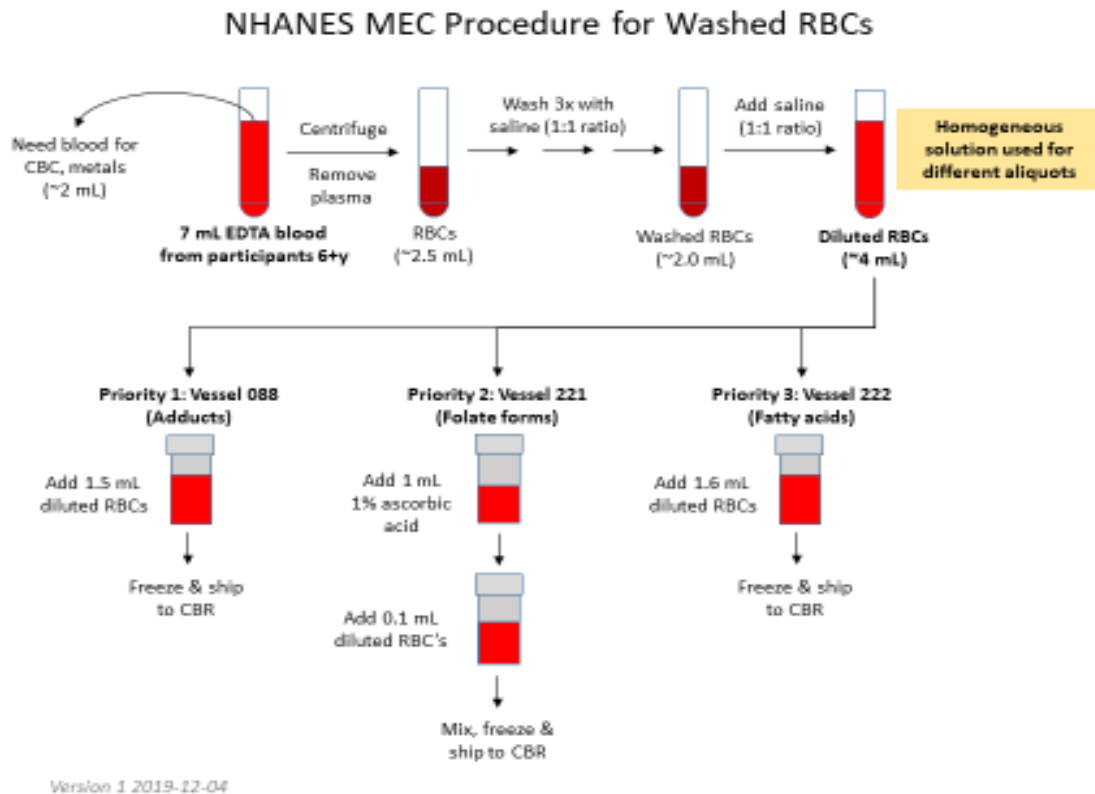
Vessel 88/221/222

Avoid using processing techniques that generate aerosols outside of the hood. Remove all caps, ream fibrin strands, and pipette within the confines of the hood.

1. Centrifuge the 7 mL EDTA tube at 2-8°C. Centrifuge at 2,900 rpm for 10 minutes to separate the plasma from the cells.
2. Use a disposable pipette to add 0.7 mL of plasma for vessel 109 (Transfatty Acids) to a 2 mL vessel.
3. Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results. Use a disposable pipette to remove the remaining plasma and the upper clear layer. There should be approximately 2.5 mL of packed RBCs in the tube.
4. Use the refrigerated squeeze bottle of 0.9 percent saline to add an equal amount (1:1 ratio) to the packed cells.
5. Close vial and mix by gently inverting to evenly mix the solution.
6. Centrifuge at 1,985 rpm and 2-8°C for 5 minutes.
7. Remove and discard the clear upper layer.
8. Repeat steps 3 through 6 two more times for a total of 3 wash cycles.
9. After the last wash cycle, use the squeeze bottle of 0.9 percent saline to add an equal amount of saline to the packed cells.
10. Close vial and gently invert tube 8-10 times without rupturing cells. Ensure that the solution is homogenous.
11. Transfer 1.5 mL of the homogenous solution to a 2 mL cryovial for vessel 88. Add 1 mL of 1 percent of ascorbic acid to vessel 221, then add 0.1 of the homogenous solution to the vessel with rinses. Vortex mix the solution for 5 seconds. For vessel 222 (fatty acids) add 1.6 mL of the solution to the appropriate cryovial.
 - A. Close all vessels securely to prevent leakage and evaporation.
 - B. Record results using the Blood Processing module as described in Section 7.6.
 - C. Store all specimens immediately as outlined in Section 7.7.

Refer to Exhibit 7-8 for the procedure for washed RBCs visual aid.

Exhibit 7-8. RBC washing procedure (visual aid)



7.5.3 Process the 2 mL Gray Tube for Glucose

Centrifuge and separate the plasma from the 2 mL gray top tube immediately after the blood is collected and received in the laboratory. Process the specimen even if the contents of the gray tube are clotted. If the tube is clotted, add a comment in blood processing. Refrigerate filled vessel 9 as soon as possible.

- 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 2 mL gray tube at 2-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (glucose).

Important Note: If the 2 mL gray top tube cannot be separated and processed *immediately* after mixing, the tube will be refrigerated until it can be separated and processed.

- Use a 3.5 mL disposable plastic transfer pipette to transfer *at least* 0.5 mL plasma from this tube for vessel 9 (glucose) on primary SPs aged 12+ years 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.
 - Close all vessels securely to prevent leakage and evaporation.
 - Record results using the Blood Processing module.
 - Store all specimens immediately.

Important Note: Verify all powdered anticoagulant is thoroughly mixed prior to storing the vessel.

7.5.4 Process the 7 mL Gray Tube for Volatile Organic Compounds (VOCs)

- Rock the 7 mL gray top tube until no particulate matter is visible. Lightly tap the bottom of the tube to loosen the particulate matter if needed. **Never** tap the tube on a hard surface.
- Determine if the plasma is clotted. If so, enter a comment when entering the processing results.
- Record results using the Blood Processing module.
- Store all specimens refrigerated.

7.5.5 Process the 6 mL Lavender Tube for Genetics

- Rock the 6 mL lavender tube until ready to process.
- Determine if the plasma is clotted. If so, enter a comment when entering the processing results.
- Record results using the Blood Processing module.
- Store all specimens refrigerated.

7.5.6 Process the 7 mL, 10 mL, and 15 mL Red Top for Pooled Sera

- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Place 7 mL, 10 mL, and 15 mL on the rocker for 10 minutes and then place in the rack to clot for the remaining time indicated on the timer (20 minutes).
- Allow the blood in each 7 mL, 10 mL, and 15 mL red top tubes to rock on a rocker for 10 minutes and sit in the rack for 20 minutes at room temperature. Do not let clot for more than 1 hour.

Place the tubes in either refrigerated tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 2-8°C and 2,900 rpm for 15 minutes to yield serum.

- If the serum in any one red top tube from an SP is *grossly* hemolyzed, do not pool it with serum from the remaining tubes. Reserve it for the storage vessels 32-37. If the serum is lipemic, icteric, or hemolyzed, select either icteric, lipemic, or hemolyzed from the drop-down menu in ISIS.
- If fibrin is observed after the first centrifugation, DO NOT record a comment in ISIS that fibrin was present in the sample. Use a wooden applicator stick to ream the sample and loosen the fibrin. Centrifuge the tube again according to the protocol. If fibrin is observed after the second centrifugation, select “Fibrin Observed” from the drop-down menu in ISIS. Submit a UFO with the SP ID indicating the number of centrifugations required to clear the fibrin. Include the lot number of the tubes in the UFO.

Vessels 236, 110, 138, 237, 99, 241, 70, 87, 13, 118, 137, 239, 17, 122, 229, 21, 18, , 23, 77, 22, 24, 240, 90, 29, and 32-37

- Use a serum separator to remove serum from all the red top tubes by gently pushing the separator to the clot barrier to ensure cell-free separation. Do not push the separator too hard. Do not touch it to the clot barrier.

Note: Serum is to be taken off the cells within 2 hours of phlebotomy.

- Label the 50 mL conical tube with SP ID #. Pool all sera. For each SP, pool the serum from all red top tubes by decanting the separated serum into the 50 mL conical tube. Be careful to avoid introducing any cellular debris. Discard all tubes and separators in a sharps container.
- Securely close the 50 mL conical tube and mix its contents by gentle inversion. If there are any delays in processing, the conical tube should be placed in the refrigerator.

- Confirm that all vessels have the correct information with the appropriate SP's barcode ID label before filling them.
- Use the 200-5,000 (purple) Eppendorf pipette and 5 mL pipette tips to aliquot the serum for all vessels.
- Using clear serum only, fill as many vessels as possible in the priority order shown in Section 7.2. Exhibits 7-1 to 7-6 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 to vessel 29.
- Use Eppendorf pipette tips and the 200-5,000 μL (purple) Eppendorf pipette to pipette +0.7 mL serum for vessel 110 (Folate 1) on primary SPs aged 1+ years into a 2 mL vessel. Pre-wet the pipette tips. Add 50 μL of the 7 percent ascorbic acid to the vessel. Mix well.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the Blood Processing module as described in Section 7.6.
- Store all specimens immediately as outlined in Section 7.7.
- If the serum cannot be immediately aliquoted, refrigerate it at 4°C for no more than 4 hours.

7.5.7 Ascorbic Acid Processing and Preparation

The CDC supplies premeasured powder to make a 1 percent ascorbic acid (AA) for vessel 3 (RBC Folate) and a premeasured powder to make 7 percent AA solution for vessel 110 (Folate 1). Prepare both reagents before processing the blood samples. Cover tubes with aluminum foil to protect the contents from light. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use the Eppendorf Research pro pipettes to make the dilution. Add 0.1 mL of whole blood to 1.0 mL of 1 percent ascorbic acid for vessel 3 (RBC Folate) and rinse the pipette tip. Add 0.05 mL of the 7 percent AA to vessel 110, then add 0.7 mL of serum. Rinse the pipette. Mix both vessels by gentle inversion.

- The 1 percent ascorbic acid powder is in a 50 mL Falcon tube. Dissolve the powder in 30 mL of deionized water using a graduated cylinder to measure the water and mix gently. Prepare this reagent **daily**. 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 Daily QC Log each time it is prepared. The 7 percent AA powder is in a 2 mL Nalgene cryovial.

Dissolve the powder in 2 mL of deionized water using a graduated cylinder to measure the water and mix gently. Prepare this reagent **daily**. Date and label the Nalgene 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 Daily QC Log each time it is prepared.

- Discard both the 1 percent and 7 percent AA prepared reagents at the end of each day and make fresh vials at the start of the next session.

7.6 Record the Results of Specimen Processing

After filling, processing, or collecting the whole blood, plasma, serum, and/or the EDTA or gray top tubes for each SP, use the Blood Processing module to enter the blood processing results.

Open and log on to the Laboratory application. Use the heads-up display, see Exhibit 7-9, to view the SPs, the modules for which they are eligible, and their current process status.

Select the correct SP and access the Blood Processing module.

Exhibit 7-9. Laboratory heads-up display

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC		
102558	102558	CI	P	M	11	B, JOSE2	●	●	-	○	●	●	-	-
103002	103002	CI	P	F	1	, BABY L	-	-	-	○	●	-	-	-
110663	110663	CI	P	M	50	NDUMU4, EMMANUEL	●	●	-	○	●	●	-	-
112888	112888	CI	P	M	3	, GRANDSON S	○	○	-	○	●	-	-	-
129626	129626	CI	P	M	15	TOOMBS1, MARCUS	○	○	-	○	●	●	-	-
130058	130058	CI	P	F	50		●	●	●	○	●	●	-	-
135655	135655	CI	P	M	48		●	○	-	○	●	●	-	-
137024	137024	CI	P	F	3		○	○	-	○	●	-	-	-
147718	147718	CI	P	F	15		○	○	○	○	●	●	-	-
151137	151137	CI	P	M	1		-	-	-	○	●	-	-	-
164571	164571	CI	P	F	13		○	○	○	○	●	●	-	-
174973	174973	CI	P	F	59		○	○	○	○	●	●	-	-
175223	175223	CI	P	F	11	GARCIA, SP2_17YEARS G	●	●	●	○	●	●	-	-

If labels have not been printed in advance, the SPs will be displayed in a red font on the heads-up display. To access the Blood Processing module, highlight the SP, right-click, and drag the mouse arrow to Blood Processing.

The SP's blood processing screen appears as shown in Exhibit 7-10.

Exhibit 7-10. Blood processing screen

BP: 175421

B processing

Tech ID: 2566 Sample ID: 175421 Name: SALK1, JASON Gender: M Age: 18
 SP ID: 175421 Appt Type: Primary Fasting Req: Afternoon/Evening

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	PbCadHgSeMn		0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617067	42
5	Mercury		0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617069	18
235	BChe		2.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617114	11
3	RBC Folate		0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617002	24
4	Glycohem		0.1	W	4 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617068	8
109	TFA		0.7	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617113	13
119	Genetics		6.0	VW	6 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617096	4
54	VOC Blood		7.0	VW	7ml	gray top	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617085	6
110	Folate 1		0.7	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617033	35
99	Fer		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617093	16
238	AGP/IFR		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617115	16
70	VitD		0.7	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617054	18
13	CRP		0.3	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617072	18
118	Thyroid		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617095	9

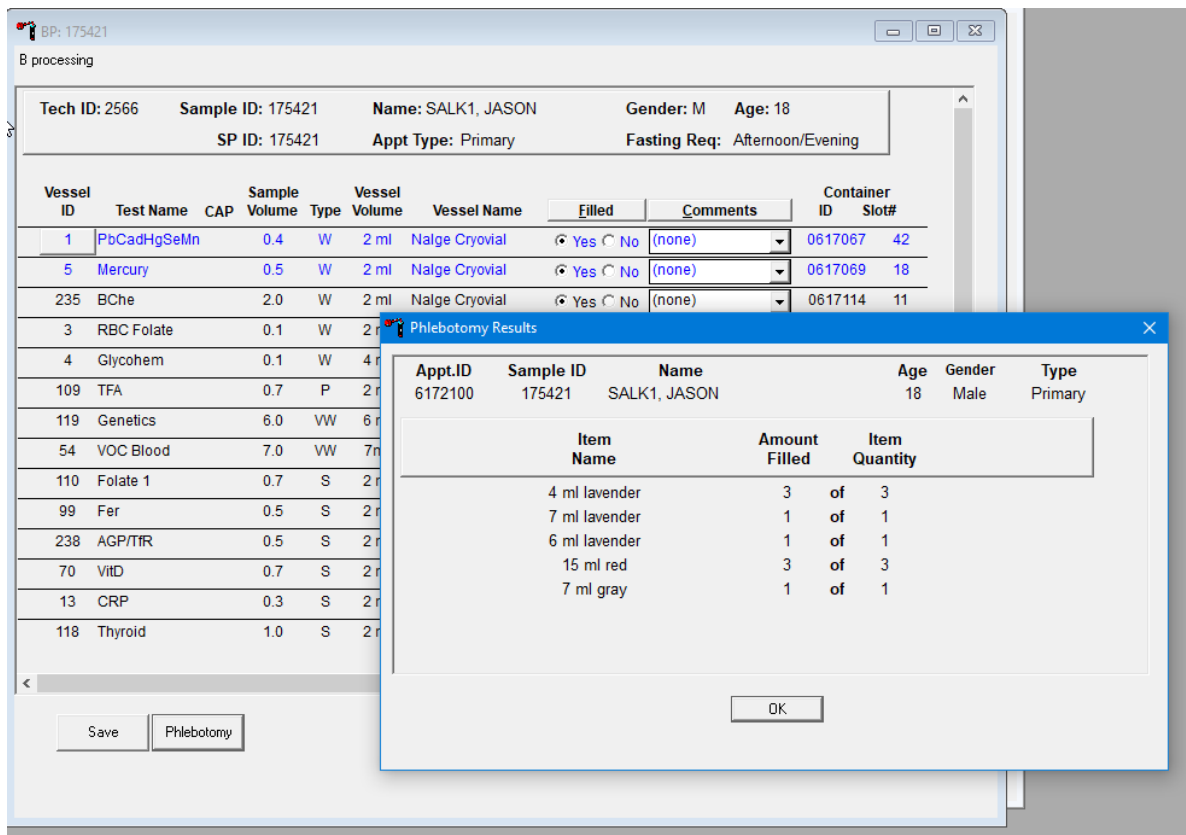
Save Phlebotomy OK Cancel

The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, Columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum), Vessel Volume, Vessel Name, Filled Radio Buttons, Comments Text Box, and a Container ID/Slot# column. Vessels that require sterile 2 mL cryovials are displayed in blue. Vessels that require a red cap have a red dot displayed next to them.

Inspect the SP's Vacutainer® tubes. Compare the Sample ID on the tubes to the barcode 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 as shown in Exhibit 7-11. To close this screen, use the mouse to direct the mouse arrow to the OK button and left-click.

Exhibit 7-11. Phlebotomy results



Record blood processing results for each SP. Individually mark each vessel as Filled—Yes.

To mark an individual blood vessel as collected or Filled—Yes, use the mouse to direct the mouse arrow to the center of 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. See Exhibit 7-12 for a visual example.

Exhibit 7-12. Filled blood processing

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	PbCadHgSeMn		0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617067	42
5	Mercury		0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617069	18
235	BChe		2.0	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617114	11
3	RBC Folate		0.1	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617002	24
4	Glycohem		0.1	W	4 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617068	8
109	TFA		0.7	P	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617113	13
119	Genetics		6.0	VW	6 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617096	4
54	VOC Blood		7.0	VW	7ml	gray top	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617085	6
110	Folate 1		0.7	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617033	35
99	Fer		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617093	16
238	AGP/IFR		0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617115	16
70	VitD		0.7	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617054	18
13	CRP		0.3	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617072	18
118	Thyroid		1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0617095	9

To mark an individual blood vessel as not collected or Filled—No, use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. Vessels marked as “No” require a comment.

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, drag the arrow to Fill All, drag the mouse arrow to {All}, and left-click. Selectively mark all whole blood or serum vessels as Filled—Yes. For an example see Exhibit 7-13.

Exhibit 7-13. Fill all example

Tech ID: 2566		Sample ID: 175421		Name: SALK1, JASON		Gender: M		Age: 18		
SP ID: 175421				Appt Type: Primary		Fasting Req: Afternoon/Evening				
Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
1	PbCadHgSeMn		0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes	Fill All	Whole Blood	
5	Mercury		0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes	Not Filled	Serum	
235	BChe		2.0	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)	Plasma	
3	RBC Folate		0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)	VOC Whole	
4	Glycohem		0.1	W	4 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)	All	
109	TFA		0.7	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)	0617113	13
119	Genetics		6.0	VW	6 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)	0617096	4

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, drag the arrow to Fill All, drag the mouse arrow to Whole Blood, and left-click. To collectively mark all serum vessels as Filled—Yes, direct the mouse arrow to the Filled button on the top of the radio buttons, left-click, drag the arrow to Fill All, drag the mouse arrow to Serum, and left-click. As each vessel is marked as Filled, it is automatically assigned to a slot in an existing (open) container.

Quality comment codes are available to describe the quality of the specimen (Exhibit 7-14).

Exhibit 7-14. Quality comment codes

Comment for filled vessels	Use when
Clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
Equipment failure	Pipettes are malfunctioning.
Hemolyzed	There is a 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.
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 a visible “jaundice” color when the concentration of bilirubin is above 430 umol/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.

To attach a quality control comment to an individual-filled vessel, direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, 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, drag the arrow to Filled Comments, drag the mouse arrow to the correct choice, and left-click. All blood tubes (vessel 54) must be marked individually.

All vessels marked as Filled—No require a comment or explanation.

Enter comment codes to describe why a vessel is marked as Filled—No, or why the protocol is incomplete (Exhibit 7-15).

Exhibit 7-15. Comments for not filled vessels

Comment for not filled vessels	Use when
Laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist error.
Quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP does not provide consent, and is consequently excluded from HIV testing.

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 attach the same comment to all Filled—No vessels, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left-click, drag the arrow to {Not Filled All}, drag the mouse arrow to the desired choice, and left-click.

If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 5 (Mercury), vessel 235 (BChe), or vessel 3 (RBC Folate).

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 the 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 the data to the database and 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.

7.7 Blood Specimen Storage

7.7.1 Blood Specimen Storage Protocol

Fill the blood vessels, enter the blood processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 7-16.

At the beginning of each stand, generate and print a series of barcoded, numbered labels for storage containers as described in Chapter 8. Use the shipping module to assign a barcode 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.

Exhibit 7-16. Storage protocol for blood

Shipping location	Vessels	Conditions	Vessel storage	Ship frequency
CBR	1 Lead/Cad/HG/Se/Mn	Frozen	9 x 9 two-inch box	Weekly
CBR	5 Mercury, Ethyl, and Methyl	Frozen	9 x 9 two-inch box	Weekly
CBR	235 Butrylcholinesterase	Refrigerated	9 x 9 two-inch box	Weekly
CBR	3 RBC Folate	Frozen	9 x 9 two-inch box	Weekly
University of Missouri	4 Glycohem	Refrigerated	5 x 5 five-inch foam box	Weekly
CBR	88 Acrylamide	Frozen	9 x 9 two-inch box	Weekly
CBR	221 RBC Folate Forms	Frozen	9 x 9 two-inch box	Weekly
CBR	222 Fatty Acids	Frozen	9 x 9 two-inch box	Weekly
CBR	109 Transfatty Acids	Frozen	9 x 9 two-inch box	Weekly
ATCC Bethesda MD	119 Genetics	Refrigerated	5 x 5 five-inch foam box	Bi-Weekly
University of Missouri	9 Glucose	Frozen	9 x 9 two-inch box	Weekly

Exhibit 7-16. Storage protocol for blood (continued)

Shipping location	Vessels	Conditions	Vessel storage	Ship frequency
CDC PGO/LMB Warehouse	54 VOC Blood	Refrigerated	5 x 5 five-inch foam box	Weekly
CDC/NCID Hepatitis Ref Lab	236 COVID Serology	Frozen	Weekly	4x4 two-inch box
CBR	110 Folate	Frozen	9 x 9 two-inch box	Weekly
CDC/NCIRD CMV Diagnostic Laboratory	138 CMV	Frozen	9 x 9 two-inch box	Monthly
CDC/NCIRD/DVD Polio, and Picornavirus Laboratory Branch	237 EVD68	Frozen	9 x 9 two-inch box	Weekly
CBR	99 Ferritin	Frozen	9 x 9 two-inch box	Weekly
CBR	70 VID	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab	87 Hepatitis ab	Frozen	9 x 9 two-inch box	Weekly
NHANES ARDL	13 CRP	Frozen	9 x 9 two-inch box	Weekly
NHANES ARDL	118 Thyroid Panel	Frozen	9 x 9 two-inch box	Weekly
CBR	137 Steroid Hormones	Frozen	9 x 9 three-inch box	Weekly
CBR	239 Sex Steroid Hormone Panel	Frozen	9 x 9 two-inch box	Weekly
CBR	17 Cotinine	Frozen	9 x 9 two-inch box	Full box/End of stand
CDC/NCID Hepatitis Ref Lab	122 Hep Profile	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab	229 Hep Xtra sera	Frozen	9 x 9 two-inch box	Weekly
NHANES ARDL	21 Lipids	Frozen	9 x 9 two-inch box	Weekly
University of Missouri	18 Biochem	Refrigerated	9 x 9 two-inch box	Weekly
University of Missouri	23 Insulin	Frozen	9 x 9 two-inch box	Weekly
CDC/DHCPP/CVDB/HPV	77 HPV-Serum	Frozen	9 x 9 two-inch box	Full box/End of stand
CDC NCID AIDS Division	22 HIV	Frozen	9 x 9 two-inch box	Weekly
Emory University	24 HSV	Frozen	9 x 9 two-inch box	Weekly
CDC/NCEH Tobacco and Volatiles Branch	240 Serum Terpenes	Frozen	9 x 9 two-inch box	Weekly
CBR	90 Perfluor	Frozen	9 x 9 two-inch box	Full box/End of stand
CBR	29 Dioxin 1	Frozen	4 x 4 five and a half-inch box	Full box/End of stand
CBR	32-37 Xtra Sera	Frozen	9 x 9 two-inch box	Full box/End of stand

7.8 How to Deal with System Failure

If the computer system fails, record results on a preprinted workstation 2 processing worksheet (Exhibit 7-17). Complete a Blood Processing worksheet for each SP while processing the blood specimens. Enter the results after the system is operational.

Exhibit 7-17. Workstation 2 processing worksheet

Blood Processing

SP ID _____

ID	Name	Ages	Sample mL	Sample type	Filled ✓	Filled comments	Not filled comments	Slot #
						<i>Icteric Lipemic Equip Failure Clotted Hemolyzed</i>	<i>QNS SP Refusal Lab Error</i>	
1	Lead/Cad/HG/Se/Mn	1+	0.4	WB				
5	Mercury, Ethyl, and Methyl	1+	0.5	WB				
235	Butrylcholinesterase	6+	1	WB				
3	RBC Folate	1+	0.1	WB				
4	Glycohem	12+	1.0	WB				
88	Acrylamide	6+	1.5	PC				
221	RBC Folate Forms	6+	0.1	PC				
222	Fatty Acids	6+	1.6	PC				
109	Transfatty Acids	3+	0.7	EDTA P				
119	Genetics	18+	6.0	WB				
9	Glucose	12+	0.5	NAFI P				
54	VOC Blood	12+	7.0	WB				
236	COVID Serology	1+	0.6	S				
110	Folate	1+	0.7	S				
138	CMV	1-5	0.4	S				
237	EVD68	1-11	0.2	S				
99	Ferritin	1-5, 12+	0.5/0.7	S				
70	VID	1-5, 6+	0.5/0.7	S				
87	Hepatitis Bs Ab	2, 3-5	1.0, 1.0	S				
13	CRP	1+	0.3	S				
118	Thyroid Panel	3-5, 6+	1.0	S				
137	Steroid Hormones	6+	3.5	S				
239	Sex Steroid Hormone Panel	3-5	0.6	S				
122	Hep Profile	6+	1.8	S				
229	Hep Xtra sera	6+	1.8	S				

Exhibit 7-17. Workstation 2 processing worksheet (continued)

Blood Processing

SP ID _____

ID	Name	Ages	Sample mL	Sample type	Filled ✓	Comments		Slot #
						Filled comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i>	Not filled comments <i>QNS SP</i> <i>Refusal</i> <i>Lab Error</i>	
21	Lipids	6-11 12+	0.5 1.0	S				
18	Biochem	12+	0.8	S				
23	Insulin	12+	0.5	S				
77	HPV-Serum	6+	0.5	S				
22	HIV	18- 59	1.5	S				
24	HSV	14- 49	0.2	S				
240	Serum Terpenes	6+	1.2	S				
90	Perflour	3-5 6+	1.5	S				
29	POP/DOX	12+	15.0	S				
32	Xtra Sera1	3+	0.5	S				
33	Xtra Sera2	3+	0.5	S				
34	Xtra Sera3	12+	0.5	S				
35	Xtra Sera4	12+	0.5	S				
36	Xtra Sera5	12+	0.5	S				
37	Xtra Sera6	12+	0.5	S				

WB = Whole blood

P = Plasma

PC = Packed cells

S = Serum

8. Printing Labels and Specimen Shipment

8.1 Introduction

Sample identification labels are essential to the NHANES laboratory component. Labels support each study participant's (SP's) unique processing protocol. The laboratory record is created when the clinical laboratory technologist opens a session for the first time. 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 mobile examination center (MEC) processing through contract laboratory receipt.

Biological specimens are shipped to a variety of CDC and contract laboratories in double-sided Styrofoam and corrugated cardboard shippers or hard-sided shippers with Styrofoam inserts using dry ice or wet ice (refrigerant packs). A copy of the shipping manifest is included with each shipment that contains a list of the items contained in the shipment and certain demographic information.

Exhibit 8-1, the sample shipping protocol, illustrates the specifications for the shipment of specimens to each contract laboratory.

Exhibit 8-1. Sample shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Whole blood				
CDC/NCEH Tobacco and Volatiles Branch Lab 122	VOC Blood Vessel 54	Refrigerated	5 x 5 five-inch box with foam insert	Weekly
CBR Lab 6	Lead/Cad/HG/Se/Mn Vessel 1	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Mercury, Ethyl and Methyl Vessel 5	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 122	BChE Vessel 235	Refrigerated	9 x 9 two-inch box	Weekly
CDC PGO/LMB Warehouse Lab 6	RBC Folate Vessel 3	Frozen	9 x 9 two-inch box	Weekly
University of Missouri Lab 10	Glycohem Vessel 4	Refrigerated	5 x 5 five-inch box with foam insert	Weekly
ATCC Bethesda Maryland Lab 123	Genetics Vessel 119	Refrigerated	5 x 5 five-inch box with foam insert	Twice weekly

Exhibit 8-1. Sample shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Plasma				
University of Missouri Lab 10	Glucose Vessel 9	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Transfatty Acids Vessel 109	Frozen	9 x 9 two-inch box	Weekly
EDTA washed packed cells				
CBR Lab 6	Acrylonitrile Vessel 88	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	RBC Folate Forms Vessel 221	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	Fatty Acid Vessel 222	Frozen	9 x 9 two-inch box	Full or end of stand
Serum				
CDC/NCID Hepatitis Ref Lab 2	COVID-19/SARS-CoV-2 Serology Vessel 236	Frozen	4 x 4 two-inch box	Weekly
CBR Lab 6	Folate Vessel 110	Frozen	9 x 9 two-inch box	Weekly
CDC/NCIRD Cytomegalovirus Diagnostic Lab Lab 116	CMV Vessel 138	Frozen	9 x 9 two-inch box	Monthly
CDC/NCIRD/DVD Polio and Picornavirus Laboratory Branch	EVD68 Vessel 237	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Ferritin Vessel 99	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	VID Vessel 70	Frozen	9 x 9 two-inch box	Weekly
CDC NCID Hepatitis Ref Lab Lab 2	Hepatitis Bs Ab Vessel 87	Frozen	9 x 9 two-inch box	Weekly
NHANES (ARLD) Lab 51	CRP Vessel 13	Frozen	9 x 9 two-inch box	Weekly
NHANES (ARLD) Lab 51	Thyroid Panel Vessel 118	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Steroid Hormones Vessel 137	Frozen	9 x 9 three-inch box	Weekly
CBR Lab 6	Sex Steroid Hormone Panel Vessel 239	Frozen	9 x 9 three-inch box	Weekly
CBR Lab 6	Cotinine Vessel 17	Frozen	9 x 9 two-inch box	Full or end of stand
CDC/NCID Hepatitis Ref Lab Lab 2	Hep Profile Vessel 122	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab Lab 2	Hep Xtra Sera Vessel 229	Frozen	9 x 9 two-inch box	Weekly
NHANES (ARLD) Lab 51	Lipids Vessel 21	Frozen	9 x 9 two-inch box	Weekly
University of Missouri	Biochem Vessel 18	Refrigerated	9 x 9 two-inch box	Weekly

Exhibit 8-1. Sample shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Serum				
CDC/NCID Hepatitis Ref Lab Lab 2	Hep Xtra Sera Vessel 229	Frozen	9 x 9 two-inch box	Weekly
NHANES (ARLD) Lab 51	Lipids Vessel 21	Frozen	9 x 9 two-inch box	Weekly
University of Missouri	Biochem Vessel 18	Refrigerated	9 x 9 two-inch box	Weekly
University of Missouri Lab 10	Insulin Vessel 23	Frozen	9 x 9 two-inch box	Weekly
CDC/NCIRD DVD Lab 52	HPV Serum Vessel 77	Frozen	9 x 9 two-inch box	Full or end of stand
CDC/NCID AIDS Division Lab 3	HIV Vessel 22	Frozen	9 x 9 two-inch box	Weekly
Emory University Lab 9	HSV Vessel 24	Frozen	9 x 9 two-inch box	Weekly
CDC/NCEH Tobacco and Volatiles Branch Lab 122	Serum Terpenes Vessel 240	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Perfluor1 Vessel 90	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	POP/Dox Vessels 29	Frozen	4x4 five and a half-inch box	Full or end of stand
CBR Lab 6	Xtra Sera Vessels 32-37	Frozen	9 x 9 two-inch box	Full or end of stand
Urine				
NHANES (ARLD) Lab 51	Alb/Creat Vessel 45	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID NCHSTD Lab 5	Chlam/Trichomonas Vessel 46	Frozen	9 x 9 three-inch box	Weekly
CDC/NCID NCHSTD Lab 5	Trichomonas Vessel 154	Frozen	9 x 9 three-inch box	Weekly
CBR Lab 6	Spc Arsenic Vessel 86	Frozen	9 x 9 two-inch box	Weekly
CDC/NCEH Pesticide Laboratory Lab 6	Prior Pest Vessel 48	Frozen	5 x 5 three-inch box	Full or end of stand
CDC/NCEH Pesticide Laboratory Lab 6	Organophos Vessel 49	Frozen	5 x 5 three-inch box	Full or end of stand
CBR Lab 6	Urin Merc/Iodine Vessel 62	Frozen	5 x 5 three-inch box	Weekly
CBR Lab 6	Metals Vessel 50	Frozen	9 x 9 three-inch box	Weekly
CBR Lab 6	Arsenic/Chromium/Nickel Vessel 220	Frozen	5 x 5 five-inch foam box	Weekly
CBR Lab 6	PAH Vessel 66	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	Phthalates Vessel 67	Frozen	5 x 5 two-inch box	Full or end of stand
CBR Lab 6	Perchlorate/VOC/Thiocyante Vessel 102	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	TSNA Vessel 156	Frozen	9 x 9 three-inch box	Full or end of stand

Exhibit 8-1. Sample shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Urine				
CBR Lab 6	Phthalates Vessel 67	Frozen	5 x 5 two-inch box	Full or end of stand
CBR Lab 6	Perchlorate/VOC/Thiocyante Vessel 102	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	TSNA Vessel 156	Frozen	9 x 9 three-inch box	Full or end of stand
CBR Lab 6	UVOC Vessel 218	Frozen	9 x 9 two-inch box	Full or end of stand
CBR Lab 6	Xtra Urine1 Vessel 52	Frozen	9 x 9 three-inch box	Full or end of stand
CBR Lab 6	Xtra Urine2 Vessel 139	Frozen	9 x 9 three-inch box	Full or end of stand

Packages are shipped using FedEx. The clinical laboratory scientist in workstation 1 is responsible for contacting FedEx at the start of each stand to determine availability. The facility and equipment specialist (FES) contacts the dry ice company at the start of each stand to establish a contact. It is the chief clinical laboratory scientist’s responsibility to confirm the arrangements for shipping and the dry ice delivery with the FES, prior to or at the beginning of each stand. The chief clinical laboratory scientist and the FES determine the total weekly weight of dry ice required and the exact shipping dates. The FES makes arrangements with the dry ice company regarding the size and amount of dry ice required for the entire stand, the date the dry ice is required, and the expected time the dry ice should be delivered for shipping.

The home office Laboratory Component Lead determines the exact days to ship specimens to the contract laboratories. Most specimens are packed and shipped once a week during the MEC split examination sessions. The exception is the Genetics samples, which are shipped bi-weekly. Hold the containers for vessels 17, 32-37, 29, 77, 90, 48, 49, 66, 67,102, 156, 218, 52, and 139. Ship once they are full, or hold and ship at the end of the stand. 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 home office Laboratory Component Lead.

8.2 Equipment and Supplies

Exhibit 8-2 contains a list of label/shipping supplies.

Exhibit 8-2. Supplies for labels/shipping

Small Styrofoam shipper (14 x 14 x 12)	Medium Styrofoam shipper (16 x 16 x 15.5)
5 mL cryovial sterile	2 mL cryovial sterile
14 mL Falcon tube	2 mL cryovial nonsterile
5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid	Caps for 2 mL cryovial
5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid	4x4 5.5-inch box
30 mL ENV vials	U-tek reusable refrigerant packs – Large
5.25 x 5.25 x 3.0 inch cardboard box w/ 5 x 5 grid	Rubber bands
STP-710 packaging system	Newsprint paper
STP-730 packaging system	Full face shield
Plastic bag 9 x 12	Lab jackets (Medium, Lg., X-Lg)
Absorbent sheets (2 x 2)	Dry ice scoop
Large padded envelope	2" packaging tape
Cryo gloves	Address labels for FedEx Class 9 sticker
Hammer	Refrigerate Do Not Freeze label
Tape gun	Avery 5160 labels
Overpack label	Printer ribbon, Zebra (thermal transfer)
UN 3373 label	13" x 18" terri wipes
Keep Frozen label	FedEx Class 9 label
Label Zebra (1.125")	Dymo Labels
Sheet-fed laser labels	FedEx preprinted return airbill – stand
FedEx large boxes	
Clear FedEx label pouches	
Toner cartridge (HP Laser Jet 4000)	

8.3 Print Vessel Labels and Label Blood Processing Racks

Before each session, the technologist assigned to workstation 1 prints all labels for all SPs assigned to a session. The correct barcoded labels automatically print for each SP based on the SP's age, sex, appointment type, and selection into one or more subsamples. Print urine processing, blood processing, and packed cells processing labels for all SPs scheduled into a MEC session. The phlebotomist and the clinical laboratory scientist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks.

Distribute Labels

- Place urine processing labels at workstation 3 in the laboratory.
- If the SP does not show up for the appointment, it is possible they will reschedule.

- Store the SP's vessel rack and urine labels in a zip-closable bag. Place racks on a shelf in a cupboard above workstation 1.
- If the SP has not shown up by the end of the stand, dispose of vessels and labels.

Assemble Blood-Processing Racks

Use extreme care in setting up the blood vessel racks and in labeling the vessels with the appropriate barcode 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 and 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 tube racks in priority order, using the rack template as an age-specific guide.

Use the following materials to set up and label blood racks:

- Plastic rack; and
- Template for processing.
- Vessels of the following sizes:
 - 2.0 mL sterile vessel;
 - 2.0 mL non-sterile vessel;
 - 5.0 mL sterile vessel; and
 - 30 mL ENV vials.
- Barcoded 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. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

- Label all serum, whole blood, and dilution tubes and place in the appropriate location on the template.
- Label all Acrylonitrile tubes (vessel 88, 221, 222) and place in the appropriate location on the template.

- Label all 30 mL Dioxin (vessel 29) vials.
- Place a colored Post-it indicating the SP ID, gender, and, if applicable, age on the end of this rack.
- Place the rack along with vessel 29 in a zip-closable bag and store on a shelf in workstation 1 that is labeled with the session block date and time.

Place the pre-labeled blood processing racks and the dioxin vessels (vessel 29) on the counter to the right of the centrifuges at the start of each session.

8.3.1 Print Vessel Labels Using the Label Print Application

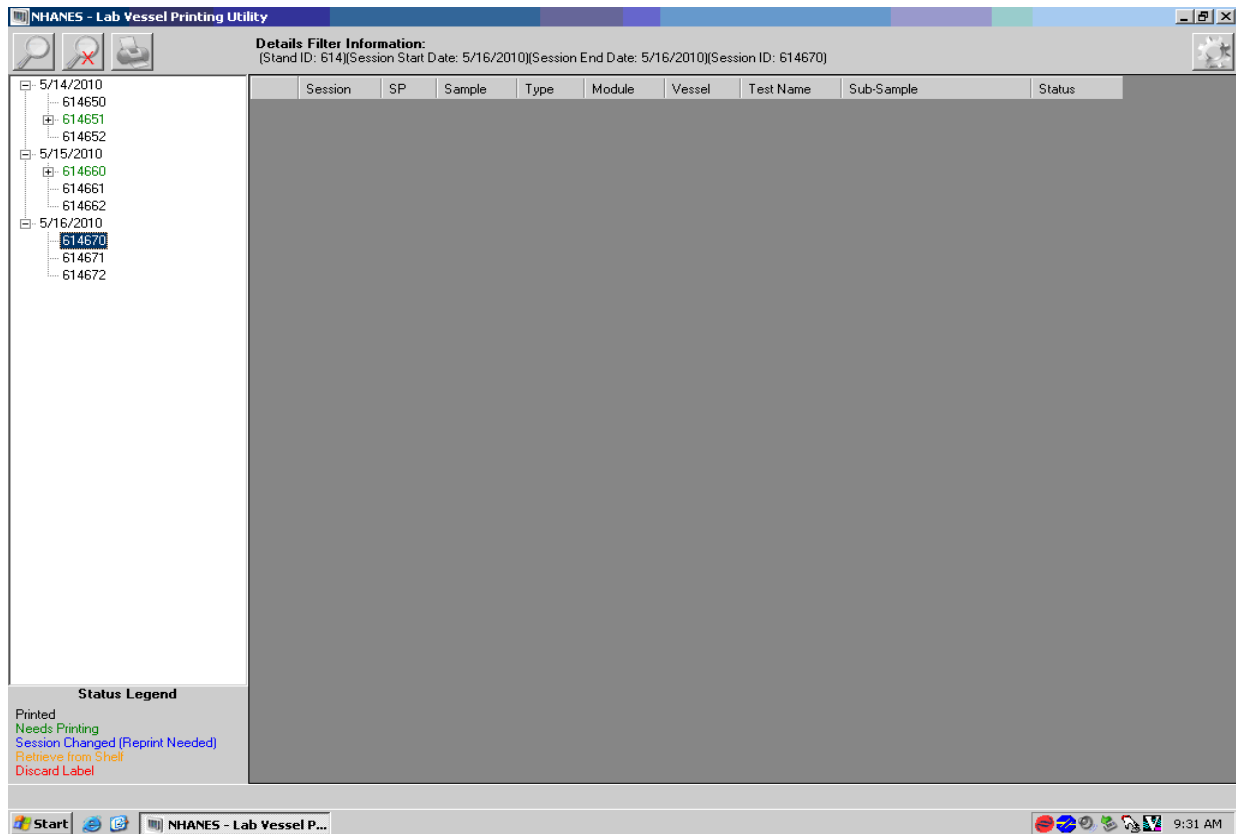
Open the Laboratory application. Log on to the computer terminal and select the Label Print Application. This application is found on the desktop of all laboratory computers and has an icon that looks like a barcode label.



8.3.2 Main Printing Screen

From the main printing screen, the current day and next 2 days the MEC is in session will be displayed in a tree view on the left side of the screen. See Exhibit 8-3. The sessions will be color coded to match the legend at the bottom left side of the screen. Sessions in green indicate that a particular session or SPs profile within that session needs to be printed. Sessions in black have already been printed and there are no SP profile changes. Sessions in blue indicate that an SP was added to that session or that a SP or SPs had a profile change and need to be reprinted. If an SP is removed from a session, that session will be displayed in red, which indicates label action is needed. Sessions where SP ID's appear in gold indicate that labels have already been printed and the rack has been placed on the upper shelf.

Exhibit 8-3. Lab vessel print utility screen



8.3.3 Filter Options

The looking-glass icon is used for the filtering options, where you can filter labels by stand start and end date, session ID, SP ID, or Sample ID. After picking the criteria you would like to filter with, press the Filter button. See Exhibit 8-4 for an example. Clearing the filter takes you back to the current date, plus 2 days, and the Cancel button takes you back to the main printing screen.

