



National Health and Nutrition Examination Survey (NHANES)

MEC Laboratory Procedures Manual



January 2020

Table of Contents

Chapter		Page
1	Overview and Laboratory Team Responsibilities.....	1-1
1.1	Overview	1-1
1.2	The Laboratory Team.....	1-2
1.3	Tasks	1-2
1.4	Organization of the Laboratory.....	1-3
1.5	Tasks—Phlebotomy Room	1-4
1.6	Tasks—Lab Workstation 1.....	1-5
1.7	Tasks—Lab Workstation 2.....	1-6
1.8	Tasks—Lab Workstation 3.....	1-7
1.9	Cross Training	1-8
2	Laboratory ISIS Functionality	2-1
2.1	Laboratory-Specific Functionality	2-1
2.2	Laboratory Heads-Up Display.....	2-1
2.3	Laboratory Task Bar.....	2-3
2.4	Menu Bar Options	2-3
2.4.1	File Menu Options	2-4
2.4.2	Utilities Menu Options	2-5
2.4.3	Quality Control Menu.....	2-6
2.4.4	Report Menu Options.....	2-6
2.4.5	Modules.....	2-7
2.4.6	Shipping	2-8
2.5	Informed Consent (IC) Exclusions.....	2-9
2.6	Set Session Utility.....	2-10
2.7	Container Map.....	2-12
2.8	Container Content Verification	2-13
2.9	Subsample Preview	2-20
2.10	Informed Consent Status.....	2-22
2.11	Access a Processing Module.....	2-23
2.12	Warning and Error Messages	2-24
2.12.1	“Not Filled” Requires a Comment	2-24
2.12.2	Labels Must Be Printed in Advance.....	2-25
2.13	Coulter and Urine Scale Icons.....	2-25

<u>Chapter</u>		<u>Page</u>
3	Venipuncture.....	3-1
3.1	Introduction.....	3-1
3.2	Equipment and Supplies.....	3-3
3.3	Overview.....	3-5
3.4	Gaining Cooperation.....	3-8
	3.4.1 Rationale.....	3-8
	3.4.2 Refusal Conversion.....	3-10
3.5	Performing the Venipuncture on SPs Who Do Not Speak English.....	3-11
3.6	Open the Exam and Log the SP into the Exam.....	3-11
3.7	The Phlebotomy Interview.....	3-15
	3.7.1 Pregnancy Shared Exclusion Question.....	3-16
	3.7.2 Safety Exclusion Questions.....	3-19
3.8	Administering the Fasting Questionnaire.....	3-26
3.9	Venipuncture Procedures.....	3-36
	3.9.1 Preparation of the Puncture Site.....	3-37
	3.9.2 Venipuncture Technique for the Nipro (19-, 21-, and 23-Gauge).....	3-39
	3.9.3 Concluding the Venipuncture.....	3-41
3.10	Pediatric Venipuncture.....	3-42
	3.10.1 Age Specific Care and Phlebotomy.....	3-44
3.11	Hand Venipuncture.....	3-51
3.12	Veinlite EMS.....	3-51
3.13	Recording the Results of the Venipuncture Procedure.....	3-53
3.14	Venipuncture Status.....	3-57
3.15	Repeat Blood Draw.....	3-60
3.16	Phlebotomy Quality Control.....	3-62
	3.16.1 Daily Quality Control.....	3-62
3.17	Red Cross Procedures for Handling Fainting (Syncope).....	3-65
3.18	How to Deal with System Failure.....	3-66

<u>Chapter</u>		<u>Page</u>
4	Urine Specimen Collection and Processing.....	4-1
4.1	Introduction.....	4-1
4.2	Supplies.....	4-2
4.3	Urine Flow Rate Background.....	4-3
4.4	Using the Scale for Urine Collection.....	4-4
4.5	Document Urine Collection.....	4-6
4.5.1	Quantity Not Sufficient (QNS) Urines	4-11
4.6	Manually Documenting Urine Collection	4-21
4.6.1	Manually Document Urine Collection with Barcode Scanning.....	4-21
4.6.2	Manually Document Urine Collection Without Barcode Scanning	4-23
4.6.3	Manually Entering Adults Who Collect in CC2.....	4-25
4.7	Urine Specimen Assays	4-25
4.8	Urine Specimen Protocols.....	4-26
4.9	Labeling Urine Processing Vessels.....	4-27
4.10	Urine Specimen Processing.....	4-27
4.11	Record the Results of Urine Specimen Processing.....	4-29
4.12	Second and Third Urine Samples	4-34
4.13	Specimen Storage.....	4-34
4.14	How to Deal with System Failure.....	4-35
5	Urine Pregnancy Test.....	5-1
5.1	Purpose and Principle of the Test.....	5-1
5.2	Special Safety Precautions.....	5-2
5.3	Computerization: Integrated Survey Information System (ISIS)...	5-3
5.4	Specimen Collection and Preparation.....	5-3
5.5	Reagents and Supplies	5-3
5.5.1	Reagents	5-3
5.5.2	Supplies	5-5
5.6	Assay Procedure.....	5-5
5.7	Reportable Range of Results	5-6
5.8	Quality Control (QC)	5-6
5.9	Interpretation of Results and Remedial Action.....	5-15

<u>Chapter</u>		<u>Page</u>
5.10	Record Results.....	5-17
5.10.1	Partial Exams Requiring Repeat Pregnancy Testing	5-20
5.11	Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions.....	5-21
5.12	Reference Ranges.....	5-24
5.13	Action Limits.....	5-24
5.14	Specimen Storage and Handling During Testing.....	5-24
5.15	Alternative Method for Performing the Test or Storing Specimens if the Test System Fails.....	5-24
5.16	Test Results Reporting System Protocol for Reporting Action Limits.....	5-24
5.17	Specimen Accountability and Tracking.....	5-24
5.18	Quality Control Summary Statistics and Graphs	5-25
5.19	References.....	5-25
6	Complete Blood Count.....	6-1
6.1	Introduction.....	6-1
6.2	Purpose and Principle of Test.....	6-1
6.2.1	Coulter Method.....	6-3
6.2.2	VCSn Technology.....	6-3
6.2.3	Dataplot Development.....	6-4
6.2.4	Parameter Measurement, Derivation, and Calculation....	6-5
6.3	Components of DxH 800.....	6-6
6.3.1	The Specimen Processing Module.....	6-6
6.3.2	The System Manager.....	6-7
6.3.3	Pneumatic Supply Module.....	6-7
6.4	Special Safety Precautions.....	6-7
6.5	Computerization: Integrated Survey Information System (ISIS)...	6-8
6.6	Specimen Collection and Preparation.....	6-8
6.6.1	Specimen Collection.....	6-8
6.6.2	Specimen Preparation	6-8

<u>Chapter</u>		<u>Page</u>
6.7	Procedure for Microscopic Examination	6-9
6.7.1	Reagents and Supplies.....	6-9
6.7.2	DxH 800 Supplies.....	6-12
6.8	Shutdown of DxH 800 System.....	6-12
6.8.1	Daily Shutdown.....	6-13
6.8.2	Shutdown at the Mobile Examination Center.....	6-13
6.8.3	Cancel Automatic Shutdown	6-14
6.8.4	Manual Shutdown of DxH Units.....	6-15
6.9	Log On as User	6-15
6.9.1	Entering New Operator.....	6-15
6.10	Run Daily Checks.....	6-16
6.10.1	Daily Checks Screen.....	6-17
6.10.2	Additional Tasks From the Daily Checks Screen	6-17
6.11	Quality Control.....	6-18
6.11.1	Frequency of Performing Quality Control	6-18
6.11.2	Setting Up a Control File.....	6-20
6.11.3	Setting Up a Latron Control File.....	6-20
6.11.4	Establishing Means and Standard Deviations (SDs) for Quality Control Material	6-20
6.11.5	To Change the Mean and Standard Deviation (SD) on the Coulter	6-21
6.11.6	What To Do When a Control Is Out of Range	6-22
6.11.7	Viewing Control Files – Data View (Menu > QA > QC)	6-23
6.11.8	Selecting a Control.....	6-30
6.11.9	Viewing Control Files Graphically (Menu > QA > QC > View Graph)	6-30
6.11.10	Using and Interpreting the Levey-Jennings Graphs.....	6-31
6.11.11	Add, Modify, or Delete Comments to QC Results	6-32
6.11.12	View Control Files Under Error Conditions.....	6-33

<u>Chapter</u>		<u>Page</u>
6.12	Sample Analysis.....	6-33
	6.12.1 Status	6-33
	6.12.2 Cassette Presentation	6-34
	6.12.3 Single-Tube Presentation.....	6-34
	6.12.4 Handling Alarms.....	6-35
6.13	Data Evaluation.....	6-35
	6.13.1 Flags.....	6-35
	6.13.2 Codes.....	6-36
	6.13.3 Messages.....	6-37
	6.13.4 All Specimens	6-38
6.14	Laser Safety	6-40
6.15	Calibration of the DxH 800.....	6-40
	6.15.1 Perform Calibration.....	6-41
	6.15.2 Verify the Calibration of Your Instrument.....	6-41
	6.15.3 Coulter Pre-Startup Procedure	6-41
	6.15.4 Initial DxH 800 Startup	6-42
	6.15.5 Repeatability, Carryover Check, and Calibration	6-43
	6.15.6 Carryover	6-44
	6.15.7 Calibration	6-45
6.16	Run Study Participants	6-47
	6.16.1 Review Data and Transmit.....	6-48
	6.16.2 Daily Shutdown.....	6-48
	6.16.3 Prolonged Shutdown.....	6-48
	6.16.4 Beginning and End of Stand Operations.....	6-49
6.17	Coulter Reportable Range of Results.....	6-50
6.18	Integrated Survey Information System.....	6-51
	6.18.1 Record 6C Cell and Latron Lot Numbers in Integrated Survey Information System.....	6-51
	6.18.2 Interlaboratory Quality Assurance Program (IQAP)	6-54
	6.18.3 Proficiency Testing.....	6-55
	6.18.4 Linearity for WBC, RBC, Hgb, and Plt Parameters	6-57

<u>Chapter</u>		<u>Page</u>
6.19	Interpretation of Results and Remedial Action.....	6-57
6.19.1	Sample Person Hemoglobin and Hematocrit Review and Remedial Actions	6-57
6.19.2	SP Parameter Value Review and Remedial Actions	6-58
6.19.3	DxH 800 Suspect Messages	6-87
6.19.4	DxH 800 Histogram Interpretations	6-88
6.19.5	Physician Review	6-93
6.20	Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions.....	6-96
6.20.1	Specimen Rejection	6-96
6.20.2	Interfering Substances and Conditions	6-96
6.21	Reference Ranges.....	6-98
6.22	Action Limits	6-99
6.23	Specimen Storage and Handling During Testing.....	6-100
6.24	Alternative Method for Performing Test or Storing Specimens if Test System Fails	6-100
6.25	Test Results Reporting System: Protocol for Reporting Action Limits	6-100
6.26	Quality Control Summary Statistics and Graphs	6-101
6.27	Troubleshooting.....	6-101
6.28	Setting Shift Times.....	6-101
6.29	Reference.....	6-101
7	Blood Processing	7-1
7.1	Introduction.....	7-1
7.2	Equipment and Supplies	7-1
7.3	Protocols	7-2
7.4	Blood Processing Age-Specific Protocols	7-5
7.5	Labeling Vessels	7-9
7.6	Equipment.....	7-10
7.6.1	Benchtop Centrifuges	7-10
7.6.2	Laminar Flow Biological Safety Cabinet Operating Sequence	7-17

<u>Chapter</u>		<u>Page</u>
7.7	Blood-Processing Procedures	7-18
7.7.1	Eppendorf Xplorer Plus Pipettes	7-19
7.7.2	Process the 3-ml and 4-ml EDTA Tubes	7-31
7.7.3	Process the 2-ml Gray Tube for Glucose	7-36
7.7.4	Process the 7-ml, 10-ml, and 15-ml Red Top for Pooled Sera	7-36
7.7.5	Ascorbic Acid Processing and Preparation.....	7-39
7.7.6	TB Blood Processing	7-40
7.8	Record the Results of Specimen Processing	7-47
7.9	Blood Specimen Storage	7-57
7.9.1	Blood Specimen Storage Protocol	7-57
7.10	How to Deal With System Failure.....	7-59
8	Printing Labels and Specimen Shipment.....	8-1
8.1	Introduction.....	8-1
8.2	Equipment and Supplies	8-4
8.3	Print Vessel Labels and Label Blood Processing Racks.....	8-5
8.3.1	Print Vessel Labels Using the Label Print Application...	8-7
8.3.2	Main Printing Screen.....	8-7
8.3.3	Filter Options	8-8
8.3.4	Print Key	8-9
8.3.5	Print Options: Print Labels	8-10
8.3.6	Print Options: Group By.....	8-12
8.3.7	Print Options: Module Filter	8-13
8.3.8	Print Order	8-13
8.3.9	Print Display Options	8-14
8.3.10	Printing One SP's Labels.....	8-15
8.3.11	Printing Individual Labels	8-16
8.3.12	Label Action	8-17
8.3.13	Label Printing Cheat Sheet.....	8-22
8.4	Create New Container Labels	8-23
8.5	Close Containers	8-34

<u>Chapter</u>		<u>Page</u>
8.6	Trash or Reprint Container Labels.....	8-40
	8.6.1 Reprint Container Labels for Existing Containers	8-41
8.7	Shipping Overview	8-42
8.8	Assign Containers to Shippers	8-44
8.9	Create Shipping Manifests	8-50
8.10	Informed Consent Exclusions	8-55
8.11	Packing Procedure for the Shippers.....	8-58
	8.11.1 Pack the Boxed Specimens.....	8-61
	8.11.2 Pack the Medium Shipping Containers for Frozen Shipment	8-62
	8.11.3 Pack the Small Shipping Containers for Frozen Shipment	8-62
	8.11.4 Pack the Medium Shipping Containers for Refrigerated Shipment	8-63
	8.11.5 Label the Shippers	8-64
8.12	Container Protocol and Weekly Shipping List	8-64
9	HPV Swab Processing	9-1
	9.1 Introduction.....	9-1
	9.2 Supplies.....	9-3
	9.3 Protocol.....	9-3
	9.4 Labeling Vessels	9-3
	9.5 HPV Protocol.....	9-4
	9.6 Record Processing Results.....	9-5
	9.7 Specimen Storage.....	9-10
	9.8 Shipping Procedures.....	9-11
	9.8.1 Pack and Ship Vessel 78	9-11
	9.8.2 Label Shippers.....	9-12
9.9	How to Deal with System Failure.....	9-12
10	Quality Control and Quality Assurance—Policies and Procedures.....	10-1
	10.1 Safety.....	10-1
	10.1.1 Introduction	10-1

<u>Chapter</u>		<u>Page</u>
10.2	Specimen Submission and Handling.....	10-1
	10.2.1 Introduction	10-1
	10.2.2 Identification of Specimens	10-2
	10.2.3 Questions on Specimen Submission and Handling.....	10-2
10.3	Test Requisition.....	10-2
	10.3.1 Introduction	10-2
	10.3.2 Laboratory Tests	10-3
	10.3.3 Human Subjects Review	10-3
10.4	Test Records	10-3
	10.4.1 Introduction	10-3
	10.4.2 Components of Test Records.....	10-3
10.5	Test Report	10-4
	10.5.1 Introduction	10-4
	10.5.2 Review, Approval, and Release of Test Results	10-4
	10.5.3 List of Methods and Method Details.....	10-5
	10.5.4 Format of the Test Report	10-5
	10.5.5 Format for the Laboratory Report Cover Letter	10-6
	10.5.6 Format for Listing of Laboratory Results.....	10-6
10.6	Quality Control.....	10-6
	10.6.1 Introduction	10-6
	10.6.2 Method-Specific QC Procedures.....	10-8
	10.6.3 QC Definitions.....	10-9
	10.6.4 Overview of the Relationship Between Internal QC, Proficiency Testing, and External QC.....	10-10
	10.6.5 Internal (“Bench”) QC.....	10-10
	10.6.6 Coulter Interlaboratory Quality Assurance Program (IQAP).....	10-11
	10.6.7 Calibration and Calibration Verification	10-16
	10.6.8 Proficiency Testing.....	10-17
	10.6.9 Calibration Verification.....	10-21
	10.6.10 Linearity	10-23
	10.6.11 Quality Control Records.....	10-23

<u>Chapter</u>		<u>Page</u>
10.7	Test Methods, Equipment, Reagents, Supplies, and Facilities	10-23
	10.7.1 Introduction	10-23
	10.7.2 Labeling of Reagents, Solutions, and Other Supplies	10-24
	10.7.3 Facilities.....	10-25
10.8	Analytical Procedure Manual.....	10-25
	10.8.1 Introduction	10-25
	10.8.2 Contents of the Analytical Procedure Documentation...	10-25
	10.8.3 Approval and Record Maintenance	10-26
	10.8.4 Method Performance Specifications.....	10-26
10.9	Equipment Maintenance and Function Checks	10-27
	10.9.1 Introduction	10-27
	10.9.2 Laboratory Equipment Calibration.....	10-27
	10.9.3 Temperature Monitoring	10-27
	10.9.4 Humidity Monitoring.....	10-30
10.10	Troubleshooting.....	10-30
	10.10.1 Introduction	10-30
10.11	Integrated Survey Information System (ISIS).....	10-31
	10.11.1 Introduction	10-31
	10.11.2 Integrated Survey Information System Data Down Times	10-31
	10.11.3 Maintenance of LAN Hardware.....	10-31
	10.11.4 Backup Schedule of Integrated Survey Information System Data.....	10-32
10.12	Communications and Complaints	10-32
	10.12.1 Introduction	10-32
10.13	Quality Promotion	10-33
	10.13.1 Introduction	10-33

<u>Chapter</u>	<u>Page</u>
10.14 Quality Assurance Program.....	10-33
10.14.1 Introduction	10-33
10.14.2 Quality Audit: Study Participant Test Management	10-34
10.14.3 Quality Audit: Quality Control	10-35
10.14.4 Quality Audit: Personnel	10-36
10.14.5 Quality Audit – Phlebotomy Refusals	10-36
10.14.6 Quality Audit – Pre-Analytic Sample Quality.....	10-37
10.14.7 Quality Audit – Post-Analytic Extreme Result Reporting	10-37
10.14.8 Quality Audit – Urine Collection from 3- to 5- Year-Old SPs.....	10-37
10.14.9 Quality Audit – Unusual Field Occurrences.....	10-38
10.14.10 Quality Assurance Review with Staff.....	10-38
10.15 Personnel Training and Evaluation	10-38
10.16 Competency Assessment	10-39
10.16.1 Introduction	10-39
10.16.2 NHANES Competency Assessment Plan	10-40
11 Operational Issues	11-1
11.1 Start-of-Stand Activities	11-1
11.1.1 Phlebotomist and Facilities and Equipment Specialists Responsibilities.....	11-2
11.1.2 Medical Technologists’ and Facilities and Equipment Specialists Responsibilities.....	11-4
11.1.3 Workstation Responsibilities for the Team	11-6
11.1.4 National Center for Health Statistics Biomedical Engineer Responsibilities	11-15
11.2 Additional End-of-Stand Activities.....	11-15
11.2.1 Packing the Phlebotomy Room.....	11-15
11.2.2 Packing the Laboratory.....	11-16
11.2.3 Sending Laboratory Files and Supplies.....	11-19
11.3 Inventory Procedures and Supplies.....	11-19
11.3.1 General Inventory Procedures.....	11-19
11.3.2 End-of-Stand Inventory Procedures	11-20

<u>Chapter</u>		<u>Page</u>
	11.3.3 Mid-Stand Inventory Procedures	11-21
	11.3.4 Start-of-Stand Inventory Procedures.....	11-22
	11.3.5 Consumables Versus Non-Consumables.....	11-23
	11.3.6 Shipping Inventory Back to the Warehouse.....	11-23
	11.3.7 Tracking Expired and Broken Inventory.....	11-23
11.4	Dry Run Session.....	11-24
	11.4.1 Dry Run Phlebotomy Protocol and Procedures.....	11-24
	11.4.2 Dry Run Urine Processing and Pregnancy Testing.....	11-26
	11.4.3 Dry Run Urine Processing	11-37
	11.4.4 Dry Run Hematology.....	11-40
	11.4.5 Dry Run Blood Processing and Storage.....	11-41
	11.4.6 Shipping Dry Run Specimens	11-43
11.5	Centrifuges Allegra X-15R—Equipment Maintenance.....	11-43
	11.5.1 Centrifuge Cleaning.....	11-44
	11.5.2 Rotor Care and Maintenance	11-44
	11.5.3 Cleaning the Rotor	11-45
	11.5.4 Care and Maintenance for Buckets	11-46
	11.5.5 Care and Maintenance for the Aerosolve Canisters	11-46
11.6	Refrigerators and Freezers—Equipment Maintenance.....	11-47
11.7	Use of the Temperature Recording Instrument.....	11-48
11.8	Use of the Class II Type A Biological Safety Cabinet	11-50
11.9	Ambient Air Temperature	11-64
11.10	Humidity Monitor.....	11-64
11.11	Mettler Toledo Scale.....	11-64
	11.11.1 Initial Scale Interface Setup.....	11-65
	11.11.2 Scale Setup	11-66
	11.11.3 Scale Teardown.....	11-67
11.12	Eppendorf Pipette Care, Sterilization, Maintenance, and Calibration.....	11-67
	11.12.1 Care and Maintenance.....	11-67
	11.12.2 Disinfecting	11-68
	11.12.3 Xplorer Pipette Assembly and Disassembly.....	11-68
11.13	Mini Vortex Mixer Care and Storage	11-73
11.14	Heratherm™ Compact Microbiological Incubator	11-73

<u>Chapter</u>		<u>Page</u>
	11.15 Laboratory Quality Control Module	11-74
	11.16 Unusual Field Occurrence	11-78
	11.17 Power Loss and Laboratory Operations.....	11-80
	11.17.1 Scenario 1—Power Loss During Exam Session with No Backup Generator.....	11-80
	11.17.2 Scenario 2—Power Loss When the MEC Is Not Conducting Exams	11-83
	11.17.3 Scenario 3—Power Loss with a Backup Generator.....	11-84
12	HPV Oral Rinse Processing.....	12-1
	12.1 Introduction.....	12-1
	12.2 Supplies.....	12-2
	12.3 Protocol.....	12-2
	12.4 Labeling Vessels	12-2
	12.5 HPV Rinse Protocol.....	12-2
	12.6 Record Processing Results.....	12-3
	12.7 Specimen Storage.....	12-6
	12.8 Shipping Procedures.....	12-7
	12.9 How to Deal with System Failure.....	12-7
13	Household Water Sample Processing.....	13-1
	13.1 Receipt of Household Water.....	13-1
	13.2 Processing	13-5
14	Household Salt Sample Processing.....	14-1
	14.1 Receipt of Household Salt.....	14-1
	14.2 Processing	14-4
	14.3 Storage and Shipping.....	14-9

<u>Tables</u>		<u>Page</u>
6-1	Coulter DxH 800 analyzers serial numbers and systems IDs	6-1
6-2	Components on the QC Data View screen	6-29
6-3	Coulter reportable range of results.....	6-51
6-4	CDC precision limits.....	6-66
6-5	Reference ranges (males)	6-98
6-6	Reference ranges (females).....	6-98
7-1	Eppendorf Research Pro electronic pipettes technical data.....	7-19
7-2	Single channel pipette technical data	7-21
7-3	Eppendorf pipette ordering information	7-31
 <u>Figures</u>		
1-1	Laboratory layout.....	1-3
1-2	Phlebotomy room layout.....	1-3
 <u>Exhibits</u>		
3-1	Venipuncture protocol — primary	3-2
3-2	Venipuncture protocol — guest.....	3-2
3-3	Alternative venipuncture protocol — primary.....	3-3
3-4	Venipuncture protocol — Dry Run	3-3
3-5	Floor plan for phlebotomy room.....	3-3
3-6	Equipment and supplies — phlebotomy	3-4
3-7	UMF 8678 phlebotomy chair.....	3-6
3-8	RX4-1000 phlebotomy chair.....	3-7

<u>Exhibits</u>		<u>Page</u>
3-9	Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB .	3-44
3-10	Age Specific Care and Phlebotomy.....	3-47
3-11	Position of Veinlite EMS while looking for a vein.....	3-52
3-12	Position of Veinlite EMS while accessing a vein.....	3-53
3-13	Comment codes for Partial and Not Done venipunctures.....	3-59
3-14	Phlebotomy worksheet – English Primary.....	3-67
3-15	Phlebotomy worksheet – Spanish Primary.....	3-70
4-1	Urine collection equipment.....	4-3
4-2	Urine collection supplies – urine processing and storage.....	4-3
4-3	Comment codes for urine collection.....	4-18
4-4	NHANES urine processing protocol – primary.....	4-26
4-5	Quality comment codes to use for filled vessels.....	4-33
4-6	Comment codes.....	4-33
4-7	Storage and shipping protocol for urine.....	4-35
4-8	Workstation 3 processing worksheet.....	4-36
5-1	ICON® 25 test device.....	5-15
5-2	Positive result.....	5-16
5-3	Negative result.....	5-16
5-4	Invalid result.....	5-16
5-5	Comparison of hCG tests.....	5-22
5-6	Interfering substances.....	5-23
6-1	Reportable parameters and analysis methods.....	6-5

<u>Exhibits</u>		<u>Page</u>
6-2	Coulter 6C Cell Control Open Vial Stability Monitoring Log.....	6-19
6-3	Examples of trends and shifts in QC data.....	6-24
6-4	Westgard Rule 1 _{2s}	6-25
6-5	Westgard Rule 1 _{3s}	6-25
6-6	Westgard Rule 2 _{2s}	6-26
6-7	Westgard Rule 4 _s	6-27
6-8	Westgard Rule 4 _{1s}	6-28
6-9	Interpretation of DxH flags.....	6-36
6-10	Picture of tubes.....	6-47
6-11	List of comments to be used.....	6-79
6-12	Cellular analysis images.....	6-88
6-13	DxH system messages.....	6-89
6-14	Red blood cell histogram examples.....	6-90
6-15	White blood cell histogram examples.....	6-91
6-16	Platelets histogram examples.....	6-92
6-17	Image of better abnormal cell detection.....	6-93
7-1	Nonconsumable supplies for blood processing.....	7-1
7-2	Consumable supplies for blood processing.....	7-2
7-3	Primary SP's whole blood processing protocol.....	7-3
7-4	Primary SP's plasma processing protocol.....	7-3
7-5	Primary SP's packed cells processing protocol all from one dedicated 7-ml EDTA.....	7-3

<u>Exhibits</u>		<u>Page</u>
7-6	Primary SP's serum processing protocol.....	7-3
7-7	Guest serum processing protocol	7-4
7-8	Blood processing protocol for primary SPs aged 1-2 years.....	7-5
7-9	Blood processing protocol for primary SPs aged 3-5 years.....	7-5
7-10	Blood processing protocol for primary SPs aged 6-11 years	7-6
7-11	Blood processing protocol for primary SPs aged 12-19 years	7-6
7-12	Blood processing protocol for primary SPs aged 20+ years.....	7-7
7-13	Blood processing protocol for guests aged 12+ years	7-8
7-14	Blood processing protocol for foreign guests aged 6-59 years and 60+ all.....	7-9
7-15	Centrifuge control panel.....	7-11
7-16	Digital displays	7-12
7-17	Packing rotors in plastic bin (1).....	7-16
7-18	Packing rotors in plastic bin (2).....	7-17
7-19	Illustration of single channel pipette.....	7-23
7-20	Removing the lower part – pipettes $\leq 1,000 \mu\text{l}$	7-29
7-21	Opening the lower part – pipettes $\leq 1,000 \mu\text{l}$	7-30
7-22	Removing the lower part for the 5 ml pipette.....	7-31
7-23	RBC washing procedure (visual aid).....	7-37
7-24	Quality comment codes	7-53
7-25	Comments for not filled vessels	7-55
7-26	Storage protocol for blood.....	7-58
7-27	Workstation 2 processing worksheet.....	7-60

<u>Exhibits</u>		<u>Page</u>
8-1	Blood and urine shipping protocol	8-1
8-2	Supplies for labels/shipping.....	8-5
8-3	Contract laboratory addresses.....	8-59
8-4	Container protocol	8-65
9-1	Equipment and supplies—HPV processing and storage.....	9-3
9-2	HPV processing protocol.....	9-3
9-3	Female HPV module.....	9-4
9-4	Male HPV module.....	9-5
9-5	Female HPV Swab Processing screen	9-6
9-6	Male HPV Swab Processing screen	9-7
9-7	Storage protocol for HPV	9-11
9-8	Shipping protocol	9-11
9-9	HPV processing worksheet.....	9-13
10-1	Example of shifts and trends in QC data.....	10-7
10-2	Westgard Rule 1_{2S}	10-12
10-3	Westgard Rule 1_{3S}	10-13
10-4	Westgard Rule 2_{2S}	10-14
10-5	Westgard Rule R_{4S}	10-15
10-6	Westgard Rule 4_{1S}	10-16
10-7	CAP hematology survey comparison criteria	10-21
10-8	Recommended storage conditions for reagents and tubes.....	10-28
10-9	Established ranges for monitoring instrument quality control.....	10-29

<u>Exhibits</u>		<u>Page</u>
10-10	NHANES competency assessment plan.....	10-41
11-1	Dry run venipuncture protocol	11-25
11-2	Dry run urine processing protocol.....	11-37
11-3	Dry run processing protocol—whole blood	11-41
11-4	Dry run blood processing protocol—serum	11-42
11-5	Lubrication points	11-45
11-6	Operating the laminar flow biological safety cabinet.....	11-52
11-7	Explorer pipette assembly and disassembly for pipettes < 5ml	11-69
11-8	Laboratory QC table	11-74
11-9	Hard-copy Unusual Occurrence Log.....	11-79
12-1	Equipment and supplies – HPV Rinse processing and storage.....	12-2
12-2	HPV Rinse processing protocol.....	12-2
12-3	Storage protocol for HPV Rinse	12-7
12-4	Shipping protocol	12-7
12-5	HPV Oral Rinse Processing worksheet.....	12-8
13-1	Container protocol	13-16
14-1	Container protocol	14-9

1. Overview and Laboratory Team Responsibilities

1.1 Overview

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

The blood collection (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, TB on foreign born SP's 6-59 and all SP's 60 years of age and older, and Liver Genetics on SP's 18 years of age and older.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 3 years and older to (1) perform a pregnancy test on selected females aged 8-17 and all females aged 18-59 to exclude pregnant participants from other components that could put them at risk; (2) allocate urine into vessels for storage and transport to multiple government and contract laboratories for analysis; (3) calculate a urine flow rate; and (4) allocate urine into a vessel for future studies.

The purpose of blood processing is to (1) perform a complete blood count (CBC); (2) allocate blood (whole blood, plasma, and serum) into vessels for transport to multiple government and contract laboratories for analysis; (3) allocate serum into vessels for future studies; and (4) process serum for environmental testing.

The purpose of collecting and processing a vaginal swab, a penile swab, and an oral rinse is to be able to store and transport the samples to a laboratory for human papillomavirus (HPV) analysis.

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

The purpose of pregnancy testing is to exclude pregnant women aged 8-59 years from participating in the dual-energy x-ray absorptiometry (DXA) and the liver ultrasound transient elastography

(LUTE) sections of the body composition component 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 water samples is to determine the fluoride levels within samples collected from SPs' households.

The purpose of collecting SP household salt samples is to determine the iodine levels in the commonly used home cooking salts.

1.2 The Laboratory Team

Each laboratory team includes three certified medical technologists or medical laboratory technicians 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, he or she is responsible for overseeing the day to day technical activities of the laboratory staff on the MEC, as well as 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. In addition, the phlebotomist acts as a backup examiner and recorder for the body measures exam and as a recorder for the oral health exam.

The medical technologists' and medical laboratory technicians' tasks include printing labels and labeling vessels; performing CBCs; conducting pregnancy tests; processing blood, urine, vaginal and

penile swabs, salt samples, water samples, and oral rinse samples; 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 (label/ship and environmental sample processing area; biological sample processing; and hematology/pregnancy testing) area. 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.

Figure 1-1. Laboratory layout

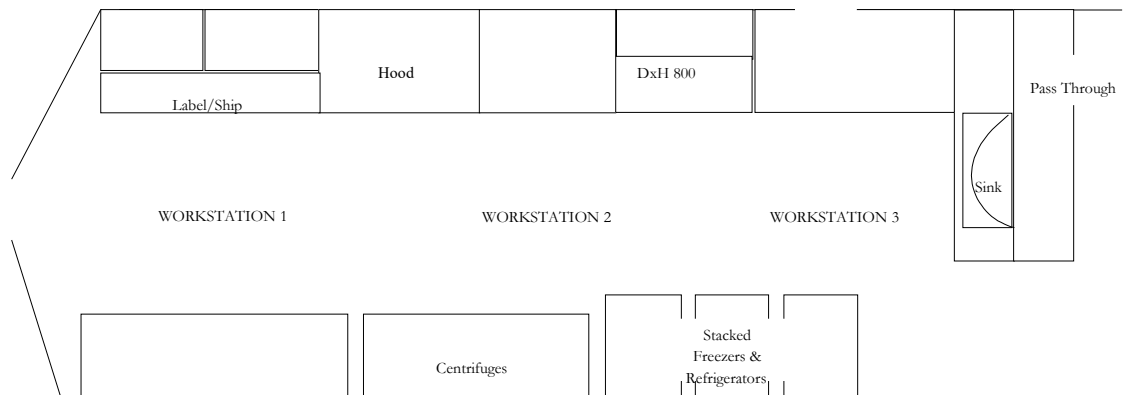


Figure 1-2. Phlebotomy room layout



‘The phlebotomist performs the phlebotomy examination in the phlebotomy room.

Laboratory Area Floor Plan

The laboratory area contains three workstations designated workstations 1, 2, and 3. Printing labels, labeling vials for each SP's blood-processing rack, processing TB samples, processing salt samples, 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; vaginal and penile swab specimen processing; water sample processing; oral rinse sample processing; genetics blood processing; VOC blood processing and routine QC activities occur at workstation 3.

1.5 Tasks—Phlebotomy Room

- Set up supplies and check expiration dates of all items with lot numbers, such as the Vacutainer[®] tubes;
- Complete the phlebotomy examination, including conducting the venipuncture interview, administering the fasting questionnaire, 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, or as needed when soiled with blood or other body fluids;
- 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;
- Assist the laboratory staff when they pack the shippers; and
- Serve as the backup examiner and recorder in body measures and recorder in oral health.

1.6 Tasks—Lab Workstation 1

- Complete blood processing tasks for the first 45 minutes of each session;
- Print blood, HPV oral rinse, and urine testing labels;
- Prelabel 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), urine, oral rinse, salt, and vaginal and penile swab samples for shipping;
- Incubate TB samples (vessels 223, 224, 225, and 226) and process;
- Process salt samples;
- 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 counters and the work area at the end of each day.

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 216 (Cr/Co), vessel 3 (RBC folate), vessel 4 (glycohem), and vessel 5 (mercury);
- Pipette the plasma from the 7-ml lavender tube and perform cell washing on the remaining cells for vessels 88 (acrylamide), 221 (folate forms), and 222 (fatty acids);
- Make the dilution for RBC folate vessels 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- of 5 ml cryovials for the serum vessels according to the age-specific protocols;
- 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 session or when the area becomes soiled with blood or other body fluids;
- 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% and 7% ascorbic acid solutions daily;
- Enter the ascorbic preparation 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 on the Coulter[®] DxH 800 and enter results;
- Process and refrigerate VOC blood (vessel 54) tube;
- Process and refrigerate water samples for those eligible SP's who have visited the MEC (vessel 144);
- 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;
- Process and store vaginal swab (vessel 78);
- Process and refrigerate penile swab (vessel 140);
- Label a 14-mL Falcon tube and pour the entire contents of the oral rinse sample into the tube. Process and refrigerate oral rinse (vessel 129);

- Process and refrigerate genetics sample (vessel 119);
- Check contents of urine, vaginal swab, and penile swab, water samples, genetic samples, and VOC samples using the content container verification module at the end of each session;
- Disinfect all work areas at the beginning of the stand and end of each session, or when they become soiled with blood or other body fluids;
- Maintain the appearance of the urine processing/hematology 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.

1.9 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 set up and tear down. Medical technologists and technicians 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 to ensure competency and proficiency, the primary phlebotomists must be available to step in and complete the blood draw even when backups are working in phlebotomy.

- When the backup phlebotomist is assigned to workstation 1 (label/ship):
 - The primary phlebotomist works at workstation 1, except on Monday when the laboratory team ships. The backup phlebotomist always works the scheduled workstation 1 assignment on shipping Mondays.
 - The backup phlebotomist works in phlebotomy when the primary phlebotomist works at workstation 1.

- The primary phlebotomist, if available, should perform the pediatric blood draws while the backup phlebotomist observes and holds the child.
- If the backup phlebotomist encounters a difficult blood draw, then the primary phlebotomist comes into the room and they work together so that the blood draw is successful. This is intended as a learning experience; the backup phlebotomist can continue to learn from the primary phlebotomist.
- There are no designated number of days the backup phlebotomist works in phlebotomy during each stand. The objective is at least 2-3 days per stand with emphasis on sessions with 8-10 adult SPs.
- On setup day, the phlebotomist completes his or her room setup and assigned tasks before helping laboratory staff. On setup day, the phlebotomist should, at a minimum, make the racks for dry run day. On teardown day, he or she helps pack the shippers and assists the laboratory staff in other ways as directed by the chief medical technologist.

THIS PAGE IS INTENTIONALLY LEFT BLANK.

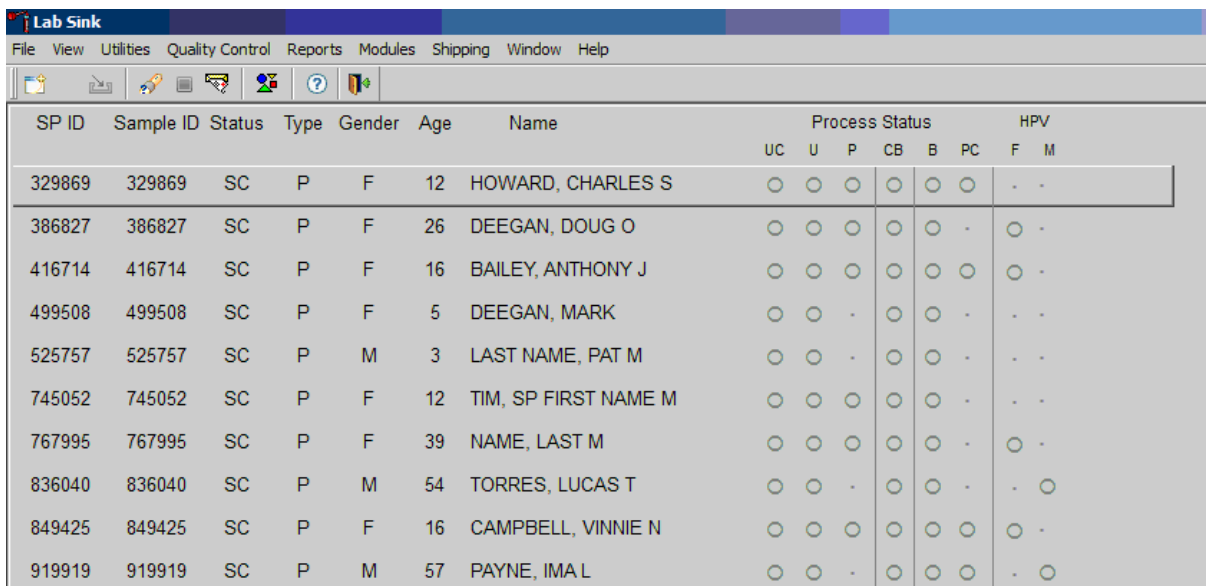
2. Laboratory ISIS Functionality

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 *Integrated Survey Information System (ISIS) User Guide*. 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						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"/>	-
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"/>	-	-	-
525757	525757	SC	P	M	3	LAST NAME, PAT M	<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"/>	-	-	-
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"/>	-
836040	836040	SC	P	M	54	TORRES, LUCAS T	<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"/>

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.)

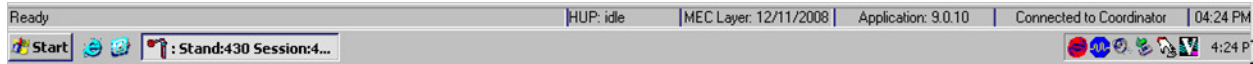
The heads-up display provides the Process Status for the following modules: UC (urine collection), U (urine processing), P (pregnancy testing), CBC (complete blood count), B (blood processing), PC (packed cell or vessels 88, 221, and 222 processing), Salt (salt sample processing), Water (water sample processing), TB (TB processing), Oral Rinse (oral rinse processing), and HPV (HPV swab processing; F for female and M for male). The SP is ineligible for a module when the process status is ○. The SP is eligible for a module, but no results have been recorded when the process status is ◯. The SP is eligible for a module, and some results have been recorded when the process status is ◐. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●.

The SP is eligible for a module (◯)Alt Text: Process status symbol (a circle with a dark outline) indicating that SP is eligible for a module, but no results have been recorded., but 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. Only SPs who have checked in are eligible for HPV processing. The process status is ◯Alt Text: Process status symbol (a circle with a dark outline) indicating that SP is eligible for a module, but no results have been recorded. 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 ◯Alt Text: Process status symbol (a circle with a light outline) indicating that SP is ineligible for a module to ◐Alt Text: Process status symbol (a circle with a dark outline) indicating that SP is eligible for a module, but no results have been recorded.. 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 are 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. The options marked with an asterisk appear on all MEC examination programs. Options are grayed (inverted) or not present when they are not available for a specific subsystem.

2.4.1 File Menu Options

The screenshot shows the 'Lab Sink' application window. The 'File' menu is open, displaying options: Open (Ctrl+O), Close, Print..., Delete, and Exit. The main window displays a table with the following columns: ID, Status, Type, Gender, Age, Name, Process Status (UC, U, P, CB, B, PC), and HPV (F, M). The table contains 10 rows of patient data.

ID	Status	Type	Gender	Age	Name	Process Status							
						UC	U	P	CB	B	PC	F	M
69	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"/>	-	-
27	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"/>	-
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"/>	-
499508	499508	SC	P	F	5	DEEGAN, MARK	<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"/>	-	-
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"/>	-	-
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"/>
836040	836040	SC	P	M	54	TORRES, LUCAS T	<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"/>	-
919919	919919	SC	P	M	57	PAYNE, IMA L	<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

The screenshot shows the 'Lab Sink' application window with the 'Utilities' menu open. The menu items are: Exam Pause (disabled), Observations, IC Exclusions (disabled), Send Message (Ctrl+M), UFO Sighting, Set Session, English (Ctrl+E), Spanish (Ctrl+S), Toolbars..., and System Configuration. The background table lists patient information with columns for SP ID, Gender, Age, Name, Process Status (UC, U, P, CB, B, PC), and HPV (F, M).

SP ID	Gender	Age	Name	Process Status						HPV	
				UC	U	P	CB	B	PC	F	M
329869	F	12	HOWARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	F	26	DEEGAN, DOUG O	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
416714	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	F	5	DEEGAN, MARK	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
525757	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	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	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	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	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	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"/>

*Utilities

*Exam Pause	This option is grayed out and not applicable.
*Observation	Submits an observation to the physician 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, STD, or HPV tests performed, or samples stored for future research; this utility is available only for coordinator, physician, 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 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"/>

*Quality Control

Quality Control Opens Quality Control for Start of Stand, End of Stand, Session, Daily, Weekly, and NCHS QC.

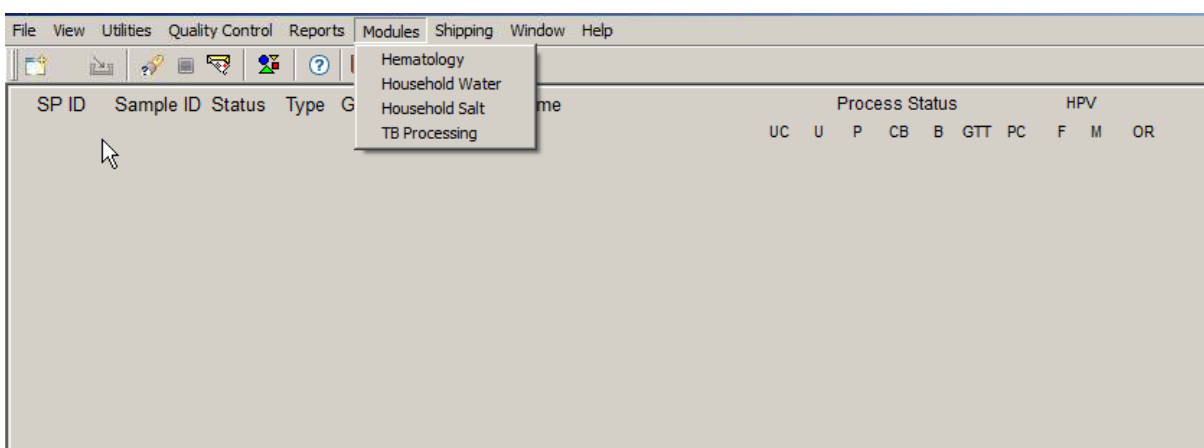
Pregnancy QC Opens pregnancy quality control window.

2.4.4 Report Menu Options

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						HPV	
							UC	U	P	CB	B	PC	F	M
329869	329869	SC				ARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC				GAN, 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"/>

*Reports	
Show Results	This option is grayed out and not applicable.
*Room Log	Lists the SPs who have completed the component, including appt/exam and component status.
*Session Preview	Lists all SPs in current session.
Subsample Preview	Lists the SPs who are eligible for the various subsamples. A complete description of this functionality is described in Section 2.9.
Partial SP Session	Lists the original session for which the partial SP was scheduled.
Informed Consent Status	Lists the various modules that require consent and displays the result of the consent – excluded or not excluded. A complete description of this functionality is described in Section 2.10.

2.4.5 Modules



Modules	
<u>Hematology</u>	Opens the laboratory hematology module. A complete description of this functionality is described in Section 6.19.2.
<u>Household Water</u>	Opens the laboratory household water processing module. A complete description of this functionality is described in Chapter 13.
<u>Household Salt</u>	Opens the laboratory household salt processing module. A complete description of this functionality is described in Chapter 14.
<u>TB Processing</u>	Opens the laboratory TB processing module. A complete description of this functionality is described in Section 7.7.6.

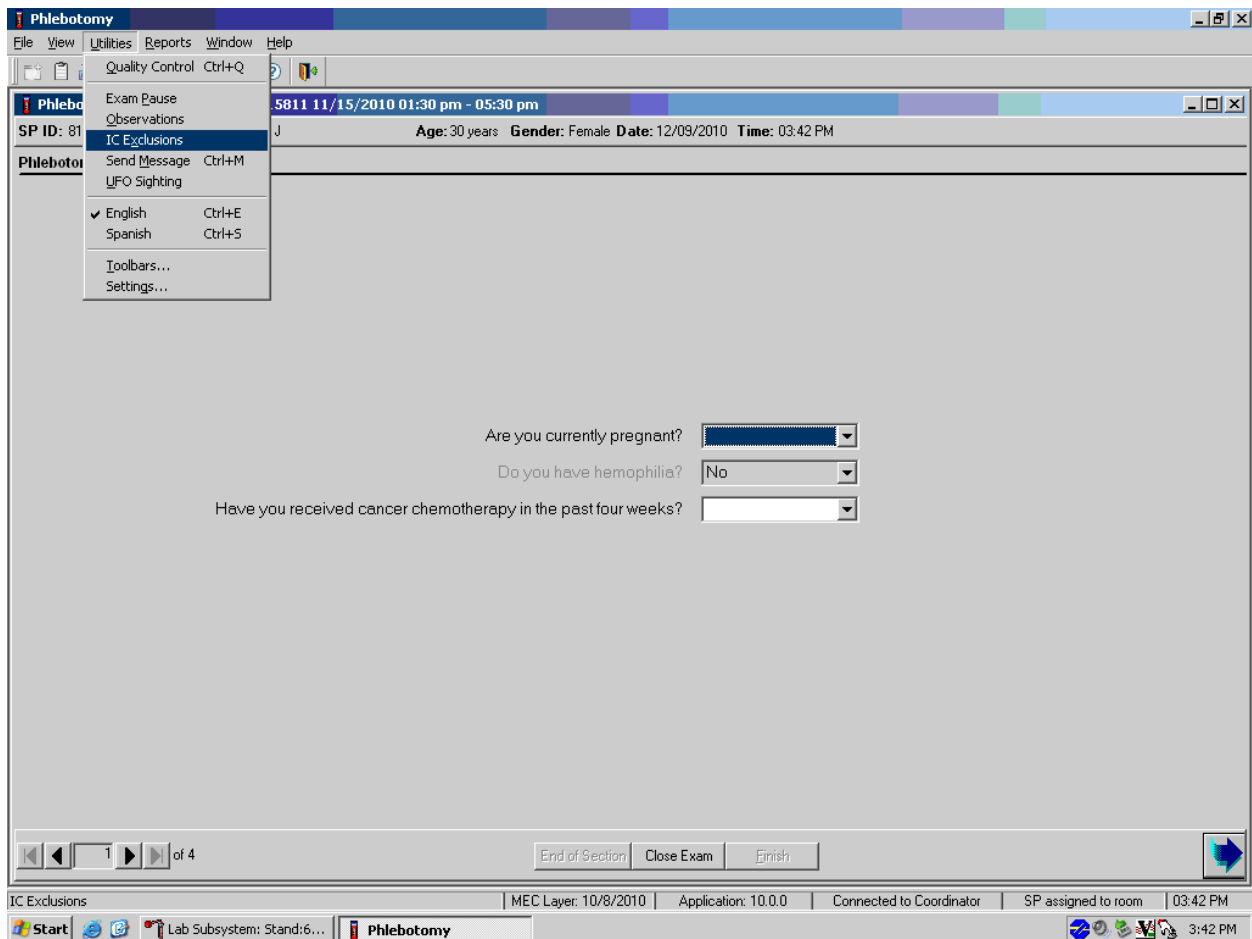
2.4.6 Shipping

Lab Sink							Shipping		Window		Help			
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"/>	<input type="radio"/>	-	-
416714	416714	SC	P	F		TO 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"/>

Shipping	
Print <u>N</u>ew Container Labels	Allows the medical technologist to print labels for containers. A complete description of this functionality is in Section 8.4.
<u>C</u>ontainer Map	Allows the medical 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.
<u>C</u>lose Containers	Allows the medical technologist to “close” active containers that have been previously opened. A complete description of this functionality is in Section 8.5.
Assign Containers to <u>S</u>hippers	Allows the medical technologist to assign or associate a closed container with a FedEx airbill number. A complete description of this functionality is in Section 8.8.
<u>T</u>rash Containers	Allows the medical 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 medical 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 medical 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 2-15 for a complete description.

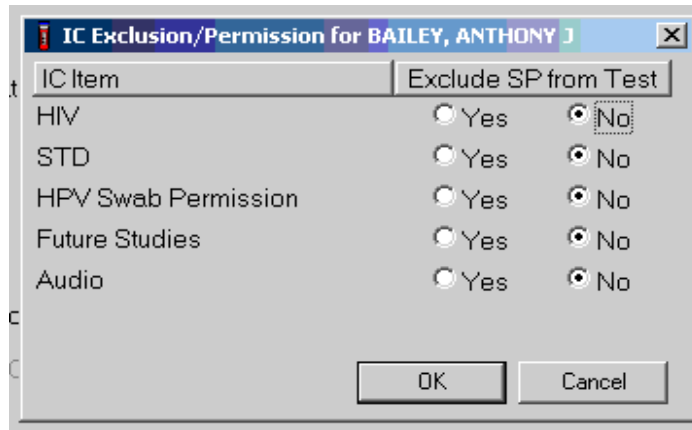
2.5 Informed Consent (IC) Exclusions

If at any time during the phlebotomy or physician exam, the SP indicates that he or she does not want his or her biological specimens tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, trichomonas, and *Mycoplasma genitalium*), HPV, or future studies, then the staff enter 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.

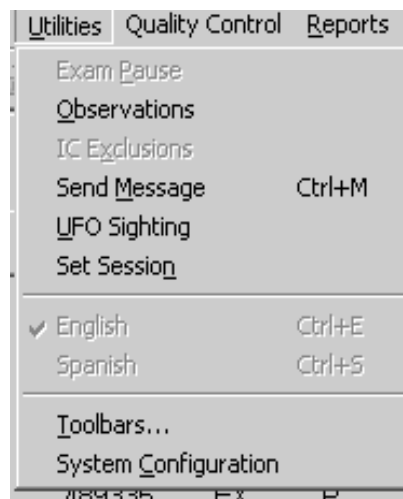
The IC Exclusions window displays all the specific exclusion item tests or groups of tests for which the SP is eligible and the status for each exclusion item.



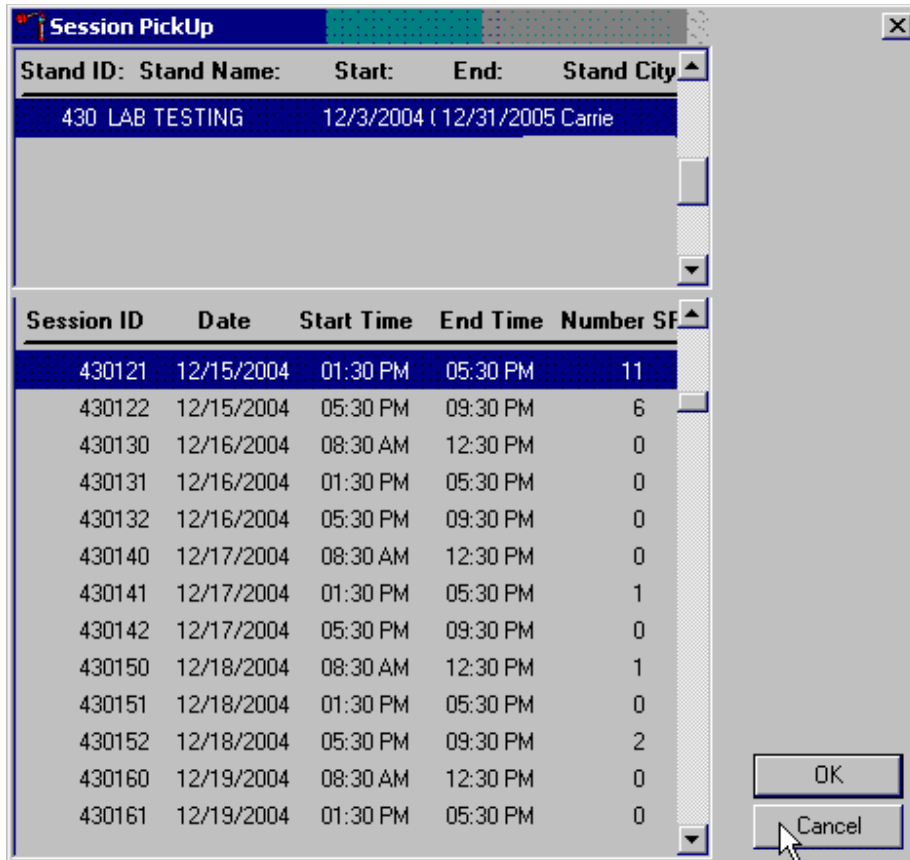
Record each item as directed by the SP. To mark each item, direct the mouse arrow to the “Yes” or “No” radio button and left-click. To record these actions and save them to the database, use the mouse to direct the mouse arrow to the OK button and left-click, or select Enter. To cancel these actions 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 onto 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						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"/>	-
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"/>	-	-	-
525757	525757	SC	P	M	3	LAST NAME, PAT M	<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"/>	-	-	-
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"/>	-
836040	836040	SC	P	M	54	TORRES, LUCAS T	<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"/>

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.

The screenshot shows the 'View Container Maps' dialog box in the Lab Sink software. The dialog contains a table of container information:

Container Id	Size	Name	Vessel ID	Vessel Name	Last Filled	Priority
616258	9x9	2 inch box	1	PbCadHgSeMn	14	15
616292	9x9	2 inch box	216	Chromium/Cob	12	16
616259	10x10	2 inch box	3	RBC Folate	31	20

Below the table, the selected container (616259) is shown with its details: Type: 2 inch box, Vessel ID: 3, Test(s): RBC Folate. A grid of slots is displayed, with one slot (139134) highlighted in red. The dialog also includes filter options for 'Opened' and 'Closed' containers, and options to show containers by 'Slot Number', 'Sample ID', or 'Household ID'.

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

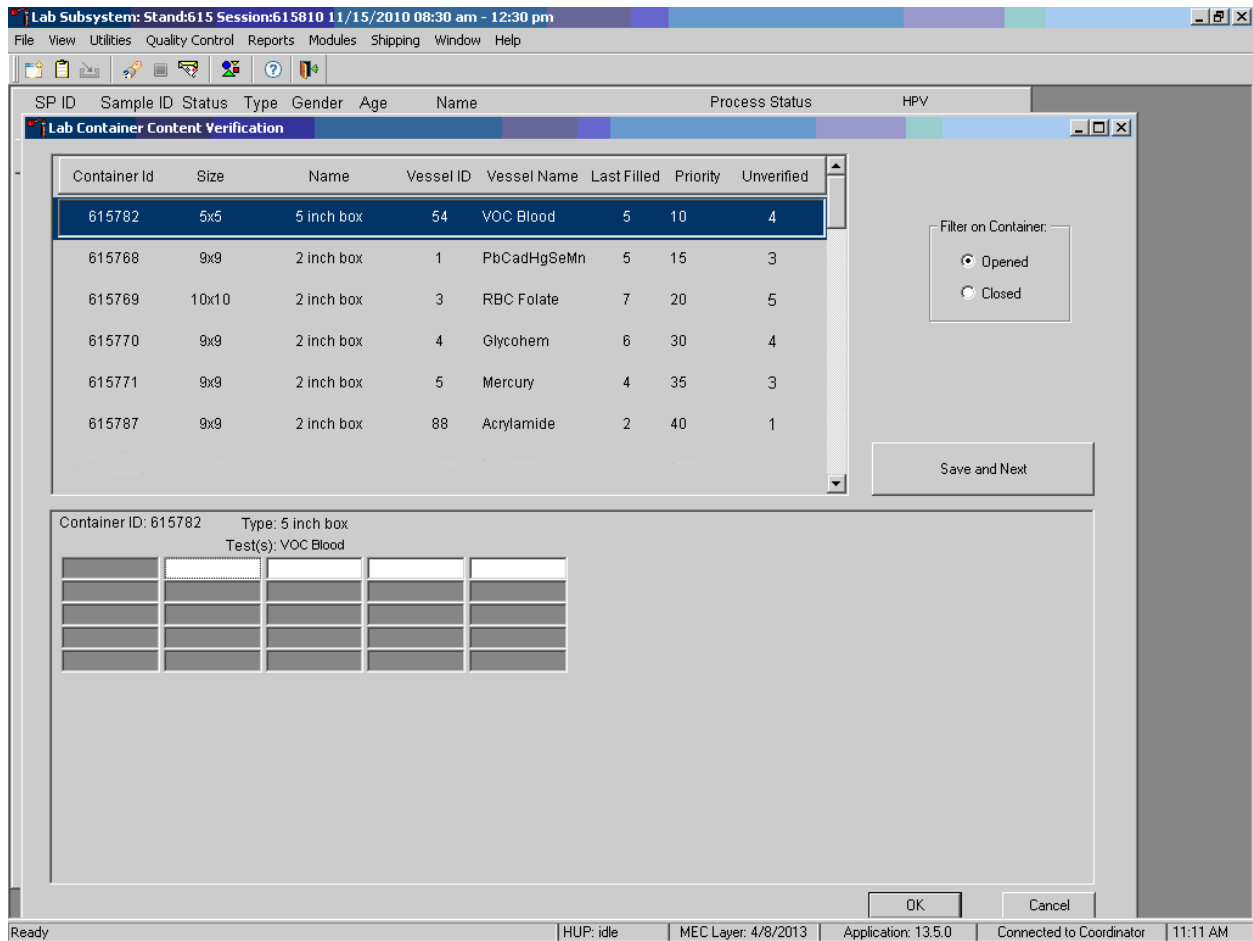
- Use Container Content Verification to verify the contents of each container.
- Access to container verification is located under the shipping tab from the lab’s heads-up display.
- Perform container verification after each session.
- Verify the container ID on the box against the container ID listed 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.

Lab Sink						
File View Utilities Quality Control Reports Modules Shipping Window Help						
SP ID	Sample ID	Status	Type	Gender		
329869	329869	SC	P	F		
386827	386827	SC	P	F		
416714	416714	SC	P	F	TO 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

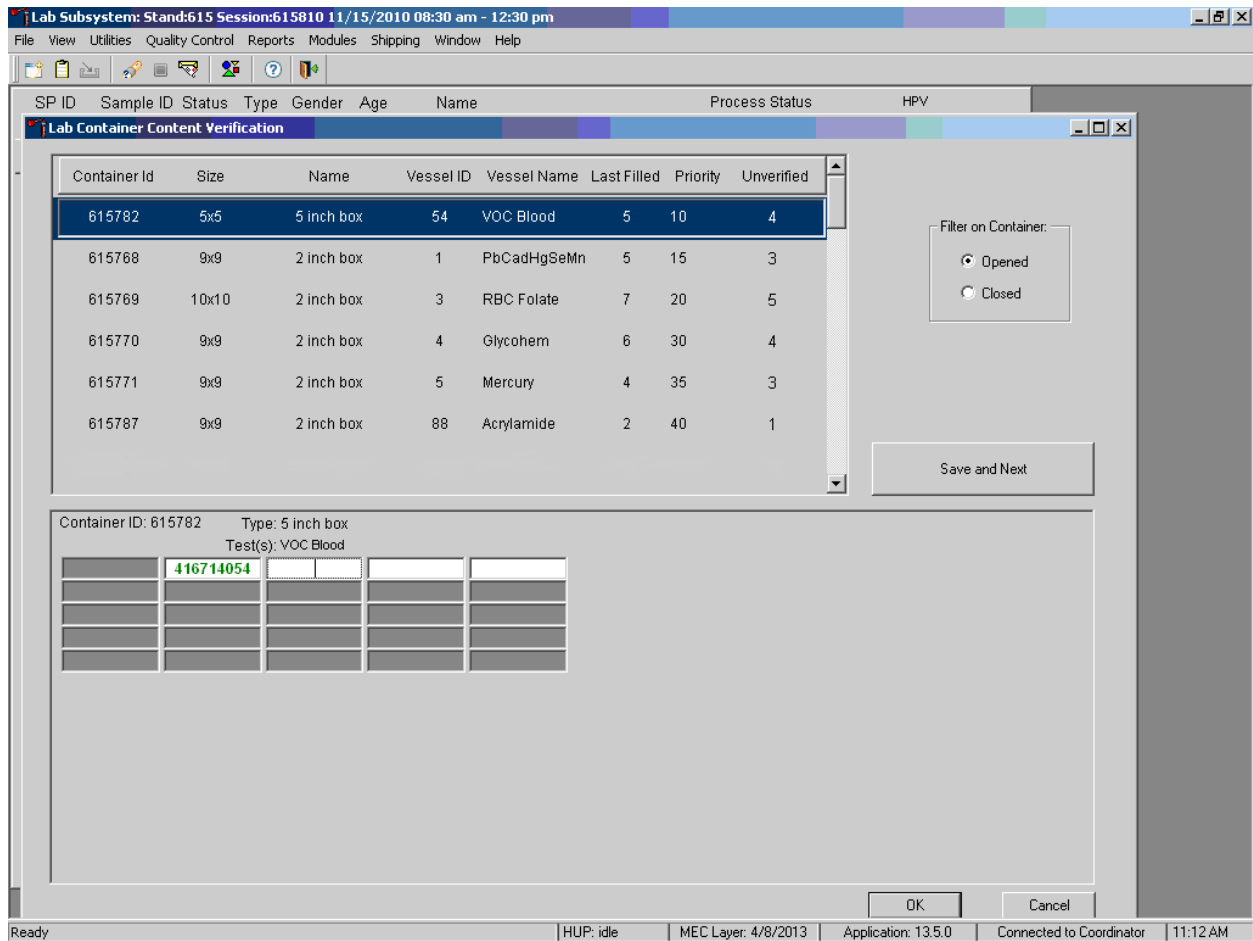
Process Status							HPV	
UC	U	P	CB	B	PC	F	M	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

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.

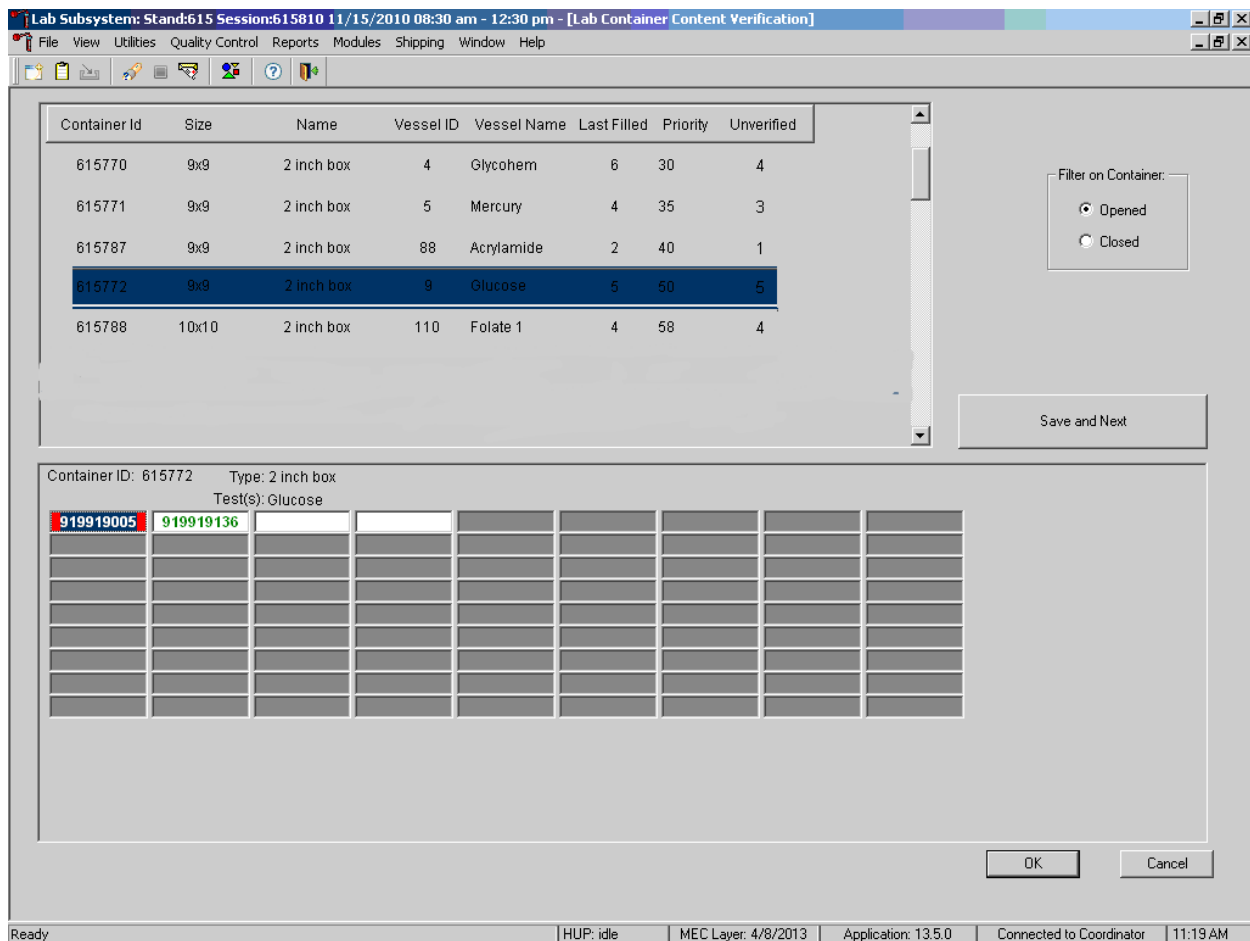


To use the container content verification application, remove a container from the freezer; using the barcode gun, scan the Sample ID or the Astro ID of the first vessel to be verified. If correct vessel is scanned in, the sample ID will be displayed in green.

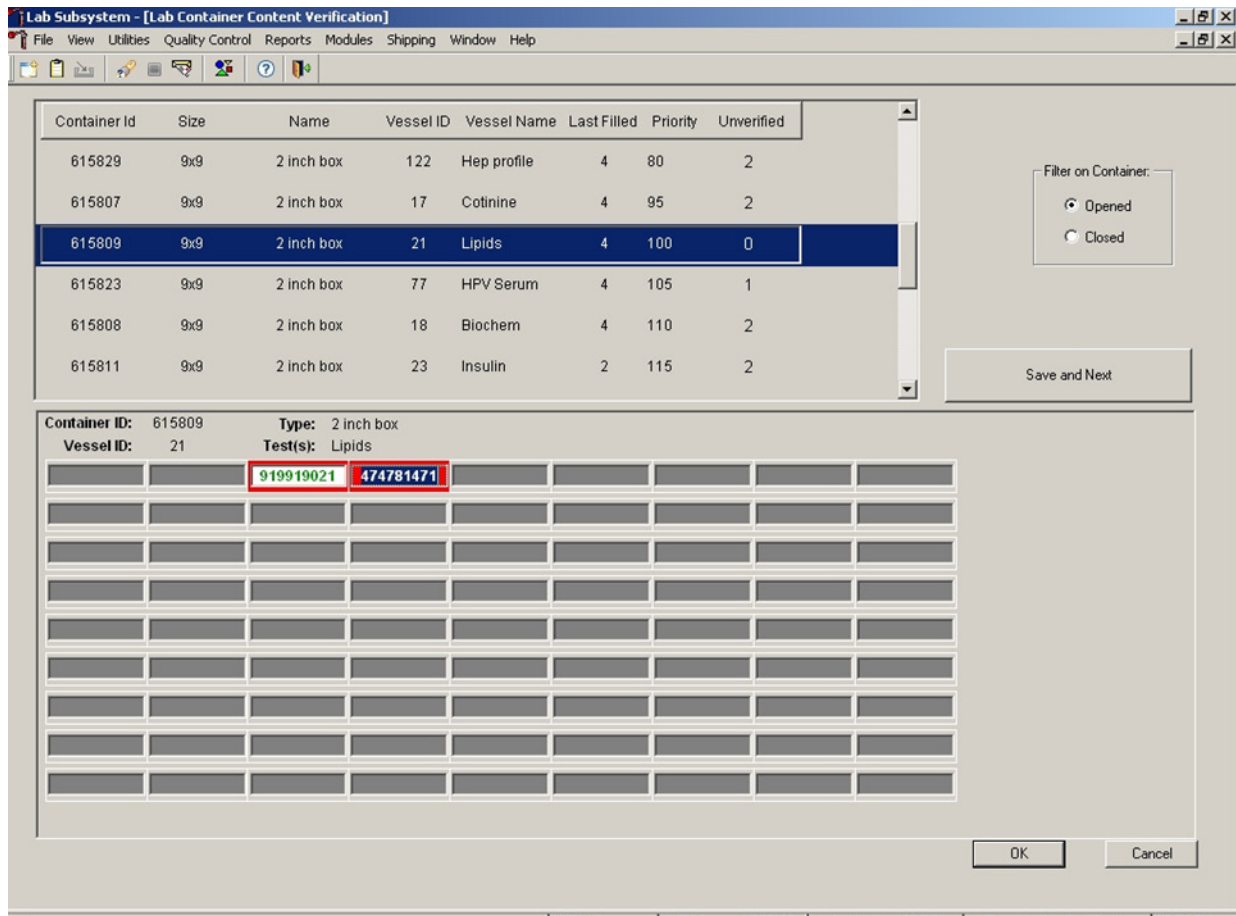


If incorrect vessel is scanned, the following will happen:

- 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.

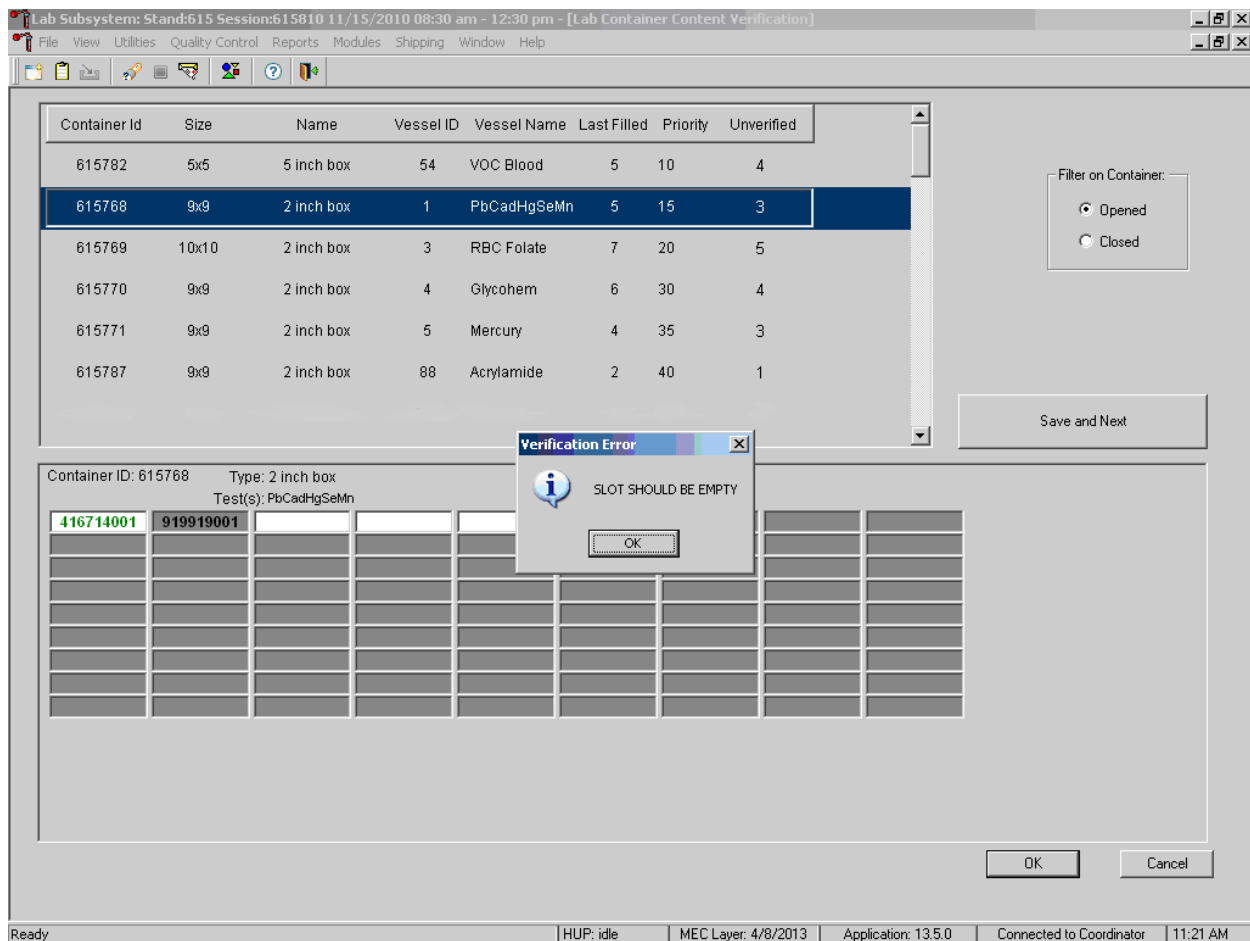


The following screenshot shows a vessel that requires a red cap insert and a vessel that is incorrectly scanned in side-by-side. The red cap insert is identified with a red outline around the box of the vessel, whereas the incorrect specimen number is highlighted in blue with red shading underneath.



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 saying 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.
- The enter key is the same as hitting the OK box 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	Name	Process Status						HPV		
				UC	U	P	CB	B	PC	F	M	
329869	329869	SC	WARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC	BAN, 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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<input type="radio"/>

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

Review the Subsample Preview report.

Subsample Report for Session 430420						
SPs Selected for Subsamples in Session 430420						
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

5/19/2009 Page 1 of 16

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.

SP ID	Sample ID	Status	Name	Process Status						HPV	
				UC	U	P	CB	B	PC	F	M
329869	329869	SC	ARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC	BAN, DOUG O	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	-
416714	416714	SC	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	DEEGAN, MARK	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
525757	525757	SC	LAST NAME, PAT M	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
745052	745052	SC	TIM, SP FIRST NAME M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-
767995	767995	SC	NAME, LAST M	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	-
836040	836040	SC	TORRES, LUCAS T	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	<input type="radio"/>
849425	849425	SC	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	PAYNE, IMA L	<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.

Appt Id	Sp Id	Hiv	Std	Future Research	HPV
6150731	256339	-	-	Y	-
6150732	329869	-	-	Y	-
6150734	416714	-	-	-	-
6150735	480354	-	-	-	-
6150736	525757	-	-	-	-
6150737	545182	-	-	-	-
6150739	836040	-	-	-	-
6150740	837622	-	-	-	-
6150742	745052	-	-	-	-
6150743	767995	-	-	-	-
6150744	784174	-	-	-	-
6150745	861215	-	-	-	-

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
- HPV Swab (vessel 78 and vessel 140).

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.

The screenshot shows the 'Lab Sink' application window. The menu bar includes 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 samples, with the row for SP ID 525757 highlighted. A context menu is open over this row, listing processing modules: Urine Processing, Blood Processing, Packed Cell Processing, Female HPV Processing, Male HPV Processing, Urine Collection, Pregnancy Testing, Hematology, and Refresh.

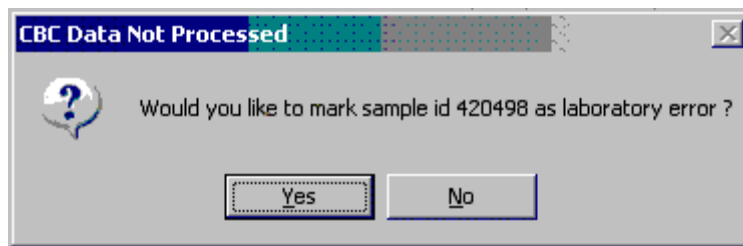
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC	F	M
329869	329869	SC	P	F	12	HOWARD, CHARLES S	○	○	○	○	○	○	-	-
386827	386827	SC	P	F	26	DEEGAN, DOUG O	○	○	○	○	○	-	○	-
416714	416714	SC	P	F	16	BAILEY, ANTHONY J	○	○	○	○	○	○	○	-
499508	499508	SC	P	F			○	○	-	○	○	-	-	-
525757	525757	SC	P	M			○	○	-	○	○	-	-	-
745052	745052	SC	P	F			○	○	○	○	○	-	-	-
767995	767995	SC	P	F			○	○	○	○	○	-	○	-
836040	836040	SC	P	M			○	○	-	○	○	-	-	○
849425	849425	SC	P	F			○	○	○	○	○	○	○	-

To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted, or click the SP. To access a specific processing module, click the module on the

heads-up screen: UC {Urine Collection}, U {Urine Processing}, P {Pregnancy Testing}, CB {Hematology}, B {Blood Processing}, PC {Packed Cell Processing}, or HPV {HPV Processing (Male or Female)}, and left-click. Alternatively, right-click on an SP and select the correct module.

2.12 Warning and Error Messages

Throughout the course of an examination, warning and error messages may appear when an attempt is made to perform an action the program cannot execute or that requires confirmation to continue the action. The message normally appears with statements explaining the error condition. Complying with the error message statement will normally remedy the error. When required to confirm an action, such as deleting records, be sure the action is necessary because, in most cases, it is irreversible.



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 9 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 DxH800 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; performing a blood draw; and administering the Volatile Toxicant Questionnaire (VTQ) to eligible participants. The phlebotomist also collects one additional blood tube from study participants (SPs) selected for the VOC (volatile organic compounds) special study.

The phlebotomist conducts an interview to screen SPs for use of pesticides by first administering the PUQ questions and then asking about any conditions that may exclude them from the blood draw. 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 in order 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 through 3-4 illustrate the various venipuncture protocols. These protocols indicate the types and numbers of tubes in priority order for each age group and person type. The Venipuncture Protocol chart that is located on the wall in the phlebotomy room 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 in the afternoon and evening sessions to be consumed after completion of the Liver Ultrasound Transient Elastography component, if eligible. Then the phlebotomist escorts the SP to his or her 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 the SP is escorted 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	1	1
7-ml lavender			1	1	1
4 – 1 mL TB QuantiFERON ⁷			1	1	1
6-ml lavender ³				1	1
2-ml gray (morning sessions only)				1	1
7-ml red	1	2		1	1
15-mL Red ^{0,2,6}				5	5
10-ml red ⁴			3		
7-ml gray (12+) ¹				1	1

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

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

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

³ Genetic testing for SPs 18+

⁴SPs selected for inclusion in the Thyroid subsample One third (1,2,5,11) (6-11)

⁵SP's included in Thyroid full sample (3-5)

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

⁷ Foreign born SPs and 60+

Exhibit 3-2. Venipuncture protocol – guest

Tube	Guest profile age in years	
	1-11	12+
3-ml lavender	1	1
3-ml red		1

³ Guest Profiles include: CBC and for 12+ Biochem Panel. Females will also get Hcg if interview question regarding menstruation response is missing or otherwise appropriate for component requirement.

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 3-3, 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 3-3. Alternative venipuncture protocol — primary

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

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

Exhibit 3-4. Venipuncture protocol — Dry Run

Tube	Dry Run Odd (12+)	Dry Run Even (12+)
4-ml lavender	2	2
7-ml lavender	2	2
2-ml gray	2	2
15-ml red	4	4

3.2 Equipment and Supplies

The phlebotomy room contains a phlebotomy chair, sink, data terminal, Dymo direct thermal label printer, refrigerator, and cabinets. Exhibit 3-5 illustrates the floor plan for the phlebotomy room.

Exhibit 3-5. Floor plan for phlebotomy room



At the start and end of each stand, take a complete inventory using procedures described in Chapter 13, Section 13.3.

The equipment and supplies used in venipuncture are listed in Exhibit 3-6.