Exhibit 8-4. Filter options

Details Filter Information:
 (Stand ID: 614)(Session Start Date: 5/14/2010)(Session End Date: 5/16/2010)

Session	SP	Sample	Type	Module	Vessel	Test Name	Sub-Sample	Status
614651	530558	530558	W	BP	1	Lead/Cad/HG		Needs Printing
614651	554728	554728	W	BP	1	Lead/Cad/HG		Needs Printing
614651	731944	731944	W	BP	1	Lead/Cad/HG		Needs Printing
614651	753743	753743	W	BP	1	Lead/Cad/HG		Needs Printing
614651	847833	847833	W	BP	1	Lead/Cad/HG		Needs Printing
614651	889468	889468	W	BP	1	Lead/Cad/HG		Needs Printing
614651	890547	890547	W	BP	1	Lead/Cad/HG		Needs Printing
614651	904789	904789	W	BP	1	Lead/Cad/HG		Needs Printing
614660	211074	211074	W	BP	3	RBC Folate		Needs Printing
614660	389587	389587	W	BP	3	RBC Folate		Needs Printing
614660	540529	540529	W	BP	3	RBC Folate		Needs Printing
614660	565809	565809	W	BP	3	RBC Folate		Needs Printing
614660	580885	580885	W	BP	3	RBC Folate		Needs Printing
614651	530558	530558	W	BP	4	Glycohem		Needs Printing
614651	554728	554728	W	BP	4	Glycohem		Needs Printing
614651	731944	731944	W	BP	4	Glycohem		Needs Printing
614651	753743	753743	W	BP	4	Glycohem		Needs Printing

Status Legend
 Printed
 Needs Printing
 Session Changed (Reprint Needed)
 Retrieve from Shelf
 Discard Label

8.3.4 Print Key

The print key (represented by the printer icon) brings up another menu that allows the user to select different print options and view print details. See Exhibit 8-5.

Needs Printing Vessel Labels

- Labels that are displayed in green are needed and will print if either option is selected.

Exhibit 8-6. Label print options

Details Filter Information:
(Stand ID: 615)(Session Start Date: 11/15/2010)(Session End Date: 11/15/2010)(Session ID: 615810)

Session	SP	Sample	Type	Module	Vessel	Test Name	Sub-Sample	Status
615810	329869	329869	U	UP	45	Alb/Creat		Printed
615810	329869	329869	U	UP	86	Spc Arsenic	Speciated Arsenic	Printed
615810	329869	329869	U	UP	62	UrineHg/I	Urine Mercury/Iodine	Printed
615810	329869	329869					als	Printed
615810	329869	329869					lorates	Printed
615810	329869	329869					AL/Nicotine analogs/Aromatic amines	Printed
615810	329869	329869					AL/Nicotine analogs/Aromatic amines	Printed
615810	329869	329869					tes	Printed
615810	329869	329869						Printed
615810	329869	329869						Printed
615810	386827	386827						Printed
615810	386827	386827						Printed
615810	386827	386827					y Pesticide	Printed
615810	386827	386827					osphate Pesticide	Printed
615810	386827	386827						Printed
615810	386827	386827						Printed
615810	386827	386827						Printed
615810	386827	386827						Printed
615810	416714	416714						Printed
615810	416714	416714						Printed
615810	416714	416714					Arsenic	Printed
615810	416714	416714					ury/Iodine	Printed
615810	416714	416714					als	Printed
615810	416714	416714						Printed
615810	416714	416714					lorates	Printed
615810	416714	416714					AL/Nicotine analogs/Aromatic amines	Printed
615810	416714	416714	U	UP	152	Aro amine	TSNA/NNAL/Nicotine analogs/Aromatic amines	Printed
615810	416714	416714	U	UP	218	Disocyn	Disocyanates	Printed
615810	416714	416714	U	UP	52	Xtra Urine1		Printed
615810	416714	416714	U	UP	139	Xtra Urine2		Printed
615810	545182	545182	U	UP	45	Alb/Creat		Printed
615810	545182	545182	U	UP	46	Chlam/Trich		Printed

Status Legend
 Printed
 Needs Printing
 Session Changed (Reprint Needed)
 Retrieve from Shelf
 Discard Label

Lab Vessel Printing Utility (Version: 1.6)

Exhibit 8-9. Lab print utility

Details Filter Information:
(Stand ID: 615)(Session Start Date: 9/12/2010)(Session End Date: 9/12/2010)(Session ID: 615171)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615171	278008	278008	U	UP	46	Chlam	Needs Printing
615171	278008	278008	U	UP	48	Prior Pest	Needs Printing
615171	278008	278008	U	UP	49	Organophos	Needs Printing
615171	278008	278008	U	UP	121	NNAL	Needs Printing
615171	278008	278008	U	UP	128	Caffeine	Needs Printing
615171	278008	278008	U	UP	52	Xtra Urine1	Needs Printing
615171	278008	278008	U	UP	139	Xtra Urine2	Needs Printing
615171	676709	676709	U	UP	45	Alb/Creat	Needs Printing
615171	676709	676709	U	UP	46	Chlam	Needs Printing
615171	676709	676709	U	UP	86	Spc Arsenic	Needs Printing
615171	676709	676709	U	UP	62	Urin Merc	Needs Printing
615171	676709	676709	U	UP	50	Heavy Metal	Needs Printing
615171	676709	676709	U	UP	66	PAH	Needs Printing
615171	676709	676709	U	UP	67	Phthalates	Needs Printing
615171	676709	676709	U	UP	102	Per/VOC/TCY	Needs Printing
615171	676709	676709	U	UP	121	NNAL	Needs Printing
615171	676709	676709	U	UP	52	Xtra Urine1	Needs Printing
615171	676709	676709	U	UP	139	Xtra Urine2	Needs Printing
615171	878199	878199	U	UP	45	Alb/Creat	Needs Printing
615171	878199	878199	U	UP	46	Chlam	Needs Printing
615171	878199	878199	U	UP	121	NNAL	Needs Printing
615171	878199	878199	U	UP	52	Xtra Urine1	Needs Printing
615171	878199	878199	U	UP	139	Xtra Urine2	Needs Printing
615171	278008	278008	W	BP	1	PbCadHgSeMn	Needs Printing
615171	278008	278008	W	BP	3	RBC Folate	Needs Printing
615171	278008	278008	W	BP	4	Glycohem	Needs Printing
615171	278008	278008	W	BP	5	Mercury	Needs Printing

Status Legend
Printed
Needs Printing
Session Changed (Reprint Needed)

8.3.9 Print Display Options

To change the display on the screen to display in numerical order for all SPs, click on the “Vessel” tab and the display will change to numerical order for the entire session.

8.3.10 Printing One SP’s Labels

Using the tree on the left side of the screen, expand the session by clicking on the + sign to the left of the session number. This will display all the SPs scheduled for that session. Click on the SP you want to display. Use the printer icon to print using the print options described in Sections 8.3.5 to 8.3.7.

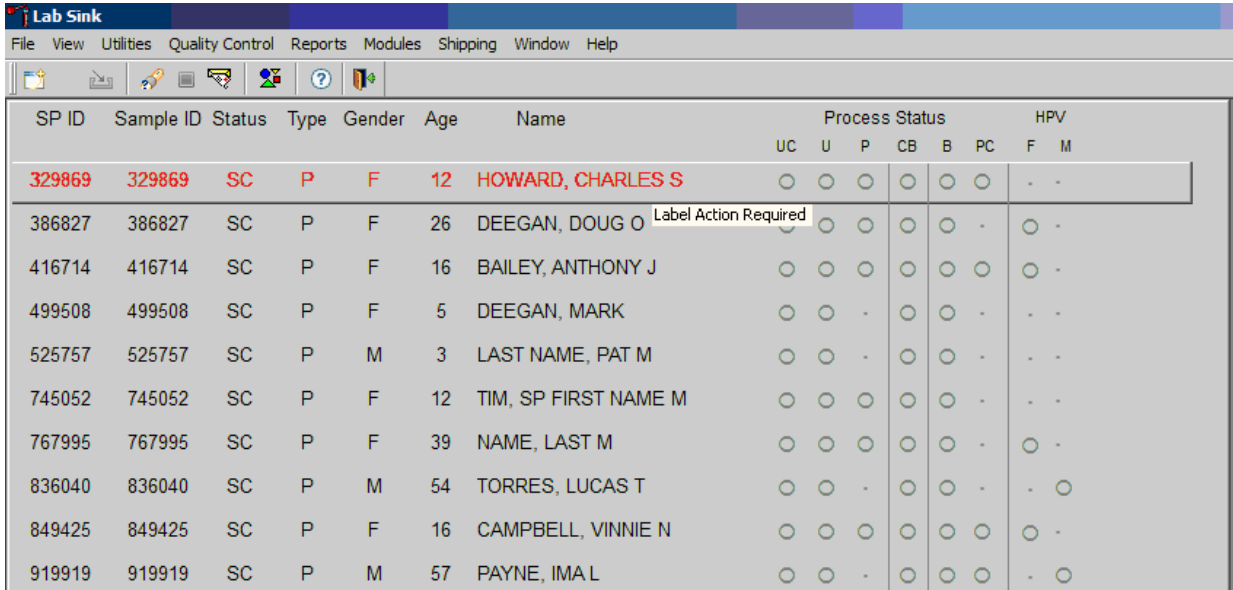
8.3.11 Printing Individual Labels

To print a single or individual label, highlight the line you wish to be printed. Use the printer icon to print using the print options described in Sections 8.3.5 to 8.3.7.

8.3.12 Label Action

If an SP's profile has changed and the labels have already been printed, the SP line will turn red on the heads-up display, shown in Exhibit 8-10, and will show "Label Action Required." Blood processing won't be enabled until the label action is performed.

Exhibit 8-10. Label action on heads-up display



The screenshot shows the Lab Sink application interface. The table below lists patient data with columns for SP ID, Sample ID, Status, Type, Gender, Age, Name, Process Status (UC, U, P, CB, B, PC), and HPV (F, M). The first row, for SP ID 329869, is highlighted in red and has a tooltip that says "Label Action Required" over the U column.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						HPV	
							UC	U	P	CB	B	PC	F	M
329869	329869	SC	P	F	12	HOWARD, CHARLES S	○	○	○	○	○	○	-	-
386827	386827	SC	P	F	26	DEEGAN, DOUG O	○	○	○	○	○	-	○	-
416714	416714	SC	P	F	16	BAILEY, ANTHONY J	○	○	○	○	○	○	○	-
499508	499508	SC	P	F	5	DEEGAN, MARK	○	○	-	○	○	-	-	-
525757	525757	SC	P	M	3	LAST NAME, PAT M	○	○	-	○	○	-	-	-
745052	745052	SC	P	F	12	TIM, SP FIRST NAME M	○	○	○	○	○	-	-	-
767995	767995	SC	P	F	39	NAME, LAST M	○	○	○	○	○	-	○	-
836040	836040	SC	P	M	54	TORRES, LUCAS T	○	○	-	○	○	-	-	○
849425	849425	SC	P	F	16	CAMPBELL, VINNIE N	○	○	○	○	○	○	○	-
919919	919919	SC	P	M	57	PAYNE, IMA L	○	○	-	○	○	○	-	○

Open up the Lab printing application.

The session will be displayed in the tree in green, which indicates something needs to be printed.

Click on the SP ID in the tree; the SP ID will also be displayed in green because labels will need to be printed and some will need to be discarded. Labels that need to be discarded are displayed in red as displayed in Exhibit 8-11.

Exhibit 8-11. Red and green SPs requiring action

NHANES - Lab Vessel Printing Utility

Details Filter Information:
 (Stand ID: 615)(Session Start Date: 10/9/2010)(Session End Date: 10/9/2010)(Session ID: 615440)(SP ID: 197633)

Session	SP	Sample	Type	Module	Vessel	Test Name	Status
615440	197633	197633	W	BP	3	RBC Folate	Printed
615440	197633	197633	W	BP	4	Glycohem	Discard Label
615440	197633	197633	W	BP	5	Mercury	Printed
615440	197633	197633	P	BP	9	Glucose	Discard Label
615440	197633	197633	S	BP	136	Se/Cu/Zn	Printed
615440	197633	197633	S	BP	70	Vit D/FA	Printed
615440	197633	197633	S	BP	122	HAV	Printed
615440	197633	197633	S	BP	17	Cotinine	Printed
615440	197633	197633	S	BP	21	Lipids	Printed
615440	197633	197633	S	BP	18	Biochem	Discard Label
615440	197633	197633	S	BP	23	Insulin	Discard Label
615440	197633	197633	S	BP	12	Vit B12/MMA	Discard Label
615440	197633	197633	S	BP	118	Thyroid	Discard Label
615440	197633	197633	S	BP	127	IgA-TTG/EMA	Printed
615440	197633	197633	S	BP	137	TST	Printed
615440	197633	197633	S	BP	110	Folate 1	Printed
615440	197633	197633	S	BP	32	Xtra Sera1	Needs Printing
615440	197633	197633	S	BP	33	Xtra Sera2	Needs Printing
615440	197633	197633	S	BP	34	Xtra Sera3	Discard Label
615440	197633	197633	S	BP	35	Xtra Sera4	Discard Label
615440	197633	197633	S	BP	36	Xtra Sera5	Discard Label
615440	197633	197633	S	BP	37	Xtra Sera6	Discard Label
615440	197633	197633	S	BP	29	Pers Pest1	Discard Label
615440	197633	197633	S	BP	89	Pers Pest2	Discard Label
615440	197633	197633	S	BP	90	Perfluor	Discard Label
615440	197633	197633	S	BP	92	BFR1	Discard Label
615440	197633	197633	S	BP	93	BFR2	Discard Label
615440	197633	197633	P	TT	98	OGTT	Discard Label
615440	197633	197633	C	OB	129	HPV Rinse	Discard Label

Status Legend
 Printed
 Needs Printing
 Session Changed (Reprint Needed)
 Retrieve from Shelf
 Discard Label

Lab Vessel Printing Utility (Version: 1.5)

Start Lab Subsystem NHANES - Lab Vessel P... 3:30 PM

Click on the printer icon and print the labels that are needed. Right-click on a line that is displayed in red to mark the label as discarded. Two options are available for labels that need to be discarded, either individually or all. Exhibit 8-12 displays an example of the action in the computer module.

Exhibit 8-12. Discard labels



After completing the Label Action, return to heads-up display and allow the display to update before proceeding. After update, the SP will change from red to black, and blood processing can be accessed.

For SPs who canceled or did not show for their appointment and are rescheduled to a new session, the label print application will trigger the SP to be shelved. These SPs will be displayed in gold in the tree in the label print application. Find the corresponding rack from the top shelf in workstation 1 and right click to bring up the action box. Click “Retrieve all shelved labels.” An example is shown below in Exhibit 8-13.

Exhibit 8-13. Retrieve shelved labels

Details Filter Information:
(Stand ID: 615)(Session Start Date: 11/15/2010)(Session End Date: 11/15/2010)(Session ID: 615810)(SP ID: 545182)

Session	SP	Sample	Type	Module	Vessel	Test Name	Sub-Sample	Status
615810	545182	545182	S	BP	23	Insulin		Printed
615810	545182	545182	P	TT	98	OGTT		Printed
615810	545182	545182	P	BP	9	Glucose		Printed
615810	545182	545182	S	BP	137	TST-Ea/SHBG		Shelved
615810	545182	545182	S	BP	13	CRP		Shelved
615810	545182	545182	S	BP	24	Lipid		Shelved
615810	545182	545182	S	BP	77			Shelved
615810	545182	545182	S	BP	18			Shelved
615810	545182	545182	S	BP	21			Shelved
615810	545182	545182	S	BP	25		Feed2/Perfluor1	Shelved
615810	545182	545182	S	BP	29		Feed2/Perfluor1	Shelved
615810	545182	545182	C	OR	129	HPV Rinse		Shelved
615810	545182	545182	S	BP	90	Perfluor	Feed1 and Ozone/Feed2/Perfluor1	Shelved
615810	545182	545182	S	BP	35	Abx Sens4		Shelved
615810	545182	545182	S	BP	34	Abx Sens3		Shelved
615810	545182	545182	S	BP	37	Abx Sens6		Shelved
615810	545182	545182	S	BP	36	Abx Sens5		Shelved
615810	545182	545182	S	BP	17	Combin		Shelved
615810	545182	545182	U	UP	87	Phthalates	Phthalates	Shelved
615810	545182	545182	U	UP	49	Organophos	Organophosphate Pesticide	Shelved
615810	545182	545182	U	UP	139	Abx Urine2		Shelved
615810	545182	545182	U	UP	52	Abx Urine1		Shelved
615810	545182	545182	U	UP	46	Chlor/Trich		Shelved
615810	545182	545182	U	UP	45	Abx Creat		Shelved
615810	545182	545182	U	UP	48	Priv Feed	EPA Priority Pesticide	Shelved
615810	545182	545182	U	UP	217	Fluoride		Shelved
615810	545182	545182	S	BP	110	Folate 1		Shelved
615810	545182	545182	P	BP	155	Fluoride		Shelved
615810	545182	545182	S	BP	122	Hep profile		Shelved
615810	545182	545182	S	BP	70	Vitamin D		Shelved
615810	545182	545182	W	BP	3	RBC Folate		Shelved
615810	545182	545182	W	BP	1	Pb/Cd/Hg/Se/Mn	Pb/Cd/Hg/Se/Mn/ Hg/Me/EI	Shelved
615810	545182	545182	W	BP	5	Mercury	Pb/Cd/Hg/Se/Mn/ Hg/Me/EI	Shelved

Status Legend
 Printed
 Needs Printing
 Session Changed (Reprint Needed)
 Session Time Conf
 Discard Label

8.3.13 Label Printing Cheat Sheet

Open Lab Vessel Printing Utility

- Select session number you wish to print.
 - Click on Print button at the top.
 - Print screen will default to print all needed.
 - Click on Print button at the bottom of print screen.
- If the session is blue in color:
 - Click on (+) sign before session number; this will open up the session and allow you to see what needs to be done.

3. If a SP's vessel labels are displayed in gold, you need to find the rack in the rescheduled area (shelves above WS 1) or find the labels in a session that is already printed.
 - A. To retrieve all shelved labels for a particular SP or SP's, select any gold vessel label and right-click; a box will appear. Select "Retrieve all shelved labels" and wait for the vessel numbers to be displayed in black.
4. Green SP vessel labels:
 - A. These labels need to be printed.
 - B. Select the session number and click Print button.
5. Red SP vessel labels:
 - A. This means there is a vial that you need to pull from rack and discard.
6. To display more sessions:
 - A. Click the magnifying glass.
 - B. Select the sessions that you want displayed.

Note: The fewer sessions you select, the quicker the filter will work.

8.4 Create New Container Labels

Store processed vessels in boxes and bags (containers). Print and assign container labels using the Create New Container Labels module. Once a label has been created, the container is designated as "open" in the database; it is available for slot assignments as vessels are marked as filled.

At the beginning of each stand, print and assign one new container ID for each vessel using either the Print module or the Shipping module. Print additional labels as needed. Each stand is allocated a maximum of 999 labels. The actual container label will include the vessel name, vessel ID, the size of the container (9 x 9 x 2-inch box, etc.), and the container number.

Chlam/GC (46)
5x5 3 inch box



410529

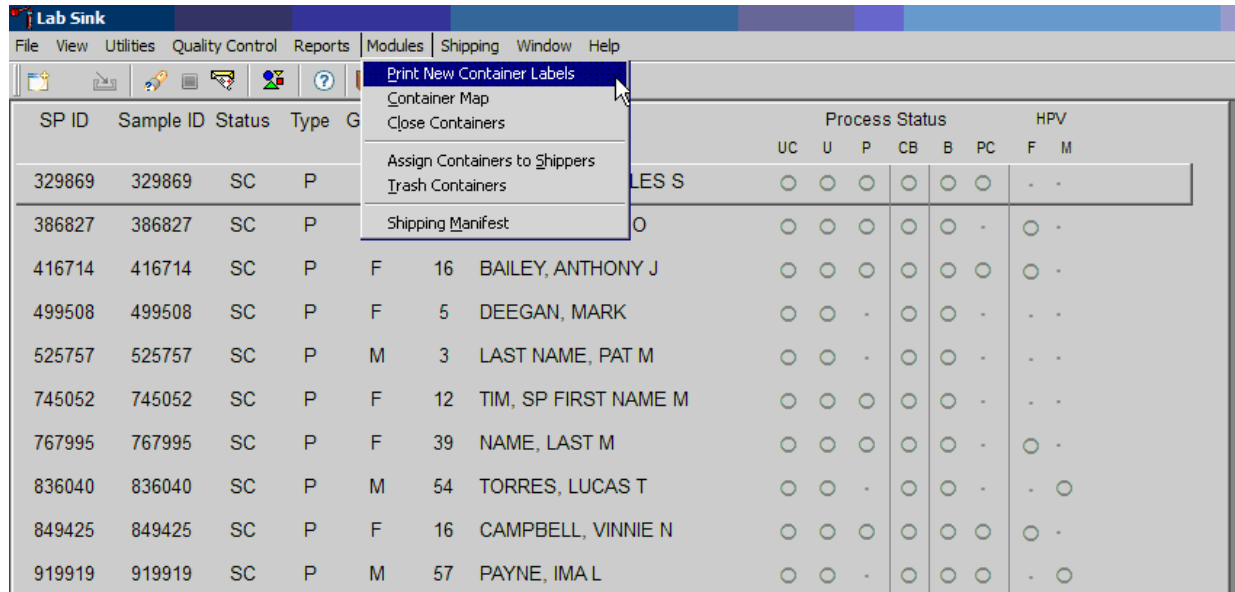
Prior Pest (48)
5x5 3 inch box



410530

Use the Shipping module within the laboratory application to print and assign new container ID numbers or labels. To see how to access the Shipping module see Exhibit 8-14 below.

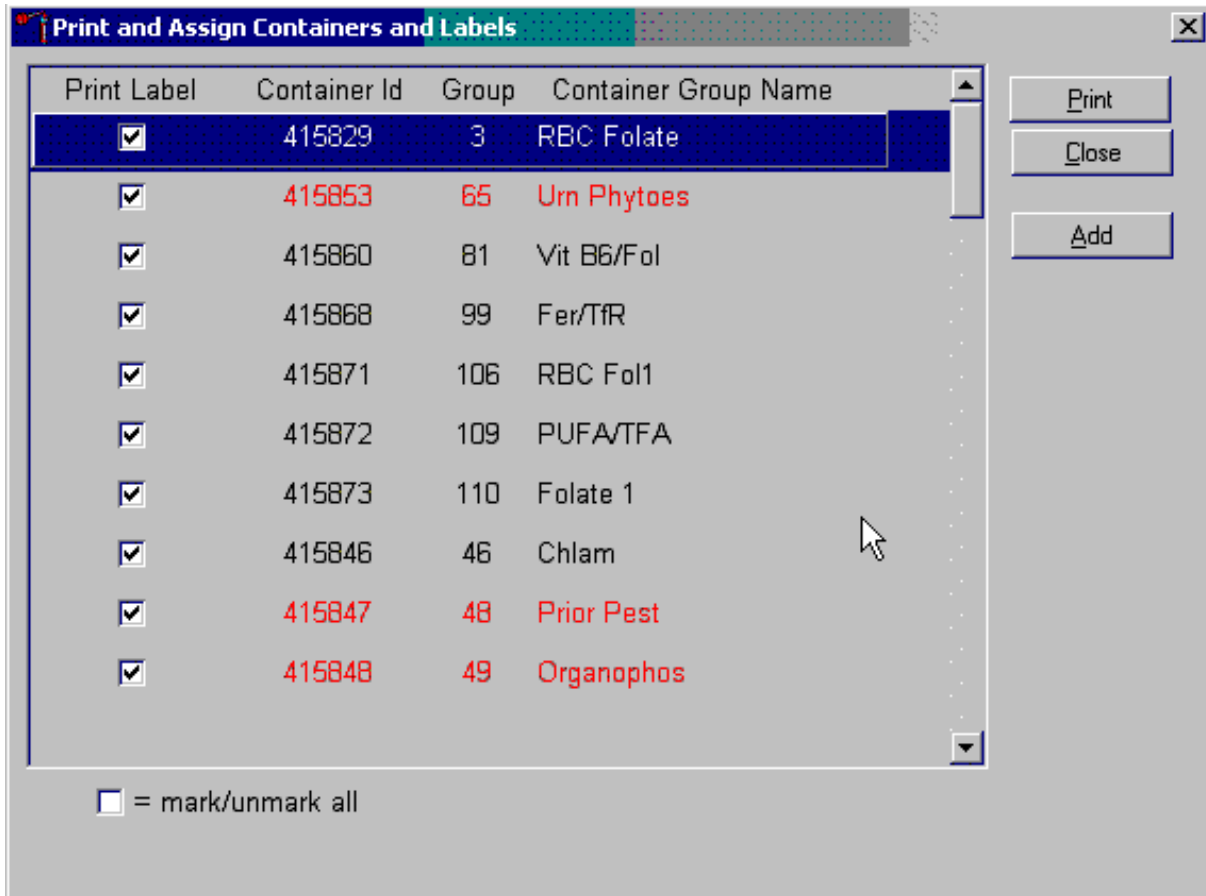
Exhibit 8-14. Shipping module menu



To access the Print New Container Labels module, direct the mouse arrow to Shipping in the menu bar and left-click. Drag the mouse arrow to Print New Container Labels, and left-click. An example of this module can be seen in Exhibit 8-15.

There are three instances when it is appropriate to use this module. At the start of each stand, create one new container label for each vessel ID or “group.” Use the same module to create a new label for a vessel after the last slot in an open container is filled. Use this module to print additional labels at any time.

Exhibit 8-15. Print new container labels module



The Print and Assign Containers and Labels window displays once the “Print New Container” module is accessed. The window includes check boxes to mark or identify specific groups, new container IDs that are assigned to the Groups, the number of the Group, and the Container Group Name or vessel name. The Group and corresponding Container Group Name listed in this screen represent the Group where the container has been “closed” and a new label has not been created. This screen also includes a “mark/unmark all” check box and three buttons: Print, Close, and Add. Use the Print button to print the container labels, use the Close button to exit the module without printing any labels or assigning container IDs to the Groups, and use the Add button to open another window that allows the user to add additional or multiple labels for any vessel. The information for the containers that do not close weekly is displayed in red.

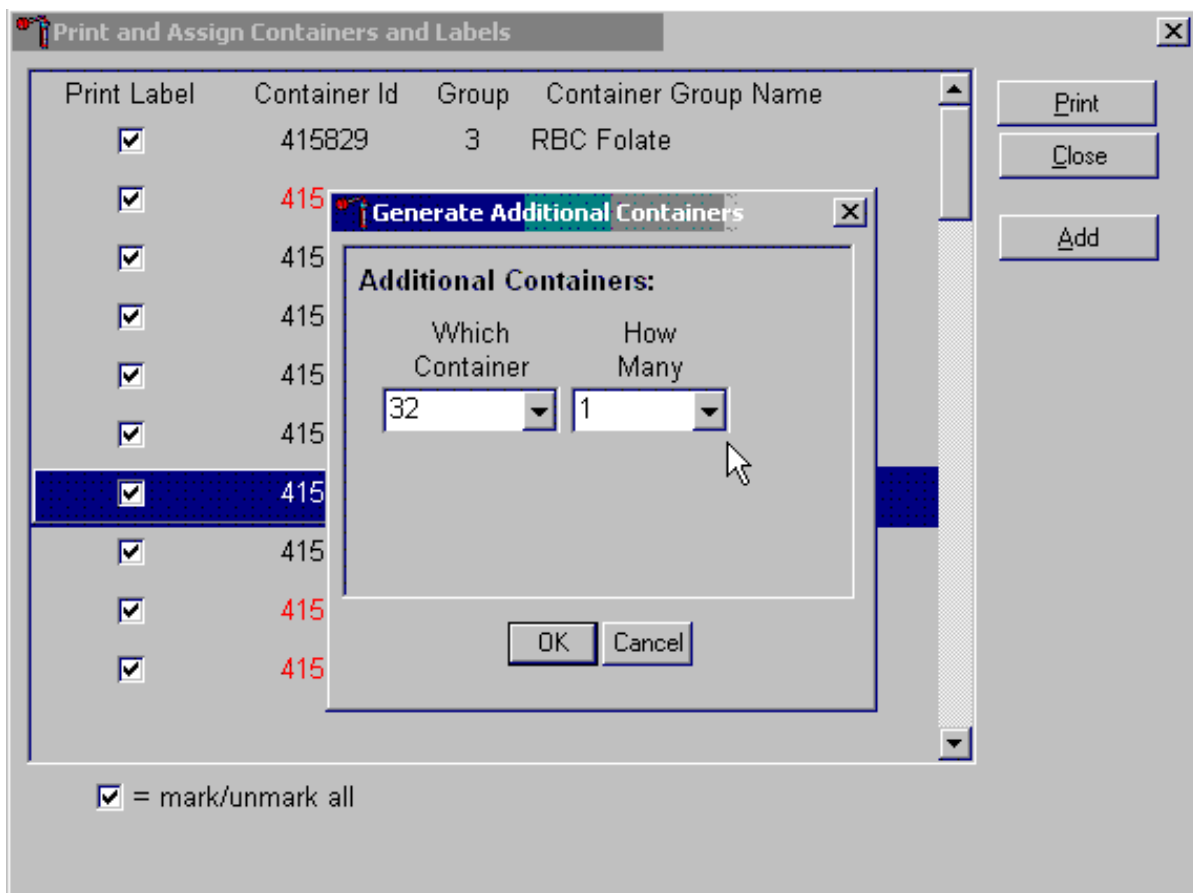
Individually mark the Print Label check box to identify vessels that require labels.

To begin the process of printing and assigning new container IDs, mark the individual check boxes that correspond to the Group (vessel) of interest. To add a checkmark to the Print Label check box, direct the mouse arrow to the Print Label check box and left-click.

To collectively mark all the check boxes, direct the mouse arrow to the mark/unmark all check box and left-click. To collectively unmark all the check boxes, direct the mouse arrow to the mark/unmark all check boxes and left-click.

Access the Generate Additional Containers window to print additional labels for any Group at any time. See Exhibit 8-16 for an example.

Exhibit 8-16. Generate additional containers

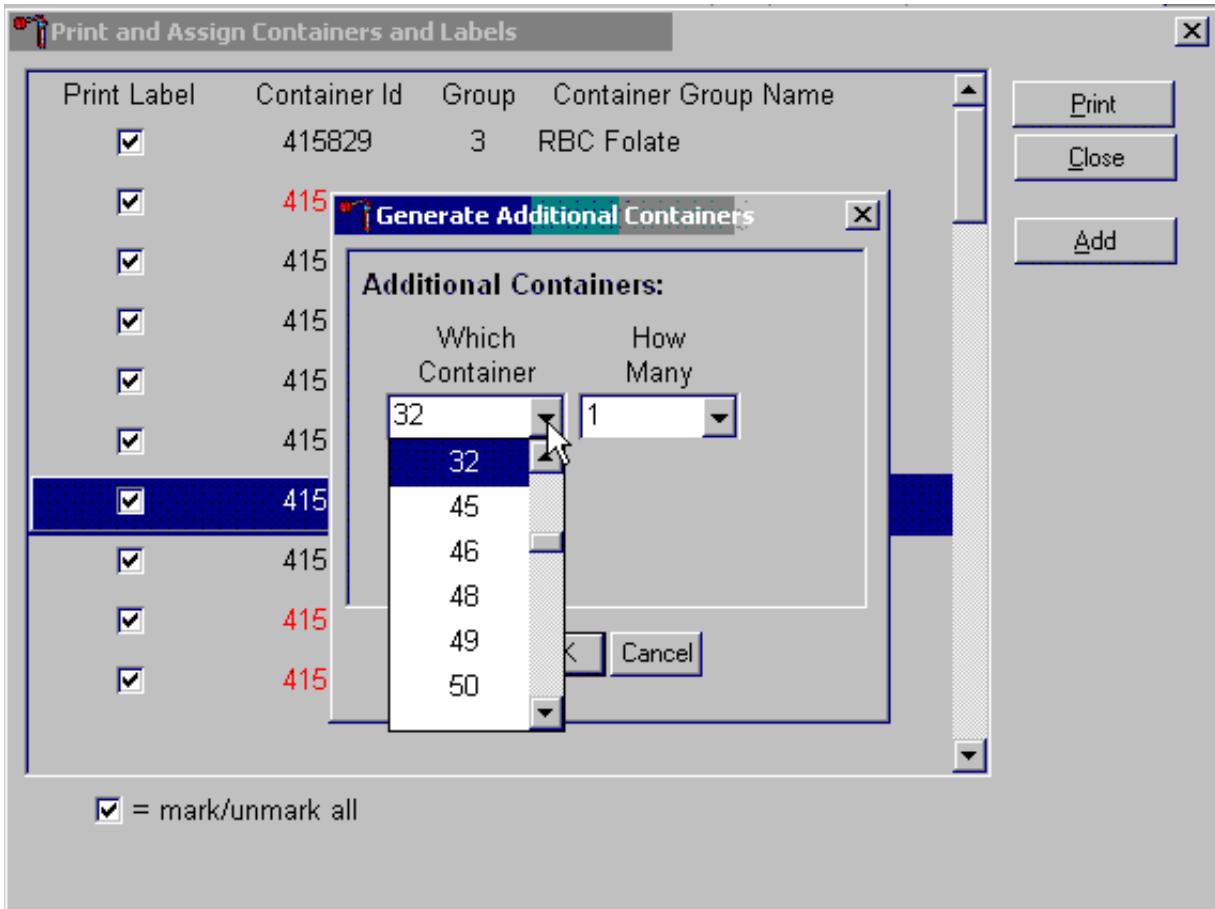


To access the Generate Additional Containers window, direct the mouse arrow to the Add button and left-click.

The Generate Additional Containers window displays.

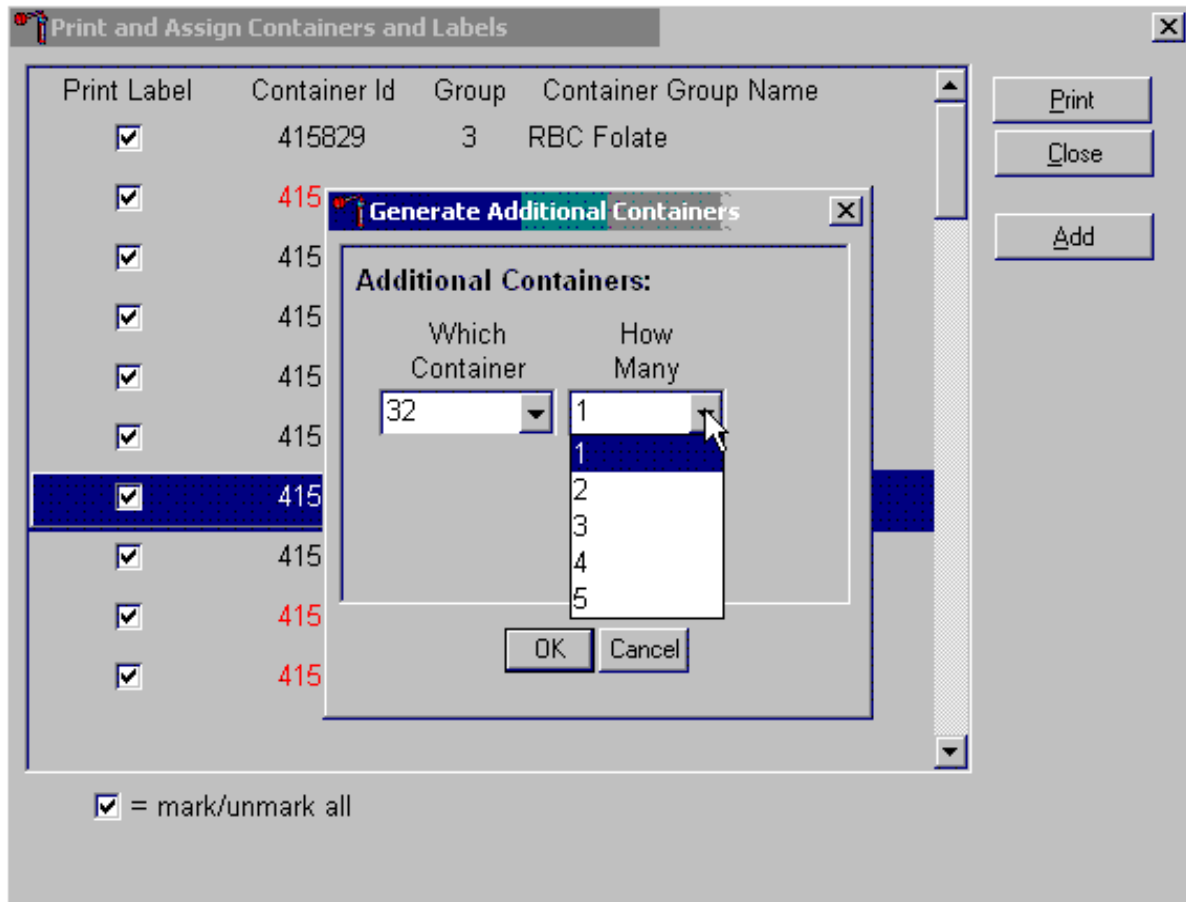
The Generate Additional Containers window includes two text boxes with drop-down lists: “Which Container” and “How Many.” The “Which Container” text box defaults to vessel 32. To select a vessel other than 32, direct the mouse arrow to the drop-down arrow and left-click, drag the arrow to the desired choice and left-click. Use the scroll bar to view all the choices. Exhibit 8-17 displays the appearance of the container drop down.

Exhibit 8-17. Add container drop down



The “How Many” text box defaults to vessel 1. To select 2, 3, 4, or 5, direct the mouse arrow to the drop-down arrow and left-click, then drag the arrow to the desired choice and left-click. Use the scroll bar to view all the choices. See Exhibit 8-18 for an example.

Exhibit 8-18. Number of containers drop down



Add these vessels to the Print and Assign Containers and Labels window or cancel the action.

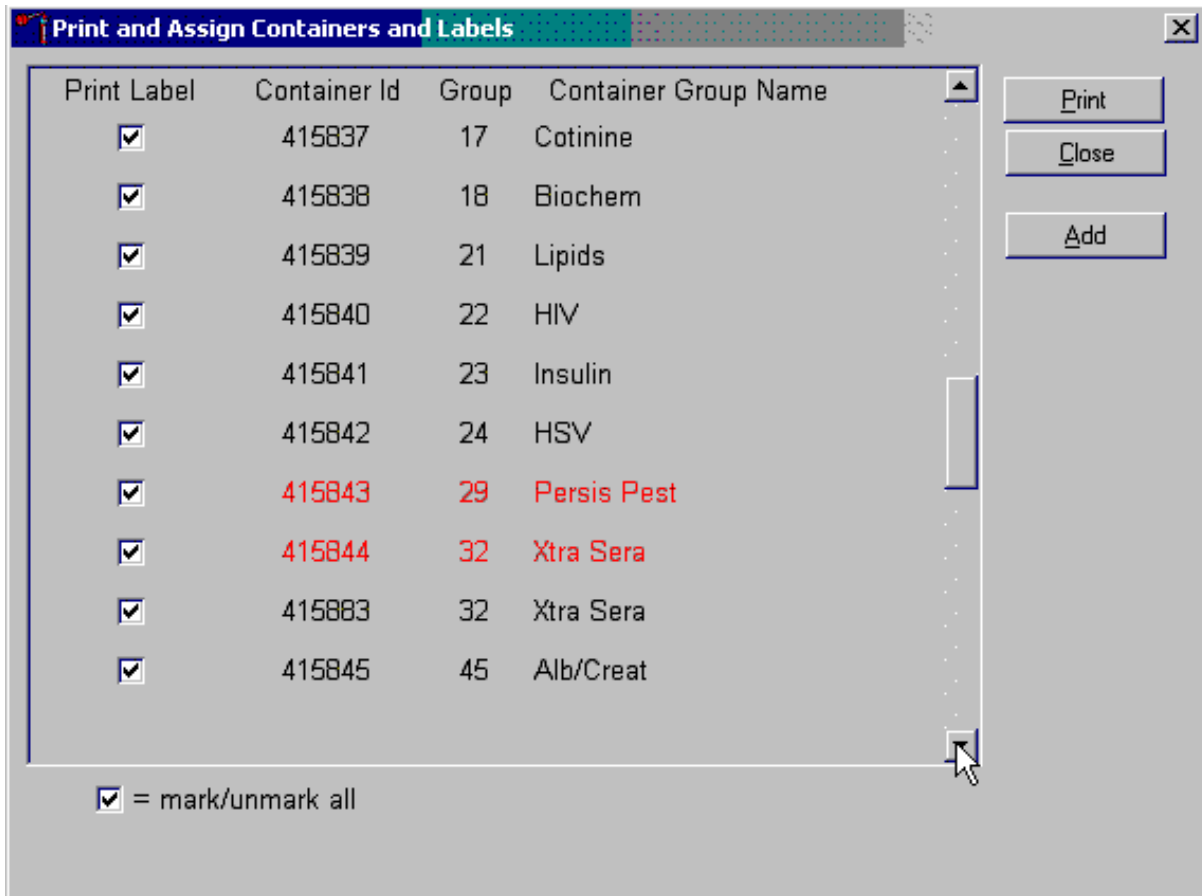
To accept the choices displayed in the Generate Additional Containers window, direct the mouse arrow to the OK button and left-click or type [Enter]. To close the window without creating a new container, direct the mouse arrow to the Cancel button and left-click.

If the OK button is selected, the containers are added to the Print and Assign Containers and Labels window.

Review the information on the screen (Exhibit 8-19).

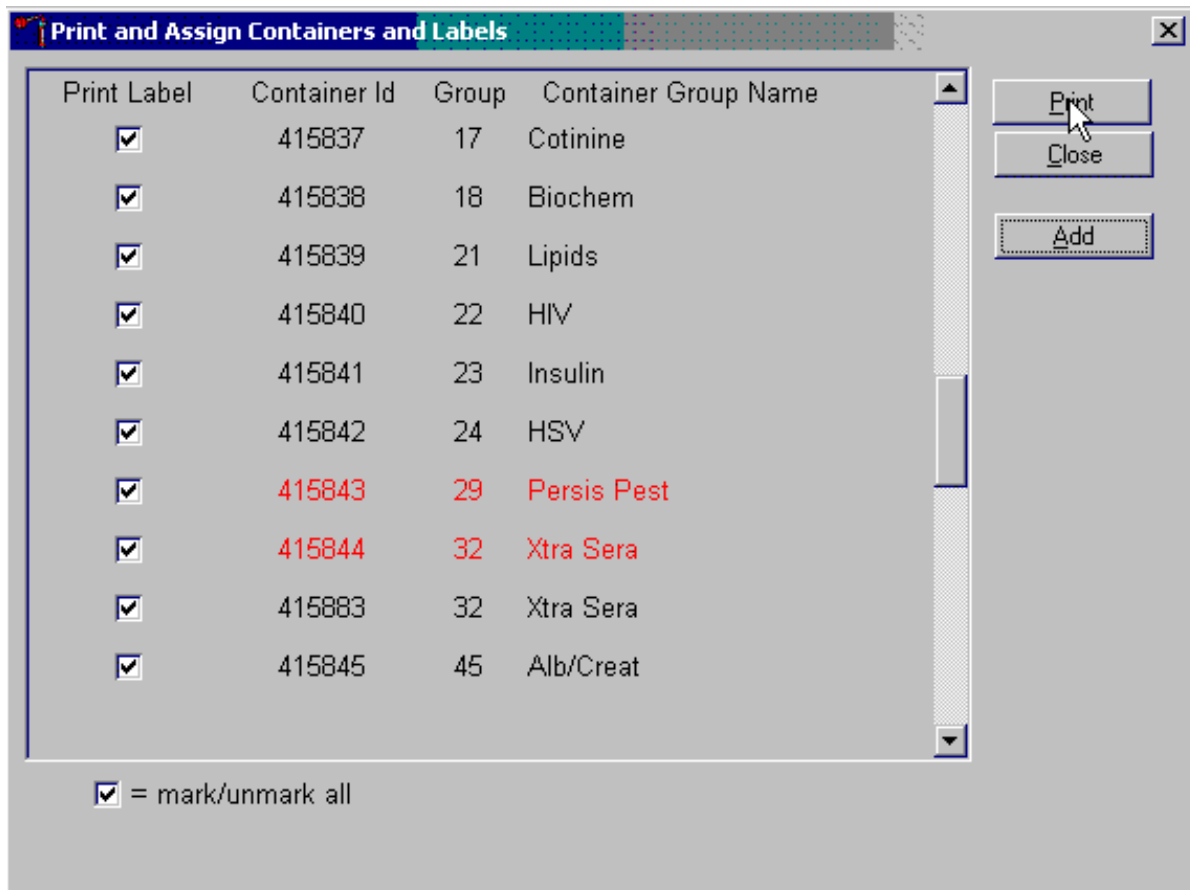
Complete the assignment process and print the labels.

Exhibit 8-19. Print and assign labels



After reviewing the screen, print the labels. To print the labels, direct the mouse arrow to the Print button (Exhibit 8-20) and left-click. To exit the window without printing any labels, direct the mouse arrow to the Close button and left-click. Affix the container ID label(s) to the appropriate container(s).

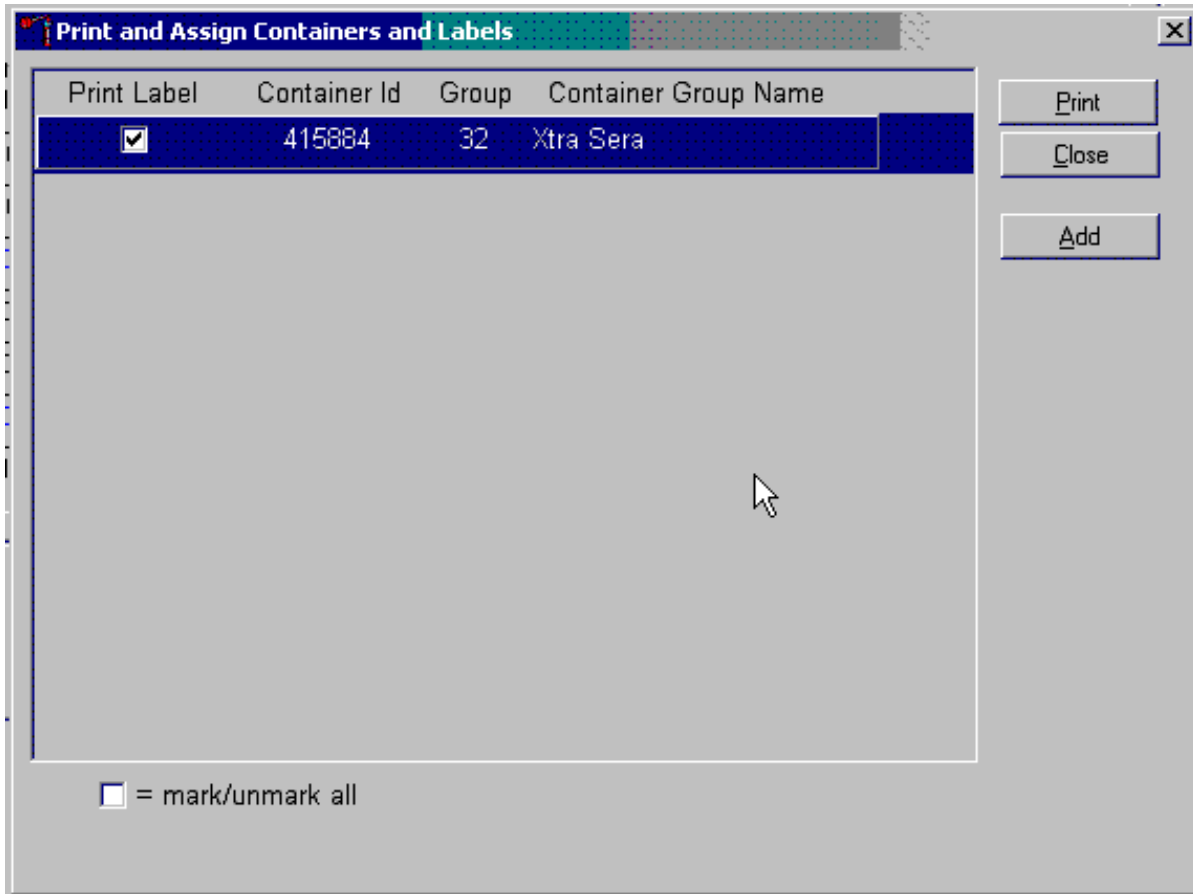
Exhibit 8-20. Print labels



If the Close button is selected before the labels have been printed, a Print and Assign Containers and Labels window displays. See Exhibit 8-21.

When a container is full, an opportunity to open a new container is automatically displayed on the Print and Assign Container and Labels window (Exhibit 8-22). Repeat the process of marking the check box and selecting the Print button.

Exhibit 8-22. Print labels – Full container



8.5 Close Containers

Use the shipping module with the laboratory application to close containers (Exhibit 8-23).

Exhibit 8-23. Close containers navigation

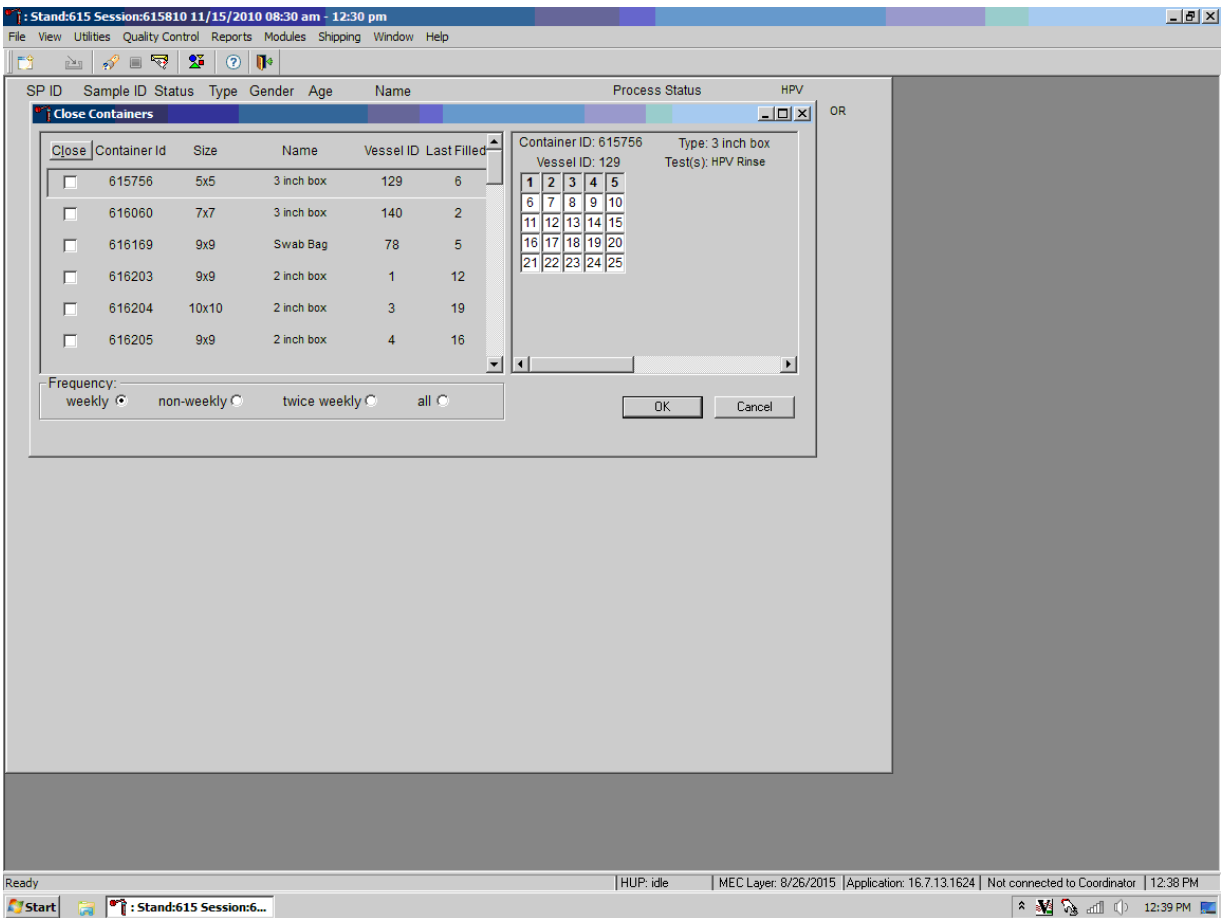
The screenshot shows the 'Lab Sink' application window with the 'Shipping' menu open. The 'Close Containers' option is highlighted. Below the menu is a table with columns for 'SP ID', 'Sample ID', 'Status', 'Type', 'Gender', and 'A'. To the right of the table is a 'Process Status' section with columns for 'UC', 'U', 'P', 'CB', 'B', 'PC', 'F', and 'M'. The 'HPV' section has columns for 'F' and 'M'. The table contains several rows of data, including sample IDs and names like 'BAILEY, ANTHONY J', 'DEEGAN, MARK', 'LAST NAME, PAT M', 'TIM, SP FIRST NAME M', 'NAME, LAST M', 'TORRES, LUCAS T', 'CAMPBELL, VINNIE N', and 'PAYNE, IMA L'.

SP ID	Sample ID	Status	Type	Gender	A	Process Status						HPV	
						UC	U	P	CB	B	PC	F	M
329869	329869	SC	P	F		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC	P	F		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	
416714	416714	SC	P	F	10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
499508	499508	SC	P	F	5	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
525757	525757	SC	P	M	3	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
745052	745052	SC	P	F	12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-
767995	767995	SC	P	F	39	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	-
836040	836040	SC	P	M	54	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	<input type="radio"/>
849425	849425	SC	P	F	16	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
919919	919919	SC	P	M	57	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>

To access the {Close Containers} module, direct the mouse arrow to {Shipping} in the menu bar and left-click. Drag the mouse arrow to {Close Containers} and left-click.

This module, shown in Exhibit 8-24, will be used every time the lab ships out any specimens to the testing labs. Close containers once all the specimens have been processed in the lab for the last session before performing shipping. The application defaults to weekly, as the frequency of shipped samples.

Exhibit 8-24. Close containers module



The non-weekly shipping frequency functions show the containers that are shipped when full or at the end of the stand. See Exhibit 8-25 for an example.

Exhibit 8-25. Non-weekly shipping

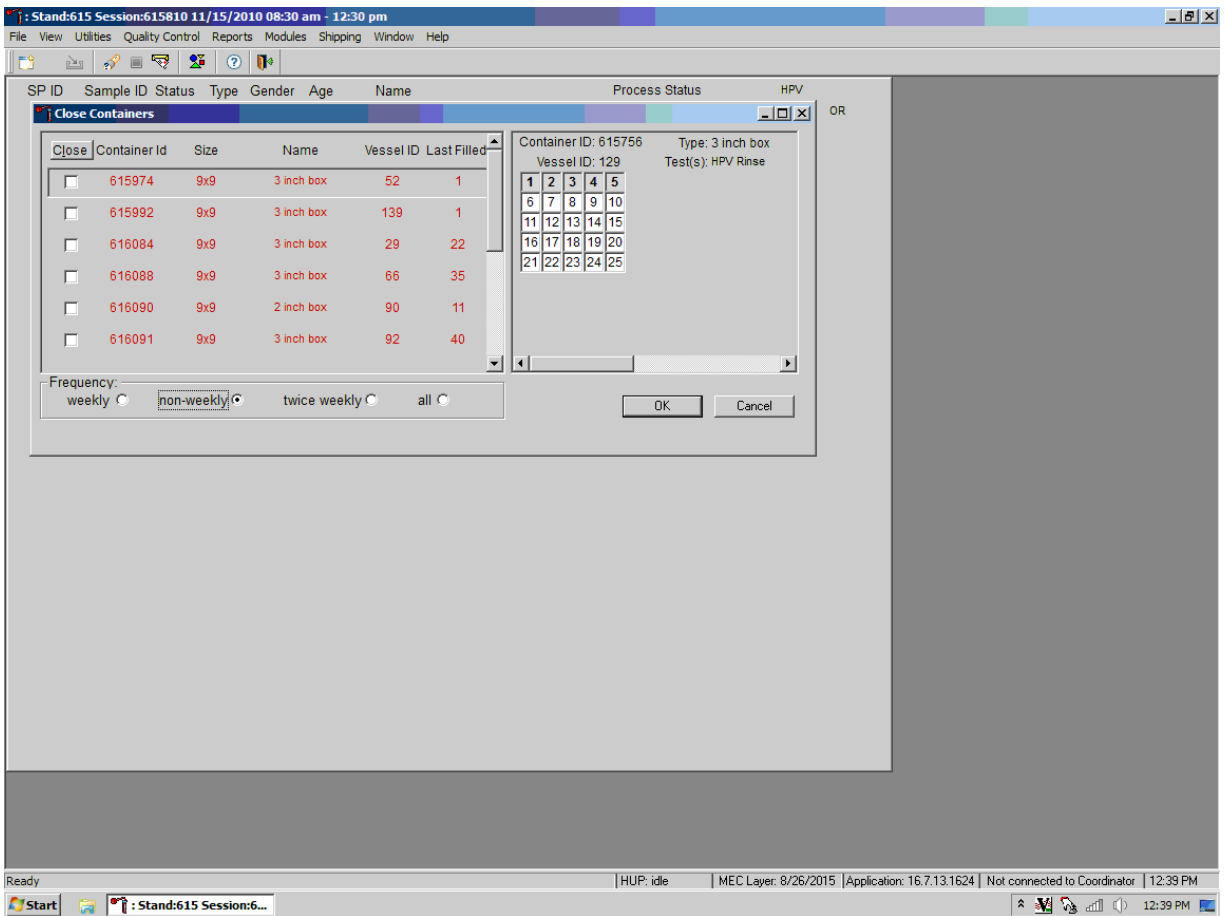
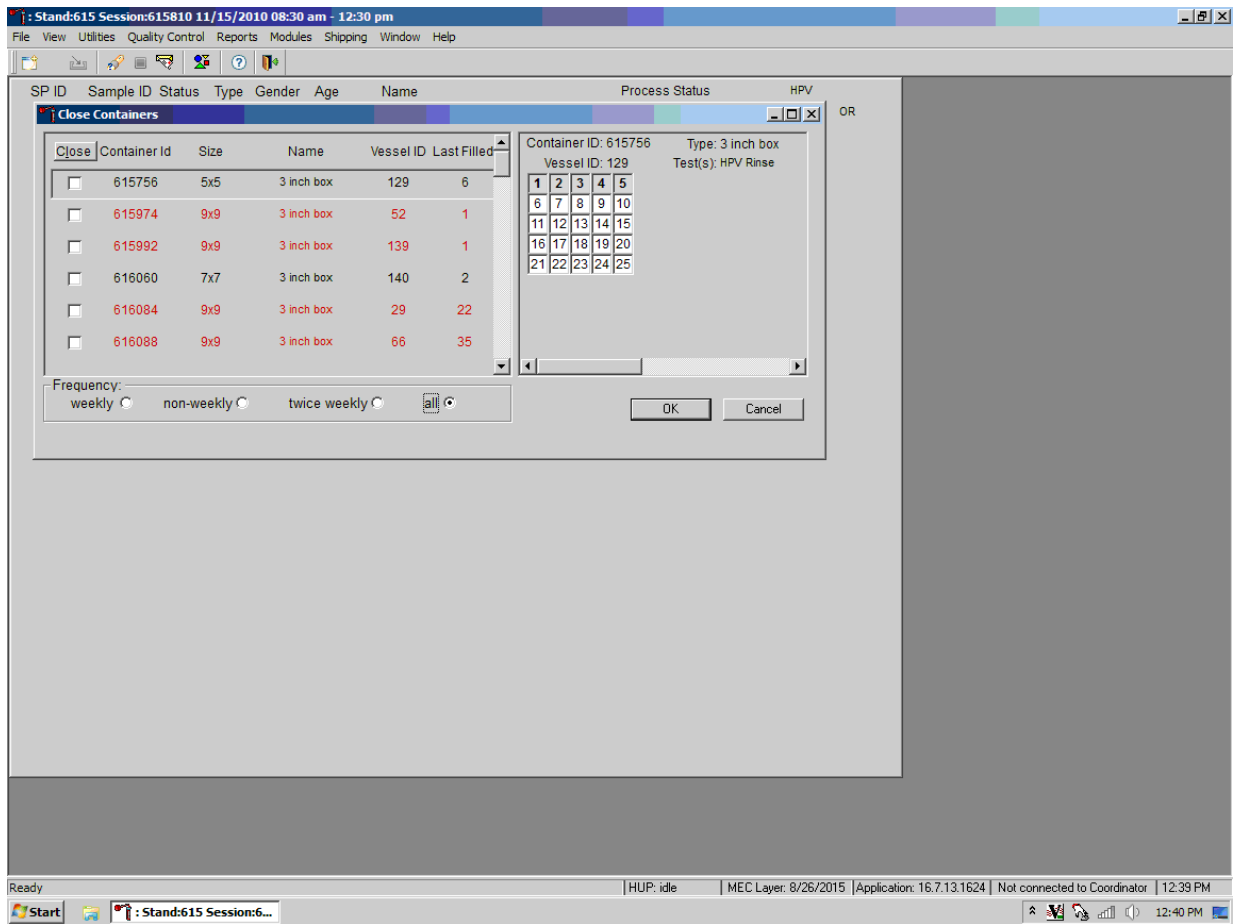


Exhibit 8-26 shows the section of the module used to close all containers. Use this function at the end of the stand. Select “All” to close all the containers to be shipped.

If any containers are closed in error, contact the ISIS team immediately to correct the error. This is especially crucial when performing End of Stand activities.

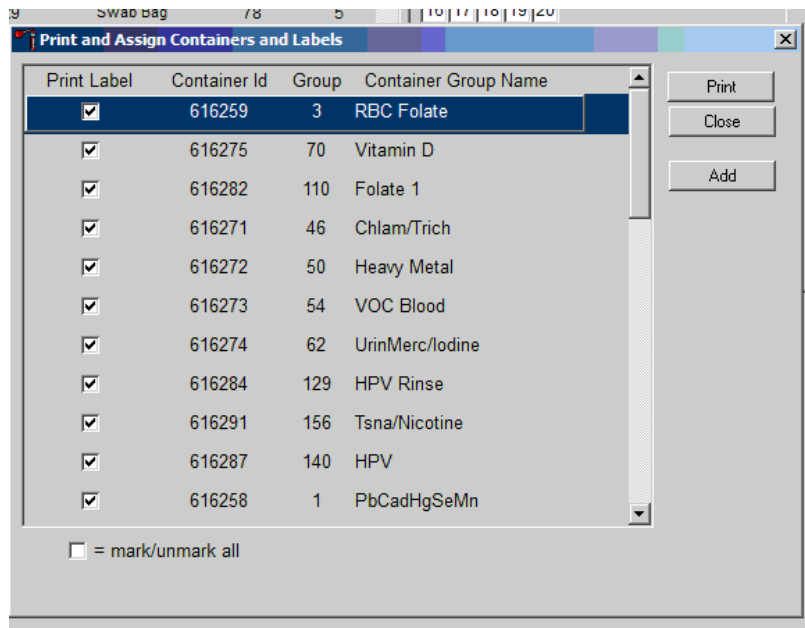
Exhibit 8-26. Close all containers



To close the containers, place a checkmark in the “Close” column, which will close the containers in the system so no more samples can be added to those containers.

After the containers are closed, a list will be displayed (Exhibit 8-27) of the containers that need labels printed before any specimens can be put into the new containers.

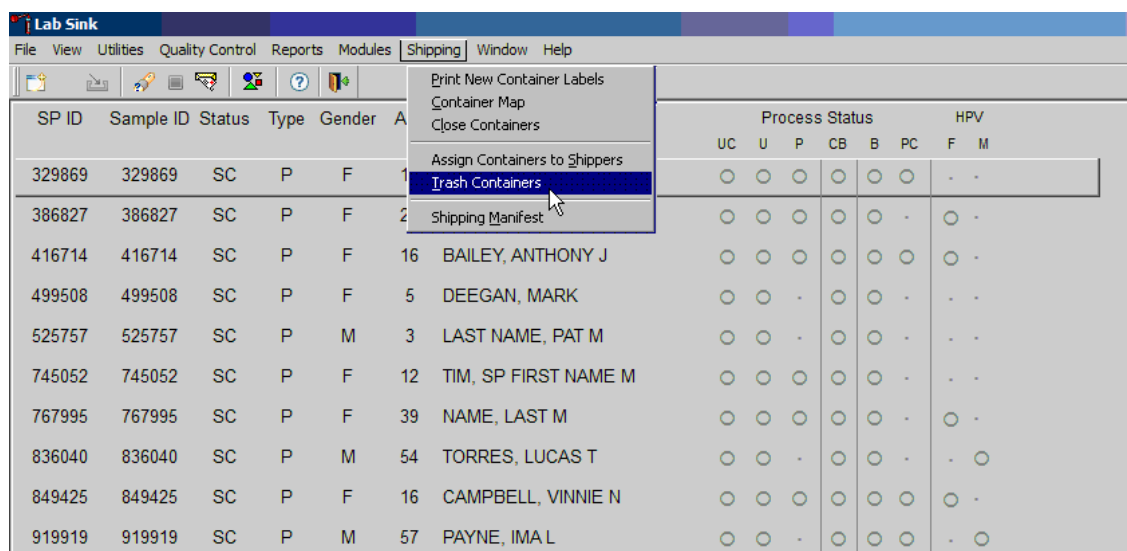
Exhibit 8-27. Print labels for closed containers



8.6 Trash or Reprint Container Labels

If unused container labels become lost or damaged, use the “Trash Containers” module (Exhibit 8-28) to delete the container IDs.

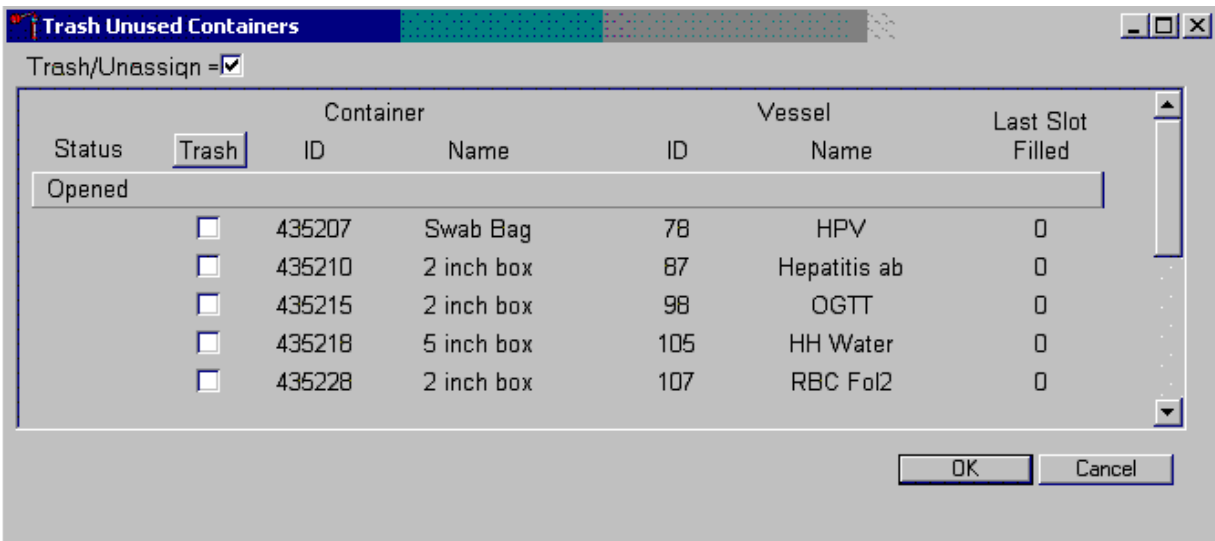
Exhibit 8-28. Trash containers



To access the “Trash Containers” module, direct the mouse arrow to “Shipping,” left-click, drag the arrow to “Trash Containers,” and left-click.

The Trash Unused Containers window displays as shown in Exhibit 8-29.

Exhibit 8-29. Trash containers module



The status of each container ID is “Opened.” To individually mark the container IDs for deletion, direct the mouse arrow to the check boxes and individually left-click on specific boxes. To collectively mark ALL containers, direct the mouse arrow to the Trash header and left-click.

As the container IDs are marked for deletion, the status changes from “Opened” to “Trashed.”

To record these actions and execute the Trash Unused Containers function, direct the mouse arrow to the OK button and left-click, or select Enter. To exit the Trash Unused Containers module without recording or executing the Trash Containers function, direct the mouse arrow to the Cancel button and left-click.

8.6.1 Reprint Container Labels for Existing Containers

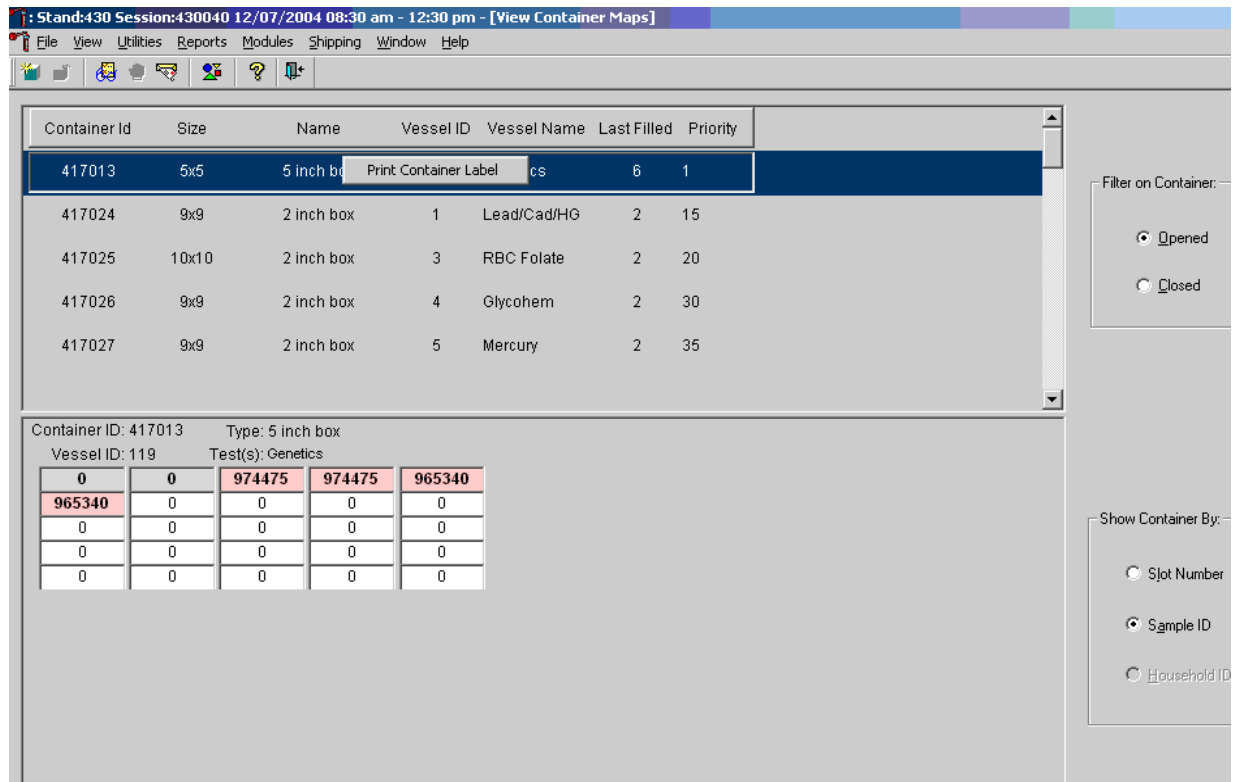
Reprint labels for existing, not shipped containers.

Reprinting Container Labels from the Container Map Screen

Right-click on the container ID you wish to reprint, select “Print Container Label.”

See Exhibit 8-30. The label will print to the associated Dymo printer.

Exhibit 8-30. Print container label



Container ID	Size	Name	Vessel ID	Vessel Name	Last Filled	Priority
417013	5x5	5 inch box	Print Container Label	cs	6	1
417024	9x9	2 inch box	1	Lead/Cad/HG	2	15
417025	10x10	2 inch box	3	RBC Folate	2	20
417026	9x9	2 inch box	4	Glycohem	2	30
417027	9x9	2 inch box	5	Mercury	2	35

Container ID: 417013		Type: 5 inch box		
Vessel ID: 119		Test(s): Genetics		
0	0	974475	974475	965340
965340	0	0	0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0

8.7 Shipping Overview

The integrity of laboratory specimens is critical to NHANES. Storage temperatures have been established for each analyte in consultation with the National Center for Health Statistics (NCHS) and contract laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient dry ice, refrigerant packs, and sending specimens by FedEx priority overnight.

FedEx priority overnight guarantees next-business-day delivery by 10:30 am to most U.S. addresses, and by noon, 4:30 pm, or 5 pm in remote areas. Delivery by FedEx can be delayed due to a weekend or holiday. This circumstance usually occurs at the end of a stand or just before vacation. Ship all specimens before vacations. The following actions are intended to mitigate foreseeable delays:

- Consider adding extra dry ice.

- 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.

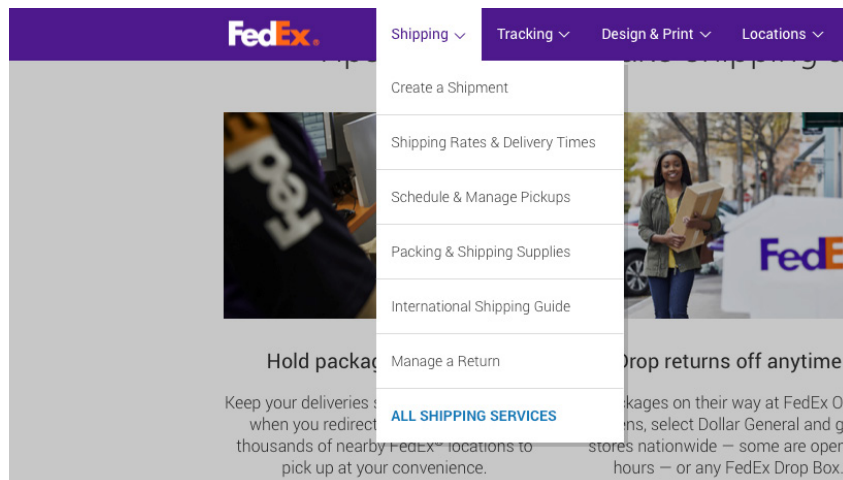
The shipping clinical laboratory scientist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other clinical laboratory scientists assist in performing each of the steps listed below to complete the shipping procedures.

Prior to the next stand, the laboratory staff creates address labels with the next stand’s MEC address to use on the Class 9 labels. Place the next stand’s MEC address label in the upper-left corner of the Class 9 label and place the appropriate Lab label in the upper-right corner of the Class 9 label. Enter the appropriate dry ice weight in kilograms (kg) in the blank space next to kg. If needed, trim both labels to fit in the space so they don’t cover up any information. Prepare Class 9 labels with the MEC address and Lab address for each shipping week.

Shipping Procedures

- Create airbill return packets.
- Create airbills before designated shipping day.
 - Select the FedEx icon on the WS1 desktop.
 - Select “Create Shipment” from the “Shipping” drop-down menu as shown in Exhibit 8-31.

Exhibit 8-31. FedEx create shipment



- Enter the username (standXXX where XXX is the current stand number).
- Enter the password (NhanesXXXXY where XXX is the current stand number and Y is a unique character).
- From the drop-down menu in the shipping screen (Exhibit 8-32), select the first lab that will receive samples from the current shipment. The laboratory information will autopopulate.

Exhibit 8-32. FedEx lab addresses

The screenshot shows the FedEx shipping interface. At the top, there are navigation links for 'Shipping' and 'Tracking'. Below that, a note states '* Denotes required field.' The main section is titled 'My Shipment Profiles' and includes a 'Select' dropdown for 'My shipment profiles (formerly Fast Ship)' and a 'Ship' button. Below this, the '1. From' section is populated with the address: 'Sean Chickery, Westat RA1106, 1600 Research Blvd., Rockville, Maryland, 20850, United States'. The '2. To' section has a 'Country/Territory' dropdown set to 'United States' and a 'Company' dropdown set to 'Select or enter'. The 'Contact name' dropdown is open, showing a list of laboratory names: 'Ship to group', 'ATCC Bioprocessing Lab', 'ATCC Bioprocessing Laboratory', 'Augusta University', 'CBR', 'CDC-NCEH', 'CDC/VRD HPV', 'CDCHuman Papillomavirus Labor', 'CDCNCEH Air Toxicant Branch', 'CDCNCEH Environmental Health', 'CDCNCEH Environmental Health', 'CDCNCEH Molecular Biology Bra', 'CDCNCEH Pesticide Laboratory', 'CDCNCEH Tobacco & Volatile Brs', and 'CDCNCEHTobacco & Volatile Brs'. There are also checkboxes for 'Perform detailed address check' and 'This is a residential address'.

- Enter the correct shipping date in the appropriate field.
- Enter the total weight in pounds in the appropriate field, based on whether the shipper is a refrigerated or frozen shipment.
- In the Special Services section of the shipping screen, select “Dry Ice” if the shipment is a frozen shipment, and enter the weight in pounds in the appropriate field.
- In the “Pick-up/Drop-off section,” select “Drop off at FedEx location.”
- In the “Signature Type” section, select “Direct Signature Required” (this is not necessary for shipment to the warehouse).
- In the Shipment Notifications section, make sure the Notification Sender via Email (HTML) is marked with seanchickery@westat.com as the email address. Additionally, make sure the Recipient email is populated with an email address.

- After double-checking your entries, select “Ship” in the bottom right corner of the shipping screen.
 1. Only click the button once even though there may be a delay in processing.
- The Shipping Manifest will be generated in another screen that will automatically display.
- Select the Print button (make sure labels have been inserted in the tray of the printer before printing manifest).
- Place the labels with the other paperwork for that package.
- Repeat the process for the remaining airbills.
- Retrieve Class 9, Keep Frozen, and refrigerated labels.
- Close containers and print new container labels when session prior to shipping is complete.
- Print shipping manifest and place in the airbill return packet.
- 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 specified in the protocols.

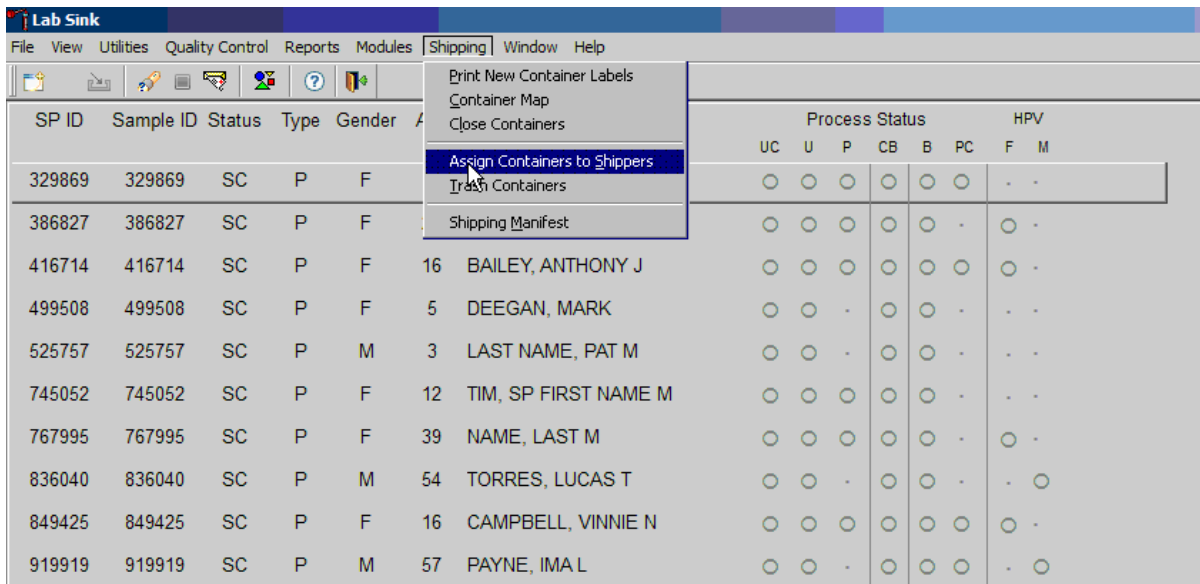
Place the appropriate paper manifest into the preprinted FedEx return airbill packet and place the plastic bag on top of the Styrofoam shipper lid.

- Label each shipper with the appropriate FedEx label and shipping labels.
- Call Fedex for pickup.
- When the contract laboratory personnel receive the shippers, they unpack the specimens and return the shippers and refrigerant packs to the warehouse.

8.8 Assign Containers to Shippers

Assign closed containers to a specific airbill. To assign a specific closed container to the airbill for that laboratory, use the Assign Container to Shippers module. For navigation to this module see Exhibit 8-33.

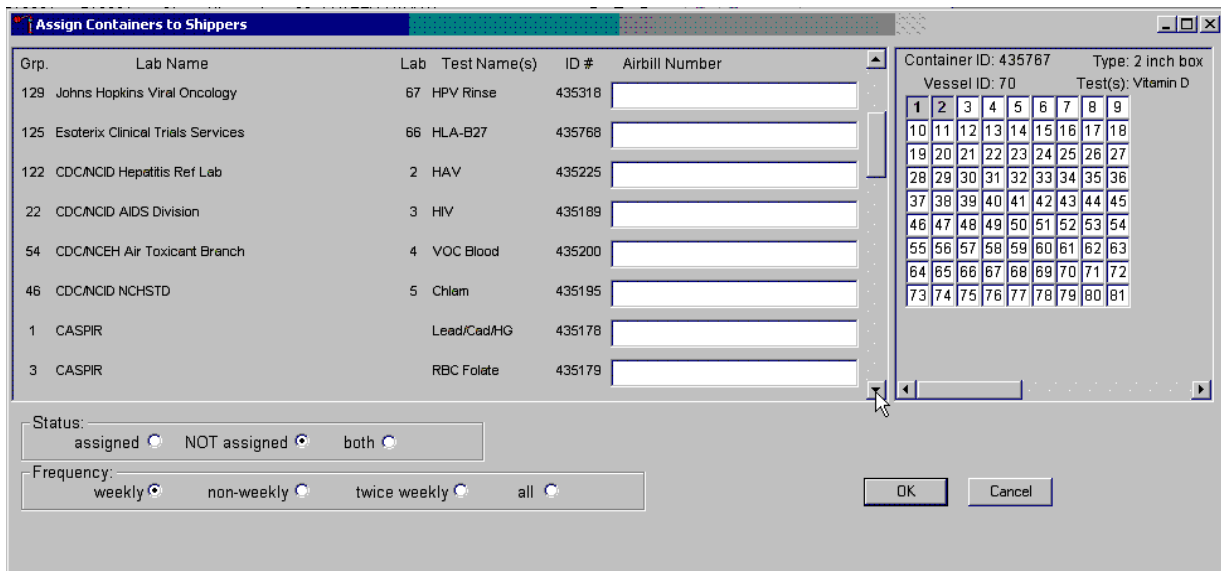
Exhibit 8-33. Assign containers to shippers (1)



To access the Assign Containers to Shippers module, direct the mouse arrow to Shipping in the top menu bar, left-click, drag the mouse arrow to Assign Container to Shippers, and left-click.

The Assign Containers to Shippers window displays (Exhibit 8-34).

Exhibit 8-34. Assign containers to shippers (2)



This left side of the screen includes columns for a group designation (which represents a Vessel ID), Lab designation, Test Name(s), Container ID number, and Airbill number. 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 left side of the bottom of the window contains three “Status” filters (radio buttons): “assigned,” “NOT assigned,” and “both.” The second line on the left side of the bottom of the window contains four “Frequency” filters (radio buttons): “weekly,” “non-weekly,” “twice weekly,” and “all.” To sort the rows, direct the mouse arrow to the desired column title and left-click. The window updates based on the selection.

Enter an airbill number into each Airbill Number text box. Ensure the cursor is in the left side of the text box. Exhibit 8-35 shows an example of the screen where this is accomplished. There are three ways to enter the airbill number:

- Use the barcode gun to scan the barcode from the FedEx Ship Manager airbill. The barcode is located in the bottom of the top half of the folded airbill. It is the tallest on the airbill. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the barcode. Once the gun successfully scans the barcode, an audible beep is emitted.
- Use the barcode gun to scan the barcode on the second page (Recipient’s Copy) of the two-part Form ID 0215. This barcode is located on the lower left side toward the bottom of the form. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the barcode. Once the gun successfully scans the barcode, an audible beep is emitted.
- Use the keyboard keys to type the airbill number from either the FedEx Ship Manager airbill or the FedEx airbill Form ID 0215.

To assign a container to the corresponding airbill:

- Set the Status filter to: “NOT assigned”; and
- Set the Frequency to: weekly, non-weekly, or both, depending on the shipping situation.

Set the Status and Frequency filters.

Exhibit 8-35. Assign containers to shippers (3)

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
129	Johns Hopkins Viral Oncology	67	HPV Rinse	435318	
125	Esoterix Clinical Trials Services	66	HLA-B27	435768	
122	CDC/NCID Hepatitis Ref Lab	2	HAV	435225	
22	CDC/NCID AIDS Division	3	HIV	435189	
54	CDC/NCEH Air Toxicant Branch	4	VOC Blood	435200	
46	CDC/NCID NCHSTD	5	Chlam	435195	
1	CASPIR		Lead/Cad/HG	435178	
3	CASPIR		RBC Folate	435179	

Status: assigned NOT assigned both

Frequency: weekly non-weekly twice weekly all

Container ID: 435787 Type: 2 inch box
Vessel ID: 70 Test(s): Vitamin D

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

OK Cancel

To select the Status filter, direct the mouse arrow to the “assigned,” “NOT assigned,” or “both,” radio button and left-click. To select the shipping frequency, direct the mouse arrow to weekly, non-weekly, twice weekly, or all, and left-click.

To sort the rows by lab name, direct the mouse arrow to the top header “Lab Name,” and left-click. All containers associated with a specific lab will be grouped together in ascending order.