Exhibit 3-6. Equipment and supplies — phlebotomy

Consumable supplies	
BD Hemogard Vacutainer® 3-mL EDTA	Alcohol wipe
Greiner-Bio Vacutainer® 6-mL EDTA	Nonsterile, powder-free, nonlatex gloves – small, medium, large
Covidien 7-mL EDTA Lavender Top Tube	Disposable lab coats (M, L, XL, XXL)
BD Hemogard Vacutainer® 2-mL gray	
Quantiferon TB Gold Plus® 1-mL purple (mitogen)	
Quantiferon TB Gold Plus® 1-mL grey (nil)	
Quantiferon TB Gold Plus® 1-mL green (TB1)	
Quantiferon TB Gold Plus® 1-mL yellow (TB2)	
Covidien 7-mL red	Co-Flex NL cohesive bandage
Covidien 15-mL red	Adhesive bandage – Coverlet
BD Vacutainer® 10-mL red	Venolite Disposable Covers
BD Vacutainer® 7-mL gray (VOC)	Transpore tape
Nipro 19 gauge x 3/4” Butterfly Needles	
Nipro Luer adapter for use with the 19 gauge Saf-T EZ® set	
Nipro 21 gauge x 3/4” Butterfly Needles	Cartoon stickers
Nipro 23 gauge with adapter	
BD Vacutainer® needle holder – single use	Pillow and disposable pillow cover
Air sickness bag	Squeeze ball
Heel warmer	Juice (apple/orange) and Animal crackers
Sani-Cloth	List of reportable tests (handout) English and Spanish
Purell hand soap	Labels for Dymo printer
Stretch disposable tourniquet	Bio-Hazard Sharps container 2 gallon (8 qt.)
Magic Marker – Ultra Fine Sharpie – Black	Batteries, AA
Emergency blanket	Batteries, AAA
VeinLite EMS	Magic Marker – Fine Point Sharpie – Black
Nonconsumable supplies	
	Tube racks
Solar wall thermometer	
Plastic supply baskets	
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
- Bandage

3.3 Overview

The coordinator uses the coordinator system to track each SP throughout the examination process within the 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 and 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, especially a morning session. 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 9-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.

The phlebotomist is responsible for completing the venipuncture section of the phlebotomy exam.

Phlebotomy Seating Options. The UMF 8678 phlebotomy chair (Exhibit 3-7) 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 3-7. 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 and 440 lbs for the RX4-1000 model. If the phlebotomist estimates that the weight of the SP is less than 375 lbs (UMF 8678) or less than 440 lbs (RX4-1000), 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, then recline the chair either before or during the blood draw as needed.

Exhibit 3-8. RX4-1000 phlebotomy chair



Seating SP's 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 into phlebotomy by scanning the barcode (using the wand), on the SP ID bracelet or manually typing the SP ID when the SP arrives in phlebotomy.

Conduct the phlebotomy interview and administer the fasting questionnaire. The phlebotomy protocol screen will then be displayed. Draw the appropriate tubes, discard all sharps in the 8-quart biohazard container, and enter the number of tubes collected next to the expected values. Labels

generate automatically. Enter the appropriate comment(s) for any tube that was not collected. Label the blood tubes in the presence of the SP. Verify that the phlebotomy completion status is correct. The phlebotomy section status is “Complete” if all blood tubes are collected, “Partial” if some but not all blood tubes are collected, and “Not Done” if no blood tubes are collected.

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, know the following information about the procedures used for the study:

3.4.1 Rationale

Although the SP has been provided much useful information in the household and individual interviews, the successful completion of the venipuncture component of NHANES is critical to the success of the study. Using the various specimens, researchers and laboratories are able to perform 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 (0.9 ounces), 1.8 tablespoon
- 6-11 years primary SP, 45-ml (1.5 ounce), 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, 10-ml (0.3 ounces), 0.6 tablespoons
- Dry Run, 86-ml (2.9 ounces), 5.8 tablespoons

An average adult male has 12 pints of blood and an average female has 9 pints. The Red Cross routinely draws 450-ml (or one pint) during a routine donation. Their requirements limit donation to every 8 weeks. The 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 he or she is not important. It also implies disinterest.
- Avoid nervous behaviors, such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

3.4.2 Refusal Conversion

The phlebotomy component maintains the highest priority among MEC examinations.

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, 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 he or she intends 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 he or she 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.”

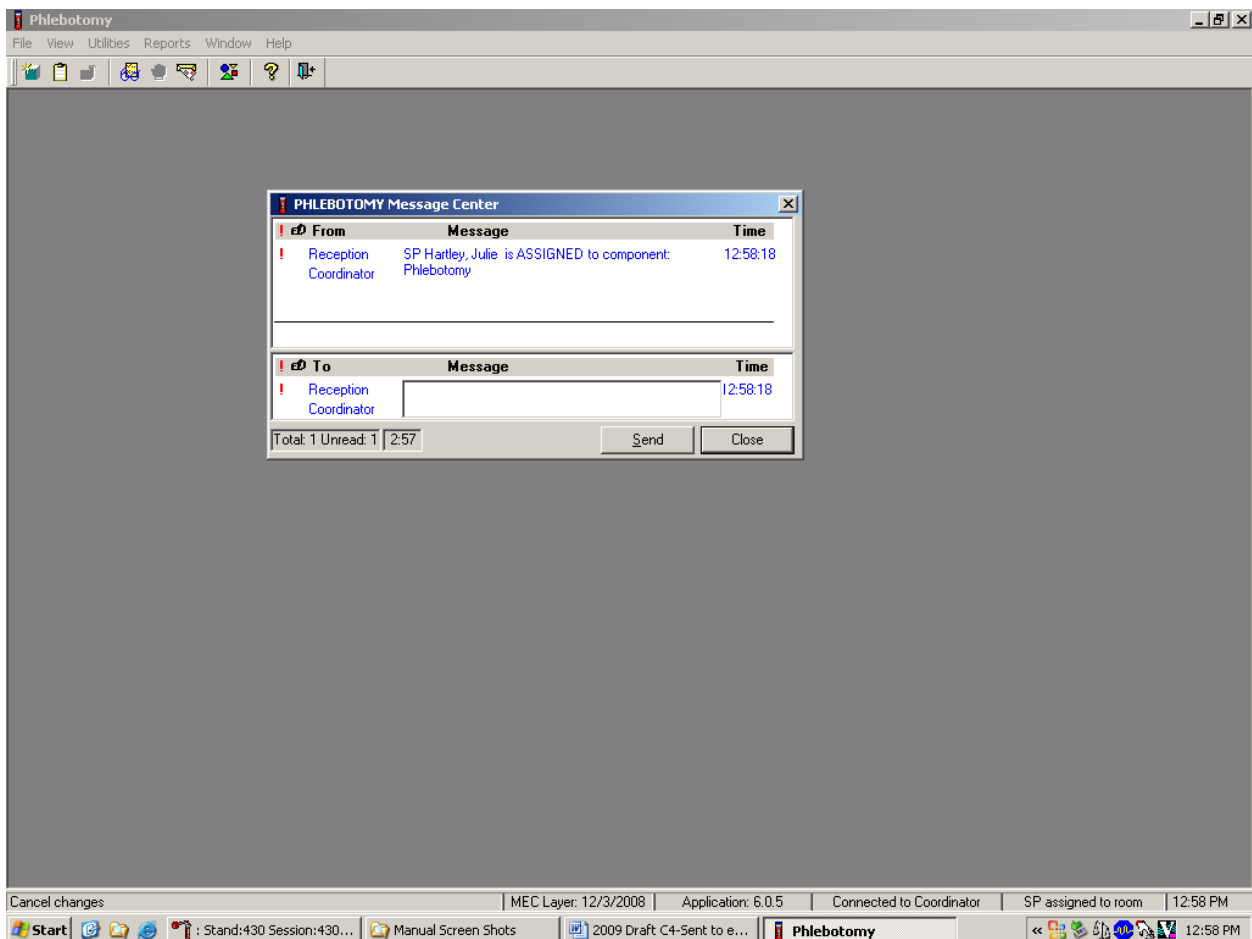
The MEC manager and coordinator should work in collaboration with the phlebotomist in assigning the NB-coded SPs; the phlebotomist is trained in refusal conversion techniques and is responsible for the overall response rate for this component. At all times, the coordinator and MEC manager must use their 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 him or her 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.

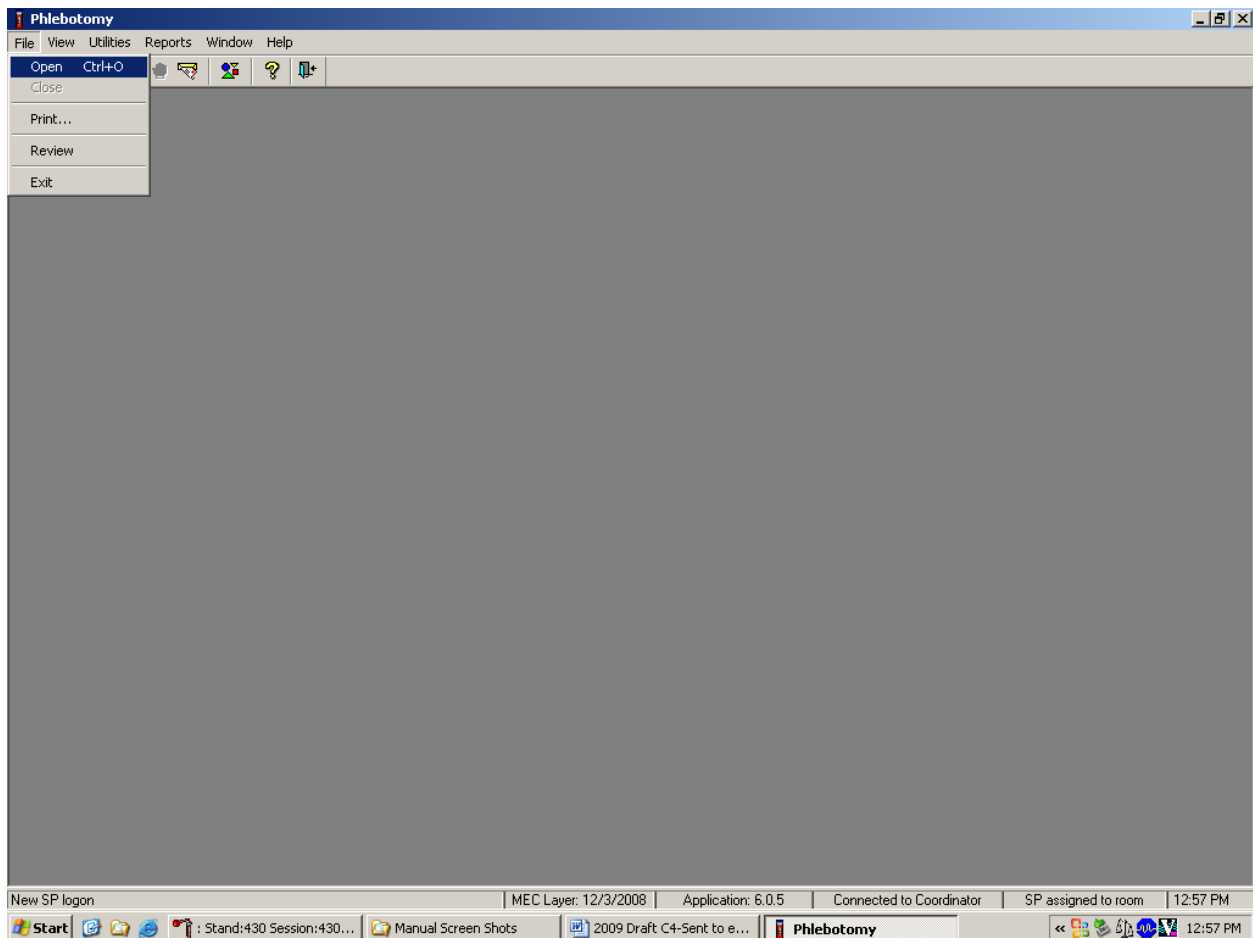
3.6 Open the Exam and Log the SP into the Exam

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



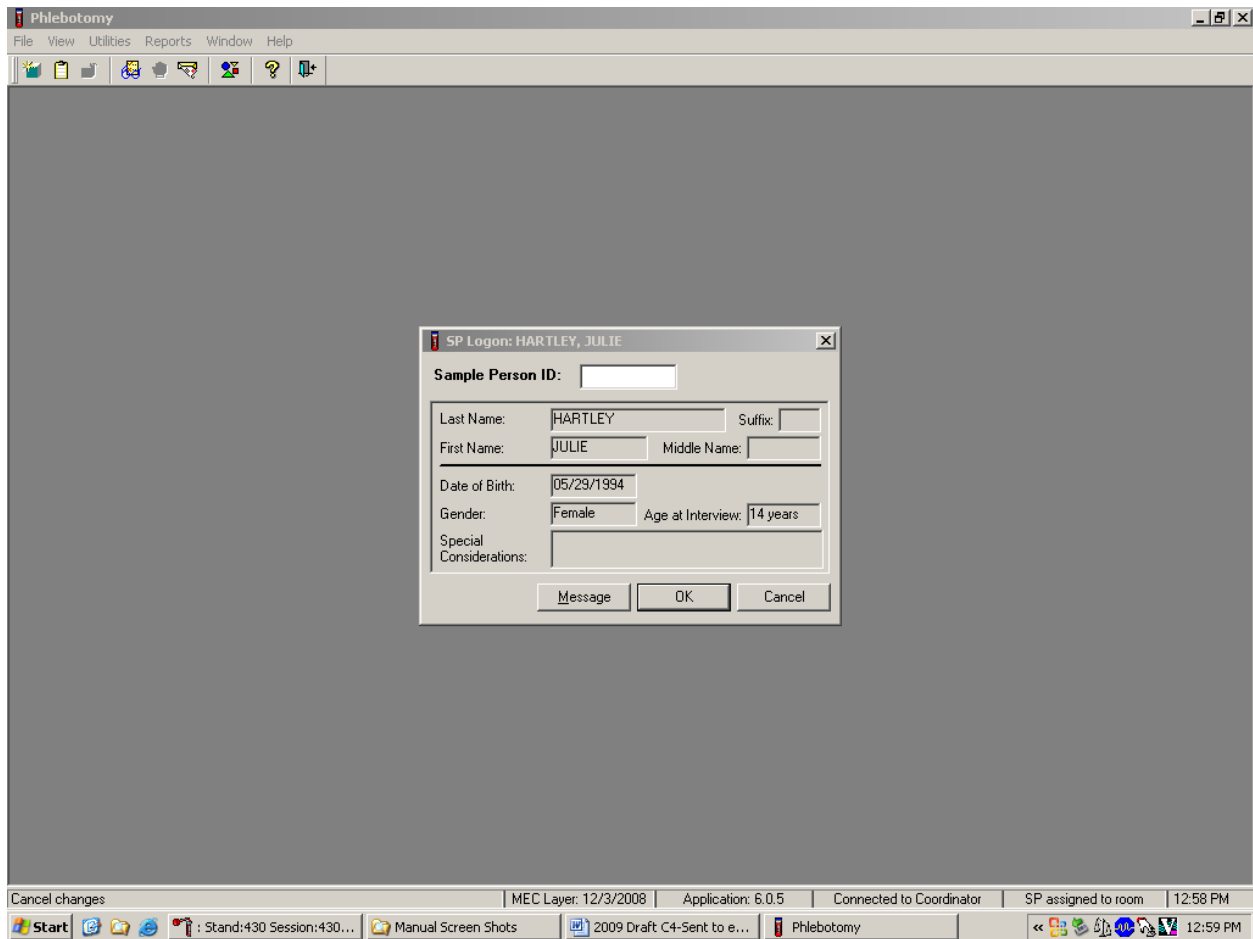
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component. Enter an optional text message and, to send the message to the coordinator, direct the mouse arrow to the Send button and left-click. To exit 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.



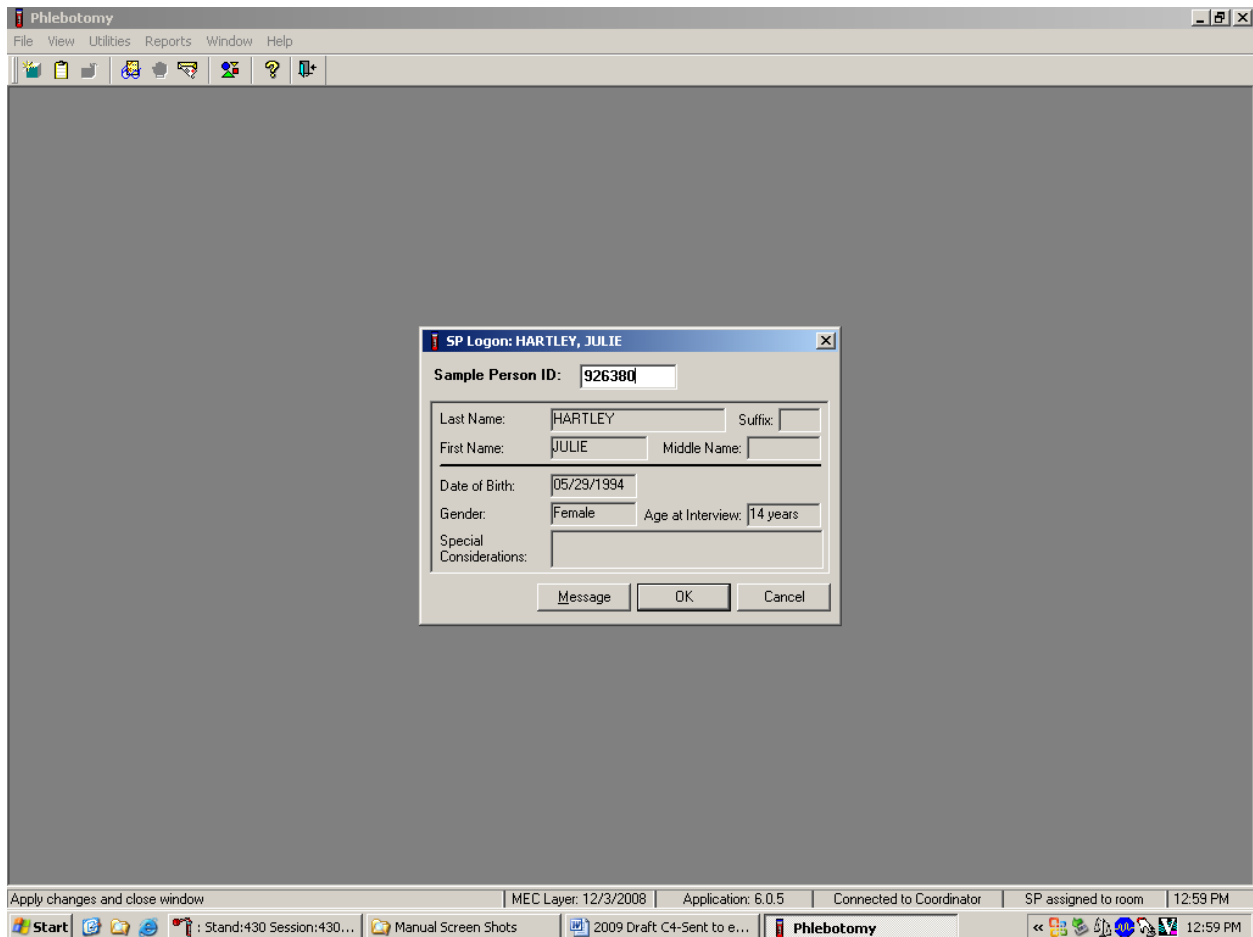
To open an exam, move the mouse to File in the menu bar, click on Open.

The SP Logon window displays.



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

Log the SP into the component.



To log the SP into 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.

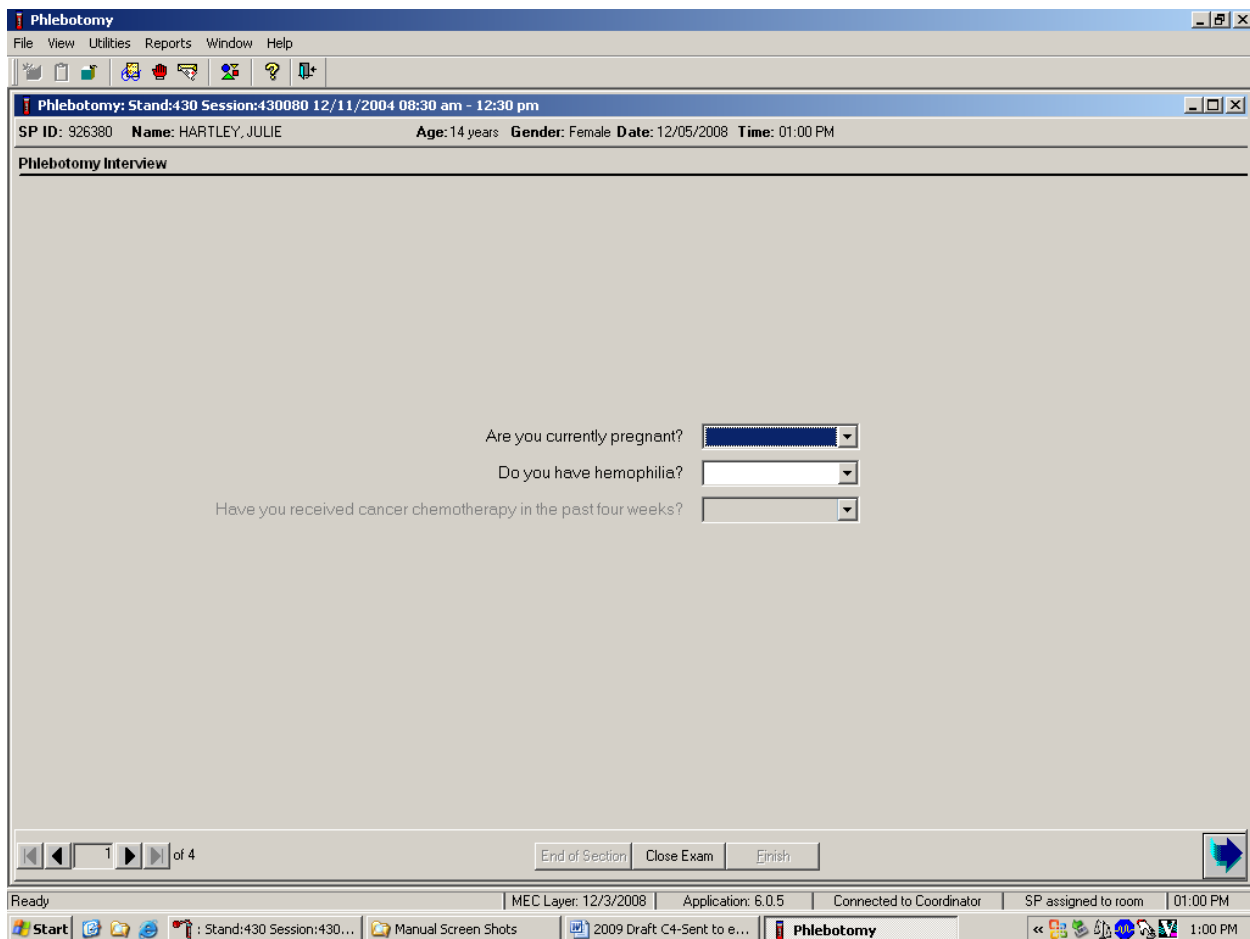
3.7 The Phlebotomy Interview

The Phlebotomy Interview includes two pesticide use questions (PUQ), a shared exclusion pregnancy question for all females aged 12-59 years and younger 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. Administer the interview (and fasting questionnaire) directly to SPs over the age of 12, or administer the interview questions (and fasting questionnaire) to the SP's parent or guardian for SPs under age 12.

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/his/her} 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/his/her} 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.”



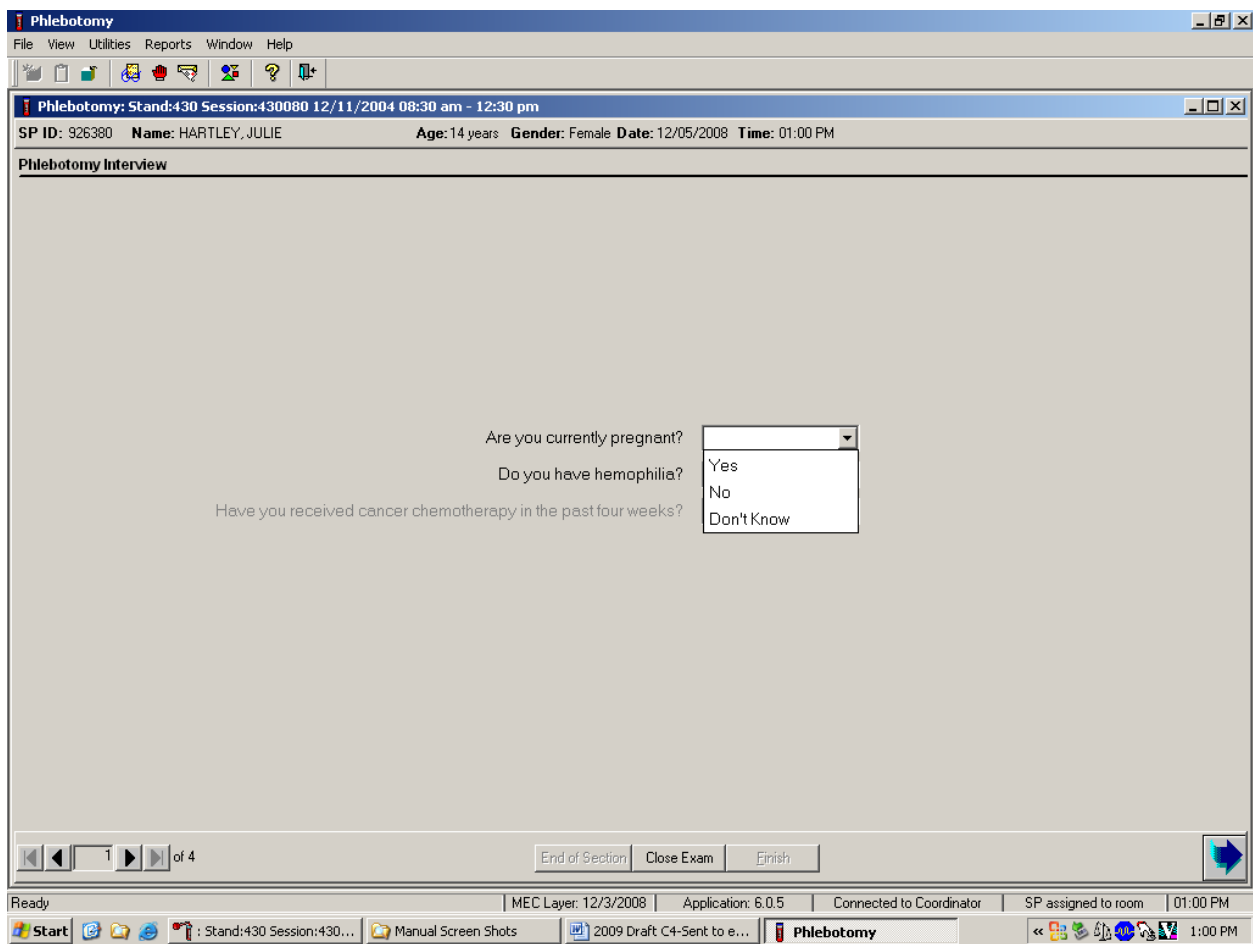
3.7.1 Pregnancy Shared Exclusion Question

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. 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 physician component before phlebotomy, the questions about

“pregnancy” and “how many weeks” would be asked by the physician. 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 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.

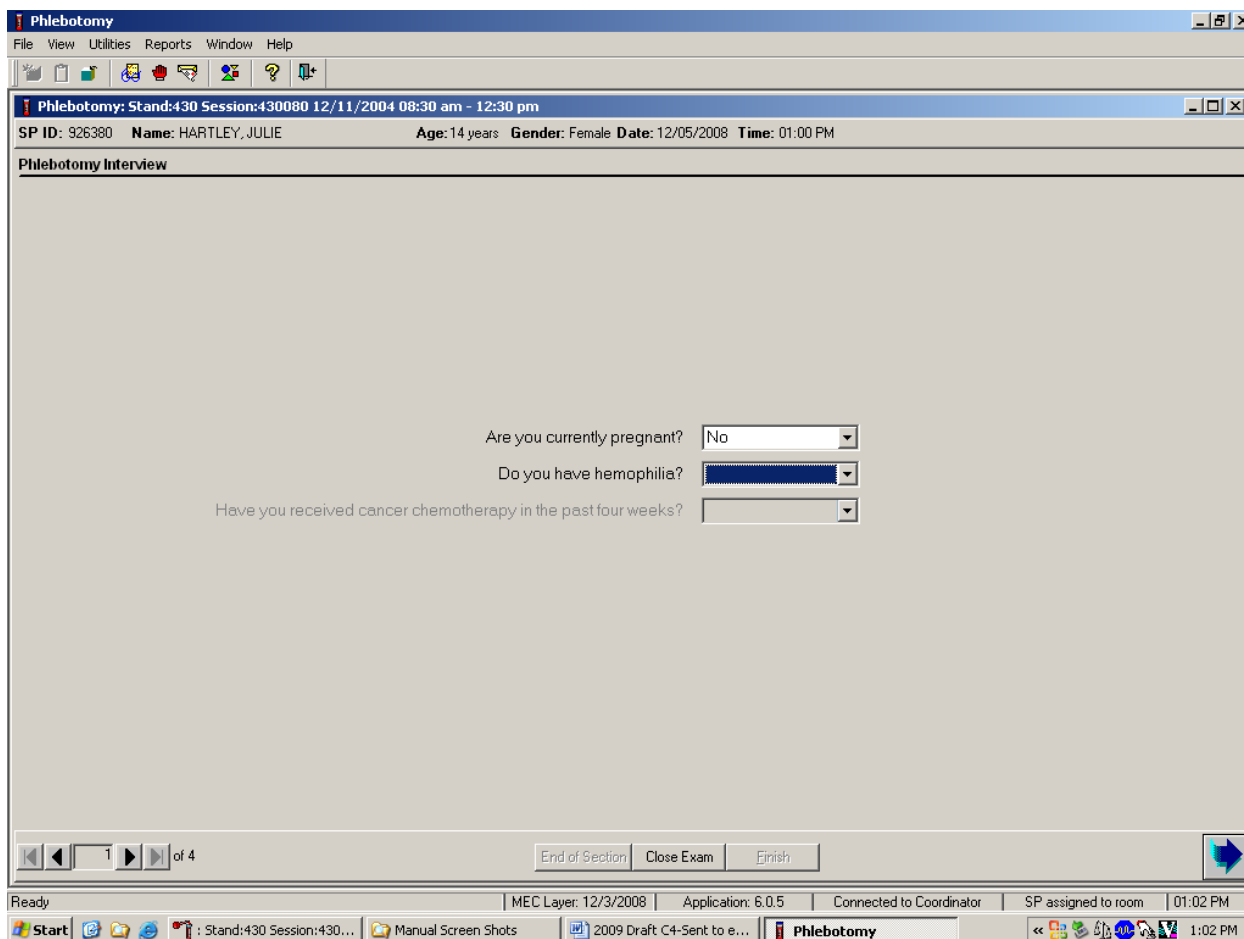
Record the response to the shared exclusion question.



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,” then 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.

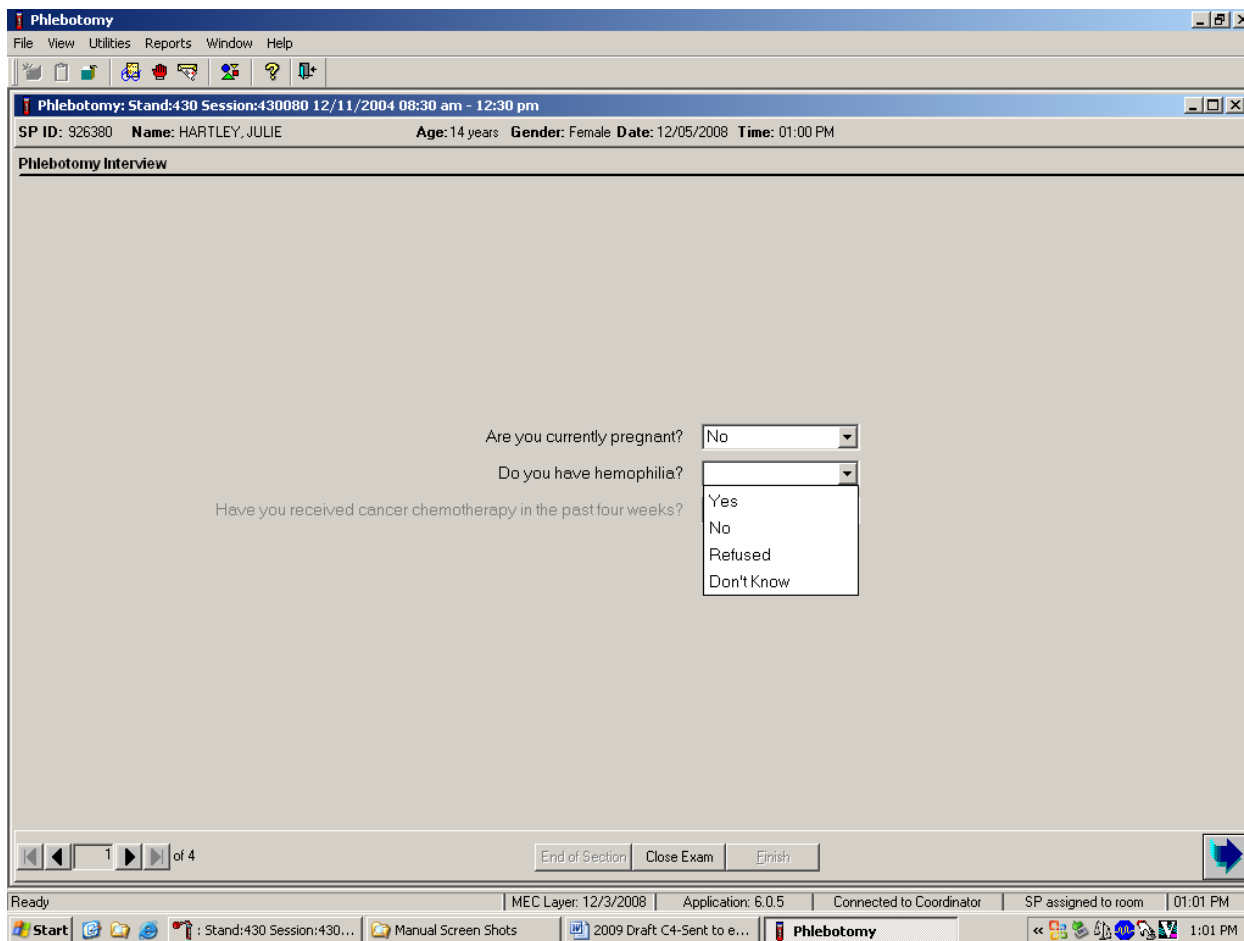
3.7.2 Safety Exclusion Questions

Continue to conduct the phlebotomy interview by asking the question displayed on the screen, “Do you have hemophilia?”

Q1: Do you have hemophilia?

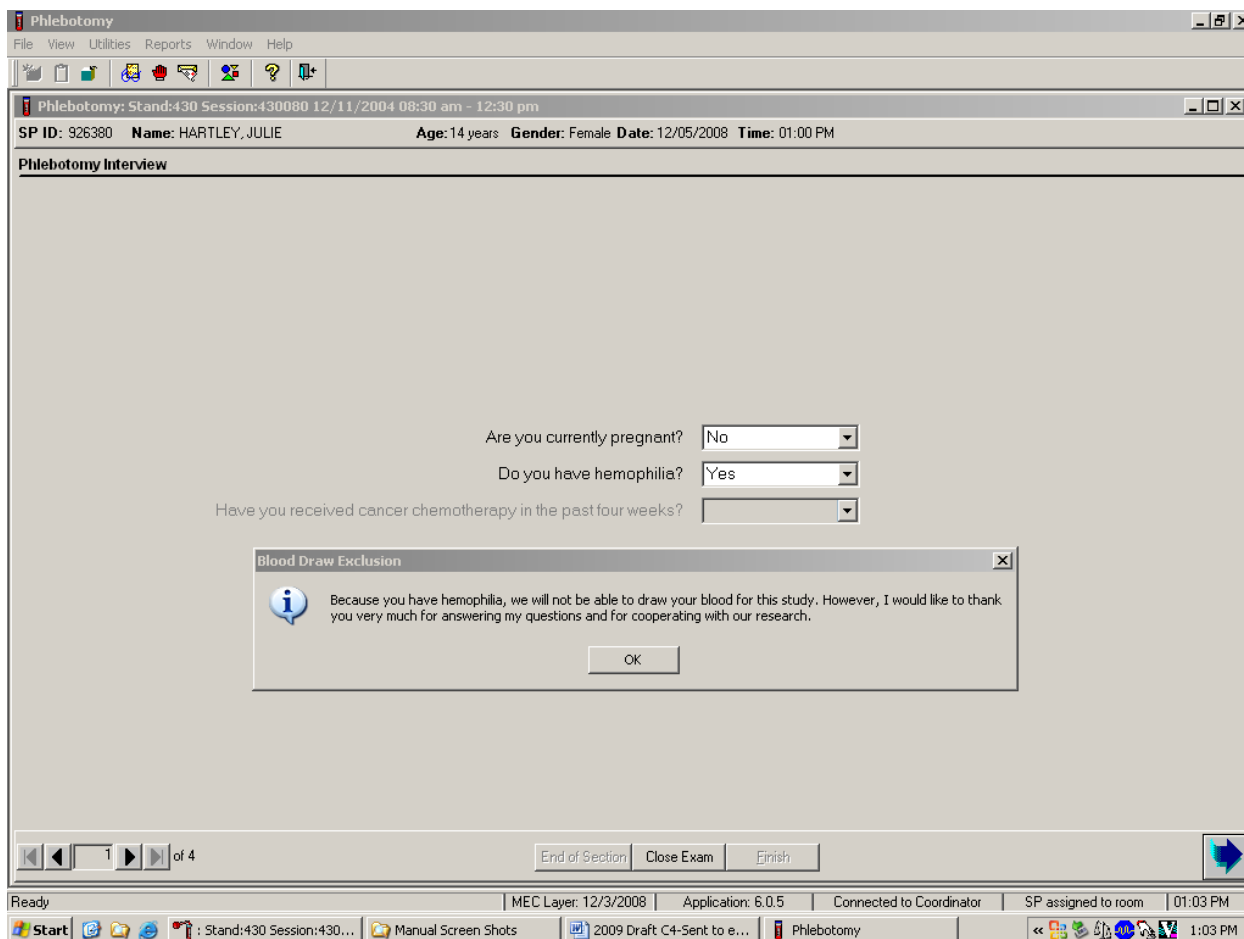
<p>Q1: This question asks whether the SP has hemophilia, which is an exclusion criterion for this procedure.</p>	<p>Explain that we cannot perform phlebotomy on participants who have hemophilia. Hemophilia is a rare disease where an individual’s blood does not clot normally. If an SP’s relative has hemophilia 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 station.</p>
--	--

Record the exact response.



Record the response by typing [Y] for “Yes,” [N] for “No,” [R] if he or she refuses, 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.

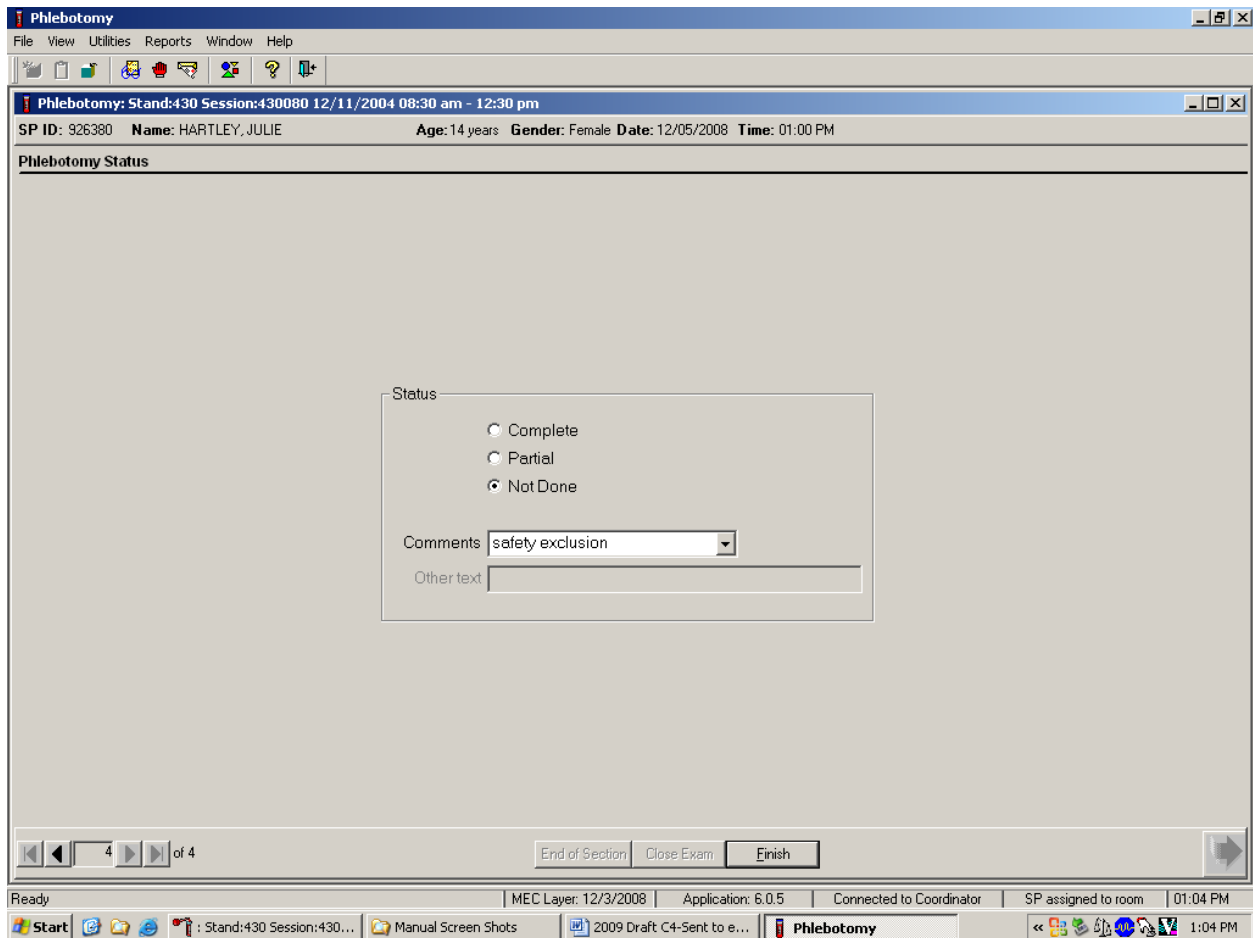


Read the script to the SP. To remove the Blood Draw Exclusion message text box, move the mouse arrow to the OK button and left-click, or press Enter.

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.

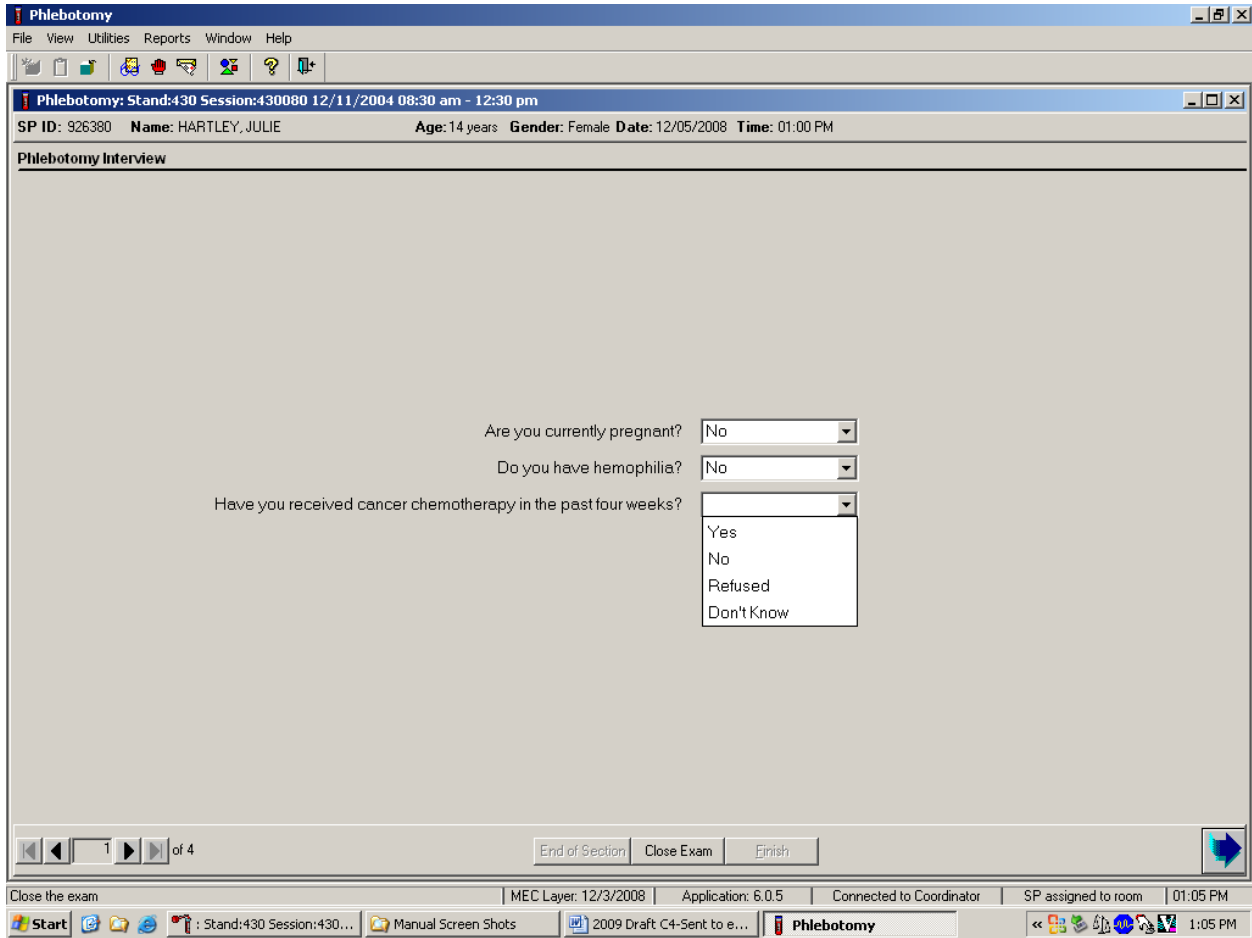
To remove the Exclusion message text box, move the mouse to the OK button and left-click, or press Enter.

Verify the status.



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?”



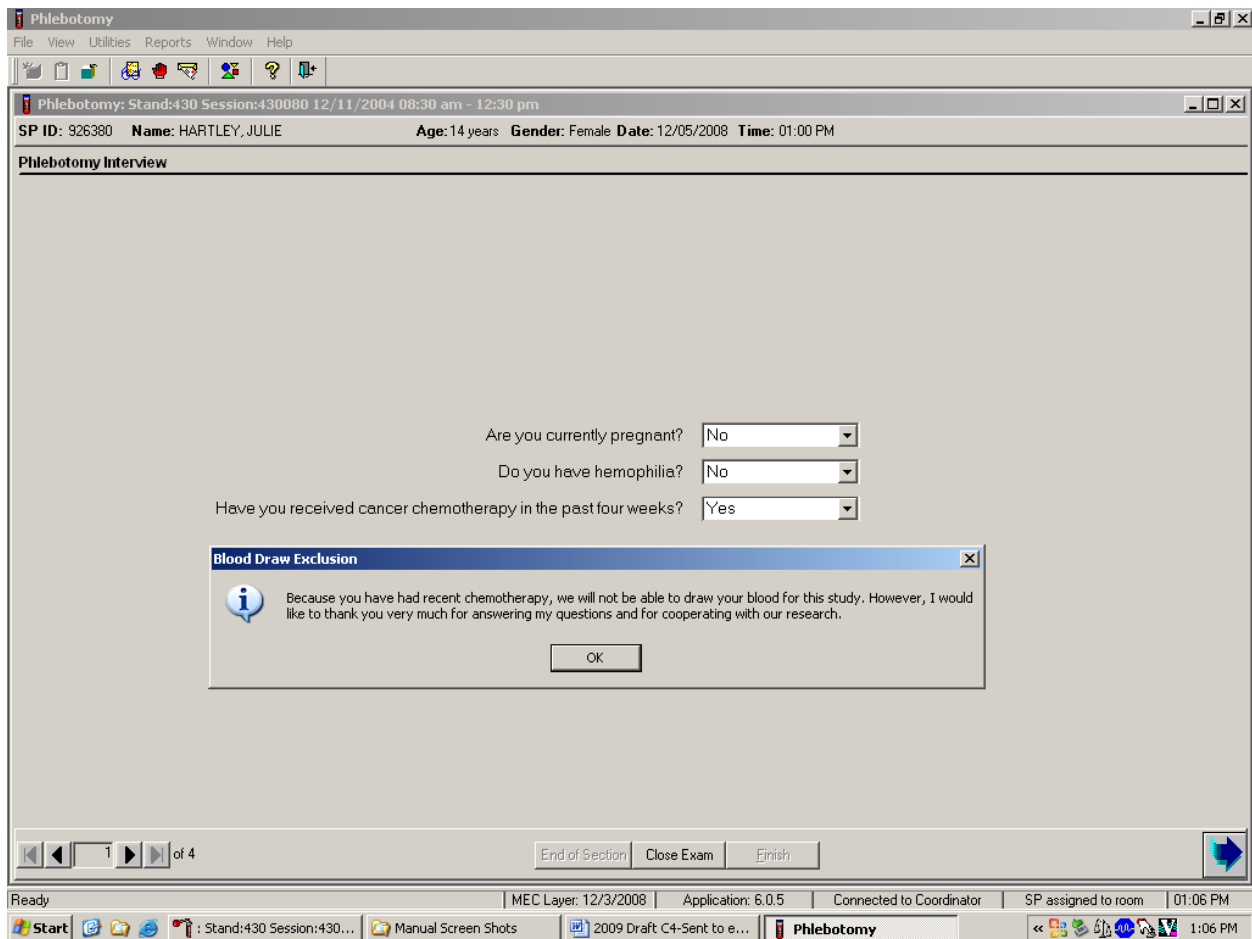
Q2: Have you received cancer chemotherapy in the past 4 weeks?

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 him or her back to the coordinator station.

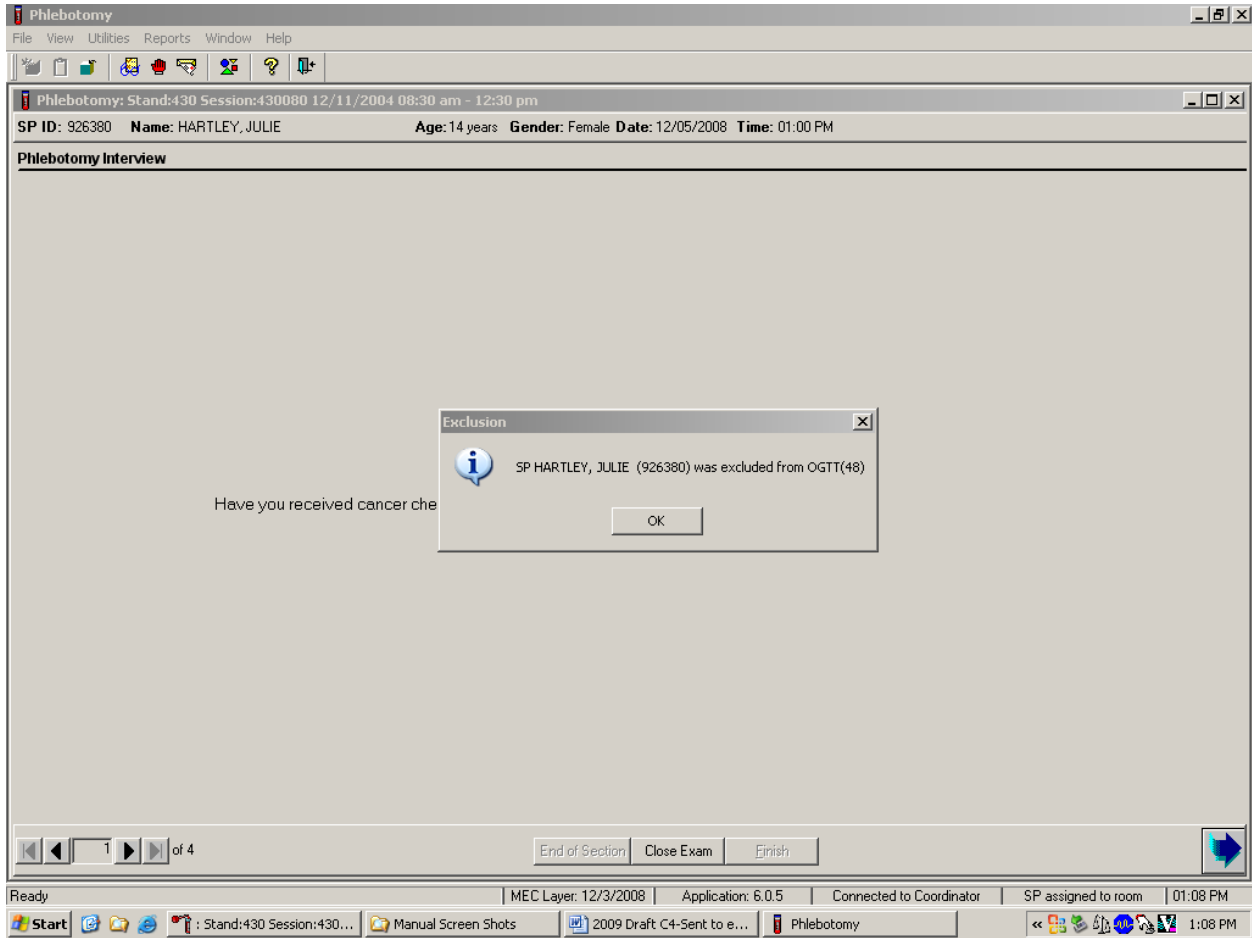
Record the response by typing Y for “Yes, N for “No,” R if he or she refuses, or D for “Don’t know.” Alternatively, move the mouse to the drop-down arrow on the drop-down list, click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t know” and left-click. If the response 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 exam because of cancer chemotherapy, the Blood Draw Exclusion informational message text box displays.



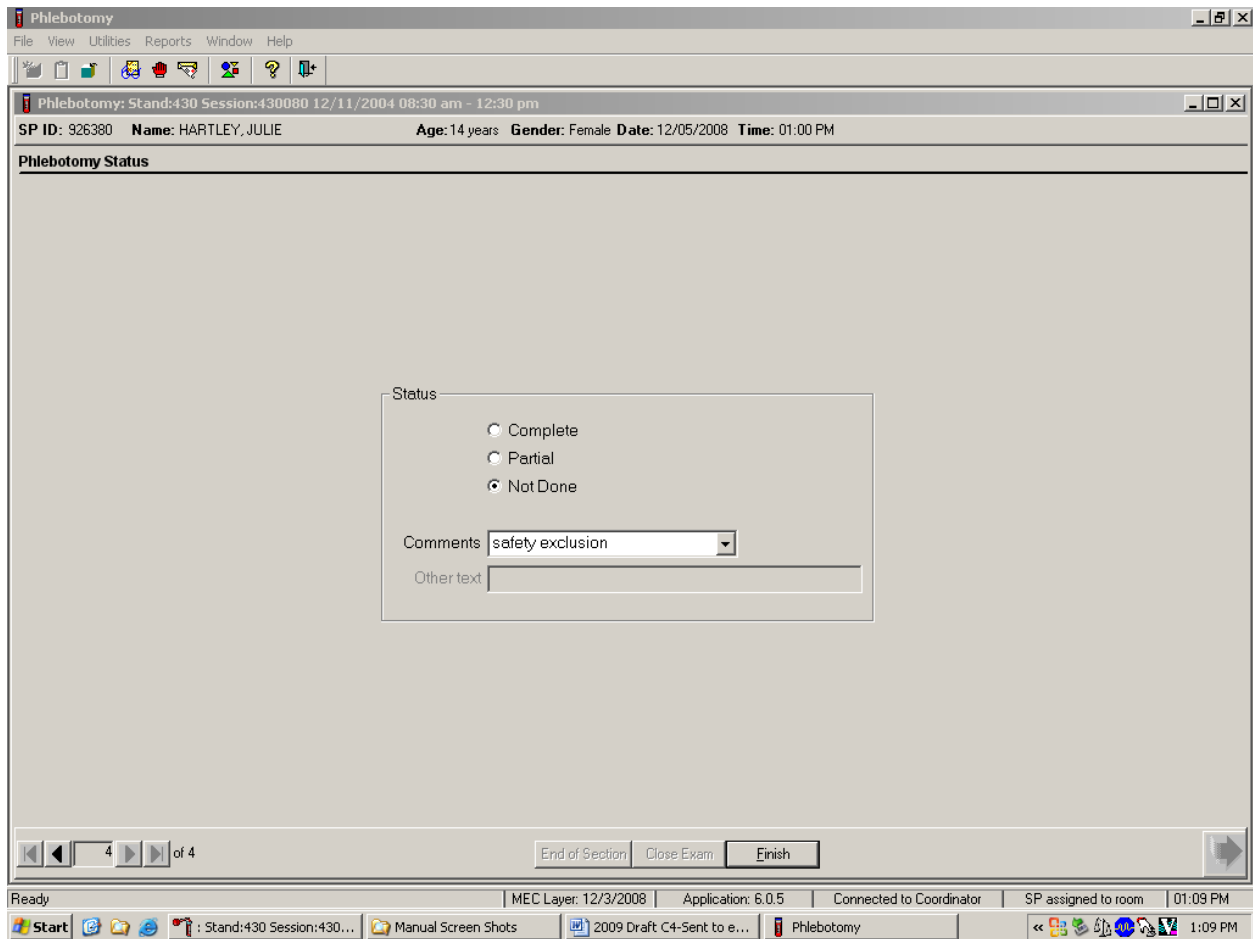
Read the script to the SP. To remove the Blood Draw Exclusion message box, direct the mouse arrow to the OK button and left-click.

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.



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.

Phlebotomy Interview

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM

Are you currently pregnant? No

Do you have hemophilia? No

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

End of Section Close Exam Finish

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 are required for correct interpretation of laboratory results. No primary SPs aged 1-11 or SPs assigned to afternoon or evening sessions are asked to fast. All other primary SPs aged 12 years and older appointed to a morning session are asked to fast for 9 hours; this includes diabetics. These SPs are given the highest priority, so the venipuncture can be completed as soon as possible after the SPs checks 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 he or she has been assigned to phlebotomy. It is always preferable to get blood from this SP before he or she leaves the MEC. The coordinator and MEC manager can provide the best overall assessment of the status of a particular SP.

Guests do not have a fasting requirement, even during morning sessions.

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 are accurate. Delete any data in the text boxes (previous responses from the initial visit) and enter the new responses.

Read the text exactly and record the time.

Phlebotomy
 File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 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.

Have you had any of the following since

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

Alcohol, such as beer, wine, or liquor?

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

Antacids, laxatives, or anti-diarrheals?

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

Fasting Hours Minutes

2 of 4

End of Section Close Exam Finish

Close the exam MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:14 PM

Start Stand:430 Session:430... Manual Screen Shots 2009 Draft C4-Sent to e... Phlebotomy 1:14 PM

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.

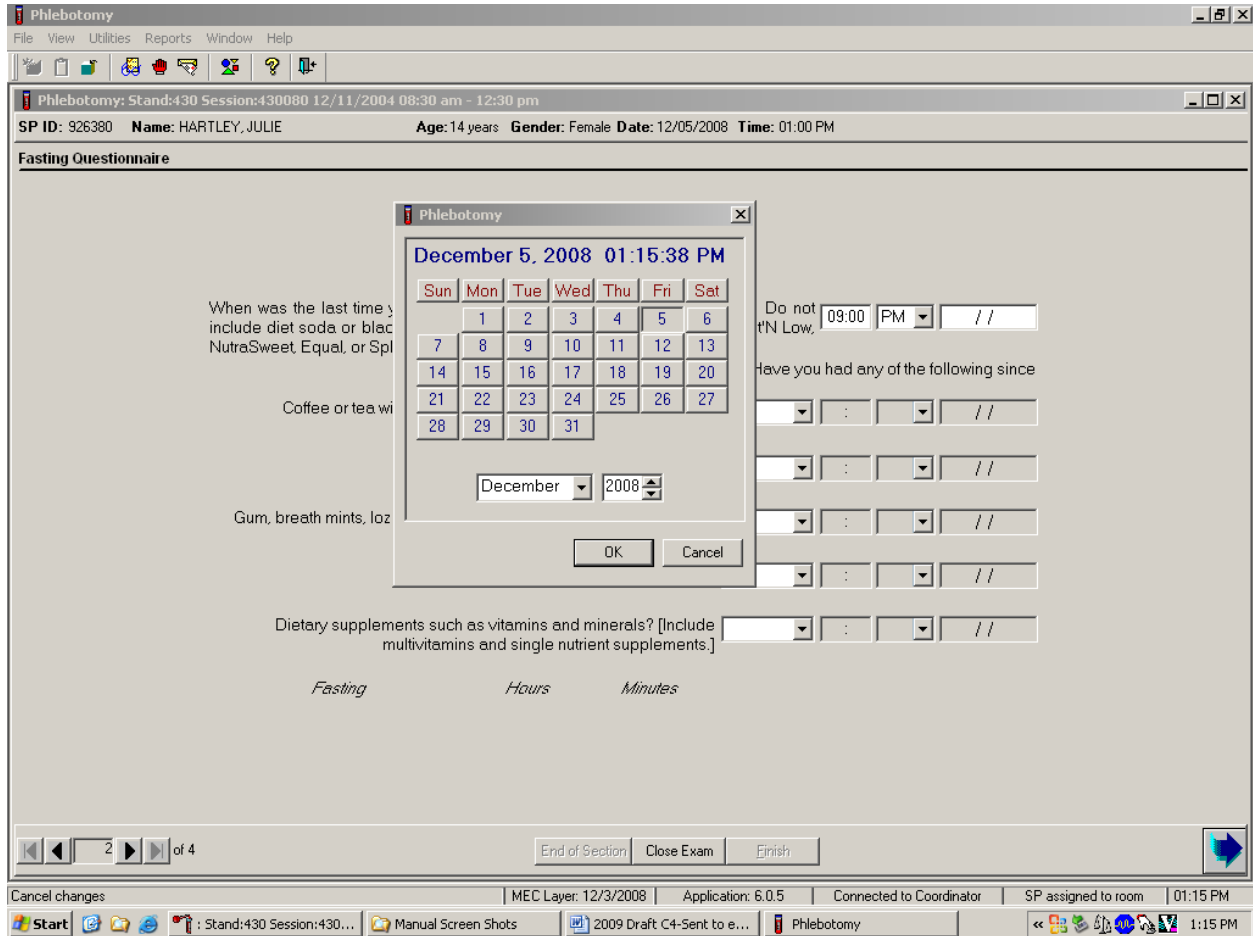
<p>Q1: This question elicits the last time the SP ate or drank anything and determines fasting time.</p>	<p>SPs are allowed to consume diet soda, black coffee, or tea with artificial sweeteners like Sweet’N Low, NutraSweet, Equal, or Splenda since these have no effect on study analytes. Do not include flavored waters.</p>
--	--

Enter the response.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area displays a "Fasting Questionnaire" for patient "HARTLEY, JULIE". The questionnaire asks for the last time the patient ate or drank (excluding plain water and artificial sweeteners) and whether they consumed coffee/tea with cream/sugar, alcohol, gum, antacids, or dietary supplements since that time. Each question has a dropdown menu and a time selection box (hours and minutes). At the bottom, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The Windows taskbar at the bottom shows the system tray with the time 1:15 PM and various icons.

Type in the reported time using the numeric keys and press Tab to move to the AM/PM space. Type in A for times between midnight and 11:59 AM or P for times between 12:00 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.

Enter the date.



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.

Phlebotomy Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm
SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 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. 09:00 PM 12/04/2008

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 16 Hours 17 Minutes

2 of 4 End of Section Close Exam Eirish

Ready MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:16 PM

Start Stand:430 Session:430... Manual Screen Shots 2009 Draft C4-Sent to e... Phlebotomy 1:16 PM

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

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]	Black coffee is acceptable, but coffee with any additives other than 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 12:00 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.

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.

Have you had any of the following since

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

Alcohol, such as beer, wine, or liquor?

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

Antacids, laxatives, or anti-diartheals?

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

Fasting Hours Minutes

For the SP who had coffee with cream and sugar, this question should have been changed to the time when she 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.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm

SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 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. 09:00 PM 12/04/2008

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 12/05/2008

Fasting 16 Hours 17 Minutes

2 of 4

End of Section Close Exam Finish

Ready MEC Layer: 12/3/2008 Application: 6.0.5 Connected to Coordinator SP assigned to room 01:17 PM

Start : Stand:430 Session:430... Manual Screen Shots 2009 Draft: C4-Sent to e... Phlebotomy 1:17 PM

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 9-Hour Fast – Morning Session Only

A system was implemented to ensure that SPs who would meet their 9-hour fast would wait until they met their fast to have their first venipuncture. The coordinator screen will turn yellow and the phlebotomy application would give a message “I will need to have you wait until approximately (time) before I can collect your blood. I will have the coordinator bring you here at the right time.” When the SP has met the 9-hour fast, the coordinator screen will turn green, which indicates the SP has met the fast and can return to phlebotomy.

The screenshot shows a software window titled "Phlebotomy: Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm". The patient information is: SP ID: 973550, Name: WEAVER_1,JOE, Age: 43 years, Gender: Male, Date: 11/06/2009, Time: 08:56 AM. The "Fasting Questionnaire" section includes the question: "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." The answer is 12:10 AM on 11/06/2009. Below this is the question: "Have you had any of the following since today at 12:10 AM?" with a sub-question "Coffee or tea with cream or sugar? [Include milk or non-dairy]". A pop-up message titled "Return for blood draw" is displayed, stating: "I will need to have you wait until approximately 09:10 AM before I can collect your blood. I will have the Coordinator bring you back here at the right time." Below the pop-up are dropdown menus for "Antacids, laxatives, or anti-diarrheals?" and "Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]", both set to "No". At the bottom, the fasting status is shown as "Fasting 8 Hours 47 Minutes".

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

Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430040 12/07/2004 08:30 am - 12:30 pm

SP ID: 973550 Name: WEAVER_1, JOE Age: 43 years Gender: Male Date: 11/06/2009 Time: 08:56 AM

Phlebotomy Status

Status

Complete

Partial

Not Done

Comments: Waiting to meet fast

Other text: _____

If the SP will never meet the 9-hour fast during the session, he or she is prompted to have his or her blood drawn at that time without waiting. If the 9-hour fast will not be met by 12:30, 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 his or her 9-hour fast and needs to leave the mobile examination center (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.

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

1. Fill tubes with additives completely to ensure proper ratio of blood to additive.
2. Thoroughly mix the lavender tubes, 2-ml and 7-ml gray-top tubes, and the TB tubes immediately after drawing the blood.
3. The TB tubes should be inverted 10 times ensuring that all inside surfaces of the tube are coated with blood.
4. Visually check the bottom of the 7 ml gray top tube to ensure all the powder has been dissolved. Remix as appropriate.
5. 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 SP or any samples without applying gloves.
- Place appropriate blood collection tubes in a test tube rack in the order outlined in the venipuncture protocol. 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 him or her to sit upright during the procedure. Instruct the SP to extend the arm palm up and straight at the elbow. If the SP is a child or infant, have a medical technologist hold the SP in the proper position.
- Position the 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 daily.
- Inspect the arm. Use the left arm unless unsuitable. The veins of choice are the cephalic, basilic, and median cubital veins located in the antecubital fossa area.
- If the veins in the antecubital space are not suitable, look for suitable veins on the forearm or on the dorsal side of the hand.
- 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.
 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 circular motion beginning with a narrow radius and moving outward so as not to cross over the area already 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 his or her fist since this action may alter certain results.
- Fix the vein about one 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 over the puncture site and apply firm pressure to the puncture site for 3 minutes. 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. If left-handed, do the reverse.
- 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 the TB tubes are collected:
 - Fill each tube with 1 mL of blood. The black mark on the side indicates the acceptable range of collection (0.8-1.2 mL)
 - Keep the tube on the needle for 2-3 seconds once the tube appears to be completed filling to ensure the correct volume is drawn
 - Immediately after collection, invert the tubes 10 times to ensure the entire surface of the tube is coated with blood. This will dissolve the antigens on the tube walls. Avoid vigorous shaking as this may cause gel disruption and cause aberrant results.
 - QFT-Plus collection tubes can be used to an altitude of 2650 feet. HA QFT-Plus Blood Collection Tubes should be used at altitudes between 3350 and 6150 feet. If using outside of these indicated altitudes, and the tubes are not filling appropriately, a syringe should be used to fill the tubes to the appropriate level.
- Insert the next tube and push it down gently onto the adapter.
- Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
- Fill tubes in the proper order, according to the NHANES protocol.
- When the last tube has filled, remove the needle in a smooth quick motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. 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 bag.
- 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.
- 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 the TB tubes with the labels containing the titles NIL, a barcode plus Sample ID – XXXXXX223, TB1, a barcode plus Sample ID – XXXXXX224, TB2, a barcode plus Sample ID – XXXXXX225, Mitogen, a barcode plus Sample ID – XXXXXX226, and a second barcode plus Astro ID on each label.
 - All four TB tubes must be collected for the testing to be performed.
 - 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 3-14 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 is complete.
- Report any adverse reaction to the venipuncture to the physician 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.
- Wash hands and change gloves before approaching the next SP.

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, age 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 medical technologist. The best techniques to use with these children are to maintain a reassuring tone, to reinforce that the child is a good boy or girl, and to draw the blood quickly. Be sure to reassure the child after the procedure and to use cartoon adhesive bandages, 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 adhesive bandages, stickers, and a snack. Try using distractions, such as pointing to, counting things in the room, and breathing deeply. These techniques may work with the older children in this age group. The phlebotomist may have a medical technologist assist with most of these children.

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

Although adolescents age 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 him or her that the best technique is being used. It is very important that the adolescent maintain control of the situation; therefore, give him or her some choices, as well as allowing him or her 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 4.9 for performing venipunctures.

3.10.1 Age Specific Care and Phlebotomy

Exhibit 3-9. 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
 - Appropriate tone of voice, eye contact and active listening skills
- Technical expertise – physical skills

Age-Specific Groups

- Neonate/Infant 0-1
- Toddlers 1-3
- Pre-School 4-5 years
- School Age 5-12 years
- Adolescent 13-18
- Young Adult 19-35
- Adulthood 36-65
- Late Adult 65+

Exhibit 3-9. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

Neonate/Infant Psycho-Social 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.

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.
- For heelsticks follow recommended procedures to the letter.
- Collect minimum amount of blood necessary.

Toddlers 1-3 Years Psycho-Social Needs

- Try not to separate from parent unless absolutely necessary.
- Parent may assist by holding, explaining to and comforting the child.
- Friendly, cheerful and empathetic manner.

Exhibit 3-9. Age Specific Care and Phlebotomy by Terry Kotrla, MS, MT(ASCP)BB (continued)

- 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.

Toddlers 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.
- Band-aids may not be appropriate, child may swallow and choke.

Pre-School 4-5 years Psycho-Social 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.”

Exhibit 3-10. Age Specific Care and Phlebotomy

Pre-School 4-5 – Fears/Safety

- Child proof collection area.
- Fear of pain.
- Avoid delays, have all equipment.
- Assemble equipment out of child’s eye sight.
- Use your best judgment whether to encourage child to look away.
- Involve child in after care by allowing selection of bandaid and sticker.

School Age 6-12 – Psycho-Social Needs

- Increased language skills and self-control.
- Move from security seeking behavior towards independence.
- Try not to embarrass the child.
- Must communicate with them as an individual using age appropriate words and appropriate eye contact.
- May want parent to hold hand.
- Explain the procedure and why blood is needed.
- Be prepared to answer questions.

School Age 6-12 – Fears/Safety

- Younger ages fear of 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.

Exhibit 3-10. Age Specific Care and Phlebotomy (continued)

Adolescent 13-18 Psycho-Social 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.

Adolescent 13-18 – 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 Psycho-Social 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.

Exhibit 3-10. Age Specific Care and Phlebotomy (continued)

- 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 critical, promotes sense of trust but be aware of cultural differences.

Young Adult 19-35 – 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 Psycho-Social 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 – 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.

Exhibit 3-10. Age Specific Care and Phlebotomy (continued)

Late Adult 65+ Psycho-Social Needs

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

Late Adult 65+ – 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.
- Band-aids 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.

References

Kirven, D.R. Age-specific techniques in phlebotomy competency. (2003). *Advance for Medical Laboratory Professionals*, 14(6), pp. 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/pes/images/pesvcs_137741.pdf.

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 utilizes 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 study participant 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 3-11).
- 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.
- When suitable vein is located, continue with the phlebotomy procedure.
- 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 3-12).
- Insert needle in the normal way.
- Discard the disposable plastic cover after each study participant and switch off the Veinlite EMS when it is not in use.

Exhibit 3-11. Position of Veinlite EMS while looking for a vein



Exhibit 3-12. 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 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.

train-05
P:\med\util\Scan\015 Session\015010_11/15/2010 00:30 am - 12:30 pm

SP ID: 553872 Name: WRIGHT, LAYLA B Age: 21 years Gender: Male Date: 12/21/2012 Time: 04:36 PM

Venipuncture

4 ml lavender	0	of 2	
2 ml gray	0	of 1	<input type="checkbox"/> Obtained all
15 ml red	0	of 3	
15 ml red	0	of 2	553872

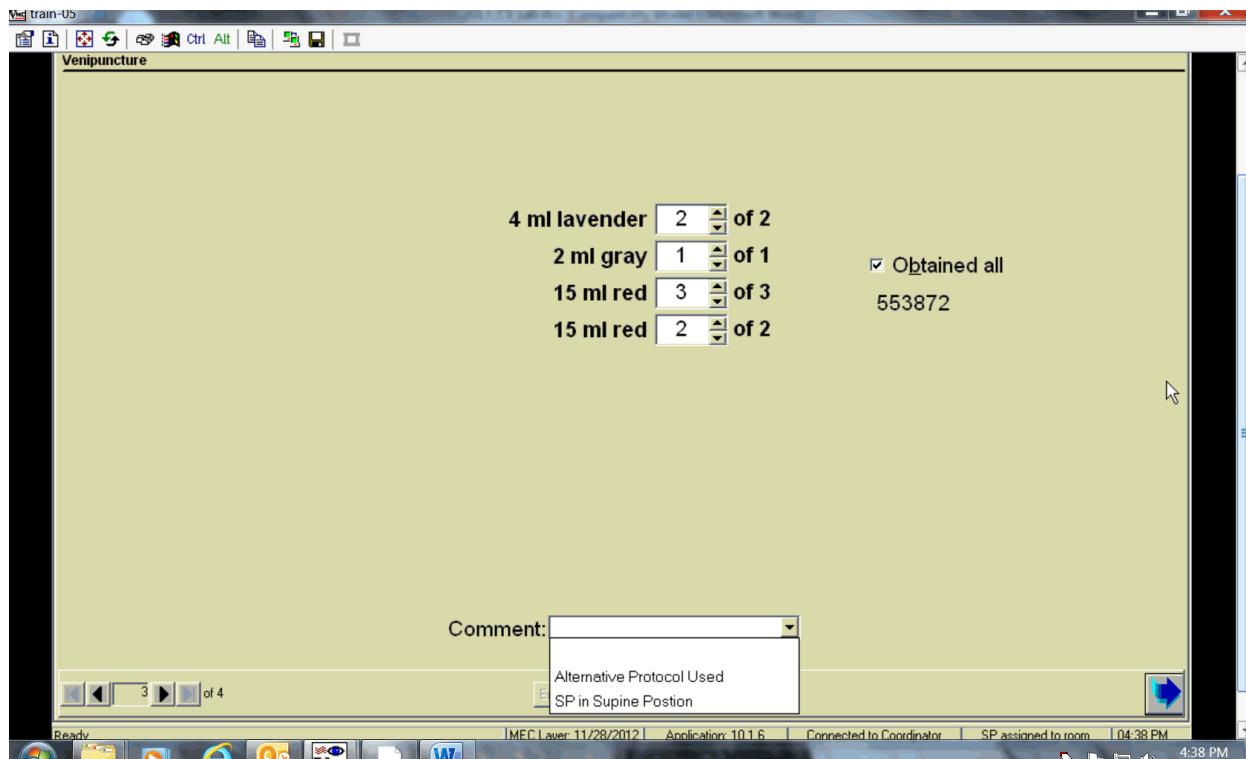
Each SP's profile is dependent on his or her age, appointment type, selection for inclusion into randomly-selected subsamples, the session time, and the testing that is being performed for the subsample the SP is assigned to.

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.

The screenshot shows a web-based interface for recording a venipuncture. At the top, it displays patient information: SP ID: 553872, Name: WRIGHT, LAYLA B, Age: 21 years, Gender: Male, Date: 12/21/2012, Time: 04:36 PM. Below this is a section titled "Venipuncture". The main area contains four rows of tube information, each with a volume and color, a spin box for the number of tubes, and a total count. The rows are: "4 ml lavender" with a spin box set to 2 and "of 2"; "2 ml gray" with a spin box set to 1 and "of 1"; "15 ml red" with a spin box set to 3 and "of 3"; and "15 ml red" with a spin box set to 2 and "of 2". To the right of these rows is a checkbox labeled "Obtained all" with the ID number "553872" below it. At the bottom of the form is a "Comment:" field with a dropdown arrow. The interface is displayed in a browser window with a Windows taskbar at the bottom showing the time as 4:38 PM.

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.

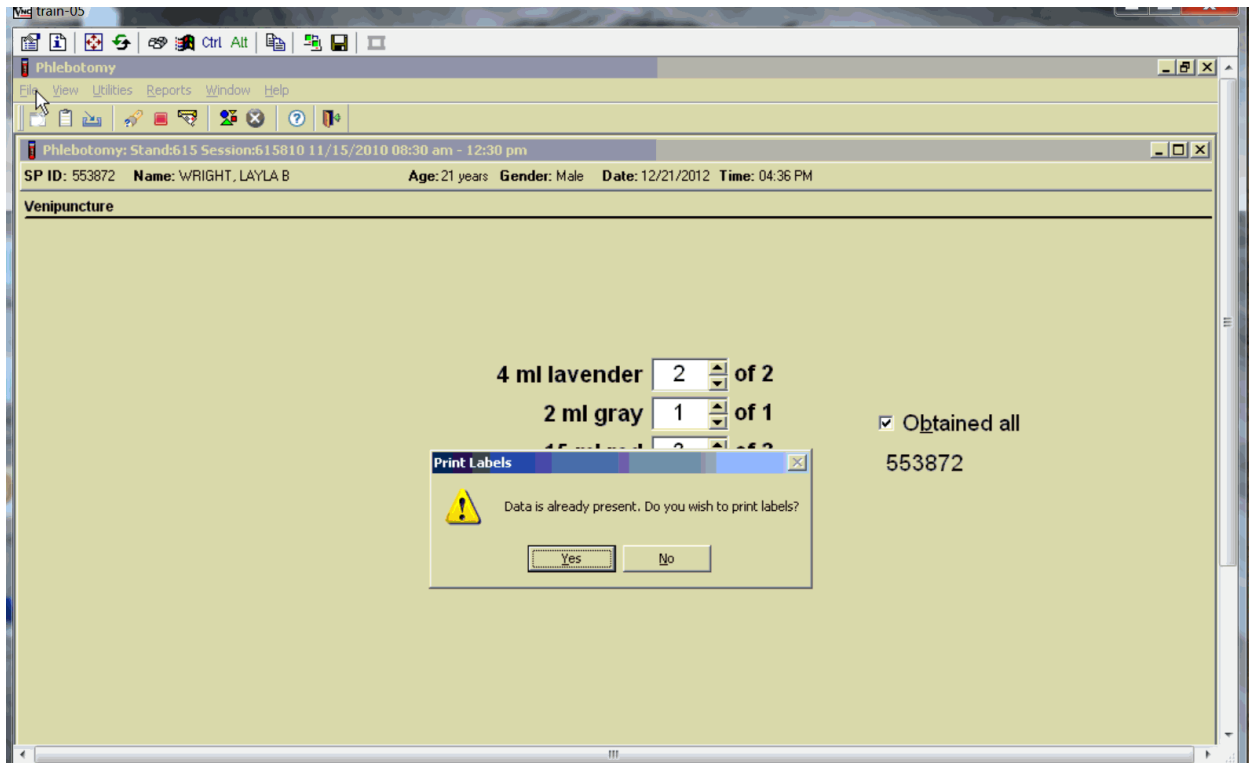
Document circumstances where the alternative protocol was used or the SP was in the supine position.



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 back 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.

3.14 Venipuncture Status

Verify the venipuncture status.

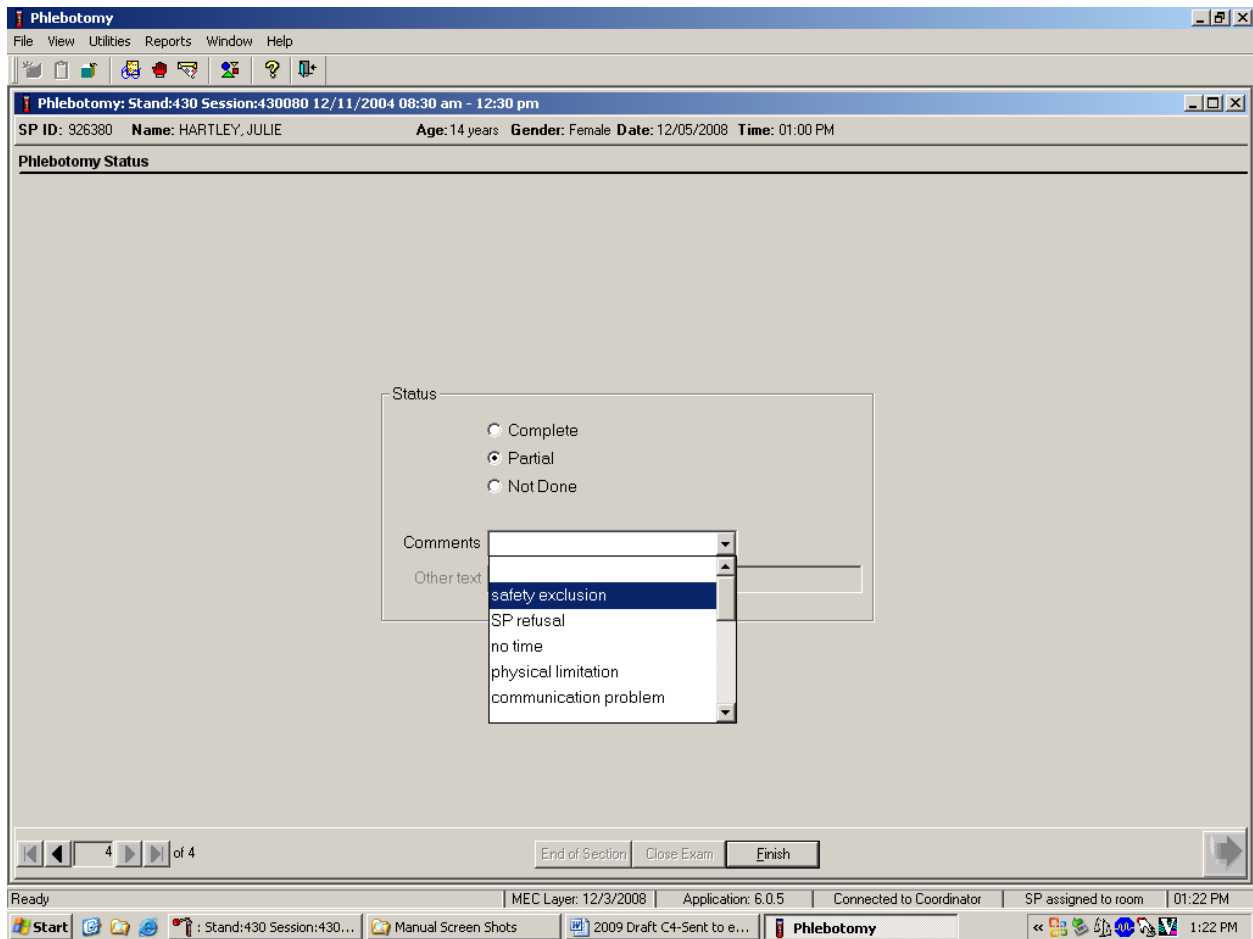
The screenshot displays the Phlebotomy software interface. At the top, the title bar reads "Phlebotomy". Below it is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons. The main window title is "Phlebotomy: Stand:430 Session:430080 12/11/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 926380 Name: HARTLEY, JULIE Age: 14 years Gender: Female Date: 12/05/2008 Time: 01:00 PM". The main area is titled "Phlebotomy Status" and contains a form with the following elements:

- Status:** Three radio buttons: Complete, Partial, and Not Done.
- Comments:** A dropdown menu.
- Other text:** A text input field.