Click on the left side of the airbill number to activate the cursor. Enter the airbill number into the Airbill Number text box (Exhibit 8-36).

Exhibit 8-36. Populate airbill number

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
70	CASPIR	Vitamin D	Vitamin D	435767	79564329876587466789098767656787
126	CASPIR	PAH HB		435769	
1	CASPIR	Lead/Cad/Hg		435178	
3	CASPIR	RBC Folate		435179	
106	CASPIR	RBC Folt		435219	
5	CASPIR	Mercury		435181	
109	CASPIR	PUFA/TFA		435220	
88	CASPIR	Acrylamide		435211	

Container ID: 435767 Type: 2 inch box
Vessel ID: 70 Test(s): Vitamin D

1	2	3	4	5	6	7	8	9
10	11	12	13	14	15	16	17	18
19	20	21	22	23	24	25	26	27
28	29	30	31	32	33	34	35	36
37	38	39	40	41	42	43	44	45
46	47	48	49	50	51	52	53	54
55	56	57	58	59	60	61	62	63
64	65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80	81

Status: assigned NOT assigned both

Frequency: weekly non-weekly twice weekly all

OK Cancel

Use the barcode gun to scan the airbill number. The scanned number contains 20 extra digits. The actual 12-digit airbill number is embedded in the 32-digit scanned number. Select the Tab key to move to the next text box. Do not select the Tab key until the application has been allowed to enter the entire number into the text box. Once the Tab key is selected, the program edits the first airbill number to delete the extra numbers.

Continue scanning the barcodes and selecting the Tab key until all closed containers are assigned to airbills.

Complete the assignment process.

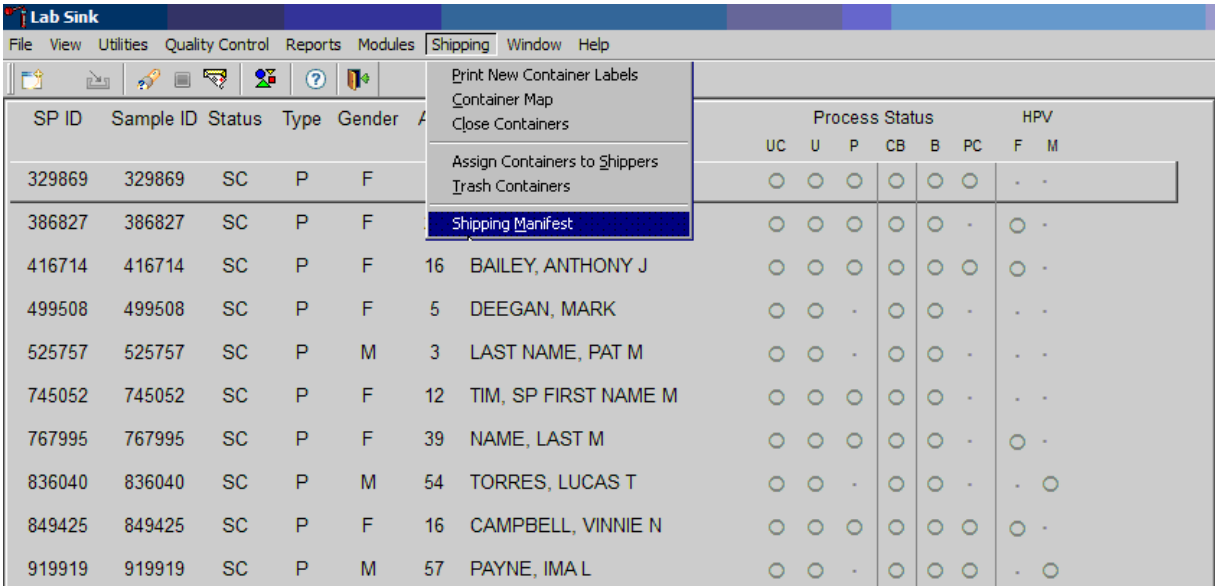
To record the assignment of containers to shippers, direct the mouse arrow to the OK button and left-click. **This step is required to save the information.** To exit the Assign Containers to Shippers module without recording any assignments, direct the mouse arrow to the Cancel button and left-click.

8.9 Create Shipping Manifests

Each shipper must include a paper manifest, which lists the inventory of the specimens in the shipping boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed below to prepare the paper manifest and send the electronic file.

Access the Shipping Manifest module as shown in Exhibit 8-37.

Exhibit 8-37. Shipping manifest navigation



To access the Shipping Manifest module, direct the mouse arrow to Shipping in the top menu bar, left-click, drag the mouse arrow to Shipping Manifest, and left-click.

A Shipping Manifest window displays either after the Shipping Manifest module is accessed or after a positive response is recorded to the IC Informed Consent Exclusion window as shown in Exhibit 8-38.

Exhibit 8-38. Shipping manifest report

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input type="checkbox"/>	796170388796	12/11/2008	CDC/NCID AIDS Division (3)

= mark/unmark all

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Health and Nutrition Examination Survey

Shipping Manifest Report

Shipment ID: 796170388765 Survey Year: 2007
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab Lab ID: 2
Address: 1600 Clifton Road Contact: Annemarie Wasley
Bldg 18 Floor 3 Rm 218 MS A33 Phone: (404)639-3103
Atlanta, GA 30329 E-Mail:

Container Id	Size	Type	Test(s)	Hep Profile
435185	9x9	2 inch box		Hep Profile

Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKWVS	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

The upper portion of the Shipping Manifest Report contains two filters “Unprocessed” and “Previously Processed,” and one row for each airbill assigned in the Assign Container to Shipper module. The row includes a Mark for Processing check box, the Airbill Number, Shipment Date, and Ship to Lab ID, and one check box to mark or unmark all airbills.

The lower portion of the window includes the Shipment ID or Airbill Number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Survey Year, Container ID 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.

Select one of the filters.

Set the filter to “Unprocessed” to print manifests and generate email files for shipments created but not previously processed using this module. Set the filter to “Previously Processed” to reprint an airbill or to re-create an electronic file for shipments previously processed using this module. To

filter on unprocessed airbills, direct the mouse arrow to the “Unprocessed” radio button and left-click. To filter on previously processed airbills, direct the mouse arrow to the “Previously Processed” radio button and left-click.

To select or mark one manifest for printing and email, direct the mouse arrow to the check box and left-click. Repeat this process to include other airbills. Use the scroll bar to display all existing airbills. The lower portion of the window updates to display only marked airbills.

To collectively mark all the airbills, direct the mouse arrow to the “mark/unmark all” check box and left-click. To collectively unmark all the airbills, direct the mouse arrow to the “mark/unmark all” check box and left-click a second time. The lower portion of the screen will update to display the marked airbills.

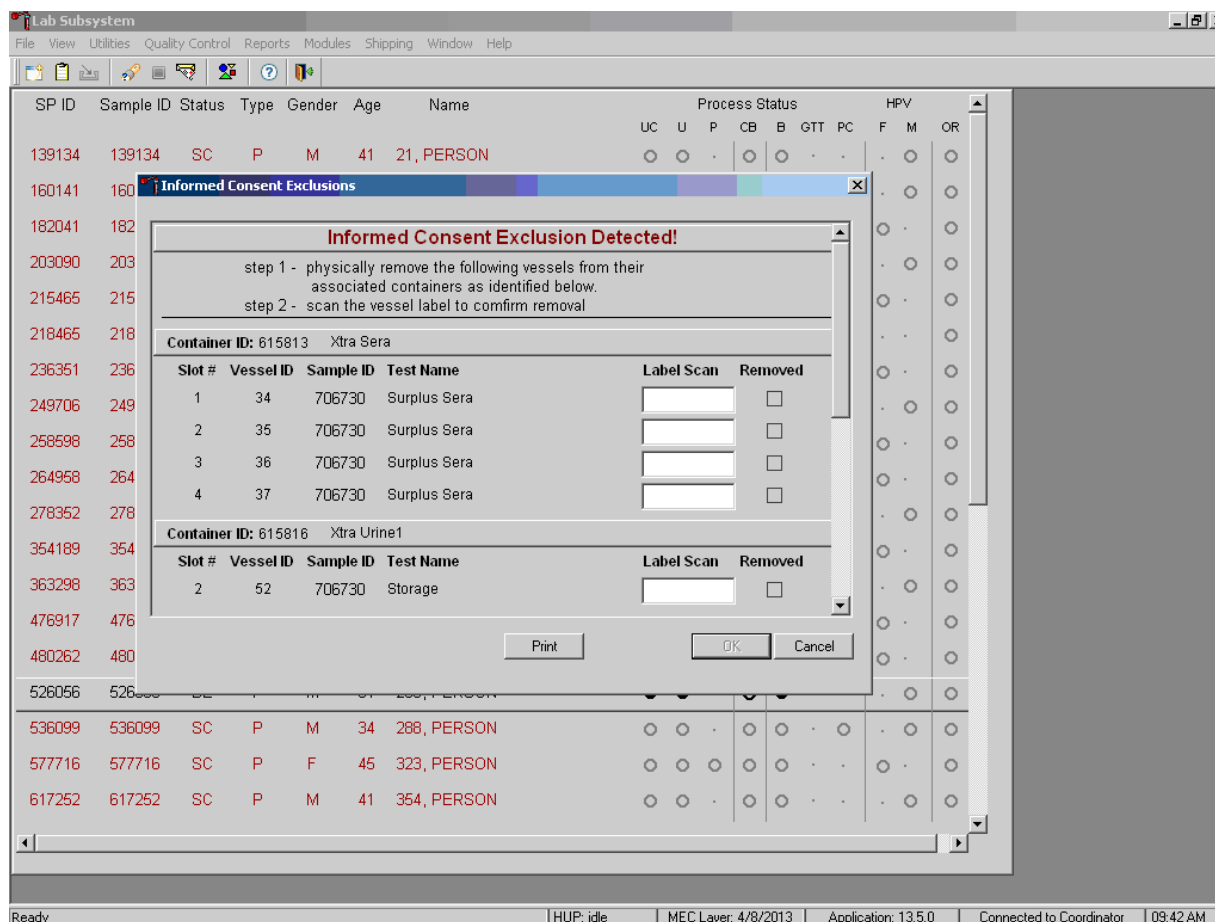
The right side of the window includes two buttons: Process and Close. Process the shipping manifests using the Process button.

Selecting the Process button will generate and print the Shipping Manifest Report(s). To print the manifests, direct the mouse arrow to the Process button and left-click. To exit the module without printing the manifest, direct the mouse arrow to the Close button and left-click.

8.10 Informed Consent Exclusions

The Informed Consent Exclusions window displays either when the Close Container or Shipping Manifest module is accessed. It displays when the following conditions have been met:

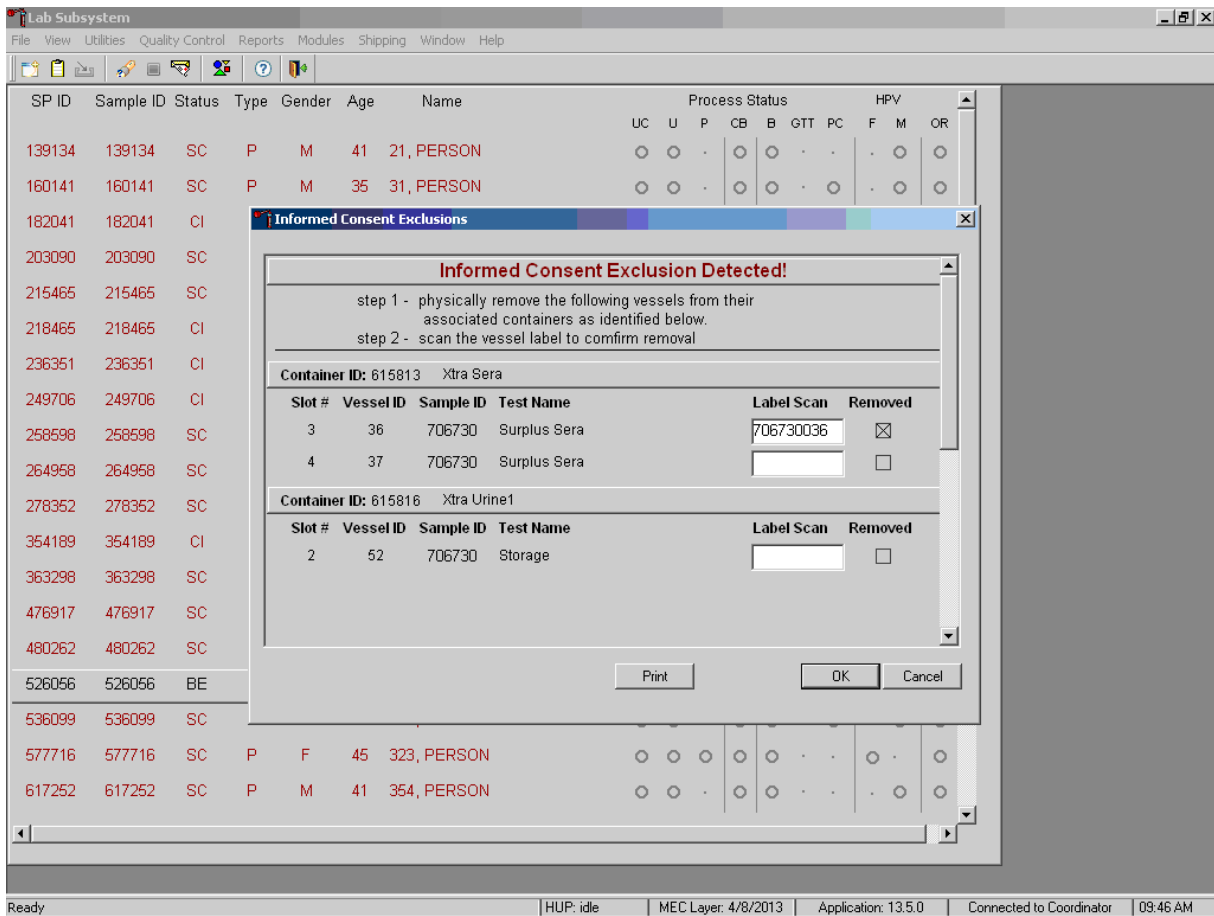
1. SPs initially signed their consent form, thereby agreeing to have their samples tested for HIV and STD testing;
2. They consent to have their vessels stored for future research;
3. They subsequently revoke either consent; and
4. The associated vessels have already been processed.



The window contains two steps that must be taken to resolve the inconsistencies. It includes the specific container ID and slot number within the container where the vessels are located, the sample ID, and the test name. Each row represents a vessel that must be marked as removed by scanning the barcode of that sample, which will place an “x” in the removed check box. A Print button on the bottom of the screen allows the list to be printed. See Exhibit 8-39 for an example.

These vessels must be removed from the container and destroyed before the container is shipped. Follow the **exact** instructions indicated in the window—”Physically remove the following vessels from their associated containers as identified below.”

Exhibit 8-39. Informed consent exclusion window



After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the barcode gun and scan the barcode for the tube to be removed. This will place an “x” in the removed check boxes for all the tubes scanned. To record these actions in the database and to close the Informed Consent Exclusion window, 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, direct the mouse arrow to the Cancel button and left-click.

If all the vessels are not marked, an Informed Consent Exclusions for Stand XXX warning pop-up box displays as shown in Exhibit 8-40.

Exhibit 8-40. Informed consent user error



The system tracks each vessel in the Informed Consent Exclusion module to ensure that every vessel is marked as removed. Follow the instructions in the pop-up box: “Please physically remove these containers and mark them removed before proceeding.” To acknowledge the message, direct the mouse arrow to the OK button and left-click, or type Enter.

8.11 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 if space is limited.) The FES will make contact with the local dry ice manufacturer and place the order for dry ice delivery, giving the specific weekly dates for delivery. It is the chief clinical laboratory scientist’s responsibility to confirm with the FES the amount and dates of delivery of dry ice pellets or blocks for shipping specimens. Use sliced blocks whenever possible since these sublimate less than pellets. Store the dry ice in the large blue insulated container provided by the dry ice facility. 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 8-41 is a list of all CDC and contract laboratory shipping addresses.

Exhibit 8-41. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name telephone number
Lab 2 CDC/NCID Hepatitis Ref Lab Attn: Jan Drobeniuc 1600 CLIFTON RD Bldg. 18 Floor 3 Rm. 218 MS A33 Atlanta, GA 30329-4018 404-639-3103	122 - Hepatitis Profile 87 - Hepatitis B _s Ab 229 - Hep Xtra ser 236 - COVID-19/SARS-CoV-2 Serology	Frozen	Jan Drobeniuc 404-639-3103
Lab 3 CDC/NCID AIDS Division Attn: Silvina Masciotra/Jeff Johnson 1600 Clifton Road NE Bldg. 17, Room 3127, MS A-25 Atlanta, GA 30329-4018 404-639-3850	22 - HIV	Frozen	Silvina Masciotra/Jeff Johnson 404-639-3850
Lab 5 CDC/NCID NCHSTD Attn: Monica Morris 1600 Clifton Road NE Bldg. 23, 3-661 Atlanta, GA 30329-4019 404-718-4082	46 - Chlam/ Trichomonas/M. genitalium 154 - Trichomonas/M. genitalium	Frozen Frozen	Monica Morris 404-718-4082
Lab 122 CBR Attn: Robert Davidson 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5950	235 - Bche	Refrigerated	Robert Davidson 770-339-5950
Lab 6 CBR Attn: Robert Davidson 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5950	1 - Lead/Cad/HG/Se/Mn 3 - RBC Folate 5 - Mercury 88 - Acrylonitrile 221 - RBC Folate Forms (all) 222 - Fatty Acids (all) 110 - Fol1 99 - Ferritin 17 - Cotinine Xtra Sera 29 - Dioxin/BFR 48 - Prior Pest/Flame Retardants 49 - Organophos 86 - Spc Arsenic 62 - Urn Merc/Iodine 50 - Metals	Frozen	Robert Davidson 770-339-5950

Exhibit 8-41. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name telephone number
Lab 6 CBR (continued)	66 – PAH 67 – Pthalates 90 – Perfluor1 102 – Perchlorate/Thio 156 – TSNA 220 – As/Cr/Ni 218 – Aromatic Diamines 52/139 – Xtra urine 137 – Steroid Hormones	Frozen	Robert Davidson 770-339-5940
Lab 9 Emory University Theda Gibson 2015 UPPERGATE DR. Lab 510E Atlanta, GA 30322-0001 404-727-5678	24 – HSV	Frozen	Theda Gibson 404-727-5678
Lab 10 Diabetes Diagnostic Laboratory University of MO – Columbia 1 Hospital Dr. Rm. M765 Columbia, MO 65201-5276 (573) 882-2708	4 – Glycohemoglobin 9 – Glucose 23 – Insulin	Refrigerated Frozen Frozen	Curt Rohlfing (573) 884-2708
NHANES ARDL Lab 51 NHANES Lipid Laboratory NHANES (ARDL) Attn: Jean Buksa 1200 Washington Ave S Suite 175 Minneapolis, MN 55415-1295 612-625-5040	45 – Alb/Creat 21 – Lipids 18 – Biochem 13 – CRP 118 – Thyroid Panel	Frozen Frozen	Jennifer Peters 612-625-5040
Lab 116 CDC/NCIRD Cytomegalovirus Diagnostic Lab 1600 Clifton Rd NE Bldg 18, Room 6-133 Mailstop G18 Atlanta, GA 30333 (404) 639-2178	138 – Cytomegalovirus	Frozen	Sheila Dollard (404) 639-2178
Lab 122 CDC/NCEH Tobacco and Volatile Branch Attn: Lalith Silva 4770 BUFORD HWY Bldg 103 Loading Dock Atlanta, GA 30341- 3717 770-488-3559	54 – VOC Blood 240 – Serum Terpenes	Refrigerated Frozen	Lalith Silva 770-488-3559

Exhibit 8-41. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name telephone number
Lab 123 ATCC Bioprocessing Laboratory 217 Perry Pkwy Gaithersburg, MD 20877 (703) 365-2700 ext. 2254	119 – Genetics	Refrigerated	ATCC Bioprocessing Laboratory (703) 365-2700 ext. 2254
Lab 126 Centers for Disease Control and Prevention RDSB/STATT Unit 76 ATTN: Polio and Picornavirus Laboratory Branch Dr. Jennifer Anstadt and Eric Rhoden 1600 Clifton Road NE Atlanta, GA 30329	237 – EV-D68		Dr. Jennifer Anstadt/Eric Rhoden

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. All samples are shipped as Biological Substance, Category B. If shipped with dry ice, all packages are also in compliance with the shipping of Class 9 Hazardous Substances. All IATA guidelines are followed and all shipping staff are appropriately trained in IATA shipping requirements for these samples.

8.11.1 Pack the Boxed Specimens

Store the specimen vessels in 2-, 3-, and 5-inch storage boxes. Separate the vessels with cardboard grids or foam inserts. Secure the top of the cardboard box to the bottom with a rubber band. Place one absorbent sheet under the rubber band. Select the appropriate size STP Biohazard Packaging system: STP 710- 9” x 9” x 2” and 10” x 10” x 2” STP730 for 9” x 9” x 3”, 5” x 5” x 3”, 7” x 7” x 3” and STP-740 for 5” x 5” x 7” with foam insert. Place the container in the plastic biohazard bag. Remove as much air as possible and seal the bag. Place the wrapped container into the Tyvek biohazard bag. Wrap and seal the Tyvek bag. Place a rubber band around STP730 packages to hold down the edges. Place the wrapped box back into the freezer or refrigerator.

8.11.2 Pack the Medium Shipping Containers for Frozen Shipment

- Place a layer 3 inches thick or at least 15 pounds (two blocks of dry ice cut to NHANES specifications) of dry ice slabs in the bottom of a medium-size Styrofoam shipper. If dry ice pellets are used, place nine scoops in the bottom of the shipper using the scoop provided in the lab inventory.
- Place the sealed specimen container boxes on top of the dry ice.
- Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.
- Place enough dry ice slabs on top so that the Styrofoam container is filled with dry ice to ¼ inch below the rim, or add a minimum of another 7.5 pounds of dry ice (one more dry ice block cut to NHANES specifications). If dry ice pellets are used, place five scoops on the top of the shipper using the scoop provided in the lab inventory.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Check shipping manifest against the labels on the containers to ensure the correct container is being sent to the correct lab.
- Place a plastic envelope containing the appropriate shipping manifest and return the preprinted label on top of the Styrofoam lid.
- Close the box.
- Secure the shipper with three pieces of packaging tape across the open flaps.
- Attach the airbill to the top of the box, secure with packaging tape.
- Attach the Class 9 label.
- Verify UP arrow, Frozen, Overpack, and UN3373 labels are attached.

8.11.3 Pack the Small Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place a layer 3 inches thick or one block of dry ice cut to NHANES specifications in the bottom of a small shipper. If dry ice pellets are used, place six scoops in the bottom of the shipper using the scoop provided in the lab inventory.
- Place the sealed specimen container boxes on top of the dry ice.

- Place enough chipped dry ice or dry ice blocks on top so that the Styrofoam container is filled with dry ice to ¼ inch below the rim, or add a minimum one block of dry ice cut to NHANES specifications. If dry ice pellets are used, place four scoops on the top of the shipper using the scoop provided in the lab inventory.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return preprinted label on top of the Styrofoam lid.
- Close the box.
- Secure the shipper with three pieces of packaging tape across the open flaps.
- Attach the airbill to the top of the box, secure with packaging tape.
- Attach the Class 9 label.
- Verify UP arrow, Frozen, Overpack, and UN3373 labels are attached.

8.11.4 Pack the Medium Shipping Containers 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 24 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.

- Seal the 9 x 12 zip-closable plastic bag or the pressure vessel containing the boxes.
- Place at least two frozen refrigerant packs in the bottom of a shipper.
- Add a layer of crumpled newsprint.
- Place the pressure vessel containing the boxes on top of the newsprint.
- Add a second layer of crumpled newsprint on top of the pressure vessel. Place two additional refrigerant packs on top or at both sides of the container(s).
- Place the Styrofoam lid on top of the Styrofoam bottom.

- Place the appropriate shipping manifest, one return FedEx preprinted airbill, and a blank white 8.5” x 11” Avery label into a 9 x 12 plastic bag and seal. Place this plastic bag containing the manifest and label on top of the Styrofoam lid.
- Vessel 54 shipped to Lab 122 is packed with 4 refrigerant packs on the bottom. Add a layer of crumpled newsprint, then a blue chux with the white padding facing up. Place the pressure vessel on the white side of the blue chux, then wrap another blue chux around the pressure vessel top with the white padding facing the pressure vessel. Place another layer of crumpled newsprint on top of the second blue chux. Place the Styrofoam lid on and proceed as above.
- Small shippers with refrigerant packs are packed the same as medium shippers with two refrigerant packs on bottom, a layer of crumpled newsprint, the pressure vessel, another layer of crumpled newsprint, and 2 more refrigerant packs on top or on both sides of the container(s).

8.11.5 Label the Shippers

Affix a preprinted FedEx barcoded airbill containing the shipping address, account number, package specifications and warehouse return address on all shippers.

All shippers must contain a FedEx barcode label and appropriate orientation and warning labels.

Label all shippers with the appropriate warning labels as follows:

- Add a “Keep Frozen” label and a FedEx Class 9 – Miscellaneous Dangerous Goods label on shippers containing dry ice.
- Add a “Refrigerate” label on shippers containing refrigerant packs.
- The warehouse places a UN 3373: “BIOLOGICAL SUBSTANCE, CATEGORY B” label on all shippers.
- The warehouse places an “overpack” label on all shippers.
- The warehouse places orientation labels on the shippers.
- 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.
- Add one additional strip of tape across the FedEx label.

8.12 Container Protocol and Weekly Shipping List

Exhibit 8-42 illustrates the container protocol. Use the container protocol as an aid at the start of each stand when opening new containers.

Exhibit 8-42. Container protocol

2021 Final container protocol					
Lab	Vessel	Test	Lab	Vessel	Container
61	1	Lead/Cad/HG/Se/Mn	CBR	2 mL sterile cryovial	9x9 two-inch box
61	5	Mercury, Ethyl, and Methyl	CBR	2 mL sterile cryovial	9x9 two-inch box
125	235	BChE	CBR	2 mL sterile cryovial	9x9 two-inch box
54	3	RBC Folate	CBR	2 mL cryovial	9x9 two-inch box
10	4	Glycohem	University of Missouri	4 mL EDTA tube	5x5 five-inch foam box
60	88	Acrylonitrile	CBR	2 mL cryovial	9x9 two-inch box
54	221	RBC Folate Forms (all)	CBR	2 mL cryovial	9x9 two-inch box
54	222	Fatty Acids (all)	CBR	2 mL cryovial	9x9 two-inch box
60	109	Transfatty Acid	CBR	2 mL cryovial	9x9 two-inch box
123	119	Genetics	ATCC Bethesda Maryland	6 mL EDTA tube	5x5 five-inch foam box
10	9	Glucose	University of Missouri	2 mL cryovial	9x9 two-inch box
4	54	VOC	CDC/NCEH Tobacco and Volatiles Branch	7 mL gray tube	5x5 five-inch foam box
2	236	COVID-19/SARS-CoV-2 Serology	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	4x4 two-inch box
54	110	Folate	CBR	2 mL cryovial	9 x 9 two-inch box
116	138	Cytomegalovirus	CDC/NCIRD CMV Diagnostic Lab	2 mL cryovial	9x9 two-inch box
126	237	EVD68	CDC/NCIRD/DVD Polio and Picornavirus Laboratory Branch	2 mL cryovial	9x9 two-inch box
54	99	Ferritin	CBR	2 mL cryovial	9x9 two-inch box
54	238	sTfR/AGP	CBR	2-ml cryovial	9x9 two inch box
54	70	VID	CBR	2 mL cryovial	9x9 two-inch box
2	87	Hepatit Bs Ab	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two-inch box
51	13	CRP	NHANES ARDL	2 mL cryovial	9x9 two-inch box
51	118	Thyroid Panel	NHANES ARDL	2 mL cryovial	9x9 two-inch box

Exhibit 8-42. Container protocol (continued)

2021 Final container protocol					
Lab	Vessel	Test	Lab	Vessel	Container
60	137	Sex Steroid Hormones	CBR	5 mL cryovial	9x9 three-inch box
60	239	Sex Steroid Hormone Panel	CBR	2 mL cryovial	9x9 two-inch box
59	17	Cotinine	CBR	2 mL cryovial	9x9 two-inch box
2	122	Hep profile	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two-inch box
2	229	Hep Xtra Sera	CDC/NCID Hepatitis Ref Lab	2 mL cryovial	9x9 two-inch box
51	21	Lipids	University of Minnesota (ARDL)	2 mL cryovial	9x9 two-inch box
51	18	Biochem	NHANES (ARDL)	2 mL cryovial	9x9 two-inch box
10	23	Insulin	University of Missouri	2 mL cryovial	9x9 two-inch box
52	77	HPV Serum		2 mL cryovial	9x9 two-inch box
3	22	HIV	CDC/NCID AIDS Division	2 mL cryovial	9x9 two-inch box
9	24	HSV	Emory University	2 mL cryovial	9x9 two-inch box
122	240	Serum Terpenes	CDC/NCEH Tobacco and Volatiles Branch	2 mL cryovial	9x9 two-inch box
24	90	Perfluor	CBR	2 mL cryovial	9x9 two-inch box
28	29	Dioxin/BFR	CBR	30 mL cryovial	4x4 five-and-a-half-inch box
6	32-37	Xtra sera 1-6	CBR	2 mL cryovial	9x9 two-inch box
51	45	Alb/Creat	University of Minnesota (ARDL)	5 mL cryovial	9x9 three-inch box
5	46	Chlam/Trichomonas/ M. genitalium	CDC/NCID NCHSTD	5 mL cryovial	9x9 three-inch box
5	154	Trichomonas/M. genitalium	CDC/NCID NCHSTD	5 mL cryovial	9x9 three-inch box
61	86	Spc Arsenic	CBR	2 mL cryovial	9x9 two-inch box
26	48	Prior Pest	CDC/NCEH Pesticide Laboratory	10 mL screwcap	5x5 three-inch box
26	49	Organophos	CDC/NCEH Pesticide Laboratory	10 mL screwcap	5x5 three-inch box
61	62	Urn Merc/Iodine	CBR	10 mL screwcap	5x5 three-inch box
61	50	Metals	CBR	5 mL cryovial	9x9 three-inch box

Exhibit 8-42. Container protocol (continued)

2021 Final container protocol						
Lab	Vessel	Test	Lab	Vessel	Container	
61	220	As/Ni/Cr	CBR	Five-0 5 mL cryovial	5x5 five-inch foam box	
31	66	PAH	CBR	5 mL cryovial	9x9 three-inch box	
24	67	Phthalates	CDC/NCEH Environmental Health Lab	10 mL screwcap	5x5 three-inch box	
62	102	Perchlorate/VOC/Thiocyanate	CBR	2 mL cryovial	9x9 two-inch box	
59	156	TSNA	CBR	5 mL cryovial	9x9 three-inch box	
62	218	UVOC	CBR	2 mL cryovial	9x9 two-inch box	
6	52	Xtra Urine 1	CBR	5 mL cryovial	9x9 three-inch box	
6	139	Xtra Urine 2	CBR	5 mL cryovial	9x9 three-inch box	

9. Quality Control and Quality Assurance—Policies and Procedures

This policies and procedures quality control and quality assurance chapter is an adjunct to the Westat policies related to workplace safety.

9.1 Safety

9.1.1 Introduction

Safety precautions for all methods are documented in the MEC Injury & Blood Exposure Procedures Manual and the Infection Control Manual. These manuals are 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 ensures that each laboratory analyst reads and is familiar with safety precautions.

9.2 Specimen Submission and Handling

9.2.1 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 Laboratory Procedure Manual (LPM). Each method in the LPM specifies the procedure to be used for preparation of the study participant (SP), specimen collection, labeling, processing, and preservation, as well as conditions for appropriate specimen transport. The methods may refer to the NHANES blood collection protocol or urine collection protocol, noting any special requirements. These protocols are a starting point due to the special contamination requirements needed for collection of specimens analyzed for metals and volatile organic compounds (VOCs).

9.2.2 Identification of Specimens

Personal identifiers (e.g., names) are not included on test specimens except the primary urine collection containers. The labels that contain the SP's name and SP ID are destroyed or blacked out with a permanent marker before placing the container in the trash receptacle. NHANES uses a random internal specimen ID number to identify and track individual samples. The Integrated Survey Information System (ISIS) at Westat and NCHS maintains information that links the specimen ID number to the SP's name.

9.2.3 Questions on Specimen Submission and Handling

The Lab Component Lead/Assistant Lead addresses questions concerning specimen collection, including handling and testing.

9.3 Test Requisition

9.3.1 Introduction

Under a congressional mandate (Section 306 of the Public Health Service Act 42 U.S.C.242k) since 1960, NCHS has collected data on the health of the people of the United States through interviews and extensive physical examinations. Seven surveys using health examination procedures have been completed since 1960. 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, non-institutionalized U.S. population. Data collection for this survey involves about 7,000 participants per year, of whom about 5,000 per year are expected to be examined. Data collection occurs in 15 different locations (stands) per year.

NHANES performs a complete blood count on SPs 1 year and older, and urine pregnancy tests on female SPs aged 12-59 years, and on girls aged 8-13 years who report, when asked during the interview, that they have experienced their first menstruation. If a urine pregnancy test is positive on any female SP aged 8-17 years, the urine pregnancy test is repeated. The clinician is notified through the ISIS observation function of the second positive or negative secondary test result or of the inability to perform a second test.

A record of the test result report is maintained electronically by Westat (the primary NHANES contractor) and by NCHS for an indefinite period. NHANES MEC laboratory staff may also perform other testing at the request of NCHS.

9.3.2 Laboratory Tests

The MEC clinician reports “critical” or abnormally high/low CBC results to the SP. The report includes laboratory tests that will be performed. The MEC clinician involved in the measurement may also confer with the SP to obtain any other pertinent information that might facilitate the laboratory measurement process.

9.3.3 Human Subjects Review

The NCHS ethics review board (ERB), as defined by the CDC institutional review board (IRB) criteria, shall allow any laboratory analyses conducted on human specimens that are part of a survey only after approval of the survey.

9.4 Test Records

9.4.1 Introduction

The purpose of test records is to ensure correct and reliable identification of study participant specimens and to report accurate test results. The laboratory test record system is distinguished from the test report referred to as the Report of Findings (ROF) that is provided to the study participant.

9.4.2 Components of Test Records

Test records include:

- Person performing the test (may be identified by initials or a unique 4-digit code);
- Printed or electronically stored output from instrumentation that the technical supervisor judges as necessary to document the analytical result;
- Date of specimen analysis;

- Date and time that specimen was collected; and
- Condition of specimens that did not meet criteria for acceptable specimens (e.g., hemolyzed or insufficient quantity for test).

Test records are maintained for a minimum of 7 years. Records may be bound in laboratory notebooks, bound in loose-leaf form, or stored electronically.

9.5 Test Report

9.5.1 Introduction

The laboratory Report of Findings, which gives the results of the tests performed on the MEC (in-house), is provided to the SP as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the SP 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 study participant.

9.5.2 Review, Approval, and Release of Test Results

Upon completion of laboratory testing, the laboratory staff is responsible for reviewing the quality control results and ensuring that the measurement process was within control limits for each of the participants' analyses.

For NHANES surveys, the initial evaluation of quality control (QC) results is accomplished electronically by comparing the QC results to QC limits stored in a relational database. The laboratory staff performing the complete blood count (CBC) and urine pregnancy test, reviews these QC performance results and ensures that only acceptable SP data is reported.

Review and approval of the CBC and urine pregnancy test results by the MEC clinician are documented. Review by the MEC clinician includes an evaluation of the consistency of SP results with information that may be available on the SP (e.g., age, sex). All SPs' CBC samples are run in duplicate, whenever possible. If inconsistent results are noted, and an adequate sample is available, the test is repeated in duplicate a second time. If the amount of sample is inadequate for repeat, the SP is informed verbally and in writing of the inconsistent result.

Laboratory reports are released only to the authorized SP. Each method includes a description of actions taken, such as when results are markedly elevated or are “panic values.” The SP is contacted immediately by the MEC clinician with such results.

9.5.3 List of Methods and Method Details

NHANES maintains a LPM, which includes detailed descriptions of each analytical procedure, including analytical sensitivity, specificity, and accuracy, interfering substances, and other information.

9.5.4 Format of the Test Report

The test report includes:

- Name and address of NCHS;
- Test result with a footnote attached representing the name and address where the laboratory test was performed;
- Units of measurement;
- Reference range for each analyte, if available;
- Condition of specimens not meeting the laboratory’s criteria for acceptability; and
- Signature of the NHANES medical officer.

The laboratory report consists of the following:

- Cover letter (first page);
- An analysis summary table (second page); and
- The name and address where the laboratory test was performed (third page).

A corrected laboratory report has the same format, except the words “corrected laboratory results” replace 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.

9.5.5 Format for the Laboratory Report Cover Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Health and Nutrition Examination Survey

Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, MS P08
Hyattsville, Maryland 20782

1/7/2021

John Doe
123 Main St
Anytown, US 12345

Dear John Doe,

We appreciate your participation in the National Health and Nutrition Examination Survey conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention. By taking part in this survey, you have helped add to our knowledge about the health status of people living in the United States. The information we collect is used to evaluate the country's health problems, develop health programs, and improve the quality of medical care.

The examination given to you was not a complete examination and was not intended to be a substitute for visits to your medical care provider. However, the enclosed report contains results of your examination that may be useful to maintaining and promoting your health.

If you have any questions about the results of your examination, you can reach me on one of our toll-free numbers below between 7:30 AM and 4:30 PM Eastern Time, Monday through Friday.

English:	1-800-452-6115, press "1"	Chinese:	1-866-887-7996, press "1"
Spanish:	1-800-452-6115, press "2"	Korean:	1-866-887-7996, press "2"
		Vietnamese:	1-866-887-7996, press "3"

Sincerely,

Duong T. Nguyen, D.O.
Senior Medical Officer

Enclosure
123456

9.5.6 Format for Listing of Laboratory Results



National Health and Nutrition Examination Survey Final Report of Findings

Laboratory - Blood Tests

	<u>Result</u>	<u>Units</u>	<u>Flag</u>	<u>Reference Range</u>
Glucose	400	mg/dL	High	60 - 109
Hemoglobin A1c	11.7	%	High	< 6.5
Alanine transaminase (ALT)	22	IU/L		< 40
Aspartate aminotransferase (AST)	21	IU/L		< 31
Alkaline Phosphatase (ALP)	92	IU/L		39 - 117
Albumin	3.9	g/dL		3.2 - 5.2
Bicarbonate	22	mmol/L		22 - 29
Blood Urea Nitrogen (BUN)	13	mg/dL		6 - 19
Calcium	8.5	mg/dL		8.4 - 10.2
Cholesterol	134	mg/dL		< 200
Creatine phosphokinase (CPK)	113	IU/L		22 - 334
Triglycerides	303	mg/dL	High	< 150
High Density Lipoprotein (HDL)	30	mg/dL	Low	> 39
Serum Creatinine	0.75	mg/dL		0.40 - 1.20
Gamma-Glutamyl Transferase (GGT)	24	IU/L		11 - 51
Low Density Lipoprotein (LDL)	44	mg/dL		< 130
Lactate dehydrogenase (LDH)	164	IU/L		94 - 250
Phosphorus	3.9	mg/dL		2.6 - 4.5
Sodium	135	mmol/L		133 - 145
Potassium	4.30	mmol/L		3.30 - 5.10
Chloride	96	mmol/L		96 - 108
Total Protein	6.9	g/dL		5.9 - 8.4
Uric Acid	4.7	mg/dL		3.4 - 7.0
Bilirubin	1.0	mg/dL		0.0 - 1.0
Serum Folate	60.6	nmol/L		10.5 - 90.7
RBC Folate	1830	nmol/L		640 - 2006
Serum Ferritin	187	µg/L		15 - 150
Iron	---	µg/dL		
Total Iron Binding Capacity (TIBC)	322	µg/dL		250 - 450
Transferrin Saturation	37	%		20 - 50
Blood Lead	0.5	µg/dL		0.0 - 10.0
Blood Selenium	163	µg/L		58 - 234
Cadmium	0.1	µg/L		0.3 - 1.2
Thyroid stimulating hormone (TSH)	---	mIU/mL		
Triiodothyronine, free (Free T3)	---	pmo/mL		
Thyroxine, free (Free T4)	---	ng/dL		
High Density Lipoprotein (HDL)	30	mg/dL	Low	> 39



Laboratory Information

The following CLIA-certified laboratories performed the named tests on biologic specimens

NHANES Mobile Examination Center Laboratory National Center for Health Statistics 3311 Toledo Road, MS P08 Hyattsville, Maryland 20782	Complete blood count
Diabetes Diagnostic Laboratory University of Missouri - Columbia 1 Hospital Drive Room M765 Columbia, MO 65212	Glucose, hemoglobin A1c, hemoglobin variant C, hemoglobin variant D, hemoglobin variant E, hemoglobin variant F, hemoglobin variant S and unknown hemoglobin variant
Centers for Disease Control and Prevention National Center for Environmental Health Nutritional Biomarkers Branch Laboratory 4770 Buford Highway, NE MS F-55 Atlanta, GA 30341	Serum ferritin, transferrin saturation, serum folate and RBC folate
Centers for Disease Control and Prevention NCEH / DLS / IRAT 4770 Buford Hwy. Building 103, Labs 1117, 1119, 1103 Mailstop F-18 Atlanta, GA 30341-3724	Total urinary arsenic, blood lead, cadmium, manganese, total blood mercury, selenium, inorganic blood mercury, urinary nickel, urinary chromium, iodine (salt) and fluoride (water)
Microalbumin Laboratory University of Minnesota 515 Delaware Street SE Room 13-219 - MOOS Tower Minneapolis, MN 55455	Urine albumin/creatinine ratio
University of Minnesota Advanced Research and Diagnostic Laboratory 1200 Washington Ave S Suite 175 Minneapolis, MN 55415	Glucose, CPK, estimated glomerular filtration rate, iron binding, transferrin saturation, iron, ALT, AST, alkaline phosphatase, albumin, bicarbonate, BUN, calcium, cholesterol, triglycerides, HDL, LDL, serum creatinine, GGT, LDH, phosphorus, sodium, potassium, chloride, total protein, uric acid, bilirubin, TSH, total Triiodothyronine (T3), Free T3, thyroxine (T4) total, Free T4, thyrolobulin, thyroglobulin antibodies, thyroid peroxidase antibodies (TPA)

9.6 Quality Control

9.6.1 Introduction

Most quantitative analytical procedures involve several operations, or steps, and each operation is subject to some inaccuracy, imprecision, or 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 purposes. A broader objective is to ensure that all laboratories produce analytical values that meet acceptable standards of precision and accuracy.