At the bottom of the form area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom of the window shows "Ready", "MEC Layer: 12/3/2008", "Application: 6.0.5", "Connected to Coordinator", "SP assigned to room", and "01:21 PM". The Windows taskbar at the very 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.

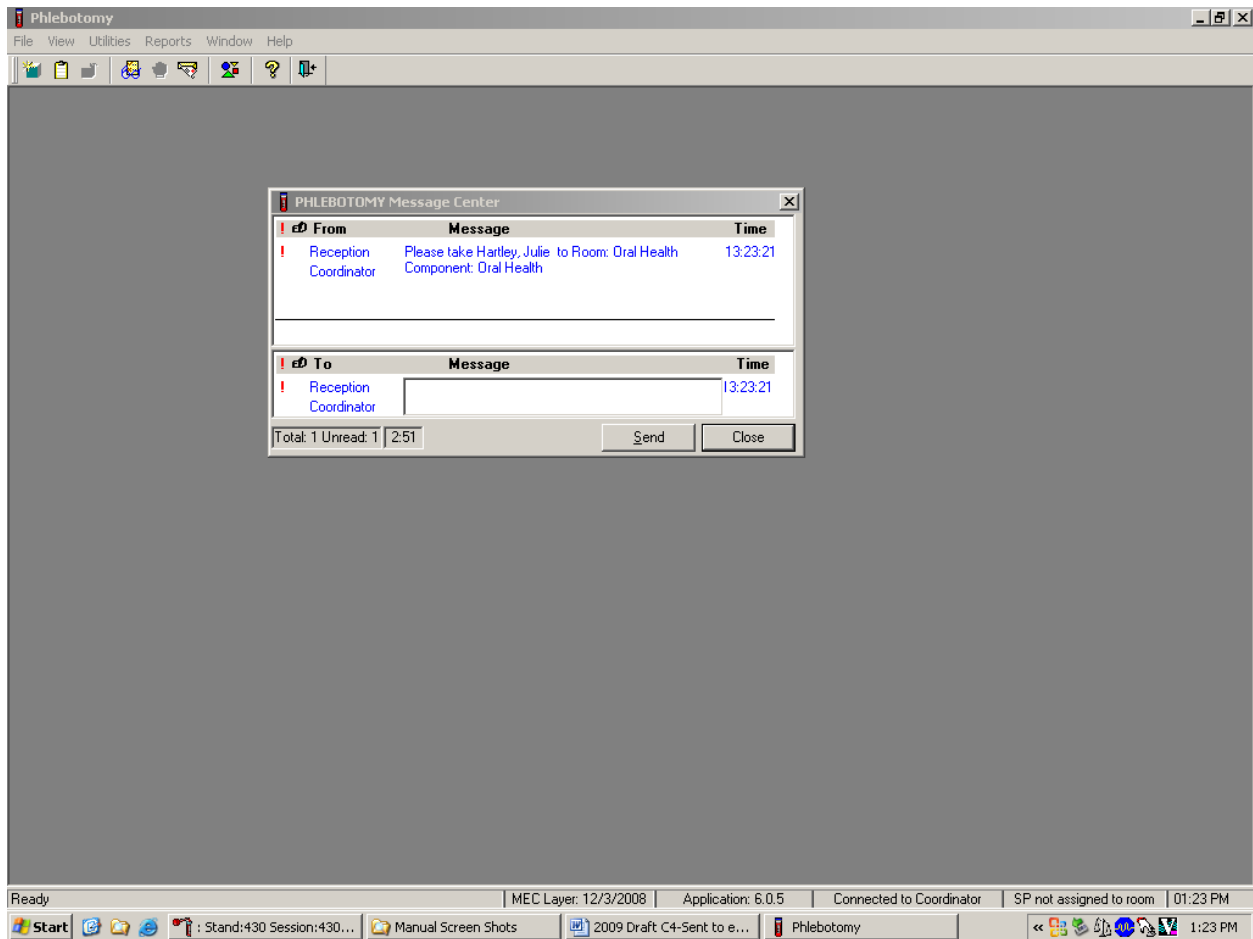
Exhibit 3-13 presents the comment codes for partial or not done venipuncture.

Exhibit 3-13. Comment codes for Partial and Not Done venipunctures

Comment code	Use when:
Safety exclusion	Not applicable. This is reserved for positive responses to the hemophilia and cancer chemotherapy exclusion questions and it is automatically coded by the application. The coordinator may code exams using this comment.
SP refusal	The SP refuses to have his or her 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 the exam room to have their arm band barcode scanned and coded. If the SP refuses after starting the exam, the examiner codes the exam. 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.
No tubes drawn	Use this comment to code exams as Partial when no tubes are drawn.
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.

3.15 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 physician may repeat the complete blood count if the participant reports no history of nosebleeds or prolonged bleeding and the physician 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 physicians on the MEC. While the medical technologists and physician 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 physician protocols that requires a second blood draw on an SP when critical results are obtained. This is only done at the physician request.

The NHANES protocol is unusual because it requires the techs to run all samples in duplicate (whenever possible), whereas a clinical lab would rerun a sample only if the result was abnormal.

Recommended Action

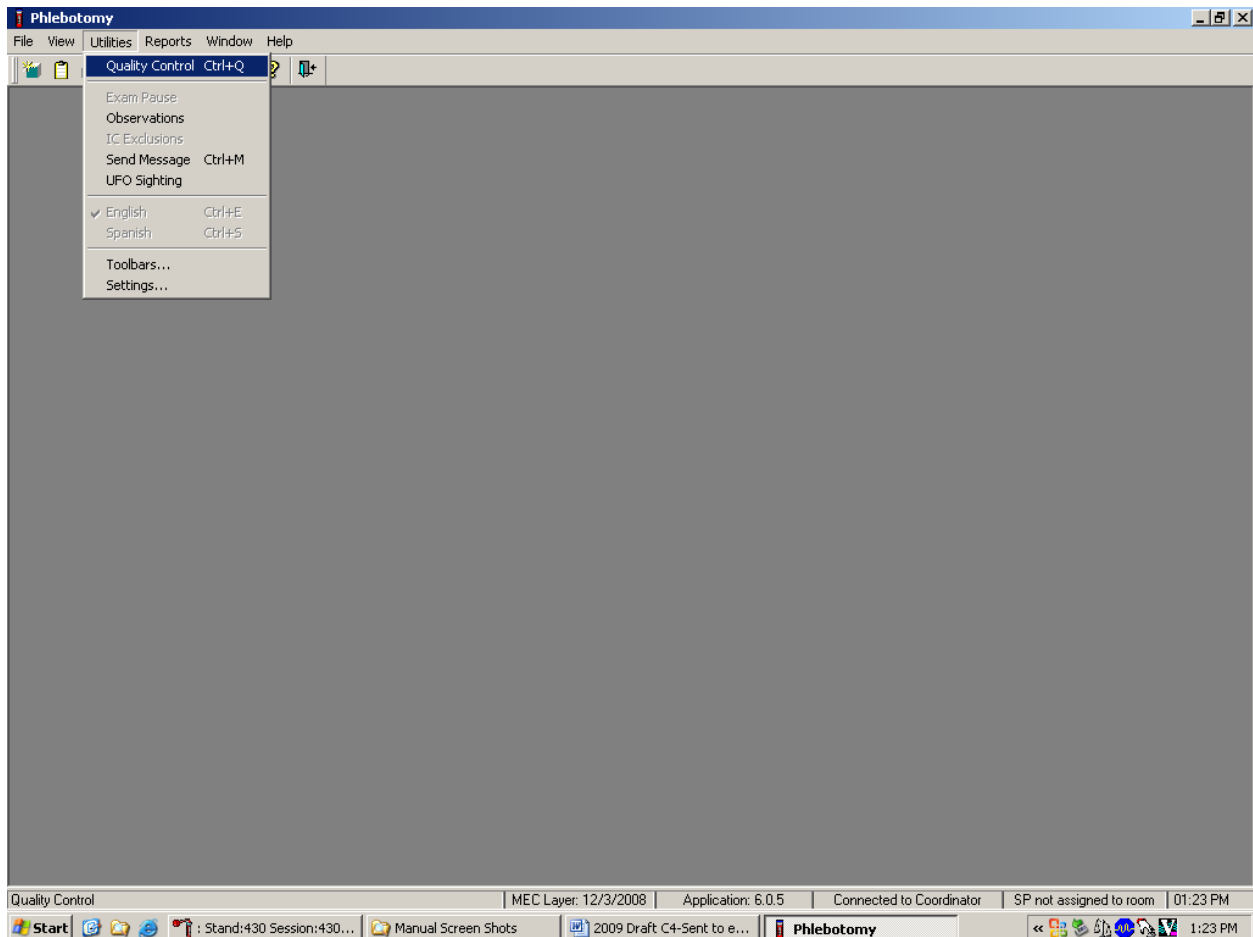
If the physician feels a repeat blood count is needed, then he or she has the discretion to discuss this with the SP and have the phlebotomist draw a 3-ml EDTA tube for a repeat CBC if the SP agrees. Prior to a second phlebotomy, the physician should visually inspect the site of the first venipuncture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

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

- The physician should consult with the MEC manager, the phlebotomist, and chief medical technologist 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 medical technologists to overwrite the existing CBC data with the new data and the new data will become the final result of record.
- The physician will document this event under observations in the physician application.

3.16 Phlebotomy Quality Control

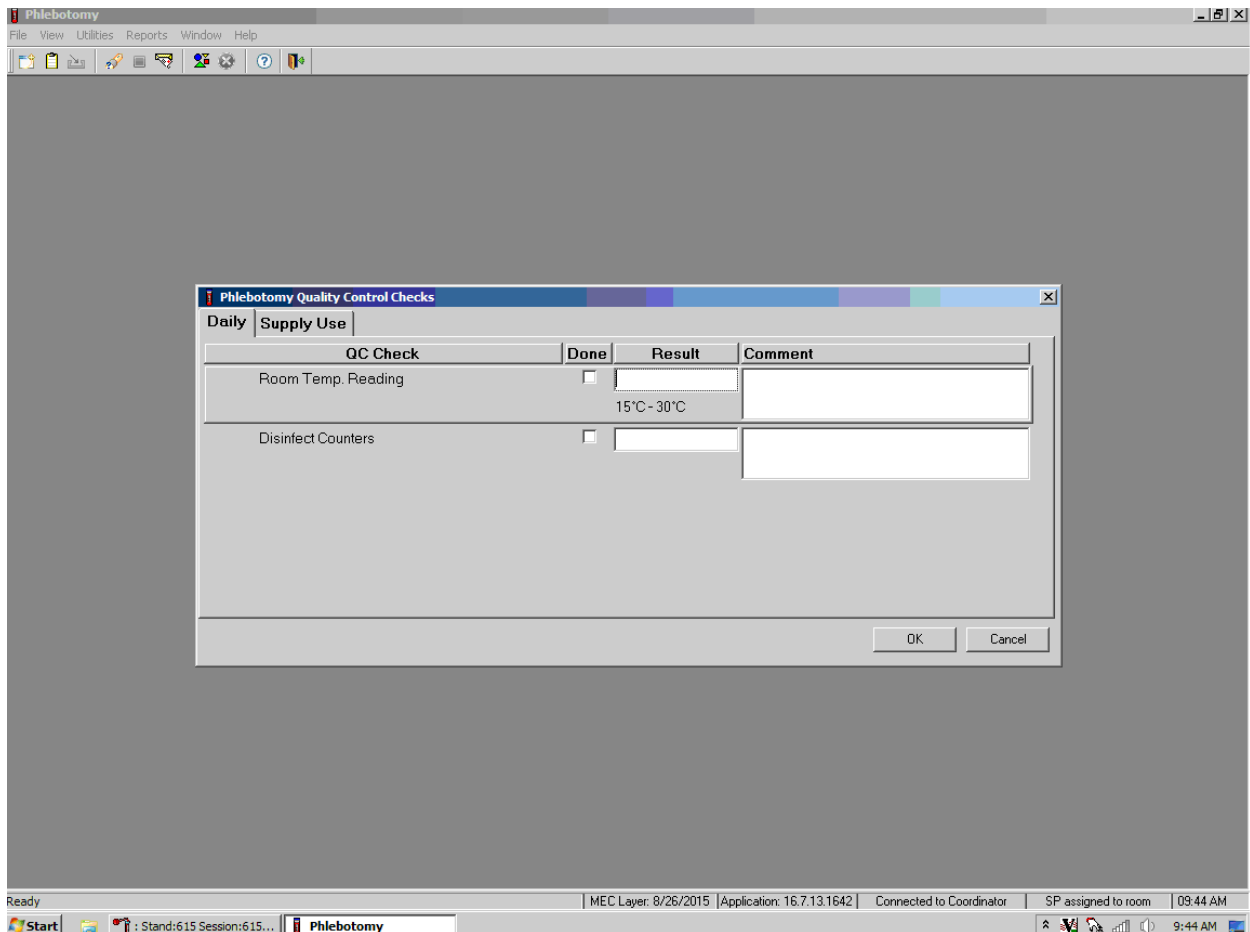
Perform phlebotomy quality control at the start of the first session even if there are no SPs scheduled into either session. Record the room temperature reading and the action that the counters were disinfected using the End of Session tab.



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.

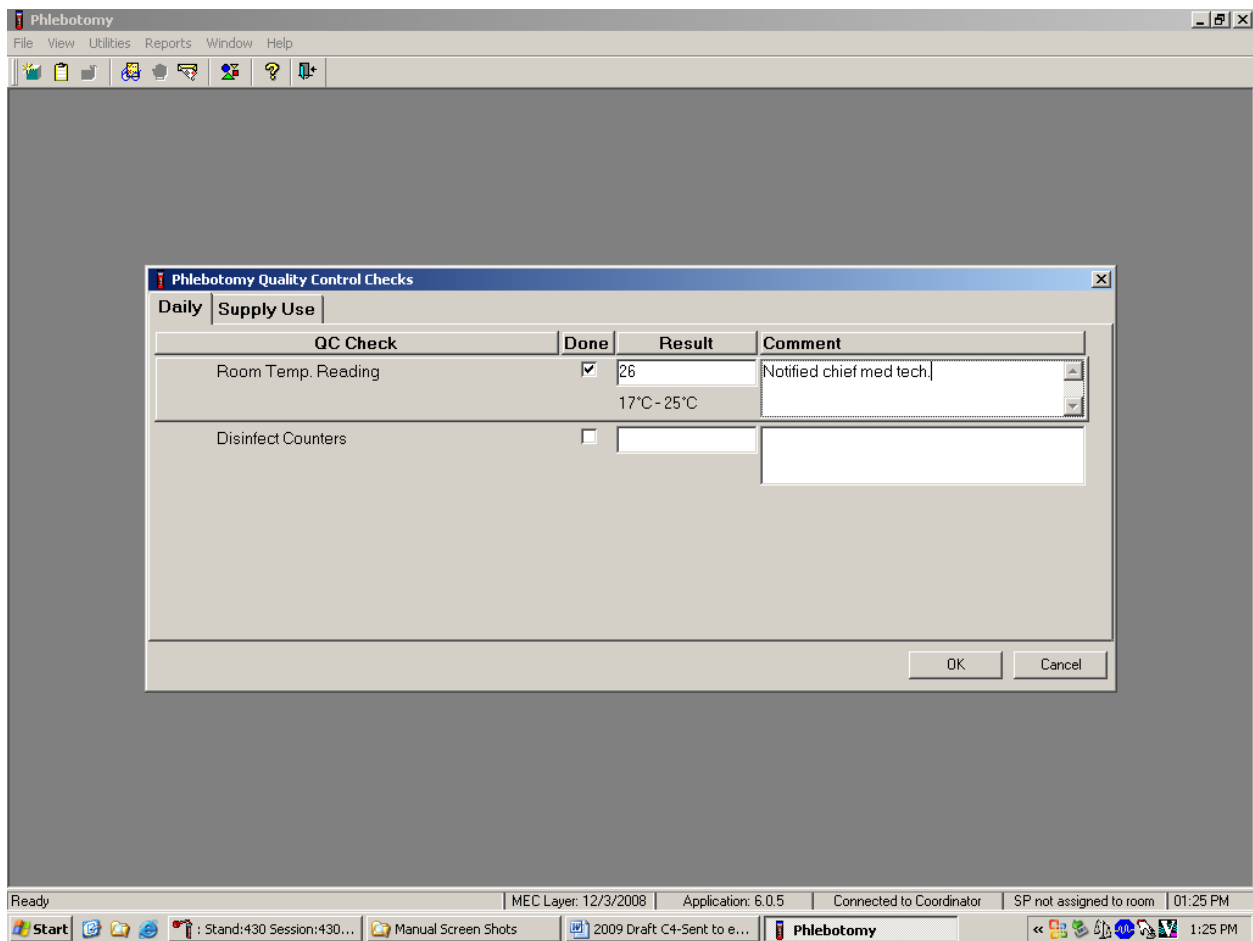
3.16.1 Daily Quality Control

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.

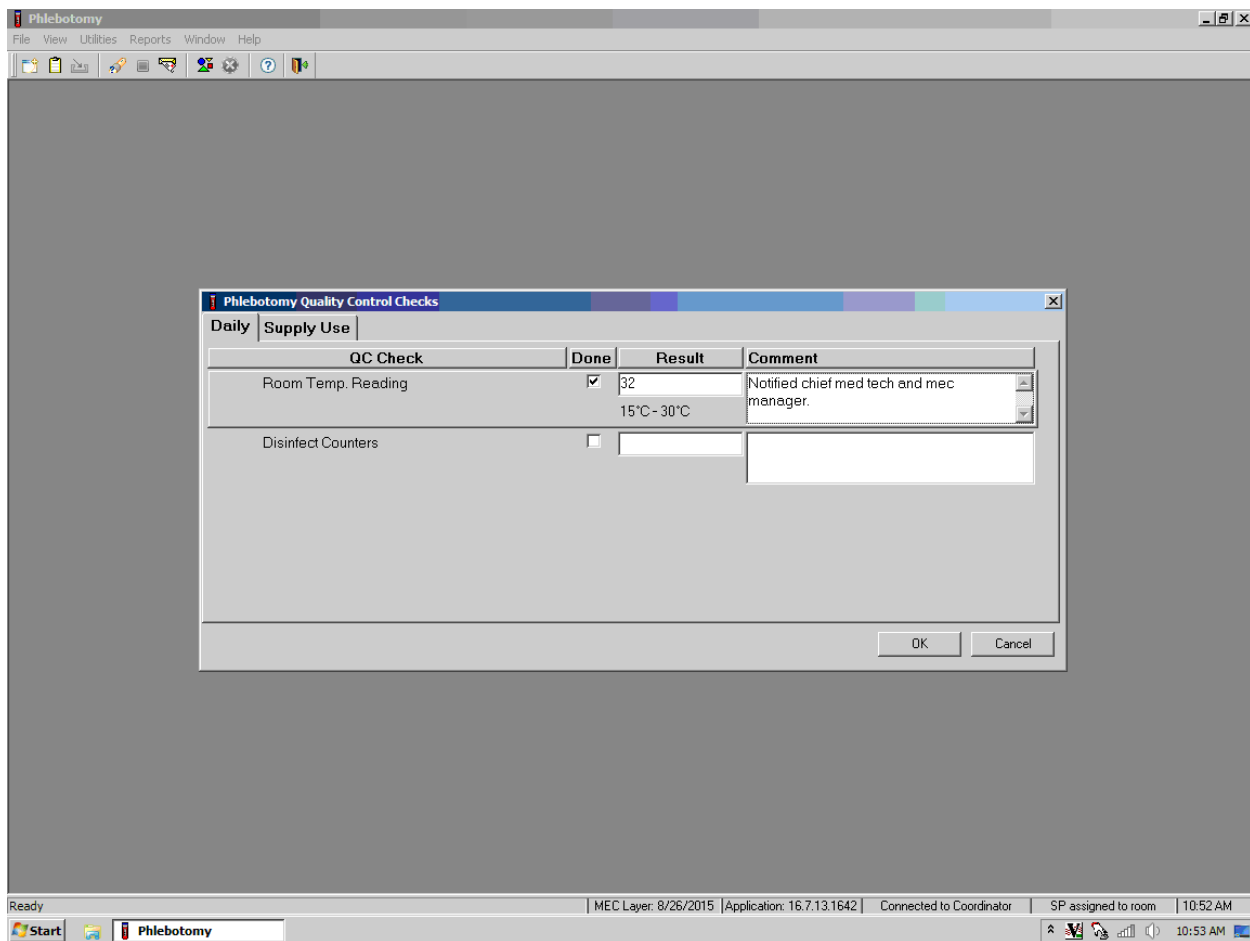


To record a check mark in the Room Temp. Reading checkbox, direct the mouse arrow to the checkbox in the Done column and left-click, and then press Tab to move to the Result text box. Enter the temperature in the Result text box and press Tab to move to the Comment text box. If the reading is outside 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.



3.17 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 his or her head at the level of the 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; and
7. Possible disturbance of vision.
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 his or her 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 he or she has suffered injury from falling.
- Seek medical assistance from the MEC physician 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, despite the possibility of breaking the SP's fast early if necessary.

3.18 How to Deal with System Failure

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibits 3-14 and 3-15). Complete a Phlebotomy worksheet for each survey participant (SP) while conducting the exam. Enter the results after the system is operational.

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

Exhibit 3-14. Phlebotomy worksheet – English Primary

**PESTICIDE USE QUESTIONNAIRE, PHLEBOTOMY INTERVIEW,
FASTING INTERVIEW, PROTOCOL PRIMARY SP, AND
VOLATIVE 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/his/her} home to control fleas, roaches, ants, termites, or other insects?		
Q2. In the past 7 days, were any chemical products used in {your/his/her} lawn or garden to kill weeds?		
Phlebotomy Interview	Responses <u>Yes, No, Refused, Don't know</u>	
Are you currently pregnant? (Females ages 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>	If Yes, record time and date
Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]		
Alcohol, such as beer, wine, or liquor?		
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?		
Antacids, laxatives, or anti-diarrheals?		
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]		

Exhibit 3-14. Phlebotomy worksheet – English Primary (continued)

Primary SP Protocol	# Filled	Not Filled
3-ml lavender (1 age 1-2, 2 age 3-5 and 1 age 40+)		
7-ml lavender (1 age 6+)		
5-ml lavender (1 age 12+)		
2-ml gray (morning only 1 age 12+)		
3-ml red (2 age 1-2)		
7-ml red (2 age 3-5, 1 age 6-11 and 1 age 12+)		
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)		
Volatile Toxicant Questionnaire (If vessel 54 was collected)	Responses Yes, No, Refused, Don't know	
Q1. Does {your/her/his} home have an attached garage?		
Q2. Is the source of water for {your/her/his} home from a private well?		
Q3. {Do you/Does she/Does he} currently store paints or fuels inside {your/her/his} home? Include {your/her/his} basement {and attached garage}.		
Q4. {Do you/Does she/Does he} currently use moth balls, moth crystals or toilet bowl deodorizers inside {your/her/his} home?		
Q5. In the last three days , did {you/she/he} inhale smoke from any source for 10 or more minutes?		
Q6. When did {you/she/he} last spend 10 or more minutes inhaling smoke? (Responses: TODAY, YESTERDAY, MORE THAN 2 DAYS, REFUSED, DON'T KNOW)		
Q7. In the last 48 hours , did {you/she/he} cook or bake with natural gas?		
Q8. How long ago, in hours, did {you/she/he} cook or bake with natural gas? (Response: 1-48 hours)		
Q9. In the last 48 hours , did {you/she/he} pump gas into a car or other motor vehicle {yourself/herself/himself}?		
Q10. How long ago, in hours, did {you/she/he} pump gas into a car or other motor vehicle {yourself/herself/himself}? (Response: 1-48 hours)		
Q11. In the last 48 hours, did {you/she/he} spend any time at a swimming pool, in a hot tub, or in a steam room?		

Exhibit 3-14. Phlebotomy worksheet – English Primary (continued)

Volatile Toxicant Questionnaire (If vessel 54 was collected)	Responses Yes, No, Refused, Don't know
Q12. How long ago, in hours, has it been since {you/she/he} spent time at a swimming pool, in a hot tub, or in a steam room? (Response: 1-48 hours)	
Q13. In the last 48 hours , did {you/she/he} use dry cleaning solvents, visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?	
Q14. How long ago, in hours, has it been since {you/she/he} used dry cleaning solvents, visited a dry cleaning shop or wore clothes that had been dry-cleaned within the last week?	
Q15. In the last 48 hours , did {you/she/he} take a hot shower or bath for five minutes or longer?	
Q16. How long ago, in hours, has it been since {your/SP's} last shower or hot bath? (Response: 1-48 hours)	
Q17. In the last 48 hours , did {you/she/he} breathe fumes from freshly painted indoor surfaces, paints, paint thinner, or varnish?	
Q18. How long ago, in hours, has it been since {you/she/he} breathed fumes from freshly painted indoor surfaces, paints, paint thinner, or varnish? (Response: 1-48 hours)	
Q19. In the last 48 hours , did {you/she/he} breathe fumes from diesel fuel or kerosene?	
Q20. How long ago, in hours, has it been since {you/she/he} breathed fumes from diesel fuel or kerosene? (Response: 1-48 hours)	
Q21. In the last 48 hours , did {you/she/he} breathe fumes from fingernail polish?	
Q22. How long ago, in hours, has it been since {you/she/he} breathed fumes from fingernail polish? (Response: 1-48 hours)	
Comments:	

Exhibit 3-15. 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: Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}?	Responses <u>Y</u> es, <u>N</u> o	If Yes, record time and date
¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.]		
¿Alcohol, tal como cerveza, vino o licor?		
¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado?		
¿Antiácidos, laxantes, o antidiarréicos?		
¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.]		

Exhibit 3-15. Phlebotomy worksheet – Spanish Primary (continued)

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)		
Volatile Toxicant Questionnaire (If vessel 54 was collected)	Responses Yes, No, Refused, Don't know	
Q1. ¿Tiene {su hogar/el hogar de él/ella} (una cochera/un garaje) unido(a) al hogar?		
Q2. ¿Es la fuente de agua para {su hogar/el hogar de él/ella} de un pozo privado?		
Q3. Actualmente, ¿guarda {usted/él/ella} pinturas o combustibles dentro de su hogar? Incluya el sótano {y (la cochera/el garaje) unido(a) a su hogar}.		
Q4. 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?		
Q5. En los últimos tres días , ¿respiró {usted/ella/él} cualquier tipo de humo por 10 o más minutos?		
Q6. ¿Cuándo fue la última vez que {usted/ella/él} respiró humo por 10 o más minutos?		
Q7. 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.		
Q8. En las últimas 48 horas , ¿horneó o cocinó {usted/ella/él} con gas natural? (Response: 1-48 hours)		
Q9. En las últimas 48 horas , ¿le echó gasolina {usted mismo/él mismo (MPR)/ella misma (FPR)} a un carro u otro vehículo de motor?		
Q10. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} {mismo/mismo/misma} le echó gasolina a un carro o a otro vehículo de motor? (Response: 1-48 hours)		
Q11. En las últimas 48 horas, ¿pasó {usted/él/ella} algún tiempo en una (alberca/piscina), en una tina tipo “hot tub” o en un cuarto de vapor?		

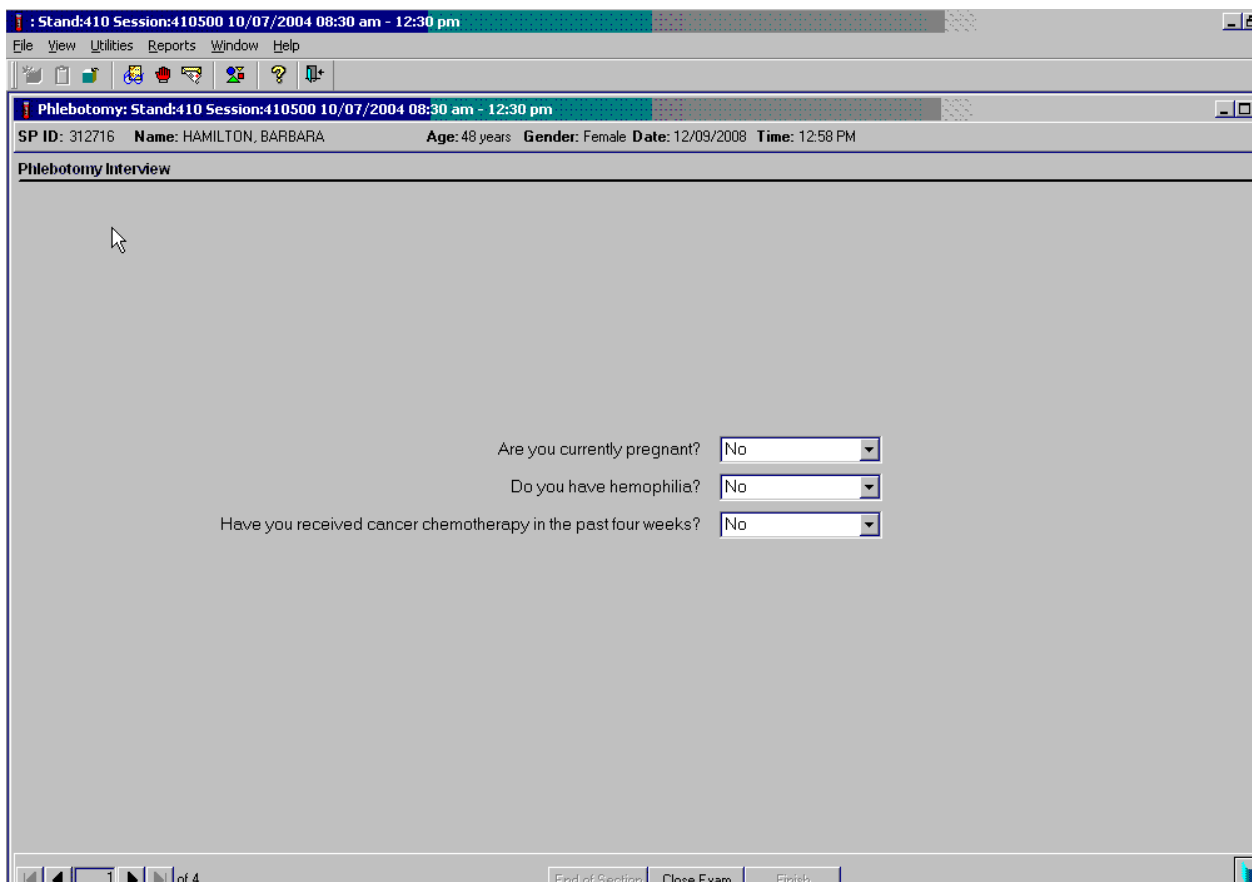
Exhibit 3-15. Phlebotomy worksheet – Spanish Primary (continued)

Volatile Toxicant Questionnaire (If vessel 54 was collected)	Responses Yes, No, Refused, Don't know
Q12. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} pasó algún tiempo en una (alberca/piscina), en una tina tipo “hot tub” o en un cuarto de vapor? (Response: 1-48 hours)	
Q13. 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?	
Q14. ¿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?	
Q15. En las últimas 48 horas , ¿se dio {usted/él/ella} una ducha o un baño caliente por cinco minutos o más?	
Q16. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} se dio una ducha o un baño caliente? (Response: 1-48 hours)	
Q17. En las últimas 48 horas , ¿aspiró {usted/él/ella} gases de lugares interiores recién pintados, de pinturas, de disolvente de pintura o de barniz?	
Q18. ¿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: 1-48 hours)	
Q19. En las últimas 48 horas , ¿aspiró {usted/él/ella} los gases de combustible diesel o de querosén?	
Q20. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} aspiró los gases de combustible diesel o de querosén? (Response: 1-48 hours)	
Q21. En las últimas 48 horas , ¿aspiró {usted/él/ella} los gases de esmalte para las uñas?	
Q22. ¿Cuánto tiempo hace, en horas, que {usted/él/ella} aspiró gases de esmalte para las uñas? (Response: 1-48 hours)	
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



The screenshot shows a software application window with a title bar that reads "Stand:410 Session:410500 10/07/2004 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar with various icons is located below the menu bar. The main content area of the window is titled "Phlebotomy Interview" and displays the following information: "SP ID: 312716", "Name: HAMILTON, BARBARA", "Age: 48 years", "Gender: Female", "Date: 12/09/2008", and "Time: 12:58 PM". Below this information, the text "Phlebotomy Interview" is displayed. The main area contains three questions, each with a dropdown menu set to "No":
Are you currently pregnant? No
Do you have hemophilia? No
Have you received cancer chemotherapy in the past four weeks? No
At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish".

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 Session Close Exam Finish

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) collect a date, time, and volume of urine collection for analysis of urine flow rate; (2) 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; (3) aliquot urine into vessels for storage and transport to multiple government and contract laboratories for analysis; and (4) 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 or correct the weight. Perform the pregnancy test if indicated, process the urine 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 he or she enters 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:

- It is important to collect ALL urine by COMPLETELY emptying your bladder into the cup.
- 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 interviewers, health technologists, or MEC managers will introduce the 3- to 5-year-old urine collection 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 utilized for the 3- to 5-year-olds in place of the urine cup, this 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 Supplies

The supplies needed for urine collection and urine processing and storage are listed in Exhibits 4-1 and 4-2.

Exhibit 4-1. Urine collection equipment

Blue scale carrying case
<p>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)</p>
Care Pac M
<p>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)</p>
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	Cardboard box, 3.0-inch with 5 x 5 grid – White
10-mL Vial CryoPro VWR screwcap – WITH ADDITIVE (Urine/Mercury)	Cube rack – 4-way flipper rack
3.5-ml Starstedt Transfer pipette	Kimwipes
15-ml VWR narrow stem, large bulb disposable transfer pipette	Nonsterile, powder-free, gloves—small, medium, large
Bench Kote paper	Sani-Cloth Plus

4.3 Urine Flow Rate Background

The NHANES protocol includes many measures of environmental toxicants or their metabolites in urine. It is difficult to quantify the level of exposure based on measurements in urine because concentrations will vary by the amount of urine produced. Currently, NHANES urine measurements are adjusted by the urinary creatinine concentration to account for variations in urinary dilution. However, creatinine excretion into the urine varies by many factors other than the urinary dilution (e.g., age, gender, muscle mass, and diet). Also, the amount of toxicant excreted in a 24-hour period is often needed to quantify exposures for risk and exposure assessment purposes.

Ideally, this requires 24-hour urine collections to quantify. However, it is possible to estimate the mass of analyte excreted in the urine in a 24-hour period by estimating the urine flow for the spot urine specimen collection (i.e., equivalent to a single urine specimen as collected in the current NHANES protocol).

The date and time of last urine void, along with the volume of the urine specimen and the date and time of urine collection captured during urine collection, will provide NCHS with a measurement of urine flow rate. These items are captured during the SP's visit to the MEC. All SPs aged 3 years and older will be eligible for urine flow rate. Urine specimen volume and date and time of collection will be captured only on SPs who submit a urine specimen.

The MEC appointment reminder letter will include the reminder “Before arriving at the exam center, please make a note of the time you last went to the bathroom and urinated (peed). Please write the time on the appointment card you were given. You will be asked for this time when you get to the exam center” and will provide a space for the SP to write a response. When the SP arrives at the MEC, the coordinator will prompt the SP to write down the time of his or her last urine void on the verification form. The coordinator will record this time. If there is any discrepancy between the time on the reminder letter and the time reported at the MEC, the coordinator should use the time reported at the MEC.

4.4 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 into 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 in order 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. “0.00” will display when the balance is back in weighing mode and ready for operation.

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.

4.5 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						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	○	○	-	○	○	○	-	○

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										HPV	
							UC	U	P	CB	B	GTT	PC	F	M	OR		
256339	256339	CI	P	M	90	MOORE, LANDON J	○	○	-	○	○	○	-	-	-	-	-	
329869	329869	BE	P	M	69	HOWARD, SOPHIA S	●	●	-	○	○	○	○	-	-	○	-	
416714	416714	BE	P	F	20	BAILEY, ANTHONY J	●	●	○	○	○	○	○	○	-	○	-	
480354	480354	SC	P	M	3	LEE, OWEN S	-	-	-	○	○	-	-	-	-	-	-	
525757	525757	BE	P	F	70	ADAMS, CALEB L	●	●	-	○	○	○	○	-	-	-	-	
545182	545182	SC	P	F	4	POWELL, AALIYAH H	-	-	-	○	○	-	-	-	-	-	-	
553872	553872	BE	P	M	21	WRIGHT, LAYLA B	⊕	○	-	○	○	-	-	○	○	-	○	
745052	745052	SC	P	F	41	EVANS, SAVANNAH M	○	○	○	○	○	○	-	○	-	○	-	
767995	767995	BE	P	M	15	MURPHY, ISAAC N	●	○	-	○	○	-	-	○	○	-	○	
784174	784174	BE	P	M	50	GONZALEZ, SIFINNA N	⊕	●	-	○	○	○	-	-	○	○	-	
813366	813366	CI	P	F	19	STEWART, SIFINNA N	○	○	○	○	○	-	○	-	○	-	○	
836040	836040	CI	P	M	19	TORRES, LUCAS T	●	○	-	○	○	-	-	○	-	○	-	
837622	837622	SC	P	F	1	MARTINE, PATRICIA	-	-	-	○	○	-	-	-	-	-	-	
849425	849425	SC	P	F	10	CAMPBELL, VINNIE N	○	○	○	○	○	○	-	-	-	-	-	
861215	861215	CI	P	M	18	SMITH, MARGARET	○	○	-	○	○	○	-	○	-	○	-	
919919	919919	BE	P	F	25	PAYNE, IMA L	●	●	○	●	○	●	-	○	-	○	-	

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.

The screenshot shows a window titled "Urine Collection Verification: 430420". It contains a table of SPs and a detailed view for the selected SP.

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	203	12/19/2008 04:16 PM	Yes	(none)	<input type="checkbox"/>

Total Collected: 203
Total Required: 55

Buttons: Save, New Collection, OK, Cancel

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
300780	300780	MARTIN_5, JOE	M	46
304240	304240	BUTLER_5, CATHY	F	22
304755	304755	MARTIN_7, THOMAS	M	22
305504	305504	HOLLAND_6, LISA	F	30
306771	306771	MILLER_3, PATTY	F	50
306998	306998	FULTON_6, JEREMY	M	54
307322	307322	ESTRADA_4, JOSE	M	25

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	26	11/04/2009 10:46 AM	QNS	quantity not suffic	<input type="checkbox"/>
2			(none)	(none)	<input type="checkbox"/>

Total Collected: 26
Total Required: 55

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.

4.5.1 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.

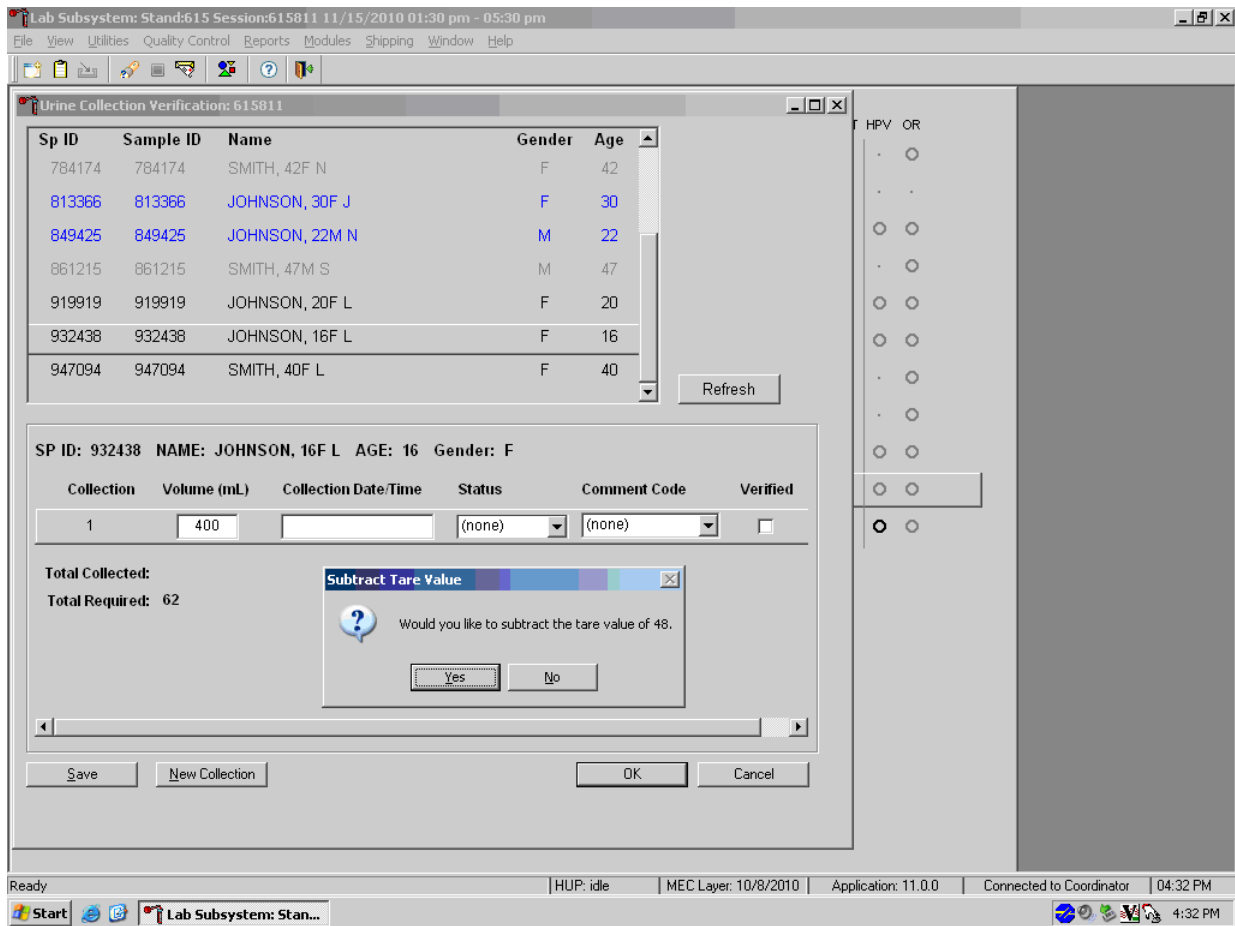
If the SP has voided <1.0 ml, the laboratory will ask the coordinator for a re-collection of Urine Collection (UC) 1. Do not record any results for this urine instance. Discard this sample and wait for a new UC 1. **An exception is when a female SP requiring a pregnancy test provides <1 ml. In this instance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

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.

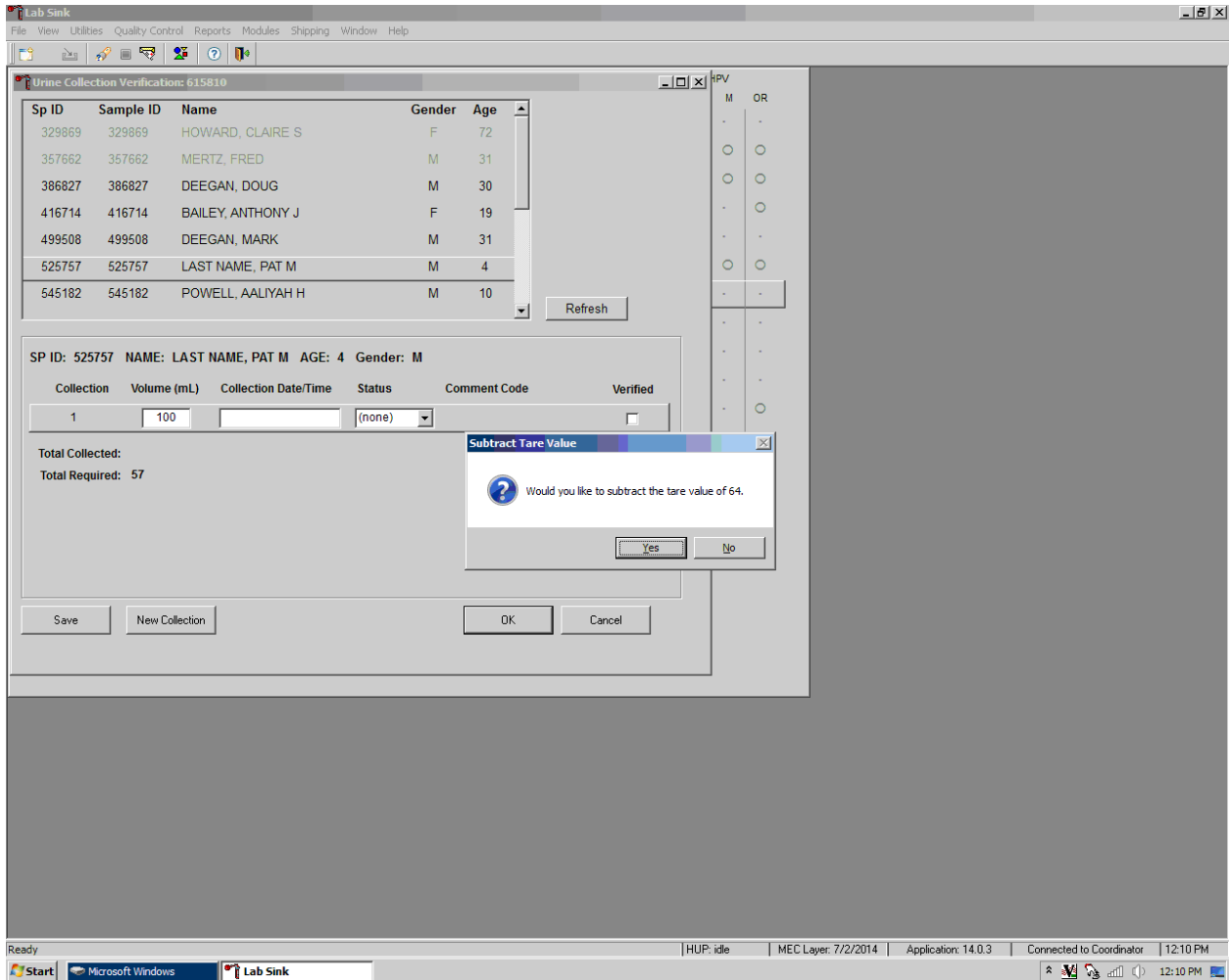
The screenshot displays the 'Lab Sink' software interface. At the top, there is a menu bar with options: File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, Help. Below the menu is a toolbar with various icons. The main window is titled 'Urine Collection Verification: 615810'. It contains a table with columns: Sp ID, Sample ID, Name, Gender, Age. The table lists several patients, including TIM, SP FIRST NAME M (M, 3), NAME, LAST M (M, 5), MERTZ, ETHEL (F, 47), GONZALEZ, SIENNA N (F, 9), TORRES, LUCAS T (F, 51), CAMPBELL, VINNIE N (F, 5), and PAYNE, IMA L (M, 11). Below the table is a 'Refresh' button. Underneath, there is a section for 'SP ID: 776512 NAME: MERTZ, ETHEL AGE: 47 Gender: F'. This section contains a table with columns: Collection, Volume (mL), Collection Date/Time, Status, Comment Code, and Verified. The first row shows Collection 1, Volume 10, Date/Time 12/04/2014 10:00 AM, Status 'QNS', Comment Code 'quantity not sufficient', and Verified checkbox. The second row shows Collection 2, Volume '(none)', Status '(none)', Comment Code '(none)', and Verified checkbox. Below this table, it shows 'Total Collected: 10' and 'Total Required: 14'. At the bottom of this section are buttons for 'Save', 'New Collection', 'OK', and 'Cancel'. A dropdown menu is open over the 'Comment Code' field, showing a list of options: 'quantity not sufficient', 'SP refusal', 'SP ill/emergency', 'no time', 'exceeds scale capacity', and 'blood/clot contamination'. The bottom of the screen shows the Windows taskbar with the Start button, 'Microsoft Windows' logo, and 'Lab Sink' application name. The system tray shows 'Ready', 'HUP: idle', 'MEC Layer: 7/2/2014', 'Application: 14.0.3', 'Connected to Coordinator', and '12:18 PM'.

The urine collection cup may contain a sample that weighs more than the scale weight capacity of 610 g. Look at the scale display for full specimens. If the scale displays dashes when it should display a weight, the reading is over the scale limit: $\Gamma - - - - \Gamma$. When the barcode for the sample is scanned in, the words “over Lmt” will display on the LCD screen instead of the barcode.

When the scale is over the limit, it does not transmit data to the ISIS application. Manually enter a volume of 610 ml in the volume column.



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 48?” 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

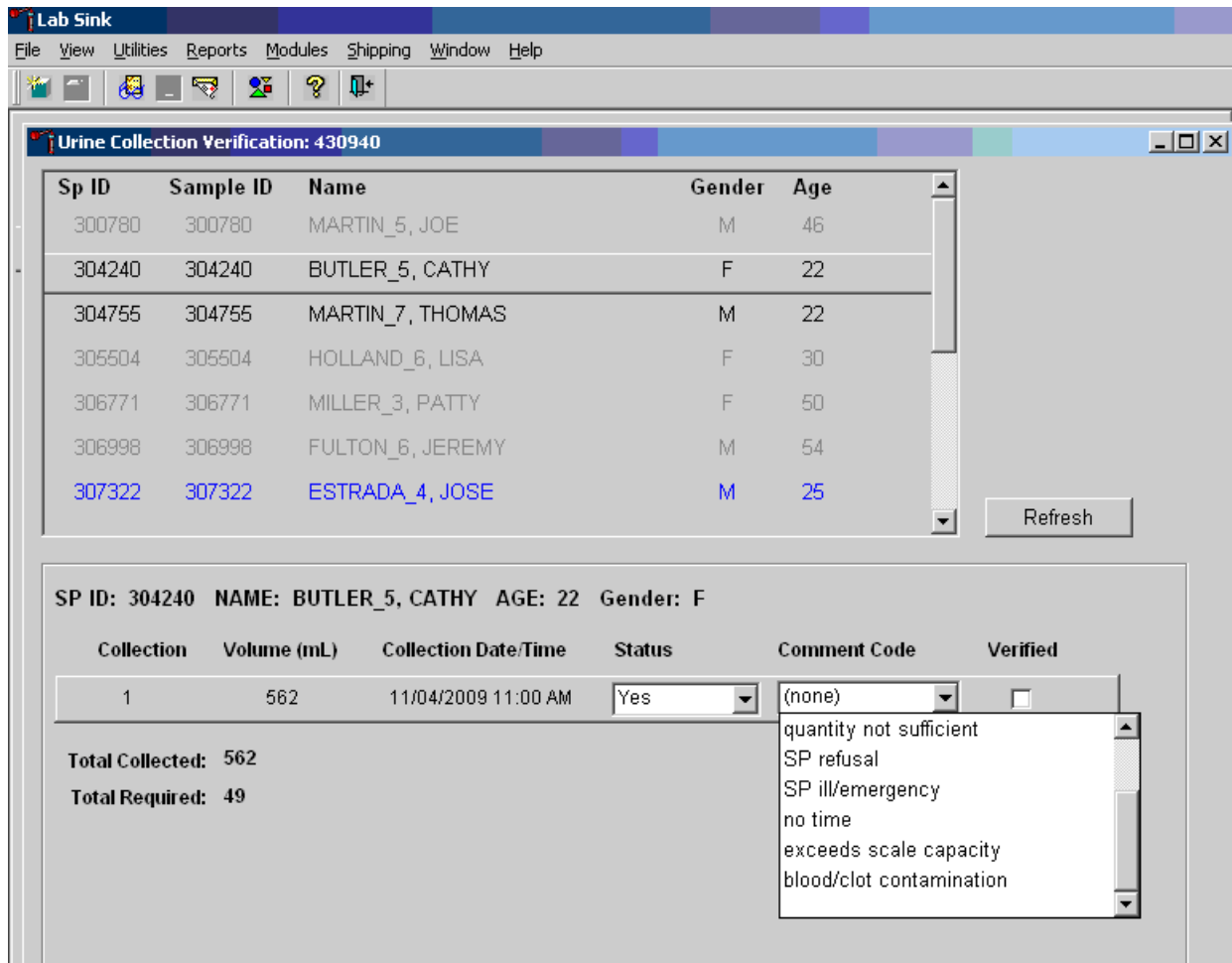
SP ID: 220901 NAME: RUSSELL_2, JACK AGE: 25 Gender: M

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

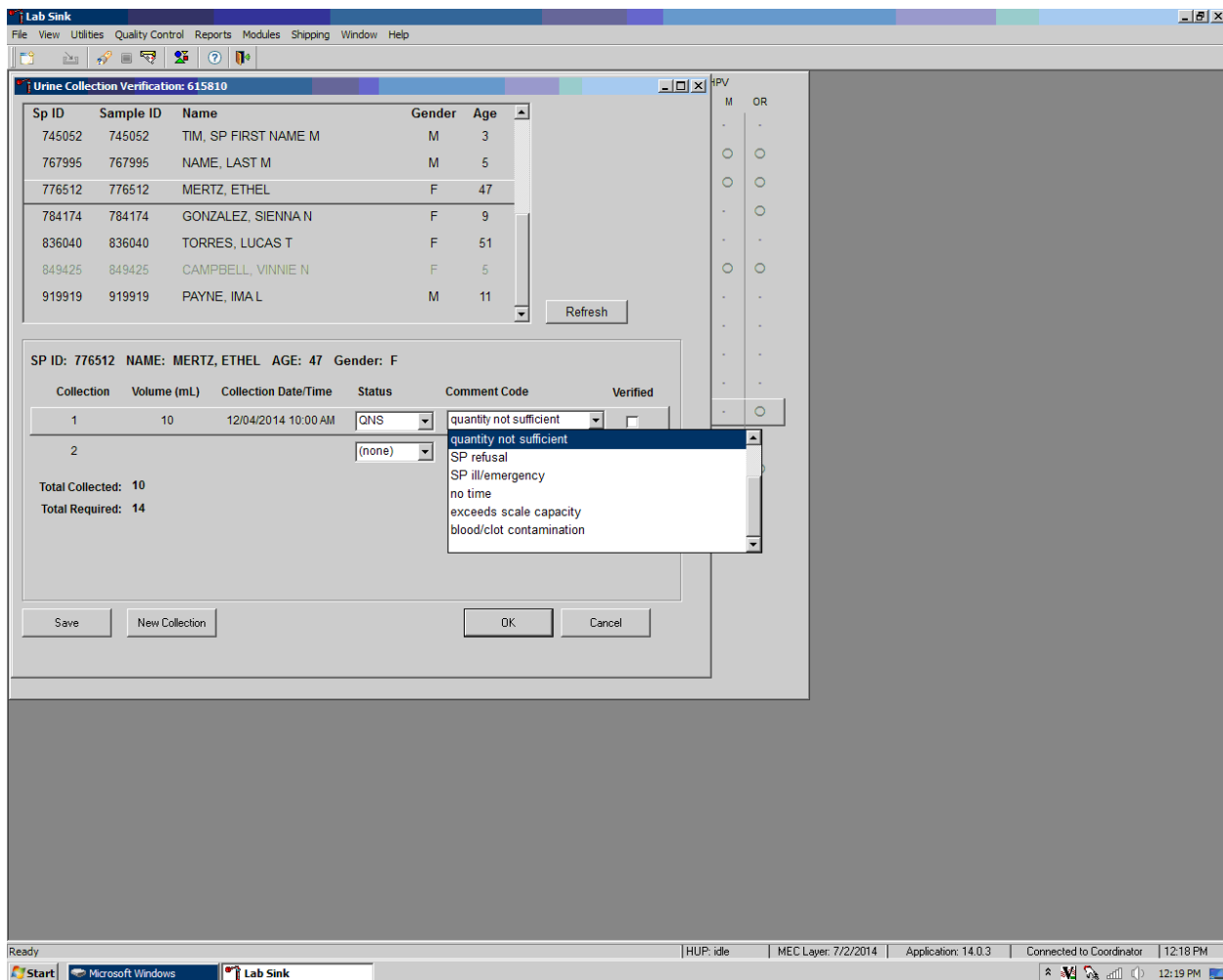
Buttons: Save, New Collection, OK, Cancel

Record a comment for sufficient urine collections if the weight of the urine exceeds the scale weight capacity of 610 g.



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.

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

To record a comment, direct the mouse arrow to the drop-down list, click to display the comment codes (Exhibit 4-3), and select the most appropriate choice.

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 him or her 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

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 his or her urine collection was insufficient to meet the SP's protocol requirement and (2) the SP has submitted less than two or three collection samples, dependent upon the age of the SP. 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.

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

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.

Verify the urine collection by checking the “Verified” box. Use “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.

4.6 Manually Documenting Urine Collection

4.6.1 Manually Document Urine Collection with Barcode Scanning

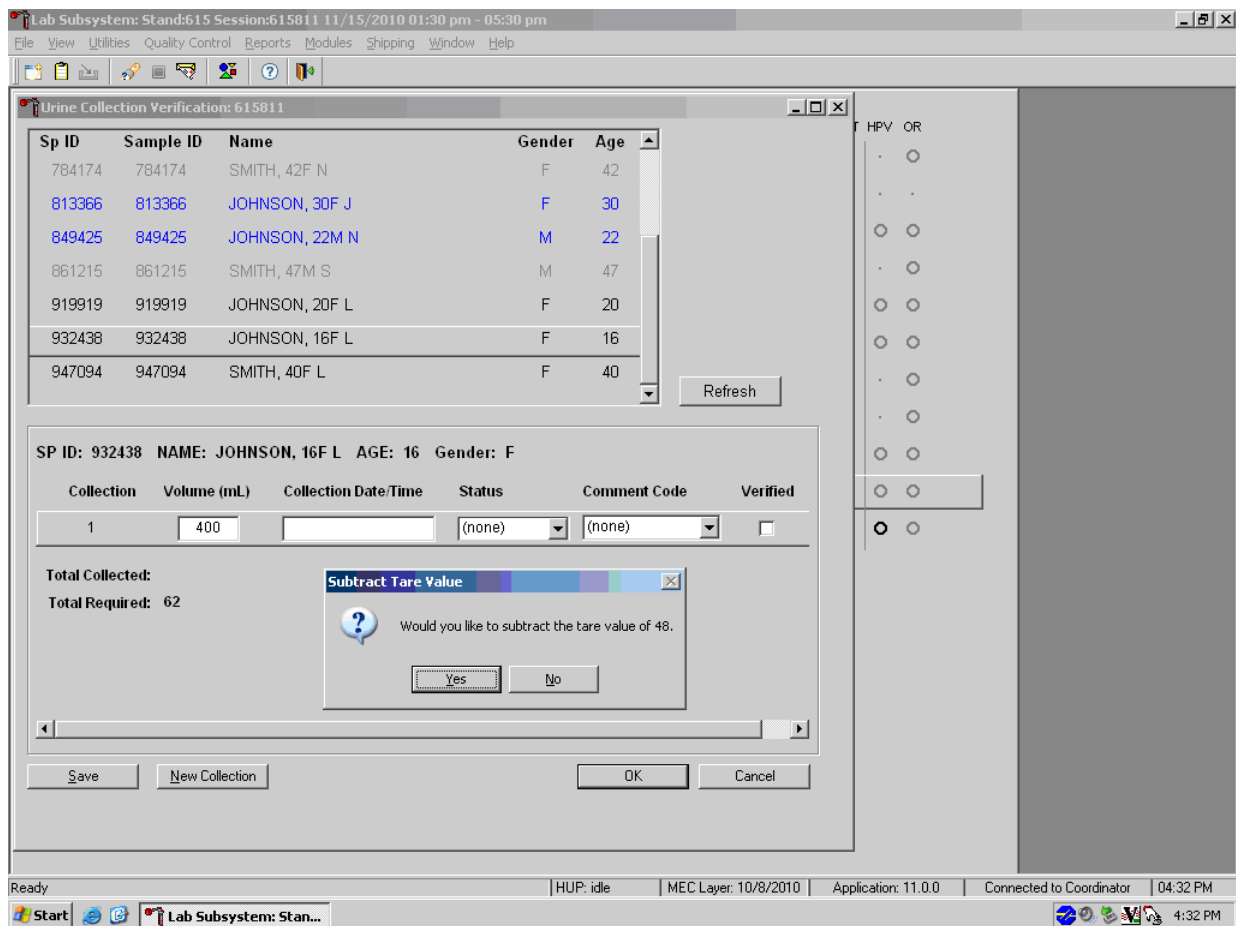
The technician can manually record the volume, status, and collection date and time in the Urine Collection module within the laboratory application. Place the urine collection cup on the scale and cover with the clear acrylic scale cover. Scan the barcode on the urine cup.

Note: Use this function when the interface between the scale and the laboratory system is not functioning properly.

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 by checking the “Verified” box.

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 by checking the “Verified” box. Use “Save” to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

4.6.2 Manually Document Urine Collection Without Barcode Scanning

If the connection between the scale and workstation 3 is down, the technician 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.

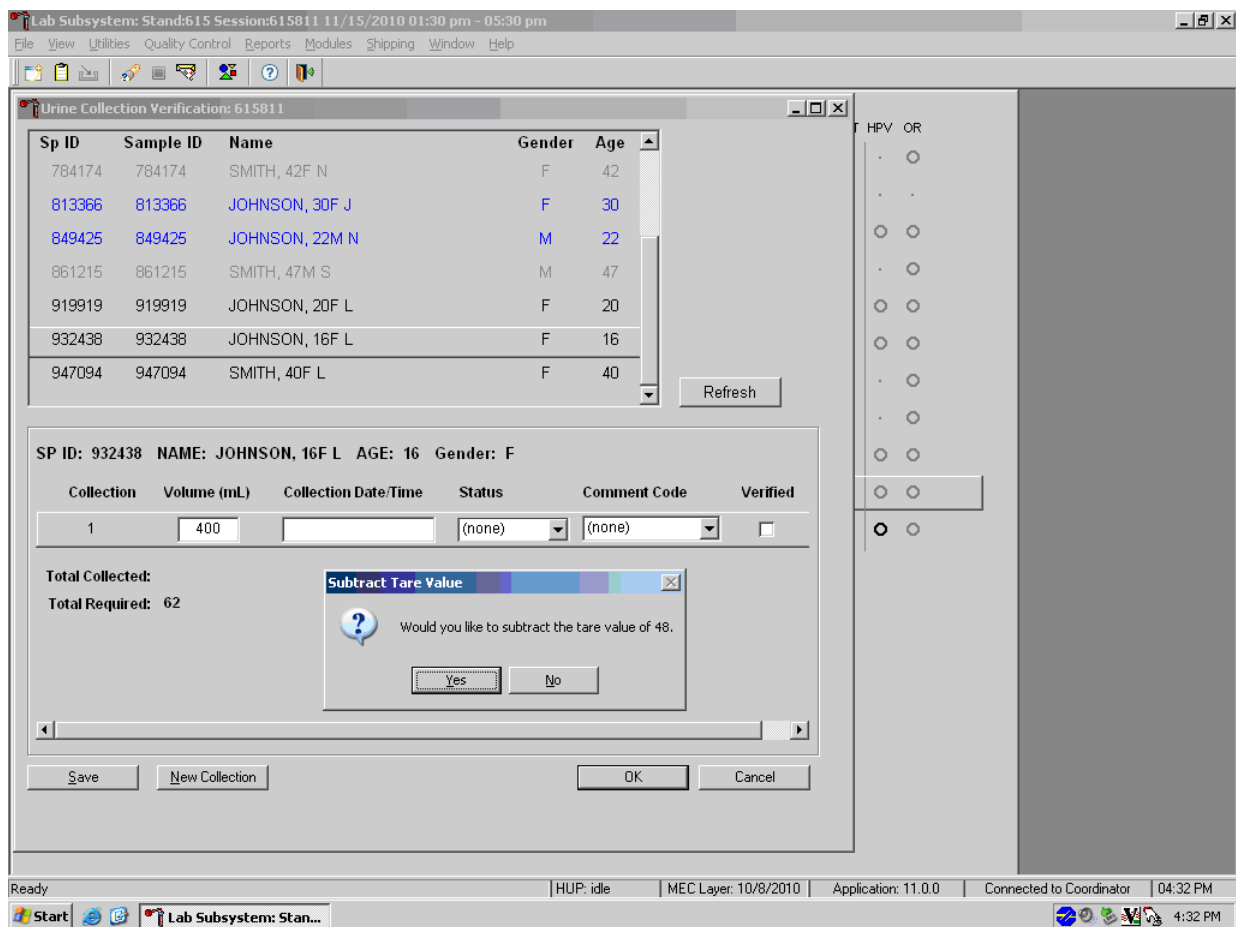
Open the Urine Collection screen from the heads-up as described in Section 2.2. The urine collection window displays. Double-click in the area underneath Volume or Collection Date/Time to open the boxes where the values can be entered. Enter the urine collection results by typing in the weight reading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

Sp ID	Sample ID	Name	Gender	Age
784174	784174	SMITH, 42F N	F	42
813366	813366	JOHNSON, 30F J	F	30
849425	849425	JOHNSON, 22M N	M	22
861215	861215	SMITH, 47M S	M	47
919919	919919	JOHNSON, 20F L	F	20
932438	932438	JOHNSON, 16F L	F	16
947094	947094	SMITH, 40F L	F	40

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1			(none)	(none)	<input type="checkbox"/>

Total Collected:
Total Required: 62

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 collection date/time, select the appropriate urine collection status, and add a comment code if applicable. Verify the urine collection by checking the “Verified” box.

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 by checking the Verify box. Click Save to save changes or select the  in the upper right corner to exit out of the Urine Collection screen.

4.6.3 Manually Entering Adults Who Collect in CC2

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 4.6.2 to enter the calculated weight into ISIS.

4.7 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, and all adult smokers (18+);
- Priority Pesticides (Prior Pest) on all SPs aged 3-5 and selected SPs aged 6 years and older;
- Organophosphates (Organophos) on all SPs aged 3-5 and selected SPs aged 6 years and older;
- Urine Mercury/Iodine (Urin Merc) on all SPs aged 3-5 and selected SPs aged 6 years and older;
- Metals on all SPs aged 3-5, selected SPs aged 6 years and older, and all adult smokers (18+);
- 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, selected SPs aged 6 years and older, and all adult smokers (18+);
- Phthalates on all SPs aged 3-5 and selected SPs aged 6 years and older;
- Perchlorate/VOCs/Thiocyanate on all SPs aged 3-5 and selected SPs aged 6 years and older;
- TSNA/NNAL/Nicotine Analogs(a tobacco-specific nitrosamine)/Heterocyclic Amines on all SPs aged 3-5, selected SPs aged 6 years and older, and all adult smokers (18+);
- Aromatic Amines on all SPs aged 3-5, selected SPs aged 6 years and older, and all adult smokers (18+);
- 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.

4.8 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+	3	5-ml cryovial
46	Chlam/Trichomonas/Mgen	14-39	5	5-ml cryovial
154	Trichomonas/Mgen	40-59	5	5-ml cryovial
86	Spc Arsenic	3+	2	2-ml cryovial
48	Prior Pest	3+	5 (3-5) 7 (6+)	10-ml screwcap
49	Organophos	3+	5 (3-5) 7 (6+)	10-ml screwcap
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-0 cryovial
66	PAH	3+	3	5-ml cryovial
67	Phthalates	3+	4.5	10-ml screwcap
102	Perchlorate/Thiocyanate	3+	2	2-ml cryovial
156	TSNA	3+	5	5-ml cryovial
152	NNAL/Nicotine Analogs	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

4.9 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 technologist at workstation 1 prints the labels at least one session in advance. The printing procedure is described in Chapter 8. The label/ship technologist 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.

Separate the labels for SPs who have checked in from SPs who have not checked in. Set the labels aside for SPs who have not checked in. If the SP does not show up for the 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 and redact the SP information from the sample cup and discard.

4.10 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.
- 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.

Using the large 15-ml plastic transfer pipette for all but vessel 62, aliquot the urine sample for each of these tests using the procedure shown below. (Pouring directly from the specimen cup into the vessel is allowed.)

Vessel	Action
45	Aliquot 3 ml of urine for Alb/Creat into a 5-ml vessel
46	Aliquot 5 ml of urine for Chlam/Trich/Mgen (14-39 years old) into a 5-ml vessel
154	Aliquot 5 ml of urine for Trich/Mgen (40-59 years old) into a 5-ml vessel
86	Aliquot 2 ml of urine for Spc Arsenic into a 2-ml vessel
48	Using a 10-ml vessel, aliquot 5 ml of urine for 3- to 5-year-olds and 7 ml of urine for 6+ for Prior Pest
49	Using a 10-ml vessel, aliquot 5 ml of urine for 3- to 5-year-olds and 7 ml of urine for 6+ for Organophos
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-O 5-ml vessel
66	Aliquot 3 ml of urine for PAH into a 5-ml vessel
67	Aliquot 4.5 ml of urine for Phthalates into a 10-ml screwcap vessel
102	Aliquot 2 ml of urine for Perchlorate/Thiocyanate into a 5-ml vessel
156	Aliquot 5 ml of urine for TSNA into a 5-ml vessel
152	Aliquot 5 ml of urine for NNAL/Nicotine Analogs 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 his or her 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.

4.11 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.

The screenshot shows the Lab Sink software interface. The main window displays a table of specimens with columns for SP ID, Sample ID, Status, Type, Gender, Age, Name, Process Status, and HPV. A context menu is open over the first specimen (SP ID: 329869), listing various processing options. The 'Urine Processing' option is highlighted.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							HPV					
							UC	U	P	CB	B	GTT	PC	F	M	OR			
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	CI	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													

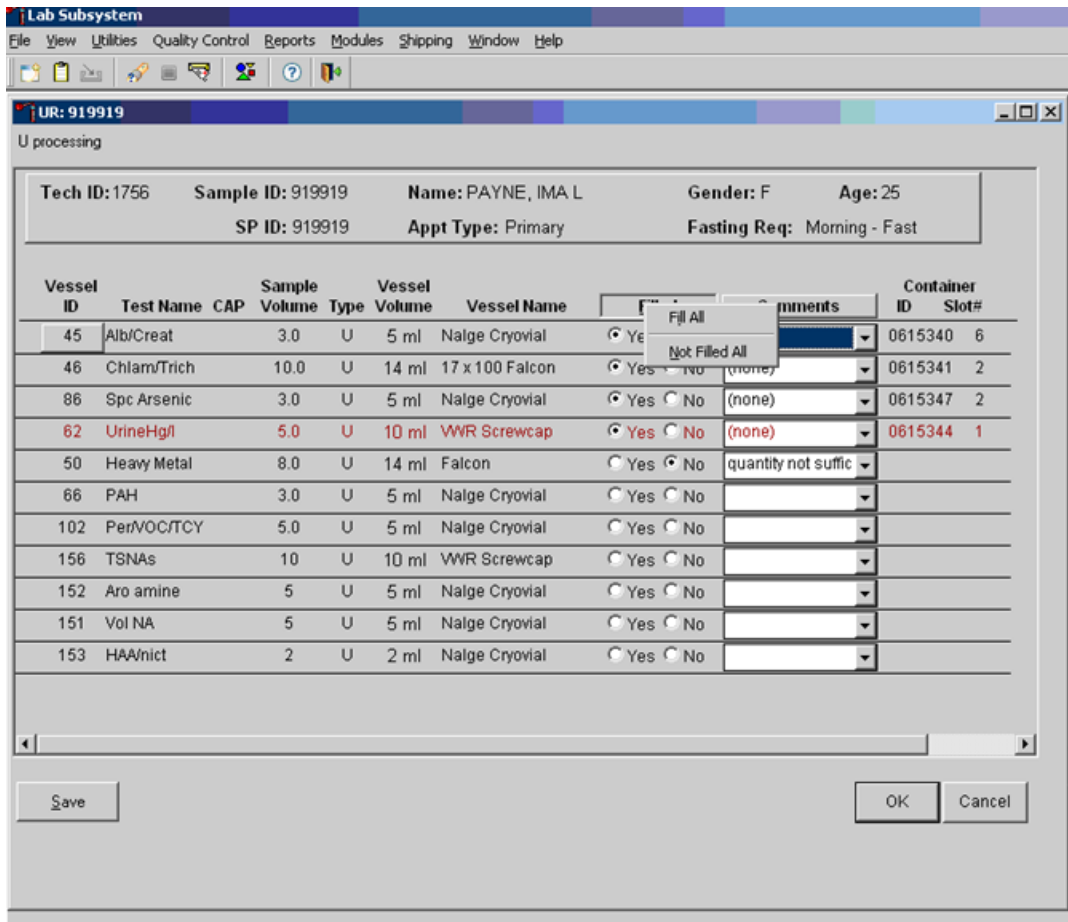
The SP's urine processing window displays.

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	Chlam/Trich/Mgon		10.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
86	Spc Arsenic		3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
62	UrineHgfl		5.0	U	10 ml	VWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
50	Metals		8.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
66	PAH		3.0	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
156	TSNAs		10	U	10 ml	VWR Screwcap	<input type="radio"/> Yes <input type="radio"/> No			
152	Aro amine		5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
151	Vol NA		5	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
153	HAA/nict		2	U	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			

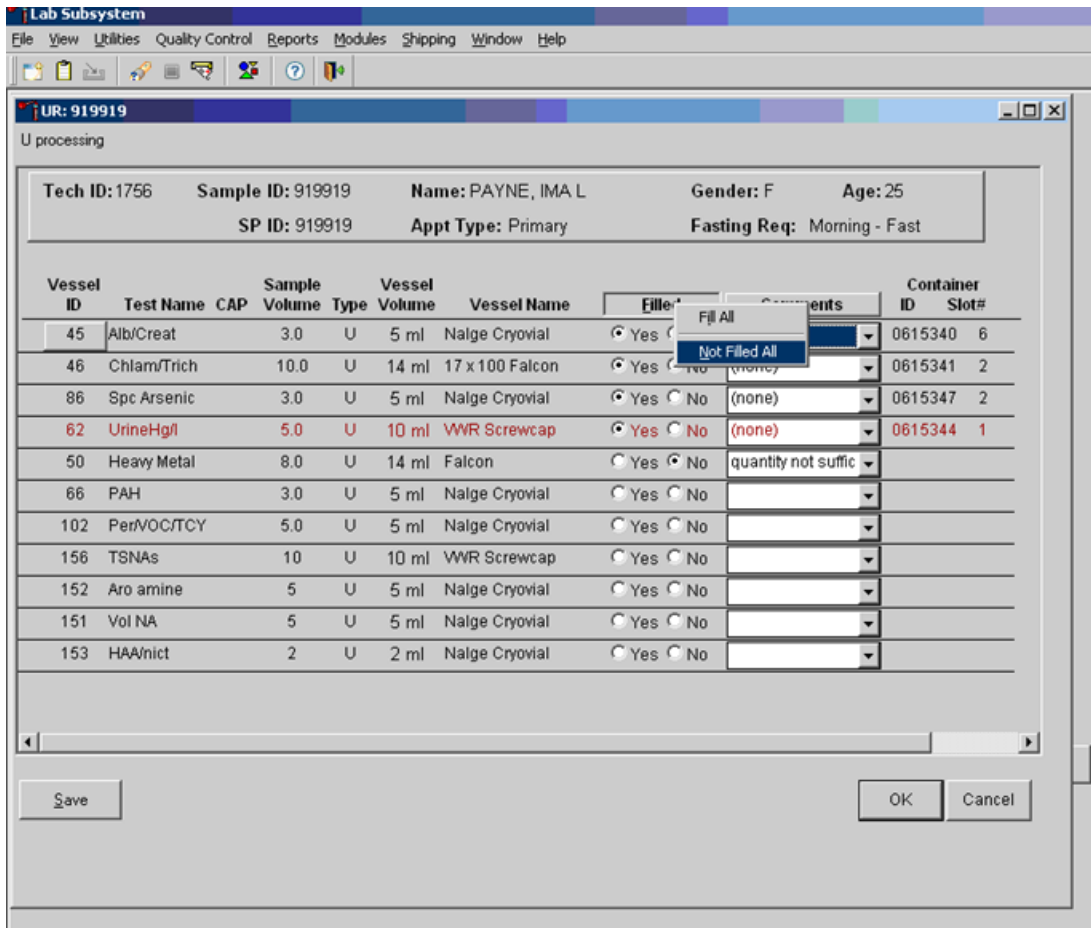
The urine processing window contains the following information for SPs: Tech ID, Sample ID, Name (last, first), Gender, Age, SP ID, Appt (appointment) Type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (U = urine), Vessel Volume, and Vessel Name; Filled (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.



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 4-5 shows quality control comments and Exhibit 4-6 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 4-5. 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 4-6. Comment codes

Comment code	Use when
Awaiting SP sample	At the end of the session 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.

4.12 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. If a subsequent sample collection fulfills the protocol requirement, pool the initial and subsequent urine samples into the most recently collected specimen 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.

4.13 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 4-7. 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 technologist.

At the beginning of each stand, generate and print a series of bar-coded, 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 4-7. Storage and shipping protocol for urine

Lab #	Shipping location		Vessels	Conditions	Frequency	Vessel storage
16	University of Minnesota	45	Alb/Creat	Frozen	Weekly	9x9 three-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 (plus)	Frozen	Weekly	9x9 three-inch box
6	CBR	152	NNAL/Nicotine Analogs	Frozen	Weekly	9x9 three-inch box
6	CBR	218	Aromatic/Dia mines	Frozen	End of stand or when full	9x9 three-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

4.14 How to Deal with System Failure

If the computer system fails, record results on a preprinted workstation 3 processing worksheet (Exhibit 4-8). 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 4-8. Workstation 3 processing worksheet

URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING

SP ID _____

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

Exhibit 4-8. Workstation 3 processing worksheet (continued)

ID	Name	Ages	Sample ml	Sample type	Tube size	Filled ✓	Comments:	
							QNS Blood Present	Slot #
45	Alb/Creat	3+	3	Urine	5-ml cryovial			
46	Chlam/Trich/ Mgen	14-39	5	Urine	5-ml cryovial			
154	Trich/Mgen	40-59	5	Urine	5-ml cryovial			
86	Spc Arsenic	3+	2	Urine	2-ml cryovial			
48	Prior Pest	3+	5 (3-5), 7 (6+)	Urine	10-ml Screwcap			
49	Organophos	3+	5 (3-5), 7 (6+)	Urine	10-ml Screwcap			
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+	3	Urine	5-ml cryovial			
67	Phthalates	3+	4.5	Urine	10-ml Screwcap			
102	Perchlorate/ Thiocyanate	3+	2	Urine	2-ml cryovial			
156	TSNA	3+	5	Urine	5-ml cryovial			
152	NNAL/Nicotine Analog	3+	5	Urine	5-ml cryovial			
218	Diaromatic Amines	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			

THIS PAGE IS INTENTIONALLY LEFT BLANK.

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 8-11 who report that they are menstruating when asked during the home interview. A positive test result excludes pregnant women aged 8-59 from participating in the dual-energy x-ray absorptiometry (DXA) and liver ultrasound transient elastography (LUTE) components of the MEC exam. Perform the test and report test results immediately, since these components are not assigned until the results of the pregnancy test are documented.

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.

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 utilizes 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-Vue™ hCG Urine Control Sets

- Sure-Vue™ 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-Vue™ 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, technologist 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 are backed up and stored at Westat's home office.

5.4 Specimen Collection and Preparation

Collect a urine specimen on all SPs 3 years and older into a clean and dry plastic container and document the collection in the Urine Collection module as described in Chapter 4. Perform a urine pregnancy test on females of all person types who are aged 12-59 years and girls aged 8-11 who report that they are menstruating when asked during the home interview.

If the urine pregnancy test is positive for SP's 8-17 years of age, repeat the pregnancy test a second time. Notify the physician of the positive results and submit a UFO confirming 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
 - 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
- 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), at which temperatures these controls are stable 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.

Sure-Vue™ hCG Urine Control Sets

- The Sure-Vue™ urine controls have droppers built into the tip. The use of the control droppers to add three drops of sample 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/Serum test at room temperature (15-25°C, 59-77°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 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.

Open the Pregnancy QC module.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							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	DEEGAN, MARK	<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	LAST NAME, PAT M	<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	TIM, SP FIRST NAME M	<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	NAME, LAST M	<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"/>

To open the pregnancy QC module, direct the mouse arrow to Utilities 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.

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, DOU	○	○	○	○	○	○	○	-
416714	416714	SC	P	F	16	JAILEY, ANTHC	○	○	○	○	○	○	○	-
499508	499508	SC	P	F	5	DEEGAN, MAR	○	○	-	○	○	-	-	-
525757	525757	SC	P	M	3	LAST NAME, P	○	○	-	○	○	-	-	-
745052	745052	SC	P	F	12	TIM, SP FIRST	○	○	○	○	○	-	-	-
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	○	○	-	○	○	○	-	○

The pregnancy QC window displays.