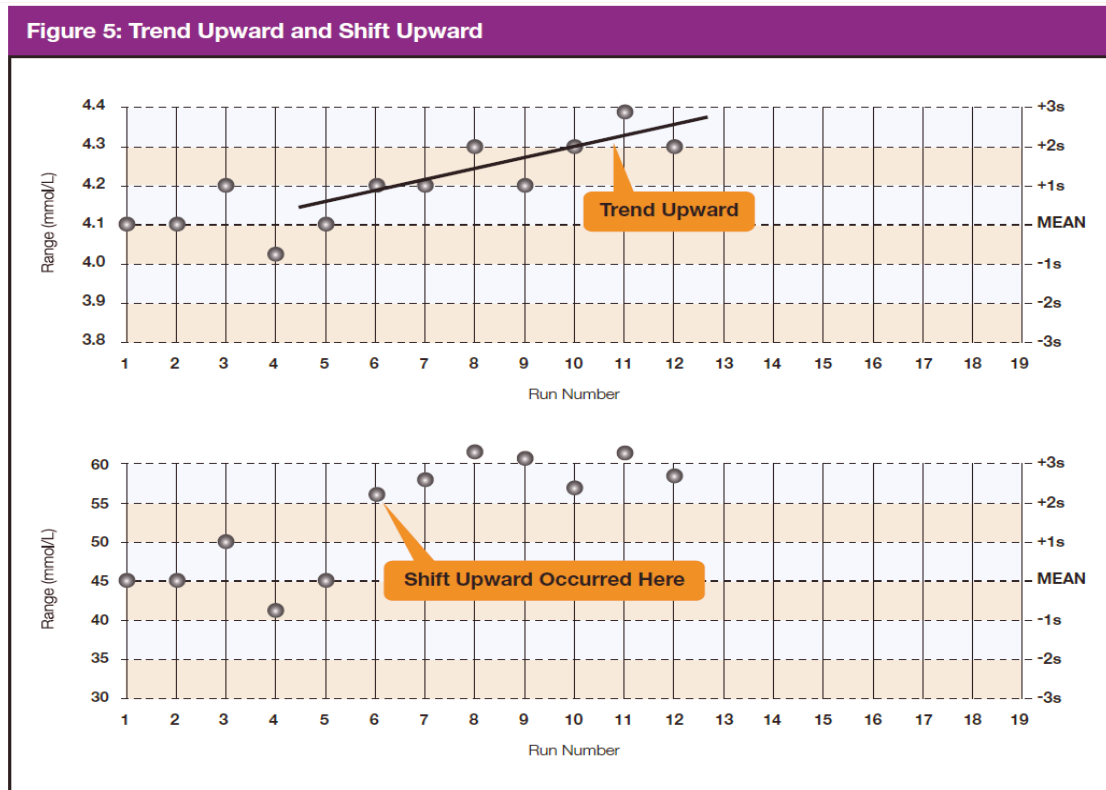
Quality control (QC) in laboratory medicine is the monitoring of the analytical measurement process to determine if it is performing correctly and patient results are reportable. The term “quality assurance” (QA) represents the entire process used to ensure with a specified degree of confidence that 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 QA program also monitors laboratory performance to detect excessive random or systematic error. Random error is defined as any deviation from an expected result. There is acceptable or expected random error as defined by standard deviation (SD). There is also unacceptable or unexpected random error that is any data point outside the expected population of data, such as a data point that is outside of ± 3 SD from the expected result. Factors contributing to random error are those that affect the reproducibility of the measurement. These include instability of the instrumentation; variations in the temperature; 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, as evidenced by a change in the mean of a control value. The change in the mean may be gradual and demonstrated by a trend in the control values, either above or below the mean. A trend may be caused by the accumulation of debris in tubing or reagent, aging of reagents, gradual deterioration of the control material, or gradual deterioration of the calibration. A change in the mean may be sudden and demonstrated as a shift in control values. Factors that contribute to systematic error are independent of the analyte concentration. Examples of these factors include change in reagent lot, major instrument maintenance, change in room temperature or humidity, failure in the sampling system, or inaccurate calibration.

Exhibit 9-1 presents examples of shifts and trends in QC data.

Exhibit 9-1. Example of shifts and trends in QC data



A QC program includes both internal (intralaboratory) and external (interlaboratory) surveillance and monitors the following five parameters:

1. **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.
2. **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.
3. **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; ensuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; and proper calibration of equipment, such as pipettes.

4. **Bench Performance.** This includes the use of controls and standards for each assay performed, a technique based on sound statistical principles that allows the clinical laboratory scientist performing the assay to detect error outside of previously determined limits before reporting data; documentation of daily bench performance for detection of less obvious error (particularly those that tend to accumulate over time, so-called “drift”); and established procedures to be followed wherever error is found to exceed previously determined limits.
5. **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, QC procedures monitor and evaluate the quality of the analytical testing process of each method to ensure 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. 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.

9.6.2 Method-Specific QC Procedures

Specific QC procedures exist for each analytical laboratory procedure in the LPM. The following are some general aspects of QC procedures.

9.6.3 QC Definitions

Internal (“Bench”) Quality Control

For purposes of this document, internal quality control 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. The IQAP compares NHANES 6C cell controls results to those of other laboratories that use the same instrument.

- **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 simply referred to 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 survey participant 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 survey participant samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for survey participant test results.”
- **QC Requirements of Each Analytical Run.** Analysis of study participant samples is organized into analytical runs. The minimum QC requirement for an analytical run, which is analyzing study participant specimens, is that the run includes at least two internal (“bench”) QC specimens that meet the NHANES-specified Westgard rules.

9.6.4 Overview of the Relationship Between Internal QC, Proficiency Testing, and External QC

A Beckman Coulter technical representative performs DxH 800 instrument setup and verification and performs and verifies QC checks according to their procedure at the beginning of each stand. Clinical laboratory scientists perform instrument calibration, precision analysis, and a repeatability evaluation.

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 6C 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 DxH 800 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 or has a value determined by repetitive testing using a reference or definitive test method”) that is useful for monitoring method performance.

9.6.5 Internal (“Bench”) QC

Complete Blood Count

The goal of internal QC is to provide a rapid feedback to the analyst on the performance of the measurement process to ensure that the analytical results and factors affecting analytical results are within acceptable limits. At least three internal QC specimens (6C 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 6C cell control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. The 6C cell control consists of stabilized human blood, so that repeated measurements to monitor daily performance of the instrument system are possible. The 6C cell control tri-pack contains three levels; when used with Beckman Coulter’s DxH diluent, DxH Lyse Reagent, DxH Diff Pack, they serve as a check on the accuracy of dilution, WBC counts, RBC counts, platelet counts, hemoglobin determinations, and differential counts.

The assigned staff members run all three levels at the beginning of each work day (8:30 am before SPs are processed), at 1:30 pm, and at the end of each day (either 6:30 pm or 9:30 pm depending on the schedule) to monitor the precision of the instrument following procedures described in Chapter 6. Successful performance of the Coulter QC is documented in the Start of Session QC tab in the Quality Control section of ISIS and on the Coulter 6C Cell Control Open Vial Stability Log.

Standard electronic Levey-Jennings QC charts are maintained for this internal QC specimen. A separate QC chart should 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 are captured by and stored in the ISIS. Any remedial actions for out-of-control conditions are documented in a QC logbook.

In addition, a latex control (Latron® CP-X control) 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 CP-X control is a ready-to-use suspension of latex particles used to monitor differential parameters on the Beckman Coulter DxH 800. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter.

9.6.6 Coulter Interlaboratory Quality Assurance Program (IQAP)

All DxH 800 instruments participate in Beckman Coulter’s Interlaboratory Quality Assurance Program (IQAP). The Beckman Coulter Data Management System saves results of 6C cell controls in files. Laboratory staff transfer the files to a CD-RW and then send the disk to the Westat Laboratory Component Lead, who uploads the data in the Beckman Coulter IQAP system and compares the results to those from other laboratories. Beckman Coulter issues a report that contains a statistical analysis to evaluate performance. The laboratory staff perform this procedure at the end of each stand, using procedures described in Chapter 6.

The chief technologist will review all Levey-Jennings charts weekly to watch for shifts or trends using the following Westgard rules (Exhibits 9-2 through 9-6). If shifts or trends are noted, the chief technologist will consult with the technical consultant on any necessary adjustments.

Exhibit 9-2. Westgard Rule 1_{2s}

Rule 1_{2s}. A single control measurement exceeds 2 SDs of control limits either above or below the mean. This rule is used as a warning rule to trigger careful inspection of the control data.

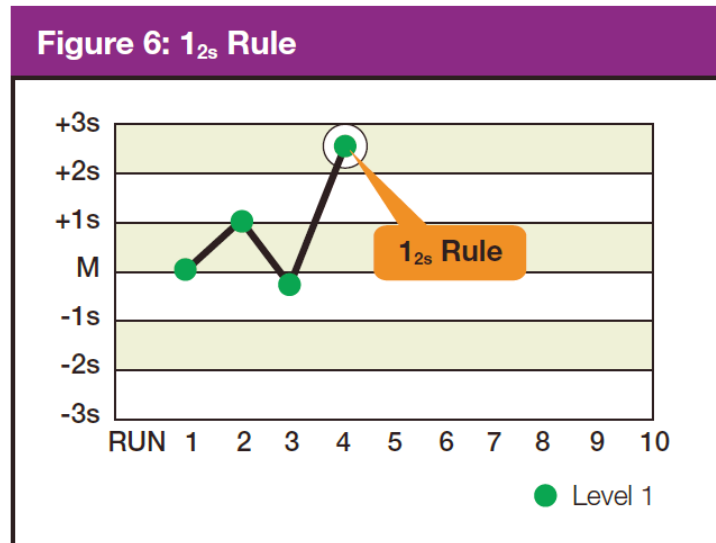


Exhibit 9-3. Westgard Rule 1_{3s}

Rule 1_{3s}. Identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC outside ± 3 SD violates this rule. A run is rejected when a single control measurement exceeds the mean ± 3 control limits.

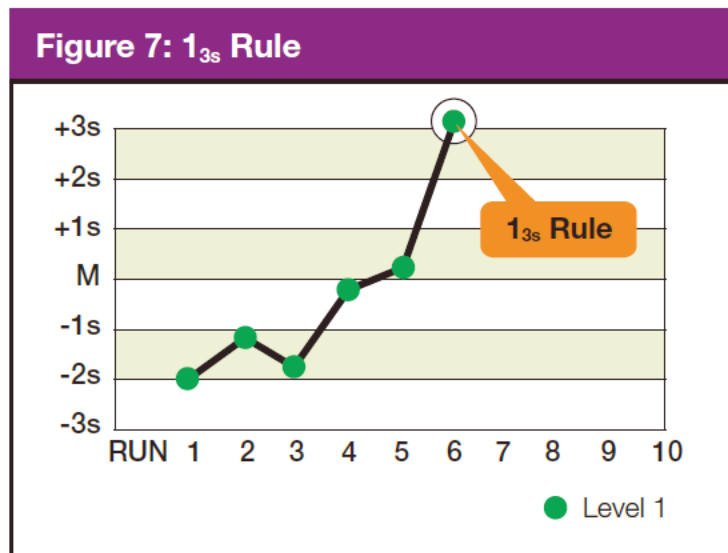


Exhibit 9-4. Westgard Rule 2_{2s}

Rule 2_{2s}. There are two rejection criteria for this rule: Two consecutive QC results that are greater than 2 SD that are on the same side of the mean. Violation within the run indicates that systematic error is present and that it potentially affects the entire analytical curve. Violation across the run indicates that only a single portion of the analytical curve is affected by the error. The control run is rejected with two consecutive control measurements that are greater than 2 SD of control limits on the same side of mean within or across the run, with this rule.

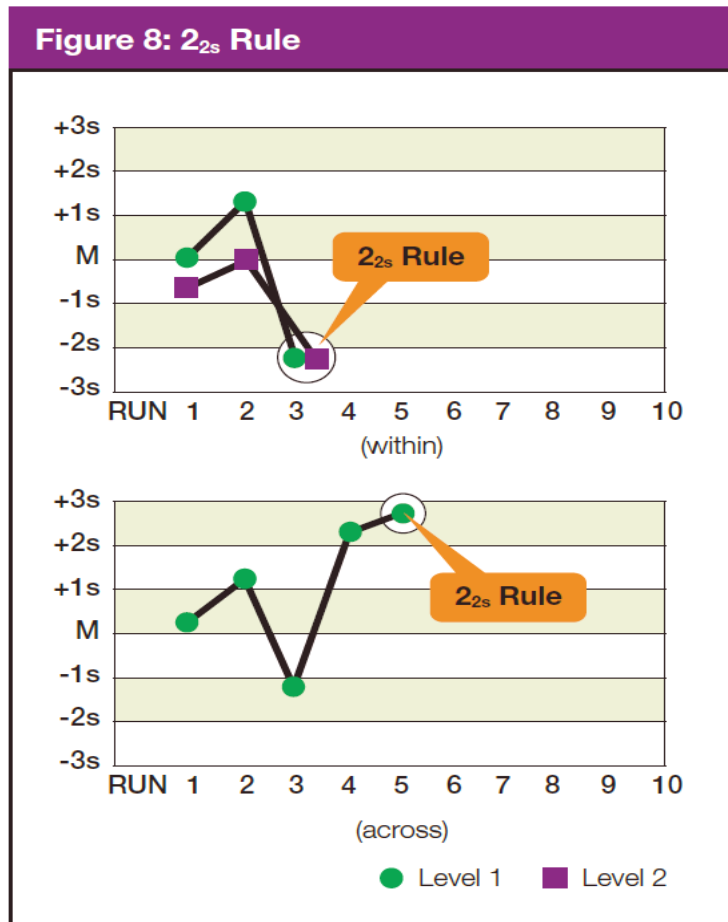
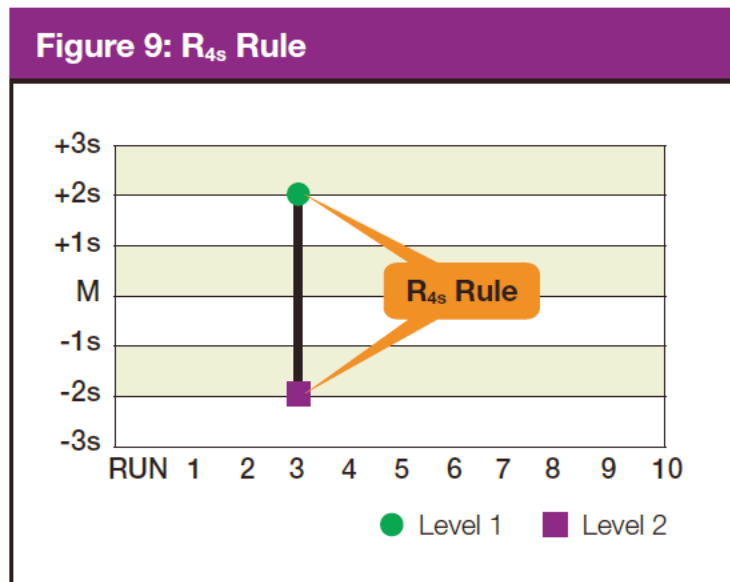


Exhibit 9-5. Westgard Rule R_{4s}

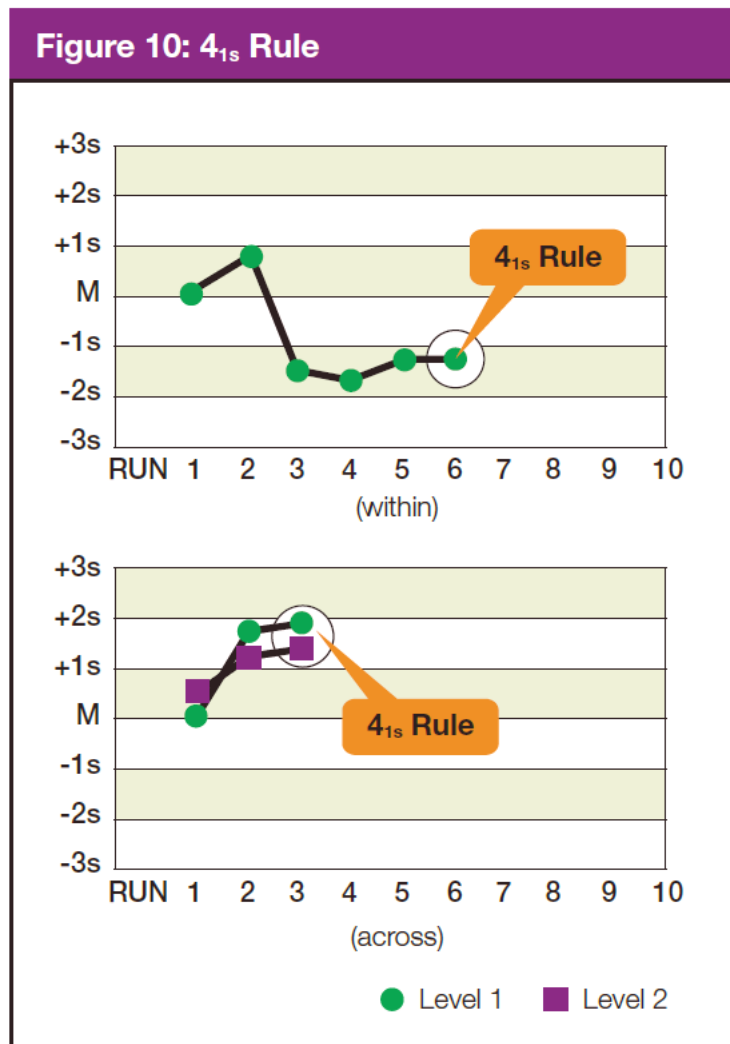
Rule R_{4s} . This rule rejects a run if there is at least a 4 SD difference between control values within a single run. For example, Level 1 control is +2.9 SD above the mean and Level 2 is -1.4 SD below the mean. The total difference between the two control levels is greater than 4 SD. This rule identifies random error and is applied only within the current run.



Note: Violation of any of the following rules does not necessarily require rejection of the analytical run. These violations typically identify smaller systematic errors or analytical bias that is not often clinically significant or relevant. Analytical bias may be eliminated by performing calibration or instrument maintenance.

Exhibit 9-6. Westgard Rule 4_{1s}

Rule 4_{1s}. This rule is violated with the fourth consecutive control measurement exceeding 1 SD on the same side of the mean. Troubleshooting action includes calling the Coulter hotline to see if other labs are reporting a bias with the same lot number of control. Perform any suggested diagnostic action or recalibrate if suggested by Coulter.



9.6.7 Calibration and Calibration Verification

9.6.7.1 Introduction

Calibration and calibration verification are specified in the documentation of the Calibration of the DXH 800 section in Chapter 6.

9.6.8 Proficiency Testing

Participation in the College of American Pathologists (CAP) proficiency testing (PT) program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens when scheduled for evaluation. CAP compares the results to established values and issues a report. A schedule of which MEC is receiving each survey is disseminated at the beginning of each year.

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 6. PT samples are handled and analyzed in a manner identical to SP samples, including the precision limits established to compare the duplicate runs of each sample. Results are entered and submitted electronically via the CAP website (www.CAP.org); a copy is also sent to the Westat home office.

CAP samples are submitted three times a year for qualitative urine hCG. Each urine shipment contains five liquid specimens. PT samples are handled and analyzed in a manner identical to SP samples.

After results have been evaluated and uploaded into the CAP online system, but while the samples are still fresh, other clinical laboratory scientists will run the samples in the same manner and send their results to the technical supervisor as part of quality assurance of each individual tech. The Laboratory Component Lead will review the results for accuracy and place the hard copy in each staff member's Competency Assessment Folder (CAF). Deficiencies will be discussed with the chief technologists for the purposes of testing supervision and/or possible retraining of staff.

9.6.8.1 CAP and API 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).

Participation in the American Proficiency Institute (API) proficiency testing program is part of the comprehensive quality control program. Each MEC submits results for API specimens to the technical supervisor. One set is sent to API for evaluation, and the Laboratory Component Lead evaluates the other sets against the API results. These samples should be handled and analyzed in a manner identical to SP samples, including the precision limits established to compare the duplicate runs of each sample.

Results are recorded on the CAP/API worksheets and are entered directly on the CAP/API website. A copy of the CAP/API worksheet is sent to the home office at the end of the stand.

Results are recorded on the CAP or API forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS at the following address:

Renee Storandt – NHANES Laboratory Director
National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Running CAP/API Proficiency Samples in the Mobile Examination Center

To make barcode labels:

- Select Utility on desktop.
- Select “Dymo test labels.”
- Highlight the label shown:
 - Click on “Properties” in far upper right.
 - Symbology – choose “Code 128 Auto.” This should be the only thing to change but check the following:
 1. Data: Barcode – delete “Click Me” or “0000001” and type in proficiency sample number, i.e., FH6-01.
 2. Align: Center
 3. Size: Medium
 4. Show Barcode Text: Below
 5. Select OK.

- Double-click on “Click Me.”
- Under Data: Barcode Data, delete “click ME” and type in proficiency sample number, i.e., FH601.
- Select OK.
- Print – will print on Dymo label maker.
- Repeat for all five samples.
- Exit out and select “No” to “Do you want to save?”

To auto-print results for proficiency samples:

- Verify that “Disable all auto printed reports” box is UNCHECKED in Menu > Setup > System > Printers > Printer setup (it should always be unchecked).
- Click on Menu.
- Click on Reporting.
- Click on Auto Report.
- Check box “Print Lab Report as Each Analysis is Complete.”
- Select OK.
- BE SURE to uncheck box after you have finished running and printing the samples.

9.6.8.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites

Coulter DxH 800 Comparisons Using American Proficiency Institute Proficiency Testing Samples, Blinded Samples, and Beckman Coulter 6C Cell Control Materials

All 3 DxH 800 instruments will be compared for MEC#1 vs. MEC#2, MEC#2 vs. MEC#3, and MEC#1 vs. MEC#3 two times each year.

NHANES compares DxH 800 analyzers using the following products: American Proficiency Institute proficiency survey samples, blinded samples, and Beckman Coulter 6C cell controls. Optimally, one would compare the CBC with differential between instruments with whole blood specimens, but this is not feasible in NHANES since the MECs are not at the same location. In

addition, we can compare only two DxH 800 analyzers at a time since the third MEC is traveling to a new location and its DxH 800 is not operational during travel status.

All DXH 800 analyzers can be compared using the American Proficiency Institute’s Hematology-5C surveys that are provided three times each year. Each Hematology-5C survey challenge contains five whole blood samples. These samples will be run on each MEC in duplicate (similar to participant specimens). We will also use five blinded samples if the MECs are within driving distance of each other. For the blinded samples, we will draw five EDTA whole blood samples from random participants. These samples will be run in duplicate and compared to the second DxH 800 instrument. Also, we will use the 6C cell control provided by Beckman Coulter. The 6C cell control contains three levels of material that will be run in duplicate and compared to the second instrument.

We will compare the two or three DxH 800 instruments for each test and results (3-5 results/test) using either a percent difference or absolute difference criteria (see Exhibit 9-7). The percent difference will be calculated as $\text{absolute } (x1-x2) / \text{mean } (x1,x2)$. An example calculation of the percent difference is the following: WBC: MEC 1=3.1 and MEC 2 =3.2. The percent difference is $|3.1-3.2| / ((3.1+3.2)/2) = 0.1/3.15$ or 3.2 percent. The absolute difference will be calculated as $\text{absolute } (x1-x2)$. An example calculation of the absolute difference is the following: Eosinophil %: MEC 1=6.4 and MEC 2=6.7. The absolute difference is $|6.4-6.7| = 0.3$. The percent difference and absolute difference criteria were derived from bench quality controls for the DxH 800 from January-May 2013 or from the Beckman Coulter DxH 800 imprecision data from the Beckman Coulter Hematology Performance Verification Manual. The following criteria (Exhibit 9-7) will be used:

Exhibit 9-7. CAP hematology survey comparison criteria

Test	Percent difference (%)	Absolute difference
WBC	7	NA
RBC	7	NA
Hgb	7	NA
Hct	6	NA
MCH	5	NA
MCHC	5	NA
MPV	7	NA
MCV	5	NA
RDW	5	NA
Platelet	10	NA
Neut%	7	NA

Exhibit 9-7. CAP hematology survey comparison criteria (continued)

Test	Percent difference (%)	Absolute difference
Neut#	11	NA
Lymph%	10	NA
Lymph#	12	NA
Mono%	25	NA
Mono#	35	NA
Eos%	NA	1.0
Eos #	NA	1.0
Baso%	NA	1.0
Baso#	NA	1.0
nRBC%	NA	1.0
nRBC#	NA	1.0

9.6.9 Calibration Verification

Calibration verification is defined by CLIA as “the assaying of calibration materials in the same manner as survey participant specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for survey participant test results.” Thus, calibration verification ensures that the accuracy of the measurement process across the reportable range is maintained over time. For methods approved by the 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; that is, 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 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, 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 DxH 800 uses the S-CAL kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. The S-CAL calibrates the WBC, RBC, Hgb, MCV, Plt, and MPV parameters. It is a stabilized human-blood preparation. The 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.

The S-CAL is used to calibrate the DxH 800 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, if 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 Chapter 6.

9.6.10 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 Beckman Coulter Lin-X™.

Beckman Coulter Lin-X linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter hematology systems that use both Beckman Coulter® III diluent and Lyse S® III diff lytic reagent. 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. Beckman Coulter Lin-C.

9.6.11 Quality Control Records

Records of all quality control results are maintained for at least 7 years. Quality control results are captured and stored in the ISIS and are available via the internal network. A QC logbook is maintained that documents 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 and calibration. The physical records are archived by MEC stand through a contract company after 2 years of being maintained at the Westat home office.

New lot number crossover studies are performed on Coulter 6C cell controls. The new lot is run against the old lot 20 times before the new lot is put into use.

9.7 Test Methods, Equipment, Reagents, Supplies, and Facilities

9.7.1 Introduction

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the methods performed in-house. The documentation of individual analytical procedures included in the 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, 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.

9.7.2 Labeling of Reagents, Solutions, and Other 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, laboratory staff initials, and any other pertinent information required for proper use. Reagent, solutions, and other supplies are not used when they have exceeded their expiration date. Reagents or supplies that are received from the manufacturer without an expiration date will have one assigned by the warehouse to be dated 5 years from the receipt of the item.

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 instrument Daily Checks report. A copy of all startup results is filed in the quality control notebook and sent back to the Westat home office at the end of each stand. The clinical laboratory scientist documents any unusual occurrence in the automated Unusual Occurrence Log or repair of the Beckman Coulter DxH 800 in the automated Equipment Tracking System.

Logs are maintained for reagents other than Beckman Coulter.

9.7.3 Facilities

Laboratories are designated to ensure that adequate space, ventilation, and utilities are available for all phases of testing: pre-analytic, analytic, and post-analytic.

9.8 Analytical Procedure Manual

9.8.1 Introduction

All procedures performed in the mobile examination center laboratory, on human specimens, are documented in the LPM. A copy of the LPM is maintained at the Westat home office and at NCHS. The individual procedure is also available at or nearby the bench site where the procedure is performed on each MEC.

9.8.2 Contents of the Analytical Procedure Documentation

Each analytical procedure includes the following, 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 study participant 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 “critical values”;
- Pertinent literature references;
- Specimen storage criteria;
- Protocol for reporting critical values;
- Course of action if test system becomes inoperable; and
- Safety considerations for performing the method.

9.8.3 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.

9.8.4 Method Performance Specifications

Method performance specifications for each analytical method are established or verified as follows:

- **Accuracy** of each analytical method will be determined by analysis of calibrators and yearly linearity checks as described in the section of this manual on quality control.
- **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** is determined for each method, including effects of potential interfering substances by the manufacturer. This may be verified by testing the effect of potential interfering substances in method development, by analyzing reference materials, comparing results on split samples with a method considered more definitive, or 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 that interfere with the analysis in the reportable range are listed in the method procedure.
- **The reportable range of test results** is described in the documentation of the analytical procedure.
- **Reference range (normal range)** of test results, if available, is described in the documentation of the analytical procedure and on the test report.
- **Other pertinent performance specifications** that are required for adequate method performance are specified in the documentation of the analytical procedure.

9.9 Equipment Maintenance and Function Checks

9.9.1 Introduction

Laboratory equipment is regularly checked to ensure acceptable performance. Maintenance (including preventive maintenance), and external checks are documented in the Laboratory and Phlebotomy Quality Control modules in ISIS. The frequency of maintenance and daily checks follows the manufacturer's recommendations, when available. The 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 automated Unusual Field Occurrence Log. In addition, corrective actions and troubleshooting must be documented in the ISIS laboratory QC module.

9.9.2 Laboratory Equipment Calibration

- Eppendorf Pipettes
 - The Eppendorf Xplorer Plus electronic pipettes are calibrated once per year. Pipettes are sent to the manufacturer and calibration certificates are kept on file at the Westat home office. Calibration verification is performed quarterly by the Laboratory Component Lead/Assistant Component Lead.
- Troemner Scale Weights
 - The Troemner Scale Weights are calibrated once per year. Scale weights are sent to the manufacturer and calibration certificates are kept on file at the Westat home office.

9.9.3 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. A TempGuard system is used to constantly monitor the refrigerator and freezer temperature in the laboratory. This system is monitored 24 hours, 7 days per week. If an alarm is not addressed within 10 minutes, a call center will begin calling the facilities and equipment specialist (FES) and MEC manager to alert them to the alarm. During normal work hours laboratory staff will respond to the alarms. Room temperature is monitored and recorded during days of operation.

The refrigerators, freezers, and TempGuard systems are calibrated twice per year. The clinical laboratory scientists record the temperature of each unit, comparing the TempGuard to a NIST-certified thermometer, and the FES uses a certified digital thermometer.

Beckman Coulter, Vacutainer, and Sure-Vue have recommended the following storage conditions for reagents and tubes (Exhibit 9-8). Quality control temperature ranges have been established based on these recommendations.

Exhibit 9-8. Recommended storage conditions for reagents and tubes

Reagent	Manufacturer's recommended storage conditions	Established range
CoulterDxH Lyse	2-40°C (36-104°F)	15-25°C (59-77°F)
DxH Diluent	2-40°C (36-104°F)	15-25°C (59-77°F)
DxH Cleaner	2-25°C (36-77°F)	15-25°C (59-77°F)
DxH Diff Pack	2-25°C (36-77°F)	15-25°C (59-77°F)
S-CAL at room temperature	16-32°C (60-90°F)	15-25°C (59-77°F)
S-CAL at refrigerated temperature	2-8°C (35-46°F)	2-8°C (36 - 46°F)
Latron	2-30°C (36-86°F)	15-25°C (59-77°F)
6C Cell Control	2-8°C (36-46°F)	2-8°C (36-46°F)
Sure-Vue Urine Controls	2-8°C (36-46°F)	2-8°C (36-46°F)
BD Vacutainer 7mL Gray VOC	unknown CDC product	15-25°C (59-77°F)
BD Hemogard 2 mL Gray Top	4-30 C°	15-25°C (59-77°F)
BD Hemogard 3mL EDTA Lavender	4-30 C°	15-25°C (59-77°F)
BD Hemogard 4 mL EDTA Purple Top	4-25 C°	15-25°C (59-77°F)
BD Vacutainer 10mL Red Top	4-25 C°	15-25°C (59-77°F)
BD 6 mL Royal Blue Top	4-25 C°	15-25°C (59-77°F)
Covidien 7mL Red Top	4-25 C°	15-25°C (59-77°F)

The following ranges have been established for monitoring instrument quality control (Exhibit 9-9).

Exhibit 9-9. Established ranges for monitoring instrument quality control

Instrument	Manufacturer's instrument range or limit	Established range
Beckman centrifuge (refrigerated)	<-5 to +30°C (23-86°F)	4-8°C (39-46°F)
Beckman centrifuge (room temperature)	-5 to +30°C (23-86°F)	15-25°C (62-86°F)
Revco freezer	-30°C (-22°F) Limit	-26 to -34°C (-15 to -29°F)
Jewett freezer	-20°C (-4°F) Limit	-18 to -23°C (0 to -10°F)
Jewett refrigerator	2-5°C (35-41°F)	2-8°C (35-46°F)
LFBSC	0.450 m/s	0.350-0.550 m/s
Phlebotomy refrigerator	None	2-8°C (35-46°F)
Mettler Toledo Scale	One 100g weight (start of stand QC)	+/- 1.0 grams
Mettler Toledo Scale	Two 300g weights (start of stand QC)	+/- 6.0 grams
Mettler Toledo Scale	One 500g weight (daily QC)	+/- 5.0 grams
Mettler Toledo Scale	One 20g weight (daily QC)	+/- 0.2 grams

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 15-25°C (59-86°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. This is monitored daily by the TempGuard system and is recorded in the Laboratory Information System.

Freezer temperatures are monitored daily by an automated TempGuard system. The range of allowable temperatures for the -20°C Jewett model is -18 to -23°C. The range of allowable temperatures for the -30°C Revco model is -26 to -34°C.

An automated continuous TempGuard system monitors the room temperature and the internal temperature of the laboratory refrigerators and freezers. When the system detects a significant increase in the temperature, it begins calling designated staff. The MEC managers and facilities and equipment specialists have been identified as those individuals responsible for responding to the call by typing in a response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of power because a circuit breaker tripped, a compressor malfunctioned, or a system failed. The MEC manager or data manager implements corrective actions that are warranted to prevent loss of biological specimens.

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 FES, MEC manager, and the laboratory study lead.

9.9.4 Humidity Monitoring

Humidity monitoring is required because unusually high, low, or extreme fluctuations in humidity can cause deterioration of reagents and test components and can affect the rate of chemical reactions and specimen interaction. This reading will be recorded daily in the daily lab QC in the laboratory information system. A range of <80 percent is acceptable to operate the laboratory. Any discrepancies must be documented in the ISIS laboratory QC module along with the troubleshooting and corrective actions taken.

9.10 Troubleshooting

9.10.1 Introduction

Troubleshooting actions are taken and documented on the designated document/ISIS application module when:

- Test systems perform outside acceptable performance specifications. Troubleshooting is documented in the appropriate QC module.
- Results of control materials and calibration materials fail to meet quality control criteria. Troubleshooting is noted in the appropriate QC logbook.
- The laboratory cannot report study participant test results within its established period. If the reporting of data will exceed the agreed upon time frame, the MEC and final Report of Findings indicate the test results are not available.
- Errors in the reported SP test results are detected. When errors are detected in the reporting of study participant results, the MEC clinician notifies the study participant by phone, followed by the issuance of a corrected report within a time period suitable to the study participant, 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 a minimum of 7 years.

9.11 Integrated Survey Information System (ISIS)

9.11.1 Introduction

One of the purposes of the ISIS is to store study participant results for retrieval in a period acceptable for the intended use of the data. Study participant test results are stored in a database. The ISIS consists of the PC databases used for storing study participant results. This form for the ISIS facilitates the interfacing of varied and complex instrumentation used in many of the analytical procedures. The MEC local area network (LAN) hardware serves as the hardware for the ISIS. The identification of the study participant result is 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, 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 Westat and NCHS may access the data.

9.11.2 Integrated Survey Information System Data Down Times

Each laboratory method is able to run and temporarily store results even if the MEC LAN is inoperable.

9.11.3 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 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.

9.11.4 Backup Schedule of Integrated Survey Information System Data

ISIS data is stored in a central database and is backed up to tape nightly and stored permanently.

9.12 Communications and Complaints

9.12.1 Introduction

Good communication between the laboratory and persons reviewing laboratory analyses is essential for proper use of laboratory results. NHANES encourages collaborative relationships between clinical laboratory scientists and clinicians using 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. The technical supervisor is the Laboratory Component Lead from Westat, whereas the laboratory director is the laboratory specialist from NCHS.

Similarly, complaints of laboratory performance are carefully considered. Usually, these complaints are fixed with minor adjustment or explanation. Each member of the laboratory staff is responsive to complaints that have merit and relate to their 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 them. Issues deemed unresolved may be taken higher up the organization chain to reach a resolution. Westat's Human Resource Services may be involved in an effort to reach an amenable outcome.

9.13 Quality Promotion

9.13.1 Introduction

High-quality laboratory results are generated when all phases of the measurement process (i.e., pre-analytic, analytic, and post-analytic) are properly conducted. 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 of these factors to enhance quality.

9.14 Quality Assurance Program

9.14.1 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 include the following requirements:

- All data is 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 clinician as soon as they are available, and the SP is notified by telephone of any abnormal results. A hard copy of the CBC results is 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 done.” In the case where blood was drawn (but it was not possible to run, CBCs within 24 hours of collection and no results were transmitted), the preliminary or final Report of Findings states, “Data not available at this time.”
- 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 SP. 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 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.

The QAP audits are reviewed monthly during the NCHS-Westat Laboratory Quality Assurance meeting.

9.14.2 Quality Audit: Study Participant Test Management

The quality audit for study participant test management is conducted at least yearly and consists of:

- A survey of the testing laboratory staff, and of the analytical procedures used in NHANES. The survey includes requests for information on:
 - Any changes that need to be made in study participant preparation, specimen collection, labeling, preservation, and transportation;
 - Any changes that need to be made in completeness and relevance of study participant 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 ISIS is adequate for their measurement systems; and
 - Nontrivial complaints from outside the laboratory about performance of the lab.

The technical supervisor and laboratory director assess the results of the audit and implement corrective actions that are warranted. Any changes to the information system are tracked through a change request process. The status of these changes are monitored monthly during the quality assurance meeting.

9.14.3 Quality Audit: Quality Control

Quality control addresses the analytic phase of measurement. The purpose of the internal (“bench”) quality audit is to ensure that the QC analyses were performed and appropriate actions were taken when out-of-control conditions occurred. The quality audit of quality control shall consist of:

- **A review of a random 10 percent sample of 6C cell and Latron control results.** The review evaluates whether appropriate corrective action was performed and documented for out-of-control conditions. This review is conducted at the end of each stand and documented by the technical supervisor. Any problems with Coulter QC will be discussed at the monthly quality assurance meeting.
- **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 the S-CAL calibrator was run on three instruments.** Typically, the S-CAL calibrator is run at the beginning of each stand to confirm calibration of the instrument. This calibration verification is reviewed by the technical supervisor.

The technical supervisor and laboratory director assess the results of the audit and, in consultation with Beckman Coulter, implement corrective actions that are warranted.

9.14.4 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 6C 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 1 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 technologist 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 1 month after remedial action is acceptable evidence of the effectiveness of remedial action.
- **The technical supervisor and laboratory director auditing 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 the first year performing a new method).** The evaluation criteria are described in Section 9.15 – Personnel Training and Evaluation. The technical supervisor maintains documentation of the results of the audit.

9.14.5 Quality Audit – Phlebotomy Refusals

Collecting laboratory samples is a priority for the overall study. A specific component of the collection is phlebotomy. Phlebotomists are trained in refusal conversion techniques. Participants

who are hesitant to have blood collected are encouraged to see the phlebotomist, who uses techniques to attempt to convert them to allow for the collection. Refusal rates for the phlebotomy component using data from the previous 18 years were analyzed to determine means and confidence intervals. This data will be used as a benchmark to compare the phlebotomy refusal rates for each stand of the study. Any negative trends will indicate the need for additional training in refusal conversion for the phlebotomists.

Age	Total	Refusals	Mean percent (C.I.)	High	Low
1-2 Year Old	5,291	1,284	24.4 (21.3-27.5)	36.3	10.6
3-5 Year Old	5,317	1,186	22.6 (19.8-25.4)	38.6	15.4
6-11 Year Old	10,680	1,481	13.8 (12.5-15.1)	17.9	9.1
12+	63,356	2,833	4.5 (4.1-4.8)	6	3.4
Total	84,644	6,784	8.0 (7.5-8.6)	0	5.7

9.14.6 Quality Audit – Pre-Analytic Sample Quality

Pre-analytic sample quality will be measured through analysis of the following variables: the number of samples hemolyzed, number of samples clotted, number of samples with insufficient volumes, and number of samples damaged during transport. The threshold for these variables is 1 percent of the total samples processed. The incidence of these occurrences are documented through the use of the Unusual Field Occurrence application with the ISIS computer system. These will be measured monthly and reported during the monthly laboratory meeting. Any variable over 1 percent of the total sample volume requires a plan of corrective action and follow-up.

9.14.7 Quality Audit – Post-Analytic Extreme Result Reporting

CBCs are performed on the MEC. Appropriate follow-up is required for all extremely high or low values. Clinical laboratory scientists are required to send an observation through ISIS to the clinician for any participant parameters flagged as extremely high or low. The clinician documents discussion with the participant and may refer the participant to a clinical physician or clinician for further evaluation. This is documented in the ISIS system. This audit will review the extremely high or low CBC values and evaluate if the correct process was followed for notification. This will be reported in the monthly laboratory meeting. Any deviations identified will be immediately addressed by the Laboratory Component Lead.

9.14.8 Quality Audit – Urine Collection from 3- to 5-Year-Old SPs

The collection of urine samples from 3- to 5-year-old SPs is challenging because of the age of the participants. The collection of the urine samples in this age group is monitored by age and gender. If trends are identified, the lab director and technical supervisor identify changes to improve the response rate. These changes are then monitored. This data is reported at the monthly quality assurance meeting.

9.14.9 Quality Audit – Unusual Field Occurrences

Any equipment failures, instrument failures, temperature problems, power outages, or technician errors are documented through the use of an Unusual Field Occurrence application with the ISIS computer system. The Westat home office staff is immediately notified via email of any occurrences, so that immediate action can be taken to resolve the occurrence and prevent further occurrences of the same type. All occurrences for the month are discussed with the laboratory director and other NCHS laboratory staff at the monthly quality assurance meeting.

9.14.10 Quality Assurance Review with Staff

The technical supervisor and laboratory director prepare a report of the results of quality audits. The technical supervisor and laboratory director review pertinent information with appropriate staff to ensure that effective remedial actions are taken. The technical supervisor and laboratory director also notify staff members who have been involved in the audit if their 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.

9.15 Personnel Training and Evaluation

The technical supervisor ensures that persons performing laboratory tests receive appropriate training. The performance of new personnel performing laboratory tests is evaluated 6 months after initial training conducted by staff deemed proficient in the laboratory task, and 6 months afterward for the first year. Assessments are performed annually thereafter. The evaluation shall consist of, at the minimum, the six elements of:

- Direct observation of test performance, including study participant 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, 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).

9.16 Competency Assessment

9.16.1 Introduction

Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by Federal regulation.

The following six procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;
2. Monitoring the recording and reporting of test results;
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observations of performance of instrument maintenance and function checks;
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Assessment of problem-solving skills.

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), and testing personnel (TP). Clinical consultants and technical consultants who perform testing on patient specimens are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their regulatory responsibilities.

The technical consultant for **moderate complexity** testing (42 CFR §493.1413(b)(8)) is responsible for performing and documenting competency assessments. The competency assessments may also be performed by other personnel who meet the regulatory qualification requirements for TC for moderate complexity testing.

Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens. Thereafter, competency assessment must be performed at least annually. Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.

Note: If test methodology or instrumentation changes, an individual's competency must be re-evaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

9.16.2 NHANES Competency Assessment Plan

The competency of the staff will be evaluated and documented by qualified staff from the Westat home office, using the competency assessment (testing personnel) form shown below (Exhibit 9-10). All aspects of the NHANES laboratory that fall under CLIA regulations will be assessed and documented. Competency assessments will occur every 6 months for the first year of employment and annually thereafter.