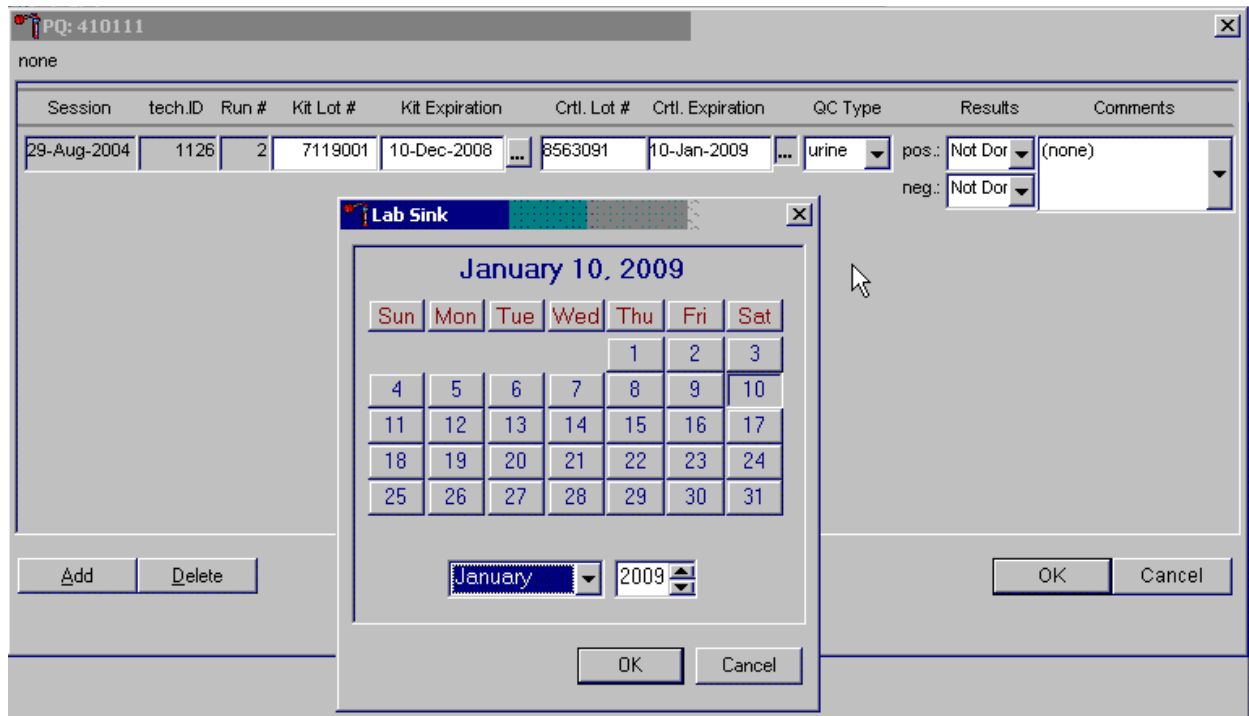
Session	tech.ID	Run #	Kit Lot #	Kit Expiration	Ctrl. Lot #	Ctrl. Expiration	QC Type	Results	Comments
29-Aug-2004	1126	2	7119001	10-Dec-2008	8563091	10-Jan-2009	urine	pos.: Not Dor neg.: Not Dor	(none)

Add Delete OK Cancel

The Pregnancy QC module automatically captures the session date and technologist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type – urine. 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.

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



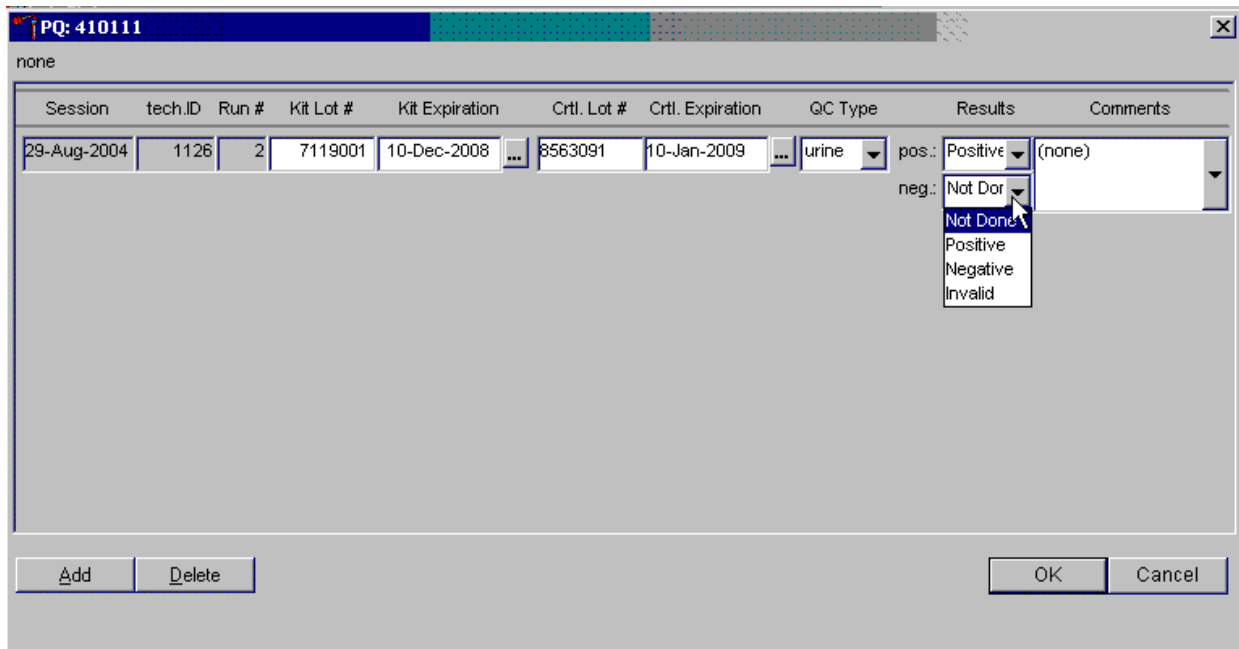
Type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and press the Tab key or use the calendar to enter the date. To access the calendar, direct the mouse arrow to the ellipsis (...) and left-click. To select the correct month, direct the mouse arrow to the drop-down list, drag 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.

Record the positive and negative control results.

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 Done neg.: Not Done	(none)

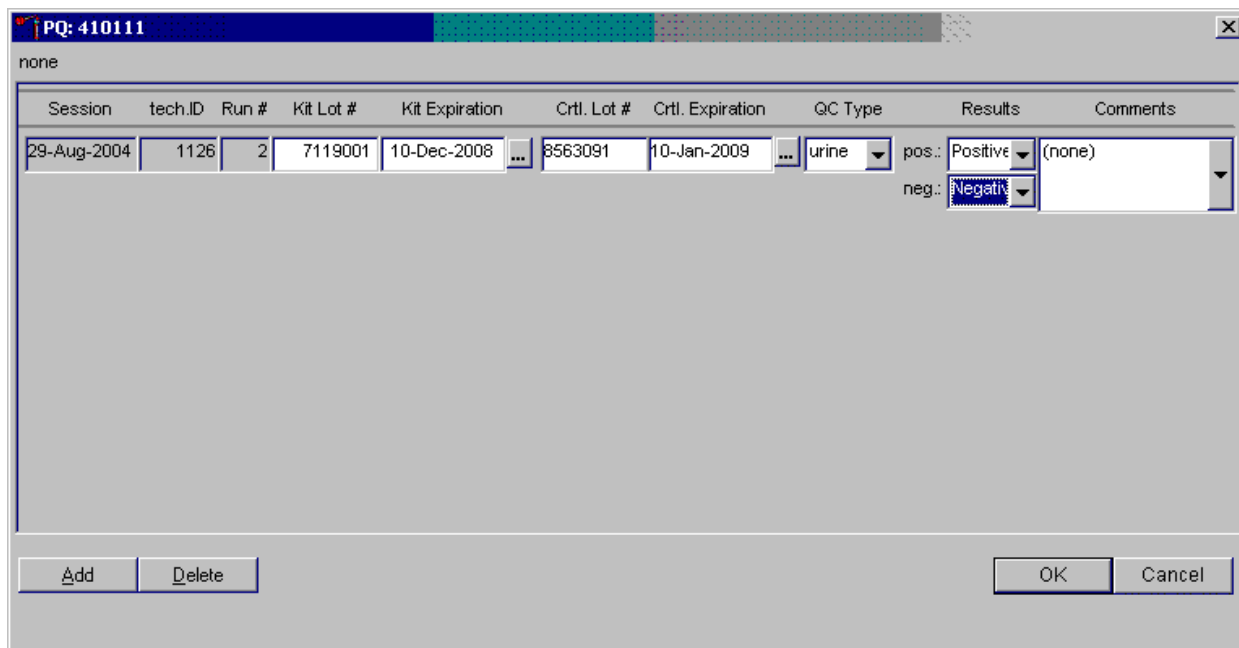
To enter a result in the positive result text box, type [P/p] for Positive, [N/n] for Negative, or [I/i] for Invalid or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid and press the Tab key. Alternatively, direct the mouse arrow to the drop-down list;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

Enter a result in the negative result text box.



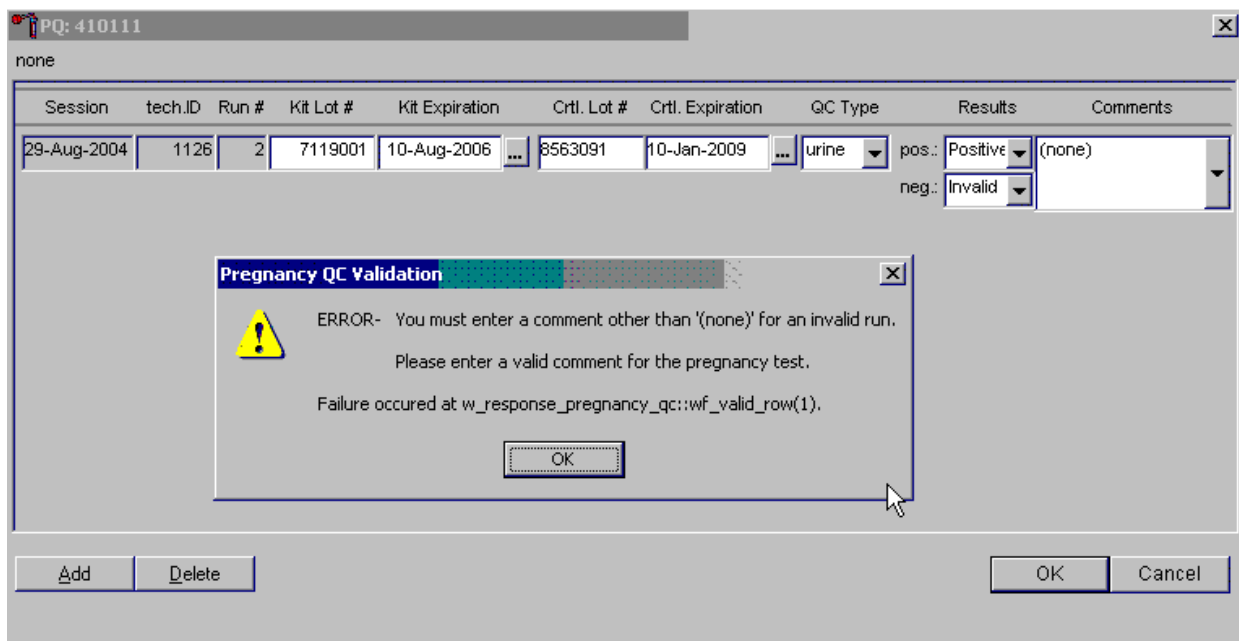
To enter a result in the negative result text box, type [P/p] for Positive, [N/n] for Negative, or [I/i] for Invalid or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid and press the Tab key. Alternatively, direct the mouse arrow to the drop-down list;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

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



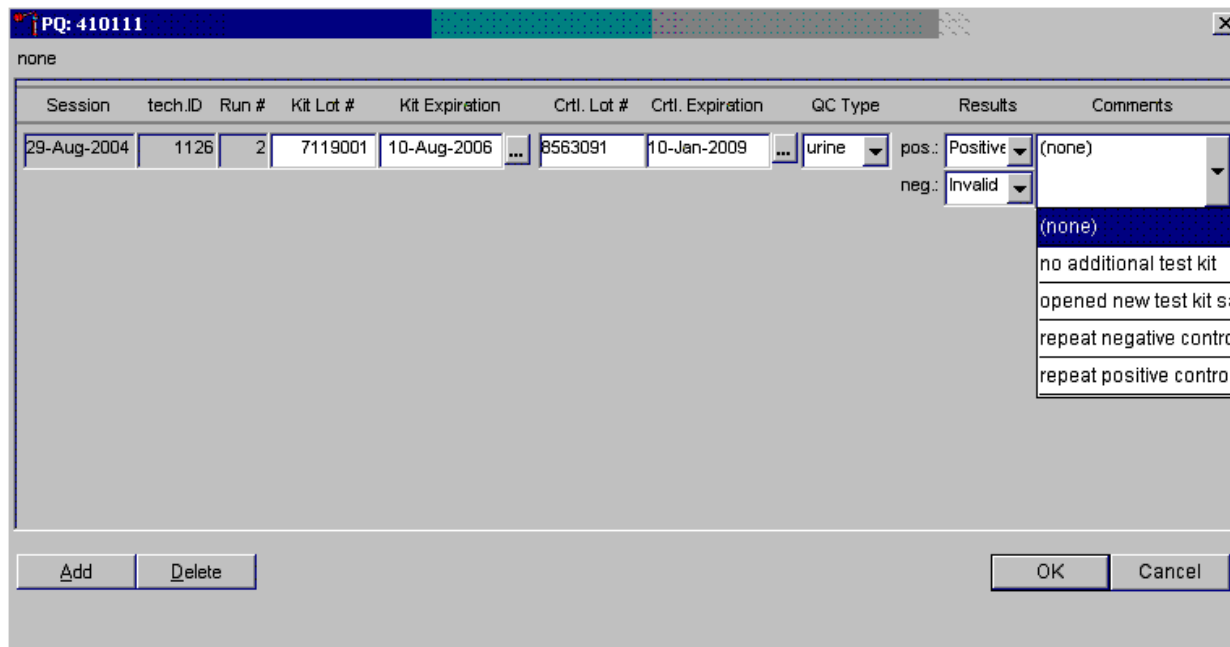
If the positive and negative controls demonstrate the expected result, direct the mouse arrow to the OK button and left-click to save these results and to proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, direct the mouse arrow to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



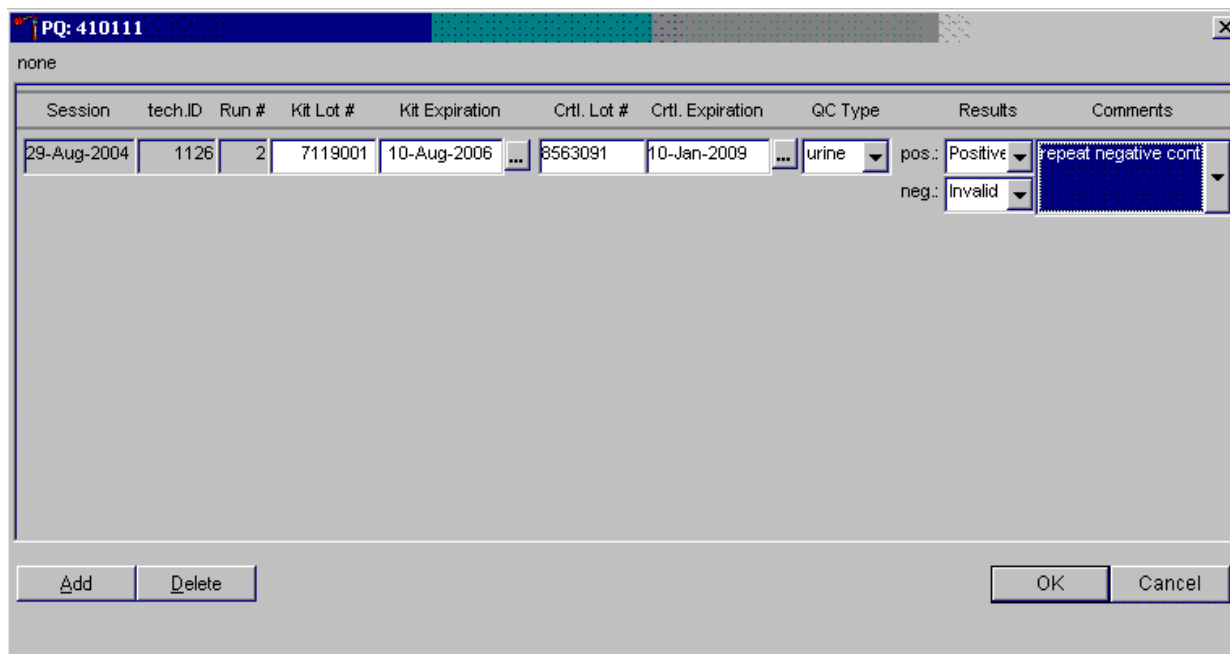
To close the box, direct the mouse arrow to the OK button and left-click or press Enter.

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.



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

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

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 conti
29-Aug-2004	1126	3	7119001	10-Aug-2006	8563091	10-Jan-2009	urine	pos.: Positive neg.: Negative	(none)

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 to proceed with pregnancy testing.

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

Add a new test line each time a control is run during a session.

PQ: 410111

none

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

Add Delete OK Cancel

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

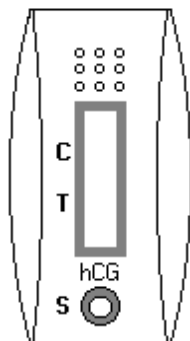
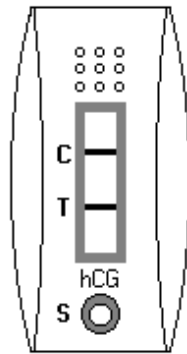
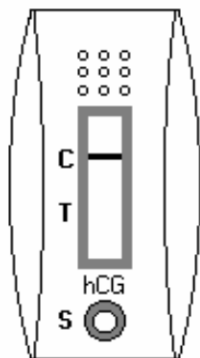


Exhibit 5-2. Positive result



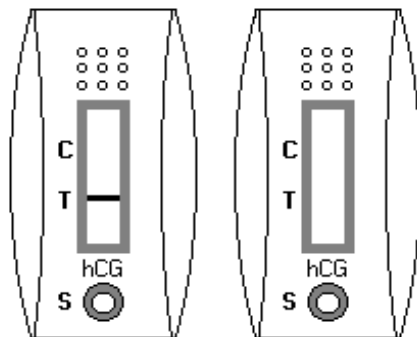
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

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



Control line fails to appear.

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						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, DOU	○	○	○	○	○	-	○	-
416714	416714	SC	P	F	16	JAILEY, ANTHC	○	○	○	○	○	○	○	-
499508	499508	SC	P	F	5	DEEGAN, MAR	○	○	-	○	○	-	-	-
525757	525757	SC	P	M	3	LAST NAME, P	○	○	-	○	○	-	-	-
745052	745052	SC	P	F	12	TIM, SP FIRST	○	○	○	○	○	-	-	-
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	○	○	-	○	○	○	-	○

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.

PT: 410111

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

Save OK Cancel

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).

Report the results for each SP as positive, negative, not done, or invalid.

The screenshot shows a software window titled "PT: 410111". Inside the window is a table with the following columns: SP ID, Person Name, Gender, Age, and Test Results. The table contains two rows of data. The first row is highlighted in black, and the second row is in gray. A dropdown menu is open over the "Test Results" column of the first row, showing options: (none), invalid, negative, not done, and positive.

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

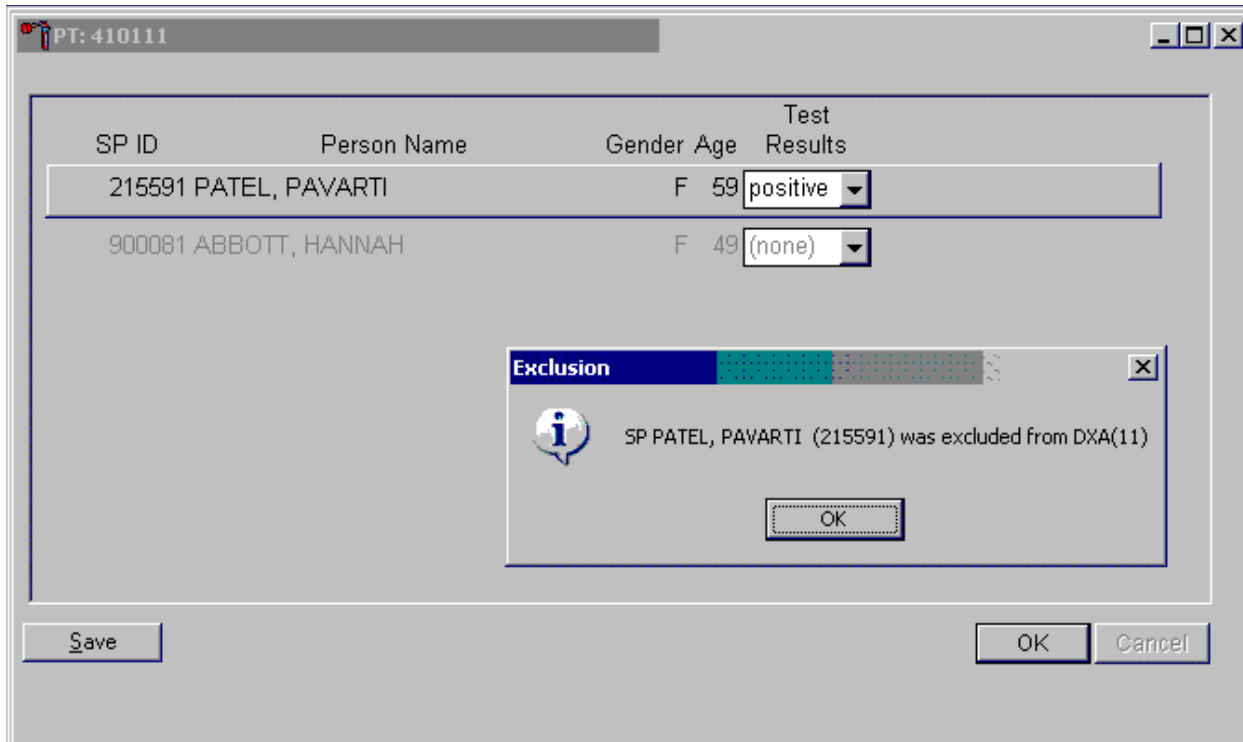
Buttons: Save, OK, Cancel

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 remove 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. While their original pregnancy test was completed and recorded in the database on the first exam day there is no opportunity to permanently record the result of the return visit, the original negative result in the database stands. In these cases, laboratory staff will perform the urine pregnancy test, then send an observation to the MEC physician with the results and will also 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 physician 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 physician 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
Benzoyllecgonine	10
Bilirubin	20
Brompheniramine	20
Caffeine	20
Cannabinol	10
Clomiphene	100
Cocaine	10
Codeine	10
Cholesterol	500
Creatine	20
Dextromethorphan	20
DMSO	5%
EDTA	80
Ephedrine	20
Ethanol	1%
Estriol	2
Estrone 3-sulfate	10
Gentisic acid	20
Glucose	2000
Hemoglobin	1,000
Heroin	1
Ibuprofen	20
Methadone	10
Methamphetamine	10
Methanol	10%
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
Urea	20

Sure-Vue™ 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 References

- Batzer, F. R. (1980). Hormonal evaluation of early pregnancy. *Fertil. Steril.*, 34(1), 1-13.
- Beckman Coulter, Inc. (2010, October). *Product instructions ICON 25 hCG*. Brea, CA: Beckman Coulter, Inc.
- Braunstein, G. D., Rasor, J., Adler, J., and Danzer, H. (1976). ME Wade serum human chorionic gonadotropin levels throughout normal pregnancy. *Am. J. Obstet. Gynecol.*, 126(6), 678-681.
- Braunstein, G. D., Vaitukaitis, J. L., Carbone, P. P., and Ross, G. T. (1973). Ectopic production of human chorionic gonadotropin by neoplasms. *Ann. Intern. Med.*, 78(1), 39-45.
- Catt, K. J., Dafau, M. L., and Vaitukaitis, J. L. (1975). Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte. *J. Clin. Endocrinol. Metab.*, 40(3), 537-540.
- Dawood, M. Y., Saxeba, B. B., and Landersman, R. (1977). Human chorionic gonadotropin and its subunits in hydatiform mole and choriocarcinoma. *Obstet. Gynecol.*, 50(2), 172-181.
- Lenton, E. A., Neal, L. M., and Sulaiman, R. (1982). Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. *Fertil. Steril.*, 37(6), 773-778.
- Steier, J. A., Bergsjø, P., and Myking, O. L. (1984). Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy. *Obstet. Gynecol.*, 64(3), 391-394.

THIS PAGE IS INTENTIONALLY LEFT BLANK.

6. Complete Blood Count

6.1 Introduction

A complete blood count (CBC) 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.

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 systems 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 CoulterDxH 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:

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. • $Hct \text{ (\%)} = RBC \times MCV^{10}$.
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 an 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 provides and monitors electronic power and supplies and monitors 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. 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 a Sani-Cloth™ wiper at the end of each session.

Certain troubleshooting procedures on the Coulter require the use of a 5% – 6% bleach solution. The MEC supply of bleach is an 8.25% solution. To make 20 mL of a 5% – 6% bleach solution using the 8.25% bleach, add 5.5 mL of DiH²O to 14.5 mL of the 8.25% bleach solution.

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

6.5 Computerization: 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 medical technologist.

All data are 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 165 μ L 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 medical technologist working in the blood specimen-processing workstation initially processes the tube by first taking off whole blood required for various tests in the SP's profile. The medical technologist working in the blood specimen-processing workstation places the specimen on a rocker until the medical 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 StabliLyse 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 90 days. 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.
 - Remove Coulter Lin-X cell control vials from 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 mixing procedure three times.
- 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.
 - 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% sodium hypochlorite
- Bottled deionized water
- Plastic squirt bottle
- Cotton gauze pads
- Three-hole paper punch
- Notebook
- Flashlight
- Precision screwdriver set
- 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:

- Log off. Select the Logoff utility  icon, then the Exit Workstation button.
- 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

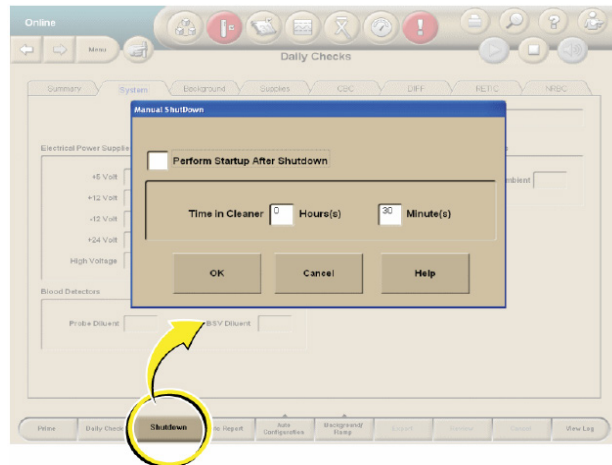
At certain times automatic shutdown will have to be cancelled. To cancel automatic shutdown:

- 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:

- Click on the  icon (person with key).
- Type your user name.
- Type your password. If you forget it, ask one of the senior techs to reset it for you.

6.9.1 Entering New Operator

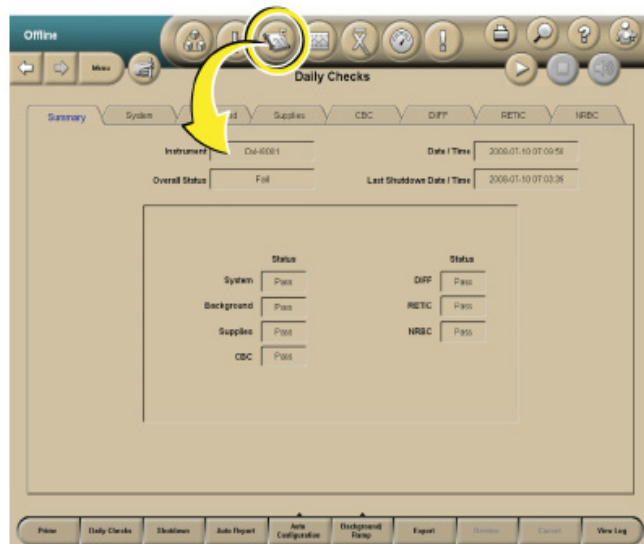
- Select Menu button in the upper left-hand corner of DxH 800 screen.
- Then select **Setup** button.

- Select **Operators & 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 and end of each session. 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. 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 medical technologist 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 medical technologist 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.

- 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 medical technologist 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 Open Date:	Level 1	Run																			
			Initials																			
	Set # 1 Exp. Date:	Level 2	Run																			
			Initials																			
	Level 3	Run																				
		Initials																				
P A C K # 2	Set # 2 Open Date:	Level 1	Run																			
			Initials																			
	Set # 2 Exp. Date:	Level 2	Run																			
			Initials																			
	Level 3	Run																				
		Initials																				
P A C K # 3	Set # 3 Open Date:	Level 1	Run																			
			Initials																			
	Set # 3 Exp. Date:	Level 2	Run																			
			Initials																			
	Level 3	Run																				
		Initials																				
P A C K # 4	Set # 4 Open Date:	Level 1	Run																			
			Initials																			
	Set # 4 Exp. Date:	Level 2	Run																			
			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.

- Procedure for establishing means and standard deviation (SD) requirements:
 - Analyze the 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.
 - 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.
 - The mean and SD measurements should be monitored and updated once sufficient data is collected.
- Changes to means, SDs, or Cal factors should only be made after consultation with the Laboratory Component Lead (Technical Consultant).
- 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 and 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.**

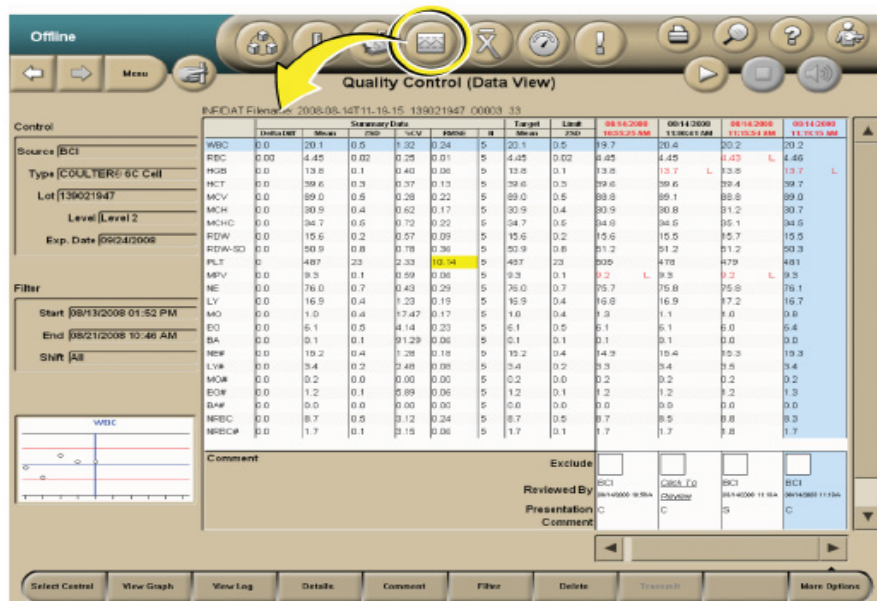
6.11.6 What To Do When a Control Is Out of Range

- 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.
- 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.
- Check the Exclude box on any Latron results that are out of range.

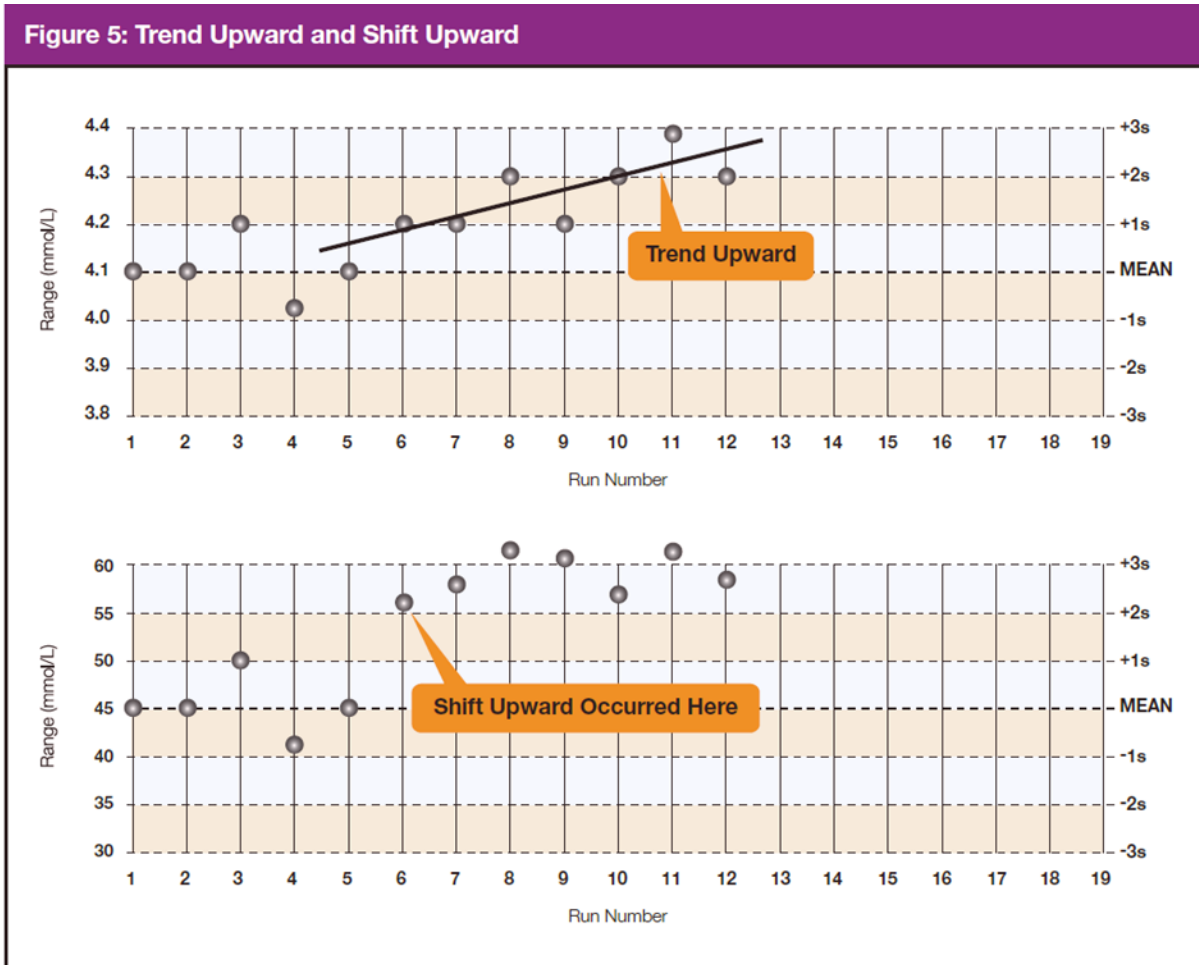
6.11.7 Viewing Control Files – Data View (Menu > QA > QC)

- 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 medical technologists 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.

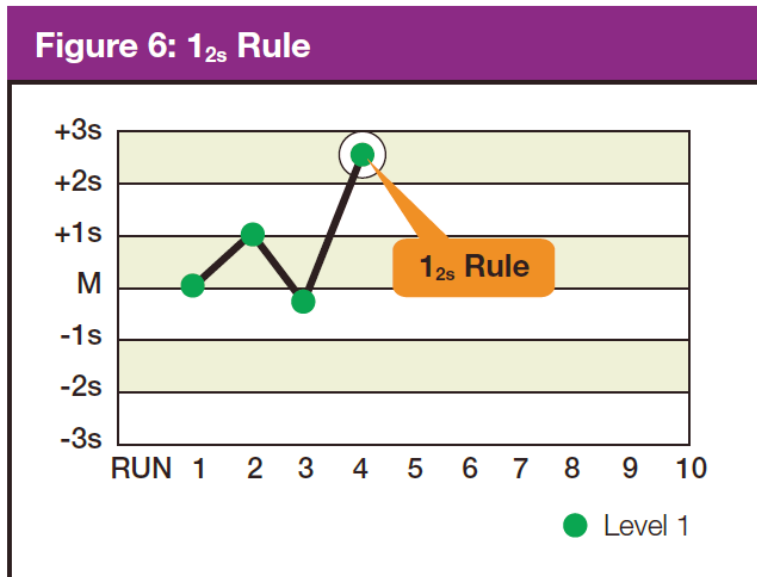


Exhibit 6-5. Westgard Rule 1_{3s}

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.

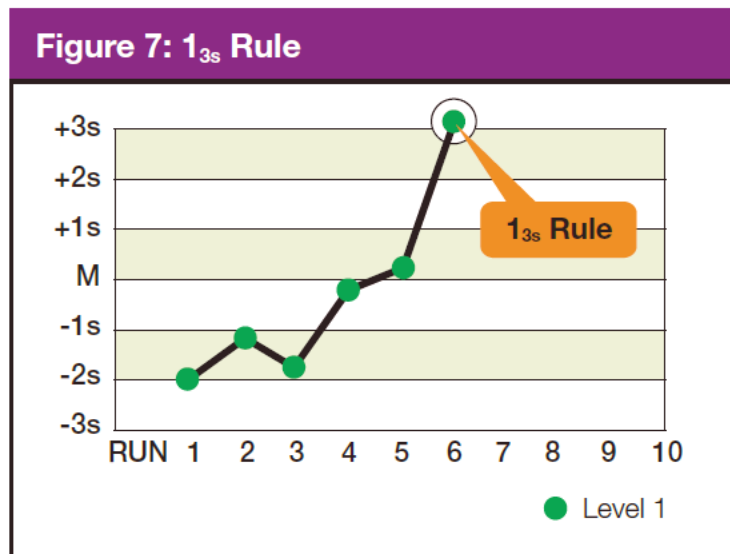


Exhibit 6-6. Westgard Rule 2_{2s}

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 with 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.

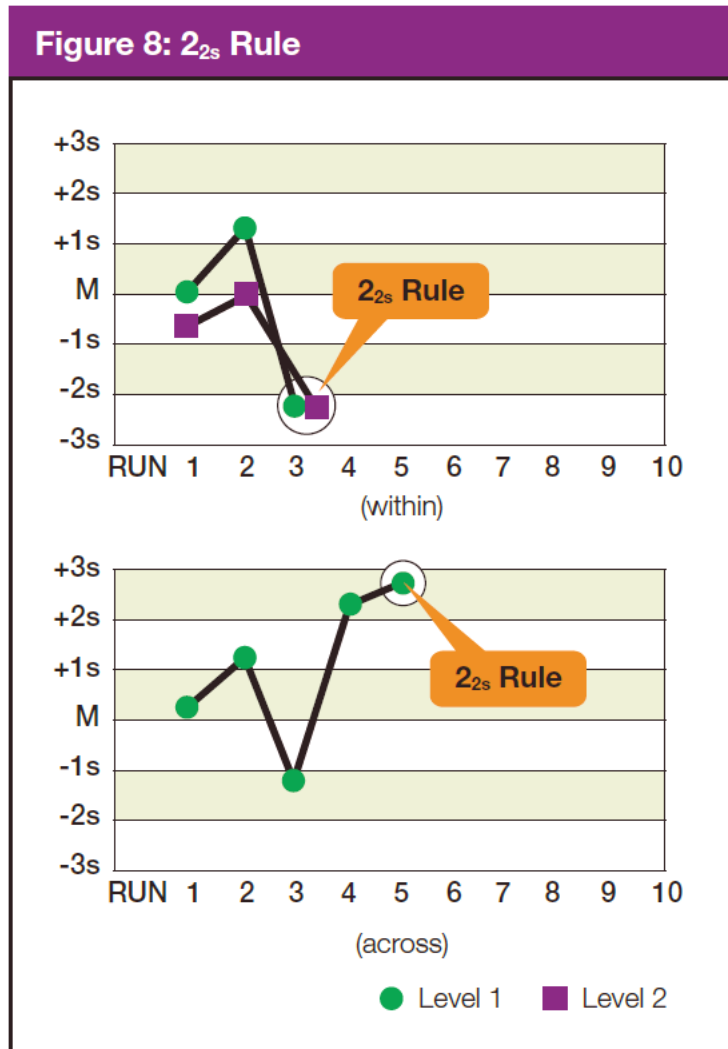
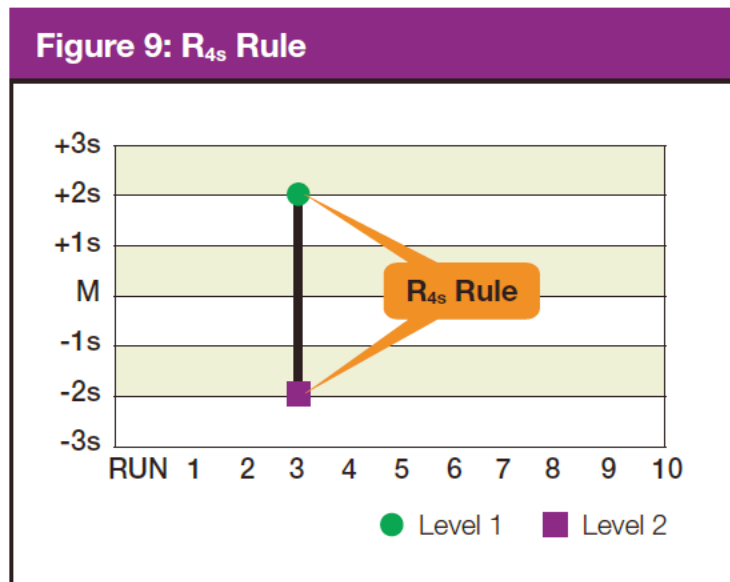


Exhibit 6-7. Westgard Rule_{4s}

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.

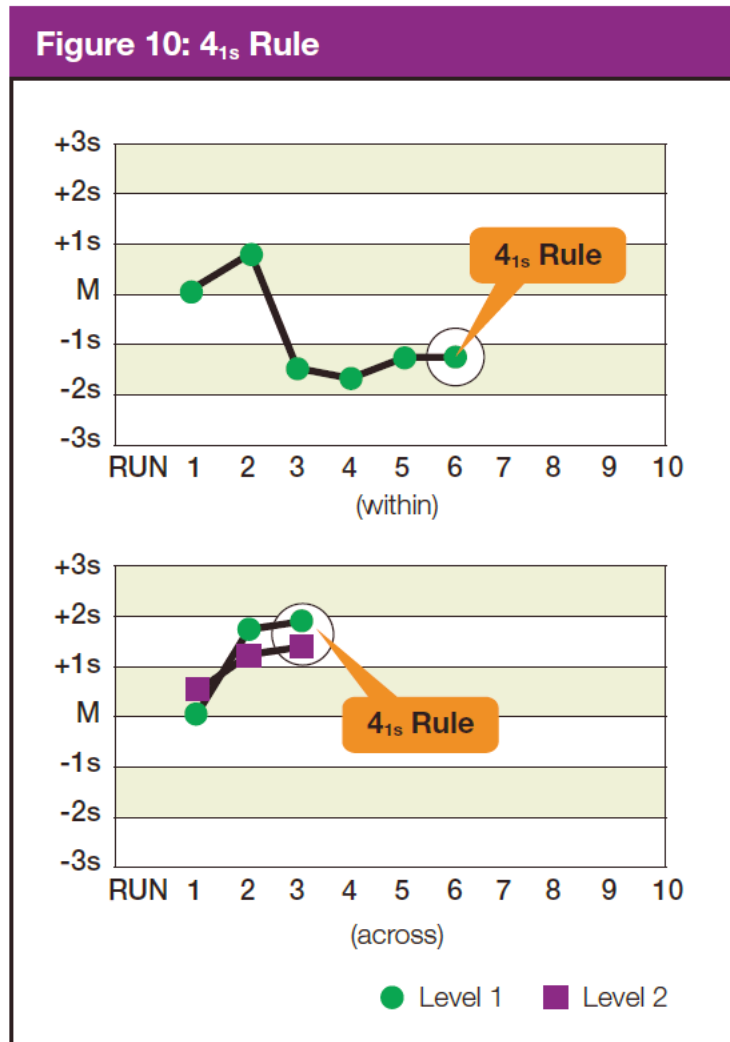



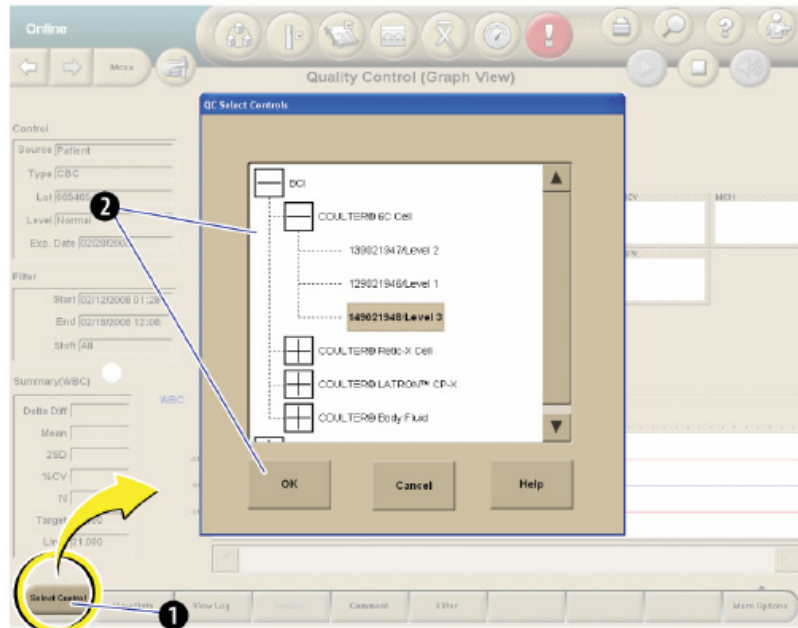
Table 6-2 lists the components seen on the QC Data View screen.

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.
%CV	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 %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. See Figure 4.2. 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, N/A 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 that 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.



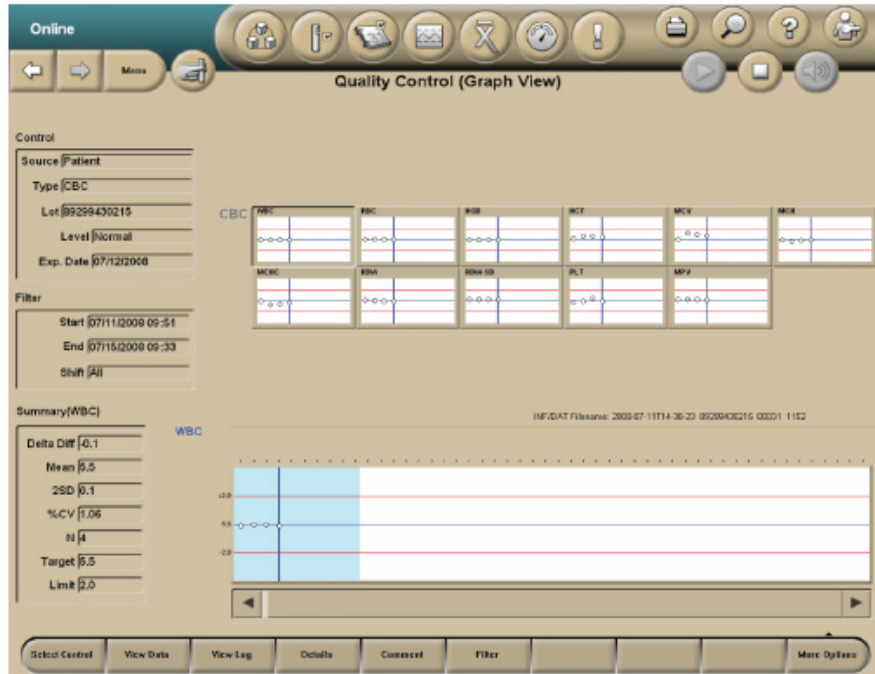
- Highlight the desired control and select OK.
- Exclude and rerun any control that is out of range. Document action taken to correct QC under comments on the Coulter screen in the affected control.

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-clicking 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.



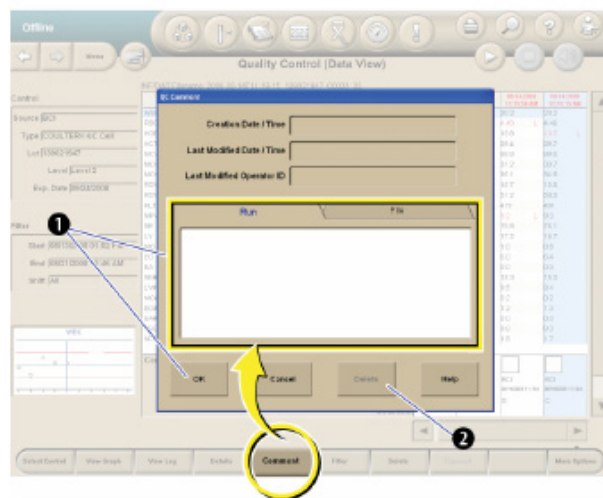
6.11.10 Using and Interpreting the Levey-Jennings Graphs

- 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.

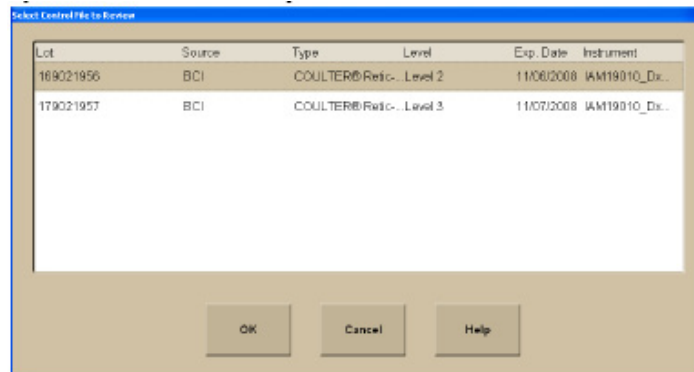


- The Creation Date/Time, Modified Date/Time, and Last Modified Operator ID will not be populated until the entry of the comment has been completed.
- To add or modify a comment on a control run, select the Run tab, type in the text box, and select OK.

- 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.

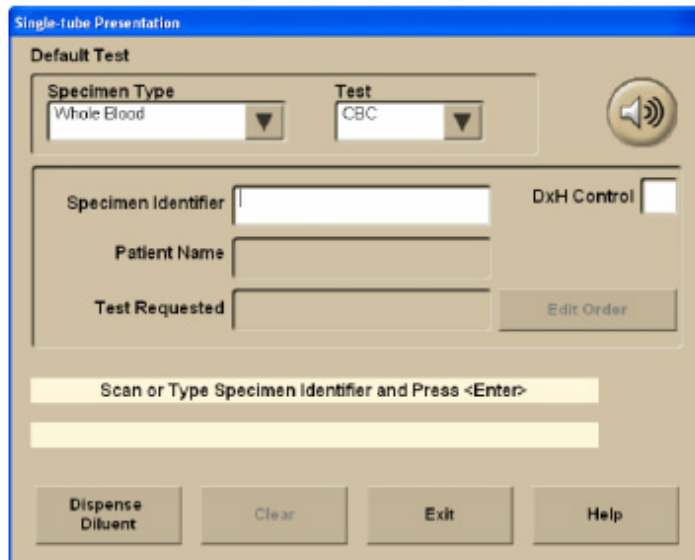


6.12.2 Cassette Presentation

- Ensure that the SPM is set up for the appropriate test for your workflow.
- Ensure that your 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.
- Select the Single-tube Presentation icon  at the top of any screen to display the Single-tube Presentation dialog box.



The image shows a software dialog box titled "Single-tube Presentation". It has a blue title bar and a tan background. At the top, under "Default Test", there are two dropdown menus: "Specimen Type" (set to "Whole Blood") and "Test" (set to "CBC"). To the right of these is a speaker icon. Below this is a section for specimen identification with three text input fields: "Specimen Identifier", "Patient Name", and "Test Requested". To the right of the "Specimen Identifier" field is a "DxH Control" checkbox. An "Edit Order" button is located to the right of the "Test Requested" field. Below the input fields is a yellow bar with the text "Scan or Type Specimen Identifier and Press <Enter>". At the bottom of the dialog are four buttons: "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.

xxxxxx	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, xxxxxx 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 (appear in blue) appear 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 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 (16–25°C, 60–77°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 medical technologist 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 medical technologist'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 into the DxH SM

BEFORE DELETING THE PREVIOUS STAND’S DATABASE OR CONTROL FILES, VERIFY WITH THE CHIEF TECHNOLOGIST 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-hand 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.

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
 - 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 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-hand 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
 - 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. Please see *Chapter 1: System Overview – Performance Specifications and Characteristics* section in the Help Menu 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 which states: Existing Data will be deleted. Select OK to continue.
 - Number of Aspirations: 11
 - Presentation: Cassette
 - 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 checkmarked) > 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. Please see the section in Chapter 1 about the Help Menu for additional information regarding calibration limits for acceptability.

- 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.

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 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 Participants

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 now 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. 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 & 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

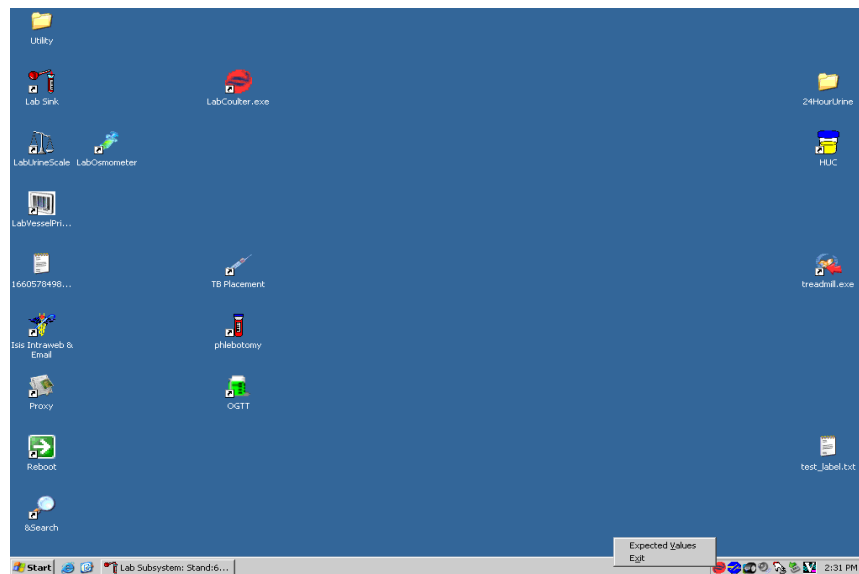
Parameter	Linearity	Limits: The greater of
WBC x 10 ³ cells/ μ l	0 to 99.9	0.2 or 3.0%
RBC x 10 ⁶ cells/ μ l	0 to 7.00	0.05 or 2.0%
Hgb g/d	0 to 25.0	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10 ³ cells/ μ l	0 to 999	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

6.18 Integrated Survey Information System

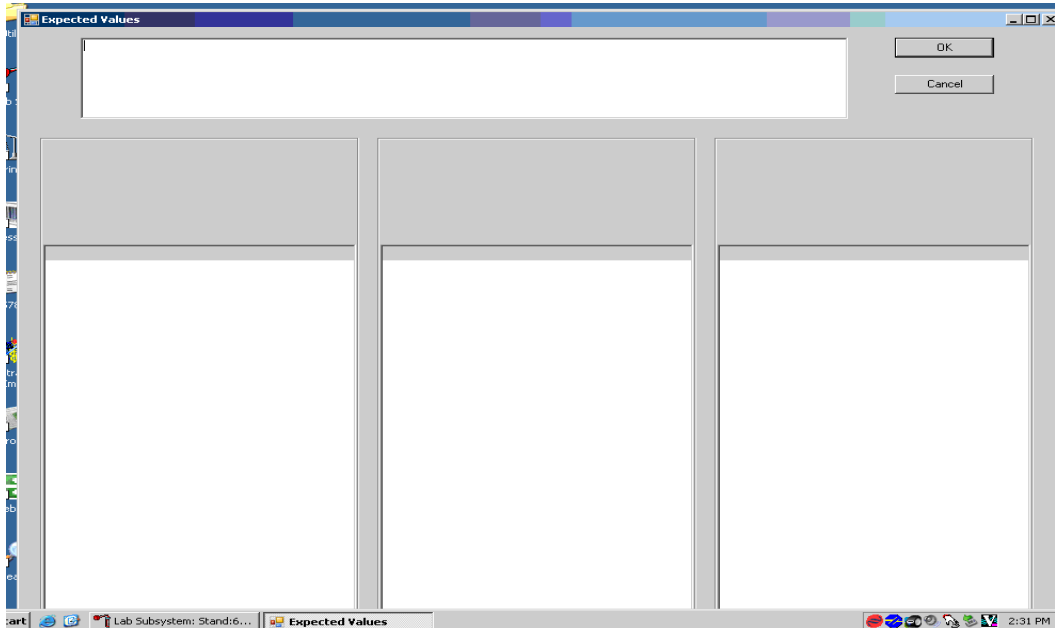
6.18.1 Record 6C Cell and Latron Lot Numbers in Integrated Survey Information System

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.

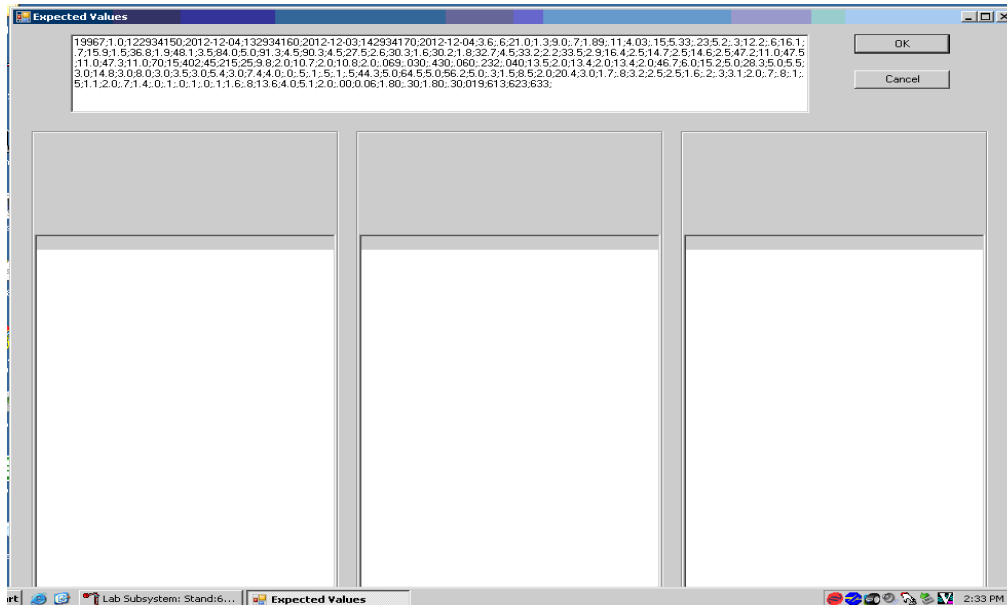
- Access the Coulter QC Lot Info module.
- Right-click on Coulter icon in the bottom right corner of window.



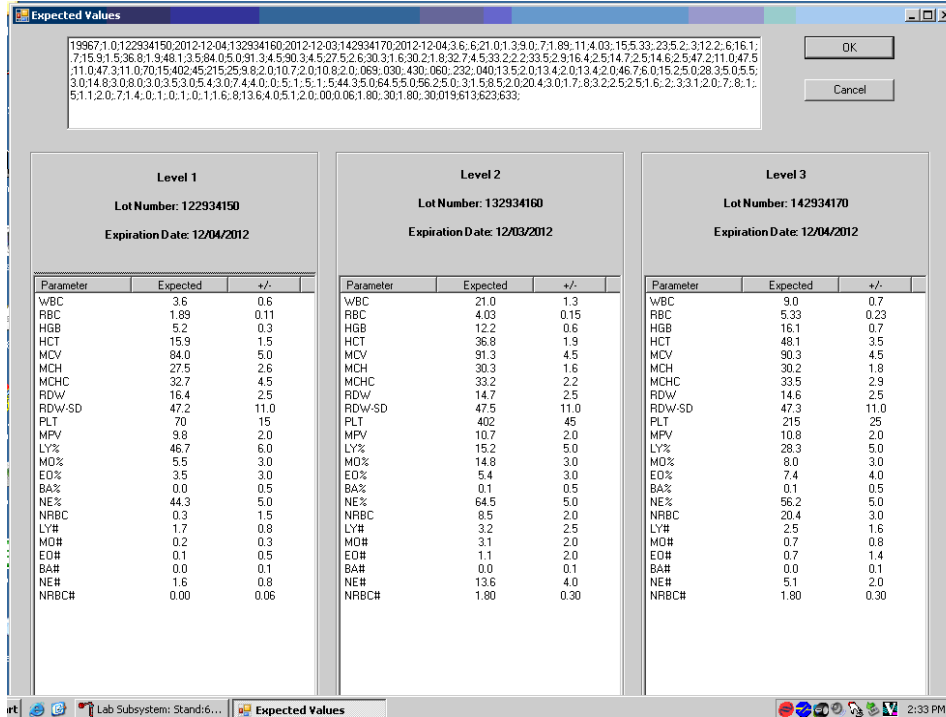
- Click on Expected Values to bring up the Coulter QC Input Screen for 6C cell controls and Latron QC.



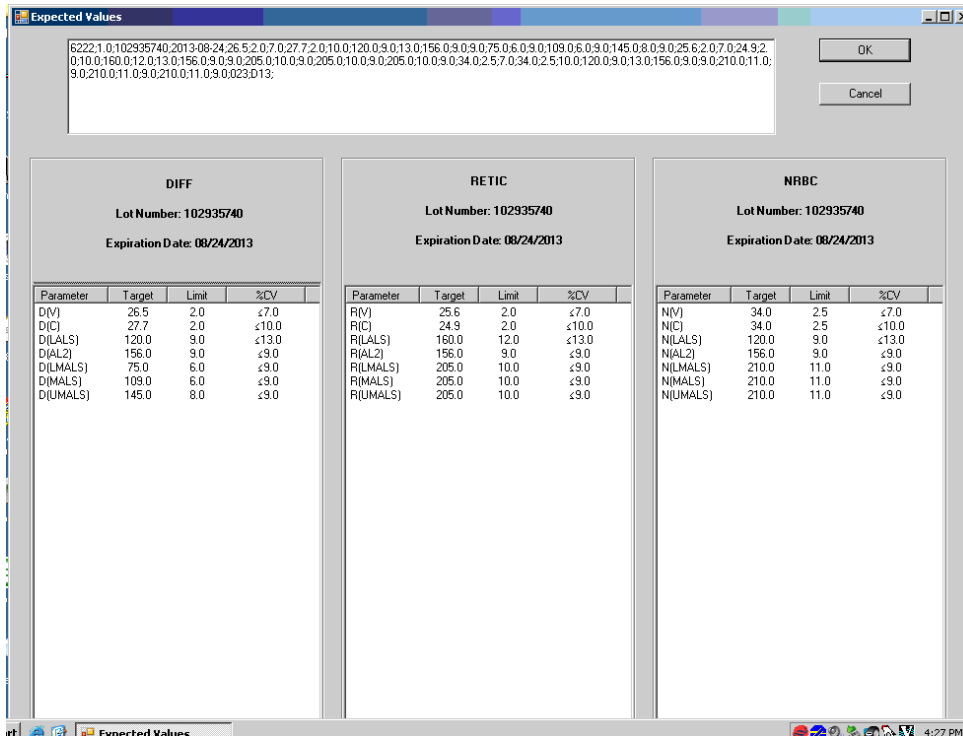
- Make sure cursor is in the top window, scan the barcode on the Coulter package insert, and wait until data fill in the top window.



- 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 logbook, and send results to CAP.

After the assigned primary medical technologist has tested and recorded results, other medical technologists are to perform the testing and record their results without consultation with the primary tech. The secondary techs' 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
 - 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 and printing samples.

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 into 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 logbook to forward to Lab 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.

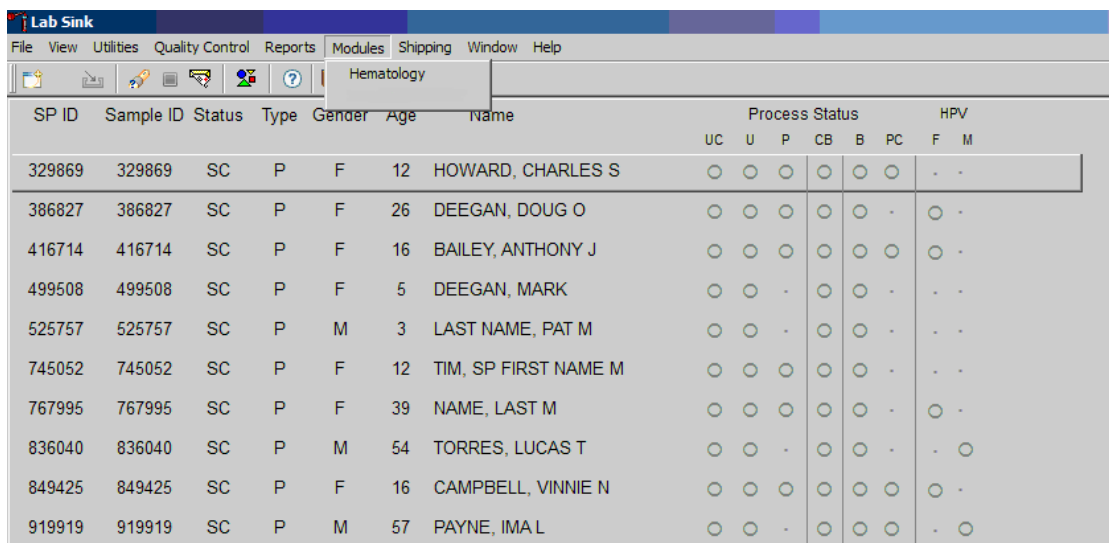
The Hematology module does not need to be open before running SP samples on the DxH 800. Note the red icon in the lower right corner of the system tray.



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.

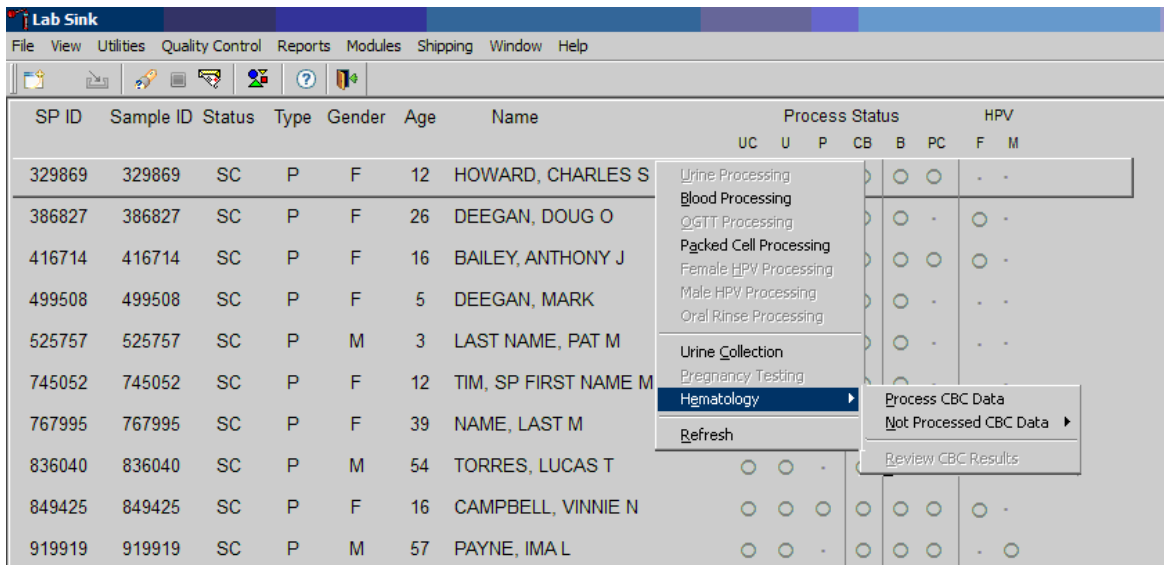


Open the Hematology module: direct the mouse arrow to Modules, in the top menu bar, left-click, drag the mouse arrow to Hematology, and right-click.



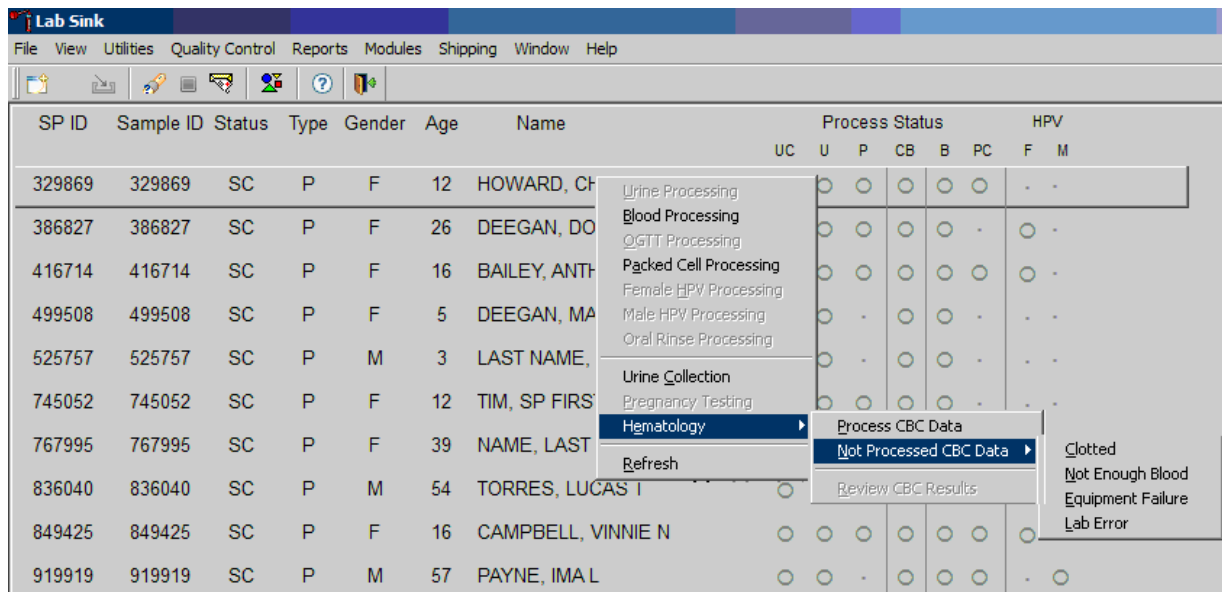
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status			HPV			
							UC	U	P	CB	B	PC	F
329869	329869	SC	P	F	12	HOWARD, CHARLES S	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
386827	386827	SC	P	F	26	DEEGAN, DOUG O	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
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"/>	-
499508	499508	SC	P	F	5	DEEGAN, MARK	<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"/>	-	-
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"/>	-	-
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"/>	-
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"/>
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"/>	-
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"/>

Alternatively, open the Hematology module from the heads-up display.



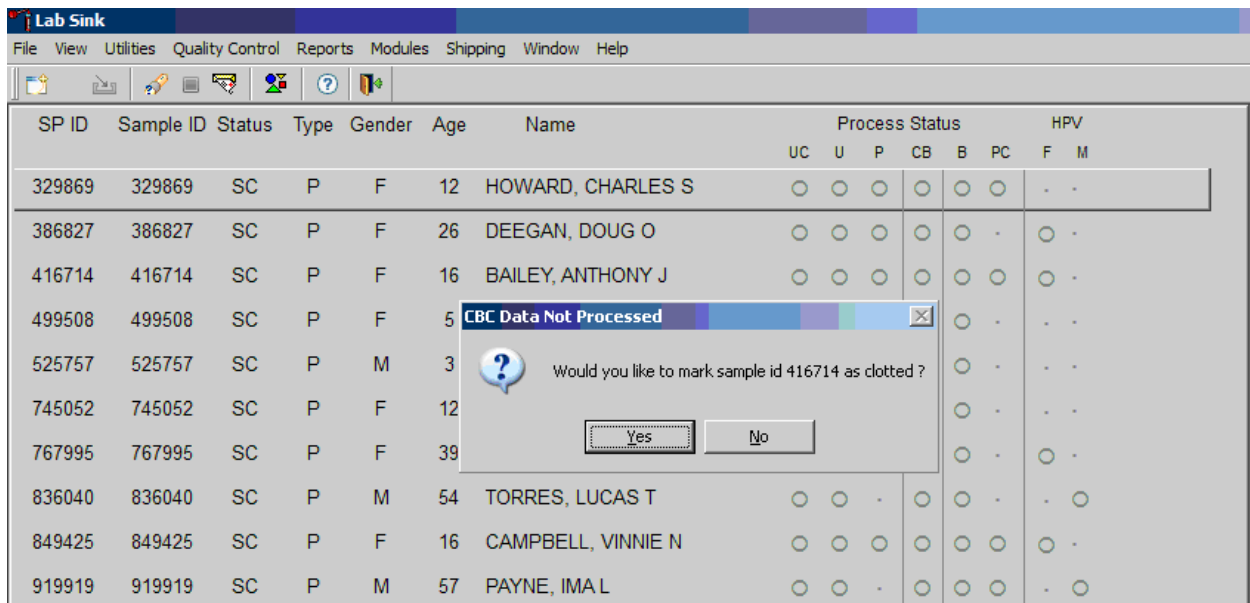
To access the Hematology module, direct the mouse arrow to any SP, right-click, drag the mouse arrow to Hematology, then to Process CBC Data, and right-click. Alternatively, use the arrow keys to move up and down the list until a particular SP is highlighted, right-click, drag the mouse arrow to Hematology 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 a reason 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 a reason 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.

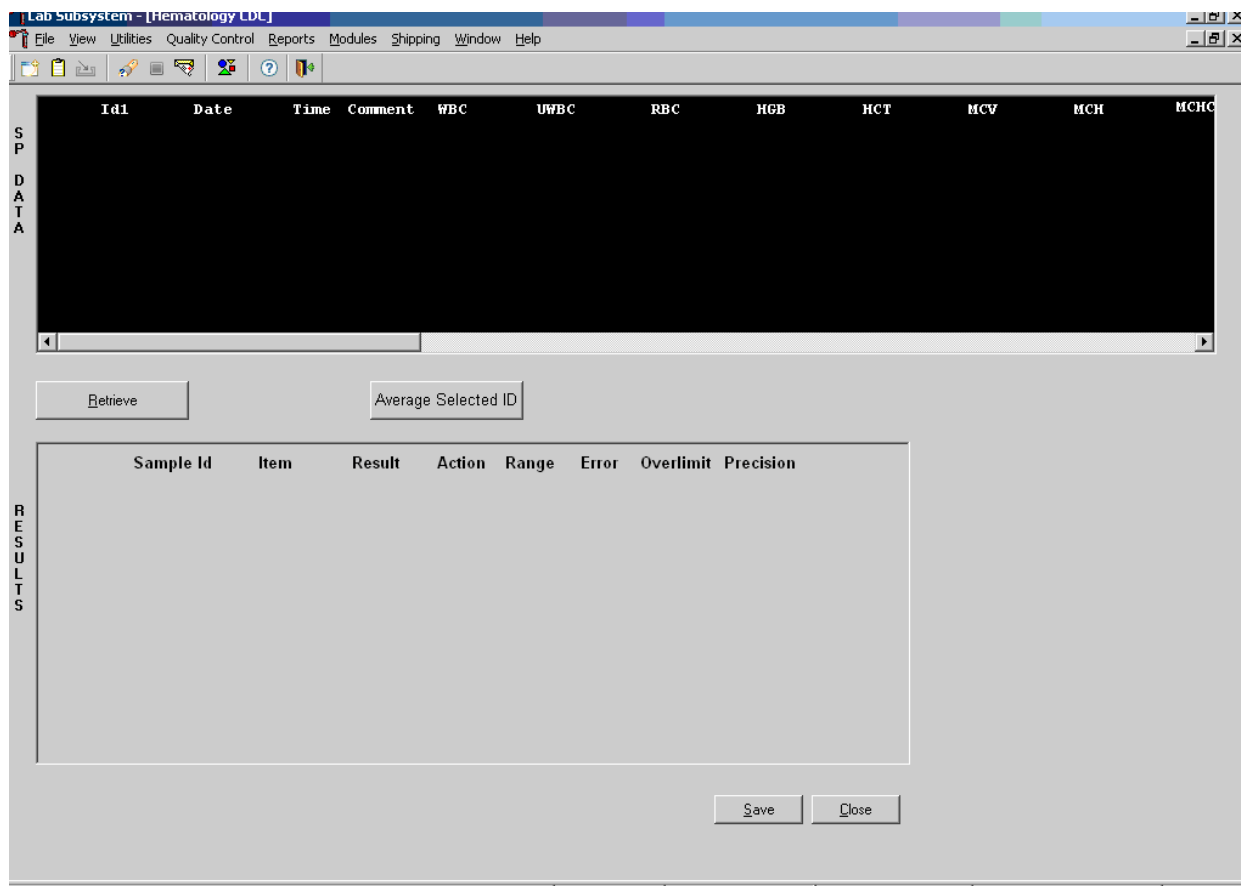


A CBC Data Not Processed message text box displays that asks, “Would you like to mark sample ID XXXXXX as Clotted/Not Enough Blood/Equipment Failure/Lab Error?” To record a “Yes” response, direct the mouse arrow to the Yes button and left-click, type [Y], or press Enter. To record a “No” response, direct 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

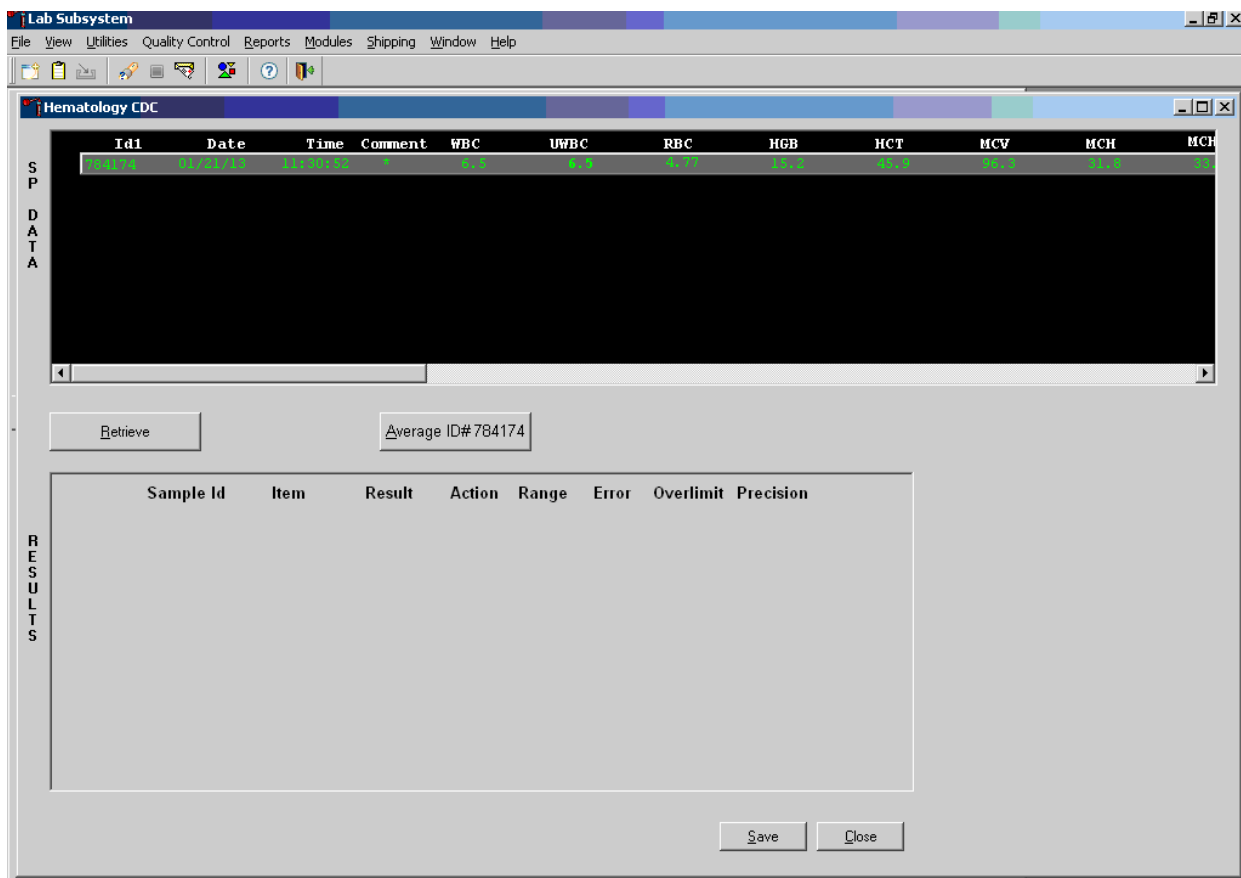
The CBC results are not automatically populated in the Hematology module. Use the Retrieve button to send the results from ISIS to the Hematology module. Select “Retrieve” after each run.

Make sure the Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



After data are retrieved, they display 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.



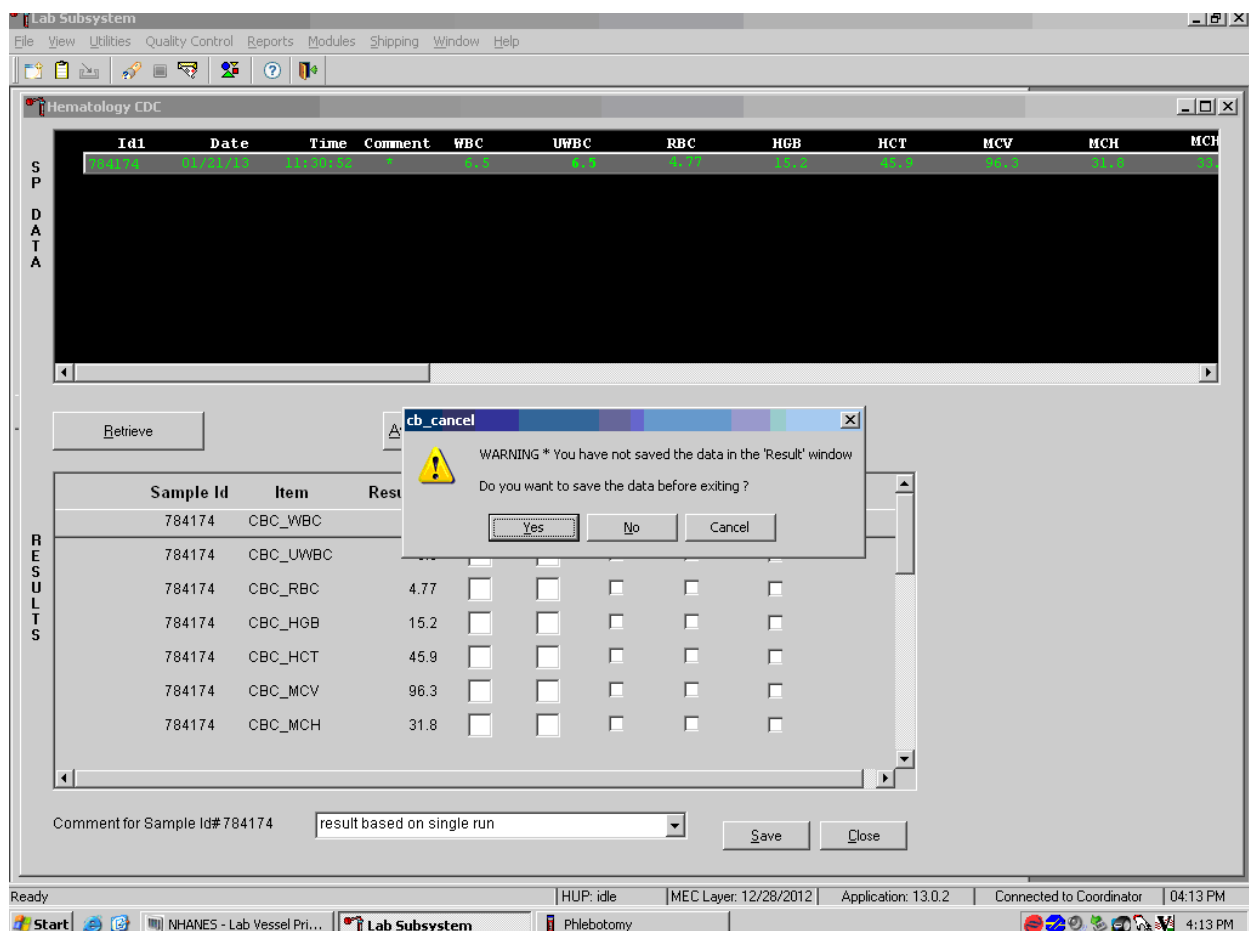
To view SP data for all parameters, direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, direct the mouse arrow to the small scroll arrows on the left and right edges 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.