Exhibit 9-10. NHANES competency assessment plan

CDC – NHANES Westat 1600 Research Blvd. Rockville, MD 20850		Assessed By: Initials: Date: Reviewed By:			
Competency Assessment (Testing Personnel)					
Name:		Job Title(s):		Lab Section:	
Elements of Competency Applicable to Test System	1. Direct Observation of Testing 2. Review/Reporting Results/Critical Values		3. Review QC, PT, PM 4. Direct Observation PM		5. Blind Testing (PT, QC, RS) 6. Evaluate Problem-Solving Skills
Test System	Component/Process/Analyte	Elements to Assess	Acceptance Criteria	Acceptable/Comments	Date Completed
Chemistry Specimen Processing <input type="checkbox"/> Waived <input type="checkbox"/> Non-Waived	Routine Specimen Collection/Transport/Processing	1,6	Pass Specimen Processing Quiz (Score >90%)		
	Criteria for Accepting/Rejecting Specimens	1,2	Evidence of daily work must demonstrate 100% proficiency with recognizing unacceptable specimens and the appropriate disposition.		
Beckman Coulter ICON 25 <input type="checkbox"/> Waived <input type="checkbox"/> Non-Waived	Beckman Coulter ICON 25 hCG Combo Test	1	Complete direct observation checklist for ICON 25 hCG combo test kit and score 100%. <ul style="list-style-type: none"> • Qualitative Urine hCG 		
		3 4,2 5	Review urine hCG QC log Review test reporting Successfully participate in CAP PT for urine hCG		

Exhibit 9-10. NHANES competency assessment plan (continued)

CDC – NHANES Westat 1600 Research Blvd. Rockville, MD 20850		Assessed By: Initials: Date: Reviewed By:			
Competency Assessment (Testing Personnel) (continued)					
Name:		Job Title(s):		Lab Section:	
Elements of Competency Applicable to Test System	1. Direct Observation of Testing 2. Review/Reporting Results/Critical Values		3. Review QC, PT, PM 4. Direct Observation PM		5. Blind Testing (PT, QC, RS) 6. Evaluate Problem-Solving Skills
Test System	Component/Process/Analyte	Elements to Assess	Acceptance Criteria	Acceptable/Comments	Date Completed
Hematology Specimen Processing <input type="checkbox"/> Waived <input type="checkbox"/> Non-Waived	Routine Specimen Collection/Transport/Processing	1,6	Pass Specimen Processing Quiz (Score >90%)		
	Criteria for Accepting/Rejecting Specimens	1,2	Evidence of daily work must demonstrate 100% proficiency with recognizing unacceptable specimens and the appropriate disposition.		
CBC Analysis <input type="checkbox"/> Waived <input type="checkbox"/> Non-Waived	Beckman Coulter DxH 800 <ul style="list-style-type: none"> • WBC • nRBC • RBC • HGB • HCT • PLT • 5-Part Diff • Segmented neutrophils • Monocytes • Lymphocytes • Eosinophils • Basophils 	1	Complete direct observation checklist for DxH 800 system and score 100%		
		2	Review of test results and critical value reporting.		
		3	Review QC results.		
		4	Complete direct observation for DxH 800 maintenance and maintenance documentation.		
		5	Successfully participate in CAP/API PT.		
		6	Complete problem-solving scenarios.		

Abbreviations

API	American Proficiency Institute
CAP	College of American Pathologists
CBC	Complete Blood Count
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare and Medicaid Services
ERB	Ethics Review Board
FES	Facilities Equipment Specialist
IQAP	Interlaboratory Quality Assurance Program
ISIS	Integrated Survey Information System
LAN	Local Area Network
LPM	NHANES Laboratory Procedures Manual
MEC	Mobile Examination Center
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
PC	Personal Computer
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
SP	Study Participant
U.S.	United States

10. Operational Issues

10.1 Start-of-Stand Activities

The Westat warehouse manager sends supplies for all stands, schedules shipments so that they arrive on or before set-up day, and ships supplies requiring refrigeration to the local field office so that they arrive the day before setup. Laboratory supplies are stored in the mobile examination center (MEC) until set-up day. On set-up day, the supplies are inventoried and put away in the laboratory and MEC trailer compartments.

On set-up day, the phlebotomists will complete the set-up activities for phlebotomy, and clinical laboratory scientists will work together to complete the set-up activities for the laboratory workstations. These activities include assisting in unpacking the warehouse boxes, sorting the laboratory supplies by storage location, completing an inventory of all existing and new supplies, organizing and storing all inventoried supplies in the MEC laboratory or trailer compartments, and setting up each work area by stocking the area with appropriate supplies.

In addition, clinical laboratory scientists will perform the following tasks:

- Maintenance on and testing the functionality of all instruments and equipment.
- Completing the inventory sheet, noting deficiencies in the inventory, and then giving the completed inventory list and list of the deficiencies to the MEC manager to send with the lists from the other components to the warehouse.
- Documenting instrument and equipment malfunctions in the Troubleshooting Log if applicable.
- Marking and storing miscellaneous hardware and original packing boxed in a safe location in the laboratory until the end of stand. Hardware includes wood blocks with Velcro (or split foam tubing) refrigerator caps, items to secure the freezer glycerin bottles during transport, restraining straps, and straps for the Beckman Coulter® DxH 800 instrument and printer.

Other tasks that the phlebotomists and clinical laboratory scientists will perform separately within each work area are described in further detail in Sections 10.1.1 and 10.1.2.

10.1.1 Phlebotomist and Facilities and Equipment Specialists Responsibilities

Phlebotomy Room

The phlebotomists' and the facilities and equipment specialists' (FESs') responsibilities include the following tasks:

Setup

- Complete the inventory sheet, note deficiencies in the inventory and then give the completed inventory list and the list of the deficiencies to the MEC Manager to send with the lists from the other components to the warehouse. Phlebotomy tube trays received from the warehouse at ≥ 80 percent filled will be considered a complete tray for inventory.
- Check the sink for hot and cold running water and proper drainage.
- Remove the wood block (or foam tubing) from the refrigerator door (done by FES).
- Turn on the refrigerator in phlebotomy (done by FES).
 - Verify the refrigerator's operation.
 - Clean the refrigerator.
- Unlock all cabinets.
- Release the phlebotomy chair restraint.
 - Pull up on the black lever on the lock and loosen just enough to separate the S bolts.
- Check the function of the telephone intercom (done by FES).
- Clean all work surfaces and storage areas using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Stock and organize supplies.
- Check the computer operations.
- Store the chair restraint and the wood block in the bottom right drawer.

Daily

- Perform daily QC;
- Perform venipunctures;
- Label and pass tubes to laboratory;
- Update Phlebotomy Refusal spreadsheet;
- Assist in WS1 labeling tubes if needed; and
- Assist in other components as needed.

Weekly

- Assist with shipping activities.

End of Stand and Teardown

- Print inventory sheets;
- Count existing inventory in phlebotomy;
- Clean refrigerator using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed;
- Clean all surfaces, storage areas, and phlebotomy chair using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed; and
- Send to the warehouse Vacutainers™ that will not expire before the current MEC is active. Send partial and unopened trays. Discard supplies that will expire at the end of stand.
 - BD Vacutainer 7 mL Gray VOC
 - BD Hemogard 2 mL Gray Top
 - BD Hemogard 3 mL EDTA Lavender
 - BD Hemogard 4 mL EDTA Purple Top

- Greiner-Bio Vacutainer® 6 mL EDTA
- BD Vacutainer 10 mL Red Top
- BD Hemogard 6 mL Royal Blue Top

Note: The EOS transfer inventory sheet will be used to indicate which items were sent back to the warehouse (refer to Section 10.3.6).

- Send Phlebotomy Refusal Spreadsheet to Home Office Staff; and
- Secure all supplies and equipment for transport.

10.1.2 Clinical Laboratory Scientists' and Facilities and Equipment Specialists' Responsibilities

Laboratory

Clinical laboratory scientists' responsibilities include the following tasks:

- Inventory consumables and non-consumables (see Section 10.3.5 to determine what items fall in these two categories).
- Add received dates to all reagents and supplies with expiration dates and/or lot numbers.
- Check the sink and eyewash for cold running water and proper drainage (done by FES).
- Perform eyewash station flush (technologist in Workstation 3):
 - Unscrew the spray head and remove the filter, if applicable, before flushing the eyewash unit.
 - Flush until water runs clear (at least 1-2 minutes).
 - Reinsert the filter, if applicable, and screw the spray head on tightly.

Note: This procedure should be performed after low pressure water events as well as the Start of Stand.

- Install Emergency Alert radio (done by FES).
- Check phone operation (done by FES).
- Remove the wood door blocks from the refrigerators and freezers and store (done by FES).

- Remove the rubber banded gloves from the freezer glycerin bottles, unwrap the probe, and place the probe assembly on the bottle (done by FES).
- Place the freezer temperature probes back into the bottles (done by FES).
- Power on the refrigerators and freezers (done by FES a week ahead).
- Verify freezer and refrigerator operation.
- Check light, blowers, and magnehelic pressure gauge reading in the Laminar Flow Biological Safety Cabinet (LFBSC).
- Remove and release the restraining strap on the Beckman Coulter® printer and store the straps until the end of the stand (done by FES).
- Contact Beckman Coulter® at 1-800-223-0130 to schedule instrument verification by a service technician at least 7 days before set-up day. Provide the current address and instrument system ID.

Note: This activity is performed at the end of stand by the technologist responsible for the Coulter at the next stand.

- Perform all Beckman Coulter® beginning of stand operations as described in Chapter 6; this includes performing a start-up procedure and reviewing and verifying the system setup.
- Calibrate the Beckman Coulter® DxH 800. Complete the calibration, carryover, and repeatability studies before running the quality control (QC) material. Verify that the instrument is working within acceptable parameters before performing routine complete blood counts (CBCs) on study participants (SPs).
- Unpack the Mettler Toledo scale and store the carrying case in an easily accessible area. Level the balance. Perform the QC and calibration on the Toledo Scale and complete the QC before performing routine urine flow rates on SPs.
- Assemble both centrifuges and perform maintenance.
- Unpack and set up the vortex in the safety hood.
- Refrigerate the urine pregnancy controls, and Beckman Coulter® Latron and 6C Cell controls as soon as they arrive.
- Make sure all work surfaces and storage areas are clean and disinfected. Clean the surface and storage areas using the NHANES COVID-19 Mitigation protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.

- Stock and organize supplies.
- Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Open and label all new specimen containers using the laboratory application.
- 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 QC activities in the Laboratory QC module.
- Call FedEx to check availability for sample shipments (1-800-463-3339).

Duties by workstation are presented in Section 10.1.3.

10.1.3 Workstation Responsibilities for the Team

Workstation 1

Setup

- Print inventory sheets.
- Assist in recording inventory and putting all the supplies away.
- Count, cut open, and store all shippers in the designated belly compartments.
- Place “date received” labels on all reagents and consumables with expiration and/or lot numbers.
- Rotate stock based on expiration dates.
- Open new specimen containers using the laboratory application and assign container IDs. Print and adhere labels to containers and store in refrigerators/freezers.
- Discard any laboratory-generated trash (i.e., boxes, plastic, etc.).

- Call FedEx and obtain the following information:
 - The latest available time to call and schedule a pickup;
 - Pickup window for the area;
 - Determine the last available pickup times Monday through Friday, as well as the weekend; and
 - Ask if there is a local facility accepting dangerous goods (e.g., dry ice for late drop-off).
- Prepare racks for the dry run session (**with the assistance of the phlebotomist**). For dry run SPs, place a yellow cryodot on the vessels when labeling the vessels for that session. Do not obscure the graduated lines on the vessels when placing the cryodots on them.
- Ensure that Workstation 1 (WS 1) is neat, clean, and organized in preparation for the start of examinations.

Daily

- Review session and prepare racks for each session (place all urine labels in WS 3).
- Prepare any newly appointed SP racks or pull any rescheduled racks that have been added to the current session.
- Prepare all racks for each upcoming sessions (through at least the first session after the upcoming weekend).
- Assist holding children in phlebotomy.

Note: In the absence of the phlebotomist, the WS 1 clinical laboratory scientist is responsible for phlebotomy.

- Check the informed consent status throughout the session and add yellow dots to the affected vessels for those SPs who refuse future studies. Let the WS 3 clinical laboratory scientist know of a “yes” informed consent status so the extra urine sample vessels can be discarded for that SP. If the SP refuses future studies, vessels 52 and 139 will not appear on the urine processing screen.
- If time permits, prepare Class 9 labels for the next stand.
- Keep workstation clean, organized, and stocked.

Weekly

- Ensure that there are enough frozen U-tek™ refrigerant packs for shipping.
- Wipe templates with Sani-Cloth Plus disposable wipes.
- Ensure that there are enough return shipment packets for shipping.
- Prepare for weekly shipping: generate airbills and return packets.

Shipping Day

- Pull and label shippers.
- Assign containers to shippers.

End of Stand and Teardown

- Assist in printing the inventory sheets.
 - Do not include in the inventory count any supplies that will expire before the next stand and before the current MEC is operational again. Discard those supplies at the end of stand.
- Record WS 1 inventory.
- Prepare for the final shipment.
- Wipe templates with Sani-Cloth Plus disposable wipes.
- Assign containers to shippers.
- On shipping day, perform functions of the “**outside person**” (pack all frozen containers into shippers with dry ice).
- Clean freezers #5 and #6.
- Tear down WS 1 (shut down and secure computer, turn off the uninterruptible power sources [UPS], strap down printer and back roller cabinet, and unplug Dymo printer and scanner and store in the phlebotomy bin, unplug the zebra printer and store in original box under counter, and wipe down back countertop).
- Shred the remaining preprinted airbills and Class 9 labels for the current stand.
- **Lock** all cabinets and drawers in the work area.
- Help strap down and secure refrigerators and freezers for transport.

Workstation 2

Setup

- Assist in recording inventory and putting away supplies.
- Place receive date on all reagents and on consumables with expiration dates and/or lot numbers.
- Rotate stock based on expiration dates.
- Set up the laminar flow biological safety cabinet (LFBSC).
- Set up the centrifuges: Apply paint to graphite, to all pins on the rotor at each lubrication point, and to each pin socket on the bucket. Apply a light coat of SPINKOTE™ to the drive hole of the rotor, and grease the black O-rings of each canister. Wipe down the drum of the centrifuge using Terri-wipes to remove any debris present.
- Set up pipettes and check settings on pipettes, especially the 5 mL pipette (purple pipettor) volumes.
- Set up the vortex in the LFBSC.
- Place new, labeled specimen containers in refrigerators and freezers.
- Ensure that WS 2 is neat, clean, and organized in preparation for the start of examinations.

Daily

- Process blood specimens (whole blood, plasma, and serum).
- Complete container mapping (**after each session block**). Verify cryodots have been applied to dry run, guests, and non-consented SPs for future studies.
- Verify that red caps are used for the appropriate vessels.

Note: This will also be detailed when verifying the vessels in the Integrated Survey Information System (ISIS).

- Stay late to finish any processing if necessary.
- At the end of each exam day, discard any 7 percent and 1 percent ascorbic acid remaining at the end of the last session of the day.
- Keep workstation clean, organized, and stocked.

Shipping Day

- Wrap all weekly or automatically closed whole blood and serum specimen containers for shipping.

End of Stand and Teardown

- Do not include in the inventory count any supplies that will expire before the next stand and before the current MEC is operational again. Discard those supplies at the end of stand.
- Record WS 2 inventory.
- Clean Eppendorf Pipettes.
- Tear down and clean centrifuges according to manufacturer's directions; clean vortexes, laminar flow hood, freezers #2 and #4 and countertops using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Tear down workstation (shut down and secure computer, turn off the UPS, strap down printer, unplug Dymo printer and scanners [store in phlebotomy bin]).
- Help strap down and secure refrigerators and freezers for transport.
- **Lock** all cabinets and drawers in the work area.

Workstation 3

Setup

- Set up the Beckman-Coulter service call before arriving at the next stand (rep should "wet the analyzer" and adjust the flow cell, if needed). Remove the travel brackets.
- Place receive date on all reagents and consumables with expiration dates and/or lot numbers. Add opened dates to the reagents and consumables as they are opened.
- Rotate stock based on expiration dates.
- Record inventory and assist in putting away supplies.
- Set up and calibrate the DxH 800.
- Set up, balance, and calibrate the scale.

- Perform SOS QC and enter into **SOS module** in ISIS.
- Perform SOS maintenance on DxH and record actions on log.
- Obtain new Hematology Troubleshooting Log and DxH Maintenance log from blank forms from Lab section in ISIS Network> Staff>Lab.
- Ensure that all freezers have antifreeze and are wiped free of dust and dirt from traveling.
- Ensure that the workstation is neat, clean, and organized in preparation for the start of examinations.
 - Clean workstation using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.

Daily

- At each session, enter and verify QC.
- Make ascorbic acids (1% and 7%) for daily use.
- Verify daily checks on DxH 800 and run and review QC:
(**First Session Block:** Latron and 6C controls; **Afternoon and End of Day Session Blocks:** 6C controls only).
- Perform pregnancy QC and record results in the **Pregnancy QC module**.
- Enter daily QC in **Daily QC module** in ISIS (scale weights, laminar flow hood pressure, humidity, preparation of 1 percent and 7 percent ascorbic acid, centrifuge temps, and room temps).
- Review and initial printed daily checks printout.
- Weigh and process urines (as they are brought into the laboratory).
- Perform urine pregnancy tests ASAP.
- Run CBCs.
- Process VOC tubes.
- Process Genetics tubes.
- Process Glycohemoglobin tubes.

- Perform container mapping (**after each session block**).
- Keep workstation clean, organized, and stocked.
- Log off DXH at the end of the day.

Weekly

- Perform and enter weekly QC into **Weekly QC module** in ISIS.
- Transmit Coulter QC into ISIS.
- Wash all racks (Nalgene cryovial racks and Nalgene 13 mm and 16 mm half racks), centrifuge cups, and rocker pads according to the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed at the end of the week.
- Perform weekly DxH maintenance.

Shipping Day

- Call FedEx and schedule a pickup.
- Label new containers and put them into their respective freezers or refrigerators.
- Wait for the scheduled FedEx pickup.

End of Stand and Teardown

- Schedule extended shutdown with Coulter 1 to 2 weeks before teardown.
- Follow the “Coulter DxH Shutdown Procedure” (print off all graphs, QC, transmit, clean analyzer, etc.).
- Return to the warehouse:
 - Unopened Coulter Cell Lyse (unless expiration date is before the opening of the next stand for this MEC).
 - Unopened Coulter Diff Pack (unless expiration date is before the opening of the next stand for this MEC).
 - Pregnancy Test Kit (ICON 25).
 - Sure-Vue hCG Urine Control Set. Do not send back opened controls; discard.

- Coulter Latron CP-X control. Discard if it has a short expiration date. Do not send back opened control; discard.
- Coulter 6C cell Control. Discard if it has a short expiration date. Do not send back opened control; discard.
- Urine Mercury tubes.

Note: The EOS transfer inventory sheet will be used to indicate which items were sent back to the warehouse (refer to Section 10.3.6).

- Dispose of:
 - Coulter Diluent
 - Coulter Cleaner

Note: Fill out the Removal of Expired/Broken/Deleted Inventory Form on the portal.

- Prepare EOS FedEx box to be sent to the lab component lead.
- Prepare box(es) of miscellaneous supplies to be returned to warehouse.
- Do not include in the inventory count any supplies that will expire before the next stand and before the current MEC is operational again. Discard those supplies at the end of stand.
- Record WS 3 inventory.
- **Wash everything**, including all racks (Nalgene cryovial racks and Nalgene 13 mm and 16 mm half and full racks), centrifuge cups, and rocker pads, and all Tupperware according to the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Unplug scale, clean platform (as above), and remove. Place cone on platform head. Place all in hard case, then store case in a cabinet.
- Clean freezer #3 and refrigerator #1 using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Help ship by assisting in the packaging of refrigerated specimens.
- Tear down WS 3: Shut down and secure computer, turn off the UPS, strap down printer, unplug Dymo printer and scanners (store in the phlebotomy bin), and wipe down workstation countertop as above.

- Be available for the Extended Shutdown of the DxH by the Beckman Coulter representative.
- Strap down and secure the DxH, as well as the DxH computer (the FES does this after the Coulter FSE has completed the shutdown procedures).
- **Lock** all cabinets in the work area.

10.1.4 National Center for Health Statistics Biomedical Engineer Responsibilities

The National Center for Health Statistics (NCHS) biomedical engineer's (annual) responsibilities include the following tasks:

- Determine the RPM of the centrifuges using a strobe or tachometer.
- Perform a timer check.
- Verify that both centrifuges are operating at 4°C to 8°C.
- Enter the results in the **Laboratory QC module**.

10.2 Additional End-of-Stand Activities

On teardown day, the phlebotomist and clinical laboratory scientists will work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Safely discard all biohazardous waste.

10.2.1 Packing the Phlebotomy Room

- Phlebotomists' responsibilities include the following tasks:
 - Inventory consumables and non-consumables (see Section 10.3.5 to determine what items fall in these two categories).
 - Discard and do not inventory any consumables—including Vacutainer[®] tubes—that will expire before the next time the MEC is operational.
 - Package and send the applicable Vacutainer[®] tubes that will not expire before the next stand to the warehouse.

- Selected phlebotomy collection tubes will be sent back to the warehouse to maintain the manufacturer’s recommended temperature range. Partial trays will be combined with same lot partial trays from the warehouse to create full trays that can be redistributed out to the MECs for use. For tube trays that are open, keep the original plastic wrapping with the tray, if possible.
- Turn off and clean the refrigerator in the phlebotomy room.
- Place wood blocks with Velcro strips on the refrigerator doors to prevent the doors from closing or moving. Be careful not to damage the rubber gasket on the door.
- Pack into drawers all cookies and juices that have not been refrigerated. Discard any loose juices (not in original eight-pack wrapping). Discard and do not inventory any juice packs or cookies that will expire before the start of the next stand for the current MEC.
- Remove all loose supplies (clock, telephone handset, etc.) and equipment from the countertops; pack loose supplies in the cupboards above the counter. If these areas are full, place the boxes in the designated compartments under the trailers. Do not store Vacutainer® tubes in the trailer compartments.
- Bolt the room doors in the open position.
- Close and lock all cabinets.
- Lock all needles in the cabinets.
- Restrain the phlebotomy chair.
 1. Attach the S bolt on the end of the orange belt to each of the two wall brackets (under the drop-down chair).
 2. Attach the center S bolts to each other in the center of the orange belt.
 3. Tighten the belt by pulling on the free end of the belt.

10.2.2 Packing the Laboratory

- Clinical laboratory scientists’ responsibilities include the following tasks:
 - Close and ship all containers to appropriate contract laboratories.
 - Inventory consumables and non-consumables. This may be done 1 to 2 days before teardown, if usage for the remaining sessions is accounted for.
 - Package and send the supplies described earlier in this chapter to the warehouse.

- Pack supplies using procedures described in Chapter 8.
- Perform the Beckman Coulter® end-of-stand procedures as described in Chapter 6.
- Check the expiration dates on the Beckman Coulter® 6C 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.
- Turn off the centrifuges.
- Turn off printers.
- Shut down all computers using the desktop computer X-shutdown icon.
- Turn off all UPSs (coordinate with FES).
- Clean refrigerators and freezers using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Replace the refrigerator temperature probe bottle caps (with holes) with the bottle caps without holes, and save the caps with holes for reuse at the start of the next stand. Place the glycerin temperature probe bottle in the sink. Clean the temperature probes and wrap securely with Terri wipes. Leave probes securely in place.
- Place wood blocks with Velcro strips or foam inserts 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.
- Turn off the Mettler Toledo scale. Disconnect the scale from the tan serial cable and black AC adapter power cord. Tape the serial cable and power cord to the countertop. Repack the Mettler Toledo scale in the blue carrying case, making sure to remove and store the weigh pan in the lid of the carrying case, and cover the scale cone with the plastic cone protector. Securely store the scale for transport.
- Disinfect and clean the pipettes.
- Clean and power down the LFBSC. Clean as described in sections above according to COVID mitigation procedures for as long as applicable.
- Remove centrifuge rotors, clean and pack in foam-lined bins. Remove and clean metal rotor buckets and store in same foam-lined bin. Clean and store in a drawer the plastic Aerosolve® canisters and sample holders. Clean interior and exterior of centrifuges. Close centrifuge lids and turn off centrifuges. Clean as described in manufacturer's directions.

- Pack all tube rockers and Zebra printer securely in boxes.
- Power down and secure with a strap the HP printer in Workstation 1.
- Remove all small supplies from the counters and LFBSC and pack in boxes or cabinets. Store mini vortex in original box keeping with other like items.
- Disconnect all barcode readers and Dymo label printers. Store in plastic bin in phlebotomy room.
- Secure all computer cables to the counter with tape or clips.
- Power down computers using the X-Shutdown icon under utilities.
- Remove the clock from the wall. Remove the battery and tape it to the back of the clock. Place clock in available space in drawer.
- Cover computers with padded sleeves and strap with bungee cord to the wall, placing the monitor and mouse securely inside the straps against the padding.
- Close all cupboards and drawers and lock.
- Clean all counters and the LFBSC using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed.
- Remove all trash, and place regular waste cans flat on their side under a counter. Remove all biohazard waste.
- After DxH has been shut down by the Coulter FSE, attach strap around the bottom front of the DxH 800-the FES does this.
- Secure the Beckman Coulter® printer by strapping it to the printer shelf.

10.2.3 Sending Laboratory Files and Supplies

At the end of each stand, use FedEx to create a label to send the following hard-copy documentation to the Lab Component Lead at the home office and place a printout cover sheet for each bulleted item listing its contents:

- Beckman Coulter® Latron and 6C Cell Control cumulative statistic and graph printouts.
- Beckman Coulter® Daily checks printouts.
- Beckman Coulter® Calibration, repeatability and carryover printouts.

- Beckman Coulter® Linearity printouts.
- Proficiency testing copies (hematology and urine).
- CD discs with IQAP, event logs, and SP data.
- Insert sheets for Coulter QC, Latron, and Calibration materials.
- Troubleshooting Log (make a copy and keep it with the instrument logbook).

10.3 Inventory Procedures and Supplies

At the start and end of each stand, take a complete inventory. The warehouse uses this inventory to stock the MEC for the next stand.

10.3.1 General Inventory Procedures

- Because item units can change, verify the unit of measure each time you record a count. Examples of units are bag, bottle, box, case, each, pack, pair, pouch, roll, and tray.
- Do not redefine or reiterate the unit of measure.
- *Par level* represents the number of units with which the component is to begin a stand. Par levels are set and adjusted by home office component staff only. All recommendations to adjust an item's par level should be directed to the home office component staff.
- Do not write any notes, comments, or concerns on the Start of Stand Inventory Count Sheets or the End of Stand Inventory Count Sheets. Write comments or concerns on a separate sheet of paper and attach it to the inventory sheet.
- Rotate items by first using what you have in the rooms, then use items in the trailer belly compartment. Place items you just received in the back of the stock, unless you need them immediately. When you are out of items in your room, restock your rooms only with items that were just shipped to the stand. Many items, such as gloves, alcohol prep pads, Sani-Cloth wipes, and blood tubes, deteriorate over time. Always use inventory with the closest expiration date first.
- Multiple inventory items onboard the MEC contain lot numbers and expiration dates. When performing physical inventory counts, pay close attention to these items and mark inventory sheets accordingly for each lot number/expiration date per item.

- Do not purchase items listed on the inventory sheets. Every item listed on the inventory sheet is supplied by the NHANES Warehouse. Purchasing items locally complicates the Inventory Management System (IMS) process.
- Do not borrow items from other components. Any additional inventory needed by a component should be requested from the NHANES Warehouse. Inventory usage is tracked by component. The “Counted By tech ID” is entered into the database to track inconsistencies and trends. Everyone is accountable for their component counts.

10.3.2 End-of-Stand Inventory Procedures

The End of Stand Inventory Count Sheet (EOSCS) includes the stand number, site ID (MEC number), a Counted By line, and Exam Supply columns for item number, general item description, unit designation, par level, and a count box. The MEC Manager prints these EOSCSs for every component. **MEC staff is responsible for accurately counting (inventorying) exam supplies and entering this number into the count box.** MEC staff will give the completed sheets back to the MEC Manager who sends them to the warehouse manager. The warehouse manager enters the item counts into the IMS.

- Print only one name in the Counted By field. This is the person responsible for taking and verifying the inventory count. Please write legibly for all counts.
- Place a number in each count box. **Do not leave any count box empty.** If there is no stock remaining for a specific item, enter a “zero” (0) in the count box.
- Do not count partial units; record only whole numbers in the count box. **Do not write** entries such as a few, .5, 1/2, couple, partial, some, many, or multiple.
- If the PAR for an item is only one (1) unit and it is more than half empty, enter a zero (0) in the count box. A full unit will be supplied to the component at the opening of the next site where the MEC is active.
- All active lot numbers and expiration dates are listed on the inventory count sheets if they are applicable for that item. Record the number of supplies remaining for each lot number/expiration date in the count box. If there is no inventory remaining for a listed lot number/expiration date, enter a “zero” (0) in the count box.

10.3.3 Mid-Stand Inventory Procedures

Mid-stand inventory is performed by each component on the MEC, approximately 2 to 2½ weeks into an operating site. A schedule of the appropriate order and delivery date for mid-stand inventory will be noted on each stand’s calendar by the chief technologist. This date will be set by the

warehouse and approved by the laboratory component lead. This inventory provides the opportunity for MEC staff to request additional supplies from the warehouse that will be needed to complete sessions at the current MEC site. Mid-stand inventory is conducted via UFO entry (per component). **Note: Mid-stand inventory is only to provide additional supplies needed to complete the current site; it is not designed to bring all supplies up to full-par level.**

- Each component will review all remaining inventory to determine if additional supplies are needed to complete sessions at the current MEC site.
- A UFO will be entered (sighted) by one MEC staff member per component.
- MEC staff will enter a UFO by component name and then select “inventory/supplies” for the type of UFO entry.
- In the description field, the MEC staff member will request the supply or supplies needed for the component.
- Entries are to be made as item description, then quantity requested (per item).
- If no additional supplies are needed for the component, record “Nothing needed” in the description field.
- **Do not:**
 - Request items in the UFO that are not on the component inventory list.
 - Request changes to set par levels in mid-stand UFOs.
 - Enter equipment issues in a UFO listed as inventory/supplies.
- All completed UFO entries will be reviewed by the MEC Manager for that MEC before the warehouse will pull and ship supplies requested.
- Once the supplies have been pulled by the warehouse and packed for shipping to the MEC, the warehouse manager will finalize the UFO.

10.3.4 Start-of-Stand Inventory Procedures

The Start of Stand Pull Sheets (SOSPS) include the stand number, site ID (MEC number), and Exam Supply columns for part number, general item description, previous EOS count number, par level, unit designation, and a ship-to-stand box. The warehouse manager uses this report to stock each item to par level. For example, if the previous EOS count (captured by the IMS) is four and the

par level is five, the ship-to-stand count box will contain the number one (1). The warehouse manager prints and packs one pull sheet for each component. **The MEC staff is responsible for accurately reconciling the supplies and numbers in the SOSPS.** The MEC staff give the completed sheets back to the MEC Manager who returns them to the warehouse manager. The warehouse manager reviews each sheet and sends additional supplies to the field if necessary. The MEC staff conduct the tasks listed below:

- Reconcile the inventory for each item.
- Verify that the start-of-stand shipment contains the exact number of each item listed in the ship-to-stand box.
- Ensure that the previous EOS count is added to the ship-to-stand count box and that it equals par level.
- Place a checkmark on the right side of the ship-to-stand count box (per item), if the total inventory equals the set par level.
- Write the physical count on hand to the right of the ship-to-stand count box (per item) if there is a discrepancy.
- Remove the excess from a component (leaving par) and return it to the warehouse, if the quantity for an item is higher than the set par level. If an item(s) is being returned to the warehouse, print a Transfer Inventory to Warehouse Count Sheet for the component. Print your name on the inventory sheet. Mark only the quantities for item(s) that are being returned. Ship the supplies back to the warehouse.

The warehouse manager will also reconcile the inventory that was sent back to the warehouse during the previous EOS inventory of the MEC. This entails the shipping by the warehouse of either unopened vacutainer tube trays or salvaged trays of the same lot obtained from the EOS transfer of supplies back to the warehouse from the other MECs. The warehouse manager will also ship either new Coulter reagents or transferred unopened items from the EOS transfer inventory of the other MECs. This procedure is done to adhere to the manufacturer's climate requirements for the medical devices/reagents and to maintain supply economy of our consumable supplies.

10.3.5 Consumables Versus Non-Consumables

Inventory items are divided into two categories—consumable and non-consumable. Inventory both types of items during each inventory. A *consumable item* is anything that is typically consumed during an examination (e.g., Vacutainer tubes). A *non-consumable item* is one that can be used more than once

(e.g., stopwatches, test tube racks, safety glasses, storage boxes). There are times when non-consumable items will need to be replaced. These instances would include items that are used in an emergency, when the item expires, or when the item breaks (e.g., clinician medical kit supplies, stopwatches, thermometers, CPR masks).

10.3.6 Shipping Inventory Back to the Warehouse

When shipping inventory back to the warehouse, print the Transfer Inventory to Warehouse Sheet, which is found on the portal. This form looks similar to the End of Stand Count Sheets. Print your name in the Counted By field and mark only the items (with quantity being returned) in the count boxes that are being shipped back to the warehouse. Ship the items to be returned along with the Transfer Inventory to Warehouse Inventory Sheet back to the warehouse. This information is entered into the Inventory Management System by the warehouse manager and is used to adjust the stand inventory and usage information and to increase the warehouse inventory counts.

10.3.7 Tracking Expired and Broken Inventory

Complete the Delete Expired/Broken Inventory Report when inventory has expired and must be destroyed, needs to be discarded at the EOS, or has broken and is no longer usable. Print your name in the Counted By field and mark only the item(s) in the count box that has expired, needs to be discarded, or is broken, or is being removed from the MEC. This report is found on the portal and should be completed and forwarded to the warehouse manager so that the expired or broken inventory can be removed from the stand inventory. Unless the item is a tool or piece of equipment, under most circumstances it can be disposed of in the field and there is no need to return it to the warehouse. Check with the MEC Manager or call the warehouse manager to verify the need to ship the expired/broken item back to the warehouse.

The clinical laboratory scientist and the phlebotomist are responsible for notifying the warehouse manager through a UFO if additional supplies are needed during the stand. However, each clinical laboratory scientist and phlebotomist is responsible for identifying any potential shortage of supplies at each workstation and in phlebotomy. If needed, contact the warehouse manager directly at 301-212-3759.

10.4 Equipment Maintenance and Use

10.4.1 Allegra X-15R—Equipment Maintenance and Use

The clinical laboratory scientist is 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.

Centrifuge Function

The Beckman Coulter Allegra X-15R centrifuge is a refrigerated benchtop centrifuge that generates centrifugal forces required for a wide variety of applications. Together with the Beckman Coulter rotors designed for use in this centrifuge, the centrifuge applications include the following:

- Routine processing such as sample preparations, pelleting, extractions, purifications;
- Concentrations, phase separations, receptor binding, and column centrifugations;
- Cell isolation;
- Binding studies and separation of whole blood; and
- Rapid sedimentation of protein precipitates, large particles, and cell debris.

Each MEC laboratory contains two Allegra X-15R benchtop refrigerated centrifuges.

Safety Features

The Allegra X-15R centrifuge has been designed and tested to operate safely indoors at altitudes up to 2,000 m (6,562 ft). Safety features include the following:

- An electromechanical door lock system prevents operator contact with spinning rotors and prevents run initiation unless the door is shut and locked. The door is locked when a run is in progress and can be opened only when the rotor is stopped and the LED (light-emitting diode) next to the DOOR key is lit. If there is a power failure, the door lock can be manually tripped for sample recovery.
- A steel barrier surrounds the rotor chamber to provide full operator protection.
- A rotor identification system prevents the installed rotor from running above its maximum rated speed. During acceleration the microprocessor checks the magnetic rotor identification. Speed is limited to the maximum safe speed of the identified rotor. If the system identifies a rotor different than the one entered by the user, the system

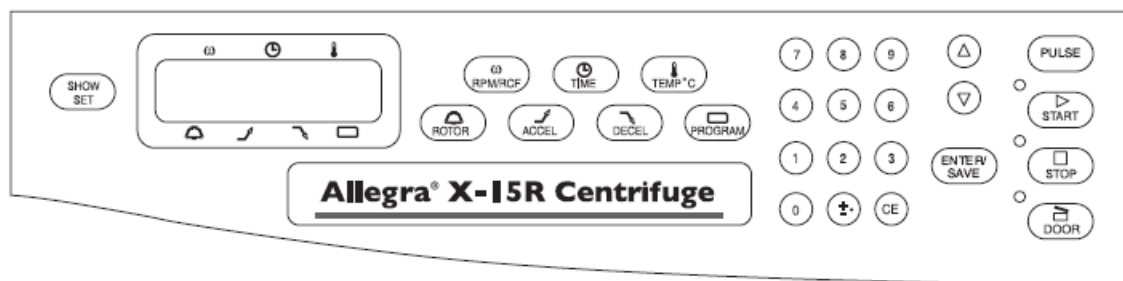
displays an error message and reduces the speed to the maximum allowable speed of the rotor.

- An imbalance detector monitors the rotor during the run, causing automatic shutdown if rotor loads are severely out of balance. At low speeds, an incorrectly loaded rotor can cause imbalance. Rotor instability can also occur if the centrifuge is moved while running, or if it is not resting on a level and secure surface.

Control Panel

Exhibit 10-1 is a diagram of the centrifuge control panel.

Exhibit 10-1. Centrifuge control panel



The control panel is mounted at an angle on the centrifuge front for easy visibility and access. It is used to enter run parameters via function keys and a keypad, and to display run parameters, program information, and user messages.


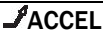





Digital Displays

The displays (Exhibit 10-2) provide run information, user messages, and diagnostics.

Exhibit 10-2. Digital displays

SPEED	Indicates rotor speed in revolutions per minute (rpm) or in relative centrifugal field, a term describing the ratio of the centrifugal acceleration at a specified radius and speed to the standard acceleration of gravity (RCF x g).
TIME	In a timed run, indicates the remaining run time in hours and minutes. The time display begins counting down when ENTER/SAVE and then START are pressed and continues counting down to 0. The run automatically ends when the set time reaches 0 and deceleration begins (a tone sounds when the rotor stops spinning). If a malfunction shuts down the centrifuge during a run, when the instrument is turned back on the time will not remain and 00:00 will be displayed in the time window. By comparing this time with the original set time, you can determine when the run ended.
TEMPERATURE	Indicates rotor temperature in degrees C at thermoequilibrium.

Exhibit 10-2. Digital displays (continued)

 ROTOR	Displays the name of the selected rotor.
 ACCEL	When the (ACCEL) key is pressed, one of 10 available acceleration rates can be entered. Displays the selected acceleration rate throughout the run. Use 10 accelerations.
 DECEL	When the (DECEL) key is pressed, one of 11 available deceleration rates can be entered. Displays the selected deceleration rate throughout the run. Use 10 decelerations.
 PROGRAM	During setup—when the (PROGRAM) key is pressed, a program number (one of 10 possible) can be selected, and program parameters entered. During centrifugation—the number of the program being run is displayed.
 START	Pressing (ENTER/SAVE), then (START) begins the run. ((START) must be pressed within 5 seconds of pressing (ENTER/SAVE).) This key combination can also be used to abort a deceleration process and restart the centrifuge.
 STOP	Can be pressed at any time while the rotor is spinning to terminate a run. The centrifuge decelerates to a complete stop according to the deceleration setting. The green light next to the key flashes while the rotor decelerates. A tone sounds when the rotor comes to a complete stop.
 DOOR	Unlocks and opens the door. (The instrument will not accept the unlock command if the rotor is spinning.)

- During a run, they show the actual (real time) operating conditions.
- When the run parameters are being entered, they show the set values selected. Set values can be recalled during operation by pressing SHOW SET. After 5 seconds, the displays return to actual conditions.
- Error messages also appear on the displays, when applicable. The centrifuge emits a series of audible tones to alert the user to an error condition.

Speed


For plasma and serum—set the speed at 2,900 rpm.

For washed packed cells vessel 88—set the speed at 1,985 rpm.


Note: To calculate to RPM, use the formula $RPM = \sqrt{\frac{RCF}{r \times 1118}} \times 1,000$ *r = radius of rotor*

Run Procedure

Manual run

1	POWER	Turn the power switch on (I).
2	(DOOR)	Press (DOOR) to open the chamber door; lift the door open.
3		Install the rotor according to the applicable rotor manual, then close the chamber door.
4	(ROTOR)	Press (ROTOR), then press (ROTOR) again or use the arrow keys to select the rotor.
5	(RPM/RCF)	Press (RPM/RCF), then use the keypad to enter the run speed. Press (RPM/RCF) a second time to toggle between RPM and RCF modes, RPM/RCF.
6	(TIME)	Press (TIME), then use the keypad to enter the run time (to 99 hours, 59 minutes); or press (TIME) twice to toggle between hold (continuous) run and set time mode.
7	(TEMP °C)	Press (TEMP °C), then use the keypad to enter the required run temperature - 10 to +40 °C.
8	(ACCEL)	Press (ACCEL), then use the keypad or arrow keys to enter the selected acceleration rate number, 1 (SLOW) through 10 (MAX).
9	(DECEL)	Press (DECEL), then use the keypad or arrow keys to enter the selected deceleration rate number, 0 (OFF) through 10 (MAX).
10	(ENTER/SAVE) (START)	Check that all parameters are correct and that the door is closed (door LED will be lit). Press (ENTER/SAVE), then press (START) (within 5 seconds).
11	(STOP)	Wait for the set time to count down to zero, or end the run by pressing (STOP).
12	(DOOR)	When the rotor stops (a tone sounds and the (DOOR) LED lights), press (DOOR) to open the chamber door; lift the door.

Programmed run

1	POWER	Turn the power switch on (I).
2	(DOOR)	Press (DOOR) to open the chamber door.
3		Install the rotor according to the applicable rotor manual, then close the chamber door.
4	(PROGRAM)	Press (PROGRAM), use the keypad or arrow keys to enter the required program number, then press (ENTER/SAVE).
5	(ENTER/SAVE) (START)	Check that all parameters are correct and that the door is closed (door LED will be lit). Press (ENTER/SAVE), then press (START) (within 5 seconds).
6	(STOP)	Wait for the run to end, or end the run by pressing (STOP).
7	(DOOR)	When the rotor stops (a tone sounds and the (DOOR) LED lights), press (DOOR) to open the chamber door; lift the door.

10.4.1.1 Centrifuge Cleaning

Clean the centrifuge as needed and at the end of each stand. Always clean up spills when they occur to prevent corrosives or contaminants from drying on component surfaces. Clean spills according to COVID-19 mitigation procedures.

- To prevent accumulations of sample dust, and/or glass particles from broken sample tubes, keep the chamber clean and dry by frequent wiping with a cloth or paper towel.
- For thorough cleaning, wash the chamber using a mild detergent such as a 1:10 dilution of Beckman Solution 555.
- Rinse thoroughly and dry completely.
- Clean the centrifuge exterior surfaces by wiping with a cloth dampened with a 1:10 dilution of Beckman Solution 555.
- Remove the rotor from the centrifuge and clean the drive hub regularly using a 1:10 dilution of Beckman Solution 555 and a soft brush.