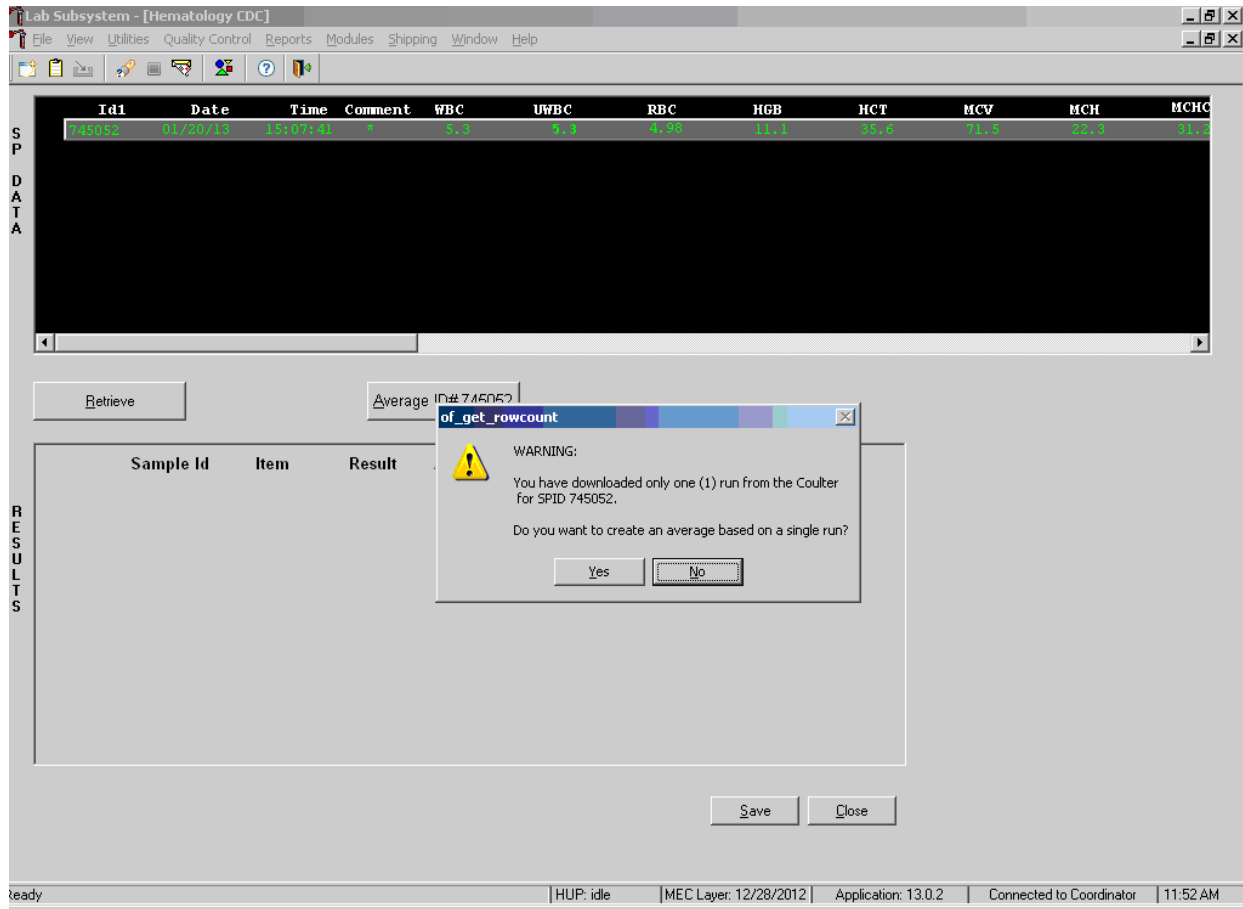


If the Close button is selected before the results are saved to the database, a warning message text box displays that states, “WARNING * You have not saved the data in the ‘Result’ window” and asks, “Do you want to save the data before exiting?” To record a “Yes” response, direct the mouse arrow to 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.



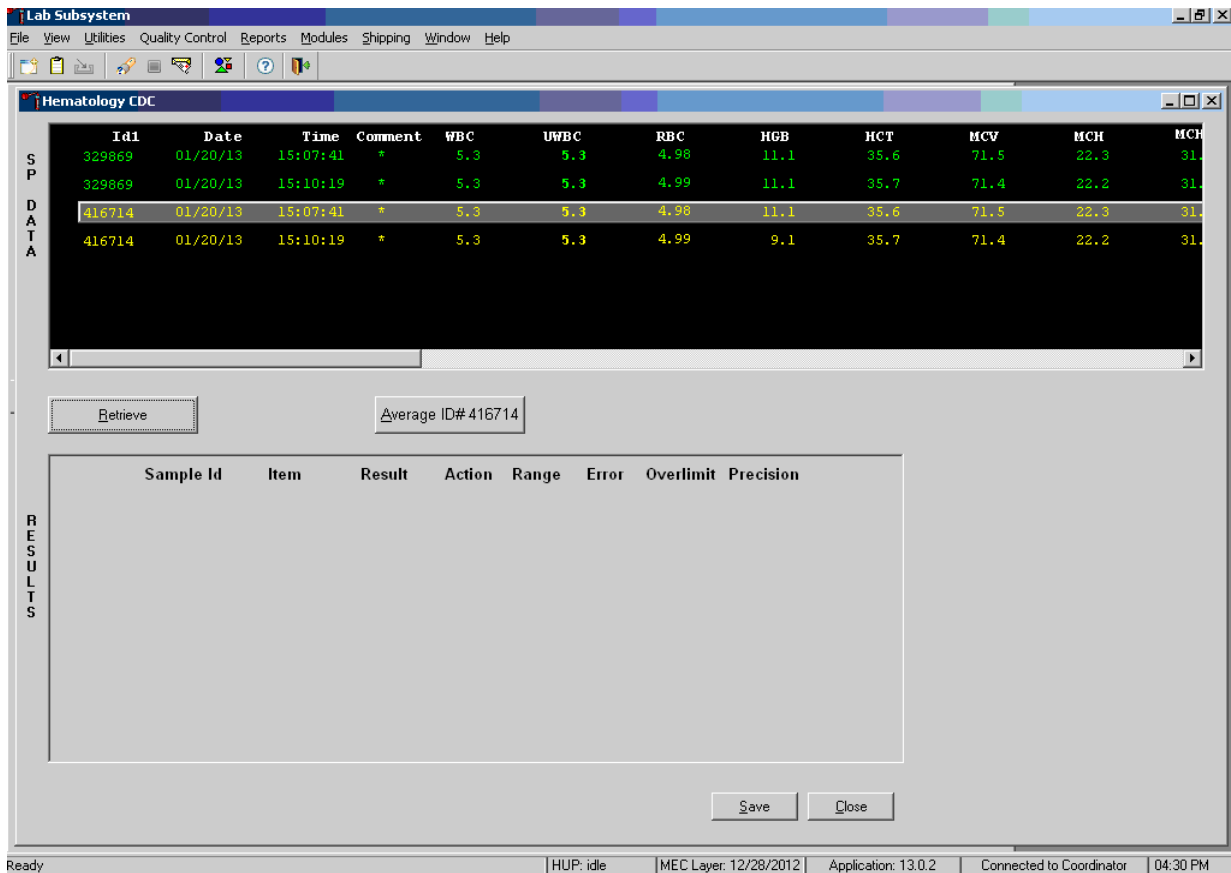
Run samples in duplicate whenever possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, direct the mouse arrow to the Average Selected ID box and left-click. A warning message text box displays that states, “You 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.”

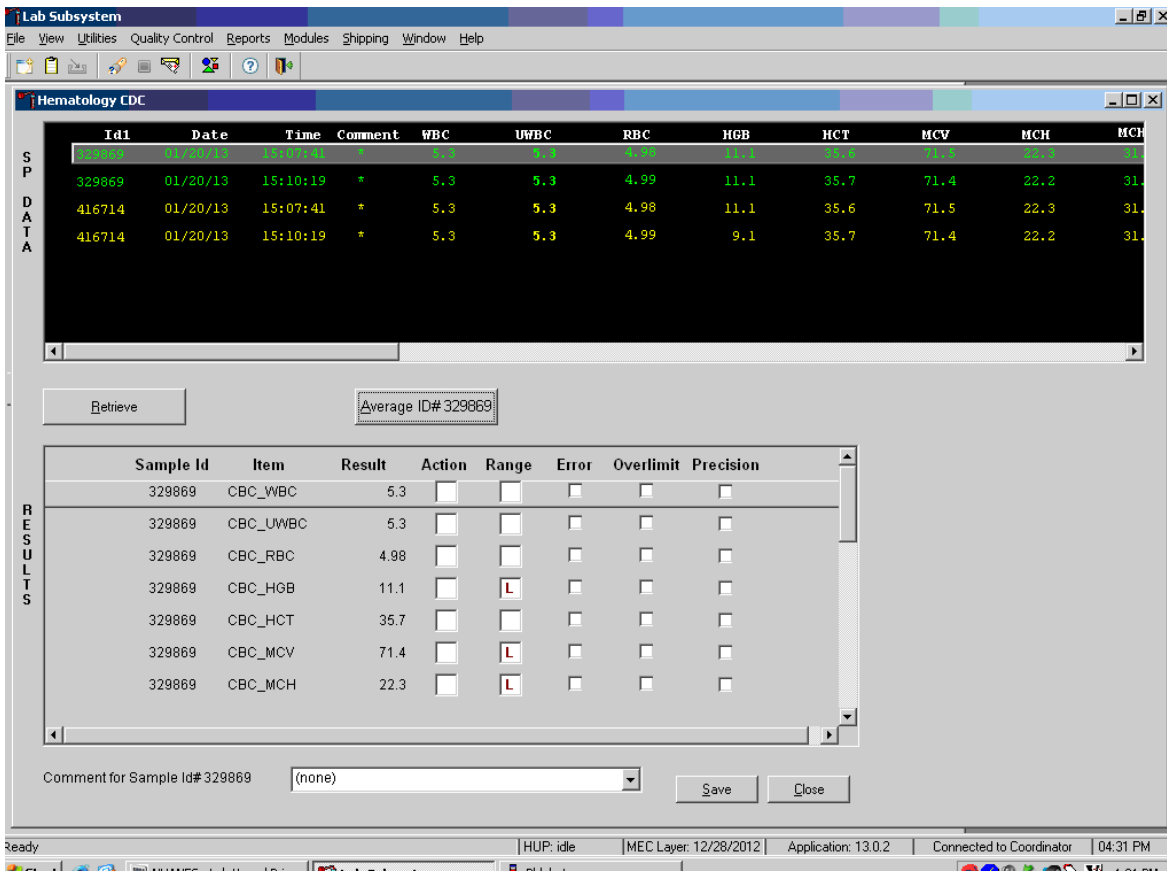
4. Running samples in duplicate

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.



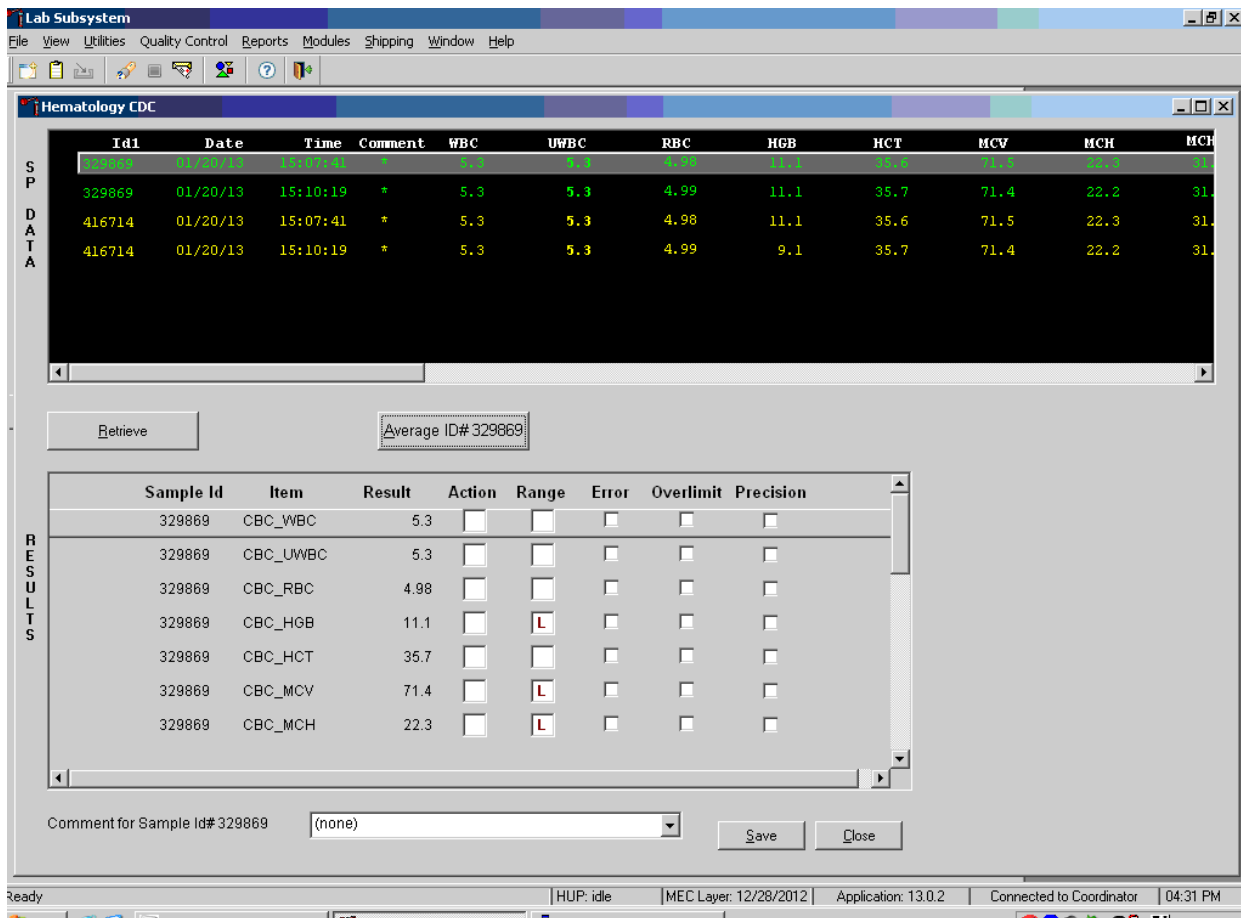
The differences between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if they are within the following CDC established precision limits (Table 6-4).

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#	$\pm 0.2 \times 10^3$

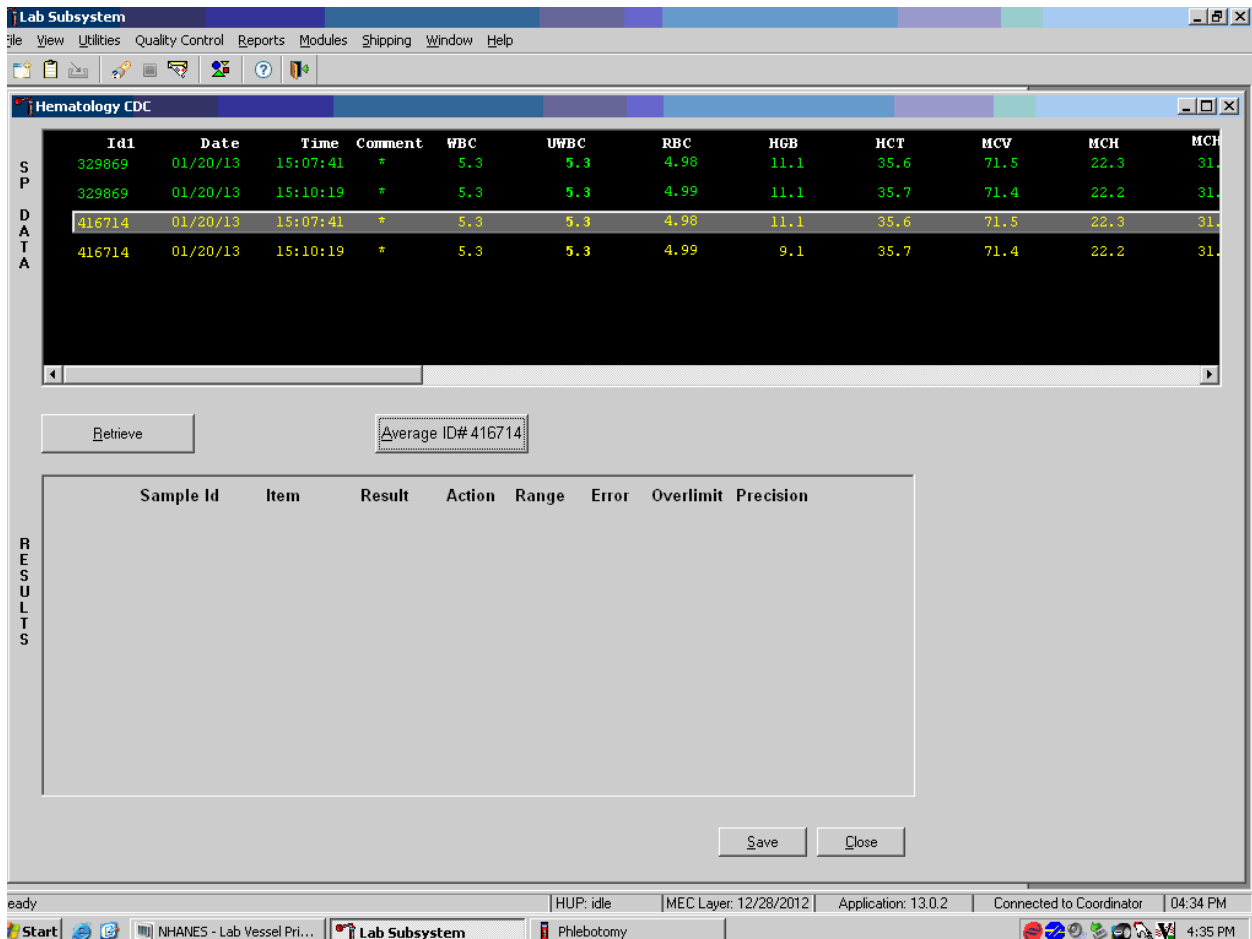
If RBC parameters are out of range, evaluate the data for drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range,

check the WBC scattergram for abnormal cell population(s). Evaluate and save results when precision limits are not exceeded.



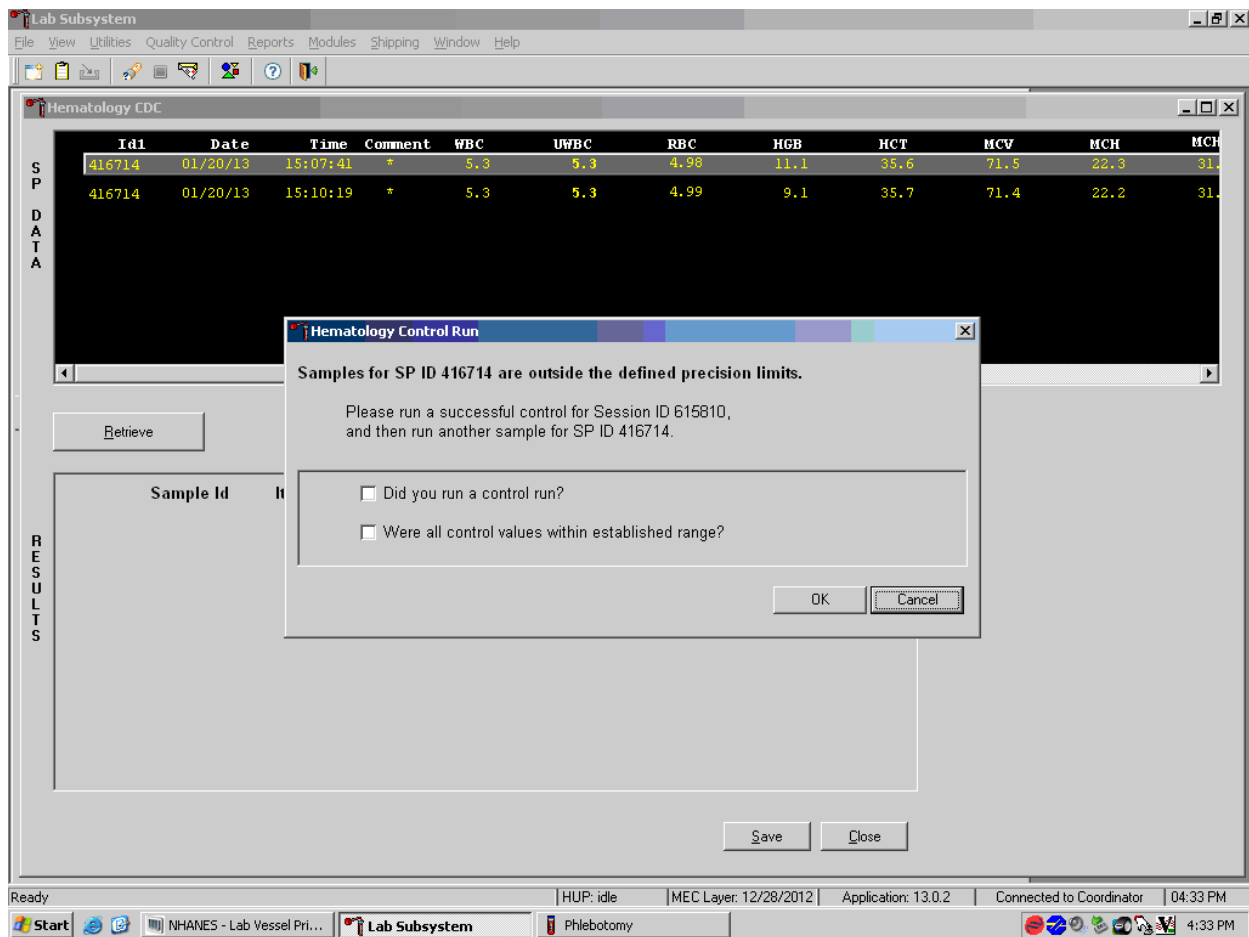
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and “H” or “L” action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results 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.



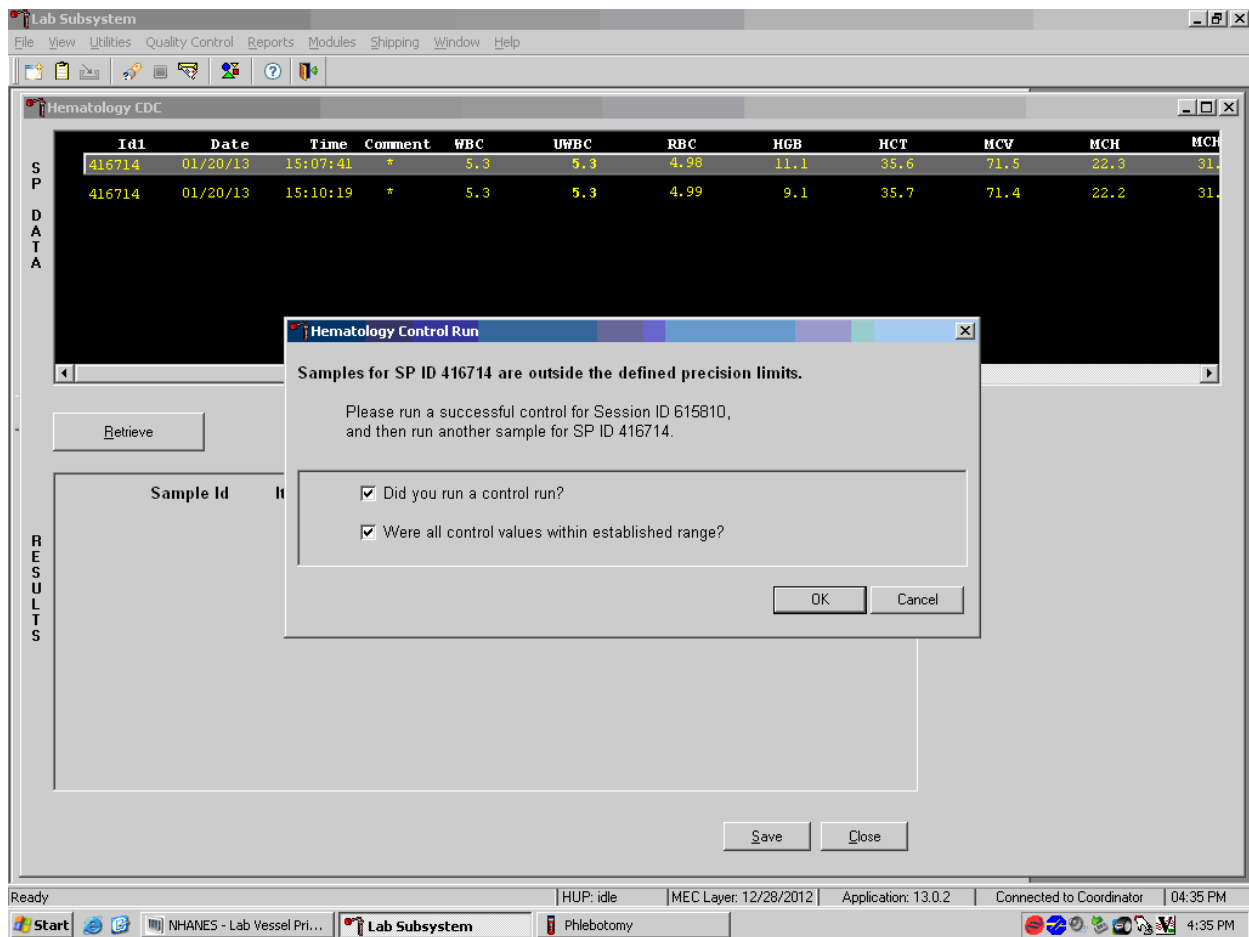
Average the two results by using the mouse to direct the mouse arrow to the Average ID#XXXXXX button and left-click. If, at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and to evaluate it to determine if all control values fall 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.

The screenshot displays the Lab Subsystem Hematology CDC interface. The top window shows a list of samples with columns: Id1, Date, Time, Comment, WBC, UWBC, RBC, HGB, HCT, MCV, MCH, and MCHC. Below this is a 'Retrieve' button and a text field for 'Average ID# 416714'. The 'RESULTS' window shows a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The table contains data for sample 416714 across various CBC parameters. At the bottom, there is a 'Comment for Sample Id# 416714' dropdown menu set to '(none)', and 'Save' and 'Close' buttons.

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
416714	CBC_WBC	5.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
416714	CBC_UWBC	5.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
416714	CBC_RBC	4.98	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
416714	CBC_HGB	10.1	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
416714	CBC_HCT	35.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
416714	CBC_MCV	71.4	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
416714	CBC_MCH	22.3	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Evaluate each parameter for error, overlimit, and precision checkmarks, and “H” or “L” action limit, 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 with 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 multiple samples. The 'RESULTS' section shows a table with columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision.

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

Buttons: Retrieve, 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

S
P
D
A
T
A

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	12/28/12	02:04:06	*	4.5	5.0	3.96	13.0	37.6	95.1	32.8

Clear This Run
Clear ID# 748968
Clear All Downloads
View Log For ID# 748968

Retrieve Average ID# 748968

R
E
S
U
L
T
S

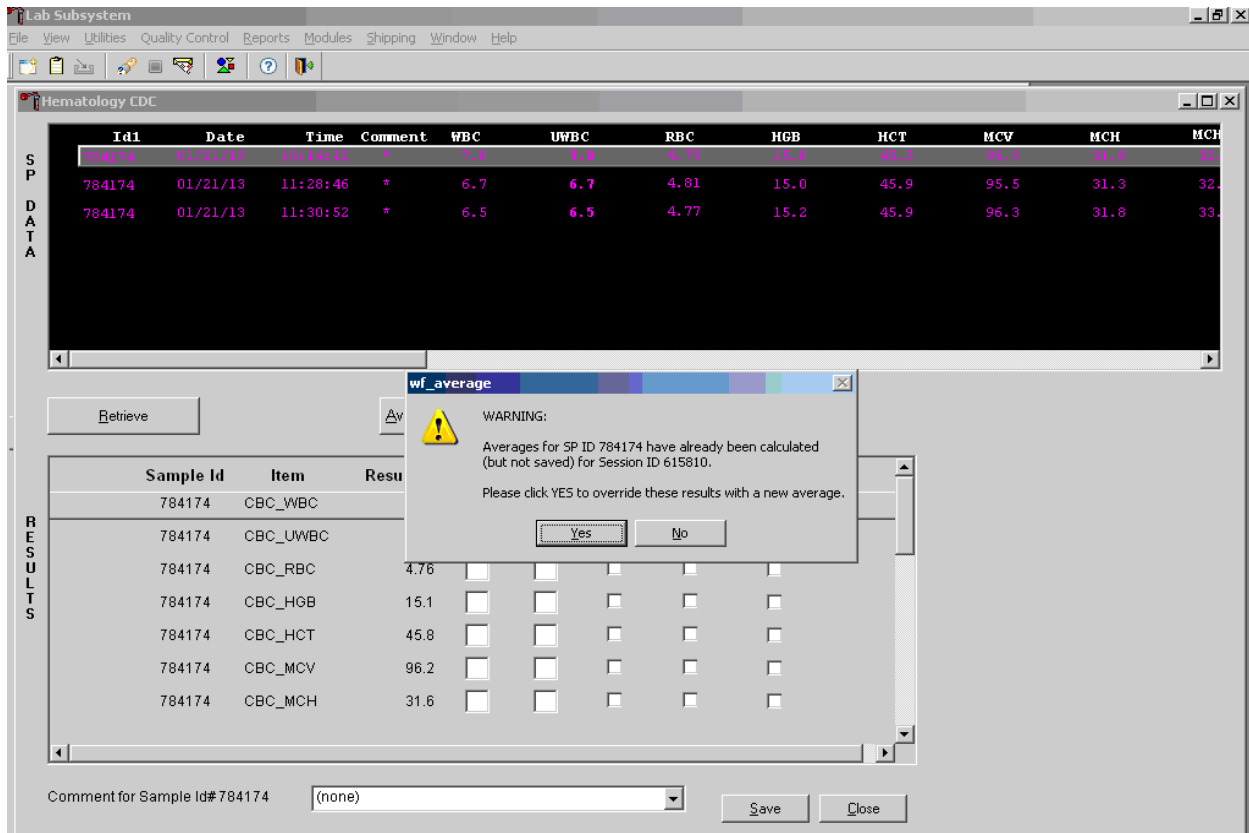
Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
-----------	------	--------	--------	-------	-------	-----------	-----------

Save Close

ready | HUP: idle | MEC Layer: 12/28/2012 | Application: 13.0.0 | Not connected to Coordinator | 02:04 PM

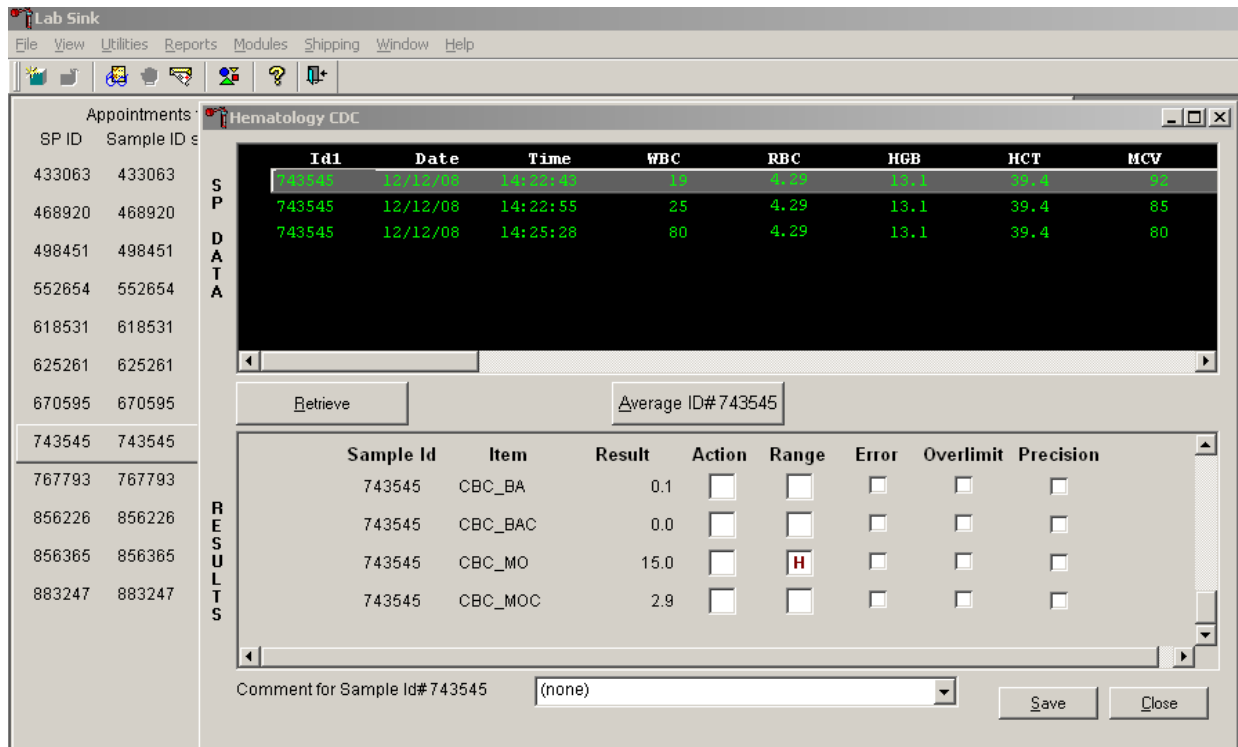
After clearing the outlier runs, re-average the two remaining runs and analyze the results.

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

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

Retrieve

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

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"/>

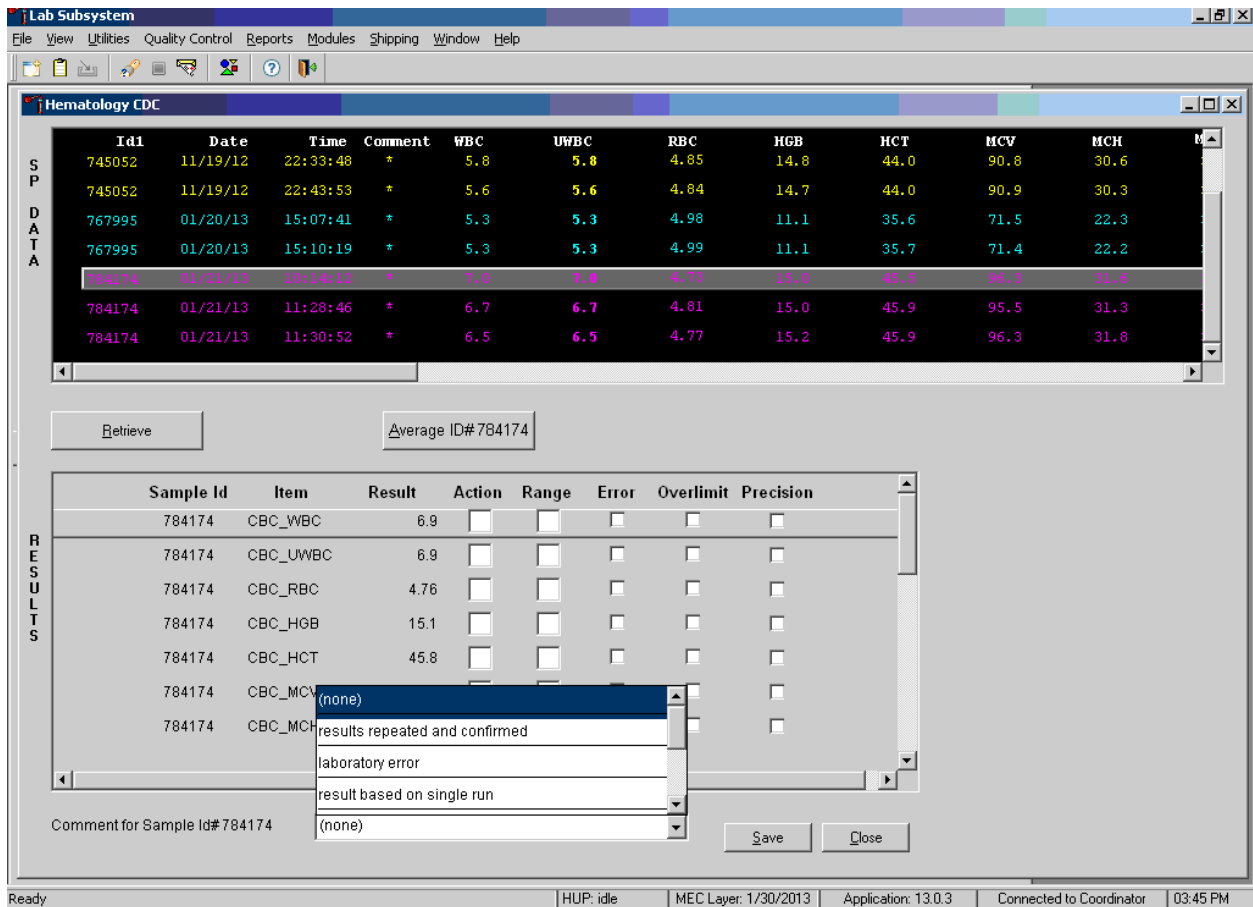
Comment Selection:

Comment for Sample Id# 743545

- (none)
- (none)
- results repeated and confirmed
- laboratory error
- result based on single run

Buttons: Save, Close

System Tray: Ready | HUP: idle | MEC Layer: 12/11/2008 | Application: 9.0.0 | Connected to Coordinator | 02:28 PM



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.

The screenshot shows the 'Lab Subsystem' interface with the 'Hematology CDC' window open. The window displays a table of test results with columns for Id#, Date, Time, Comment, WBC, UWBC, RBC, HGB, HCT, MCV, and MCH. Below this table, there is a 'Retrieve' button and a text field containing 'Average ID#784174'. A 'RESULTS' table is also visible, listing parameters like CBC_WBC, CBC_UWBC, CBC_RBC, CBC_HGB, CBC_HCT, CBC_MCV, and CBC_MCH with their respective results and checkboxes for Action, Range, Error, Overlimit, and Precision. At the bottom, there is a 'Comment for Sample Id# 784174' dropdown menu with 'results repeated and confirmed' selected, 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	95.3	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"/>

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' window with the 'Hematology CDC' module. The 'SP DATA' section displays a table of sample data with columns: Id1, Date, Time, Comment, WBC, UWBC, RBC, HGB, HCT, MCV, and MCH. The 'RESULTS' section displays a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. Below the results table, there is a 'Comment for Sample Id#784174' field with a dropdown menu showing 'results repeated and confirmed', and 'Save' and 'Close' buttons.

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

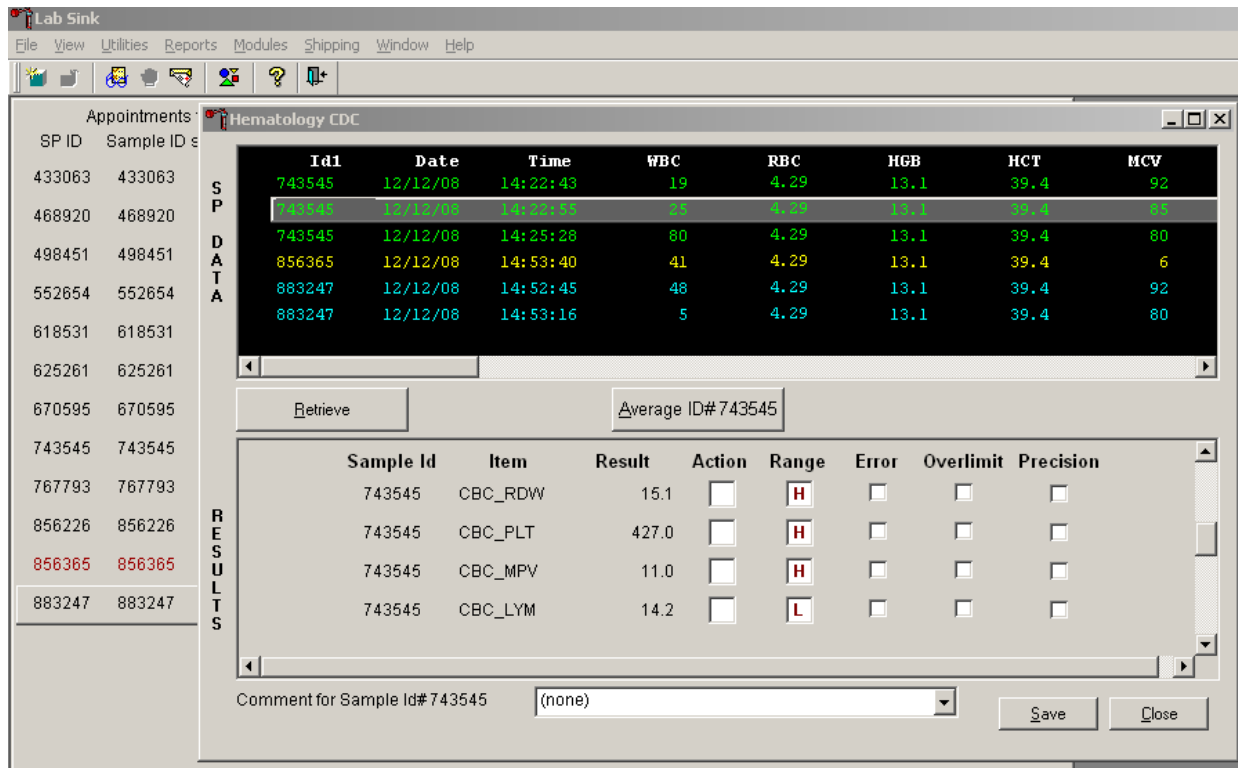
RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
	784174	CBC_WBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	784174	CBC_UWBC	6.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<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

Buttons: Save, Close

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, overlimit, and precision checkmarks, and “H” or “L” action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, 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

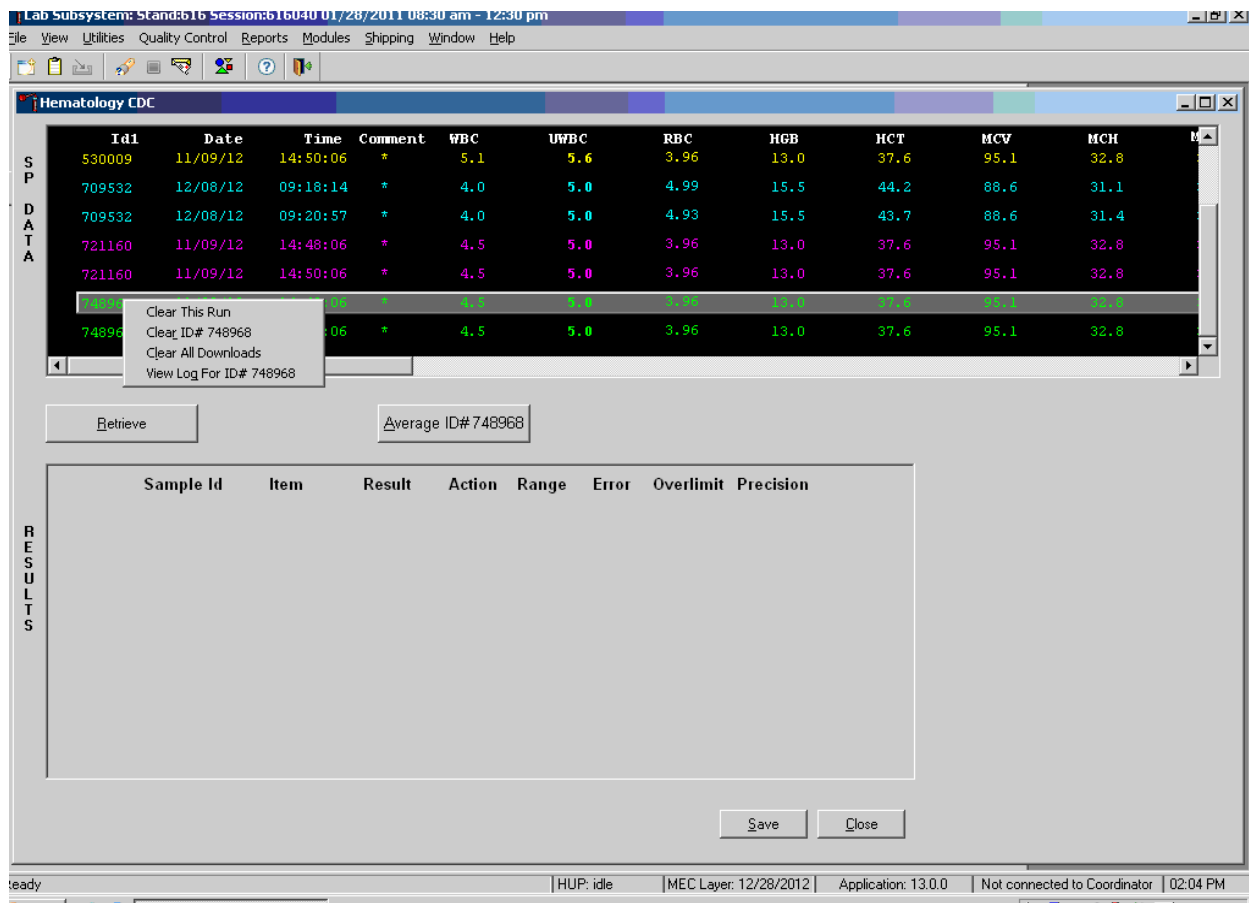
Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
743545	CBC_RDW	15.1	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
743545	CBC_PLT	427.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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

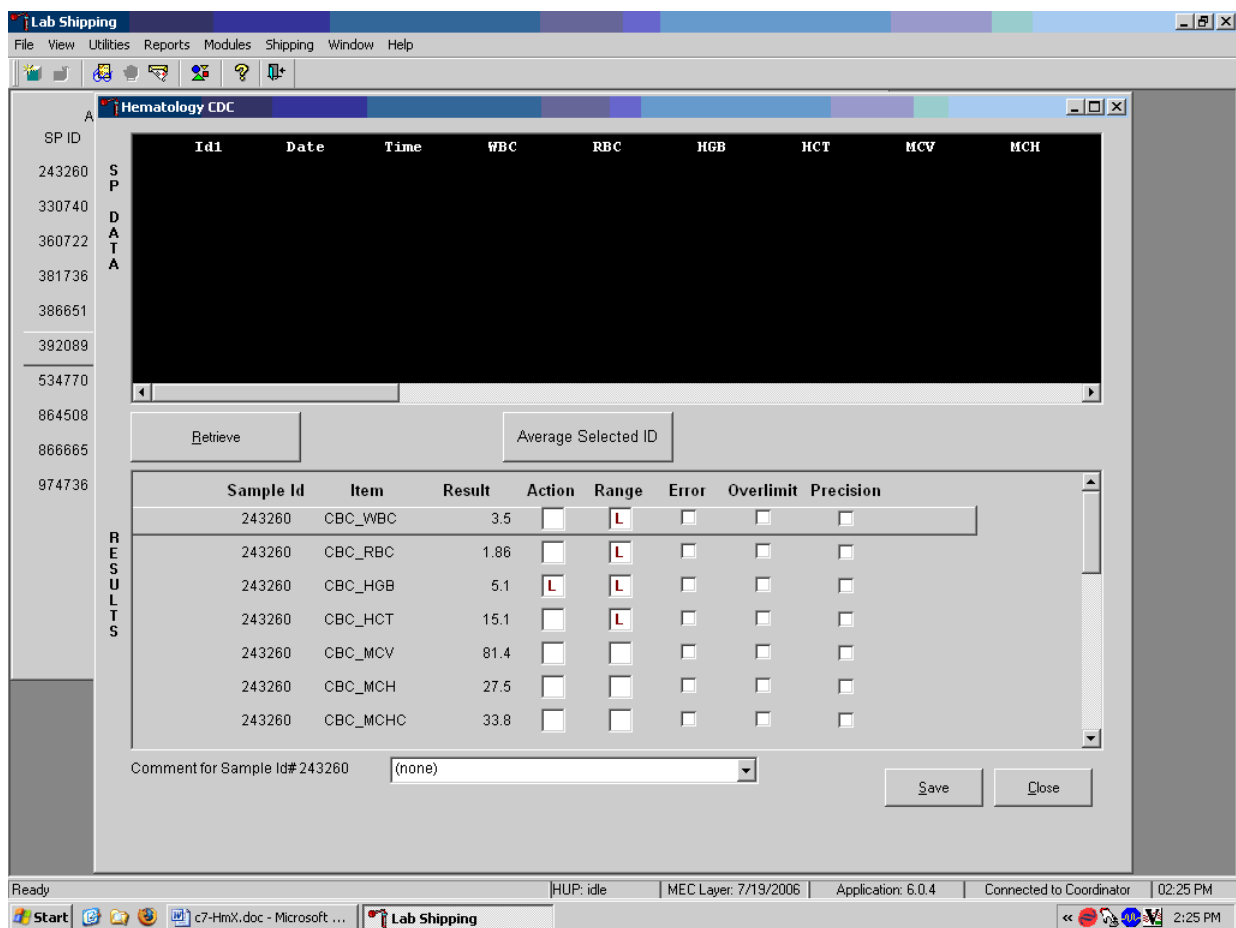
Ready | HUP: idle | MEC Layer: 12/11/2008 | Application: 9.0.0 | Connected to Coordinator | 02:56 PM

Start | Manual Screen Shots (No...) | 2009 Draft: C7.doc - Micr... | Lab Sink | Phlebotomy | 2:56 PM



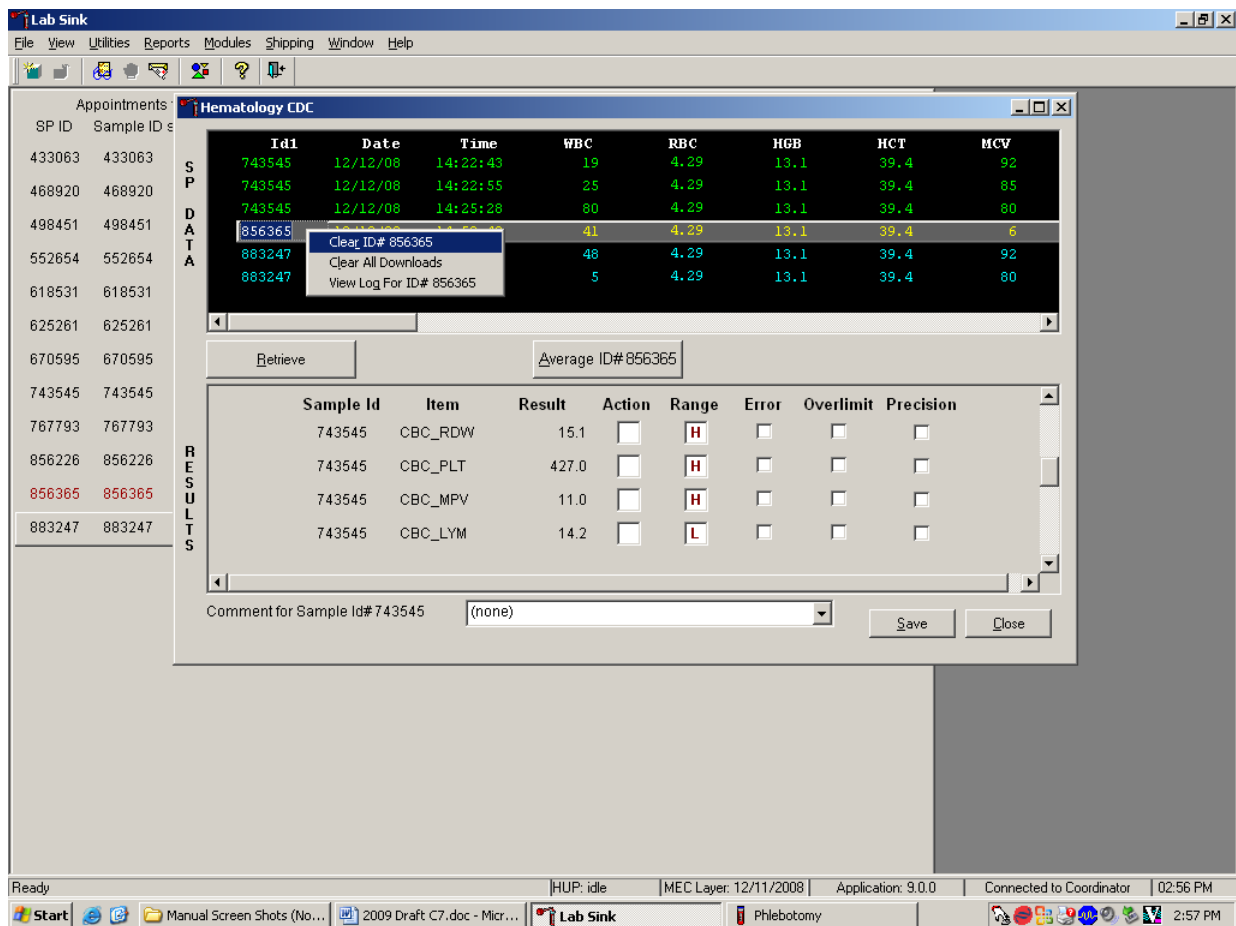
To clear all downloads from the SP Data section, direct the mouse arrow to any row in the SP Data section and right-click to display the alternative data manipulation choices. To select “Clear All Downloads,” drag the mouse arrow to the Clear All Downloads choice and left-click.

Release the mouse button to clear all downloads.



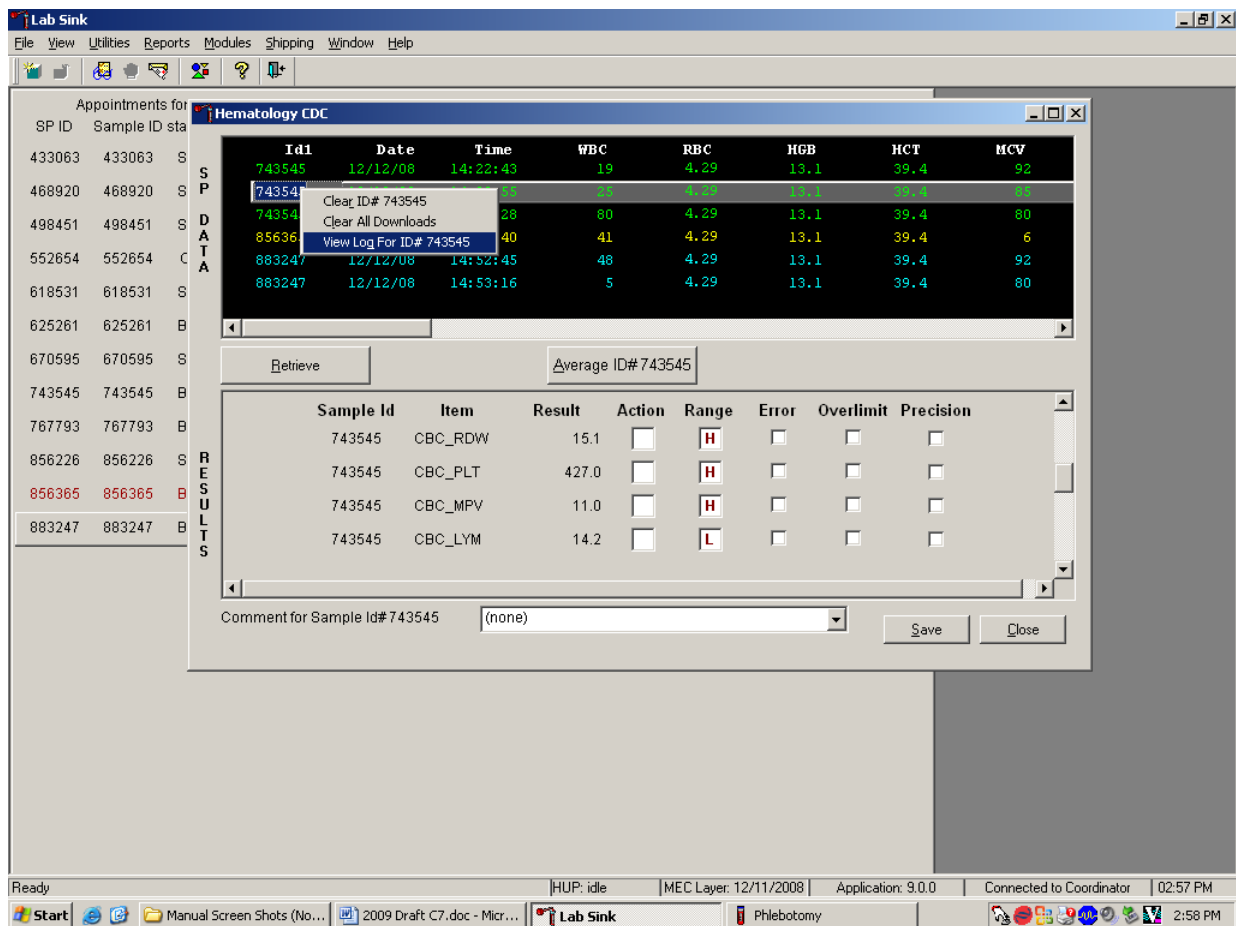
All data in the SP Data section are erased, but any averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the Hematology module, direct the mouse arrow to the Close button and left-click.

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



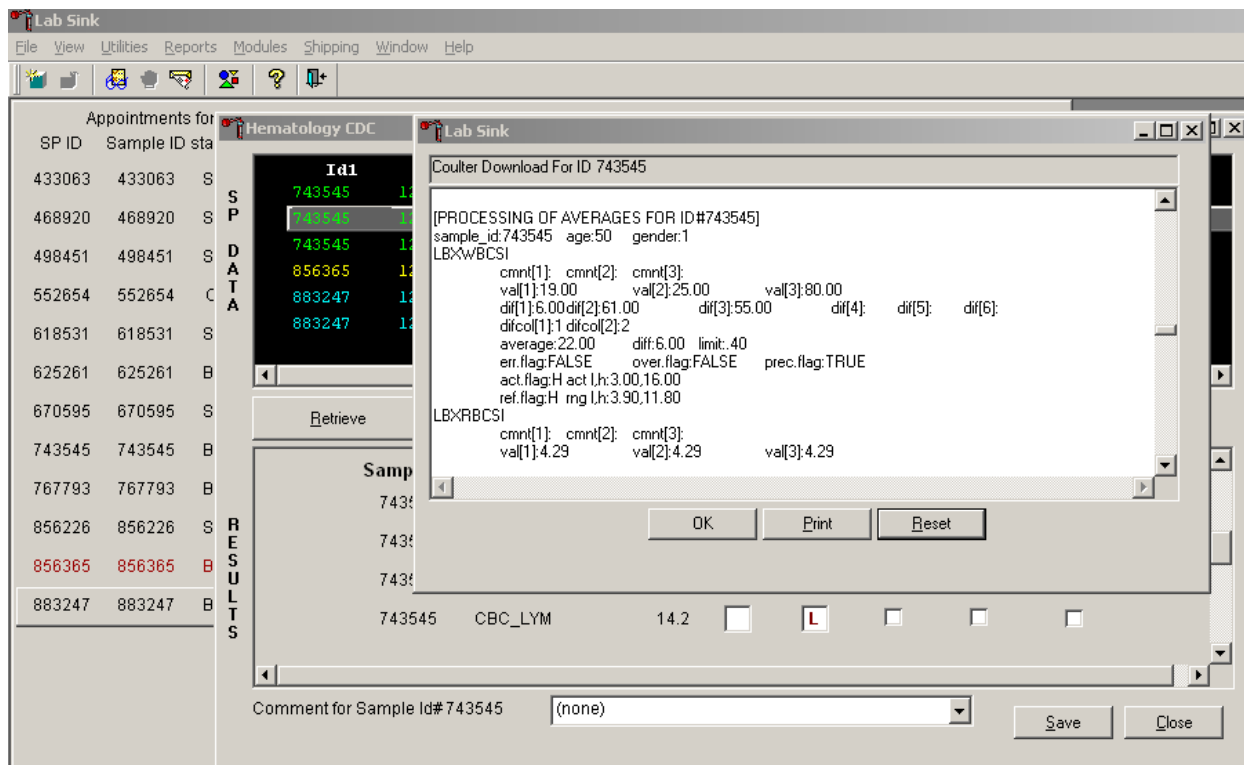
To clear the Coulter downloads for any one SP, direct the mouse arrow to the individual row in the SP Data section, right-click to display the alternative data manipulation choices, drag the mouse arrow to Clear ID#XXXXXX, and right- or left-click. Release the mouse button to clear this download. Retransmit, 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

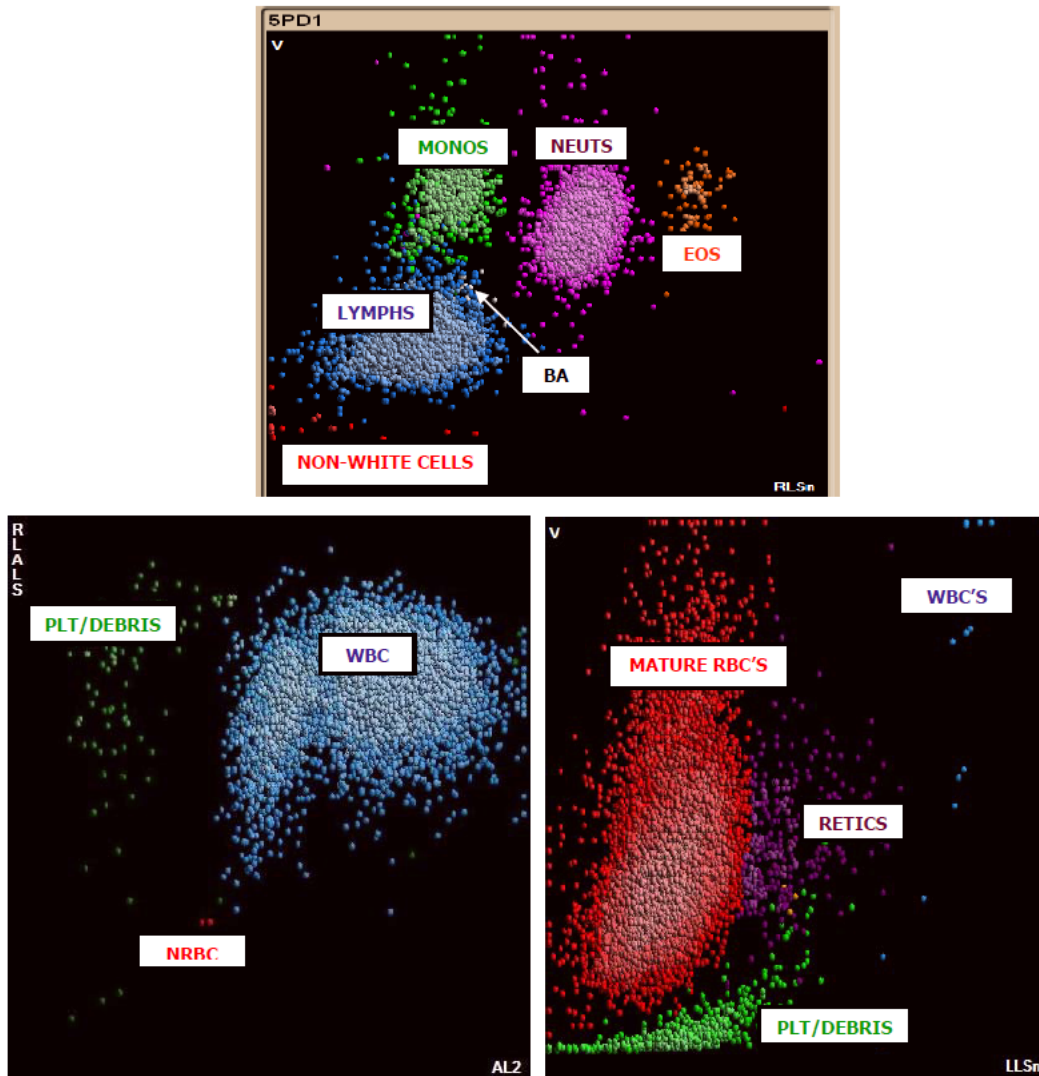


Exhibit 6-13 presents DxH system messages.

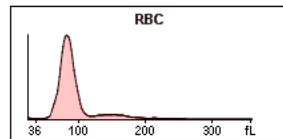
Exhibit 6-13. DxH system messages

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).

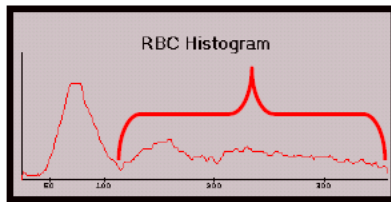
SYSTEM MESSAGE DXH	SYSTEM MESSAGE DXH
WBC	PLT
Abn WBC Pattern	Platelet Clumps
Cellular Inter	PLT Carryover
System Event: WBC	PLT Inter: Debris
WBC Carryover	RBC-PLT Overlap
RBC	System Event: PLT
Abn RBC Pattern	NRBC
System Event: RBC	Abn NRBC Pattern
HGB	AL2 Blank Volt: N
HGB Inter: WBC	DataDisc: N
HGB 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 RMALES 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.

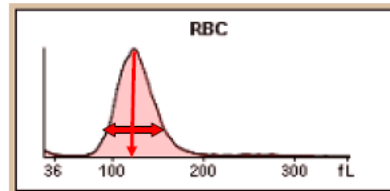
RBC Histogram Examples



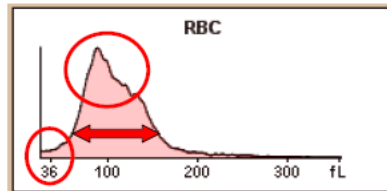
NORMAL



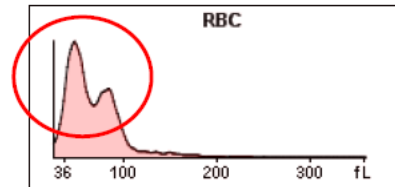
RBC AGGLUTININ



MACROCYTIC, Elevated RDW

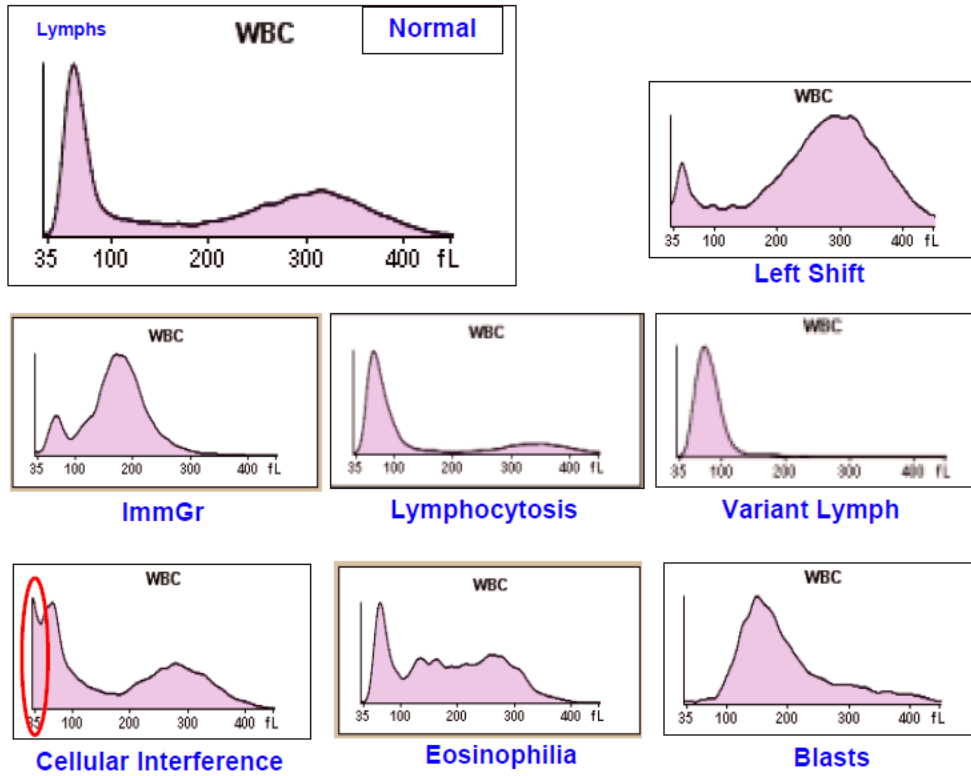


RBC Fragments / DI RBC / Elevated RDW



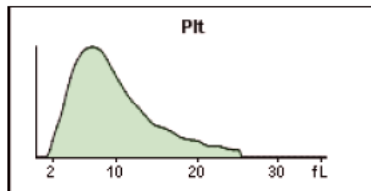
DI RBCs, RBC Frags, Elevated RDW

WBC Histogram Examples

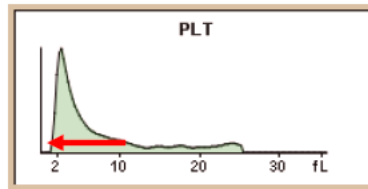


PLT Histogram Examples

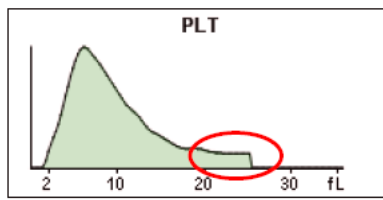
Normal



Small Platelets



Giant Platelets



RBC/PLT Overlap

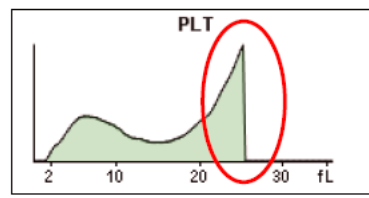
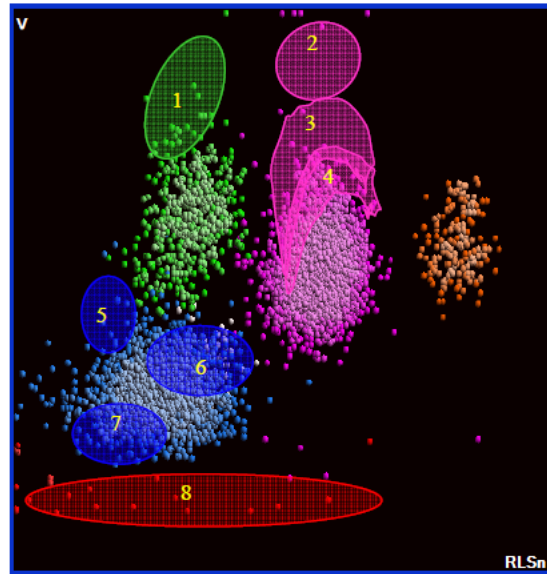


Exhibit 6-17. Image of better abnormal cell detection

Better Abnormal Cell Detection

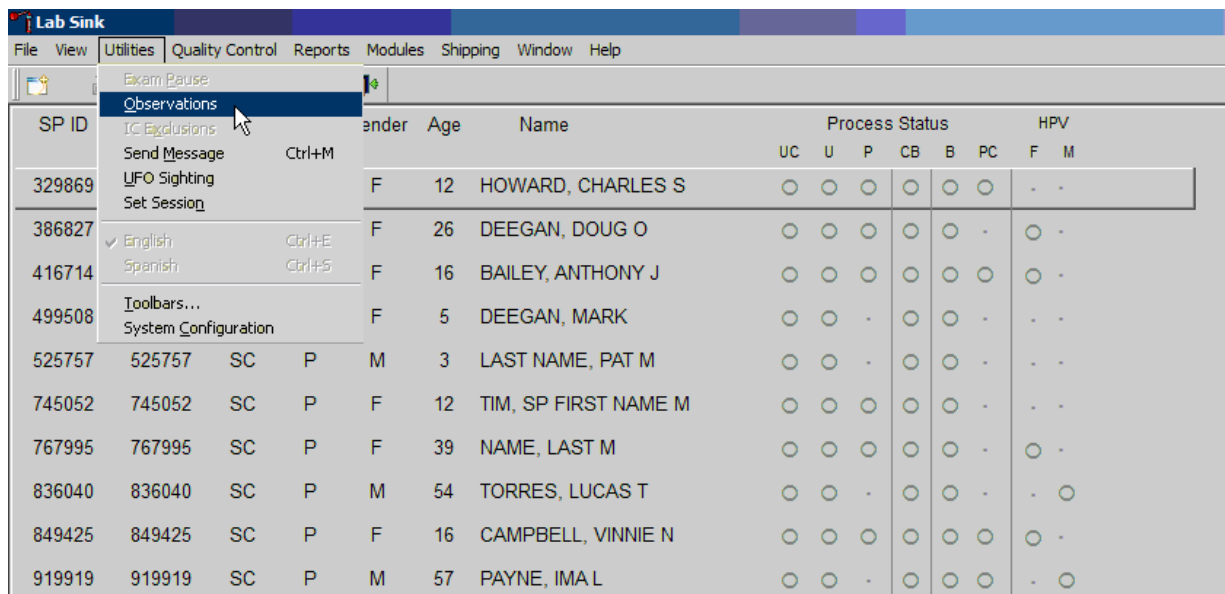


1. MO Blasts
2. NE Blasts
3. Immature Granulocytes
4. Band Neutrophils
5. LY Blasts
6. Variant Lymphocytes
7. Small Lymphs / Low Opacity
8. Non-White Cells

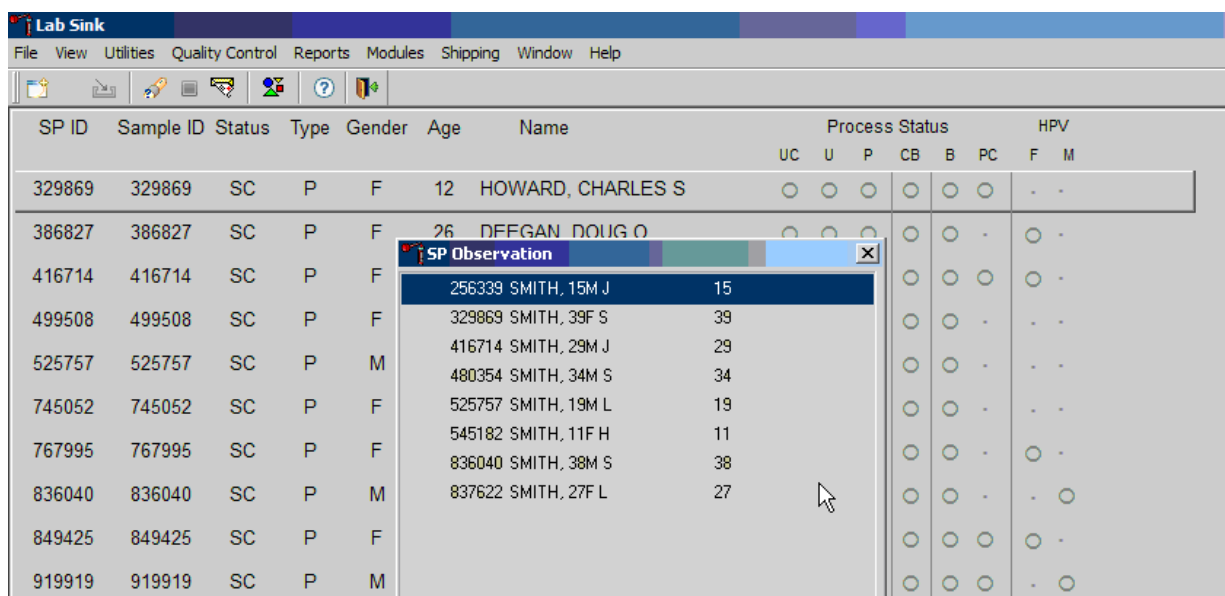
6.19.5 Physician Review

The MEC physician reviews and interprets all CBC results. Results outside action limits flash and transmit to the physician immediately. The physician determines if referral for the SP for treatment is necessary. The medical technologist sends an observation to the physician whenever a critical or action limit is detected for any CBC parameter. This observation includes the date, time, responsible laboratory individual, person notified, and test results.

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

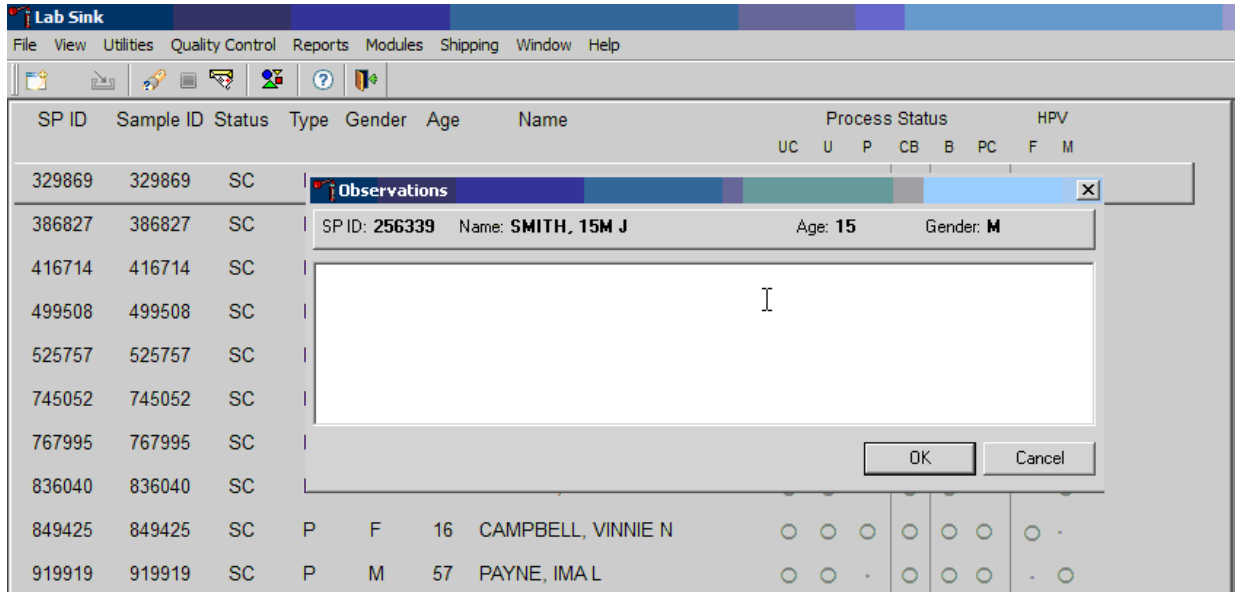


To access the observation function, direct the mouse arrow to Utilities in the menu bar, left-click, drag the mouse arrow to Observations, and left-click. Select or highlight the correct SP.



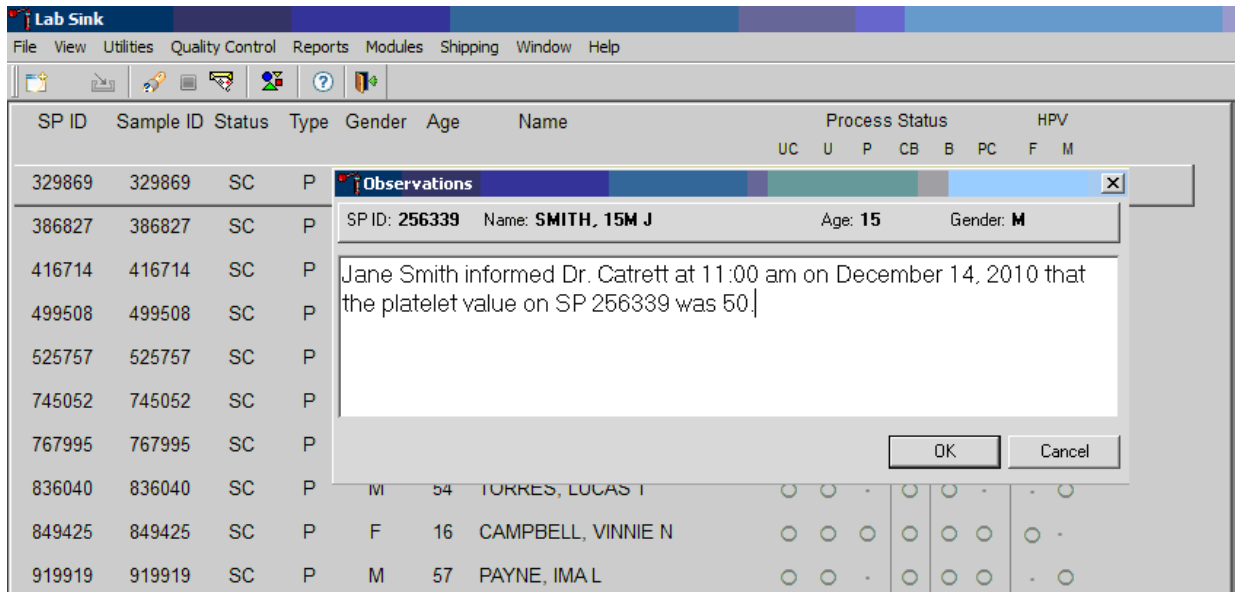
To select or highlight an SP, drag the mouse arrow to the correct SP and left-click or use the keyboard arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, direct the mouse arrow to the OK button and 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 physician, 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 physician 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
Lymphocyte percent (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Monocyte percent (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14.0
Segmented neutrophils percent (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Eosinophils percent (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6

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

Table 6-6. Reference ranges (females) (continued)

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
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
Monocyte percent (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Segmented neutrophils percent (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Eosinophils percent (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7

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 physician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- WBC male and female (all ages) < or = to $3 \times 10^3 \mu\text{l}$ 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
- 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 (usually physician's room upper cabinet). 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 physician's attention by sending the physician 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.

THIS PAGE IS INTENTIONALLY LEFT BLANK.

7. Blood Processing

7.1 Introduction

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood into vessels for storage and transport to laboratories across the United States for analysis; and (3) allocate serum into vessels for storage and transport to laboratories across the United States for analysis, future studies and storage. The purpose of packed cell processing is to allocate washed packed cells for storage and transport to the reference laboratory. 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.

7.2 Equipment and Supplies

The blood processing area includes two laboratory-grade refrigerators, four laboratory-grade freezers, two refrigerated centrifuges, two data terminals, a laminar flow hood, and two specimen rockers. This area also includes counter space for processing blood. Extra processing supplies are stored in cabinets and/or the trailer compartments. Exhibits 7-1 and 7-2 list nonconsumable and consumable supplies for blood processing.

Exhibit 7-1. Nonconsumable supplies for blood 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 pipettes 50-1,000 μ l (Blue)
One Eppendorf pipette 5-100 μ l (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 7-2. Consumable supplies for blood processing

Cotton swabs	Eight gallon biohazard sharps containers
Ascorbic acid 1%	Ascorbic acid 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	Biohazard bags 25 x 35
5-ml cryovial sterile	14-ml snap cap test tubes
Conical tubes 50-ml	2-ml cryovials sterile
2-ml cryovials non-sterile	Caps for 2-ml cryovial
30-ml ENV Vials	5 ½" long x 5 ½" deep x 4 ½" with 4 x 4 grid
Serum filters 13 mm x 4 inches	Serum filters 16 mm x 6 inches
Heratherm™ Compact Microbiological Incubator, Thermo Scientific	Other TB Supplies: QuantiFERON-TB Gold Plus Dispenser Pack (use HA pack for altitudes 3,350-6,150 feet)
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 9 x 9 cardboard grid
5.25 x 5.25 x 3.0-inch cardboard boxes with 5 x 5 grid	10 x 10 three-inch boxes
5.25 x 5.25 x 5.0-inch cardboard boxes with 5 x 5 foam insert	7 x 7 two-inch cardboard boxes
10 x 10 two-inch boxes	5.25 x 5.25 x 3-inch boxes with 7x7 grid
Nonsterile, powder-free, nonlatex gloves—small, medium, large	Red cap inserts
Sterile saline	Deionized water
Sharpie pens	Lab markers—fine

7.3 Protocols

Exhibits 7-3 through 7-6 illustrate the primary sample person's (SP's) protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or biased results will occur if the exact procedures are not followed. Exhibit 7-7 shows the blood processing protocol for guests.

Exhibit 7-3. Primary SP's whole blood processing protocol

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
54	VOC Blood	12+	7.0	Whole blood	7-ml Gray	7-ml	½ subsample 1, 2, 4, 5, 10, 11
1	Lead/Cad/HG/ Se/Mn	1+	0.4	Whole blood	EDTA	2-ml sterile	Full sample
216	Cr/Co	40+	1.0	Whole blood	EDTA	2-ml sterile	
3	RBC Folate	1+	0.1	Whole blood	EDTA	2-ml	Dilute with 1 ml AA 1%
4	Glycohem	12+	0.4	Whole blood	EDTA	2-ml	Refrigerate
5	Mercury, ethyl & methyl	1+	0.5	Whole blood	EDTA	2-ml sterile	Full sample

Exhibit 7-4. Primary SP's plasma processing protocol

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
9	Glucose	12+	0.5	Plasma	Gray	2-ml	Morning SPs only

Exhibit 7-5. Primary SP's packed cells processing protocol all from one dedicated 7-ml EDTA

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
88	Acrylamide (Adducts)	6+	1.5	Packed cells	7-ml EDTA.	2 ml	Wash 3 times, 1/3 subsample (1, 2, 5, 11)
221	Folate Forms	6+	1.0-ml 1%AA + 0.1	Packed cells	7-ml EDTA.	2 ml	Wash 3 times, 1 ml 1% AA Add 0.1 ml diluted RBCs Full sample
222	Fatty Acids	6+	1.6	Packed cells	7-ml EDTA.	2 ml	Wash 3 times, 1.6 ml diluted RBCs Full sample

Exhibit 7-6. Primary SP's serum processing protocol

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
110	Folate	1+	0.7	Serum	Red	2-ml	Add 0.05 ml AA 7% Full sample
138	Cytomegalovirus (CMV)	1-5	0.4	Serum	Red	2-ml	
118	Thyroid Panel	3-5 6+	1.0	Serum	Red	2-ml	3-5 Full sample 6+ (1, 2, 5, 11)

Exhibit 7-6. Primary SP's serum processing protocol (continued)

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
99	Ferritin/TfR	1-5, 12+	0.3 0.4	Serum	Red	2-ml	Add red cap inserts to 12-49 female SP's Males 12+ and females 50+ ferritin, only
122	Hep Profile	6+	1.8	Serum	Red	2-ml	
229	Hep xtra sera	6+	1.8	Serum	Red	2-ml	
87	Hepatitis B _s Ab	2	0.3	Serum	Red	2-ml	Age 2-5 only
17	Cotinine	3-5	0.5	Serum	Red	2-ml	
		6-11	1.0				
		12+	1.8				
21	Lipids	6-11	0.5	Serum	Red	2-ml	Add cap insert AM, only
		12+	1.0				
11	Iron/TIBC/% Saturation	12+	0.5	Serum	Red	2-ml	
18	Biochem	12+	0.8	Serum	Red	2-ml	
23	Insulin	12+	0.5	Serum	Red	2-ml	Morning SPs only
13	CRP	1+	0.3	Serum	Red	2-ml	
22	HIV	18-59	1.0	Serum	Red	2-ml	18-59 only
24	HSV	14-49	0.2	Serum	Red	2-ml	14-49 only
137	Steroid Hormone	6+	3.5	Serum	Red	5-ml	Add red cap to females for vessel 137
29	Dioxin 1*	12+	15.0	Serum	15-ml Red	30-ml	1/3 subsample 0, 3, 7, 10
90	Perfluor*	12+	1.5	Serum	15-ml Red	2-ml sterile	1/3 subsample 1, 2, 5, 11
32	Xtra Sera1	3+	0.5	Serum	Red	2-ml	
33	Xtra Sera2	3+	0.5	Serum	Red	2-ml	
34	Xtra Sera3	12+	0.5	Serum	Red	2-ml	
35	Xtra Sera4	12+	0.5	Serum	Red	2-ml	
36	Xtra Sera5	12+	0.5	Serum	Red	2-ml	
37	Xtra Sera6	12+	0.5	Serum	Red	2-ml	

* Use pooled serum from 2-15 ml red tops to fill vessels 29 and 90

Exhibit 7-7. Guest serum processing protocol

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type	Remarks
18	Biochem	12+	0.8	Serum	Red	2-ml	

7.4 Blood Processing Age-Specific Protocols

Exhibits 7-8 through 7-12 illustrate the blood processing protocols for each primary SP by age group.

Exhibit 7-8. Blood processing protocol for primary SPs aged 1-2 years

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	1-2	0.4	Whole blood	3-ml EDTA	2-ml sterile
3	RBC Folate	1-2	0.1	Whole blood	3-ml EDTA	2-ml
5	Mercury, Ethyl, & Methyl	1-2	0.5	Whole blood	3-ml EDTA	2-ml sterile
110	Folate	1-2	0.7	Serum	7-ml Red	2-ml
138	Cytomegalovirus (CMV)	1-2	0.4	Serum	7-ml Red	2-ml
99	Ferritin/Transferrin Receptor	1-2	0.3	Serum	7-ml Red	2-ml
87	Hepatitis ab	2	0.3	Serum	7-ml Red	2-ml
13	CRP	1-2	0.3	Serum	7-ml Red	2-ml

Exhibit 7-9. Blood processing protocol for primary SPs aged 3-5 years

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	3-5	0.4	Whole blood	3-ml EDTA	2-ml sterile
3	RBC Folate	3-5	0.1	Whole blood	3-ml EDTA	2-ml
5	Mercury, Ethyl, & Methyl	3-5	0.5	Whole blood	3-ml EDTA	2-ml sterile
110	Folate 1	3-5	0.7	Serum	7-ml Red	2-ml
138	Cytomegalovirus (CMV)	3-5	0.4	Serum	7-ml Red	2-ml
118	Thyroid Panel	3-5	1.0	Serum	7-ml Red	2-ml
99	Ferritin/Transferrin Receptor	3-5	0.3	Serum	7- and 3-ml Red	2-ml
87	Hepatitis ab	3-5	0.5	Serum	7-ml Red	2-ml
17	Cotinine	3-5	0.8	Serum	7-ml Red	2-ml
13	CRP	3-5	0.3	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 7-10. Blood processing protocol for primary SPs aged 6-11 years

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	6-11	0.4	Whole blood	7-ml EDTA	2-ml sterile
3	RBC Folate	6-11	0.1	Whole blood	7-ml EDTA	2-ml
5	Mercury, Ethyl & Methyl	6-11	0.5	Whole blood	7-ml EDTA	2-ml sterile
88	Acrylamide	6-11	1.5	Packed cells	7- ml EDTA	2 ml
221	RBC Folate (all)	6-11	0.1	Whole blood	7-ml EDTA	2 ml
222	Fatty Acids (all)	6-11	1.6	Whole blood	7-ml EDTA	2 ml
110	Folate 1	6-11	0.7	Serum	10- ml Red	2-ml
118	Thyroid Panel	6-11	1.0	Serum	10- ml Red	2-ml
122	Hep Profile	6-11	1.8	Serum	10- ml Red	2-ml
229	Hep Xtra sera	6-11	1.8	Serum	10-mL Red	2-mL
17	Cotinine	6-11	1.0	Serum	10- ml Red	2-ml
21	Lipids	6-11	0.5	Serum	10- ml Red	2-ml
13	CRP	6-11	0.3	Serum	10- ml Red	2-ml
137	Steroid Hormone °	6-11	3.5	Serum	10- ml Red	5-ml
32	Xtra Sera1	6-11	0.5	Serum	10- ml Red	2-ml
33	Xtra Sera2	6-11	0.5	Serum	10- ml Red	2-ml

°Add red caps to all females for vessel 137.

Exhibit 7-11. Blood processing protocol for primary SPs aged 12-19 years

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
54	VOC Blood	12-19	7.0	Whole blood	7-ml Gray	7-ml
1	Lead/Cad/HG/Se/Mn	12-19	0.4	Whole blood	7 -ml EDTA	2-ml sterile
3	RBC Folate	12-19	0.1	Whole blood	7-ml EDTA	2-ml
4	Glycohem	12-19	0.4	Whole blood	7-ml EDTA	2-ml
5	Mercury, Methyl & Ethyl	12-19	0.5	Whole blood	7-ml EDTA	2-ml sterile
88	Acrylamide	12-19	1.5	Packed Cells	7-ml EDTA	2 ml
221	RBC Folate (all)	12-19	0.1	Whole blood	7-ml EDTA	2 ml
222	Fatty Acids (all)	12-19	1.6	Whole blood	7-ml EDTA	2 ml
119	Genetics	18+	6.0	Whole blood	6-ml EDTA	5-ml
9	Glucose	12-19	0.5	Plasma	2-ml Gray	2-ml
110	Folate1	12-19	0.7	Serum	15- and 7-ml Red	2-ml
118	Thyroid Panel	12-19	1.0	Serum	15- and 7-ml Red	2-ml
99	Ferritin/Transferrin Receptor	12-19	0.4	Serum	15- and 7-ml Red	2-ml
122	Hep Profile	12-19	1.8	Serum	15- and 7-ml Red	2-ml

Exhibit 7-11. Blood processing protocol for primary SPs aged 12-19 years (continued)

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
229	Hep Xtra sera	6-11	1.8	Serum	10-mL Red	2-mL
17	Cotinine	12-19	1.8	Serum	15- and 7-ml Red	2-ml
21	Lipids	12-19	1.0	Serum	15- and 7-ml Red	2-ml
11	Iron/TIBC/% Saturation	12-19	0.5	Serum	15- and 7-ml Red	2-ml
18	Biochem	12-19	0.8	Serum	15- and 7-ml Red	2-ml
23	Insulin	12-19	0.5	Serum	15- and 7-ml Red	2-ml
13	CRP	12-19	0.3	Serum	15- and 7-ml Red	2-ml
22	HIV	18-19	1.0	Serum	15- and 7-ml Red	2-ml
24	HSV	14-49	0.2	Serum	15- and 7-ml Red	2-ml
137	Steroid Hormone °	12-19	3.5	Serum	15- and 7-ml Red	5-ml
29	Dioxin 1*	12-19	15.0	Serum	15- and 7-ml Red	5-ml sterile
90	Perflour1*	12-19	1.5	Serum	15- and 7-ml Red	2-ml sterile
32	Xtra Sera1	12-19	0.5	Serum	15- and 7-ml Red	2-ml
33	Xtra Sera2	12-19	0.5	Serum	15- and 7-ml Red	2-ml
34	Xtra Sera3	12-19	0.5	Serum	15- and 7-ml Red	2-ml
35	Xtra Sera4	12-19	0.5	Serum	15- and 7-ml Red	2-ml
36	Xtra Sera5	12-19	0.5	Serum	15- and 7-ml Red	2-ml
37	Xtra Sera6	12-19	0.5	Serum	15- and 7-ml Red	2-ml

° Add red caps to all females for vessel 137.

Exhibit 7-12. Blood processing protocol for primary SPs aged 20+ years

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
54	VOC Blood	20+	7.0	Whole blood	7-ml Gray	10-ml Gray
1	Lead/Cad/HG/Se/Mn	20+	0.4	Whole blood	7-ml EDTA	2-ml sterile
216	Cr/Co	40+	1.0	Whole blood	7-ml EDTA	2-ml sterile
3	RBC Folate	20+	0.1	Whole blood	7-ml EDTA	2-ml
4	Glycohem	20+	0.4	Whole blood	7-ml EDTA	2-ml
5	Mercury, Methyl & Ethyl	20+	0.5	Whole blood	7-ml EDTA	2-ml sterile
88	Acrylamide	20+	1.5	Packed Cells	7-ml EDTA	2 ml
221	RBC Folate (all)	20+	0.1	Whole blood	7-ml EDTA	2 ml
222	Fatty Acids (all)	20+	1.6	Whole blood	7-ml EDTA	2 ml
119	Genetics	20+	6.0	Whole blood	6-ml EDTA	5-ml
9	Glucose	20+	0.5	Plasma	2-ml Gray	2-ml

Exhibit 7-12. Blood processing protocol for primary SPs aged 20+ years (continued)

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
110	Folate 1	20+	0.7	Serum	15- and 7-ml Red	2-ml
118	Thyroid Panel	20+	1.0	Serum	15- and 7-ml Red	2-ml
99	Ferritin/Transferrin Receptor	20+	0.4	Serum	15- and 7-ml Red	2-ml
122	Hep Profile	20+	1.8	Serum	15- and 7-ml Red	2-ml
229	Hep Xtra sera	6-11	1.8	Serum	10-mL Red	2-mL
17	Cotinine	20+	1.8	Serum	15- and 7-ml Red	2-ml
21	Lipids	20+	1.0	Serum	15- and 7-ml Red	2-ml
11	Iton/TIBC/% Saturation	12-19	0.5	Serum	15- and 7-ml Red	2-ml
18	Biochem	20+	0.8	Serum	15- and 7-ml Red	2-ml
23	Insulin	20+	0.5	Serum	15- and 7-ml Red	2-ml
13	CRP	20+	0.3	Serum	15- and 7-ml Red	2-ml
22	HIV	20-59	1.0	Serum	15- and 7-ml Red	2-ml
24	HSV	20-49	0.2	Serum	15- and 7-ml Red	2-ml
137	Steroid Hormone ^o	20+	3.5	Serum	15- and 7-ml Red	5-ml
29	Dioxin 1*	20+	15.0	Serum	15- and 7-ml Red	5-ml sterile
90	Perflour1*	20+	1.5	Serum	15- and 7-ml Red	5-ml sterile
32	Xtra Sera1	20+	0.5	Serum	15- and 7-ml Red	2-ml
33	Xtra Sera2	20+	0.5	Serum	15- and 7-ml Red	2-ml
34	Xtra Sera3	20+	0.5	Serum	15- and 7-ml Red	2-ml
35	Xtra Sera4	20+	0.5	Serum	15- and 7-ml Red	2-ml
36	Xtra Sera5	20+	0.5	Serum	15- and 7-ml Red	2-ml
37	Xtra Sera6	20+	0.5	Serum	15- and 7-ml Red	2-ml

^oAdd red caps to all female vessel 137.

Exhibit 7-13 illustrates the blood processing protocol for each guest.

Exhibit 7-13. 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

Exhibit 7-14 illustrates the blood processing protocol for each guest.

Exhibit 7-14. Blood processing protocol for foreign born guests aged 6-59 years and 60+ all

ID	Test name	Ages	Sample (ml)	Sample type	Collection type	Vessel type
223, 224, 225, 226	TB (QuantiFERON-TB Gold Plus)	6-59 (foreign born guests) 60+ (all)	4.0	Whole blood	(4) 1-ml TB tubes (gray, green, yellow, purple)	(4) 2-ml

7.5 Labeling Vessels

The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood processing racks and in labeling the vessels with the appropriate barcode label.

Use the following materials to set up and label blood racks:

- Rack;
- Age-appropriate processing template;
- Storage vessels of the following sizes:
 - 2.0-ml sterile vessel,
 - 2.0-ml nonsterile vessel, and
 - 5.0-ml sterile vessel;
 - 30 mL nonsterile vessel.
- 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. 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 technologist assigned to workstation 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 technologist assigned to shipping is responsible for labeling the vessels and setting up the blood processing racks, it is the blood processing technologist's responsibility to verify that **each vessel** has the correct label **before filling**. Do not rely only upon memory or the positioning of the vessels in a rack to indicate which vessels to fill.

Ensure:

- The SP's ID number on the barcode label;
- The vessel number on the label;
- 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, then it is possible that he or she will reschedule. Store the SP's labeled vials in the clear bin or 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 he or she refuses phlebotomy during a session, discard vessels from the rack.

7.6 Equipment

7.6.1 Benchtop Centrifuges

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

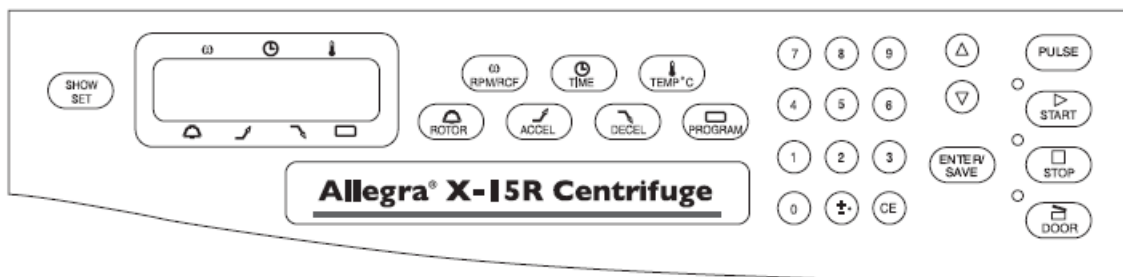
The Allegra X-15R centrifuge has been designed and tested to operate safely indoors at altitudes up to 2000 m (6,562 ft). Safety features include the following:

- 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 7-15 is a diagram of the centrifuge control panel.

Exhibit 7-15. 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 7-16) provide run information, user messages, and diagnostics.

Exhibit 7-16. 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.
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.
	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.
	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.
	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.

Time

For plasma and serum—set appropriate time and temperature for each tube as follows:

- 3-ml or 4-ml EDTA	10 minutes	4-8 °C
- 2-ml gray	10 minutes	4-8 °C
- 3-ml, 7-ml, 10-ml or 15-ml red	15 minutes	4-8 °C
- (4) 1 ml TB Gold Plus (QFT-Plus)	15 minutes	4-8 °C

For washed packed cells—set appropriate time and temperature for each tube as follows:

Vessel 88	7-ml EDTA	5 minutes	4-8 °C
-----------	-----------	-----------	--------

Speed

For plasma and serum—set the speed at 2,900 rpm.

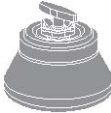
For washed packed cells vessel 88—set the speed at 1,985 rpm.

For TB Gold Plus (QFT Plus)—set the speed at 2000 to 3000 RCF (g) **Note: to calculate to RPM**


use the formula $RPM = \sqrt{\frac{RCF}{r \times 1.118}} \times 1,000$ *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 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.

Preparation

Prepare the rotor for centrifugation as described in Section 11.5 in Chapter 11. For runs at other than room temperature, refrigerate or warm the rotor beforehand for fast equilibration.

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 pressing down firmly on both sides. The door locks. When the latches engage, the LED next to the DOOR key lights up.

Note: For Allegra X-15R Centrifuge cleaning and maintenance, refer to the centrifuge maintenance manual.

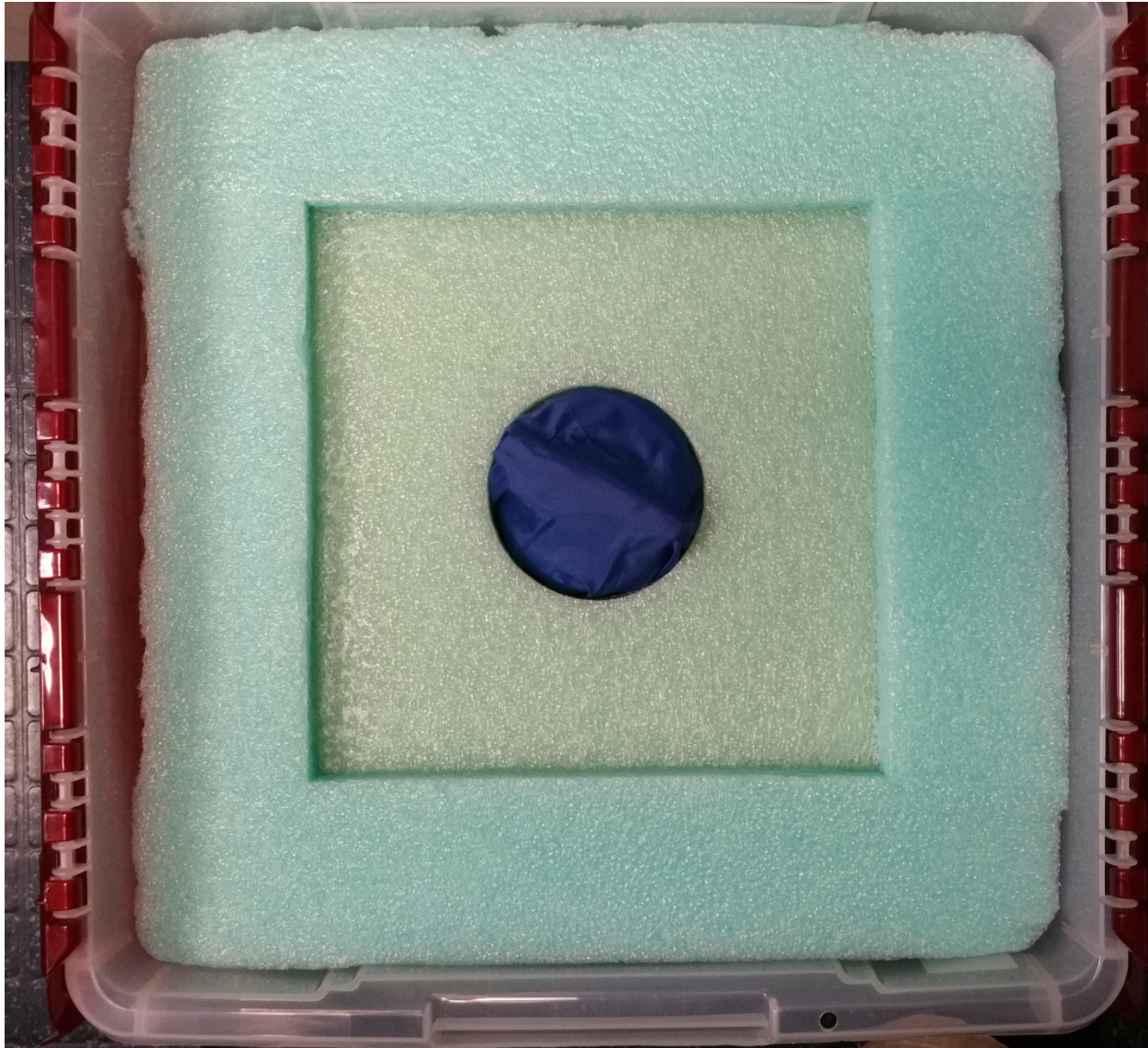
End of Stand Centrifuge Packing Procedure

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. See photos (Exhibits 7-17 and 7-18) for proper packing.

Exhibit 7-17. Packing rotors in plastic bin (1)



Exhibit 7-18. Packing rotors in plastic bin (2)



7.6.2 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 magnehelic gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the FES who may need to have a service engineer visit. Record the pressure reading and any comments in the Laboratory QC module.
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.

- Disinfect the interior of the workspace by wiping it down with a disinfectant (i.e., Sani-wipe).
- Place a disposable paper blotter on the work surface. Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange and separate clean and contaminated materials.
- Wait 2 to 3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all “loose” contamination.
- Wear a long-sleeved laboratory coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect hands and arms from viable agent contamination. Wash hands with soap and water before and after working in the cabinet.
- After completing work, leave the blower on for 2 to 3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazard waste by wiping them with Sani-Cloths.
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

7.7 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 spattering that may occur when opening the Vacutainer® tubes or when pouring or pipetting the specimens. It also prevents drawing contaminated air or dust over the specimens. It is mandatory to use the blower.

Always wear gloves when handling specimens. Check gloves for small holes or tears. Change gloves if they become visibly contaminated with blood. Immediately soak visibly contaminated racks in 1:10 bleach solution. Decontaminate the workstation, including the biological safety hood, using Sani-wipes or a 10 percent bleach solution 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 Sani-Cloth. Place on blotter to air dry.

7.7.1 Eppendorf Xplorer Plus Pipettes

Pipette whole blood for vessel 3 and 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 5-100µl (Yellow), one 50-1,000 µl (Blue), and one 0.2-5 ml (Purple) (Table 7-1). 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.

- 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% 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% ascorbic acid solution for RBC Folate – vessel 3. Use this pipette to aliquot the 1% 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.

Table 7-1. 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 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

7.7.1.1 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 dispensed correctly.
- 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

- 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.

7.7.1.2 Technical Data for the Xplorer Plus

Table 7-2 presents the technical data for the Xplorer Plus.

Table 7-2. 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

The technical data are 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 $20^{\circ}\text{C} - 25^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$;
- Set speed level: 5;
- Dispense against the tube wall; and
- Use water in accordance with ISO 3696.

Battery

- Lithium polymer battery: 750 mAh/3.7 V
- Charging time: approximately 3 hours for a fully discharged battery; overcharging protection with the pipette

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. Do not try to recharge a pipette if the battery is not installed. 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 remain stored.

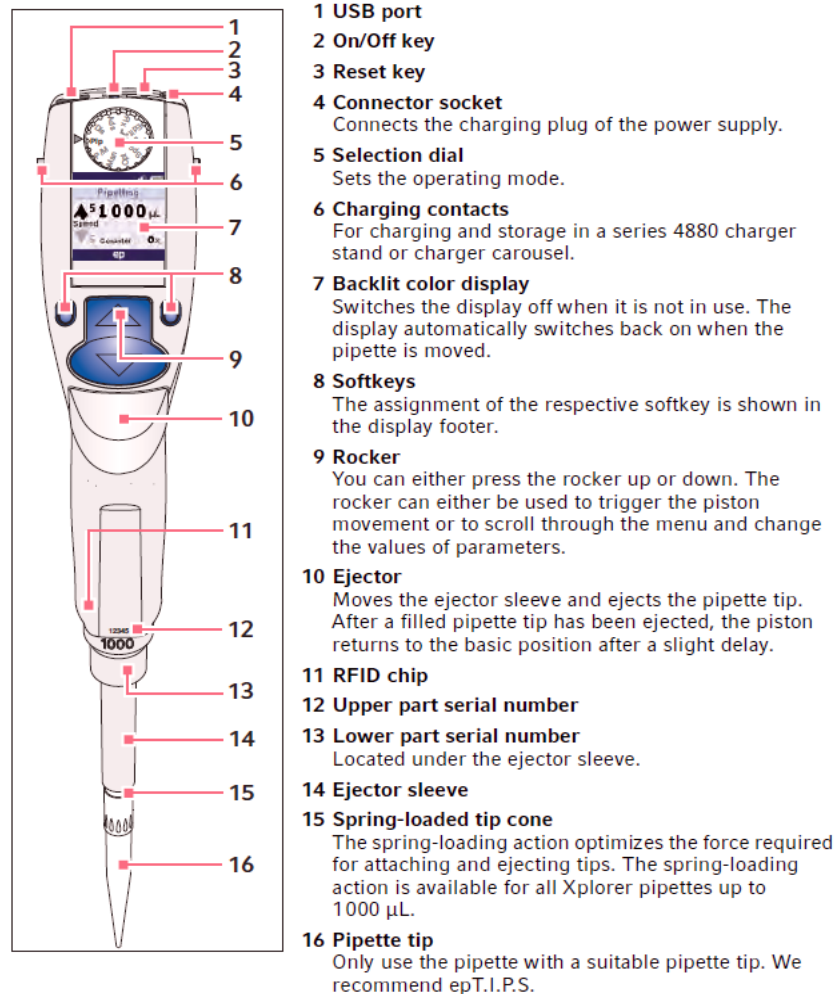
7.7.1.3 Operating Principle

Display and Keypad

- To switch on: Switch on the ON switch (Exhibit 7-19).
- To switch off: Switch off the ON switch.

Exhibit 7-19. Illustration of single channel pipette

3.1 Main illustration – single-channel pipette



- 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.

7.7.1.4 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.

7.7.1.5 Programming the Pipettes

PIP Mode

Use this mode for the Blue 50-1,000 μl pipette for dispensing 1% 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, 1000 μl s from the 50-1,000 μl (Blue) pipette. Use for vessel 110 serum and 1% 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% 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, 1000). 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.”

Programming – PRG	
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 age 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 following volumes to the program: 0.7, 0.4, 0.9, 0.1, 1.0, 1.8 ml. 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 following steps and volumes: a. 8 steps 1.0, 0.5, 0.8, 0.5, 0.3, 1.0, 0.2, 0.5 ml
Step 18	Press the “Next” softkey and repeat steps 7-16 using the following steps and volumes: a. 5 steps 0.6, 1.0, 1.0, 1.0, 1.0 ml
Step 19	Press the “Next” softkey and repeat steps 7-16 using the following steps and volumes: a. 5 steps 0.5, 0.5, 0.5, 0.5, 0.5 ml
Step 20	Press the “Save” softkey to save the program. The program will now appear in the program list.
Step 21	Set the selection dial to “Program” after all editing is complete.

Programming – SD	
Programming – SD 6- to 11-year-olds	
Step 1	Follow steps 1-4 in the 12 & 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 Up” programming instructions using the following steps and volumes: a. 7 steps b. 0.7, 0.9, 0.1, 1.0, 1.0, 0.5, 0.3 ml
Step 4	Press the “Next” softkey and repeat steps 7-16 in the “12 Up” program using the following steps and volumes: a. 4 steps b. 0.5, 0.5, 0.5, 0.5 ml
Step 5	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 & 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 Up” programming instructions using the following steps and volumes: a. 9 steps b. 0.7, 0.4, 0.3, 0.5, 0.5, 0.8, 0.3, 0.5, 0.5 ml
Step 4	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 & 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 Up” programming instructions using the following steps and volumes: a. 6 steps b. 0.7, 0.4, 0.3, 0.5, 0.3, 0.3 ml
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 & 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 Up” programming instructions using the following steps and volumes: a. 8 steps b. 0.5, 0.5, 0.5, 0.5, 0.5, 0.5, 0.5, 0.5 ml

7.7.1.6 Mode of Operation – Pipetting for 5-100 μ l, 50-1,000 μ l & 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, reaspirate using same pipette tip and dispense per protocol.
- Discard the pipette tip by pressing the ejector, then attach a new tip and reaspirate liquid.

7.7.1.7 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% isopropanol.

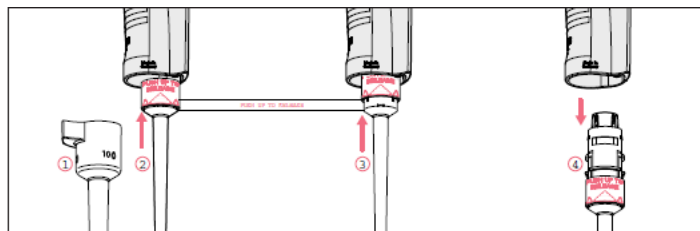
At the End of Stand, if the pipette is very contaminated, or if very aggressive chemicals are dispensed, disassemble the lower half of the Xplorer Plus. Rinse the individual parts in distilled water and then dry them. Then lightly lubricate the piston, using silicone grease.

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 7-20).

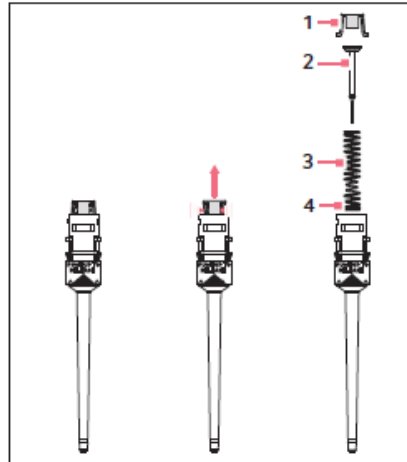
Exhibit 7-20. Removing the lower part – pipettes $\leq 1,000 \mu\text{l}$



Opening the lower part for pipettes $\leq 1,000 \mu\text{l}$:

1. Slightly push the stop pins together on the piston mount (Exhibit 7-21).
2. Remove piston mount.
3. Remove the piston and the piston spring.

Exhibit 7-21. Opening the lower part – pipettes $\leq 1,000 \mu\text{l}$



Installing the lower part and ejector sleeve for the $\leq 1,000 \mu\text{l}$:

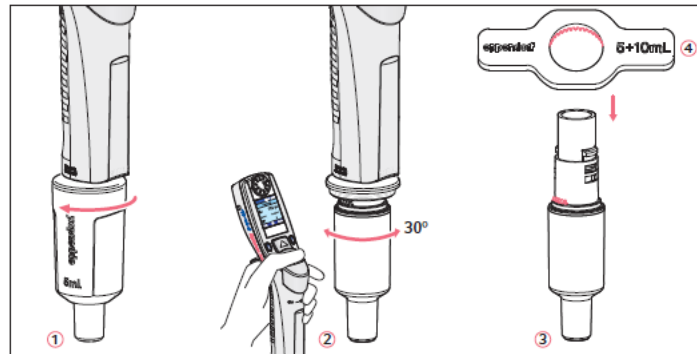
1. Insert the lower part into the upper part until it audibly engages.
2. Set the maximum volume and move the rocker up and down several times.
3. Keep the ejector pressed.
4. Fit the ejector sleeve onto the ejector rod.

Removing the lower part for the 5 ml pipette (Exhibit 7-22):

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. Unscrew the ejector sleeve.
2. Keep the ejector pressed and turn the lower part 30° to the left or right. Pull the lower part down to cancel the magnetic coupling of the lower part.
3. Open the lower part – fit the pipette key into the lower part.
 - A. Hold the cylinder and unscrew it from the lower part.

Exhibit 7-22. Removing the lower part for the 5 ml pipette



4. The upper part and the piston cannot be disassembled any further.

Reassemble the 5 ml pipette in reverse order. Make sure the magnet on the piston in the lower part is coupled with the magnet on the spindle in the upper part.

A complete list of troubleshooting information is included on pages 62-65 of the *Eppendorf Explorer Plus Manual*. Table 7-3 presents the Eppendorf pipette ordering information.

Table 7-3. Eppendorf pipette ordering information

Item	Size	Part number
Eppendorf Xplorer Plus	5-100 μ l	4861000716
Eppendorf Xplorer Plus	50-1,000 μ l	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	200 μ L	2249-002-8
In Boxes 5 x 96 = 480 tips		
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free	1,000 μ L	2249-006-1
In Boxes 5 x 96 = 480 tips		
Additional accessories		
Spare rechargeable lithium ion battery	1,200 mAh	4861601000

7.7.2 Process the 3-ml and 4-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 and

4-ml EDTA (contain K2 EDTA) tubes for the hematology profile complete blood count (CBC) and the 3-mL and 7-mL (contains K3 EDTA) for certain whole blood tests. Use the 7-ml (age 6+) EDTA tubes for washed packed cells.

Please Note: Never use the 7-mL EDTA tube for CBC's. These tubes contain K3 EDTA and cannot be used for CBC's since the Coulters are calibrated and precision limits are based on using K2 EDTA tubes.

7.7.2.1 Process the 3-ml, 4-ml, and 7-mL EDTA Tube for Lead/Cad/HG/Se/Mn, Cr/Co, RBC Folate, Glycohem, and Mercury

The hematology technologist runs the CBC on the room temperature 3-ml (aged 1-5 years) EDTA tube after the blood-processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad/HG/Se/Mn, RBC Folate, Glycohem, and Mercury. For ages 6+ a 4-mL and a 7-mL EDTA tubes are 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 technologist 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 216 (Cr/Co), vessel 3 (RBC Folate), vessel 4 (Glycohem), or vessel 5 (Mercury). If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad/HG/Se/Mn), vessel 216 (Cr/Co), and 5 (Mercury) was pipetted, do not process these three vessels and add the comment "laboratory error" to vessel 1, vessel 216, and vessel 5.

Note: 3 mL EDTA tubes are not screened for CR/CO. Do Not use the 3 mL EDTA tube for vessel 216 if 4 mL or 7 mL EDTA tubes are not available for the SP.

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 3-ml EDTA tube for CBC.
- Aged 6-11 years
 - Process the 7-mL tube for all whole blood tests, and the washed packed cells (vessel 88, 221, and 222).
 - Process the 4-ml tube for CBC.
- Aged 12-19 years
 - Process the 4-ml tube for the CBC.
 - Process the 7-ml tube for all whole blood tests and washed packed cells (vessel 88, 221, and 222).
- Aged 20+ years
 - Process the 4-ml tube for the CBC.
 - Process the 7-ml tube for all whole blood tests and the washed packed cells (vessels 88, 221, 222).
- Aged 40+ years
 - Process the 4-ml tube for the CBC .
 - Process the 7-ml tube for all whole blood tests and the washed packed cells (vessels 88, 221, 222).

The blood-processing technologist processes the 3-, 4- or 7-ml EDTA tube for the whole blood tests.

- Invert the appropriate EDTA tube several times to remix contents thoroughly.
- Pre-wet pipette tip.
- Refrigerate L-ascorbic acid diluent in between sessions each 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 or 7-ml EDTA tube (dependent upon SP age) into vessel 1 (Lead/Cad/HG/Mn/Se) for primary SPs. Use a sterile 2 ml vessel.

Vessel 216

- Use 3.5 ml disposable transfer pipette to aliquot 1.0 ml whole blood from the 7-ml EDTA tube drawn in phlebotomy into vessel 216 for primary SPs aged 40+. Use a sterile 2 ml vessel.

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% 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 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

- Use 3.5 ml disposable transfer pipette to aliquot 0.4 ml whole blood from the 7-mL EDTA tube into vessel 4 (Glycohem) for primary SPs aged 12+ into a 2-ml vessel.

Vessel 5

- Use 3.5 ml disposable transfer pipettes to aliquot 0.5 ml whole blood from the 3 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 7.8.
 - Store all specimens immediately as outlined in Section 7.9.

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.

7.7.2.2 Process the 7-ml EDTA for Washed Packed Cells for Acrylamide (Vessel 88), Folate Forms (Vessel 221), and Fatty Acids (Vessel 222)

Remove 2.4 ml of whole blood needed for vessels 1-5. 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 to 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

1. Centrifuge the 7-ml EDTA tube at 4-8°C. Centrifuge at 2900 rpm for 10 minutes to separate the plasma from the cells.
2. Use a disposable pipette to remove the plasma and the upper clear layer. There should be approximately 1.8 - 2.2 ml of packed RBCs in the tube.
3. Use the refrigerated squeeze bottle of 0.9 percent saline to add an equal amount (1:1 ratio) to the packed cells.
4. Close vial and mix by gently inverting in order to evenly mix the solution.
5. Centrifuge at 1,985 rpm and 4°C for 5 min.
6. Remove and discard the clear upper layer.
7. Repeat steps 3 thru 6 two more times for a total of 3 wash cycles.
8. 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.
9. Close vial and gently invert tube 8-10 times without rupturing cells. Ensure that the solution is homogenous.
10. Transfer 1.5 ml of the homogenous solution to a 2-ml cryovial for vessel 88. Add 1mL 1% 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 7.8.
- C. Store all specimens immediately as outlined in Section 7.9.

Refer to Exhibit 7-23 for the procedure for washed RBCs visual aid.

7.7.3 Process the 2-ml Gray Tube for Glucose

Centrifuge and separate the plasma from the 2-ml gray top tube within 30 minutes from the time the blood was collected. 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.

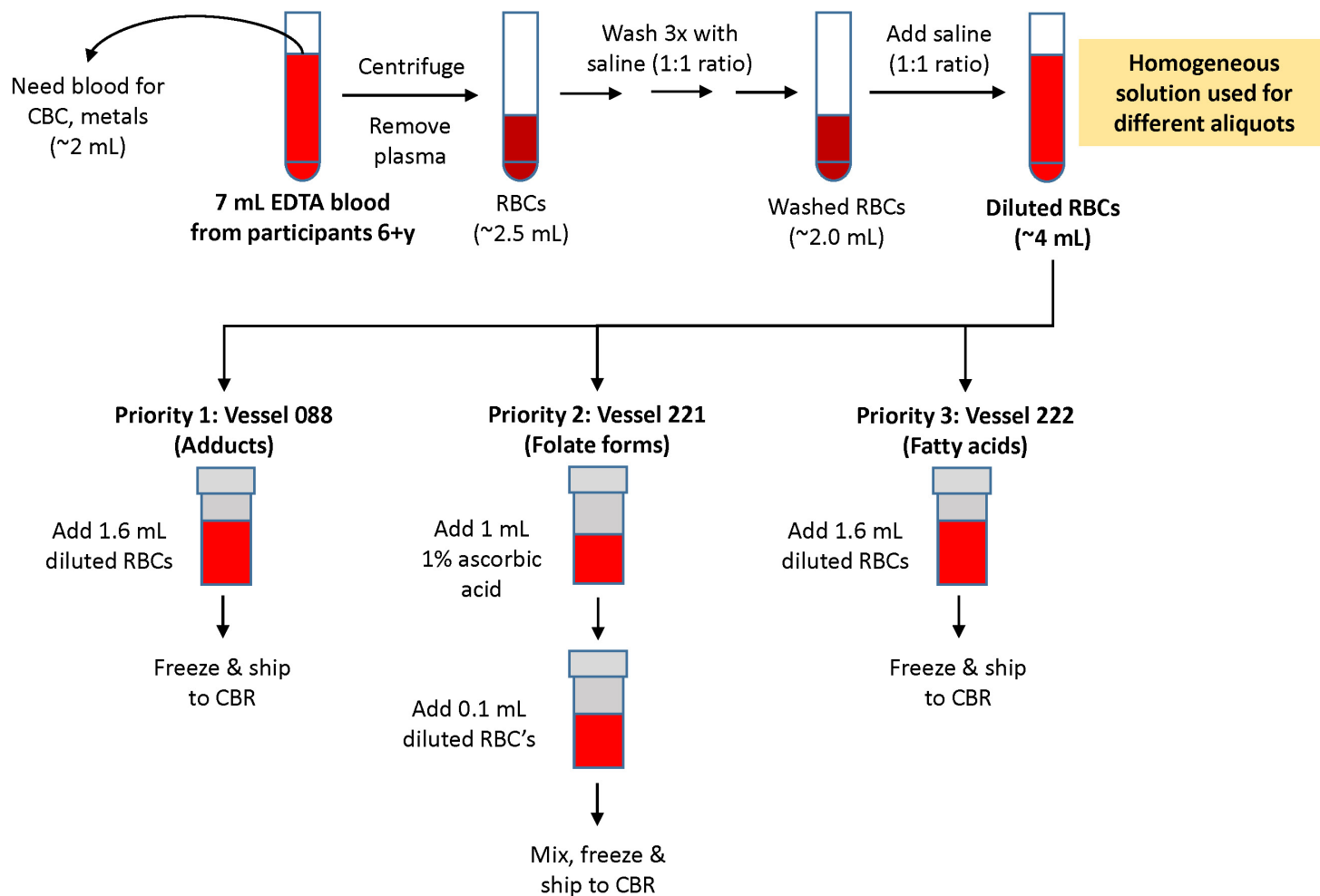
- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 2-ml gray tube at 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (glucose).
- Use a 3.5 ml disposable plastic transfer pipette to transfer all plasma from this tube but at least 0.5 ml plasma for vessel 9 (glucose) on primary SPs aged 12+ into a 2-ml vessel.
 - Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
 - Close all vessels securely to prevent leakage and evaporation.
 - Record results using the Blood Processing module.
 - Store all specimens immediately.

7.7.4 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 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 4-8°C and 2,900 rpm for 15 minutes to yield serum.

Exhibit 7-23. RBC washing procedure (visual aid)

NHANES MEC Procedure for Washed RBCs



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 dropdown 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 dropdown 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.**

If the serum in all red top tubes for a SP is turbid, lipemic, or icteric, pool it and allocate as usual.

Vessels 110, 138, 99, 122, 229, 87, 17, 21, 11, 18, 23, 13, 22, 24, 29, 90, and 32-37

- Use a serum separator to remove serum from all the red top tubes by pushing the separator to the clot barrier gently 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 7.3. Exhibits 7-7 to 7-12 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+ into a 2-ml vessel. Pre-wet the pipette tips. Add 50 µl of the 7% 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 7.8.
 - Store all specimens immediately as outlined in Section 7.9.
 - If the serum cannot be aliquoted immediately, refrigerate it at 4°C for no more than 4 hours.

7.7.5 Ascorbic Acid Processing and Preparation

The CDC supplies premeasured powder to make a 1% ascorbic acid (AA) solution for vessel 3 (RBC Folate) and a premeasured powder to make a 7 percent AA solution for vessel 110 (Folate1). 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% ascorbic acid for vessel 3 (RBC Folate) and rinse the pipette tip. Add 0.05 ml of the 7% AA to vessel 110, then add 0.7 ml of serum. Rinse the pipette. Mix both vessels by gentle inversion.




- The 1% 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.

7.7.6 TB Blood Processing

QuantiFERON-TB Gold Plus (QFT-Plus) is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of interferon- γ (IFN- γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to these peptides that are associated with *Mycobacterium tuberculosis* infection.

Sample preparation requires the use of vendor supplied 4- 1mL antigen coated tubes and an incubation period of 16-24 hrs at 37°C.

- Workstation 1 is responsible for incubating and processing the TB blood tubes. After the blood has been collected in phlebotomy, store and batch the TB blood In-Tubes at room temperature until the end of the day. Room temperature must be between 17 and 25° C. The Thermo Heratherm IMC18 portable incubator has a temperature setting range of 17° C to 40° C. This incubator works with 12V DC power and also AC/DC power with the included adaptor.

- Connect the incubator to power a source and push the  button to turn the incubator ON. Push the   button to select the desired temperature. The unit may take up to 2 hours to equilibrate to 37° C. This unit will be monitored and documented each session in the Quality Control record under Daily QC. The acceptable temperature range has been set to 37° C +/- 1° C. A 24 hour digital timer on the power strip will be used with this unit to shut the unit off after the 16-hour incubation period has elapsed.



- Record the temperature of the incubator at the start of each session. To record the temperature, access (click) the quality control menu to show the drop down menu. Select quality control and then the daily tab. Record the temperature for the incubator. The acceptable range is (36-38 ° C).

The screenshot shows a software window titled "Lab Shipping" with several tabs: "Start of Stand", "Daily", "Weekly", "End of Stand", "Yearly", "Supply Use", and "NCHS QC". The "Daily" tab is selected. Below the tabs is a table for "QC Check" with columns for "QC Check", "Done", "Result", and "Comment".

QC Check	Done	Result	Comment
Osmette Dropper Urine Chemistry Control 2	<input type="checkbox"/>	(yes/no)	
1% Ascorbic acid	<input type="checkbox"/>	(yes/no)	
7% Ascorbic acid	<input type="checkbox"/>	(yes/no)	
Incubator temperature reading (36 to 38 °C)	<input type="checkbox"/>	degrees C	

At the bottom right of the window are "OK" and "Cancel" buttons.

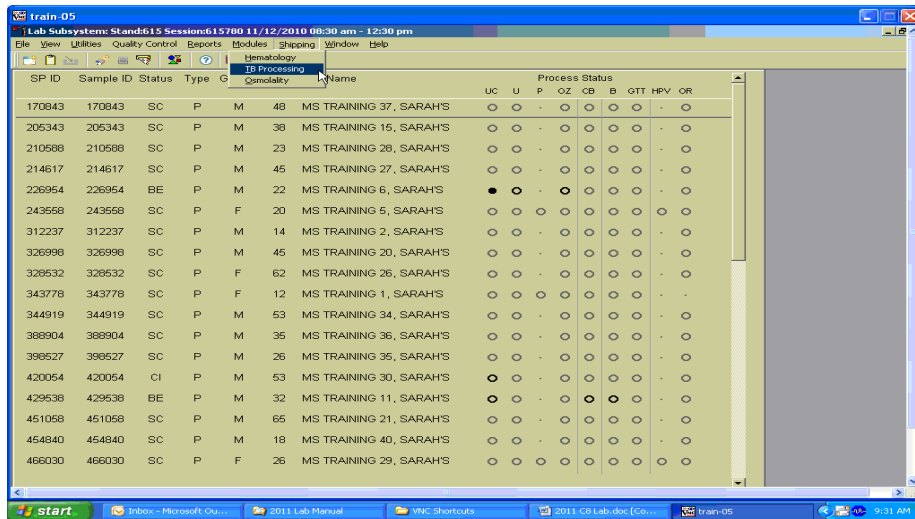
- Use digital the display to set only one program on one day for a 16 hour incubation period. Turn on the incubator 1-2 hours prior to incubation. Mix the TB blood tubes prior to incubation. Invert the tubes approximately ten times just firmly enough to make sure the entire inner surface of the tube is coated with blood. This ensures that the antigen present in the tube is dissolved off the walls of the tube. Over vigorous shaking may cause gel disruption and could lead to aberrant results.

Note: TB blood tubes must be incubated within 16 hours of collection. Prior to incubation maintain tubes at room temperature (17-25°C).

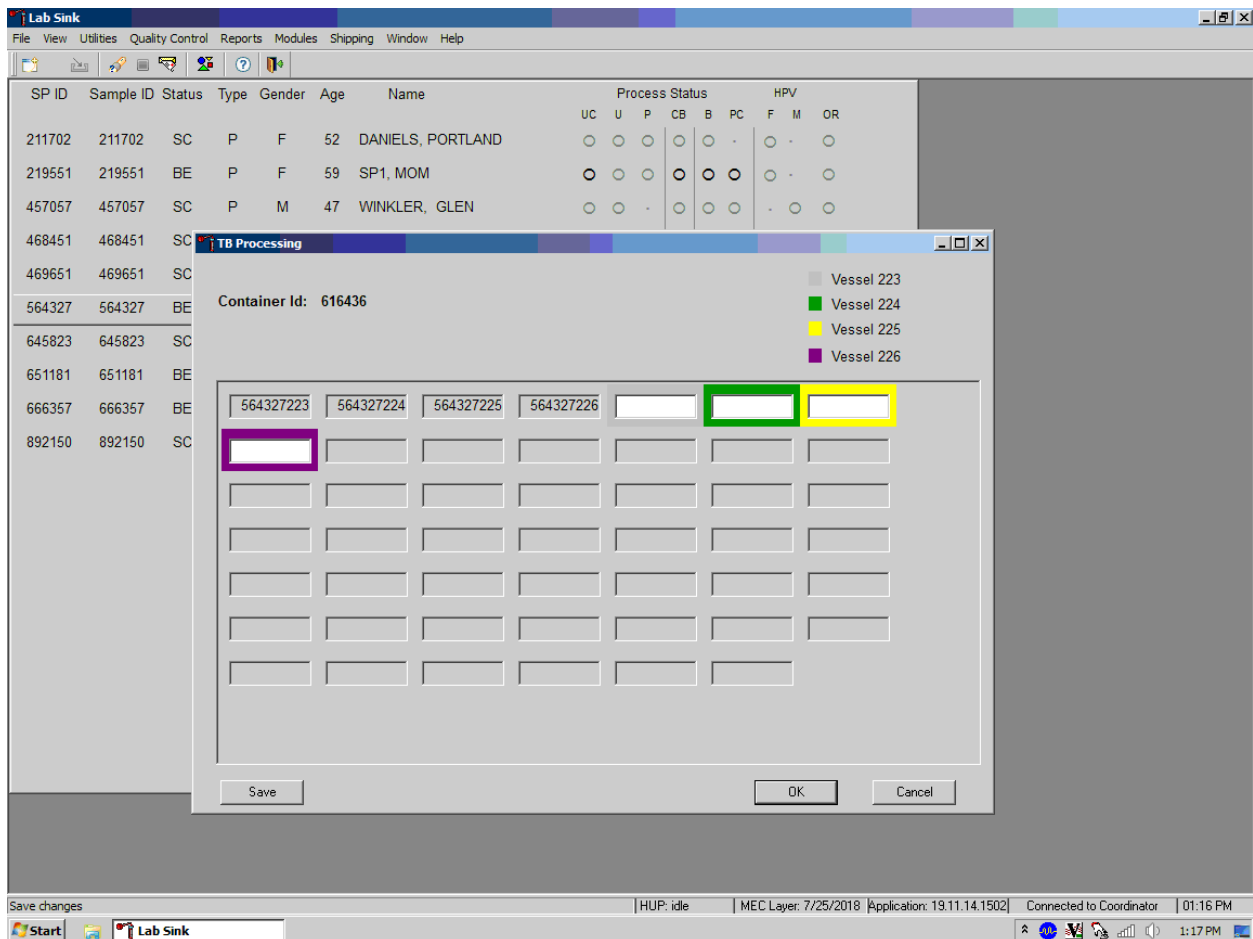
- Incubate TB blood tubes upright for **16 to 24** hours at 37° C. To allow the air to flow effectively, the tube racks should be placed lengthways (front to back) inside the incubator. Place racks in between the guides in the base of the unit. Prior to incubation, ensure that the incubator lid is secured.
- After the incubation period, centrifuge the tubes for 15 minutes at 2000-3000 RCF (g) at a temperature of 4-8°C. The gel plug will separate the cells from the plasma. If separation does not occur, the tubes should be re-centrifuged.

Note: Plasma samples can be stored in centrifuged QFT-Plus blood collection tubes for up to 28 days at 2°C to 8°C. A minimum of 150 µL of plasma is needed for each tube.

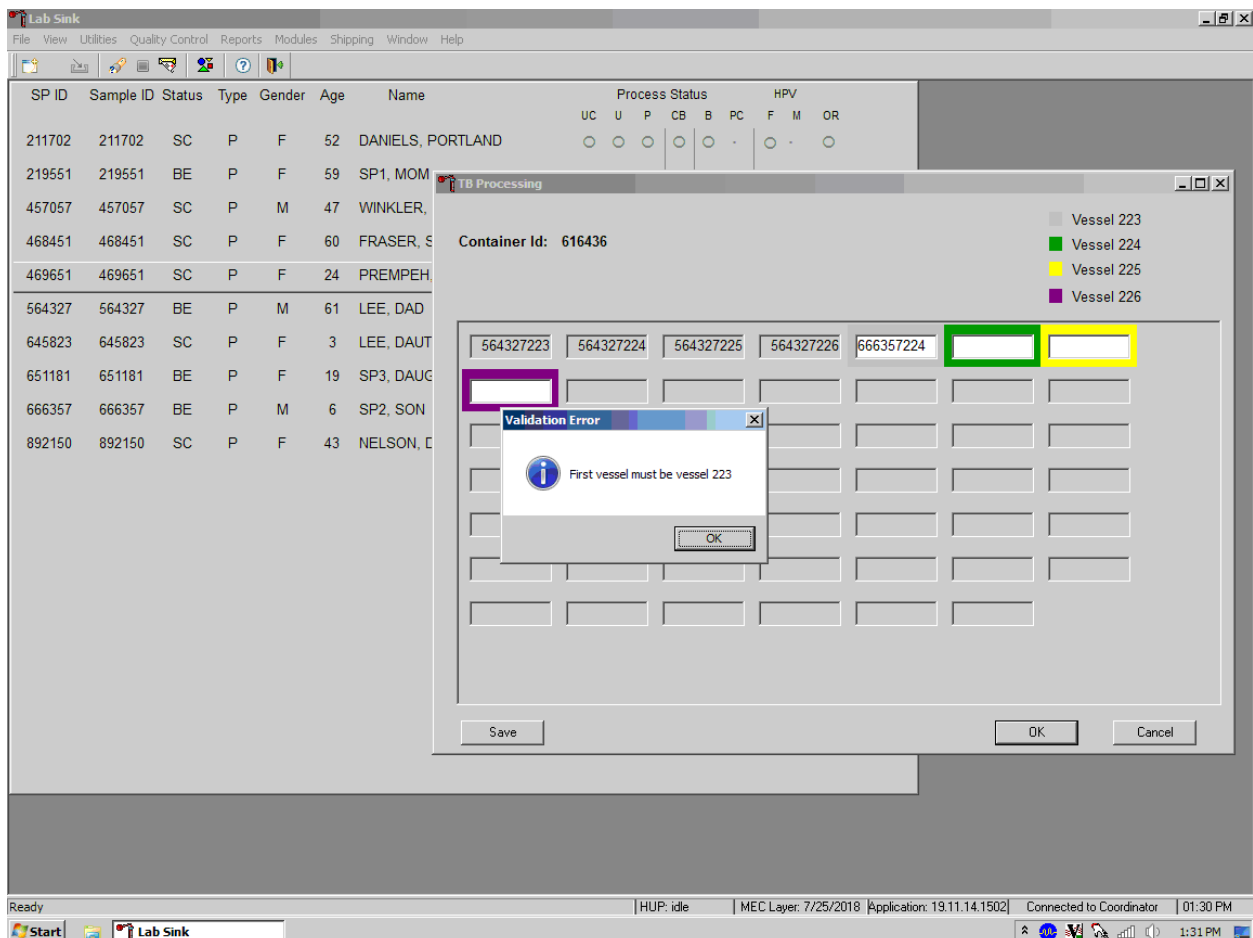
- Immediately after centrifugation, assign the QFT blood tubes to a container by using the TB Processing module located under Modules on the heads up display. Assign all TB blood tubes container slots and store refrigerated at 2-8° C.



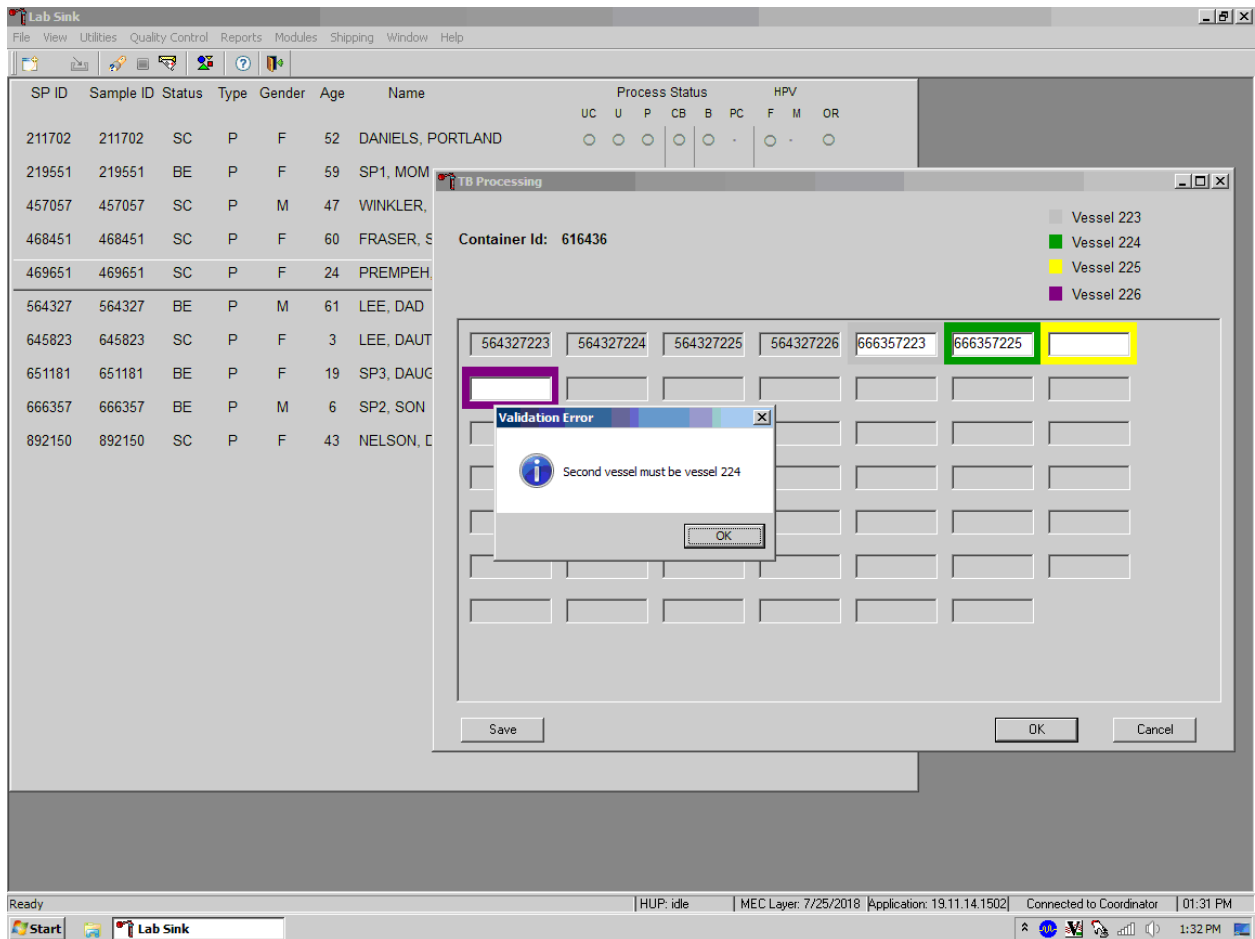
- The TB processing module, which is a container map of the 7x7 box used for TB storage and shipping, displays the container ID and a color code, where gray represents the gray tube or vessel 223, green represents the green tube or vessel 224, purple represents the purple tube or vessel 226, and yellow represents the yellow tube or vessel 225.



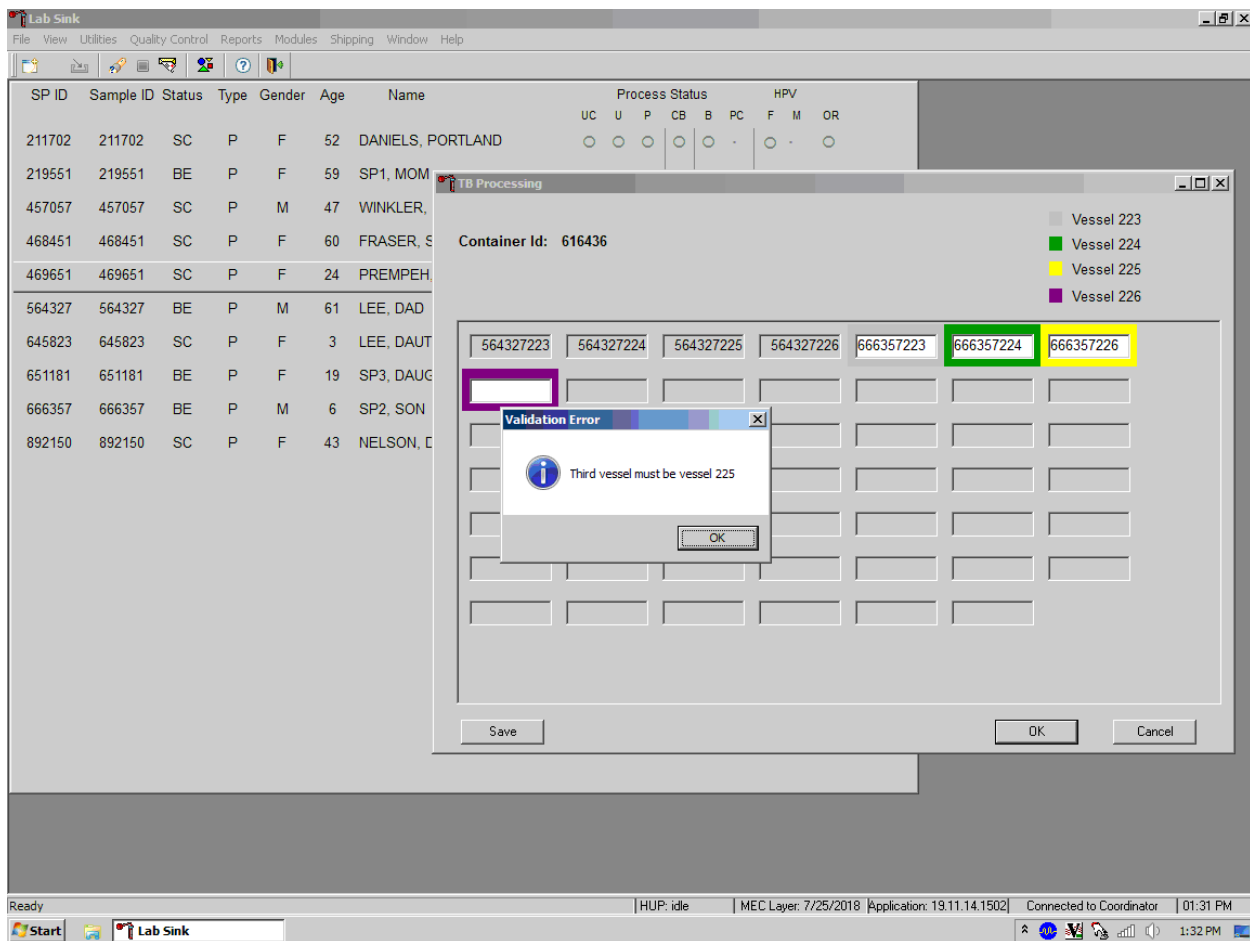
- To save currently scanned tubes, the save button must be clicked before exiting the TB processing module. If you accidentally exit without clicking the save button your work will be lost and you will need to re-scan the tubes. If only one or two tubes are scanned for a SP and the save button is clicked, a validation error will be displayed.
- The TB Processing module requires that the tubes are scanned in order according to the color prompts located on the container map. If the tubes are scanned in the wrong order or if a different SPs label is scanned prior to completing the sequence of the four tubes, an error will be displayed on the screen. If any other vessel, such as 224, 225 or 226 is scanned in the first position (gray) a validation error will be displayed. This error states, "First vessel must be vessel 223."



If any tube other than vessel 224, such as 223, 225 or 226 is scanned into the second position (green) a validation error will be displayed. This error states, "Second vessel must be vessel 224."

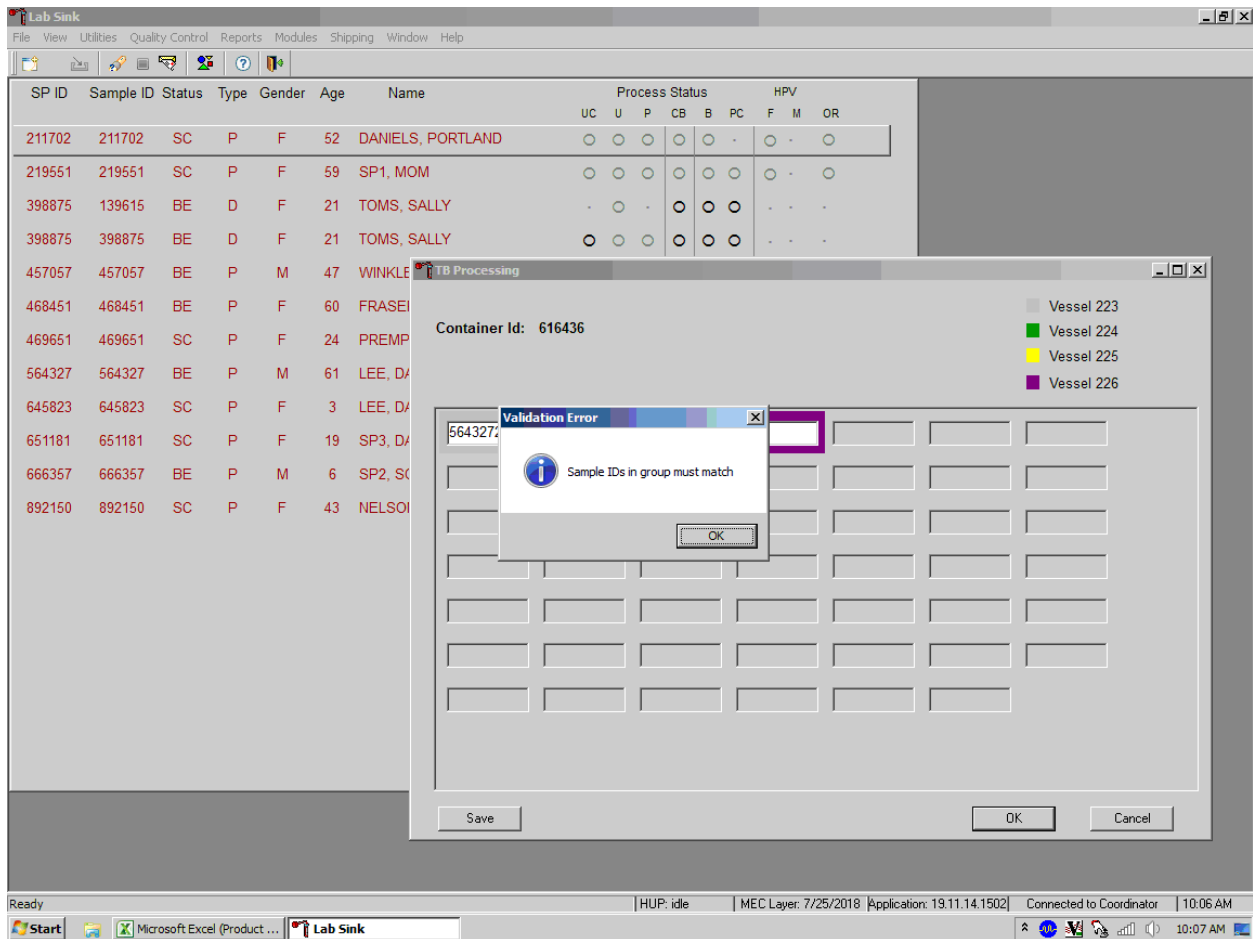


If any tube other than vessel 225, such as 223, 224 or 226 is scanned into the third position (yellow) a validation error will be displayed. This error states, "Third vessel must be vessel 225."

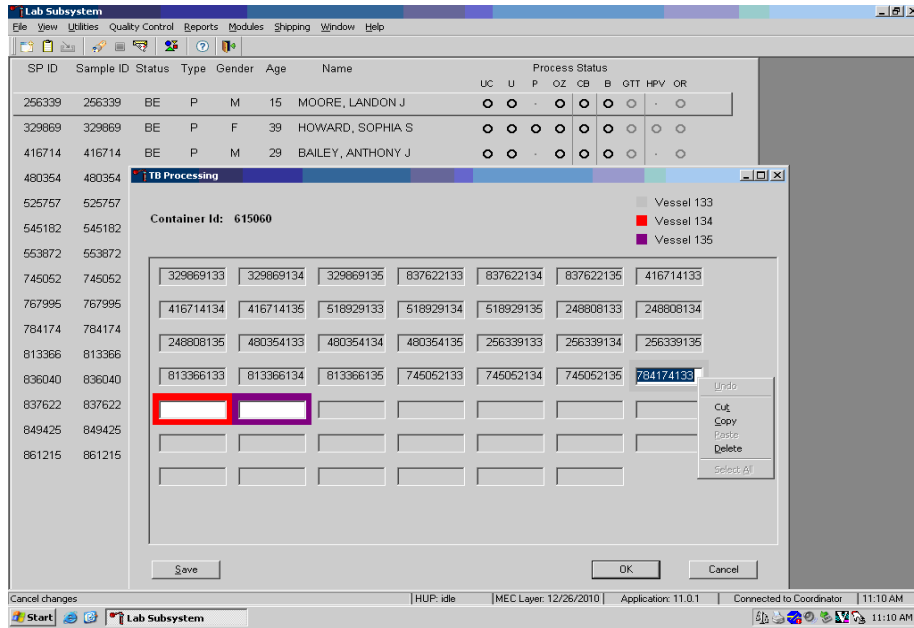


If any tube other than vessel 226, such as 223, 224 or 225 is scanned into the fourth position (purple) a validation error will be displayed. This error states, "Fourth vessel must be vessel 226."

If a different SP is scanned prior to completing the sequence of four for one SP, a validation error will be displayed. This error states, "Sample IDs in group must match."



If a Sample ID was scanned in error and it needs to be removed, double click the ID you want to delete so it is highlighted. Right click to bring up a menu that contains the following options: cut, copy, and delete. Click on delete to remove the highlighted sample ID.

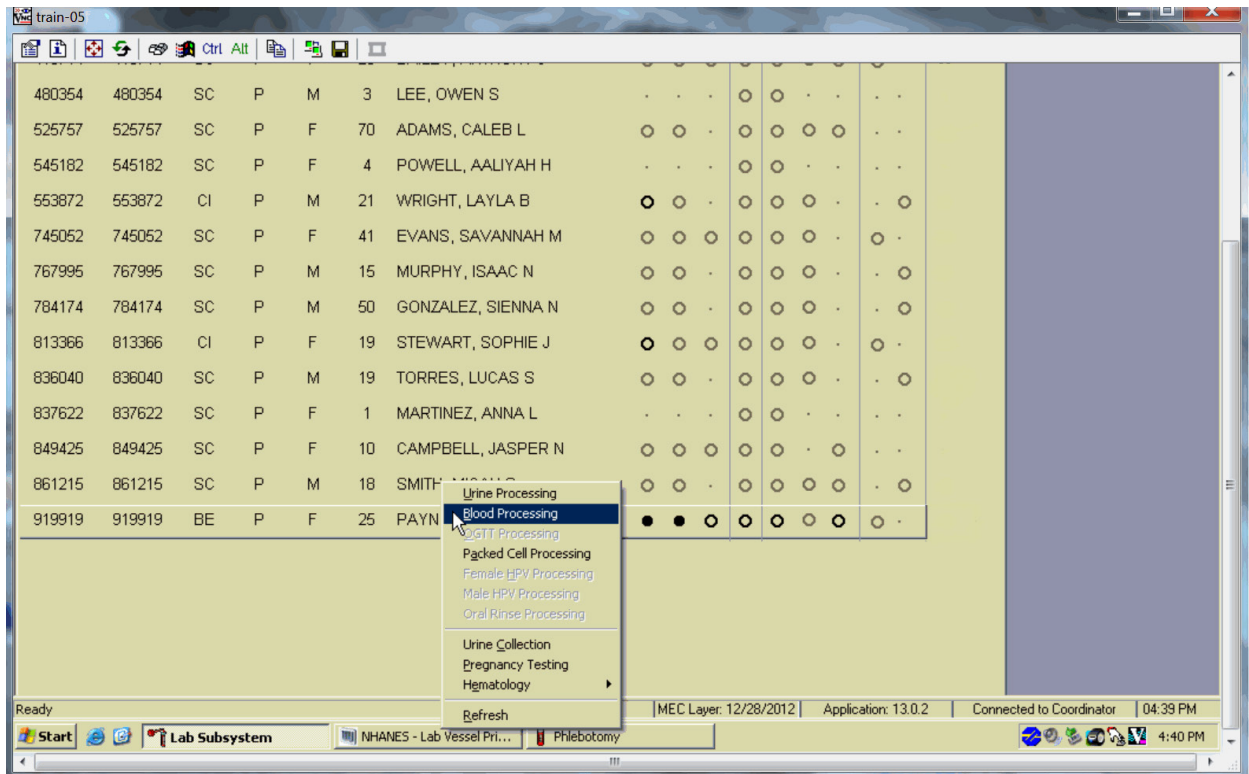


7.8 Record the Results of Specimen Processing

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 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.



If labels have not been printed in advance, the SPs will show up in a red font on the heads-up display. To access the Blood Processing module, highlight the SP, right-click, drag the mouse arrow to Blood Processing.

The SP's blood processing screen displays.

BP: 919919
B processing

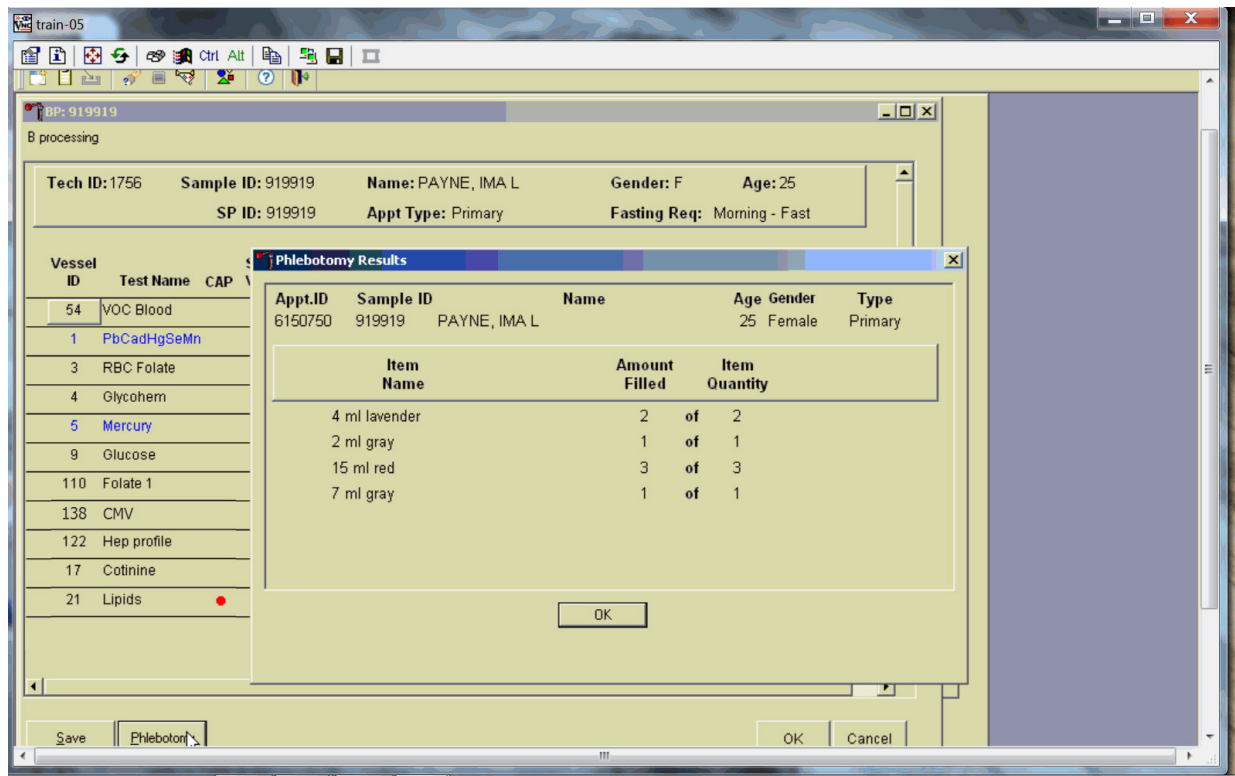
Tech ID: 1756 Sample ID: 919919 Name: PAYNE, IMA L Gender: F Age: 25
 SP ID: 919919 Appt Type: Primary Fasting Req: Morning - Fast

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
54	VOC Blood		7.0	VW	7 ml	gray top	<input type="radio"/> Yes <input type="radio"/> No			
1	PbCdHgSeMn		0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
3	RBC Folate		0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
4	Glycohem		0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
5	Mercury		0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
9	Glucose		0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
110	Folate 1		0.7	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
138	CMV		0.4	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
122	Hep profile		1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
17	Cotinine		1.8	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
21	Lipids	●	1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			

Buttons: Save, Phlebotomy, OK, Cancel

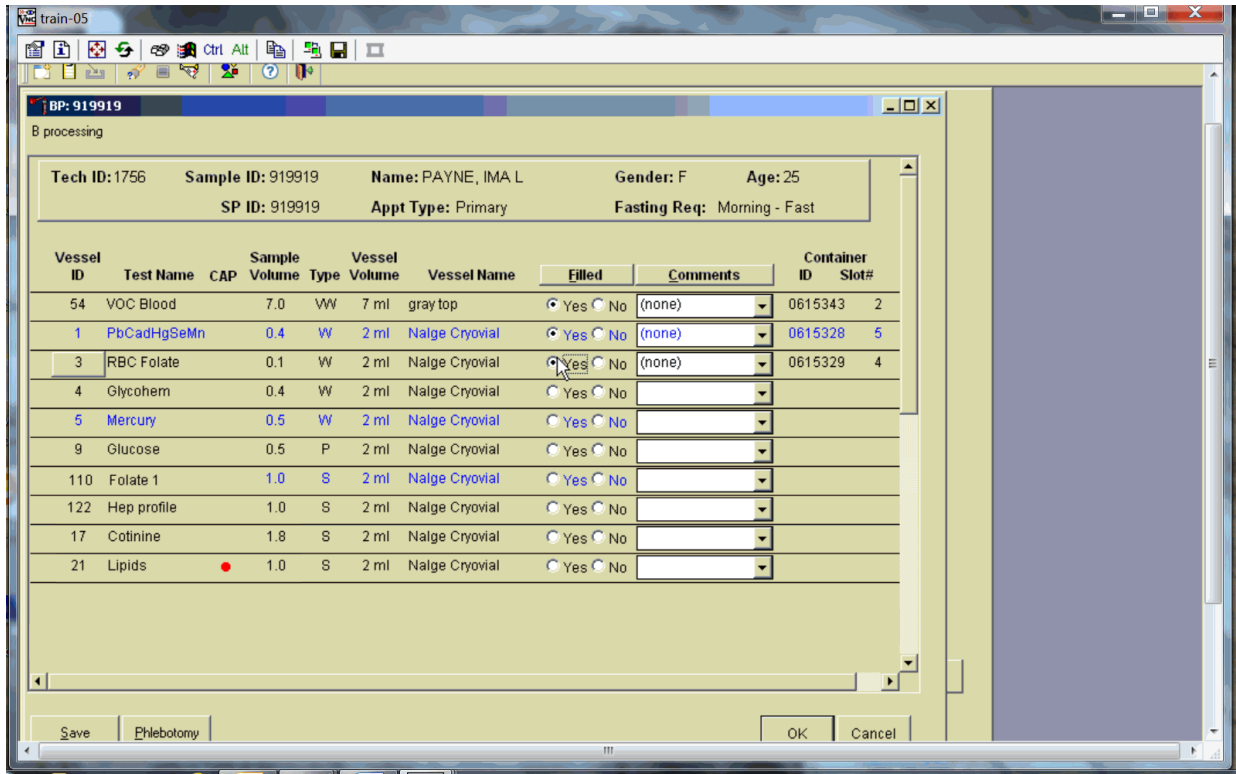
The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, Columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum), Vessel Volume, Vessel Name, Filled Radio Buttons, 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.