10.4.1.2 Rotor Care and Maintenance

Note: Do not use sharp tools on the rotor that could cause scratches in the rotor surface. Corrosion begins in scratches and may open fissures in the rotor with continued use.

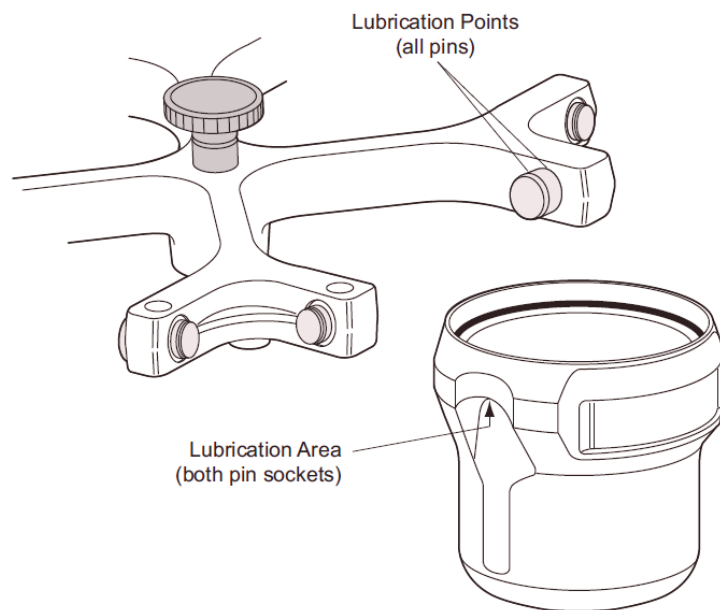
- At the start of stand, inspect the rotor yoke and buckets, especially inside cavities, for rough spots or pitting, white powder deposits—frequently aluminum oxide—or heavy discoloration.
- If any of these signs are evident, do not run the rotor.
- Contact your Beckman Coulter® representative for information about the Field Rotor Inspection Program and the rotor repair center.
- At the start of stand and after cleaning, wipe the rotor pins and pin sockets with a paper towel, and then coat the sockets with Paint-On Graphite lubricant (see Exhibit 10-3).
- Allow the lubricant to dry for at least 5 minutes before installing the rotor in a centrifuge.

Installing the Rotor

- The power must be turned on before you can unlock and open the chamber door. (To end a run for any reason, do not turn the power switch off; press STOP instead.)

- Turn the power switch on. The control panel display shows “Allegra X-15R” and the software version.
- Press DOOR. The centrifuge will accept this command only when the rotor is at rest and the DOOR LED is lit. The door opens and the LED goes out.
- Install the rotor. Ensure that the rotor is seated on the drive hub. Avoid bumping the control panel keys during rotor installation or removal.
- Close the chamber door by firmly pressing down on both sides. The door locks. When the latches engage, the LED next to the DOOR key lights up.

Exhibit 10-3. Lubrication points



10.4.1.3 Cleaning the Rotor

Note: Do not wash the rotor components or accessories in a dishwasher. Do not soak components in detergent solution for long periods, such as overnight.

- If spillage has occurred, or if salt solutions or other corrosive materials are used, immediately clean the rotor and components, and at the end of each stand.
- Do not allow corrosive materials to dry on rotor components.
- After cleaning or at the start of each stand, clean the pins and bucket pin sockets and then lubricate as described under Rotor Care and Maintenance.

- At the end of stand, remove the rotor from the centrifuge for cleaning and lubrication to prevent buildup of residues.
- Use a 1:10 dilution of Beckman Solution 555 and a soft brush to clean the rotor yoke and tie-down knob.

Before reinstalling the rotor, lightly lubricate the drive hole of the rotor (middle hole in the center of the underside) with Anti-Seize (SPINKOTE) 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.

End of Stand Rotor Packing Procedure

Remove rotors from the Allegra X-15R centrifuges and pack in plastic bins designed for rotor storage, for safe traveling. The balance detection mechanism is very sensitive during travel and needs to be protected.

Store the rotor inside of the foam-lined bin. Place the white, cross-shaped hard foam piece onto the rotor spindle after removing the rotor. The hard foam should remain in place until the start of the next stand. See photos (Exhibits 10-4 and 10-5) for proper packing.

Exhibit 10-4. Proper packaging of centrifuge rotors



Exhibit 10-5. Proper packaging of centrifuge rotors (2)



10.4.1.4 Care and Maintenance for Buckets

- Clean the buckets at the end of each stand with a 1:10 dilution of Beckman Solution 555, and then rinse thoroughly and dry completely.
- After cleaning the buckets, lubricate bucket pin sockets with Paint-On Graphite Lubricant as described under Rotor Care and Maintenance.

10.4.1.5 Care and Maintenance for the Aerosolve® Canisters

- Remove the O-ring from the canister before cleaning.
- Clean the canister and O-ring at the end of each stand with a 1:10 dilution of Beckman Solution 555, 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 canister.

Items needed for care and maintenance of the buckets and canisters of the Allegra X-15R, include the Vacuum Grease Silicone, Paint-On Graphite, and SPINKOTE lubricant seen below in exhibit 10-6.

Exhibit 10-6. Vacuum grease silicone, paint-on graphite, and SPINKOTE lubricant



The NCHS biomedical engineer annually certifies both centrifuges. The NCHS engineer determines the RPM of the instruments using a strobe light or a tachometer. The engineer records multiple readings for each centrifuge. The Beckman Coulter® Allegra X-15R 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 in the Laboratory QC module—NCHS QC.

Document beginning and end of stand cleaning procedures in the Laboratory QC module.

For Allegra X-15R Centrifuge cleaning and maintenance, refer to the centrifuge maintenance manual.

10.4.2 Refrigerators and Freezers—Equipment Maintenance

The freezers require proper ventilation to operate efficiently. The air around the freezers must be free to circulate. Do not store anything between the freezers or between rack supports and the freezer. Do not store anything on the top grill.

Quality Control (QC) procedures for the refrigerators and freezers include cleaning them at the beginning and end of the stand and whenever necessary and recording daily temperatures. Document the QC in the Laboratory QC document. Continually monitor the temperatures of refrigerators and freezers on a daily basis, using the Temperature Guard system, which automatically captures and graphs the refrigerator and freezer temperatures, and is available in real time.

Document all unscheduled maintenance for the refrigerators and freezers in the automated Unusual Field Occurrence utility.

10.4.3 Use of the Temperature Recording Instrument

The Temperature Guard system is a multiple device monitor and alarm system that is equipped with an integrated autodialer and data logging capabilities. The Temperature Guard system automatically monitors the interior temperature of the refrigerators, freezers, and room temperature in the laboratory and phlebotomy rooms.

The system can monitor up to eight temperature sensors and each sensor must have a probe submerged into a bottle of resin.

The Temperature Guard system has been programmed with upper and lower limits for all units, including the room temperature, and a 60-second delay for the allowable time the freezer door can be left open before the system will alarm. The system has the capability to send out calls and emails to alert staff to temperature issues.

Checking Temperature Guard Sensors

All temperature sensors connected will have their temperature readings displayed next to the sensor number on the display.

Disabling Alarm

- Push the black button on the left side of the Temperature Guard for MEC 1 and MEC 3 to see any alarm conditions. For MEC 2, the black button is on the top of the Temperature Guard unit.
- Hold the button for 5 seconds to confirm the alarm condition.
- Alarm conditions must be confirmed individually.
- The alarm relay will de-energize, and the Temperature Guard will stop making callouts for the current alarm condition.

Start of Stand Setup

The (FES) will program the Autodialer functions. See the task list below:

Note: The MEC manager phone number needs to be updated at each stand.

- Enter the “Full Access” PIN (Enter **0000**).
- From the Program Menu, Select **1** to set telephone numbers.
- You will hear “**Select contact.**”
- Select **1** for the first contact number (FES phone #).
- Enter your phone number, using this format “**1 + area code + 7 digit #**”
- You will hear “Contact 1 is xxxxxxx” or “Contact x is Empty, press one to change.”
- Press 1 to make a change or enter a telephone number.
- You will hear “Enter number, then press pound.”
- Enter the number, followed by the # key.
 - Entering the # key will erase the currently programmed contact telephone number.

- You will hear the telephone number you just entered.
- You will be prompted to select another contact to program.
- Select 2 for the second contact number (MEC manager's number).
 - For Team 1, enter **1-240-315-3068**
 - For Team 2, enter **1-240-205-0193**
- Press 0 to return to the Program Menu.

The acceptable temperature range for refrigerators used for storage of Clinical Laboratory Improvement Amendments- (CLIA-) regulated specimens and reagents is 2°C to 8°C and is checked and recorded daily.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. All freezers are monitored automatically by built-in visual systems (with thermographic or digital reading), which is determined by the probe in the antifreeze solution. The range of allowable temperature for the -30 Revco model is -26°C to -34°C. If the range is exceeded, the clinical laboratory scientist should contact the FES.

Digital Thermometer Verification Process

- Check the (NIST) traceable thermometers to ensure the expiration date has not been exceeded. If the thermometer's certificate is expired, contact the warehouse to have a new thermometer delivered.
- Place the appropriate thermometer probe in the refrigerator, freezer, or next to the room temperature digital thermometer (Temp-Guard). Placing the traceable thermometer probe next to the digital thermometer probe yields more consistent results. The same thermometer can be used for the refrigerators and room temperature checks.
- Allow the thermometer to remain in the environment to equilibrate for a sufficient amount of time. Avoid opening and closing the refrigerator and freezer doors during this time.
- After the thermometers have equilibrated, record the temperature from the traceable thermometer and the digital thermometer on the Laboratory NIST Temperature Check Sheet.

- Calculate the difference between the two temperatures.
- If the temperatures differ (+/-) by more than 2°C, contact the FES to have the digital temperature reading adjusted to be within the 2°C limits.
- After the adjustment is completed, repeat the process and record the temperature on a new Laboratory NIST Temperature Check Sheet.

Repeat this process until all refrigerator, freezer, and room temperature digital readings are within 2°C of the traceable thermometers.

10.4.4 Use of the Class II Type A Biological Safety Cabinet

The Labgard Model NU-425 Class II, Type A2, 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

Arrangements are made for a certified engineer to perform the required annual certification that includes replacement of high efficiency particulate air (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 (w.g.)” pressure. 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.

Clean the LFBSC at the beginning and end of each stand using the NHANES COVID-19 Mitigation Protocols for as long as the protocols are applicable, or using other cleaning protocols when the COVID protocols are no longer needed. 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. Wash the bottom outside floor and legs of the hood where splashes from the biohazard container may have contaminated the surface. 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 the first session of each exam day.

Document all unscheduled maintenance for the LFBSC in the automated Unusual Field Occurrence utility.

Exhibit 10-7. Operating the laminar flow biological safety cabinet

Operating the NU-425, Laminar Flow Biological Safety Cabinet*

1.1 Operator Controls and Indicators

The following is a description of the controls and indicators found on both the front panel (see Drawing BCD-05322) and cabinet.

1.1.1 Circuit Breaker-Blower (Top of Control Center)

The motor/blower is protected with a circuit breaker. The circuit breaker in conjunction with the motor's thermal protector is designed to open under locked rotor or half-wave power conditions. Should the circuit breaker open (pop-out button will appear), merely depress to reset. If the circuit breaker continually opens, a failure has occurred in the motor or solid-state speed controller.

Consult a qualified repair technician or NuAire, Inc. for replacement.

1.1.2 Circuit Breaker-Outlets (Top of Control Center)

The duplex outlet located in the sidewall of the work area is protected with a 3-amp circuit breaker. The circuit breaker may trip at 110 percent of load rating but will trip at 145 percent of load rating in less than 2 seconds. Should the circuit breaker open, (pop-out button will appear), unplug the appliance plugged into the outlet and merely depress the pop-out button to reset.

1.1.3 Fluorescent/Ultraviolet Light Switch

This switch provides on/off control for the fluorescent light and/or the ultraviolet (UV) light if present (optional). With the UV light option, the switch provides for on-center off-on operation so that both the fluorescent light and the UV light cannot be energized at the same time. The UV light is also interlocked, so it will only operate if the sliding window is closed. Proper care should be exercised when the UV light is on.

* Adapted from NuAire, Inc., (2005). *Operation and Maintenance Manual*. Plymouth, MN: Author.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.1.4 Outlet Switch

This switch provides on/off control for the 115 VAC power available in the outlet(s) within the cabinet work zone.

1.1.5 Blower Switch

The blower switch applies power to the internal motor/blower when in the ON position. The blower switch also has a second set of poles, which are available for use as a contact closure for an exhaust system. In addition, power can be applied to the accessory outlet located on the upper left corner of the cabinet, behind the front window assembly.

The purpose of the outlet is to provide “switched” power for the following:

- Exhaust transition with integral blower; or
- Low power appliance, such as the low airflow alarm or power capper.

The rating of the outlet is 115 VAC at 2 amp maximum.

1.1.6 Indicator Light

An indicator light is located above the blower on/off switch and indicates when power is applied to the blower.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.1.7 Audible Alarm Enable

As the sliding window is raised above its normal working height, a micro switch located in the glide channel activates both an audible and visual alarm. This switch disables the audible alarm but will not disable the red indicator visual alarm.

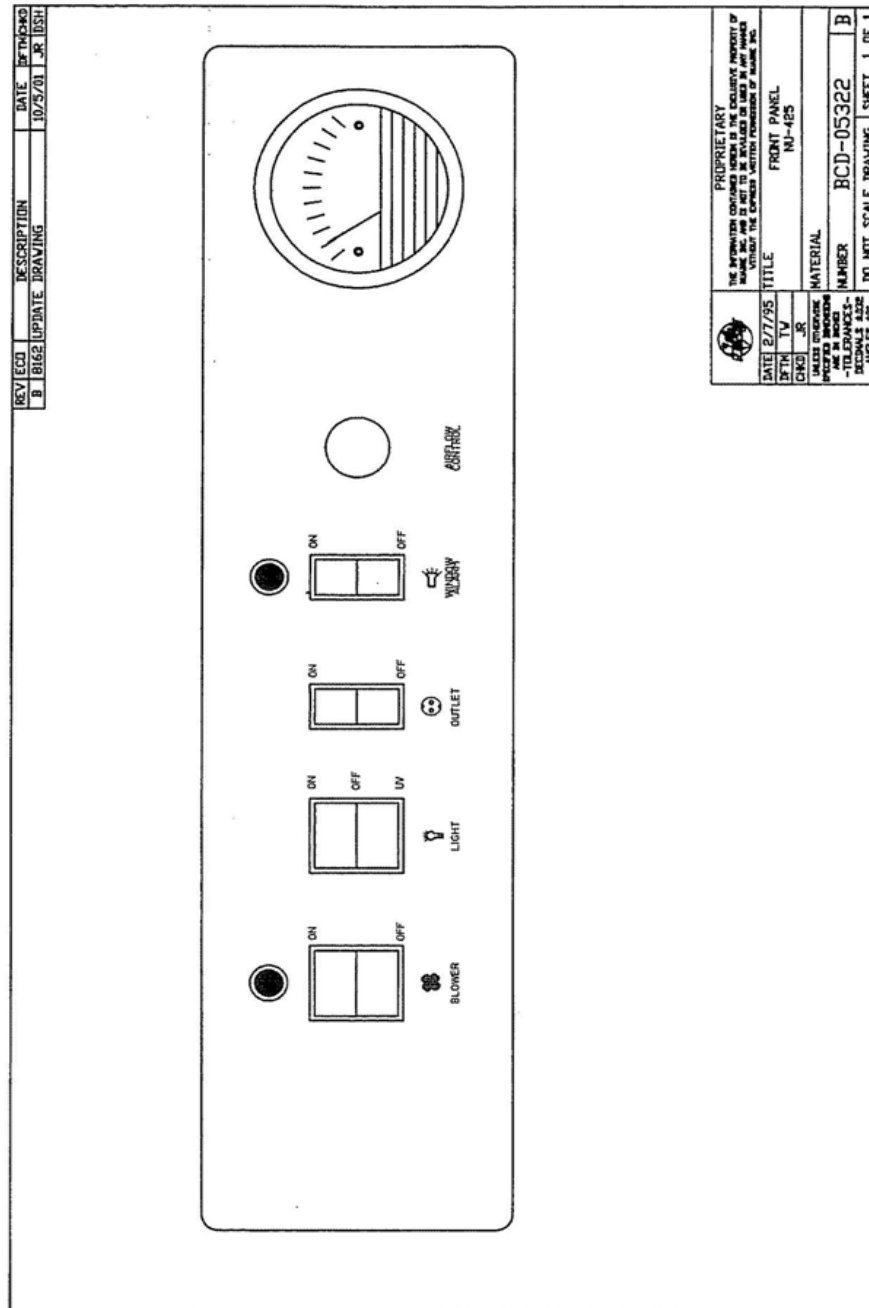


Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.1.8 Airflow Control

The operating airflows within the cabinet (i.e., 70 LFPM [.35 m/s] downflow and 105 LFPM [.53 m/s] air inflow barrier) are controlled by a potentiometer and an exhaust damper.

The potentiometer controls the operating voltage applied to the motor/blower. The potentiometer is adjustable over 270 degrees with a slotted screwdriver, which varies the applied voltage from 70 to 115 Vac. **This adjustment should only be made by a qualified technician employing the proper instruments to ensure airflows per NSF STD. No. 49.**

1.1.9 Magnehelic Gauge

The unit is equipped with a magnehelic gauge. The magnehelic gauge displays the static pressure within the pressure plenum supplying the downflow and exhaust filters. The gauge is calibrated in inches of w.g. pressure. As the HEPA filters load with particulate matter, the amount of static pressure will increase, giving an indication of the “health” of the cabinet. The initial pressure reading will be approximately 0.05 w.g to 0.550 w.g. depending on altitude from sea level.

1.1.10 Sliding Window Operation

The cabinet has a full counter balanced and removable sliding tempered glass window with two operational features. As the window is raised above its specified operating height, an audible alarm alerts the operator of possible compromised personnel protection. At the same time, an audible and visual alarm are activated. The audible alarm may be switched off while the visual alarm remains on until lowered to the safe operating position. When the window is lowered below 2 inches (50 mm), the motor/blower automatically shuts down to prevent stress on the motor/blower in the form of overheating. The maximum window height is 19½ inches (495 mm).

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.1.11 Convenience/Accessory Outlet

A convenience/accessory outlet is in the upper-left corner behind the window assembly. The outlet is normally wired “hot” through the motor/blower circuit breaker. If an accessory is purchased, the outlet is defined as an accessory outlet supplying 115 VAC at 2.0 amp maximum and is wired to the blower switch (see electrical schematic).

1.2 Operating Guidelines

The intent herein is to present general operational guidelines that will aid in the use of the LFBSC to control airborne contaminants of low to moderate risk as stated in Technical Report No. FPS 56500000001 prepared by Dow Chemical U.S.A. for the National Cancer Institute, May 1, 1972.

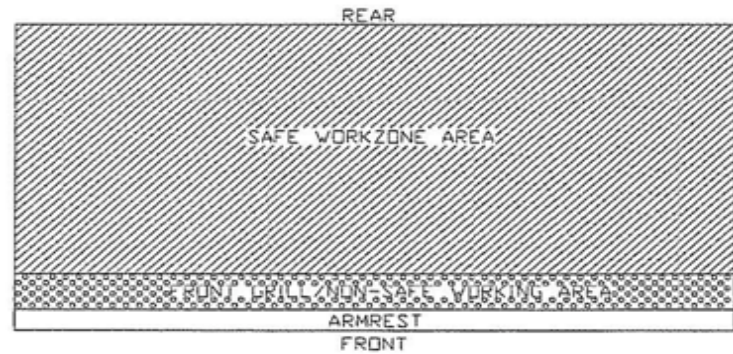
Procedure protocols defined in terms of the barrier or control concepts unique to LFBSC must be developed to obtain a maximum potential for safety and protection. The pre-planning necessary to develop these protocols is based on several fundamental considerations, each of which will contribute to optimum benefits from the equipment:

- Know your “safe working area.”
- Minimize disruption of “air curtain.”
- Minimize room activity.
- Use unidirectional airflow.
- Employ aseptic techniques.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.2.1 Know Your “Safe Working Area”

The LFBSA safe working area is basically the work tray or depressed area. All work should be performed on or above the work tray. The area on or above the front grill is a non-safe working area.



1.2.2 Minimize Penetration of “Air Curtain”

The minimum number of items necessary should be placed into the cabinet to prevent overloading, but the work should also be planned to minimize the number of times an operator’s hands and arms must enter and leave the air curtain at the open face. The ideal situation is to have everything needed for the complete procedure placed in the hood before starting, so that nothing need pass in or out through the air barrier at the face until the procedure is completed. This is especially important in working with moderate risk agents.

Unnecessary raising of the hands inside the cabinet above the level of the work opening should be avoided. This presents an inclined plane from hands to elbows along which the downflow of air may run to, and possibly out of, the open face.

Note: When working with agents of lower risk, it is not as important for all materials to be placed in the cabinet before starting, or for the procedure to be finished before materials are removed. In addition, the time period for a unit may be continued over a more extended period during which entries and withdrawals from the cabinet may be made.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.2.3 Minimize Room Activity

Activity in the room itself should be held to a minimum. Unnecessary activity may create disruptive air currents as well as interfere with the work of the operator. A person walking past the front of a cabinet can cause draft velocities up to **175 fpm (.89 m/s), which are sufficient to disrupt the air balance of the laminar flow unit.**

1.2.4 Use Unidirectional Air Flow

The operator must keep two important facts in mind: (1) the air, as supplied to the work area through filters from the top, is contaminant free and (2) airborne contamination generated in the work area is controlled by the unidirectional flow of parallel air streams in a top-to-bottom direction.

A solid object placed in a laminar air stream will disrupt the parallel flow and consequently, the capability of controlling lateral movement of airborne particulates. A cone of turbulence extends below the object and laminarity of the air stream is not regained until a point is reached downstream, approximately equal to three to six times the diameter of the object. Within the parameters of this cone, particles may be carried laterally by multidirectional eddy currents.

Transfer of viable materials and manipulations that may generate aerosols should not be performed above sterile or uninoculated materials. Items should be localized on the work surface in “clean” and “dirty” groups.

Items of equipment in direct contact with the etiologic agent must remain in the cabinet until enclosed or until surface is decontaminated. Trays of discard pipettes must be covered before removal from the cabinet (aluminum foil may substitute for fabricated covers).

If an accident occurs that spills or splatters suspensions of etiologic agent around the work area, all surfaces and items in the cabinet must be surface-decontaminated before being removed.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.3 Operating Sequence

1.3.1 Startup

Turn on cabinet blower and lights, check air intake and exhaust portals of the cabinet to make sure they are unobstructed.

Good procedure includes the decontamination or wipe down of cabinet surfaces with chemical disinfectant before work commences. This practice eliminates the need for UV lights, whose primary utility in this application is inactivation of surface contamination because the filters effectively remove all airborne contaminants. UV lights, therefore, are not recommended in the LFBSC.

Allow blowers to operate for a minimum of 15 minutes before aseptic manipulations are begun in the cabinet. If the filtered air exhausted from the unit is discharged into the room, as in some installations, an additional advantage is obtained from purification (filtration) of the room air circulated through the equipment. Because of this characteristic contributing to the quality of the laboratory environment, some owners of LFBSC leave them in operation beyond the time of actual use.

1.3.2 Wipe Down

The interior surfaces of the workspace should next be disinfected (see cleaning procedures) by wiping them thoroughly with 70 percent alcohol or similar noncorrosive antimicrobial agents. **Use of chlorinated or halogen materials in the cabinet may damage stainless steel.**

1.3.3 Materials and Equipment

The apparatus and materials should next be placed into the cabinet. Care must be exercised that no items be placed over the front intake grills. Materials should be arranged so that clean, dirty (used), and virus materials are well separated. Passage of contaminated materials over uninoculated cultures or clean glassware should be avoided and transfer of viable materials should be performed as deeply into the cabinet (away from open face) as possible.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.3.4 Air Purge

Additional purging of the workspace without user activity should be allowed for 2 to 3 minutes after materials and apparatus have been placed in it. This will rid the area of all “loose” contamination that may have been introduced with the items.

1.3.5 Perform Work

The work can now be performed. The technician performing the work is encouraged to wear a long-sleeved gown with knit cuffs and rubber gloves. This will minimize the shedding of skin flora into the work area and concurrently protect the hands and arms from viable agent contamination. At a minimum, the hands and arms should be washed well with germicidal soap before and after work in the cabinet.

1.3.6 Terminal Purging and Wipe Down

Following completion of work, allow the cabinet to run for a 2- to 3-minute period without personnel activity to purge the unit. The decontamination of the interior surfaces should be repeated after removal of all materials, cultures, apparatus, etc. A careful check of grills and diffuser grids should be made for spilled or splashed nutrients that may support fungus growth and resulting spore liberation that contaminates the protected work environment.

1.3.7 Shutdown

Turn off blowers and lights. Do not use the cabinet as a depository for excess laboratory equipment during periods of non-operation.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.4 Ergonomics

Ergonomics, the study or accommodation of work practices, is extremely important for proper cabinet usage and user health and safety. An evaluation of normal work practices should be performed with each user when working in a cabinet. Evaluation criteria should be at a minimum:

- Proper user posture
- Effective work zone layout for work practice
- Vision or sightlines

For each of the above evaluation criterion, several aids may be supplied to accommodate the user.

For the ergonomic chair, be sure feet are resting on the floor, chair foot support, or footrest. Also be sure that your back is fully supported with proper chair adjustments.

- **Forearm/Armrest Support.** The cabinet is provided with a forearm support on the work access opening. Periodic mini breaks during work practice should be taken resting the forearm to avoid stress and fatigue.
- **Effective Work Zone Layout.** Always prepare your work procedure to minimize reach to avoid neck and shoulder stress and fatigue. Rotating tables are optional to maximum work zone and minimize reach.
- **Vision and Sightline.** Always prepare your work procedure to eliminate glare and bright reflections on the window. Keep your window clean and sightlines clear to your work zone.

Exhibit 10-7. Operating the laminar flow biological safety cabinet (continued)

1.5 Cleaning Procedures

Cleaning the cabinet is an important function in terms of both containment and sterility. Use the following procedure to effectively clean or surface-disinfect the cabinet work zone surfaces.

- Raise the sliding window to a full-open position, if desired.
- Press the audible alarm silence or cleaning key on the front control panel to silence the audible alarm during the cleaning process.
- Apply appropriate disinfecting solution to cabinet surfaces. Most surface disinfectants require a specific contact time, depending upon the microbiological agents used within the cabinet. **Consult appropriate disinfectant documentation for proper application and safety precautions.**
- **Note:** Disinfectants that use chlorides and halogens will cause damage to the stainless steel surfaces if left on for long periods.
- After the specified contact time, wipe up excess disinfectant.

10.4.5 Thermometers – Ambient Air Temperature

Three thermometers monitor ambient temperature in the laboratory and phlebotomy. Quality control procedures for ambient air temperatures involve checking these thermometers for damage, monitoring the temperature during each session, and documenting any unusual occurrences. Check the three thermometers for damage at the beginning of each stand. Notify the warehouse manager of any damage and request a new thermometer.

The allowable ambient temperature range for the laboratory is 17°C to 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 automated Unusual Field Occurrence (UFO) utility and inform the FES immediately. If using the portable air conditioner, document use for each session by way of a UFO.

10.4.6 Humidity Monitor

One humidity monitor monitors the humidity in the laboratory. Quality control procedures for room humidity monitoring involve checking the monitors for damage, monitoring the humidity during each session, and documenting any unusual occurrences. Check the humidity monitor for damage at the beginning of each stand. Notify the warehouse manager of any damage and request a new monitor.

The allowable room humidity range for the laboratory is <80 percent.

Note: Monitor the humidity monitor for unusual reading (e.g., a reading of zero percent humidity). If the reading is suspect, change the battery.

10.4.7 Mettler Toledo Scale

The Mettler Toledo PL 602E scale is a very sensitive-precision weighing instrument with a weighing limit of 610 grams. Handle the scale with care at all times. Do not weigh anything on the scale other than urine cups and specimens. The weigh pan will get dirty during use. Clean the weigh pan as needed by removing the metal plate from the scale and cleaning using the NHANES COVID-19 Mitigation Protocols, for as long as the protocols are applicable, or other cleaning protocols when the COVID protocols are no longer needed. Replace the weigh pan when clean.

Always use the clear, acrylic scale cover to protect the scale from damage while not in use. Use the scale cover to protect from drafts when weighing samples.

10.4.7.1 Initial Scale Interface Setup

1. Press and hold the Menu key until the word BASIC appears.
 - A. Press Cal key until display shows INT.FACE.
 - B. Press Menu key (this becomes your enter key).
2. R5232 will appear on display.
 - A. Press Cal key until BAUD shows. Press Menu key.
 - B. Press Cal key until 2400 appears then hit Menu key.
3. Press Cal key until BIT.PAR shows on display. Press Menu key.
 - A. Press Cal key until “7/EVEN” shows. Press Menu key.
4. Press Cal key until “STOPBIT” shows. Press Menu key.
 - A. Press Cal key until “1 BIT” shows. Press Menu key.
5. Press Cal key until “HD.SHK” shows. Press Menu key.
 - A. Press Cal key until “OFF” shows. Press Menu key.
6. Press Cal key until “RS.TX.E.O.L.” shows. Press Menu key.
 - A. Press Cal key until “CR.LF” shows. Press Menu key.
7. Press Cal key until “RS.CHAR” shows. Press Menu key.
 - A. Press Cal key until “ANSI.WIN” shows. Press Menu key.
8. Press and hold Menu key until SAVE: Yes shows. Press Menu key.

The scale never really shuts off. It will go to darkened display with the words MT.GREEN. There are three ways to turn on the scale:

1. The scale application is turned on via the computer.
2. Touching the scale plate.
3. Pressing the ON/OFF button.

The scale has no warm-up time and zeroes itself each time it is turned on. If the scale needs to “wake up” via touching the scale plate, do not place urine on the plate until the scale has zeroed.

10.4.7.2 Scale Setup

- Open the blue carrying case.
- Remove the scale from the case and place it on the counter next to the barcode scanner.
- Verify that the scale is free of dust and debris. Clean the scale with an approved cleaner and lint-free cloths.

Locate the tan serial cable taped to the counter. The serial cable has a broad end with a trapezoid input with a screw on either side. See exhibit 10-8 for a picture of the cable.

Exhibit 10-8. Serial cable



Insert the male end of the cable into the back of the scale. Use the screws to firmly fasten the cable to the back of the scale.

Locate the black AC adapter power cord taped to the counter. Place the round end in the round hole labeled “Power” on the back side of the scale. The LCD display on the front of the scale should say “Off.” Remove the small, round, plastic cone protector from the top of the scale. Be sure to place the cone protector back into the blue carrying case so that it does not get lost.

Remove the weigh pan from the case lid. Gently place the pan on top of the scale, being sure to align the notch on the bottom of the pan with the bump on the right side of the cone. The pan should fit snugly and not wobble around when properly seated.

Note: Never move or turn over the scale without first placing the cone protector on the scale's cone.

Balance the scale using the liquid level in the back right corner of the scale. Adjust the feet of the scale by screwing them in or out until the bubble in the liquid level stays within the center circle.

10.4.7.3 Scale Teardown

Place the carrying case on the counter near the scale. Turn off the scale by pressing and holding the On/Off button. Hold until "Off" appears on the LCD display. Gently remove weigh pan from the scale. Slide weigh pan back into slot in lid of carrying case. Remove the protective cone cover from the carrying case and place it over the cone.

Turn the scale around on the counter so the back of the scale is visible. Unplug the AC adapter power cord from the back of the scale. Tape the end of the power cord to the counter so it is easily found at the next setup.

Unplug the serial cable from the back of the scale by unscrewing the two screws and gently pulling the end of the serial cable away from the back of the scale. Tape the cord to the counter so it is easily found at the next setup.

Place the scale in the protective carrying case. Close the lid and snap black locks tightly closed so that the lid and bottom of the case do not come apart. Place the carrying case into a cabinet during relocation of the MEC between stands.

10.4.8 Eppendorf Pipette

The MEC laboratory has three Eppendorf Xplorer Plus electronic pipettes: one 5-100 μL , one 50-1,000 μL , and one 0.2-5.0 mL. The lab also uses 100 μL and 1,000 μL Biopur pipette tips and 5 mL bulk pipette tips. Charge the pipettes in the four-stand charger.

10.4.9 Safety Precautions, Handling, and Battery for the Xplorer Plus

Before using the Xplorer Plus for the first time, please read the entire **Eppendorf Xplorer Plus Instruction Manual**.

Observe the following points:

Handling

- Use the Xplorer Plus only when a pipette tip is attached.
- Do not lay down the Xplorer Plus when a filled pipette tip is attached.
- After liquid has been aspirated, press the Actuate key only when you are sure the liquid will be correctly dispensed.
- When the pipette is switched on and when the Reset key is pressed, the piston may move. Please ensure beforehand that the liquid in the pipette tip will be dispensed correctly.
- Emergency stop: pressing the Reset key can stop a moving piston.
- Operate the Xplorer Plus at temperatures between 17°C-25°C. Operate at a maximum humidity of 80 percent at a temperature up to 25°C.

Battery

- Lithium polymer battery: 750 mAh/3.7 V.
- Charging time: Approximately 3 hours for a fully discharged battery; there is overcharging protection with the pipette.
- Charge the battery before operating the device for the first time.
- Charge the battery in the pipette only, using the charging stand and the original power unit.
- If a flashing battery symbol appears in the display, stop dispensing and charge the battery.
- When charging the battery, do not allow it to be exposed to any metallic surfaces.
- Dispose of used batteries as special waste.
- Never charge the Xplorer Plus without a battery.

Power Unit

- Input voltage: 100 V to 240 \pm 10%, 50/60 Hz
- Output voltage: 5 V, 1 A

Delivery Package

The Xplorer Plus is supplied as a single-channel pipette for different volume ranges. The pipette is delivered without a charging adapter, but each lab is supplied with a charging stand. Each package contains the following:

- Charging stand with separate power unit;
- Special tool(s) according to pipette type;
- Operating manual with measuring protocol and CE conformity assurance document; and
- Lithium polymer battery.

Inserting the Battery

Charge the battery in the pipette. Make sure the battery is plugged in on the Xplorer pipettes. The battery should be charged by using the charging stand with the original power unit. A new battery does not attain its full capacity until several complete charging/discharging cycles have been completed.

For charging purposes, place the pipette in the charging stand. During the charging process a flashing rechargeable battery will flash in the display. The display is switched on during the charging process to monitor the flashing rechargeable battery. During charging, the dispensing function is frozen. When the charging process has finished, the battery symbol appears in the display without moving.

When the pipette has been fully charged, it may remain in the charging stand. If the rechargeable battery is almost completely discharged, the display will only switch on after a slight delay. To avoid accidental discharge, remove the battery from the Xplorer plus during extended periods of nonuse. In this case, all data remains stored.

Care, Maintenance, and Ordering Information

The outside of the pipette can be wiped with a moist cloth. Using water with a wetting agent is also permitted.

DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.

Only the lower part of the pipette should be rinsed with distilled water and dried. The pipette may be wiped clean with 70 percent isopropanol.

At the End of Stand, if the pipette is very contaminated, or if very aggressive chemicals are dispensed, disassemble the lower half of the Xplorer Plus. Rinse the individual parts in distilled water and then dry them. Then, lightly lubricate the piston, using silicone grease.

Only the lower half of the pipette can be disassembled. The individual parts of the lower part must be disassembled as separate pieces.

Removing the lower part – for pipettes $\leq 1,000 \mu\text{L}$:

1. Keep the ejector pressed and remove the ejector sleeve.
2. Push up on the ring marked “PUSH UP TO RELEASE” until the lower part comes off.
3. Remove the lower part from the upper part (Exhibit 10-9).
4. Never use corrosive cleaning fluids, strong solvents, or abrasive polishes.
5. Do not use acetone to clean the Xplorer Plus pipette.

Note: Do not use sharp objects to clean the Xplorer Plus pipette. Remove any contamination on the outside of the Xplorer Plus with a wet Sani-Cloth or alcohol wipe.

Technical Data

The technical data is shown in Tables 10-1 and 10-2.

The technical data is valid only when the Xplorer Plus is used with Eppendorf pipette tips.

- Test conditions and test evaluation in compliance with ISO 8655, Part 6. Test using a standardized fine balance with a moisture trap;

- Check the volumes in the PIP mode; keep the rocker pressed during the blow-out;
- Number of determination: 10;
- Test at 20°C – 25°C ± 0.5°C;
- Set speed level: 5;
- Dispense against the tube wall; and
- Use water in accordance with ISO 3696.

Table 10-1. Eppendorf Research Pro electronic pipettes technical data

Pipette	Tip	Mode	Volume	Matrix
5-100 µL (Yellow)	200 µL	FIX?	100 µL 50 µL	Whole blood Washed packed cells 7% ascorbic acid
50-1,000 µL (Blue)	1,000 µL	FIX?	200 µL 500 µL 700 µL 1,000 µL	Serum Serum Serum 1% ascorbic acid
0.2 – 5 mL (Purple)	5 mL	PRG	Program 12+ Program 3 – 1-2 Program 4 – 3-5 Program 5 – 6-11	Pooled serum

Table 10-2. Single channel pipette technical data

Volume range	Increment µL	Color code	Pipette tip	Test volume	Systematic error %	Random error %
5-100 µL	0.1	Yellow	2 – 200 µL	100 µL	± 0.8	± 0.2
50-1,000 µL	1	Blue	50 – 1,000 µL	1,000 µL	± 0.6	± 0.2
0.2-5 mL	5	Purple	0.1 – 5 mL	5 mL	± 0.6	± 0.15

10.4.10 Disinfecting

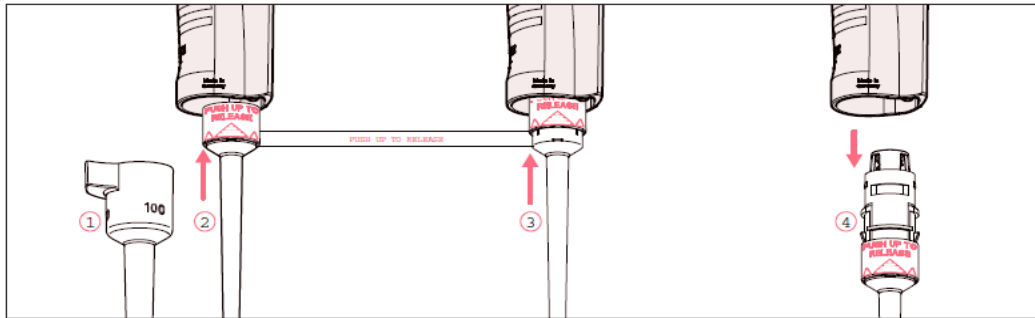
- Carefully wipe off the outer surfaces, tip cone, and ejector sleeve with a disinfectant, such as 70 percent alcohol solution or a Sani-Cloth.

10.4.10.1 Xplorer Pipette Assembly and Disassembly

Exhibit 10-9 presents information and diagrams on this process.

Exhibit 10-9. Explorer pipette assembly and disassembly for pipettes < 5 mL

7.5.1.1 Removing the lower part

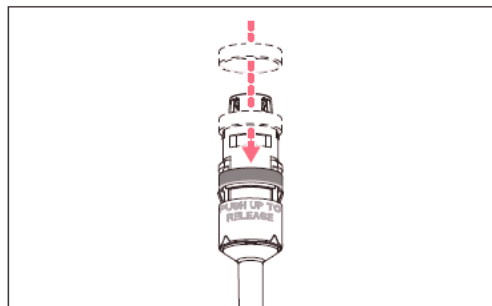


1. Keep the ejector pressed and remove the ejector sleeve ①.
2. ② and ③: On the lower part, slide the ring marked "PUSH UP TO RELEASE" up by about 5 mm until the lower part comes off.
3. ④: Remove the lower part from the upper part.

70 Eppendorf Xplorer®/Eppendorf Xplorer® plus English (EN)

7.5.1.2 Deactivating the spring-loading action of single-channel pipettes

You can deactivate the springs of the tip cones if you want to use pipette tips which require a higher attachment force. The spring-loading action of the tip cone can be deactivated by installing the locking ring. The locking ring is included in the delivery package.



1. Push the black locking ring onto the lower part from the top by slightly squeezing the clamps on the lower part.
2. Insert the lower part into the upper part until it audibly engages.
3. Keep the ejector pressed. The ejector rod protrudes from the upper part.
4. Fit the ejector sleeve onto the ejector rod. If correctly fitted, it will engage slightly.

i Remove the locking ring to reactivate the spring-loading action.

Exhibit 10-9. Explorer pipette assembly and disassembly for pipettes < 5 mL (continued)

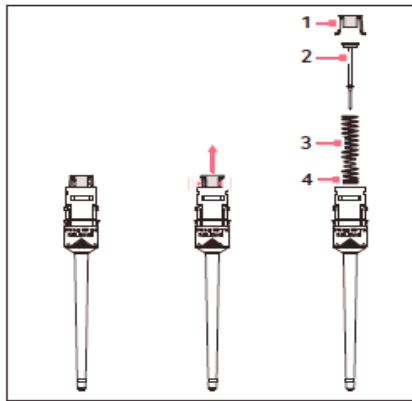
7.5.1.4 Opening and assembling the lower part ($\leq 1000 \mu\text{L}$)

Prerequisites

The piston is in the basic position.

- i** To avoid confusing the parts, only disassemble and assemble one pipette at a time.

Opening the lower part



1. Slightly push the stop pins together on the piston mount (1).
2. Remove the piston mount.
3. Remove the piston (2) and the piston spring (3). The piston is under spring tension.

- i** The appearance of pistons and piston springs varies according to the individual volume versions.

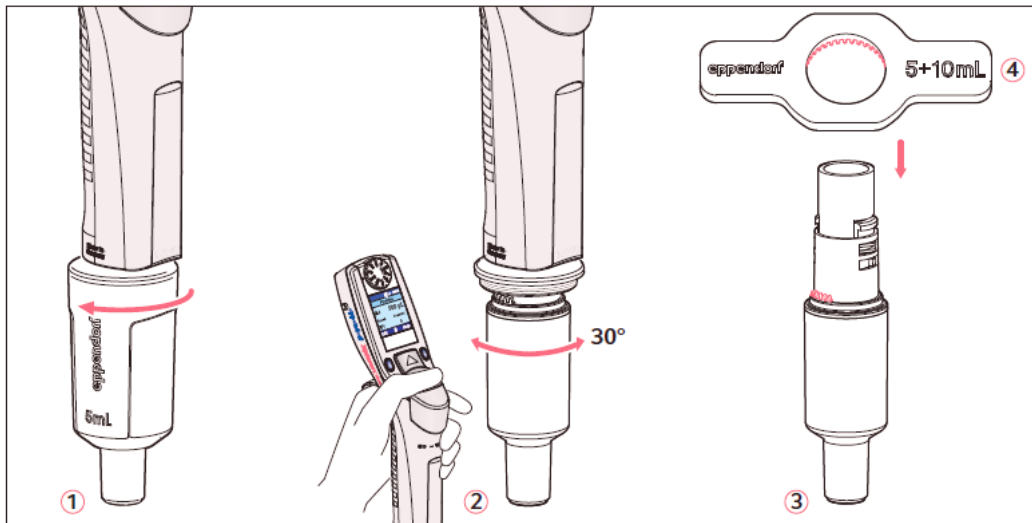
Assembling the lower part

1. Carefully guide the piston and the piston spring into the cylinder. Make sure that the piston is guided correctly in the piston spring and the cylinder. There must not be any perceptible resistance. **Stop pushing as soon as any resistance is felt** This may indicate that the piston is not positioned correctly in the cylinder. There is a risk of bending the piston if too much force is applied. Carefully pull out the piston and repeat the process correctly. In the case of piston springs with double windings (4), these windings must point downwards.
2. Keep the piston and the piston spring pressed.
3. Keep the stop pins on the piston mount pressed with the other hand.
4. Mount the piston mount so that the two stop pins engage in their retainers.
5. Gently press a pipette tip against the inserted piston. The piston must move down in the cylinder without any noticeable resistance.

Exhibit 10-9. Explorer pipette assembly and disassembly for pipettes < 5 mL (continued)

7.5.2 5 mL and 10 mL single-channel

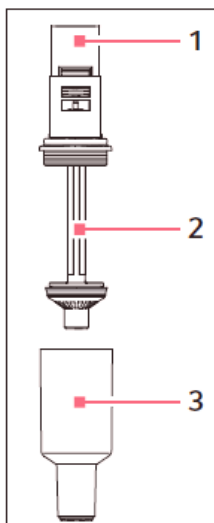
The piston must be in its basic position before separating the lower and upper part. Press the rocker down to move the piston to its basic position.



1. ①: Unscrew the ejector sleeve.
2. ②: Keep the ejector pressed and turn the lower part approximately 30° to the left or right. Pull the lower part down to cancel the magnetic coupling of the lower part. The lower part is separated from the upper part.
3. ③: Open the lower part: fit the pipette key ④ (included in the delivery package) onto the lower part. Hold the cylinder and unscrew it from the lower part. The cylinder with the tip cone is separated from the upper part of the lower part. The upper part of the lower part and the piston cannot be disassembled any further. See the next figure.

Exhibit 10-9. Explorer pipette assembly and disassembly for pipettes < 5 mL (continued)

The lower part consists of the following:



1 Upper part of the lower part

3 Cylinder and tip cone

2 Piston (with seal)
Piston with magnet

Assembly is performed in reverse order. Make sure that the magnet on the piston in the lower part is coupled with the magnet on the spindle in the upper part. After the assembly:

- ▶ Carry out a gravimetric test of the systematic and random errors.
This test ensures that no parts were confused during assembly and that the pipette has been assembled correctly.
- i** For replacing an ejector sleeve, the 5 mL and 10 mL sizes are delivered with an ejector sleeve and ejector carrier. The lower part must be removed in order to install a new ejector carrier.

Yearly Calibration by the Manufacturer

The Eppendorf Xplorer Plus pipettes, see Table 10-3, are calibrated on an annual basis by the manufacturer, usually while the MEC is on vacation in December. When instructed, package and send the pipettes back to the warehouse (usually the last three stands of the calendar year). The pipettes are sent to Eppendorf for recalibration by the warehouse manager. When the pipettes are received back from Eppendorf, they are sent back to the field and put into use. The calibration report is sent to the home office to the laboratory component lead. In addition, the pipettes will have a calibration verification performed by the laboratory component leads.

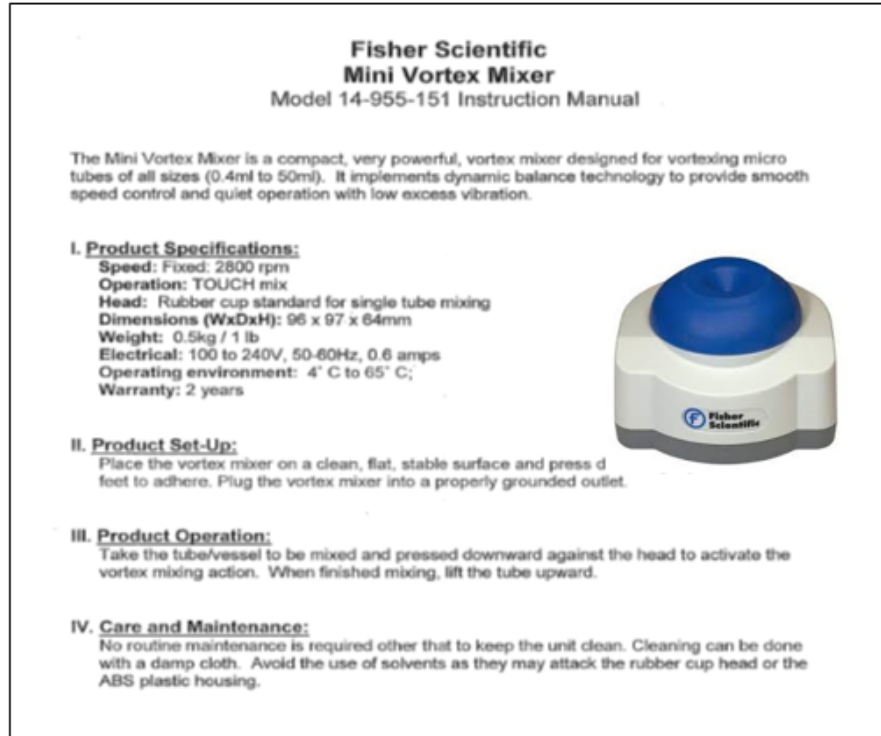
Table 10-3. Eppendorf pipette ordering information

Item	Size	Part number
Eppendorf Xplorer Plus	5-100 µL	4861000716
Eppendorf Xplorer Plus	50-1,000 µL	4861000732
Eppendorf Xplorer Plus	0.2 – 5 mL	486000740
Charging carousel	Four pipettes	4880
Pipette tips		
Bulk-packaged, in bags	5 mL	2235-081-1
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	200 µL	2249-002-8
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	1,000 µL	2249-006-1
Additional accessories		
Spare, rechargeable, lithium ion battery	1,200 mAh	4861601000

10.5 Mini Vortex Mixer Care and Storage

The Fisher Scientific Mini Vortex Mixer, see Exhibit 10-10, is to be used inside the LFBSC to mix selected vessels. This is a simple device that is to be wiped down with Sani-Cloths at the end of each day and stored in the original packaging during transport of the MEC.

Exhibit 10-10. Fisher scientific mini vortex mixer



10.5.1 Blood Equipment and Supplies

The blood processing area includes two laboratory-grade refrigerators, four laboratory-grade freezers, two refrigerated centrifuges, one data terminal, a laminar flow hood, and one specimen rocker. This area also includes counter space for processing blood. Extra processing supplies are stored in cabinets and/or the trailer compartments. Exhibits 10-11 and 10-12 list nonconsumable and consumable supplies for blood processing.

Exhibit 10-11. Nonconsumable supplies for processing

Blood processing template (6-11/12+ and 1-2/3-5)	Nalgene cryovial racks
One Eppendorf pipette 0.2-5 mL (Purple)	One Eppendorf pipette 50-1,000 µL (Blue)
One Eppendorf pipette 5-100 µL (Yellow)	Pipette charging stand
One pipette battery	50 mL and 10 mL graduated cylinder
13 mm half racks	Cube rack – 4-way flipper rack
16 mm full racks	Protective eyewear
16 mm half racks	Saline squeeze bottles
Deionized water bottles	

Exhibit 10-12. Consumable supplies for blood processing

Cotton swabs	Eight gallon biohazard sharps containers
Ascorbic acid 1%	Ascorbic acid 1% and 7%
Kimwipes	Bench Kote paper
Pipette tips 1,000 µL	Pipette tips 200 µL
Pipette tips 5 mL	Wooden applicator sticks
Zip closable bags	3.5 mL transfer pipettes nonsterile
15.0 mL transfer pipettes nonsterile	14 mL snap cap test tubes
5 mL cryovial sterile	2 mL cryovials sterile
Conical tubes 50 mL	Caps for 2 mL cryovial
2 mL cryovials non-sterile	5 ½" long x 5 ½" deep x 4 ½" with 4 x 4 grid
30 mL ENV vials	Serum filters 16 mm x 6 inches
Serum filters 13 mm x 4 inches	5.25 x 5.25 x 3.0 inch cardboard boxes with 9 x 9 cardboard grid
5.25 x 5.25 x 2.0 inch cardboard boxes with 9 x 9 cardboard grid	
5.25 x 5.25 x 3.0 inch cardboard boxes with 5 x 5 grid	5.25 x 5.25 x 3 inch boxes with 7x7 grid
5.25 x 5.25 x 5.0 inch cardboard boxes with 5 x 5 foam insert	Red cap inserts
Nonsterile, powder-free, nonlatex gloves— extra small, small, medium, large	Deionized water
Sterile saline	Lab markers - fine
Permanent markers	

10.5.2 Urine Equipment and Supplies

The supplies needed for urine collection and urine processing and storage are listed in Exhibits 10-13 and 10-14.

Exhibit 10-13. Urine collection equipment

Blue scale carrying case
Mettler Toledo PL602E Scale
Cone protector
Weigh pan
One Troemner 100 g weight (start of stand QC)
Two Troemner 300 g weights (start of stand QC)
Care Pac M
Cleaning cloth
Two gloves
Weight transfer tool for 500 g weight
Weight transfer forceps for 20 g weight
Cleaning brush
One Ohaus 500 g weight (daily QC)
One Ohaus 20 g weight (daily QC)
Clear acrylic scale cover
Barcode scanner

Exhibit 10-14. Urine collection supplies – urine processing and storage

2 ml cryovial sterile	Cardboard box, 5.25" x 5.25" with foam insert
5 ml cryovial sterile; Five-0 screwcap	Cardboard box, 3.0 inch with 9 x 9 grid
5 ml cryovial sterile	Cardboard box, 3.0 inch with 5 x 5 grid – White
10 mL Vial CryoPro VWR screwcap	Cube rack – 4-way flipper rack
10 mL Vial CryoPro VWR screwcap – WITH ADDITIVE (Urine/Mercury)	Kimwipes
3.5 mL Starstedt Transfer pipette	Nonsterile, powder-free, gloves—small, medium, large
Bench Kote paper	Sani-Cloth Plus
Cardboard box, 2.0 inch with 9 x 9 grid	

10.6 Laboratory Quality Control Module

Document the following items in the Laboratory QC module based on the frequency described in the following table (Table 10-4).

Table 10-4. Laboratory QC table

Item	Acceptable result
Start of Stand	
Freezer #3 cleaned	Yes
Freezer #4 cleaned	Yes
Freezer #5 cleaned	Yes
Freezer #6 cleaned	Yes
Refrigerator #1 cleaned	Yes
Refrigerator #2 cleaned	Yes
Centrifuge #1 cleaned	Yes
Centrifuge #2 cleaned	Yes
LFBS cleaned	Yes
LFBS magnahelic gauge reading	0.050 to 0.550
Class 6 one hundred gram weight +/- 1.0 g	99 to 101
Two Class 6 three hundred gram weights +/- 6.0 g	594 to 606
Remove filter from and flush eyewash for 1-2 minutes	Yes
Daily	
Centrifuge #1 refrigerator temperature reading	4 °C to 8 °C
Centrifuge #2 refrigerator temperature reading	4 °C to 8 °C
LFBS magnahelic gauge readings	0.050 to 0.550
Workstation 2 room temperature reading	17 °C to 25 °C
Workstation 3 room temperature reading	17 °C to 25 °C
Humidity reading	<80%
Class F2 twenty gram weight +/- 0.2 g	19.8 to 20.2
Class F2 five hundred gram weight +/- 5.0 g	495 to 505
1% ascorbic acid	Yes
7% ascorbic acid	Yes
Heratherm™ Compact Microbiological Incubator, Thermo Scientific	36 °C to 38 °C

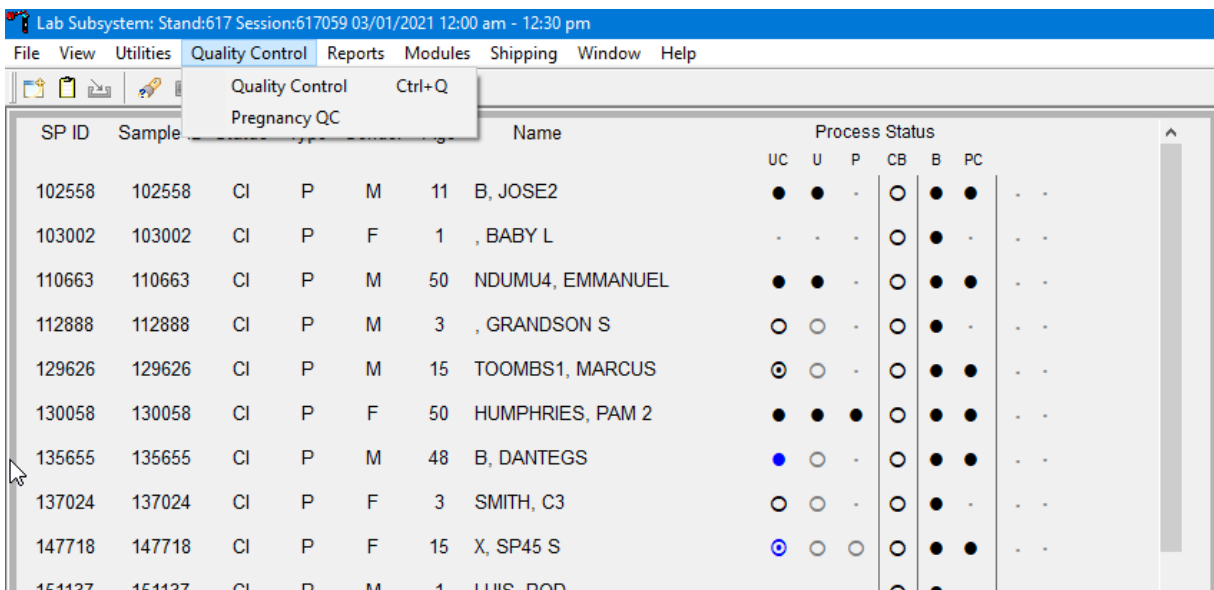
Table 10-4. Laboratory QC table (continued)

Item	Acceptable result
Annually	
Eppendorf Pipette Calibration	Date
Hood Certification Expiration Date	Date
Scale Weight Calibrations	Date
DxH 800 PM	Date
Refrigerator #1	Date
Refrigerator #2	Date
Freezer #3	Date
Freezer #4	Date
Freezer #5	Date
Freezer #6	Date

Document all instrument quality control activities in the Laboratory QC module.

See Exhibit 10-15 showing where to access the Laboratory QC module.

Exhibit 10-15. Laboratory QC module



Enter quality control activities and readings.

Select the correct activity (start of stand, daily, weekly, end of stand, or NCHS QC) by directing 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 setup. Mark activities as Done and enter the result. Exhibit 10-16 provides a visual representation of the quality control display.

Exhibit 10-16. Quality Control Application

QC Check	Done	Result	Comment
Centrifuge 1 Refrigerator Temperature Reading (4 to 8°C)	<input type="checkbox"/>	degrees C	
Centrifuge 2 Refrigerator Temperature Reading (4 to 8°C)	<input type="checkbox"/>	degrees C	
LFBSC guage reading (0.050 to 0.550)	<input type="checkbox"/>	w.g.	
Workstation 2 room temp reading (17 to 25°C)	<input type="checkbox"/>	degrees C	
Workstation 3 room temp reading (17 to 25°C)	<input type="checkbox"/>	degrees C	
Lab Humidity Reading (<80%)	<input type="checkbox"/>	enter %	
Class F2 twenty gram weight +/- 0.2 g	<input type="checkbox"/>	enter weight	

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 checkmark. Press Tab or Enter to move to the Result text box.

Enter the response or reading in the Result text box as shown in Exhibit 10-17.

Exhibit 10-17. Data entry in the Quality Control Application

QC Check	Done	Result	Comment
Centrifuge 1 Refrigerator Temperature Reading (2 to 8°C)	<input type="checkbox"/>	degrees C	
Centrifuge 2 Refrigerator Temperature Reading (2 to 8°C)	<input type="checkbox"/>	degrees C	
LFBSC guage reading (0.050 to 0.550)	<input type="checkbox"/>	w.g.	
Workstation 2 room temp reading (15 to 30°C)	<input checked="" type="checkbox"/>	32 degrees C	Air conditioner not working. Notified FES, Mec Manger and chief MT.
Workstation 3 room temp reading (15 to 30°C)	<input type="checkbox"/>	degrees C	
Lab Humidity Reading (<80%)	<input type="checkbox"/>	enter %	
Class F2 twenty gram weight +/- 0.2 g	<input type="checkbox"/>	enter weight	

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. Press 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.

A red checkmark on the top of the file header indicates that all QC activities associated with that requirement were successfully recorded and saved to the database as shown in Exhibit 10-18.

Exhibit 10-18. Quality control complete

QC Check	Done	Result	Comment
Freezer #3 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Freezer #4 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Freezer #5 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Freezer #6 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Refrigerator #1 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Refrigerator #2 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	
Centrifuge #1 cleaned?	<input checked="" type="checkbox"/>	yes (yes/no)	

10.7 Unusual Field Occurrence

Document any unusual occurrence using the Unusual Field Occurrence (UFO) utility. The Hard-Copy Unusual Occurrence Log (see Exhibit 10-19) is available as a backup. 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 serial number of the instrument.

Exhibit 10-19. Hard-Copy 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 _____

Enter information onto the appropriate line(s):

- Stand number;
- Beginning stand date;
- Technologist name and ID;
- Date;
- Time;
- Comments or issue;
- Action taken; and
- Resolution.

Note: 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.

10.8 Power Loss and Laboratory Operations

Three scenarios may occur if power is lost to the MEC. Scenario 1 occurs when power is lost during an exam session and there is no backup generator. Scenario 2 occurs when power is lost when the MEC is not conducting a session. Scenario 3 occurs when power is lost but there is a backup generator available. Procedures to address each scenario are described in detail.

10.8.1 Scenario 1—Power Loss During Exam Session With No Backup Generator

If a power loss occurs during a MEC session, action must be taken to either continue processing the blood or preserve the integrity of the processed specimens. The phlebotomist should not draw blood during a power loss because of safety concerns due to insufficient light.

Centrifuges

Overview. Each MEC has two centrifuges. Both centrifuges are operated at refrigerated temperatures (4°C to 8°C). All blood tubes can be spun in the refrigerated centrifuge.

While power is generally required to open or unlock the centrifuge door, an emergency pull cord under the centrifuge will allow the technologists to open the door to retrieve the blood tubes if a power failure occurs.

Consequences. According to the manufacturer, all blood tubes can remain in the locked centrifuge for up to 4 hours; however, for optimal test results, serum/plasma should be separated from the red blood cells within 2 hours from collection.

Actions. During a power failure, pull the emergency pull cord under the centrifuge to open to retrieve the blood tubes from the centrifuge. Aliquot the serum and plasma into the vessels if the serum or plasma has sufficiently separated from the cells.

Laminar Flow Hood

Overview. The clinical laboratory scientists require the laminar flow hood to process the blood for two reasons: (1) the hood provides an uncontaminated or clean environment for processing environmental blood specimens, and (2) the hood is required to provide a full-face shield in case of an accidental blood splash. In addition, the outlet in the hood provides power to the electronic pipettes. The electronic pipette is required to perform an accurate dilution for vessel 3 (RBC Folate), vessel 110 (Folate), and vessel 221 (RBC Folate Forms).

Consequences. The environmental specimens may become contaminated. The pipette will lose battery power after 60 minutes.

Actions. Complete an Unusual Occurrence Log to document the SP IDs of the samples processed without a fully functioning hood. This information will be recorded subsequently in an annual summary for NCHS.

- Attach the comment “equipment failure” to vessels 3, 110, and 221.
- Process vessel 3 immediately so that the specimens are not lost due to battery failure.

Freezers and Refrigerators

Overview. Each MEC lab has four freezers and two refrigerators. The refrigerators and freezers are located in a stacked configuration across from the Coulter. Three freezers are stacked on top of the rack, and two refrigerators are located with the remaining freezer on the bottom. Refrigerators and freezers are numbered according to which port they are in on the TempGuard system. Freezers are numbered 3 through 6 and refrigerators are numbered 1 and 2. Port 7 is for room temperature monitoring. Refrigerant gel packs are stored in freezer #6. Most specimens are stored in various plastic vessels and the vessels are placed in cardboard boxes with grids; the cardboard boxes are then stored in the freezers and refrigerators. In addition, some blood tubes (vessels 54, 119) and the Coulter and pregnancy controls are stored in the refrigerator.

Consequences. Specimen integrity is affected if frozen specimens thaw or if refrigerated specimens reach ambient temperature. Some analytes are more sensitive than other analytes. A full freezer takes approximately 3 hours to rise from -20°C to -10°C ; a half-filled freezer takes 2 hours and 25 minutes to rise to -10°C ; and a one-quarter-filled freezer takes 1 hour and 45 minutes to rise to -10°C . Once the temperature reaches -10°C the staff has approximately 30 minutes before the specimens thaw.

Actions:

- Do not open the freezer or refrigerator doors, if possible.
- **Refrigerators.** After 30 minutes or when the TempGuard reading reaches 7°C , add 14 frozen gel packs (stored in freezer #6) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. **Do not add dry ice to the refrigerators; this will cause the refrigerator to explode.**
- **Freezers.** Contact the local dry ice company and order 200 pounds of dry ice or check the dry ice bin from Monday's shipment. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the TempGuard reading reaches -10°C , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. **Do not add dry ice to the freezers; this will cause the freezer to explode.**

Coulter DxH 800

Overview. The Coulter consists of the DxH 800, the monitor, hard drive, and printer. The DxH will not function without the hard drive and monitor. The blood components for the CBC (complete blood count) are stable for a maximum of 24 hours when stored at room temperature.

Consequences. None.

Actions. None.

10.8.2 Scenario 2—Power Loss When the MEC Is Not Conducting Exams

If the power loss occurs when the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The lab staff can continue to ship if all of the ISIS processes are complete. If the ISIS processes are not complete, the lab staff can still pack the shippers and complete the ISIS process once power is restored.

Freezers and Refrigerators

Overview. All three MECs have the Temperature Guard system installed. This system monitors the room temperature and the internal temperature of the refrigerators and freezers in the MEC laboratory. When the system detects a significant increase in the temperatures, it begins calling designated staff. The MEC Managers and facilities and equipment specialists (FESs) have been identified as those individuals responsible for responding to the call by typing in the response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of power because a circuit breaker tripped, or due to a compressor malfunction or failure. Whoever enters the code must act to prevent loss of biological specimens. The Temperature Guard temperature trigger was established to allow 30 minutes of travel time. After 30 minutes, frozen specimens may begin to thaw.

Consequences. Same as Scenario #1.

Actions:

- Examine each Temperature Guard reading to verify which unit(s) is/are affected.
- **Refrigerators.** If one refrigerator has been affected, move all the specimens to the other refrigerator. If both refrigerators have been affected, keep the specimens cold by adding 14 frozen gel packs (stored in freezer #6) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. **Do not add dry ice to the refrigerators. This will cause the refrigerator to explode.**
- **Freezers.** If only one freezer has been affected, move all the specimens from the affected unit to an unaffected unit. If more than one freezer has been affected and there is sufficient space in the unaffected freezers to accommodate the specimens, move the specimens to the other unaffected freezers. If there is insufficient space to accommodate the frozen specimens in the unaffected units, or if all four freezers are affected, try to reach the chief clinical laboratory scientist or any of the staff clinical laboratory scientist to assist. Contact the local dry ice company and order 200 pounds of dry ice or check the dry ice bin from Monday's shipment. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the Temperature Guard reading reaches -10°C , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. **Do not add dry ice to the freezers. This will cause the freezer to explode.**
- Leave a note on the unit indicating the new location of the specimens.
- Turn off the affected unit by flipping the corresponding wall switch to the left of the units.

10.8.3 Scenario 3—Power Loss With a Backup Generator

If the power loss occurs when the MEC is conducting a session and there is a backup generator available, continue to monitor the temperature of the freezers and refrigerators and assess the situation with the MEC Manager. If the temperature approached the established thresholds, the FES will do the following:

- Retrieve the generator from the trailer belly compartment.
- Retrieve the power strip.
- Plug the freezers into the power strip.

- Start the generator.
- If both refrigerators have been affected, keep the specimens cold by adding 14 frozen gel packs (stored in freezer #6) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

If a power loss occurs and the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The Temperature Guard system alerts the MEC Manager and/or FES that the temperature of the freezers and/or refrigerators has exceeded established thresholds. The MEC Manager or FES must respond to the call, travel to the MEC immediately, and do the following:

- Retrieve the generator from the trailer belly compartment.
- Retrieve the power strip.
- Plug the freezers into the power strip.
- Start the generator.
- If both refrigerators have been affected, keep the specimens cold by adding 14 frozen gel packs (stored in freezer #6) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

11. Dry Run

11.1 Overview

After setting up the phlebotomy and laboratory rooms at each new stand, the staff conducts a “dry run” session using volunteers to verify data 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. Two distinct IDs are assigned to each non-test volunteer—the original SP ID and a second unique sample ID.

Document the results of the dry run session in the same manner as an actual session except for entering the results twice: first using the SP ID and again using the sample ID.

Collect the amount of blood and urine specified in the Dry Run Protocols. These amounts are less than the blood and urine amounts required for a routine examinee. Split samples will be prepared for each volunteer per the Dry Run Protocol.

11.2 Dry Run Phlebotomy Protocol and Procedures

The dry run venipuncture protocol is shown in Exhibit 11-1. If the last digit is an odd number, the volunteer’s protocol includes two 4 mL ethylene diamine-tetracetic acid (EDTA), one 2 mL gray tube, one 6 mL blue-top tube, one 7 mL red top tube, and one 15 mL red-top tube. If the last digit is an even number, the volunteer’s protocol includes two 4 mL EDTA, one 2 mL gray tube, one 7 mL red-top tube, and one 15 mL red-top tube.

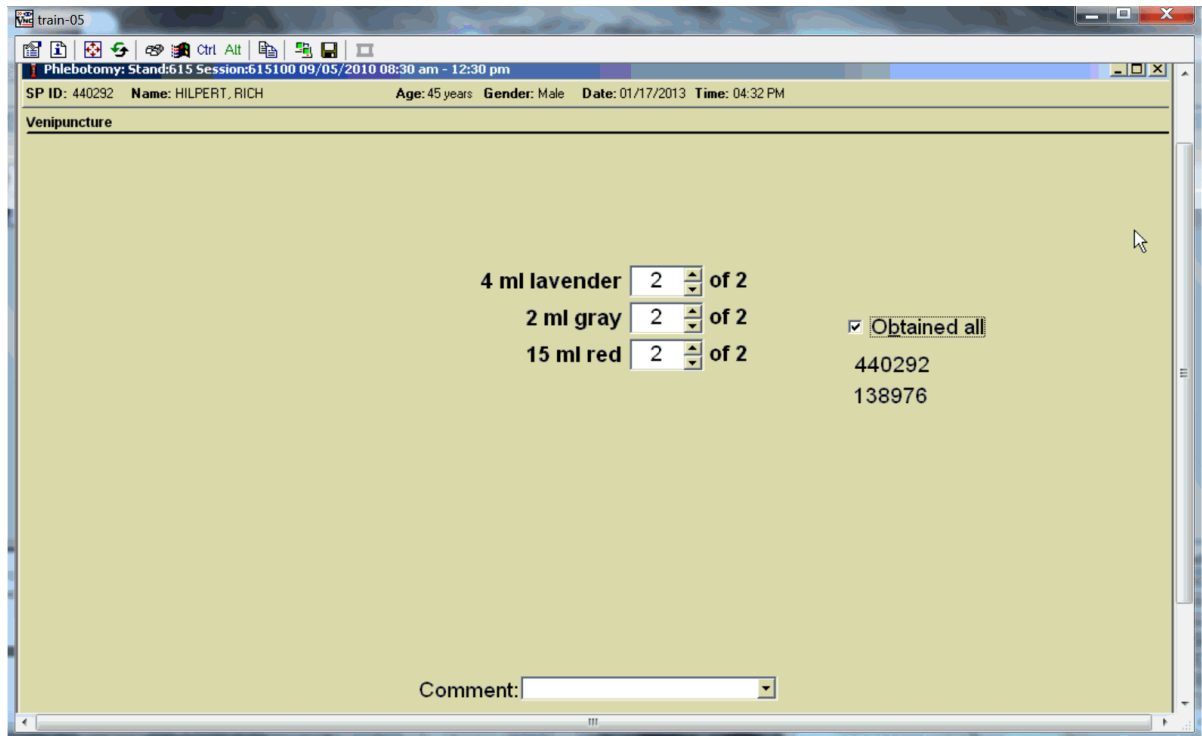
Exhibit 11-1. Dry run venipuncture protocol

Tube type (in priority order)	Last digit in SP ID = Odd	Last digit in SP ID = Even
4 mL EDTA	2	2
2 mL gray	1	1
6 mL EDTA	1	0
7 mL red	1	1
15 mL red	1	1

On dry run day, the phlebotomist will conduct the phlebotomy procedures in the following manner:

1. Access the phlebotomy application; open the exam and wand the dry run volunteer barcode into the component in ISIS.
2. Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 3.
3. Perform the venipuncture using procedures described in Chapter 3.

The correct venipuncture protocol automatically displays. As shown in the screenshot below, note that there are two IDs for each Dry Run SP—a SP ID (440292) and a Sample ID (138976). Both IDs display under the “Obtained all” check box.



Enter the venipuncture results. Enter any reasons for a tube not being drawn according to protocol, and any comments about the venipuncture. Refer to Chapter 3 for specific instructions.

Label the Vacutainer® tubes for each volunteer; label half of the tubes with the SP ID and the other half with the Sample ID. If only one tube is drawn, discard it. If an odd number of tubes are drawn, discard the odd tube.

For dry run volunteers with the SP ID and sample ID ending in an odd number, do the following:

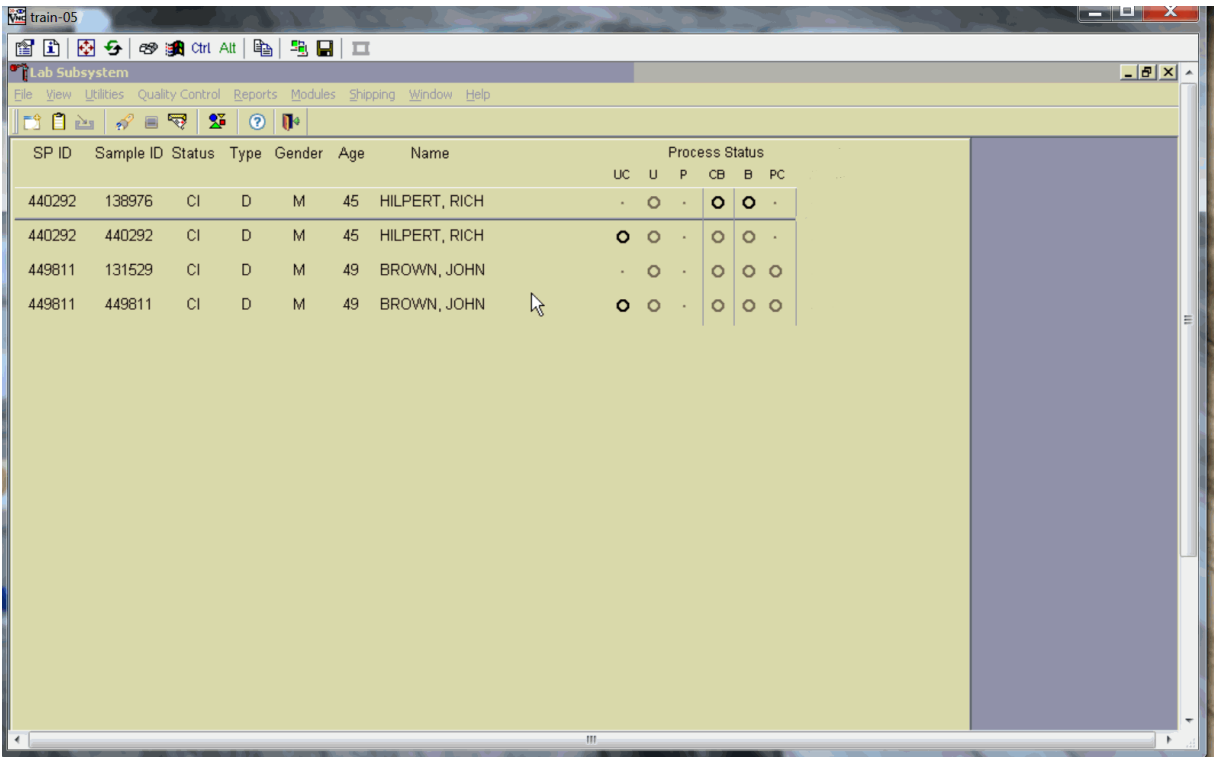
1. Place one label with the original SP ID on one of the 4 mL EDTA tubes, and the other label with the sample ID on the other 4 mL EDTA tube.
2. Place one label with the original SP ID on one of the 4 mL EDTA glycohemoglobin tubes, and the other label with the sample ID on the other 4 mL EDTA glycohemoglobin tube.
3. Place one label with the original SP ID on one of the 6 mL EDTA tubes, and the other label with the sample ID on the other 6 mL EDTA tube.
4. Place the label with the original SP ID on one of the 2 mL gray tubes, and the label with the sample ID on the other 2 mL gray tube.
5. Place the label with the original SP ID on one of the 7 mL red tubes, and the label with the sample ID on the other 7 mL red tube.
6. Place the label with the original SP ID on one of the 15 mL red tubes, and the label with the sample ID on the other 15 mL red tube.

For dry run volunteers with the SP ID and sample ID ending in an even number:

1. Place one label with the original SP ID on one of the 4 mL EDTA tubes, and the other label with the sample ID on the other 4 mL EDTA tube.
2. Place one label with the original SP ID on one of the 6 mL EDTA tubes, and the other label with the sample ID on the other 6 mL EDTA tube.
3. Place the label with the original SP ID on one of the 2 mL gray tubes, and the label with the sample ID on the other 2 mL gray tube.
4. Place the label with the original SP ID on one of the 7 mL red tubes, and the label with the sample ID on the other two 7 mL red tubes.
5. Place the label with the original SP ID on one of the 15 mL red tubes, and the label with the sample ID on the other 15 mL red tube.

11.3 Dry Run Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window.



The screenshot shows a window titled 'Lab Subsystem' with a menu bar (File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, Help) and a toolbar. Below the toolbar is a table with the following data:

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status					
							UC	U	P	CB	B	PC
440292	138976	CI	D	M	45	HILPERT, RICH	-	○	-	○	○	-
440292	440292	CI	D	M	45	HILPERT, RICH	○	○	-	○	○	-
449811	131529	CI	D	M	49	BROWN, JOHN	-	○	-	○	○	○
449811	449811	CI	D	M	49	BROWN, JOHN	○	○	-	○	○	○

Place urine and pregnancy labels at Workstation 3. Each volunteer has two unique blood processing racks—one with labels containing the SP ID and the second with labels containing the sample ID.

Review the laboratory heads-up display. Use the heads-up display to view the modules for which the dry run volunteer is eligible and for the current process status.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status					
							UC	U	P	CB	B	PC
440292	138976	CI	D	M	45	HILPERT, RICH	-	○	-	○	○	-
440292	440292	CI	D	M	45	HILPERT, RICH	○	○	-	○	○	-
449811	131529	CI	D	M	49	BROWN, JOHN	-	○	-	○	○	○
449811	449811	CI	D	M	49	BROWN, JOHN	○	○	-	○	○	○

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 with an SP ID and sample ID ending in either an odd or even digit are eligible for urine collection and processing, CBC, blood processing, and the pregnancy test (if female). The urine and blood protocols constitute a limited subset of the primary SP's test protocol. Each test has the same age and gender restrictions as a primary SP. Notice that only one urine collection result and one pregnancy test is required for each dry run volunteer whether or not the SP ID and Sample ID end in an odd or even digit.

Collect at least 6 mL urine from all dry run volunteers. The MEC coordinator will instruct each volunteer to void as soon as they feel able to provide a urine specimen. The coordinator, local assistant, or MEC staff member transports the initial specimen to the laboratory.

Place the urine collection cup on the scale and scan in the urine collection specimen barcode as described in Chapter 4.

11.4 Dry Run Urine Processing

Use the urine processing labels printed in advance to label the SP's urine vessels. The urine processing protocol is displayed in Exhibit 11-2. Dry run volunteers are eligible for at least one vessel, vessel 45. There are two sets of labels for each dry run volunteer. Label one set of vessels with the first set of labels (SP ID) and the second set with the second set of labels (sample ID).

Exhibit 11-2. Dry run urine processing protocol

ID	Assay	Sample size mL	Vessel
45	Alb/Creat	3	5 mL cryovial

Procedures for Dry Run Volunteers

1. Label one 5 mL cryovial for the first test – #45. Label one tube with the volunteer's original SP ID. Label the other tube with the volunteer's sample ID.
2. Aliquot 3 mL of urine into each of the two #45 vessels using a large plastic transfer pipette.
3. Enter the results of urine processing for the original SP ID and again for the sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the urine processing status results as described in Chapter 4.

The urine-processing clinical laboratory scientist performs the pregnancy test on female dry run volunteers who require one, and documents the results following the procedures described in Chapter 5.

11.5 Dry Run Hematology

The clinical laboratory scientist at Workstation 3 runs two CBCs, in duplicate, for each dry run volunteer from the 4 mL EDTA tubes. Run the first CBC in duplicate on the first 4 mL EDTA tube with the original SP ID on the tube. Evaluate results and save the data using procedures described in Chapter 6.

Run the second CBC in duplicate on the second 4 mL EDTA tube using the sample ID. Evaluate results and save the data using procedures described in Chapter 6.

11.6 Dry Run Blood Processing and Storage

Print blood-processing labels using procedures described in Chapter 8. Prepare two blood processing racks (one with the SP ID labels and one with the sample ID labels) using the blood-processing template for ages 12+.

The clinical laboratory scientist in Workstation 2 processes whole blood from the 4 and 6 mL EDTA tubes according to the whole blood processing protocol (see Exhibit 11-3).

Exhibit 11-3. Dry run processing protocol—whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	Both	0.4	Whole blood	6 mL EDTA	2 mL
3	RBC Folate	Even	0.1	Whole blood	6 mL EDTA	2 mL
4	Glycohem	Odd	0.4	Whole blood	4 mL EDTA	2 mL
5	Mercury	Both	0.5	Whole blood	6 mL EDTA	2 mL
88	Acrylonitrile	Odd	1.6	Packed cells	6 mL EDTA	2 mL
221	RBC Folate Forms	Odd	1.1	Packed cells	6 mL EDTA	2 mL
222	Fatty Acids	Odd	1.6	Packed cells	6 mL EDTA	2 mL
235	Acetylcholinesterase	Even	2.0	Whole blood	6 mL EDTA	2 mL

Each set of venipuncture tubes and pre-labeled blood processing racks should be treated 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, and then process the second set of venipuncture tubes and blood processing vessels using the sample ID.

For volunteers whose SP ID and sample ID ends in an odd digit, process one of the 4 mL EDTA tubes for Lead/Cad/HG/Se/Mn, and acrylonitrile. Process one of the 4 mL EDTA tubes for glycohemoglobin. For volunteers whose SP ID and sample ID ends in an even digit, process one of the 4 mL EDTA tubes for Lead/Cad/HG/Se/Mn, acetylcholinesterase (BChe), RBC folate, and mercury. Use processing procedures described in Chapter 7. Match the EDTA tube with the SP ID to the corresponding blood processing rack. Match the second EDTA tube with the Sample ID to the corresponding blood processing rack.

When the SP ID ends in an even or an odd digit, process each of the 2 mL gray-top tubes for glucose using the same procedures described in Chapter 7.

Process pooled serum for the dry run volunteers using the dry run blood processing protocol – serum (Exhibit 11-4).

Exhibit 11-4. Dry run blood processing protocol—serum

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
110	Folate1	Even	0.7	Serum	15- and 7-mL Red	2 mL
118	Thyroid Panel	Both	1.0	Serum	15- and 7-mL Red	2 mL
99	Ferritin	Odd	0.4	Serum	15- and 7-mL Red	2 mL
238	AGP/Ter	Odd	0.5	Serum	15- and 7-mL Red	2 mL
70	Vit D	Odd	0.9	Serum	15- and 7-mL Red	2 mL
137	Sex Steroid Hormones	Both	3.5	Serum	15- and 7-mL Red	5 mL
122	Hepatitis Profile	Even	1.0	Serum	15- and 7-mL Red	2 mL
229	Hep C Cond/extra	Even	1.8	Serum	15- and 7-mL Red	2 mL
17	Cotinine	Even	1.8	Serum	15- and 7-mL Red	2 mL
21	Lipids	Both	1.0	Serum	15- and 7-mL Red	2 mL
18	Beachem	Both	0.5	Serum	15- and 7-mL Red	2 mL
23	Insulin	Odd	1.0	Serum	15- and 7-mL Red	2 mL
13	CRP	Even	0.3	Serum	15- and 7-mL Red	2 mL

- Fill each vessel as described in the blood processing protocol in Chapter 7.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID.
- Process the second set of venipuncture tubes and blood processing vessels using the second sample ID.
- Use the same techniques for spinning and separating the blood as described in Chapter 7.
- Check the labels before filling the vessel, making sure that each vessel has the correct SP ID or sample ID.

Match the two processing racks to each other. Enter the results of blood processing using the correct sample ID and SP ID numbers and procedures described in Chapter 7. Place a yellow cryodot on each vessel filled during the dry run to ensure these samples are not shipped to the Centers for Disease Control and Prevention’s biorepository by the labs after testing. Store the blood vessels in a manner identical to blood vessels processed during a regular session.

11.7 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 8.

Appendix A
Example CBC Report of Findings

Appendix A

Example CBC Report of Findings



National Health and Nutrition Examination Survey Preliminary Report of Findings

Complete Blood Count

	<u>Result</u>	<u>Units</u>	<u>Flag</u>	<u>Reference Range</u>
White Blood Count	8.4	($\times 10^9$ /L)		3.9 - 11.8
Lymphocytes	29.6	(%)		16.1 - 47.9
Monocytes	7.3	(%)		4.4 - 13.5
Neutrophils	60.9	(%)		37.8 - 74.6
Eosinophils	1.5	(%)		0.7 - 8.5
Basophils	0.8	(%)		0.1 - 1.6
Red Blood Count	5.30	($\times 10^{12}$ /L)		4.18 - 5.86
NRBC	0.0	(/100 WBC)		0.0 - 0.6
Hemoglobin	15.4	(g/dL)		13.1 - 17.5
Hematocrit	45.3	(%)		38.7 - 51.4
MCV	85.4	(fL)		79.8 - 99.1
MCH	29.2	(pg)		26.3 - 34.0
MCHC	34.1	(g/dL)		32.3 - 35.3
RDW	12.6	(%)		11.4 - 14.5
Platelet Count	195	($\times 10^9$ /L)		152 - 386

This finding was not confirmed by microscopy and follow-up may be necessary.



- Test not done
- AAA Results Still Pending
- <<< Lower than the limit of detection
- >>> Above the limit of detection
- vvv Delayed Results



John Doe, 57 years, Male, 123456, 2/29/2020
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