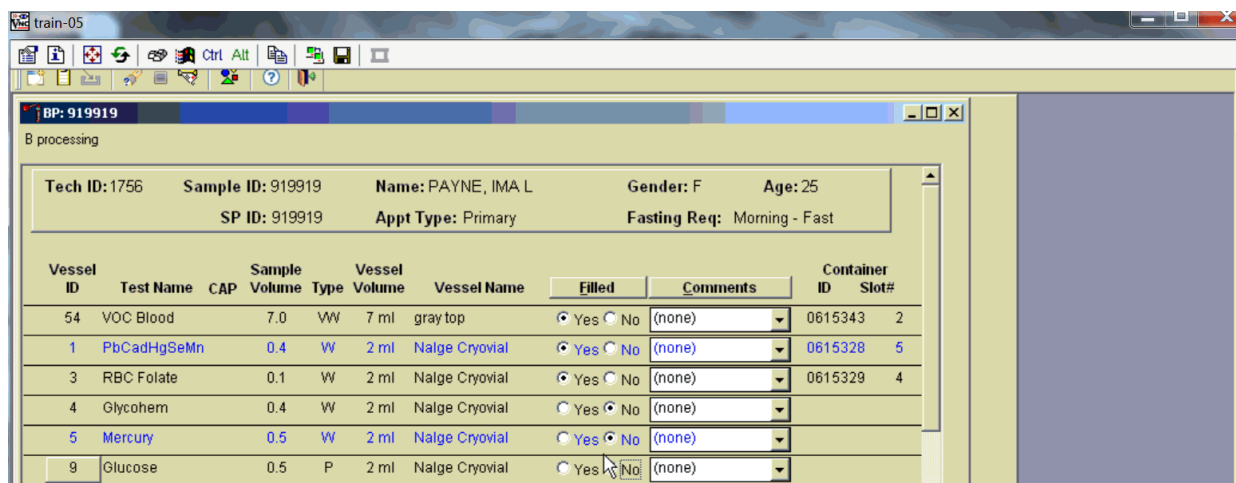
To review the phlebotomy results, use the mouse to direct the mouse arrow to the Phlebotomy button on the blood processing screen and left-click. The phlebotomy protocol and number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the OK button and left-click.

Record blood processing results for each SP. Individually mark each vessel as Filled–Yes.



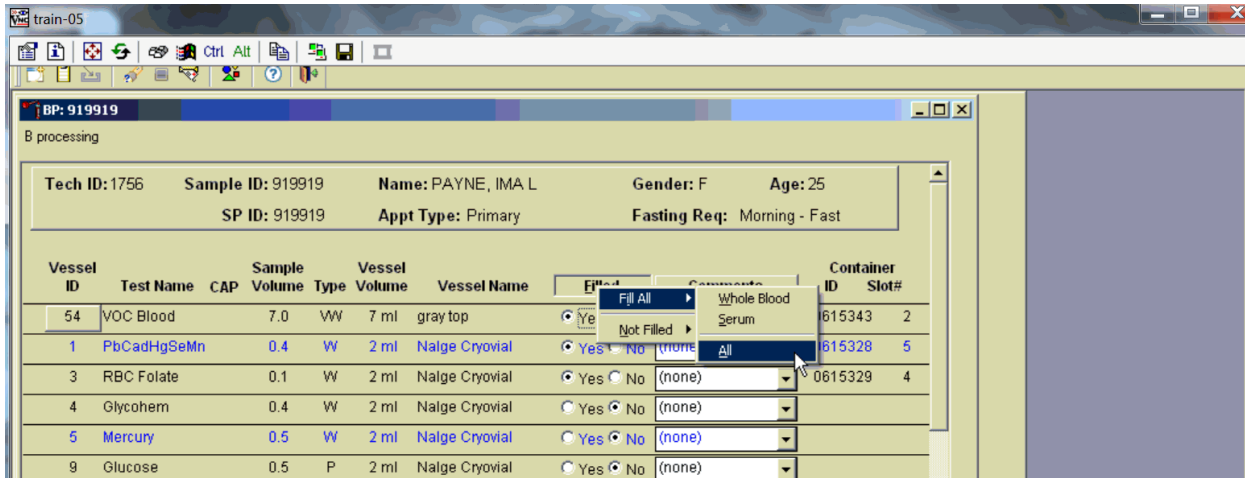
To mark an individual blood vessel as collected or Filled–Yes, use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left-click. As each vessel is marked as Filled–Yes, it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled–No.

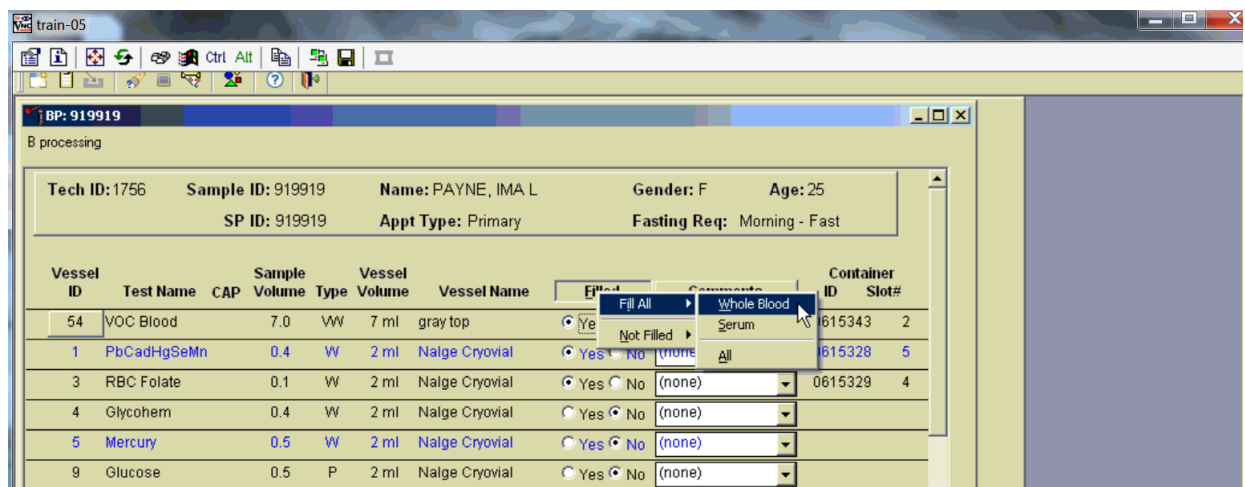


To mark an individual blood vessel as not collected or Filled–No, use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. Vessels marked as “No” require a comment.

Collectively mark all vessels as Filled–Yes.



To collectively mark all vessels as Filled–Yes, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left-click, 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.



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,

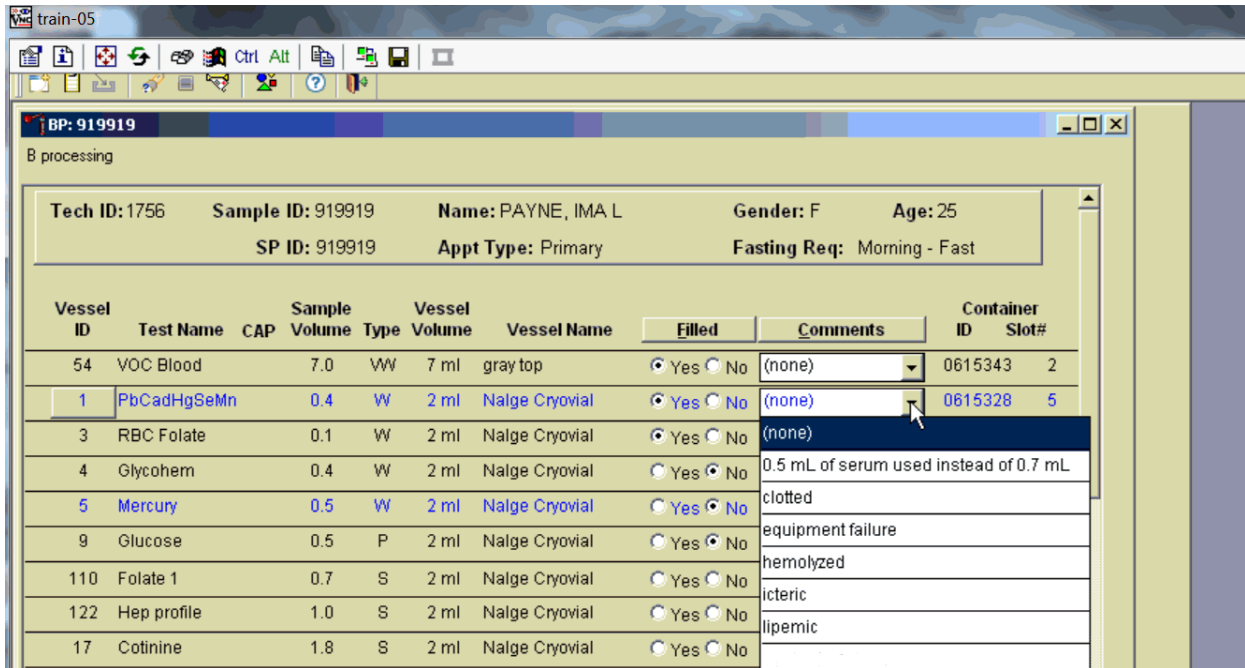
direct the mouse arrow to the Filled button on the top of the radio buttons, left-click, drag the arrow to Fill All, drag the mouse arrow to Serum, and left-click. As each vessel is marked as Filled, it is automatically assigned to a slot in an existing (open) container.

Quality comment codes are available to describe the quality of the specimen (Exhibit 7-24).

Exhibit 7-24. Quality comment codes

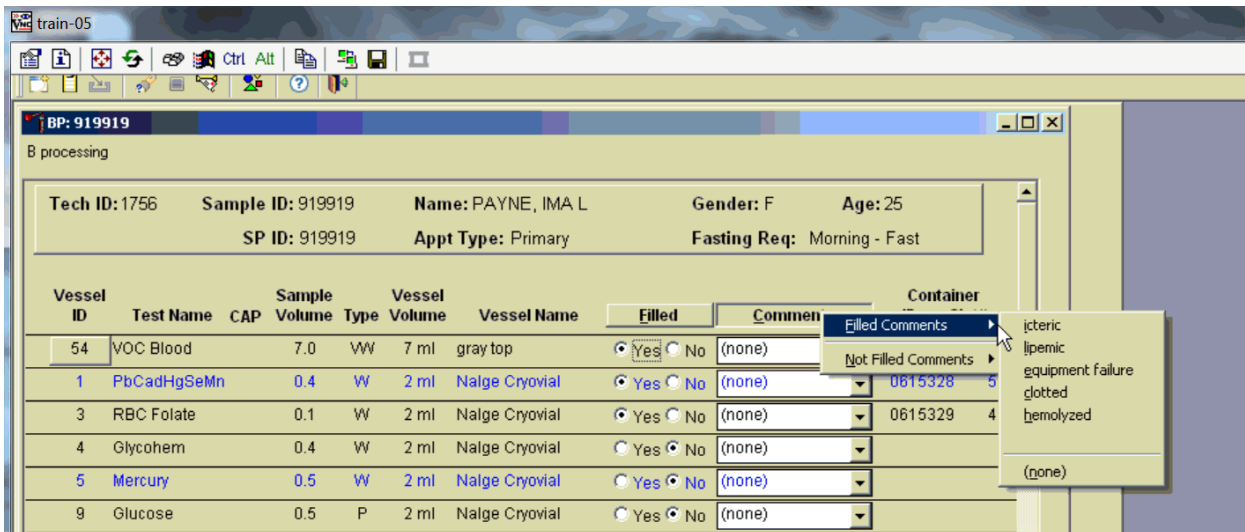
Comment for filled vessels	Use when:
Clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
Equipment failure	Pipettes are malfunctioning.
Hemolyzed	There is a red appearance to the serum or plasma. "Hemolysis" refers to the abnormal lysis 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.

Attach a comment to an individual-filled vessel.



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 7-25).

Exhibit 7-25. 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.

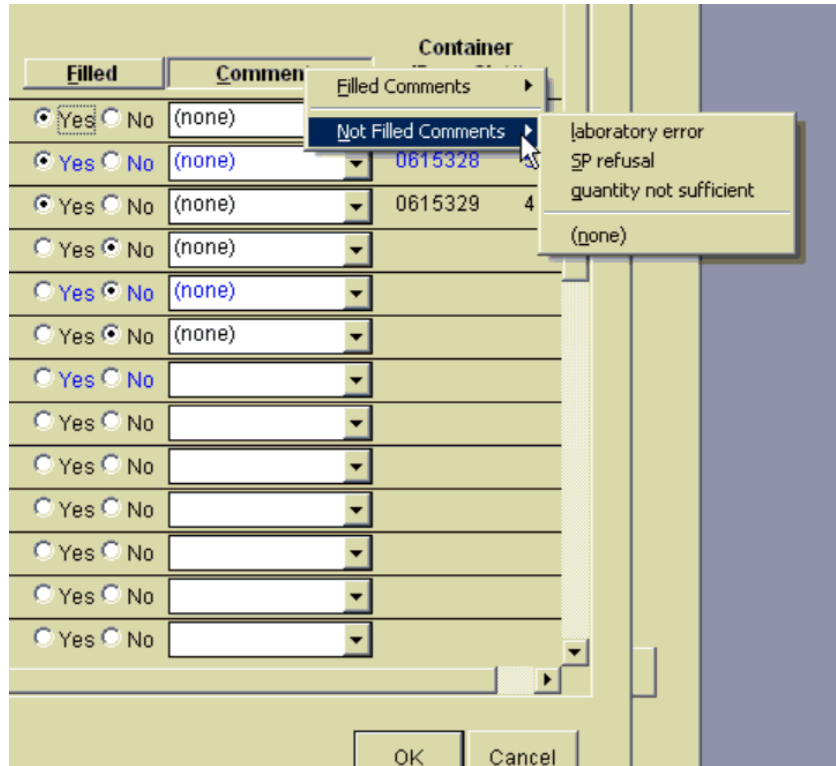
Attach a comment to an individual Filled–No vessel.

Filled	Comments	Container ID	Slot#
<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0615343	2
<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0615328	5
<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)	0615329	4
<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
<input type="radio"/> Yes <input checked="" type="radio"/> No	laboratory error		
<input type="radio"/> Yes <input checked="" type="radio"/> No	quantity not sufficient		
<input type="radio"/> Yes <input checked="" type="radio"/> No	SP refusal		
<input type="radio"/> Yes <input checked="" type="radio"/> No			
<input type="radio"/> Yes <input checked="" type="radio"/> No			
<input type="radio"/> Yes <input checked="" type="radio"/> No			
<input type="radio"/> Yes <input checked="" type="radio"/> No			

OK Cancel

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 216 (Cr/Co), vessel 3 (RBC Folate), vessel 4 (Glycohem), or vessel 5 (Mercury).

Continue to enter results as vessels are processed. Review the information in the blood processing window and save the data to the database.

Filled		Comments	Container ID	Slot#
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615343	2
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615328	5
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615329	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615330	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615331	3
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615332	5
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615355	3
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615351	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615345	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615352	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615334	4
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615336	6
<input checked="" type="radio"/> Yes	<input type="radio"/> No	(none)	0615346	2

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.

7.9 Blood Specimen Storage

7.9.1 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 7-26.

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 7-26. Storage protocol for blood

Shipping location	Vessels	Conditions	Vessel storage	Ship frequency
CDC/NCEH Air Toxicant Branch	54 VOC Blood	Refrigerated	5 x 5 five-inch foam box	Weekly
CBR	1 Lead/Cad/HG/ Se/Mn	Frozen	9 x 9 two-inch box	Weekly
CBR/	216 Cr/Co	Frozen	9 x 9 two-inch box	Weekly
CBR	3 RBC Folate	Frozen	10 x 10 two-inch box	Weekly
University of Missouri	4 Glycohem	Refrigerated	9 x 9 two-inch box	Weekly
CBR	5 Mercury, Ethyl & Methyl	Frozen	9 x 9 two-inch 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
Univ. of Washington Virology Lab	223, 224, 225, 226 TB (QuantIFERON-TB Gold Plus)	Refrigerated	7x7 3 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
CBR	110 Folate	Frozen	10 x 10 two-inch box	Weekly
CDC/NCIRD CMV Diagnostic Laboratory	138 CMV	Frozen	9 x 9 two-inch box	Monthly
University of Minnesota (ARDL)	118 Thyroid Panel	Frozen	9 x 9 two-inch box	Weekly
CBR	99 Ferritin/Transferrin Receptor	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab	122 Hep Profile	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab	TBD Hep Xtra sera	Frozen	9 x 9 two-inch box	Weekly
CDC/NCID Hepatitis Ref Lab	87 Hepatitis ab	Frozen	9 x 9 two-inch box	Weekly
CBR	17 Cotinine	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL)	21 Lipids	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL)	11 Iron/TIBC/% Saturation	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL)	18 Biochem	Refrigerated	9 x 9 two-inch box	Weekly
University of Missouri (ARDL)	23 Insulin	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota	13 CRP	Frozen	9 x 9 two-inch box	Weekly
CDC NCID AIDS Division	22 HIV	Frozen	9 x 9 two-inch box	Weekly

Exhibit 7-26. Storage protocol for blood (continued)

Shipping location	Vessels	Conditions	Vessel storage	Ship frequency
Emory University	24 HSV	Frozen	9 x 9 two-inch box	Weekly
CBR	137 Steroid Hormones	Frozen	9 x 9 three-inch box	Weekly
CBR	29 Dioxin 1	Frozen	4 x 4 5 ¹ / ₂ inch box	Full box/End of stand
CBR	90 Perfluor	Frozen	9 x 9 two-inch box	Full box/End of stand
CBR	32-37 Xtra Sera	Frozen	9 x 9 two-inch box	Full box/End of stand

7.10 How to Deal with System Failure

If the computer system fails, record results on a preprinted workstation 2 processing worksheet (Exhibit 7-27). Complete a Blood Processing worksheet for each SP while processing the blood specimens. Enter the results after the system is operational.

Exhibit 7-27. Workstation 2 processing worksheet

BLOOD PROCESSING

SP ID _____

ID	Name	Ages	Sample ml	Sample type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i>	Not Filled Comments <i>QNS SP</i> <i>Refusal Lab Error</i>	Slot #
54	VOC Blood	12+	7.0	WB				
1	Lead/Cad/HG/Se/Mn	1+	0.4	WB				
216	Co/Cr	40+	1.0	WB				
3	RBC Folate	1+	0.1	WB				
4	Glycohem	12+	0.4	WB				
5	Mercury, Ethyl, & Methyl	1+	0.5	WB				
88	Acrylamide	6+	1.5	PC				
221	RBC Folate Forms	6+	0.1	PC				
222	Fatty Acids	6+	1.6	PC				
223, 224, 225, 226	TB (QuantiFERON-TB Gold Plus)	Foreign born and 60+	4.0 (1mL per tube)	WB				
119	Genetics	18+	6.0	WB				
9	Glucose	12+	0.5	P				
110	Folate	1+	0.7	S				
138	CMV	1-5	0.4	S				
118	Thyroid Panel	3-5 6+	1.0	S				
99	Ferritin/Tfr	1-5 12-49	0.3 0.4	S				
122	Hep Profile	6+	1.8	S				
229	Hep Xtra sera	6+	1.8	S				
87	Hepatitis Bs Ab	2 3-5	0.3 0.5	S				

Exhibit 7-27. Workstation 2 processing worksheet (continued)

BLOOD PROCESSING

SP ID _____

ID	Name	Ages	Sample ml	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i>	Not Filled		Slot #
							Comments	<i>QNS SP</i> <i>Refusal Lab Error</i>	
17	Cotinine	3-5	0.8	S					
		6-11	1.0						
		12+	1.8						
21	Lipids	6-11	0.5	S					
		12+	1.0						
11	Iron/TIBC/% Saturation	12+	0.5	S					
18	Biochem	12+	0.8	S					
23	Insulin	12+	0.5	S					
13	CRP	1+	0.3	S					
22	HIV	18-59	1.0	S					
24	HSV	14-49	0.2	S					
137	Steroid Hormones	6+	3.5	S					
90	Perfluor	3-5	1.5	S					
		6+							
29	POP/DOX	12+	15.0	S					
90	Perfluor1	6+	1.5	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 PC = Packed cells
P = Plasma S = Serum

THIS PAGE IS INTENTIONALLY LEFT BLANK.

8. Printing Labels and Specimen Shipment

8.1 Introduction

Labels are essential to the laboratory component. Labels support each study participant's (SP's) unique processing protocol. The laboratory record is created when the medical 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 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 Blood and urine shipping protocol, illustrates the specifications for the shipment of blood and urine specimens to each contract laboratory.

Exhibit 8-1. Blood and urine shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Whole blood				
CDC/NCEH Tobacco & 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	Cr/Co Vessel 216	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	RBC Folate Vessel 3	Frozen	10 x 10 two-inch box	Weekly
University of Missouri Lab 10	Glycohem Vessel 4	Refrigerated	9 x 9 two-inch box	Weekly
CBR Lab 6	Mercury, Ethyl and Methyl Vessel 5	Frozen	9 x 9 two-inch box	Weekly
University of Washington Virology Lab Lab 115	TB Vessel 223, 224, 225, 226	Refrigerated	7 x 7 three-inch	Weekly
ATCC Bethesda Maryland Lab 123	Genetics Vessel 119	Refrigerated	5 x 5 five-inch box with foam insert	Twice Weekly

Exhibit 8-1. Blood and urine 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
EDTA Washed packed cells				
CBR Lab 6	Acrylamide Vessel 88	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	RBC Folate Forms (all) Vessel 221	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Fatty Acid Vessel 222	Frozen	9 x 9 two-inch box	Weekly
Serum				
CBR Lab 6	Folate Vessel 110	Frozen	10 x 10 two-inch box	Weekly
CDC/NCIRD Cytomegalovirus Diagnostic Lab Lab 116	CMV Vessel 138	Frozen	9 x 9 two-inch box	Monthly
University of Minnesota (ARDL) Lab 51	Thyroid Panel Vessel 118	Frozen	9 x 9 two-inch box	Weekly
CBR Lab 6	Ferritin/TfR Vessel 99	Frozen	9 x 9 two-inch box	Weekly
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 TBD	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
CBR Lab 6	Cotinine Vessel 17	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL) Lab 51	Lipids Vessel 21	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL) Lab 51	Iron/TIBC/%Saturation Vessel 11	Frozen	9 x 9 two-inch box	Weekly
University of Minnesota (ARDL) Lab 51	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
University of Minnesota (ARDL) Lab 51	CRP Vessel 13	Frozen	9 x 9 two-inch box	Weekly
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
CBR Lab 6	Steroid Hormones Vessel 137	Frozen	9 x 9 three-inch box	Weekly

Exhibit 8-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Serum (continued)				
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	4x4-5.5 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				
University of Minnesota Lab 16	Alb/Creat Vessel 45	Frozen	9 x 9 three-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 three-inch box	Full or end of stand
CBR Lab 6	Phthalates Vessel 67	Frozen	5 x 5 three-inch box	Full or end of stand
CBR Lab 6	Perchlorate/VOC/ Thiocyanate 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	Weekly
CBR Lab 6	Nicotine Analogs Vessel 152	Frozen	9 x 9 three-inch box	Weekly
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
Additional Testing				
CDC Human Papillomavirus Lab 37	HPV Swab Female Vessel 78	RT	9 x 12 Ziplock Bag	Weekly
CDC Human Papillomavirus Lab 37	HPV Swab Male Vessel 140	Refrigerate d	9 x 12 Ziplock Bag	Weekly

Exhibit 8-1. Blood and urine shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Additional Testing (continued)				
CDC Human Papillomavirus Lab Lab 37	HPV Oral Rinse Vessel 37	Refrigerated	5 x 5 five-inch box with foam insert	Weekly
CDC Biorepository (CBR)	Fluoride, water Vessel 6	Refrigerated	5 x 5 three-inch box	Weekly
CDC Biorepository (CBR)	Salt Samples Vessel 227 and 228	Room Temp	10x10 three-inch box	Weekly

Packages are shipped using FedEx. The medical technologist 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 medical technologist’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 medical technologist 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 is required, and the expected time the dry should be delivered for shipping.

The home office Laboratory Component Lead determines the exact days to ship specimens to the contract laboratories. As a rule, most specimens are packed and shipped once a week during the MEC split examination sessions. Hold the containers for vessels 32-37, 29, 90, 48, 49, 66, 67, 102, 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 Lab 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 x16 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	5.25 x 5.25 x 3.0 inch box with 7 x 7 grid
30 mL ENV vials	4x4 5.5 inch box
5.25 x 5.25 x 3.0 inch cardboard box with 5x5 grid	10 x 10 three-inch box
10 x 10 two-inch box	
STP-710 Packaging System	U-tek Reusable Refrigerant Packs Large
STP-730 Packaging System	Rubber bands
Plastic bag 9 x 12	Newsprint paper
Absorbent sheets (2 x 2)	Full face shield
Large padded envelope	Lab jackets (Medium, Lg., X-Lg, 2xl.)
Cryo gloves	
Hammer	Dry ice scoop
Tape gun	Packaging tape 2"
Overpack label	Address labels for FedEx class 9 sticker
UN 3373 label	Refrigerate Do Not Freeze label
Keep Frozen label	Avery 5160 labels
Label Zebra (1.125")	Printer ribbon, Zebra (thermal transfer)
Sheet-fed laser labels	Wipes, Terri 13" x 18"
FedEx large boxes	FedEx Class 9 label
Clear FedEx label pouches	Dymo Labels
Toner cartridge (HP Laser Jet 4000)	FedEx preprinted return airbill - stand

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 bar-coded 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, HPV oral rinse processing (the dentist is responsible for printing the sample container label), blood processing, and packed cells processing labels for all SPs scheduled into a MEC session. The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. The MEC physician prints the HPV swab labels.

Distribute Labels

- Place urine processing and HPV oral rinse processing labels at workstation 3 in the laboratory.
- If the SP does not show up for the appointment, it is possible he or she will reschedule.
 - Store the SP's vessel rack, urine and HPV oral rinse (if applicable) 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

The phlebotomist and the medical technologist assigned to workstation 1 are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood vessel racks and in labeling the vessels with the appropriate bar-code label.

Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally 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
- Template for processing
- Vessels of the following sizes:
 - 2.0-ml sterile vessel
 - 2.0-ml non-sterile vessel
 - 5.0-ml sterile vessel
 - 30 mL ENV vials
- Bar-coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, appointment type, and inclusion in selected subsamples. 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 in the appropriate location on the template.
- Label all Acrylamide tubes (vessel 88, 221, 222) and place in in the appropriate location on the template.
- Label all 30 mL Dioxin (vessel 29) vials.
- Place a colored post-it indicating the date and session time on the end of this rack.
- Place the rack along with vessel 29 in a Zip-lock bag and store on a shelf in Workstation 1 that is labeled with the session date and time (AM/PM/EVE).

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

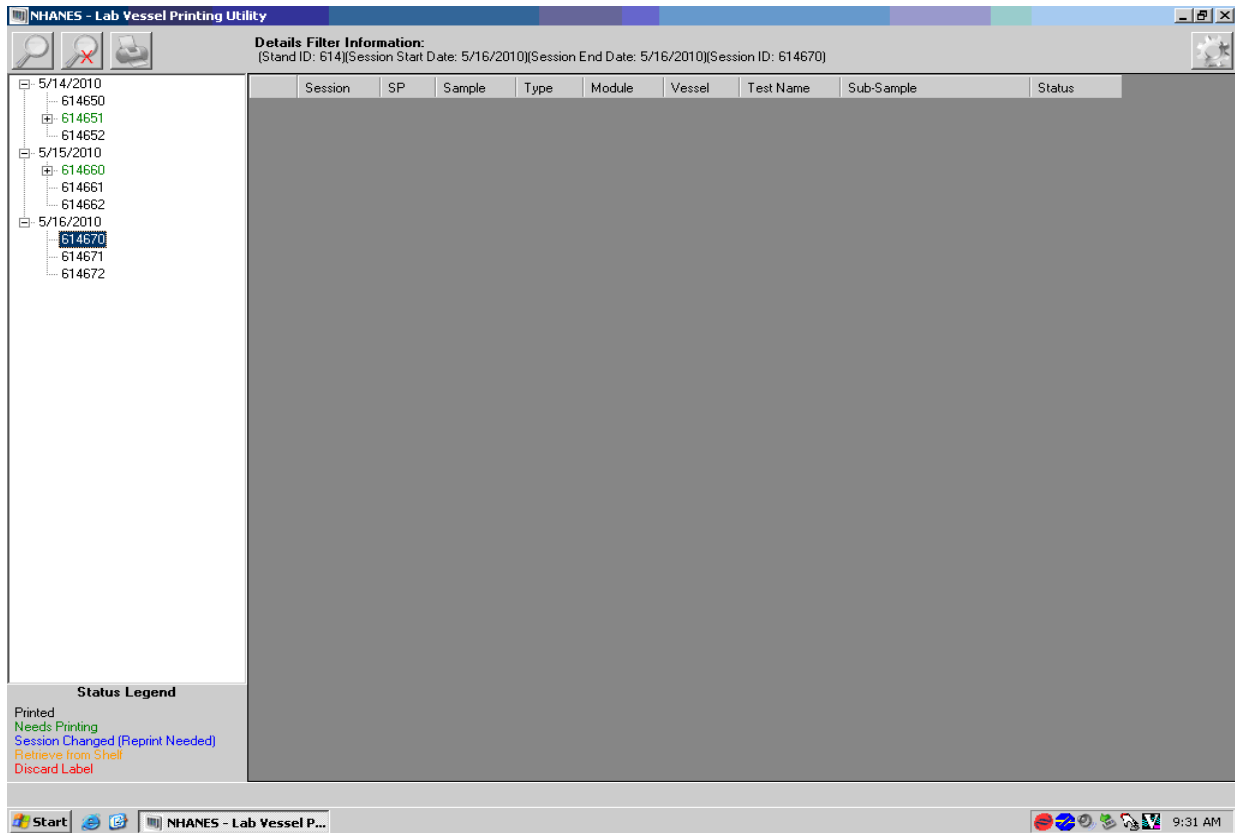
Open the Laboratory application. Log onto the computer terminal and select the Label Print Application. This application is found on the desktop of all laboratory computers and has an icon that looks like a barcode label.



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. The sessions will be color coded to match the legend at the bottom left-hand side of the screen. Sessions in green indicate that a particular session or SPs within that session need 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 with orange indicate labels have already been printed and the rack has been placed on the upper shelf.



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. 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.

NHANES - Lab Vessel Printing Utility

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	1	Lead/Cad/HG		Needs Printing
614660	389587	389587	W	BP	1	Lead/Cad/HG		Needs Printing
614660	540529	540529	W	BP	1	Lead/Cad/HG		Needs Printing
614660	565809	565809	W	BP	1	Lead/Cad/HG		Needs Printing
614660	580885	580885	W	BP	1	Lead/Cad/HG		Needs Printing
614651	530558	530558	W	BP	3	RBC Folate		Needs Printing
614651	554728	554728	W	BP	3	RBC Folate		Needs Printing
614651	731944	731944	W	BP	3	RBC Folate		Needs Printing
614651	753743	753743	W	BP	3	RBC Folate		Needs Printing
614651	847833	847833	W	BP	3	RBC Folate		Needs Printing
614651	889468	889468	W	BP	3	RBC Folate		Needs Printing
614651	890547	890547	W	BP	3	RBC Folate		Needs Printing
614651	904789	904789	W	BP	3	RBC Folate		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	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

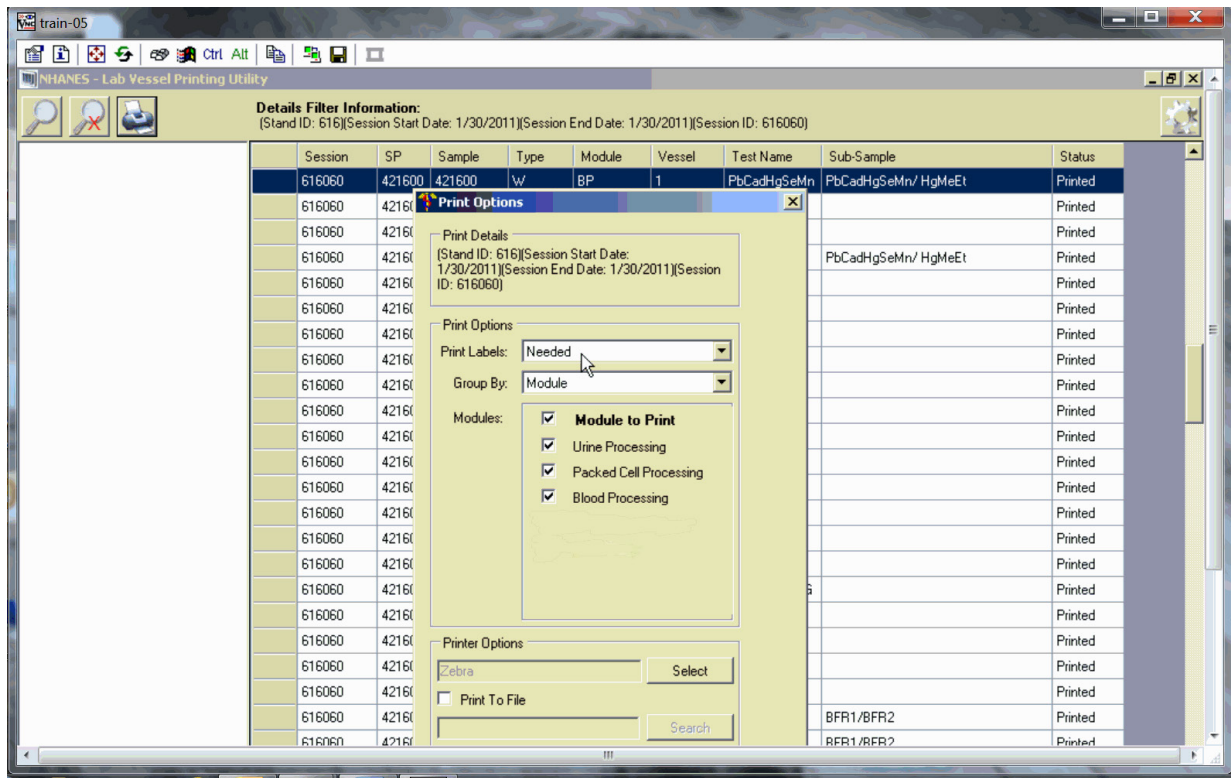
Filter Options dialog box:
 Stand: 614
 Start Date: Friday, May 14, 2010
 End Date: Sunday, May 16, 2010
 Session ID: [dropdown]
 SP ID: [input]
 Sample ID: [input]
 Buttons: Filter, Clear Filter, Cancel

Taskbar: Start, NHANES - Lab Vessel Pri..., Filter Options, 9:27 AM

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.

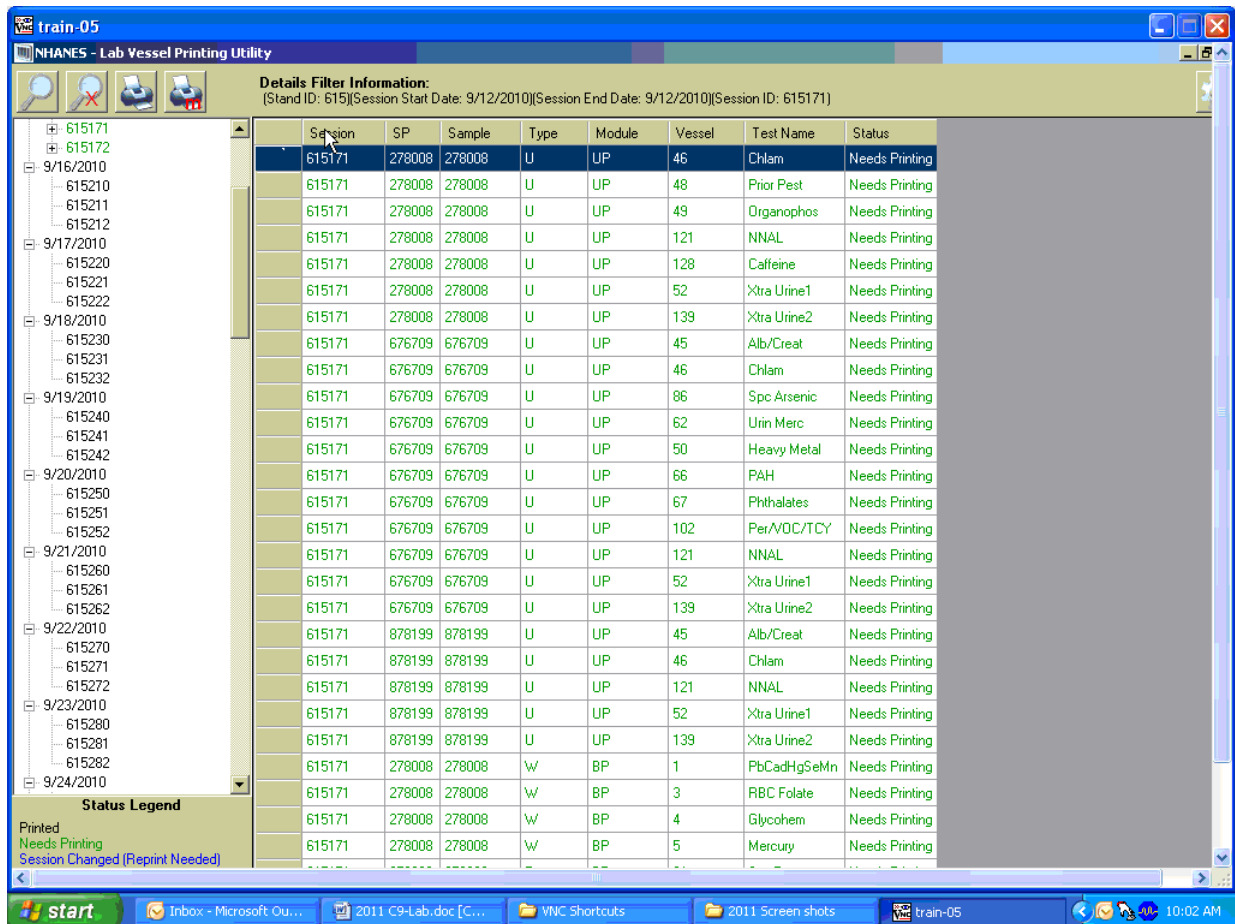
8.3.7 Print Options: Module Filter



Option to select all modules, a single module, or a combination of modules using the checkbox in front of the desired module.

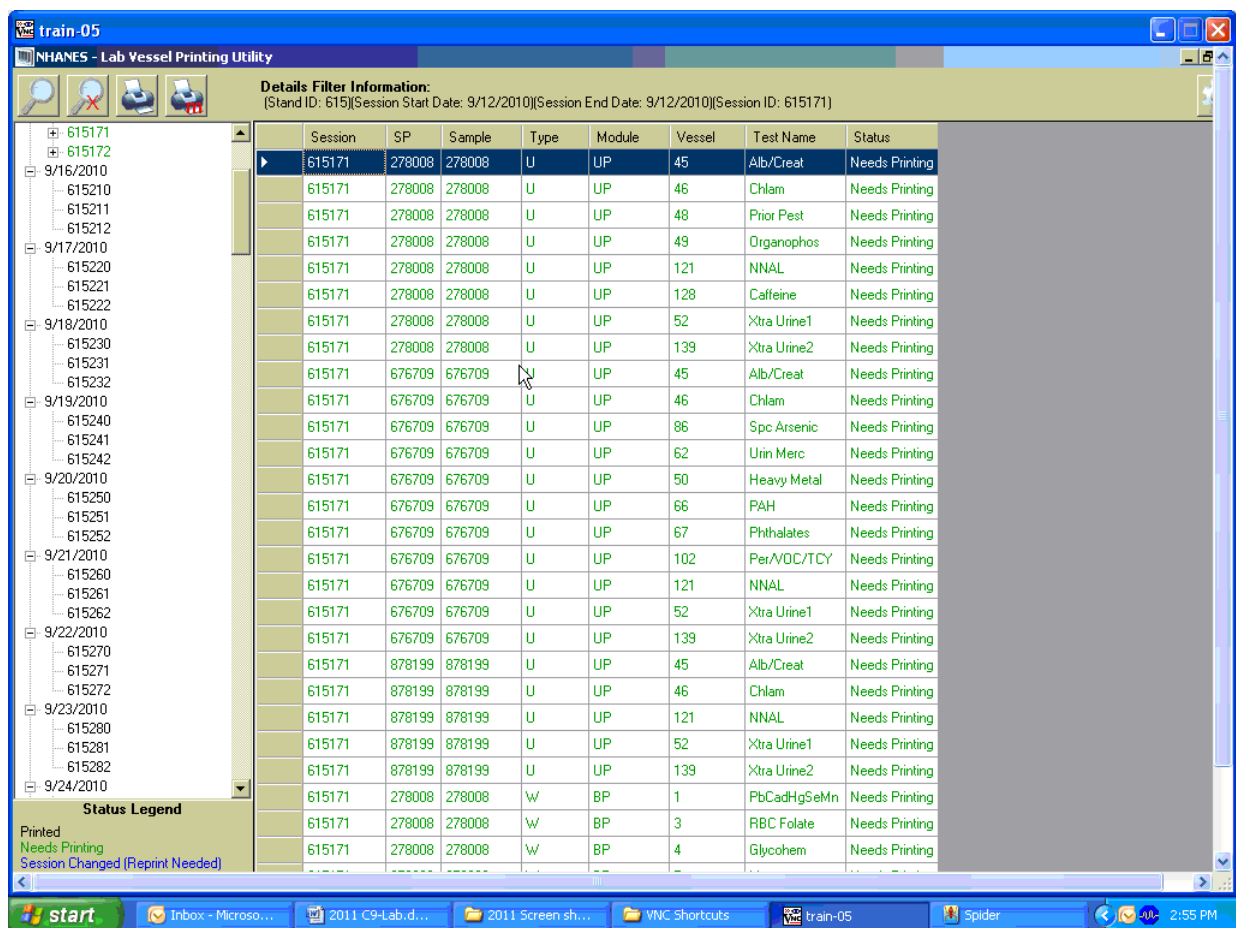
8.3.8 Print Order

The print order matches the order the vessels are displayed on the print screen for the entire session. All urine vessels are printed first, which are grouped by SP ID. Do not label urine or the HPV oral rinse vessels; save the urine and HPV oral rinse labels together, which will be distributed to workstation 3 the day of the session being labeled.



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-hand 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 displayed. Use the printer icon to print using the print options described in Sections 8.3.5 to 8.3.7.

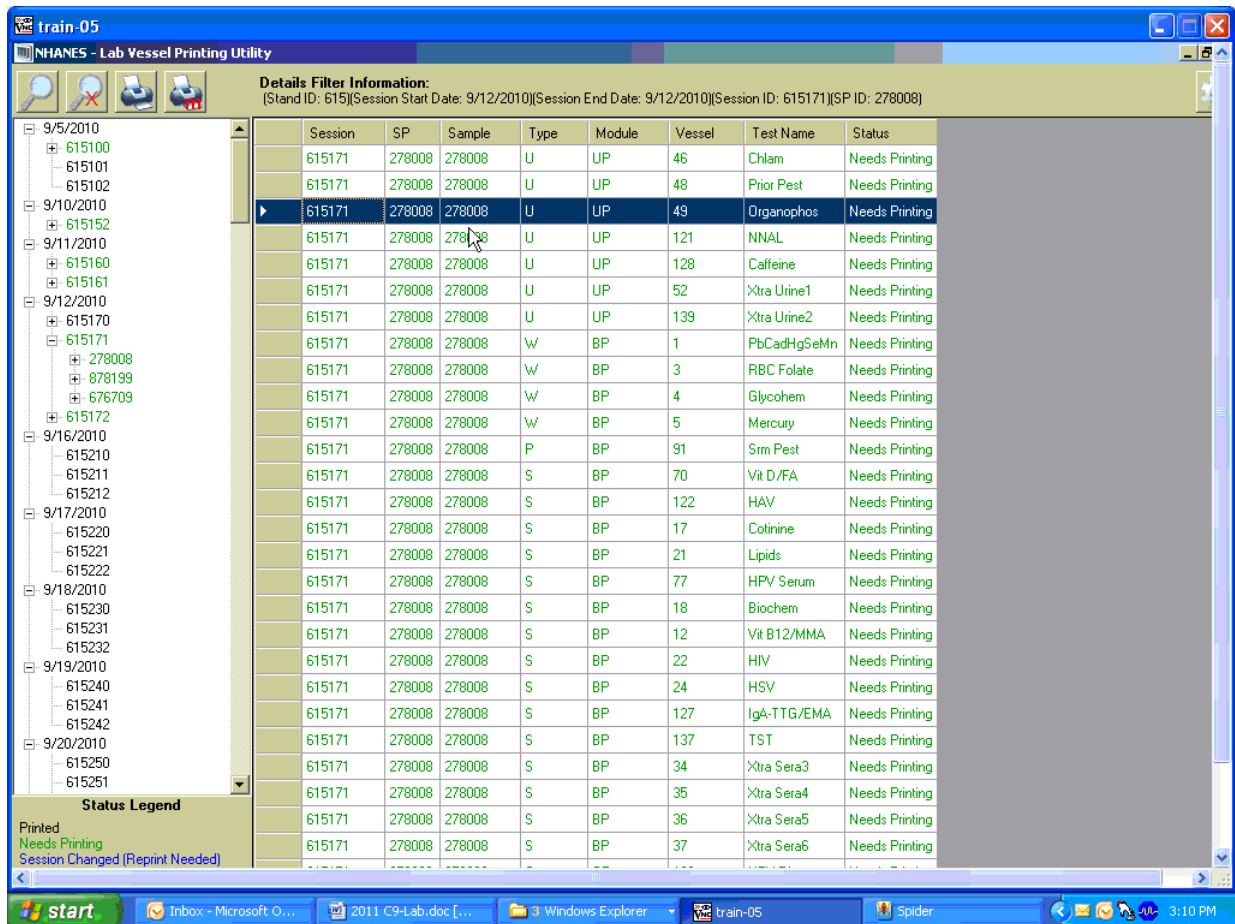
Details Filter Information:
 (Stand ID: 615)(Session Start Date: 9/12/2010)(Session End Date: 9/12/2010)(Session ID: 615171)(SP ID: 278008)

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	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
615171	278008	278008	P	BP	91	Srm Pest	Needs Printing
615171	278008	278008	S	BP	70	Vit D/FA	Needs Printing
615171	278008	278008	S	BP	122	HAV	Needs Printing
615171	278008	278008	S	BP	17	Cotinine	Needs Printing
615171	278008	278008	S	BP	21	Lipids	Needs Printing
615171	278008	278008	S	BP	77	HPV Serum	Needs Printing
615171	278008	278008	S	BP	18	Biochem	Needs Printing
615171	278008	278008	S	BP	12	Vit B12/MMA	Needs Printing
615171	278008	278008	S	BP	22	HIV	Needs Printing
615171	278008	278008	S	BP	24	HSV	Needs Printing
615171	278008	278008	S	BP	127	IgA-TTG/EMA	Needs Printing
615171	278008	278008	S	BP	137	TST	Needs Printing
615171	278008	278008	S	BP	34	Xtra Sera3	Needs Printing
615171	278008	278008	S	BP	35	Xtra Sera4	Needs Printing
615171	278008	278008	S	BP	36	Xtra Sera5	Needs Printing
615171	278008	278008	S	BP	37	Xtra Sera6	Needs Printing

Status Legend
 Printed
 Needs Printing
 Session Changed (Reprint Needed)

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 and show "Label Action Required." Blood processing won't be enabled until the label action is performed.

Lab Sink													
File View Utilities Quality Control Reports Modules Shipping Window Help													
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status			HPV			
							UC	U	P	CB	B	PC	F
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"/>
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"/>	<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"/>	<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"/>	<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"/>

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.

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	QR	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 what is needed. Right-click on a line that is displayed in red to mark label as discarded. Two options are available for discarding, either individually or all.

train-05
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	U	UP	45	Alb/Creat	Printed
615440	197633	197633	U	UP	86	Spc Arsenic	Printed
615440	197633	197633	U	UP	62	Urin Merc	Printed
615440	197633	197633	U	UP	50	Heavy Metal	Printed
615440	197633	197633	U	UP	66	PAH	Printed
615440	197633	197633	U	UP	67	Phthalates	Printed
615440	197633	197633	U	UP	102	Per/VOC/TCY	Printed
615440	197633	197633	U	UP	121	NNAL	Printed
615440	197633	197633	U	UP	52	Xtra Urine1	Printed
615440	197633	197633	U	UP	139	Xtra Urine2	Printed
615440	197633	197633	W	BP	1	PbCadHgSeMn	Printed
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	W	BP	6	Glucose	Discard Label
615440	197633	197633	W	BP	7	Se/Cu/Zn	Printed
615440	197633	197633	W	BP	8	Vit D/FA	Printed
615440	197633	197633	W	BP	9	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

Status Legend
Printed
Needs Printing
Session Changed (Reprint Needed)

Print
Discard
Discard All
Retrieve Shelved Label
Retrieve All Shelved Labels

start | Inbox - Microsoft Out... | 2011 C9-Lab.doc [Co... | VNC Shortcuts | train-05 | 3:42 PM

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.

Lab Sink													
File View Utilities Quality Control Reports Modules Shipping Window Help													
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status			HPV			
							UC	U	P	CB	B	PC	F
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, IMAL	○	○	-	○	○	-	○

For SPs that 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 orange 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 Retrieved All 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	Urea		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			Shelved
615810	545182	545182	S	BP	29			Shelved
615810	545182	545182	C	OR	129	HPV Rinse		Shelved
615810	545182	545182	S	BP	90	Peppercorn	Peri Peat 1 and Doane/Peat2/Peppercorn1	Shelved
615810	545182	545182	S	BP	35	Xbra Sens4		Shelved
615810	545182	545182	S	BP	34	Xbra Sens3		Shelved
615810	545182	545182	S	BP	37	Xbra Sens5		Shelved
615810	545182	545182	S	BP	36	Xbra Sens5		Shelved
615810	545182	545182	S	BP	17	Cobalamin		Shelved
615810	545182	545182	U	UP	67	Phthalates	Phthalates	Shelved
615810	545182	545182	U	UP	43	Organophos	Organophosphate Pesticide	Shelved
615810	545182	545182	U	UP	139	Xbra Urine2		Shelved
615810	545182	545182	U	UP	52	Xbra Urine1		Shelved
615810	545182	545182	U	UP	46	Chloro/Trich		Shelved
615810	545182	545182	U	UP	45	Abi/Creat		Shelved
615810	545182	545182	U	UP	48	Prior Peat	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/ HgMeEt	Shelved
615810	545182	545182	W	BP	5	Mercury	Pb/Cd/Hg/Se/Mn/ HgMeEt	Shelved

Status Legend:
 Shelved
 Needs Printing
 Session Changed (Reprint Needed)
 Session Cancelled
 Record Label

8.3.13 Label Printing Cheat Sheet

Open Lab Vessel Printing Utility

1. Select session number you wish to print.
 - A. Click on print button at the top.
 - B. Print screen will default to print all needed.
 - C. Click on print button at the bottom of print screen.
2. If the session is blue in color:
 - A. Click on (+) sign before session number; this will open up the session and allow you to see what needs to be done.
3. If there is a gold-colored number you need to find this in the rescheduled area or in a session that is already printed.
 - A. Retrieve all shelved labels. Select any gold test and right-click; a box will appear. Click on the line that says “Retrieve all shelved labels,” and wait.
4. If there is more than one gold number: you then need to retrieve all shelved labels.
 - A. Select any gold test and right-click; a box will appear. Click on the line that says “Retrieve all shelved labels,” and wait. This will retrieve all the gold-colored SP labels.
5. Green SP numbers:
 - A. These need to be printed.
 - B. Select session number and Click print button.
6. Red SP numbers: This means there is a vial that you need to pull from rack and scan to discard.
7. To get more days to appear:
 - A. Click the magnifying glass.
 - B. Select the day that you want to see in both slots.

Note: The fewer days you select, the quicker the filter will work.

8.4 Create New Container Labels

Store processed vessels and biological samples 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.

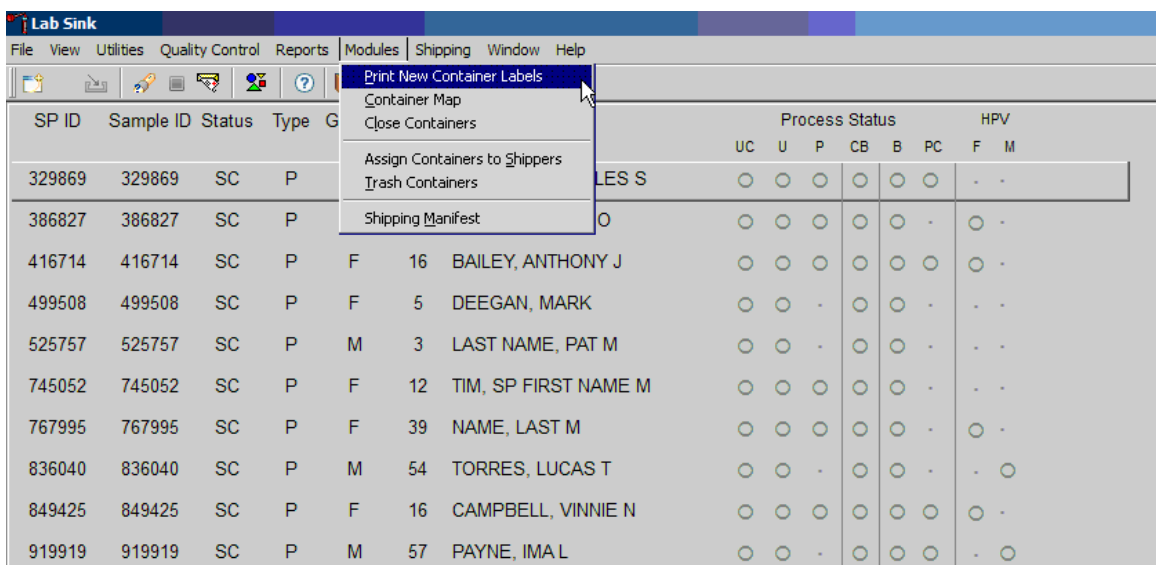
Chlam/GC (46)
5x5 3 inch box



Prior Pest (48)
5x5 3 inch box

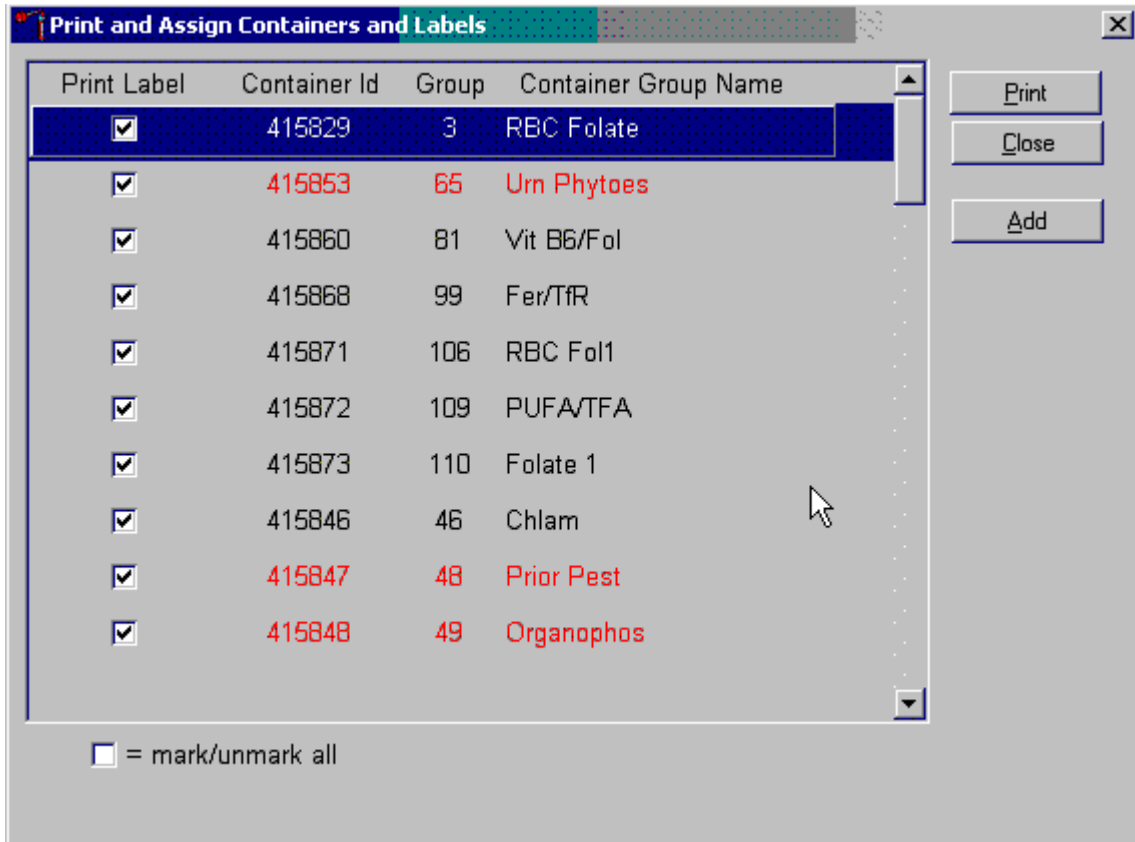


Use the Shipping module within the laboratory application to print and assign new container ID numbers or labels.



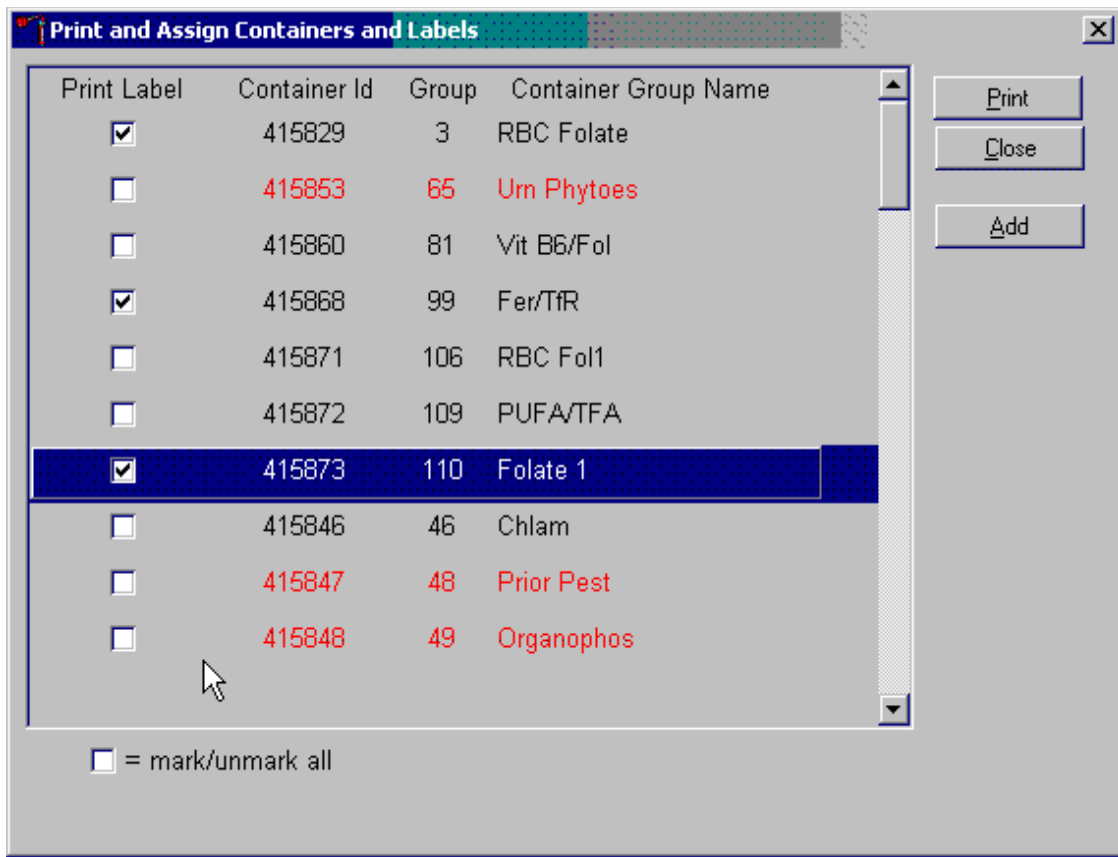
To access the Print New Container Labels module, direct the mouse arrow to Shipping in the menu bar and left-click, drag the mouse arrow to Print New Container Labels, and left-click.

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.



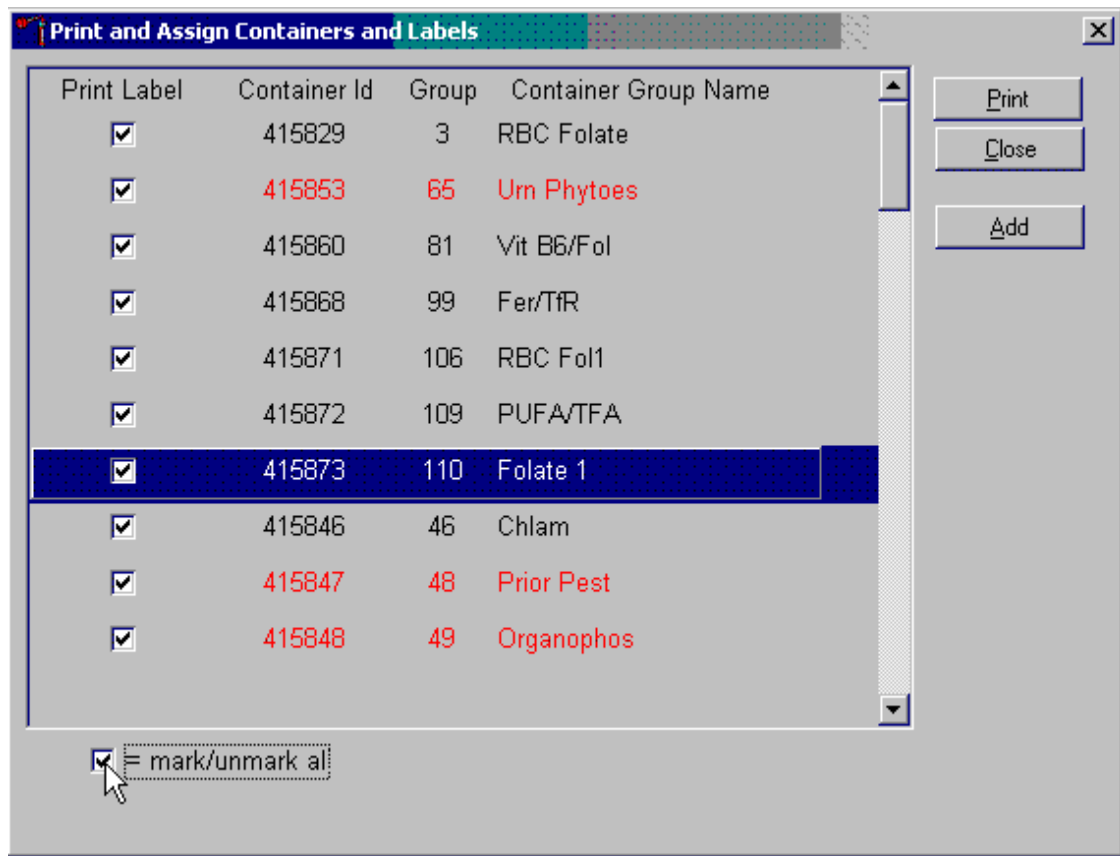
The Print and Assign Containers and Labels window displays once the “Print New Container” module is accessed. The window includes checkboxes to mark or identify specific groups, new Container Ids that are assigned to the Groups, the number of the Group, and the Container Group Name or vessel name. The 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” checkbox 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 checkbox to identify vessels that require labels.



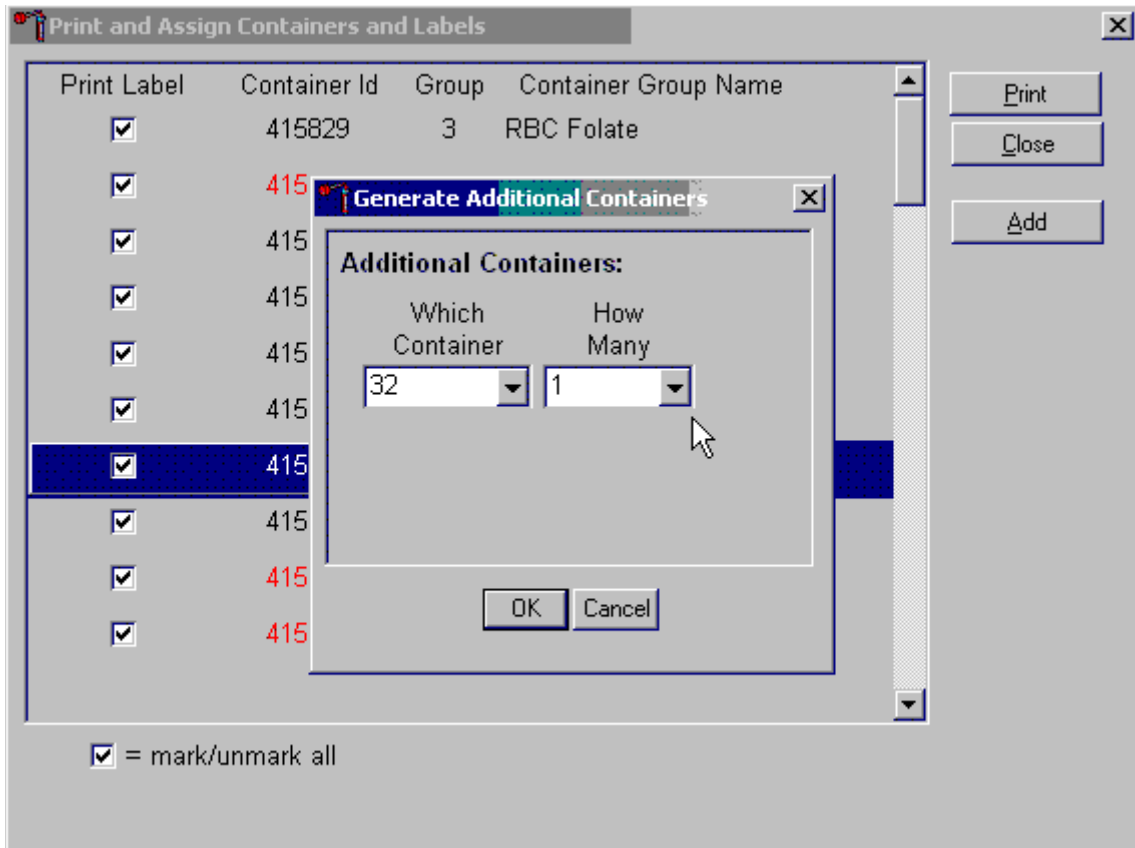
To begin the process of printing and assigning new Container IDs, mark the individual check boxes that correspond to the Group (vessel) of interest. To add a checkmark to the Print Label checkbox, direct the mouse arrow to the Print Label checkbox and left-click.

Collectively mark all the Print Label checkboxes for all the Groups listed in the window.



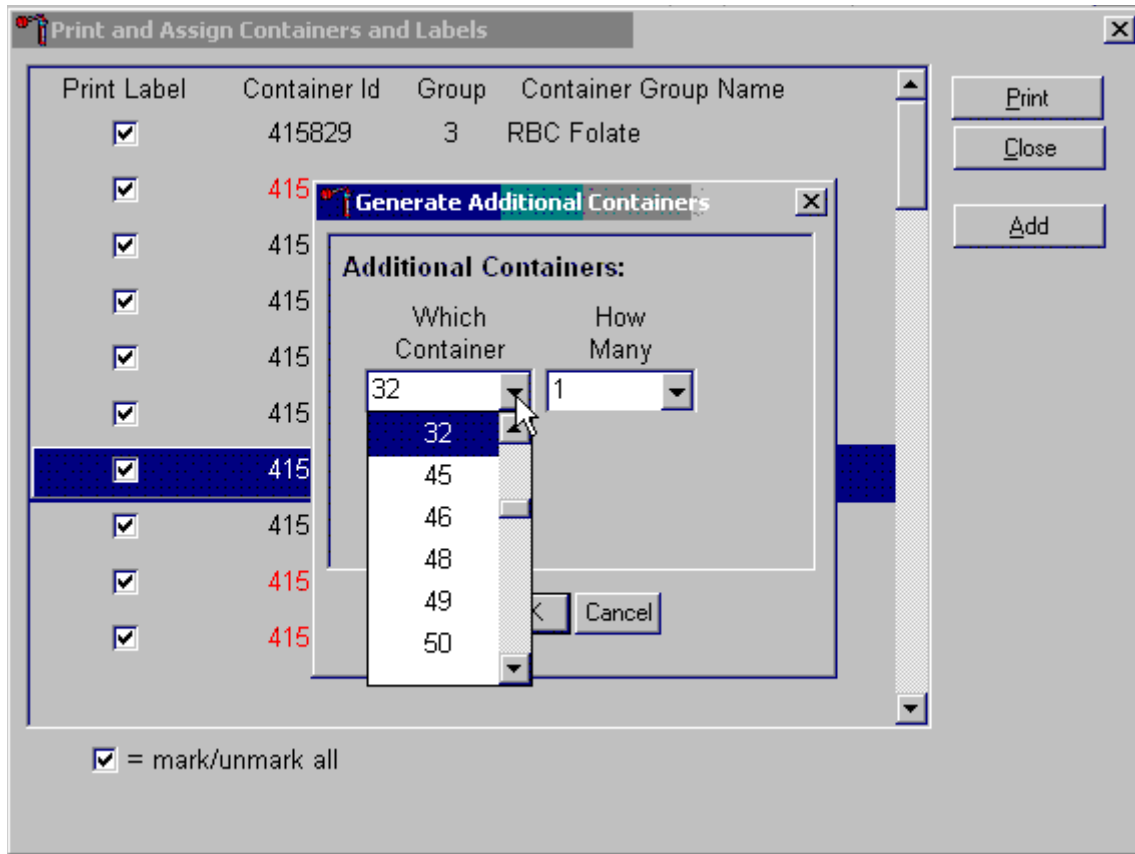
To collectively mark all the checkboxes, direct the mouse arrow to the mark/unmark all checkbox and left-click. To collectively unmark all the checkboxes, direct the mouse arrow to the mark/unmark all checkboxes and left-click.

Access the Generate Additional Containers window to print additional labels for any Group at any time.



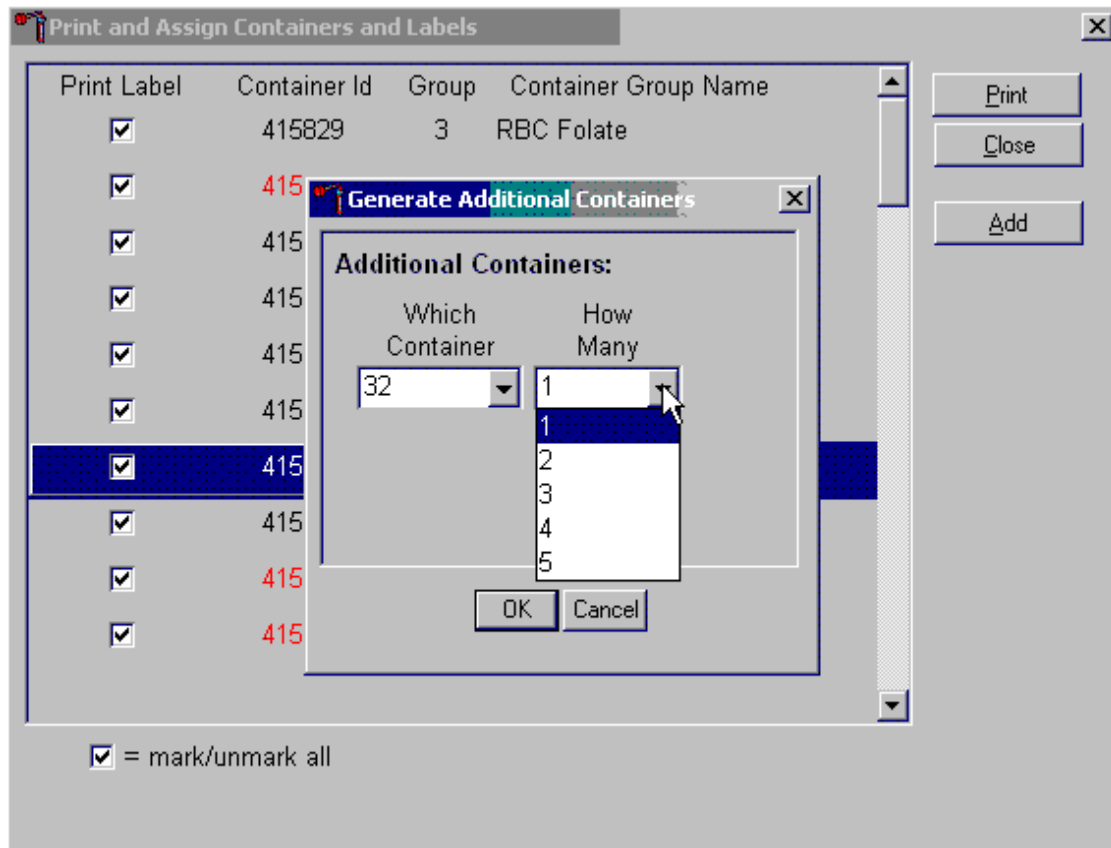
To assess the Generate Additional Containers window, direct the mouse arrow to the “Add” button and left-click.

The Generate Additional Containers window displays.



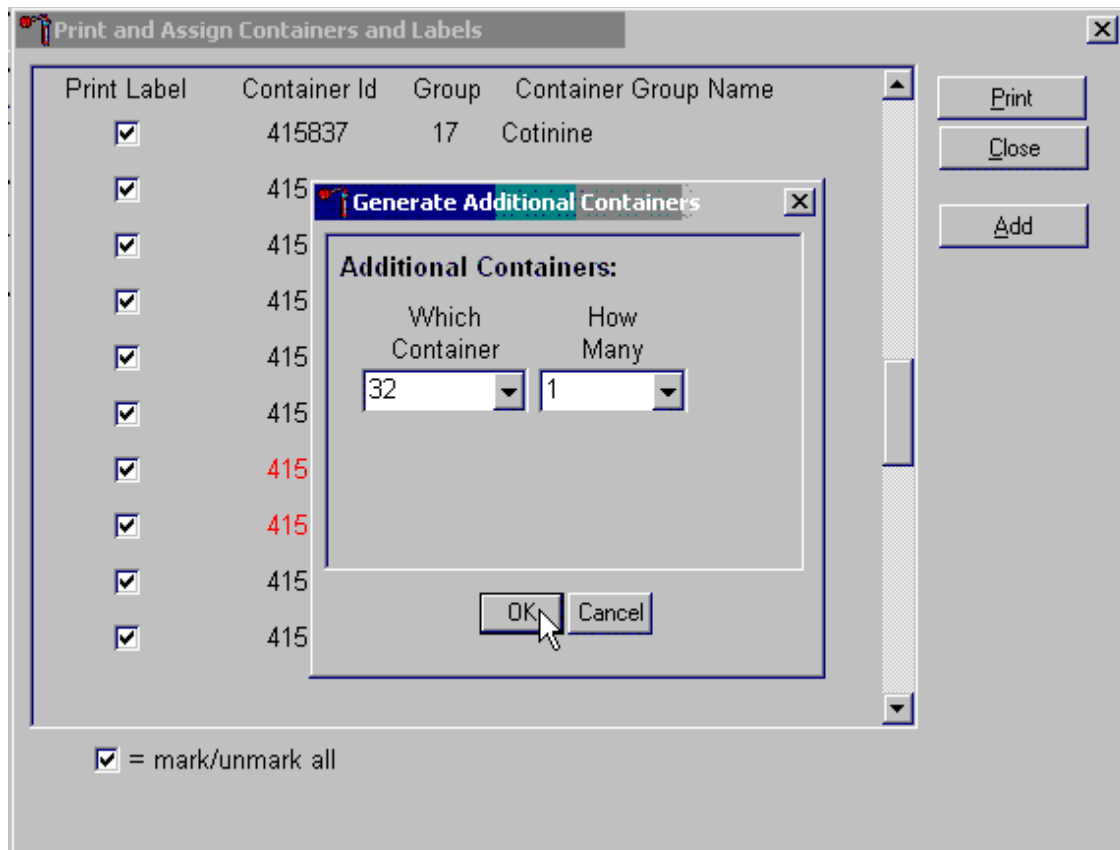
The Generate Additional Containers window includes two text boxes with drop-down lists: Which Container and How Many. The Which Container text box defaults to vessel 32. To select a vessel other than 32, direct the mouse arrow to the drop-down arrow and left-click, drag the arrow to the desired choice and left-click. Use the scroll bar to view all the choices.

Select the number (1-5) of additional container labels.



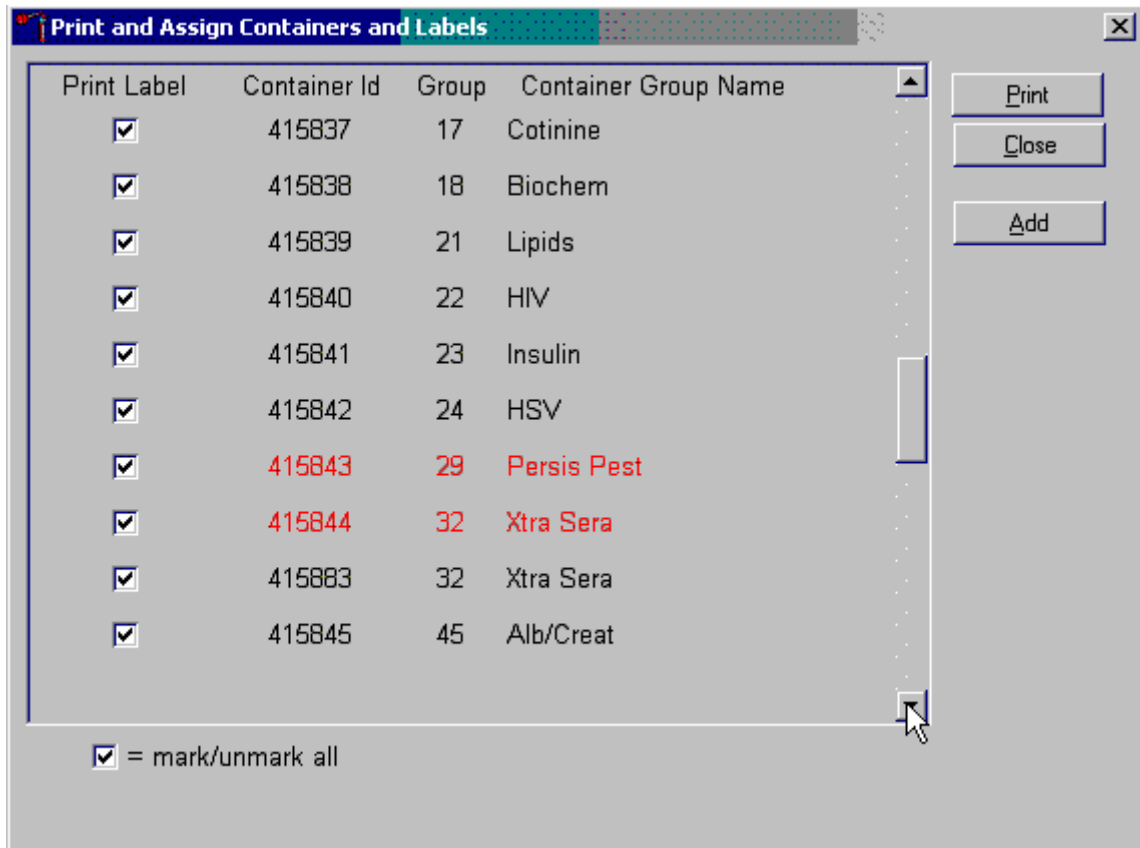
The How Many text box defaults to vessel 1. To select 2, 3, 4, or 5, direct the mouse arrow to the drop-down arrow and left-click, then drag the arrow to the desired choice and left-click. Use the scroll bar to view all the choices.

Add these vessels to the Print and Assign Containers and Labels window or cancel the action.



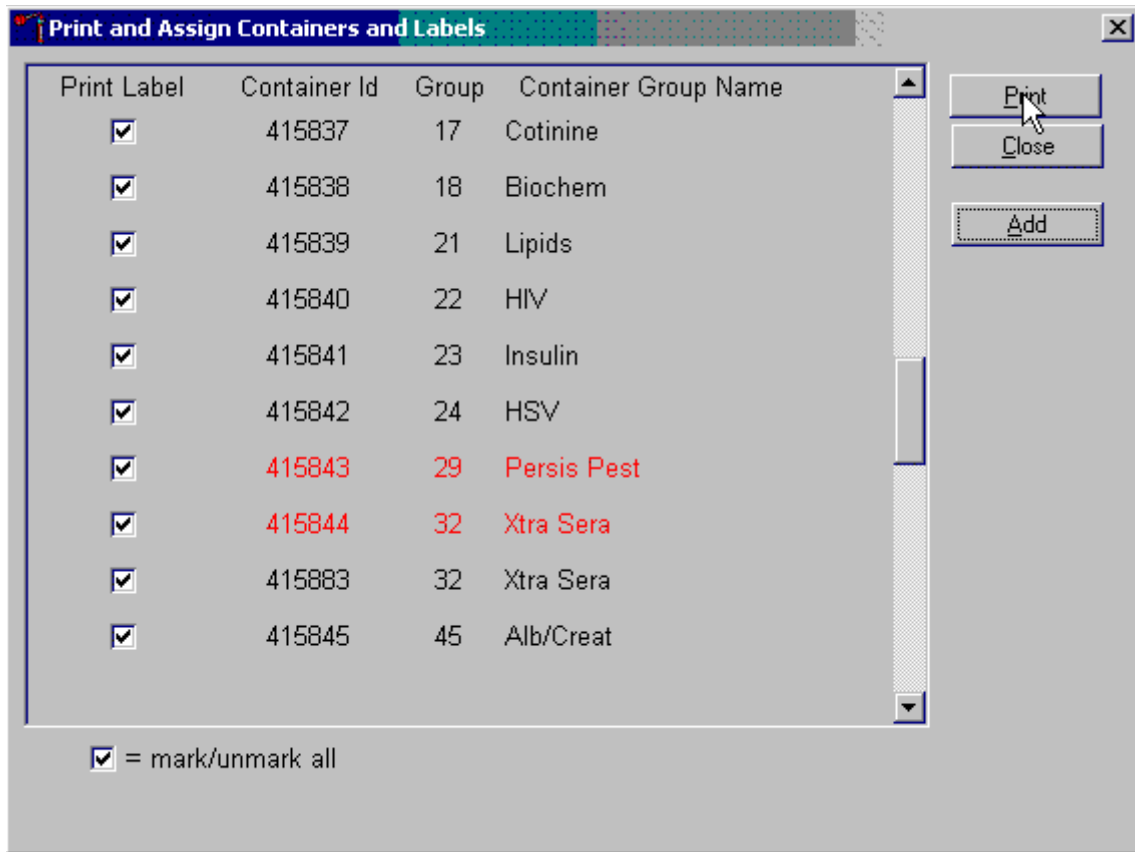
To accept the choices displayed in the Generate Additional Containers window, direct the mouse arrow to the OK button and left-click or type [Enter]. To close the window without creating a new container, direct the mouse arrow to the Cancel button and left-click.

If the OK button is selected, then the containers are added to the Print and Assign Containers and Labels window.



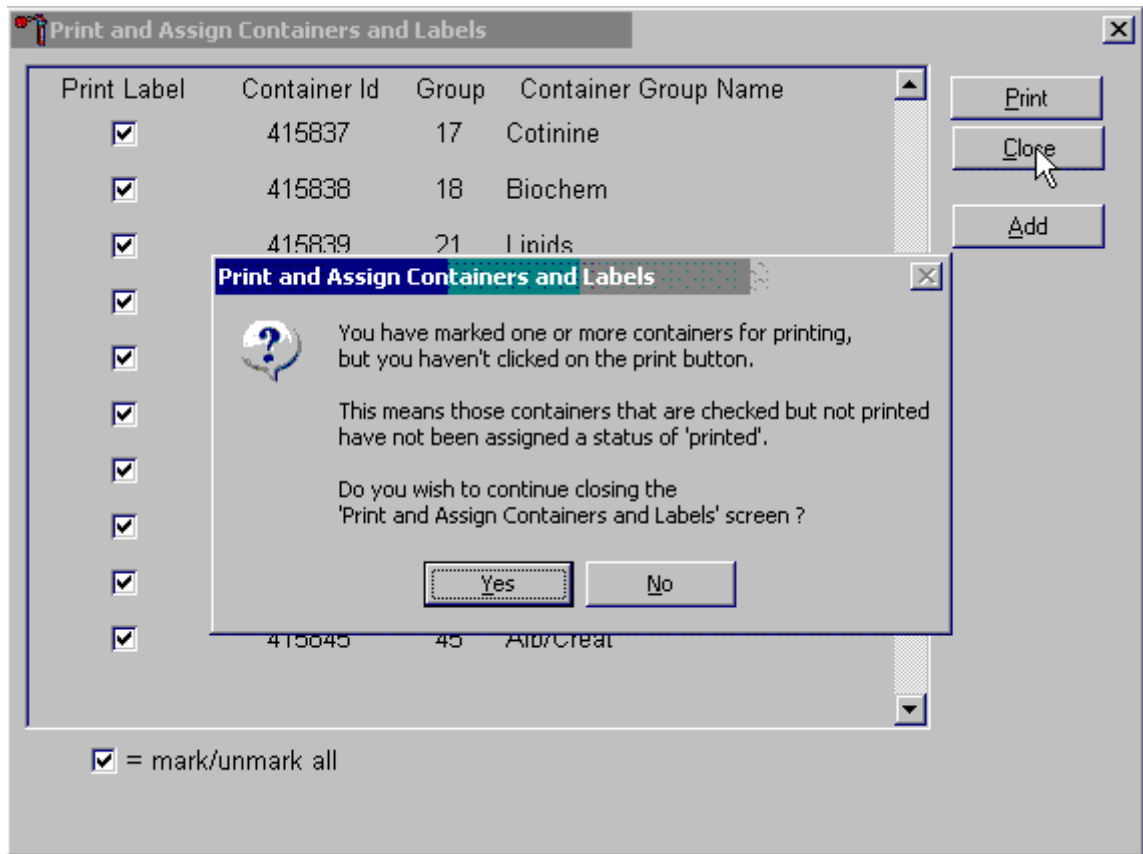
Review the information on the screen.

Complete the assignment process and print the labels.



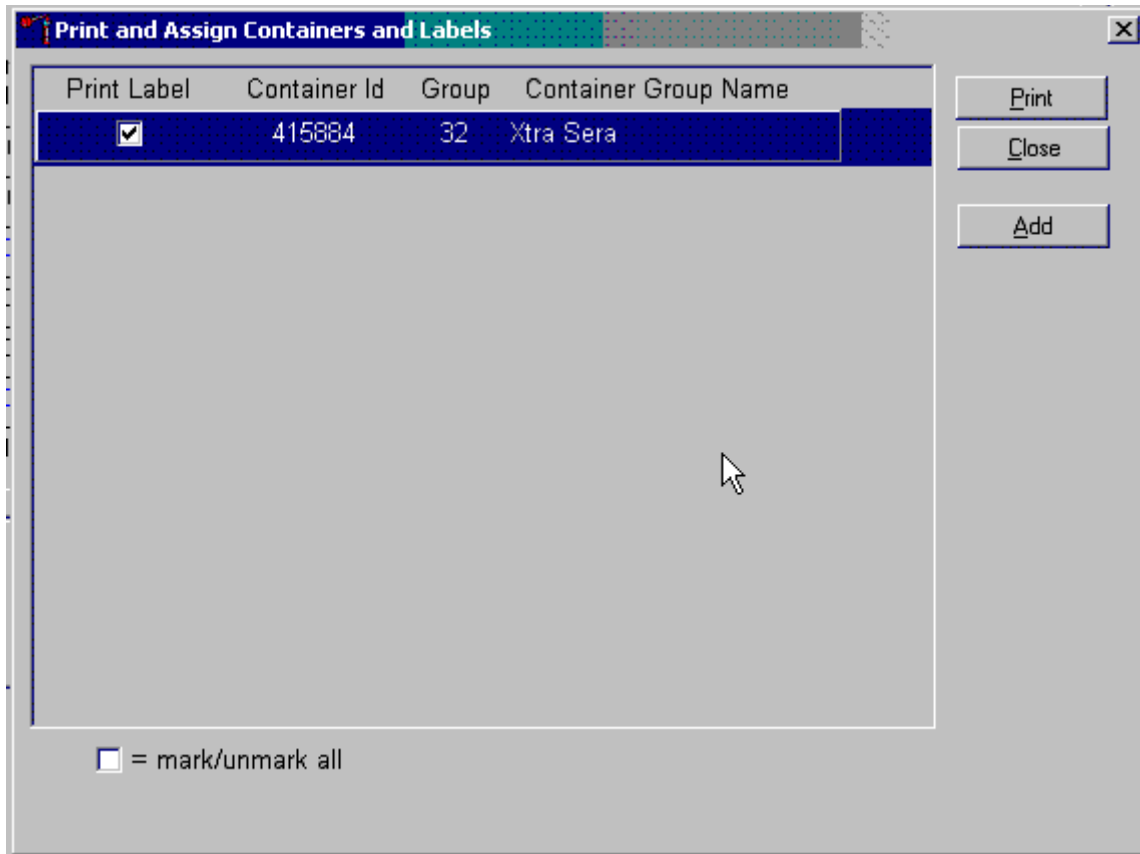
After reviewing the screen, print the labels. To print the labels, direct the mouse arrow to the “Print” button and left-click. To exit the window without printing any labels, direct the mouse arrow to the “Close” button and left-click. Affix the container ID label(s) to the container(s) of the correct type.

If the “Close” button is selected before the labels have been printed, then a Print and Assign Containers and Labels window displays.



Review the Text. To close the Print and Assign Containers and Labels screen, select the “Yes” button. To return to the Print and Assign Containers and Labels screen, select the “No” button.

When a container is full, the container will automatically “close,” and the Print and Assign Containers and Labels window opens with that vessel displayed and the check mark prefilled. Alternatively, open a new container to replace the closed container by using the Print and Assign Containers and Labels window.



When a container is full, an opportunity to open a new container is automatically displayed on the “Print and Assign Container and Labels” window. Repeat the process of marking the checkbox and selecting the “Print” button.

Samples are shipped either weekly, semi-weekly (Genetics), or when full/at the End of Stand.

8.5 Close Containers

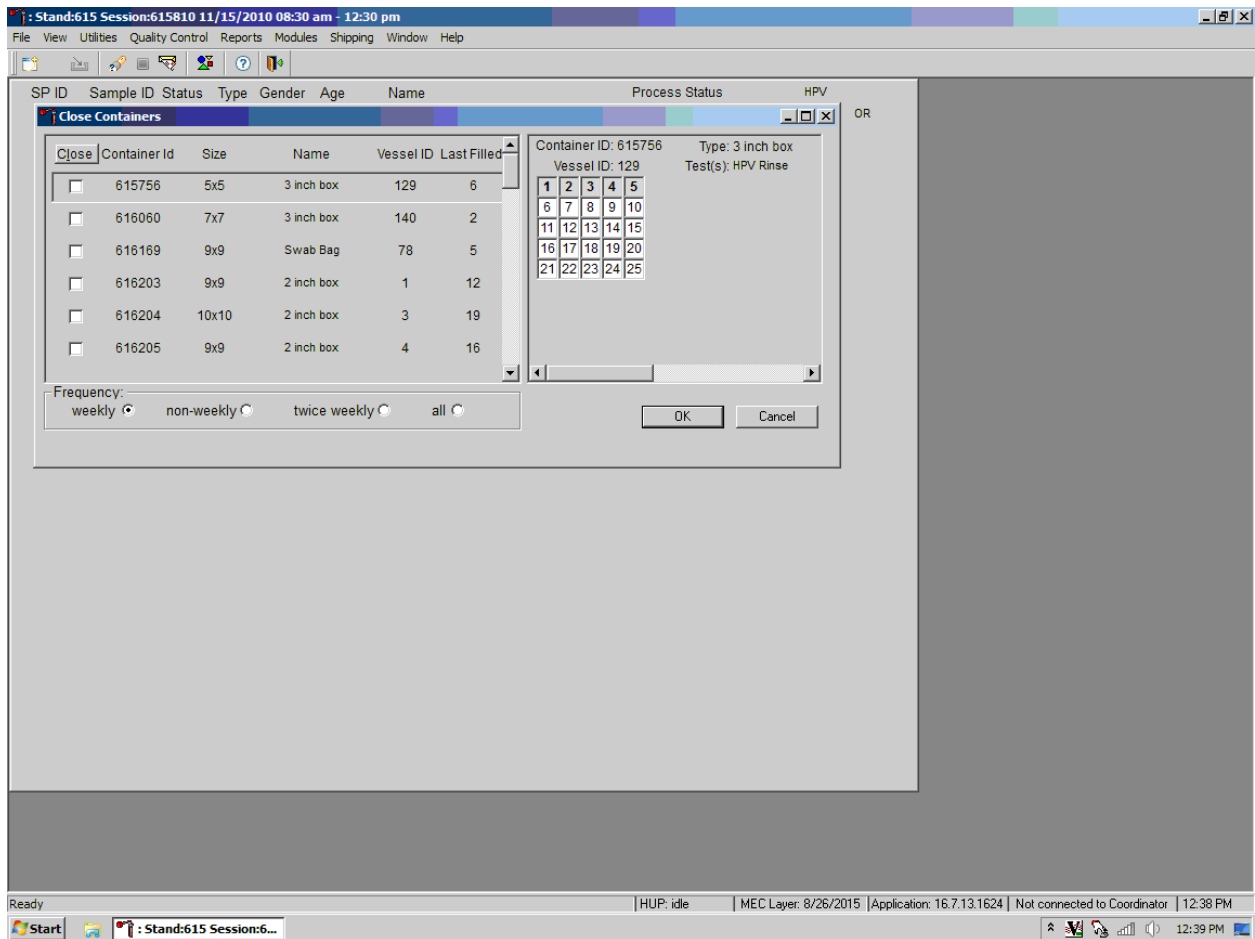
Use the shipping module with the laboratory application to close containers.

Lab Sink						
File View Utilities Quality Control Reports Modules Shipping Window Help						
SP ID	Sample ID	Status	Type	Gender		
329869	329869	SC	P	F		
386827	386827	SC	P	F		
416714	416714	SC	P	F		
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

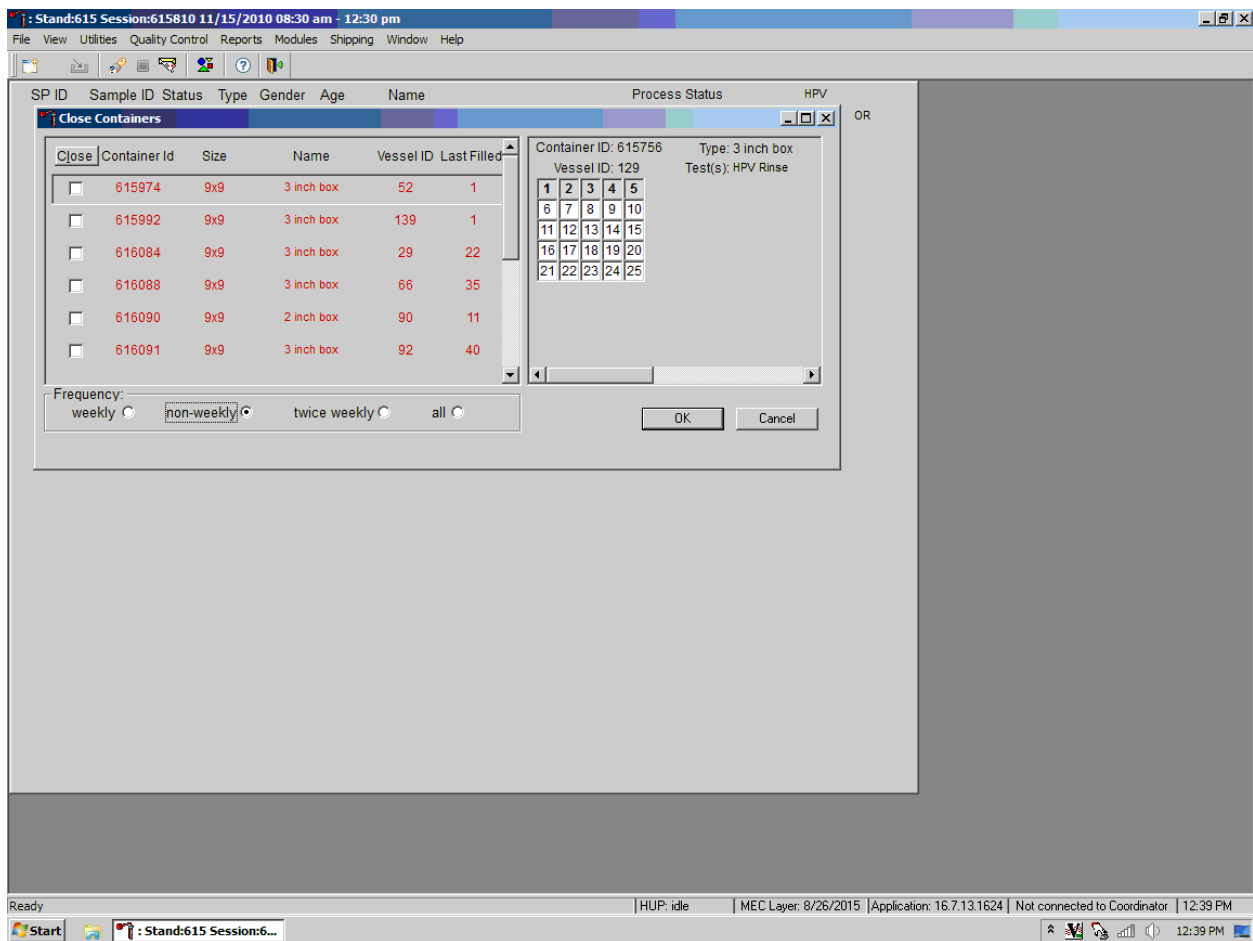
		Process Status					HPV		
		UC	U	P	CB	B	PC	F	M
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	-
		<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
		<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	-
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	-
		<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	-	-	<input type="radio"/>
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-
		<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 will be utilized 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 that session. The application defaults to weekly, as the frequency of shipped samples.

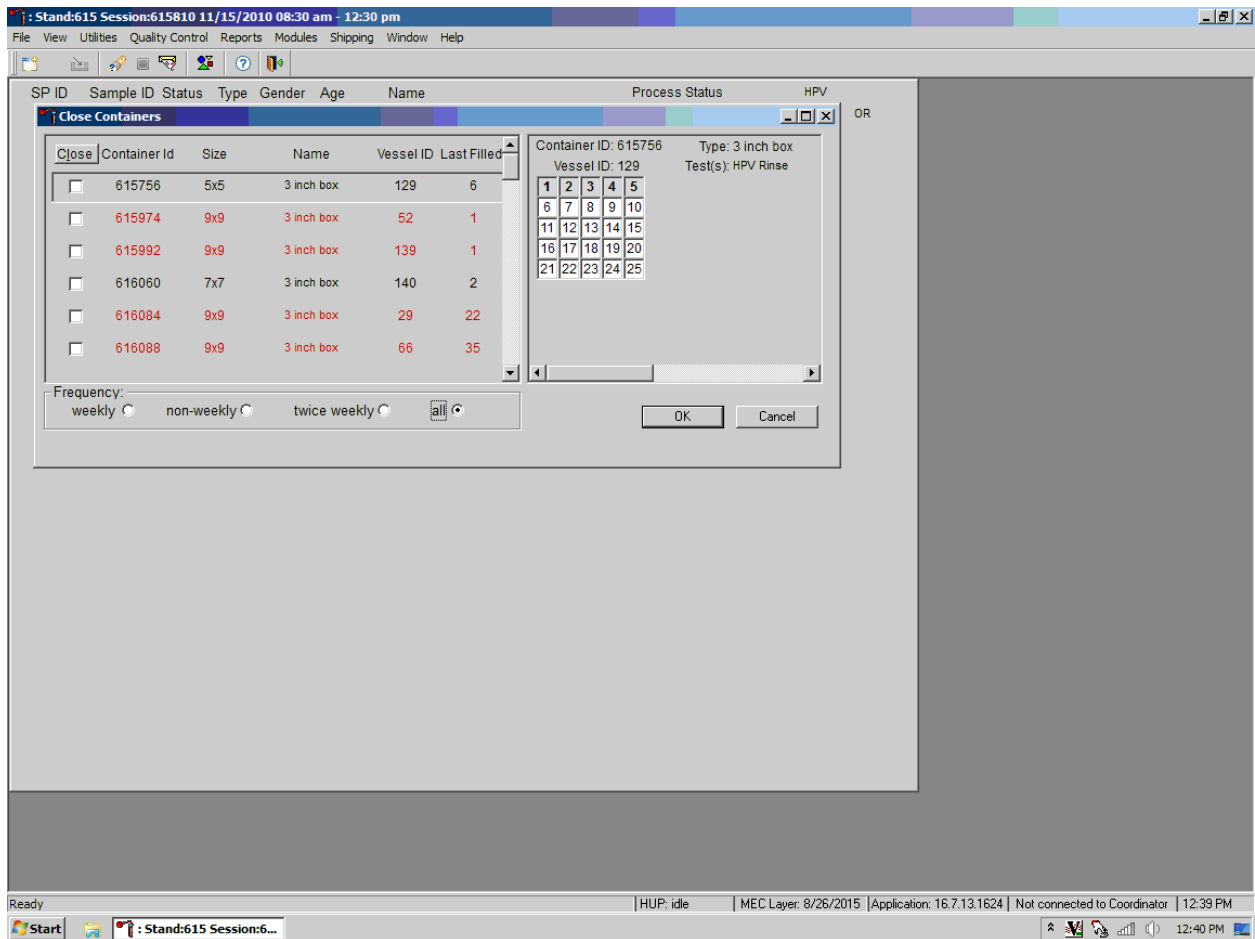


The non-weekly shipping frequency functions show the containers that are shipped when full or at the end of the stand.

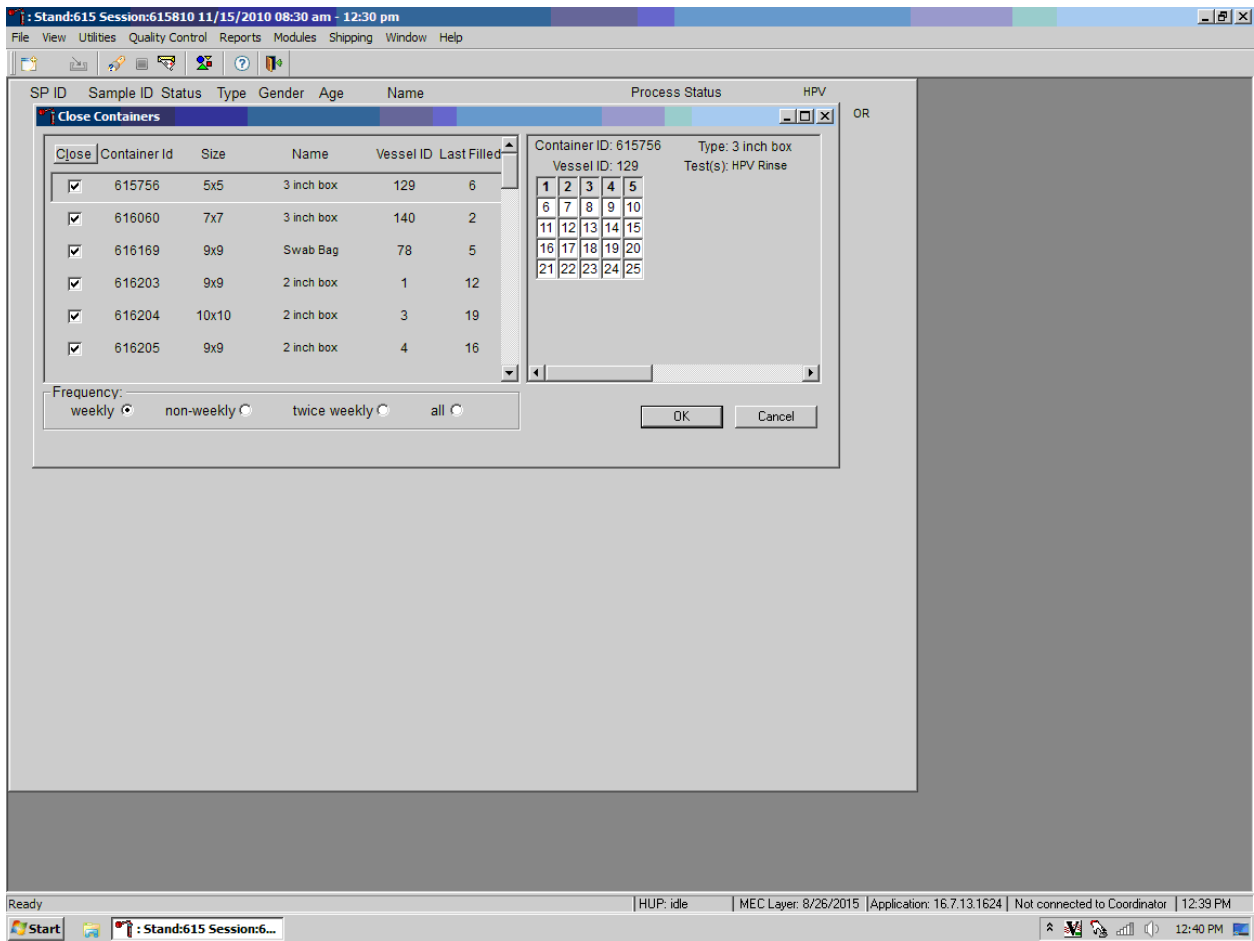


Use this function at the end of the stand, select all to close all the containers to ship out to the testing labs.

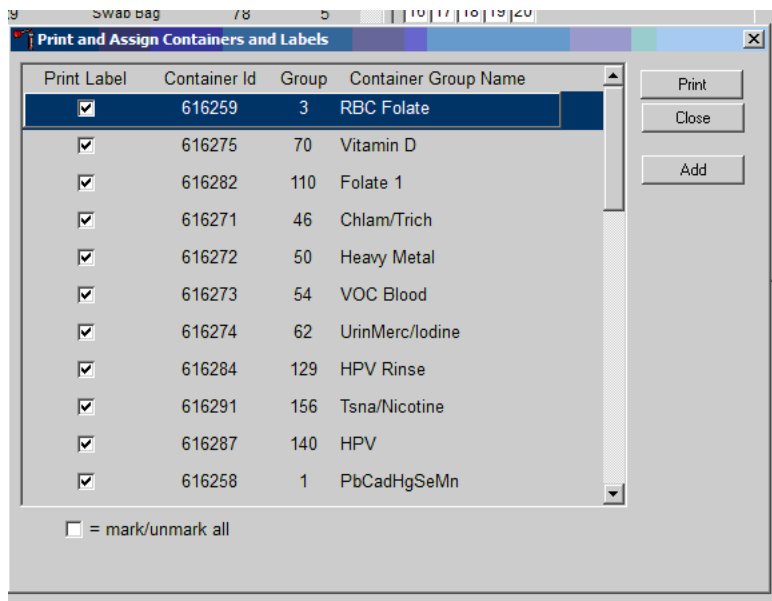
If any containers are closed in error contact the ISIS team immediately to correct the error. This is especially crucial when performing End of Stand activities.



To close the containers, place a checkmark in the “Close” column, which will close these containers in the system so no more samples can be added to these containers.



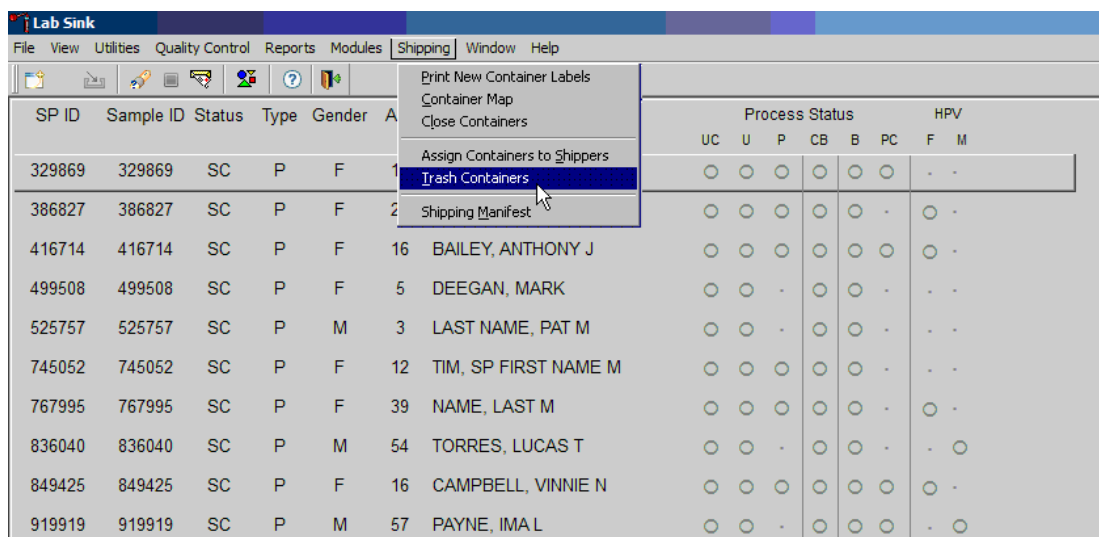
After the containers are closed, a list will be displayed of the containers that need labels printed before any specimens can be put into the new containers.



8.6 Trash or Reprint Container Labels

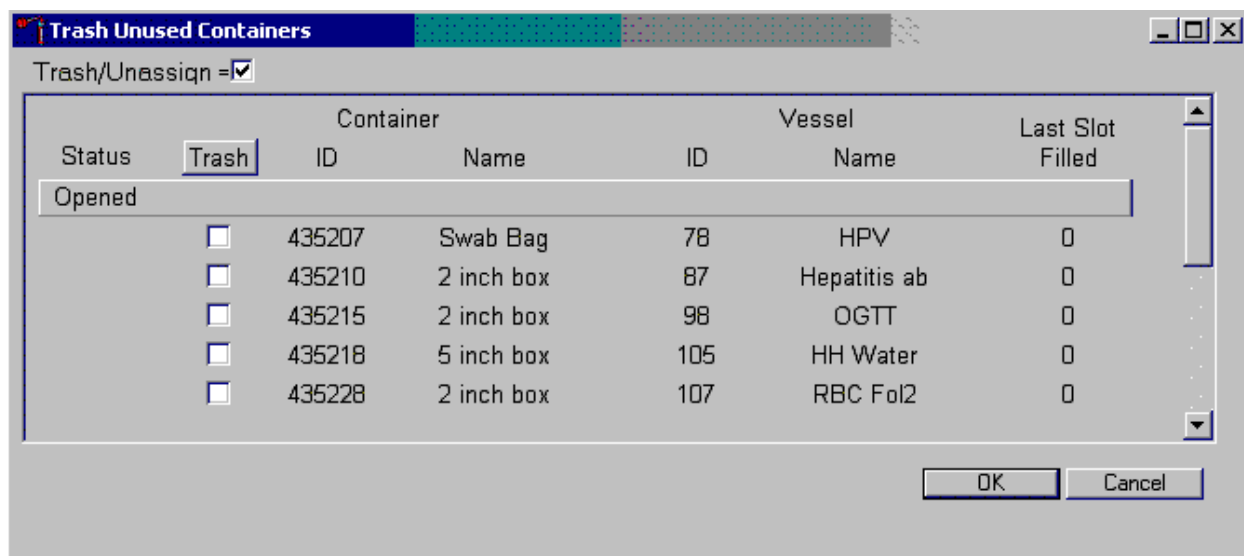
Each stand is allocated a maximum of 999 container IDs.

If unused container labels become lost or damaged, use the Trash Containers module to delete the container IDs. Access the Trash Containers module.



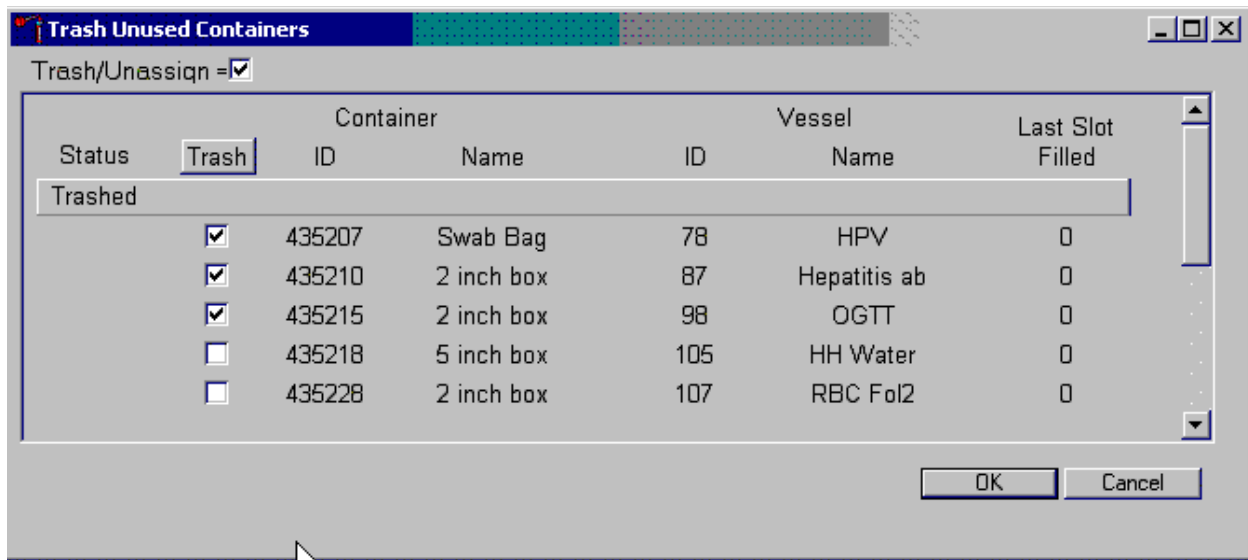
To access the Trash Containers module, direct the mouse arrow to Shipping, left-click, drag the arrow to Trash Containers, and left-click.

The Trash Unused Containers window displays.



The status of each container ID is “Opened.” To individually mark the container IDs for deletion, direct the mouse arrow to the checkboxes and individually left-click on specific boxes or, to mark all outstanding container IDs for deletion, direct the mouse arrow to the “Trash” button and left-click. 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.”



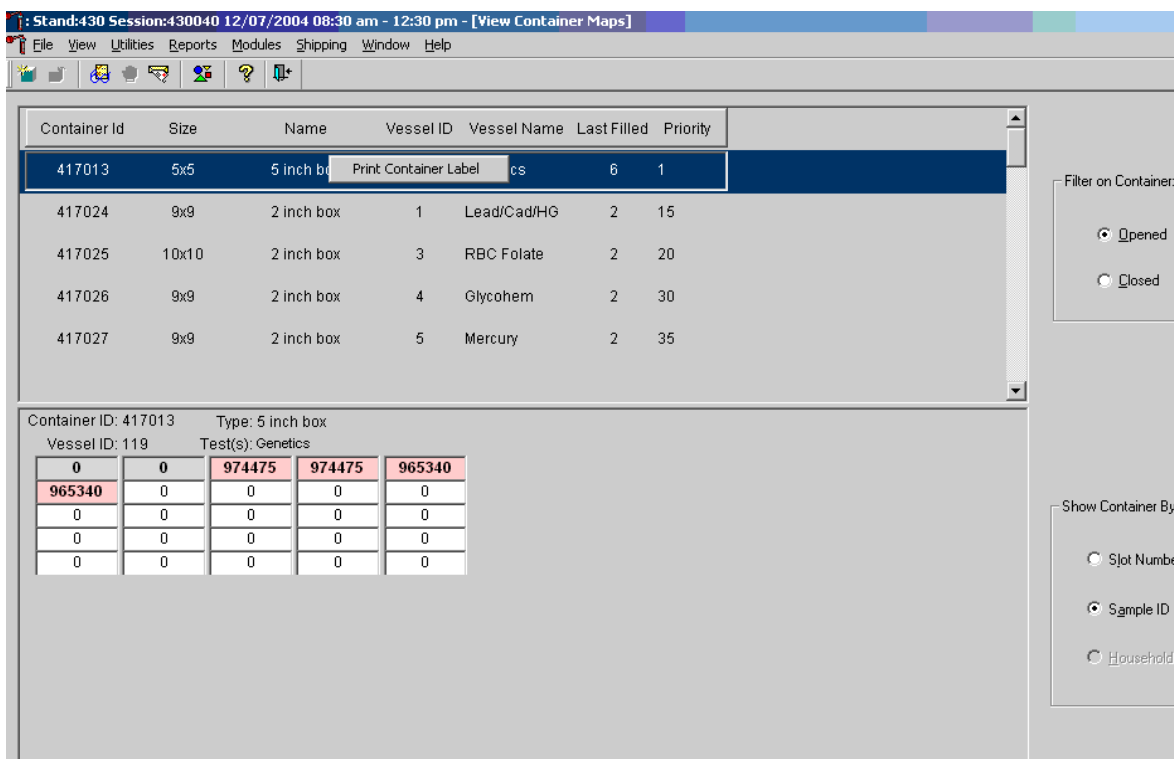
To record these actions and execute the Trash Unused Containers function, direct the mouse arrow to the OK button and left-click, or select Enter. To exit the Trash Unused Containers module without recording or executing the Trash Containers function, direct the mouse arrow to the Cancel button and left-click.

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. The label will print to the associated Dymo printer.



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 ultimate 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 a.m. to most U.S. addresses and by noon, 4:30 p.m., or 5 p.m. in remote areas. Delivery by FedEx can be delayed due to a weekend or holiday. This extraordinary circumstance usually occurs at the end of a stand or just before vacation. In any case, ship all specimens before vacations. The following actions are intended to mitigate unforeseen delay:

- Consider adding extra dry ice. Use a medium shipper for all international shipments.
- 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 technologist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other medical technologists 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 of the Class 9 label and place the appropriate Lab label in the upper right of the Class 9 label. Enter the appropriate dry ice weight in kilograms (kg) in the blank space next to kg. 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” dropdown menu
 - Enter the username (standXXX where XXX is the current stand number)
 - Enter the password (NhanesXXX where XXX is the current stand number)
 - From the dropdown menu in the shipping screen select the first lab that will receive samples from the current shipment. The laboratory information will autopopulate.
 - Enter the correct shipping date in the appropriate field
 - Enter the total weight, based on whether the shipper is a refrigerated or frozen shipment, in pounds in the appropriate field
 - 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 “Use an already scheduled pick-up at my location”

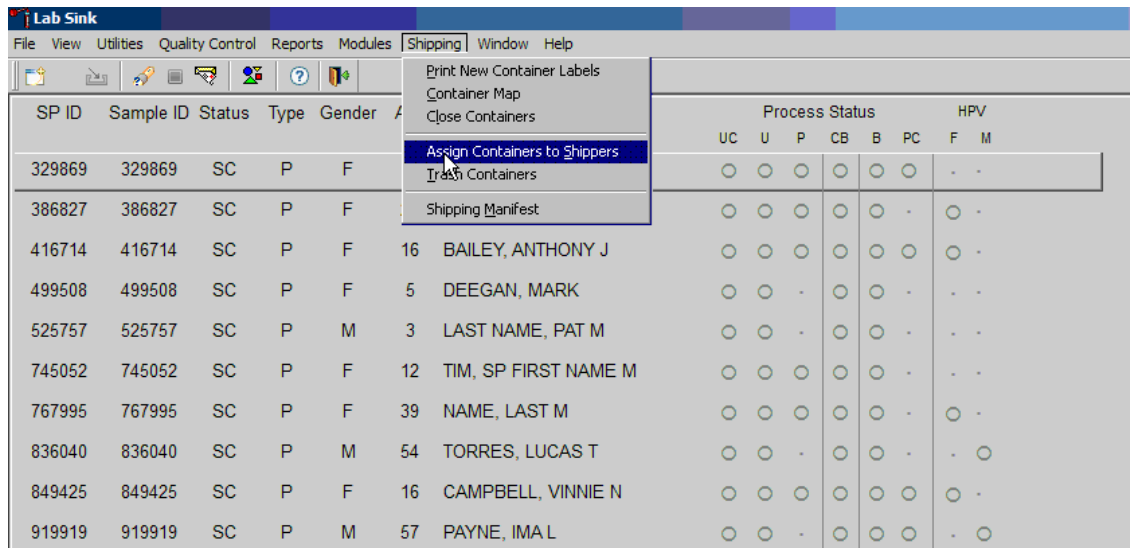
- In the “Signature Type” section, select “Direct Signature Required” (this is not necessary for shipment to the warehouse)
 - After double-checking your entries, select “Ship” in the bottom right hand corner of the shipping screen
 - The Shipping Manifest will be generated in another screen that will display automatically
 - Select the “Print” button (make sure labels have been inserted in the tray of the printer before printing manifest)
 - 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 appropriate.

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.

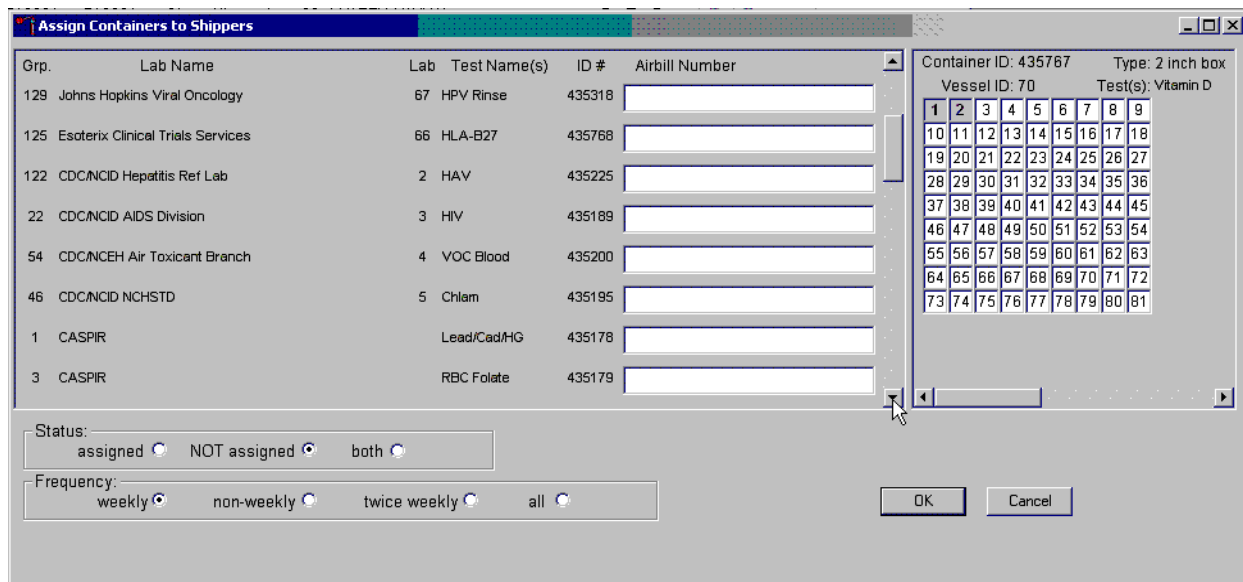
8.8 Assign Containers to Shippers

Assign closed containers to or associate closed containers with a specific airbill. To associate a specific closed container to the airbill for that laboratory, use the Assign Container to Shippers module.



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.



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 left side of the bottom of the window contains three “Frequency” filters (radio buttons): “weekly,” “non-weekly,” “twice weekly,” and “all.” Use the column titles to sort the rows. To sort the rows, direct the mouse arrow to the desired column title and left-click. The window updates based on the selection.

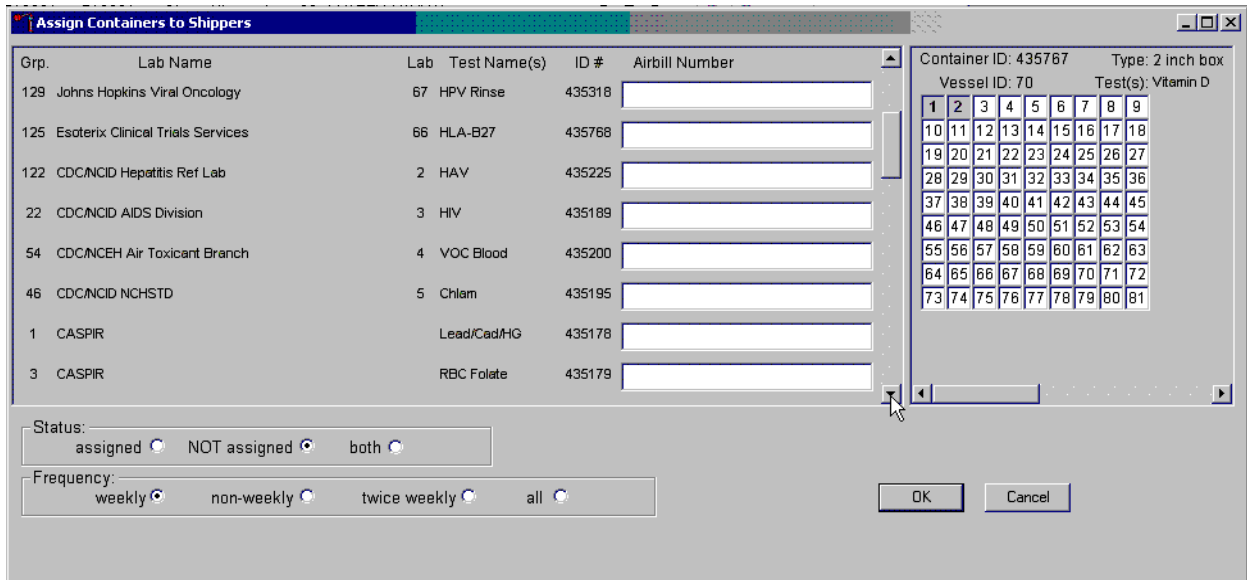
Enter an airbill number into each Airbill Number text box. Ensure the cursor is in the left side of the text box. There are three ways to enter the airbill number:

- 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-hand 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 0215.

To assign a container to the corresponding airbill:

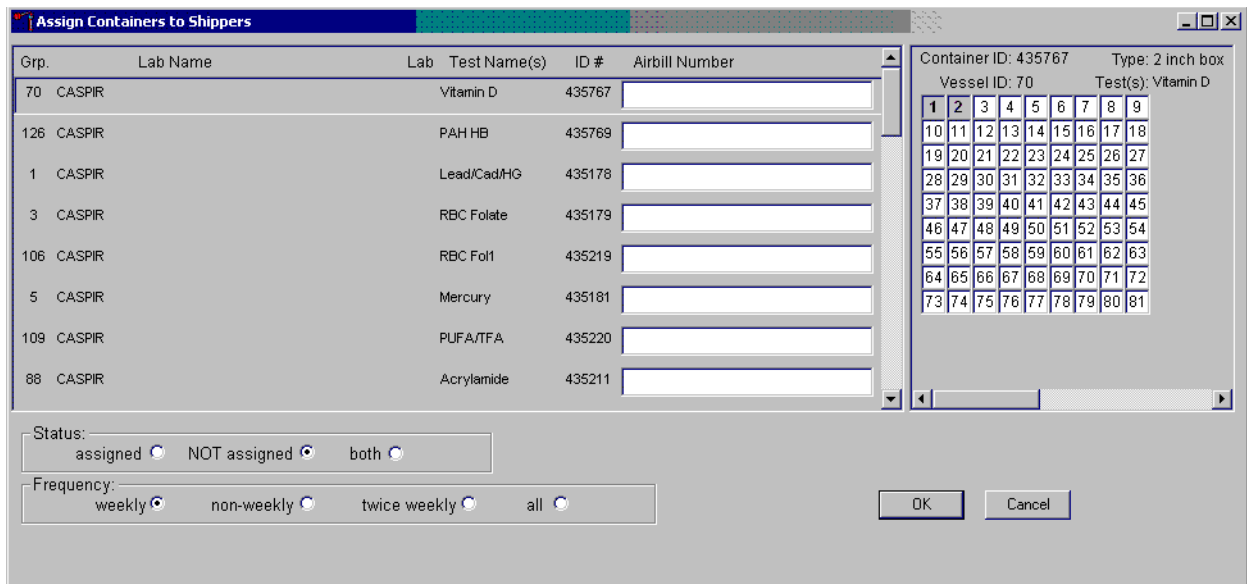
- Set the Status filter to: “NOT assigned”; and
- Set the Frequency to: weekly, non-weekly, or both, depending on the shipping situation.

Set the Status and Frequency filters.



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.

Sort the rows by Lab Name.



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.

Grp.	Lab Name	Lab	Test Name(s)	ID #	Airbill Number
70	CASPIR		Vitamin D	435767	79564329876587466789098767656787
126	CASPIR		PAH/HB	435769	
1	CASPIR		Lead/Cad/HG	435178	
3	CASPIR		RBC Folate	435179	
106	CASPIR		RBC Foli	435219	
5	CASPIR		Mercury	435181	
109	CASPIR		PUFA/TFA	435220	
88	CASPIR		Acrylamide	435211	

Status: assigned NOT assigned both

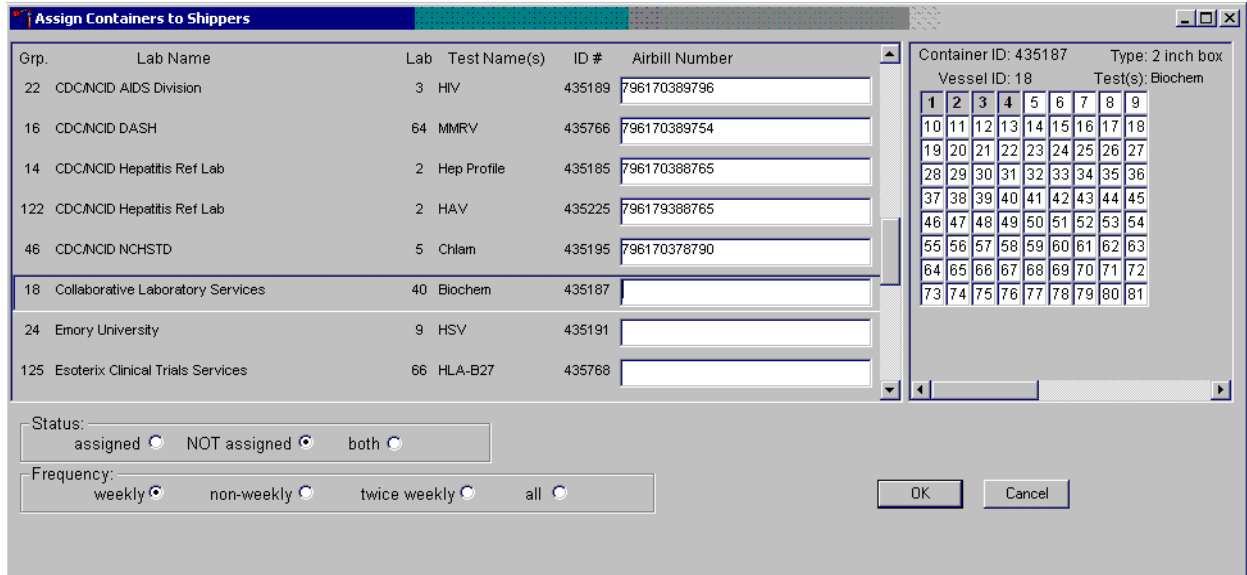
Frequency: weekly non-weekly twice weekly all

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

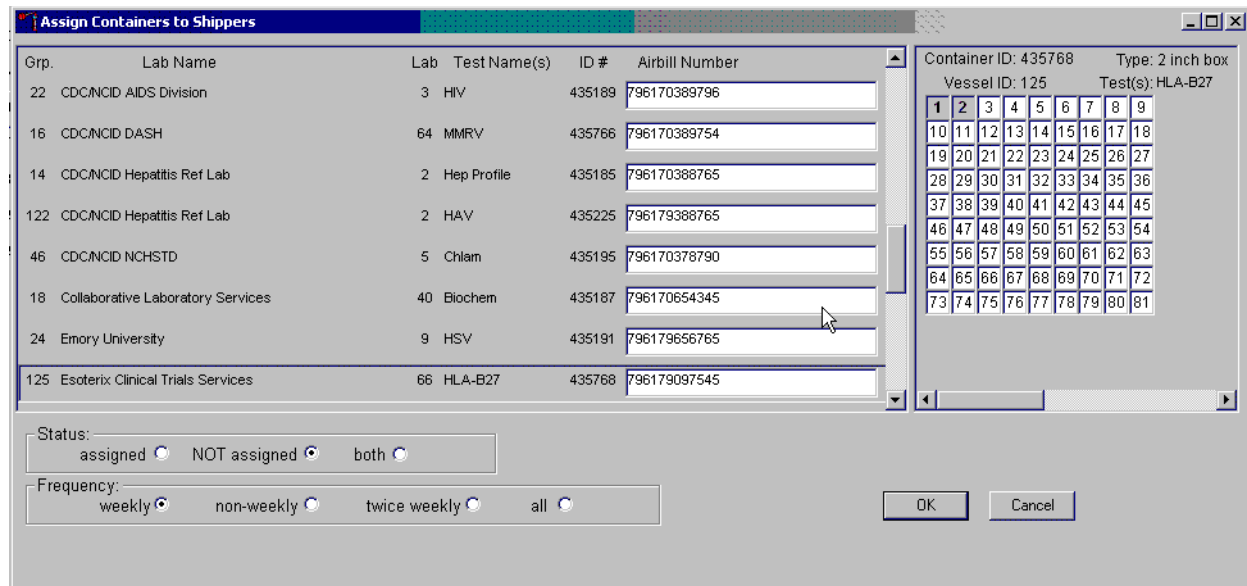
Use the barcode gun to scan the airbill number. The scanned number contains 20 extra digits. The actual 12-digit airbill number is embedded in the 32-digit scanned number. Select the Tab key to move to the next text box. Do not select the Tab key until the application has been allowed to enter the entire number into the text box. Once the Tab key is selected, the program edits the first airbill number to delete the extra numbers.

Continue the assignment process.



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 to send the electronic file.

Access the Shipping Manifest module.

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"/>	<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"/>	-
499508	499508	SC	P	F	5	DEEGAN, MARK	<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"/>	-	-
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"/>	-	-
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"/>	-
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"/>
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"/>	-
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"/>

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.

Shipping Manifest

Filter: Unprocessed Previously Processed

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"/>	796170389796	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
National Center for Health Statistics
3311 Toledo Road, Rm 4323
Hyattsville, Maryland 20782

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
Bldg 18 Floor 3 Rm 218 MS A33
Atlanta, GA 30329 Contact: Annemarie Wasley
Phone: (404)639-3103
E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	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 checkbox, the Airbill Number, Shipment Date, and Ship to Lab ID, and one checkbox 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.

Shipping Manifest

Filter: Unprocessed Previously Processed

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"/>	796170389796	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
 National Center for Health Statistics
 3311 Toledo Road, Rm 4323
 Hyattsville, Maryland 20782

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 Bldg 18 Floor 3 Rm 218 MS A33 Atlanta, GA 30329
 Contact: Annemarie Wasley Phone: (404)639-3103 E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	Hep Profile
Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKW5	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

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.

Select one or more manifests by placing a checkmark in the Mark for Processing checkboxes.

Shipping Manifest

Filter: Unprocessed Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" 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
 National Center for Health Statistics
 3311 Toledo Road, Rm 4323
 Hyattsville, Maryland 20782

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 Bldg 18 Floor 3 Rm 218 MS A33 Atlanta, GA 30329
 Contact: Annemarie Wasley Phone: (404)639-3103 E-Mail:

Container Id: 435185	Size: 9x9	Type: 2 inch box	Test(s):	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

To select or mark one manifest for printing and email, direct the mouse arrow to the checkbox 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.


Collectively mark or unmark all the airbills.

Shipping Manifest

Filter: Unprocessed Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796170389796	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
National Center for Health Statistics
3311 Toledo Road, Rm 4323
Hyattsville, Maryland 20782

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 Bldg 18 Floor 3 Rm 218 MS A33 Atlanta, GA 30329	Contact: Annemarie Wasley Phone: (404)639-3103 E-Mail:

Container Id	Size	Type	Test(s)	Hep Profile
435185	9x9	2 inch box		

Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKW0S	12/9/2008	2
3	244969014	000OKW0P	12/10/2008	2

To collectively mark all the airbills, direct the mouse arrow to the mark/unmark all checkbox and left-click. To collectively unmark all the airbills, direct the mouse arrow to the mark/unmark all checkbox 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.

Shipping Manifest

Filter: Unprocessed Previously Processed

Mark for Processing	Airbill Number	Shipment Date	Ship to Lab
<input checked="" type="checkbox"/>	796170388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796179388765	12/11/2008	CDC/NCID Hepatitis Ref Lab (2)
<input checked="" type="checkbox"/>	796170389796	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
National Center for Health Statistics
3311 Toledo Road, Rm 4323
Hyattsville, Maryland 20782

Shipping Manifest Report

Survey Year: 2007

Shipment ID: 796170388765
Shipment Date: 12/11/2008

Lab Name: CDC/NCID Hepatitis Ref Lab	Lab ID: 2
Address: 1600 Clifton Road Bldg 18 Floor 3 Rm 218 MS A33 Atlanta, GA 30329	Contact: Annemarie Wasley Phone: (404)639-3103 E-Mail:

Container Id	Size	Type	Test(s)	Hep Profile
435185	9x9	2 inch box		

Slot Id	Sample/Vessel Id	Astro Id	Date Collected	Age Group
1	184869014	000OKW0A	10/20/2008	2
2	312716014	000OKW0S	12/9/2008	2
3	244969014	000OKWBP	12/10/2008	2

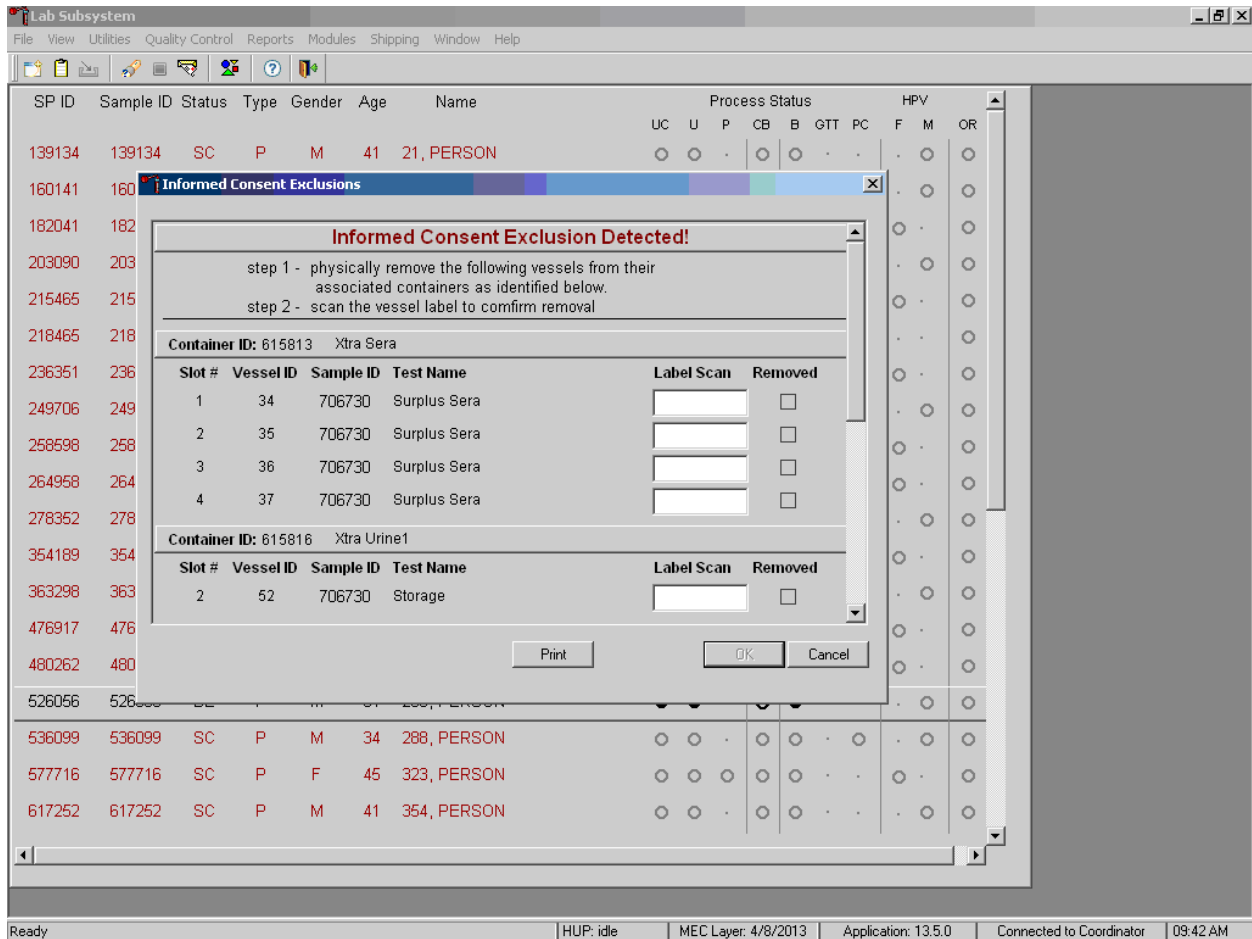
Selecting the “Process” button will generate and print the Shipping Manifest Report(s). To print the manifests, direct the mouse arrow to the Process button and left-click. To exit the module without printing the manifest, direct the mouse arrow to the “Close” button and left-click.

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, HPV, and STD testing;
2. They consent to have their vessels stored for future research;

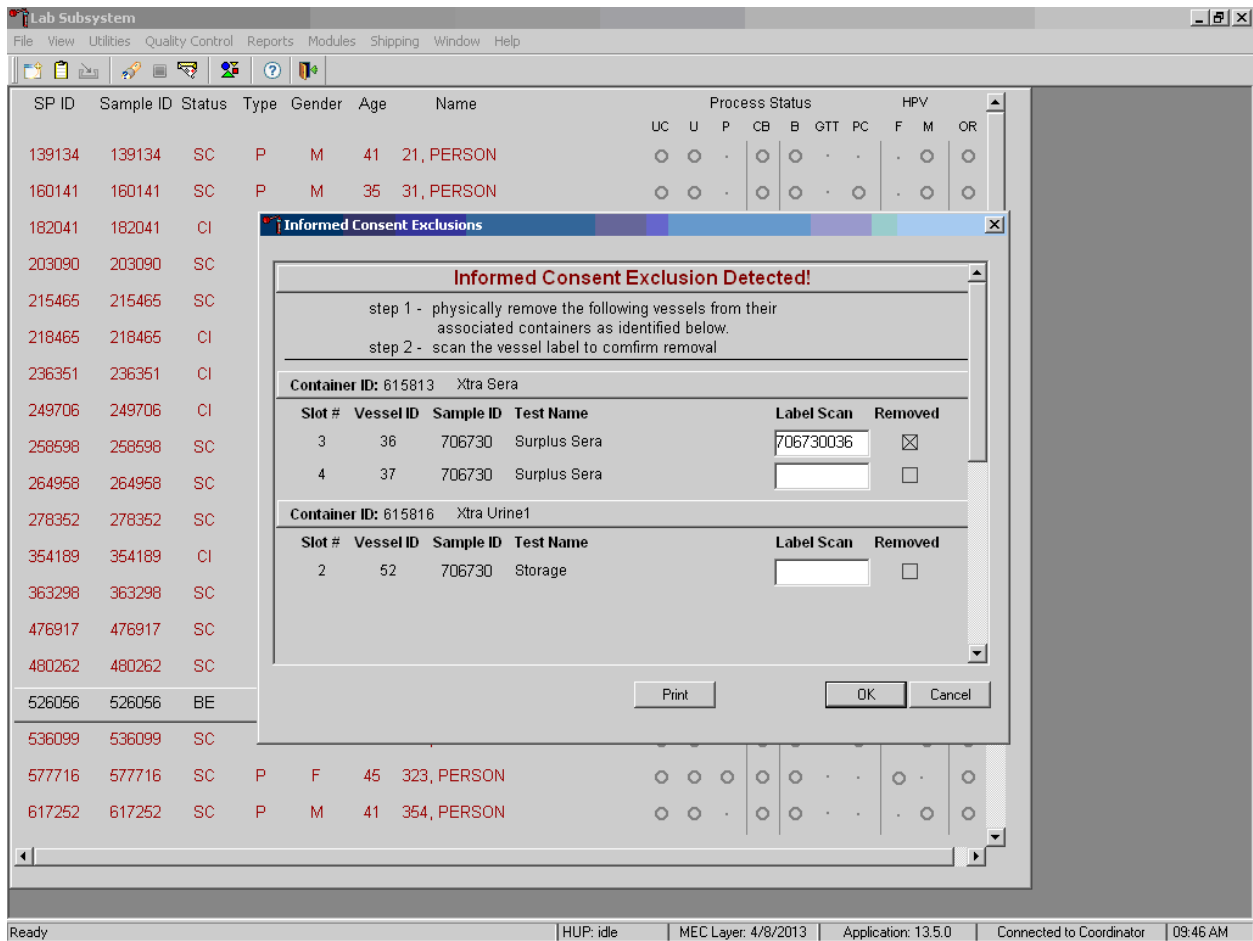
3. They subsequently revoke either consent; and
4. The associated vessels have already been processed.



The window contains two steps that must be taken in order 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 checkbox. A “Print” button on the bottom of the screen allows the list to be printed.

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.”

Affirm the actions taken to resolve these exclusions.



After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the barcode gun and scan the barcode for the tube to be removed. This will place an “x” in the removed checkboxes 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, then an Informed Consent Exclusions for Stand XXX warning pop-up box displays.



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 medical technologist’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 8-3 is a list of all contract laboratory addresses.

Exhibit 8-3. 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 TBD-Hep Xtra ser	Frozen	Jan Drobeniuc 404-639-3103
Lab 3 CDC/NCID AIDS Division Attn: Tim Granade/Vickie Sullivan 1600 Clifton Road NE Bldg. 17, Room 3127, MS A-25 Atlanta, GA 30329-4018 404-639-3850	22 – HIV	Frozen	Tim Granade/ Vickie Sullivan 404-639-3850
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	Refrigerated	Lalith Silva 770-488-3559
Lab 5 CDC/NCID NCHSTD Attn: Christi Phillips 1600 Clifton Road NE Bldg. 23, 3-661 Atlanta, GA 30329-4019 404-639-2147	46 – Chlam/Trichomonas/ M. genitalium 154 – Trichomonas/M. genitalium	Frozen Frozen	Christi Phillips 404-639-2147
Lab 6 CBR Attn: Robert White 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5942	1 – Lead/Cad/HG/Se/Mn 216- Cr/Co 3 – RBC Folate 5 – Mercury 88 – Acrylamide 221- RBC Folate Forms (all) 222- Fatty Acids (all) 110 –Fol1 99-Ferritin/Tfr 70 – Vitamin A, D, E, and Carotenoids 79 – Vitamin C 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 White 770-339-5942

Exhibit 8-3. 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 152 – Nicotine Analogs 220 – As/Cr/Ni 218-Aromatic Diamines 52/139 – Xtra urine 137-Steroid Hormones	Frozen	Robert White 770-339-5942
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	Refrigerate d Frozen Frozen	Curt Rohlfing (573) 884-2708
Lab 16 University of Minnesota Attn: Susan Kupcho 515 Delaware Street SE Room 13-219 – MOOS Tower Minneapolis, MN 55455-0357 612-624-6153	45 – Alb/Creat	Frozen	Susan Kupcho 612-624-6153
Lab 37 CDC/Human Papillomavirus Laboratory Attn: Mariela Scarbrogh 1600 Clifton Road NE MS G41 Bldg. 23/Rm. 4-409 Atlanta, GA 30329-4018 404-639-2187	78 – HPV Female Swab 140 – HPV Male Swab 129-HPV Oral Rinse	Refrigerated Refrigerated Refrigerated	Mariela Scarbrogh Krystal 404-639-2187
Lab 51 NHANES Lipid Laboratory University of Minnesota (ARDL) Attn: Jean Buksa 1200 Washington Ave S Suite 175 Minneapolis, MN 55415-1295 612-625-5040	21 – Lipids 18 – Biochem 13 – CRP 11 – Iron/TIBC/% Saturation 118-Thyroid Panel	Frozen	Jennifer Peters 612-625-5040

Exhibit 8-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name Telephone number
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 115 Univ. of Washington Virology Lab 1616 EASTLAKE AVE E STE 320 Seattle, WA 98102-3795 Attn: Gregory Pepper (206) 685-8037	223-226 - TB	Wet Refrigerated	Attn: Gregory Pepper (206) 685-8037
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

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. A complete description of these regulations is contained in Appendix A.

8.11.1 Pack the Boxed Specimens

Store the blood and urine 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 rubberband 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.
- 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).
- 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.

8.11.3 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.
- 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.
- 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 large 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 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.

8.11.5 Label the Shippers

For all destinations, include a preprinted FedEx barcoded airbill containing the shipping address, account number, package specifications and warehouse return address. Tape the airbill to the top of the shipper.

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 an UN 3373: “BIOLOGICAL SUBSTANCE, CATEGORY B” label to all shippers.
- The warehouse places an “overpack” label on all shippers.
- The warehouse places orientation labels to 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 pouch.

8.12 Container Protocol and Weekly Shipping List

Exhibit 8-4 illustrates the Container protocol. Use the container protocol as an aid at the start of each stand when opening new containers.

Exhibit 8-4. Container protocol

2020 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	216	Cr/Co	CBR	2-ml sterile cryovial	9 x9 two inch box
54	3	RBC Folate	CBR	2-ml cryovial	10x10 two inch box
10	4	Glycohem	University of Missouri	2-ml cryovial	9x9 two inch box
61	5	Mercury, Ethyl, & Methyl	CBR	2-ml sterile cryovial	9x9 two inch box
60	88	Acrylamide	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	CBR	2-ml cryovial	9x9 two inch box
115	115	TB (TB Gold Plus)	Univ. of Washington Virology Lab	TB Collection Tubes	9x9 three inch box
123	119	Genetics	ATCC Bethesda Maryland	6-mL EDTA tube	5x5 5 inch foam box
10	9	Glucose	University of Missouri	2-ml cryovial	9x9 two inch box
54	110	Folate	CBR	2-ml cryovial	10x10 two inch box
116	138	Cytomegalovirus	CDC/NCIRD CMV Diagnostic Lab	2-ml cryovial	9x9 two inch box
51	118	Thyroid Panel	University of Minnesota (ARDL)	2-ml cryovial	9x9 two inch box
54	99	Ferritin/Tfr	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	TBD	Hep Xtra Sera	CDC/NCID Hepatitis Ref Lab	2-ml cryovial	9x9 two inch box
2	87	Hepatit Bs Ab	CDC/NCID Hepatitis Ref Lab	2-ml cryovial	9x9 two inch box
59	17	Cotinine	CBR	2-ml cryovial	9x9 two inch box
51	21	Lipids	University of Minnesota (ARDL)	2-ml cryovial	9x9 two inch box
51	11	Iron/TIBC/% Saturation	University of Minnesota (ARDL)	2-ml cryovial	9x9 two inch box
51	18	Biochem	University of Minnesota (ARDL)	2-ml cryovial	9x9 two inch box
10	23	Insulin	University of Missouri	2-ml cryovial	9x9 two inch box
51	13	CRP	University of Minnesota (ARDL)	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

Exhibit 8-4. Container protocol (continued)

2020 Final container protocol					
Lab	Vessel	Test	Lab	Vessel	Container
60	137	Steroid Hormones	CBR	5-ml cryovial	9x9 three inch box
24	29	Dioxin/BFR	CBR	30-ml vial	4x4 five and a half inch box
28	90	Perfluor	CBR	2-ml cryovial	9x9 two inch box
6	32-37	Xtra sera 1-6	CBR	2-ml cryovial	9x9 two inch box
16	45	Alb/Creat	University of Minnesota	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
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
59	152	Nicotine Analogs	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
4	54	VOC Blood	CDC/NCEH Air Toxicant Branch	7-ml Gray tube	5x5 five inch foam box
37	78	HPV Swab - Female	CDC/Human Papillomavirus Lab	Swab	9x12 Ziploc bag* In shipper with Vessel 140
37	140	HPV Swab - Male	CDC/Human Papillomavirus Lab	Swab	7x7 three inch box
37	129	HPV Oral Rinse	CDC/Human Papillomavirus Lab	14-mL Falcon tube	5x5 five inch foam box

Exhibit 8-4. Container protocol (continued)

2020 Final container protocol					
Lab	Vessel	Test	Lab	Vessel	Container
61	144	Fluoride, water	CBR	10-mL plastic tube	5x5 three inch box
61	227, 228	Salt Samples	CBR	15 mL HDPE Container	10x10 three inch box

Bold- Ship at end of stand or when full.

THIS PAGE IS INTENTIONALLY LEFT BLANK.

9. HPV Swab Processing

9.1 Introduction

The purpose of collecting vaginal and penile swabs is to obtain suitable biological specimens to test for human papillomavirus (HPV). Human papillomavirus infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. The “high-risk” types of HPV (e.g., HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) are associated with cervical cancer, and the “low-risk” types (e.g., HPV 6, 11, 42, 43, 44) with genital warts. No national surveillance system exists to measure the full burden of HPV infection, and no reliable national population estimate of HPV exists. Therefore, NHANES offers a unique opportunity to assess the prevalence of HPV infection in the general population.

Reducing the prevalence of HPV infection is a Developing Healthy People 2020 objective: “Reduce the proportion of females with human papillomavirus (HPV) infection.” Detection and typing of HPV DNA in vaginal and penile swabs (in conjunction with testing of HPV oral rinse samples) will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. Studies have demonstrated that recovery of HPV from self-collected swabs is comparable to that from physician-collected cervical and penile samples.

HPV vaccine is available, and knowledge of the national prevalence of HPV infection will be critical for planning vaccination strategies in the United States. HPV vaccine is recommended for males and females from 11 to 26 years of age. It protects against new HPV infections; however, it does not cure existing HPV infections or disease.

DNA prevalence data are needed to improve baseline assumptions for models evaluating the impact of a prophylactic HPV vaccine on herd immunity and transmission of HPV 6, 11, 16, and 18, and to monitor the impact of HPV vaccine on prevalence of vaccine as well as non-vaccine types to identify trends indicative of type-replacement or vaccine failures. The objectives of this component are to estimate current HPV infection in the U.S. male population 14-59 years old; to describe relevant characteristics of men with HPV infection; and to provide baseline estimates to measure the impact of prophylactic vaccines.

For females, the HPV Hybrid Capture® II DNA results will be reported to survey participants via the same reporting system as for STD/HIV testing. This system is a respondent-initiated toll-free phone call to the National Center for Health Statistics (NCHS). Results are given to persons tested after a password is provided to verify identity.

For males, the Roche Linear Array HPV Genotyping results will not be reported to the survey participant via the same reporting system as for STD/HIV testing. If the participant explicitly requests the results for the HPV testing when calling for other STD test results by phone, the health educator will explain that HPV tests take several months to process. If the participant is willing to wait, results will be mailed at a later date.

Primary female and male study participants (SPs) aged 14-59 years collect the HPV swab. The physician prints the appropriate label. Each label includes the test name, six-digit SP ID that correlates with the vessel ID, and the corresponding barcode. The physician counsels each eligible SP and introduces the females to the vaginal collection technique and the males to the penile collection technique using a prepared collection kit.

The female collection kit is designed for SPs aged 14-59 years and includes illustrated collection instructions and one Epicentre® Dacron swab with foam tip. The physician removes the appropriate swab from the collection kit and labels the Epicentre® Dacron swab with the foam tip with the label displaying the vessel ID #78. The physician then places the swab back into the collection kit and gives the collection kit to the eligible SP.

The male collection kit is designed for SPs aged 14-59 years and includes illustrated collection instructions. This kit also includes the Diagene specimen transport media (STM) and Dacron swab. The physician opens the package and places a label on the STM vial, which includes the SP ID and vessel ID 140. The physician then places the swab back into the collection kit and gives the collection kit to the eligible SP.

The SP self-collects the appropriate swab in the mobile examination center (MEC) bathroom. Male SPs place the swab into the labeled vial and place the vial in the designated rack in the bathroom. The vial is then delivered to the laboratory by MEC personnel. The female SP places the swab back into the plastic container and returns it to the plastic bag. MEC personnel then deliver the plastic bag to the laboratory.

The laboratory staff verifies the SP ID and the vessel ID (#78) on the label of the Epicentre® Dacron swab with the foam tip, records the collection in the HPV module, and stores the swab at room temperature. For vessel 140, the laboratory staff verifies the SP ID and correct vessel number on the Diagene STM vial, and checks to verify there is sufficient liquid in the vial and that the cap fits securely. The medical technologist then stores it in a 3-inch box with a 7” x 7” grid in the refrigerator. The laboratory staff ships the specimens weekly to the Centers for Disease Control and Prevention (CDC) laboratory.

9.2 Supplies

The supplies needed for HPV processing and storage are shown in Exhibit 9-1.

Exhibit 9-1. Equipment and supplies—HPV processing and storage

Large padded envelope	Zip closable bag (9” x 12” clear)
7” x 7” three-inch box	

9.3 Protocol

Exhibit 9-2 illustrates the SP’s protocol for HPV processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 9-2. HPV processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Appointment type
78	HPV	14-59 females	1 swab	Vaginal swab	Epicentre® Dacron swab	Primary only
140	HPV	14-59 males	1 swab	Penile swab	Diagene transport media	Primary only

9.4 Labeling Vessels

The physician prints the vessel label and labels the specimen.

9.5 HPV Protocol

Process male and female HPV swabs and verify that the swabs are labeled correctly and that the label is legible.

Access the HPV Processing module for all SPs.

- Vessel 78 — HPV (female)
 - Verify that the tip of the Dacron swab in the clear plastic tube is foam. Verify that the SP ID on the label matches the SP ID on the processing screen (see Exhibit 9-3). Record the processing results in the HPV module and store the swab at room temperature.
- **Note:** If the swab is visibly contaminated with blood place in a bitron bag before storing with the other swabs. Vessel 140 — HPV (male)
 - Verify that there is liquid in the bottom of the vial. If not, ask for a re-collection.
 - Verify that the top of the swab is not pressed against the lid so that it loosens the lid.
 - Verify that the lid is tightly on the vial.
 - Record the processing results in the HPV module (see Exhibit 9-4) and store the swab in the refrigerator.

Exhibit 9-3. Female HPV module

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"/>	-	-
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"/>	-	-
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"/>	-	-
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"/>	-	-
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"/>	-	-
919919	919919	SC	P	M	57	PAYNE, IMAL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-

Exhibit 9-4. Male HPV module

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							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	○	○	-	○	○	○	-	○

9.6 Record Processing Results

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.

To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted, or drag the mouse arrow to the correct SP and right-click. To access the HPV Processing module, drag the mouse arrow to HPV Processing 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, and drag the mouse arrow to the correct module.

Document processing results (see Exhibits 9-5 and 9-6).

Exhibit 9-5. Female HPV Swab Processing screen

Lab Subsystem

File View Utilities Quality Control Reports Modules Shipping Window Help

Female HPV Processing: 615810

Sp ID	Sample ID	Name	Gender	Age
416714	416714	BAILEY, ANTHONY J	F	20
745052	745052	EVANS, SAVANNAH M	F	41
813366	813366	STEWART, SOPHIE J	F	19
919919	919919	PAYNE, IMA L	F	25

Refresh

Tech ID: 1756 Sample ID: 813366 Name: STEWART, SOPHIE J Gender: F Age: 19
 SP ID: 813366 Appt Type: Primary Fasting Req: Morning - Fast

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Exhibit 9-6. Male HPV Swab Processing screen

Sp ID	Sample ID	Name	Gender	Age
553872	553872	WRIGHT, LAYLA B	M	21
767995	767995	MURPHY, ISAAC N	M	15
784174	784174	GONZALEZ, SIENNA N	M	50
836040	836040	TORRES, LUCAS S	M	19
861215	861215	SMITH, MICAH S	M	18

Refresh

Tech ID: 1756 Sample ID: 836040 Name: TORRES, LUCAS S Gender: M Age: 19
 SP ID: 836040 Appt Type: Primary Fasting Req: Morning - Fast

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
140	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Both the Female and Male HPV Processing windows contain the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Type (SW = swab), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, and a Container ID and Container Slot# column. There is one row associated with vessel 78. Use radio buttons to record the processing results, Filled — Yes or Filled — No. If necessary, attach a comment using the Comment drop-down box, and store the vessel in the assigned Container ID and Slot#.

Mark vessel 78 as Filled — Yes if the swab was collected.

HPV: 446446

HPV processing

Tech ID: 1126 Sample ID: 446446 Name: CHAVEZ, ESPERANZA S Gender: F Age: 18
 SP ID: 446446 Appt Type: Primary Fasting Req: No Fasting Required

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No		0415803	1

Save OK Cancel

To mark vessel 78 as collected or Filled — Yes, direct the mouse arrow to the “Yes” radio button and left-click. As a vessel is marked as Filled — Yes, it is automatically assigned to a slot in an existing (open) container.

Mark vessel 78 as Filled — No if the swab was not collected.

HPV: 446446

HPV processing

Tech ID: 1126 Sample ID: 446446 Name: CHAVEZ, ESPERANZA S Gender: F Age: 18
 SP ID: 446446 Appt Type: Primary Fasting Req: No Fasting Required

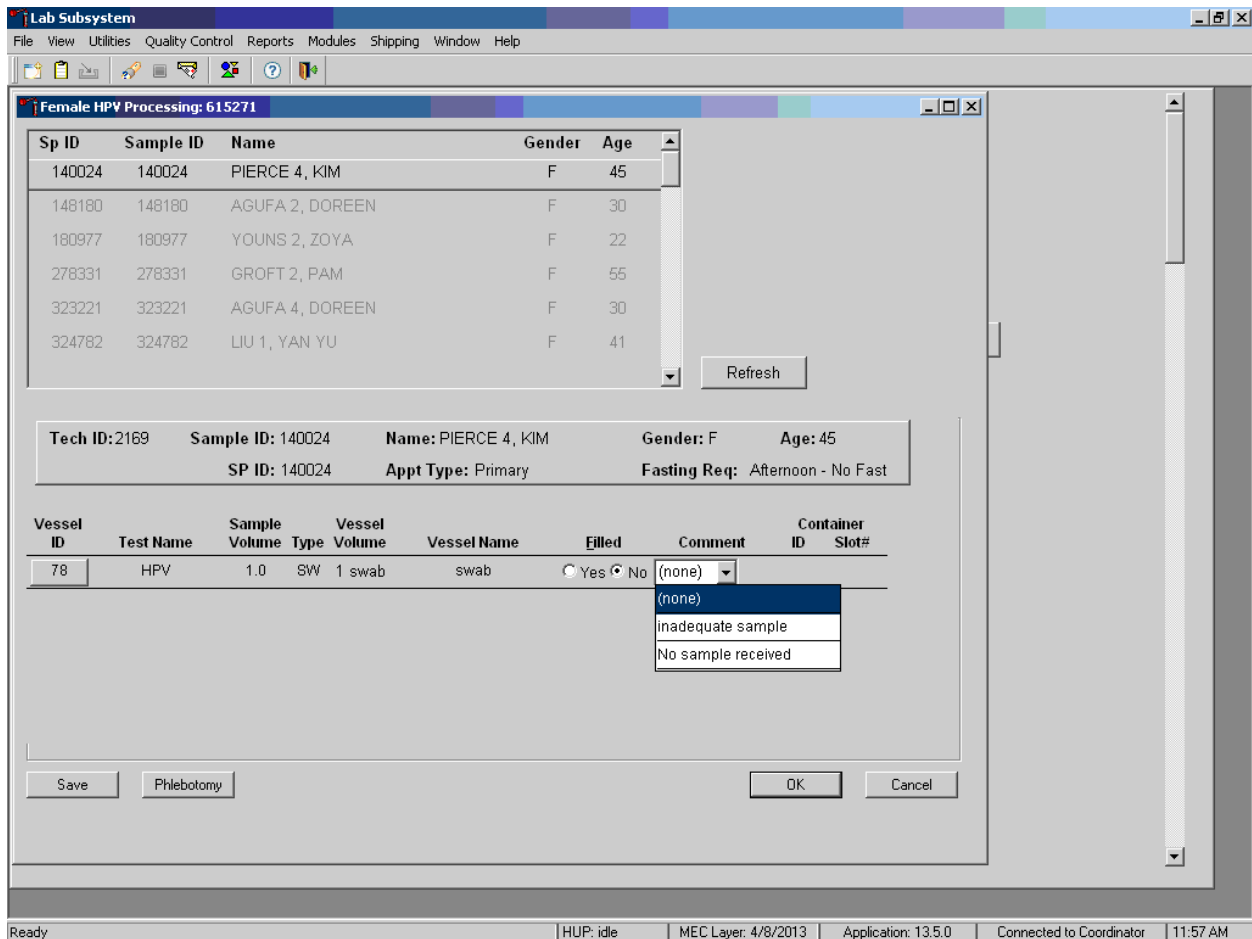
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none) ▼		

Save OK Cancel

To mark vessel 78 as not collected or Filled — No, direct the mouse arrow to the “No” radio button and left-click.

Enter a quality control (QC) comment for vessel 78 when the swab is dry and the judgment is that the SP did not attempt to collect the sample.

Note: Send any swab that looks as if it was collected, including bloody swabs. No comment is required.



To record an “inadequate sample” comment or “no sample received,” direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “inadequate sample” or “no sample received,” and left-click.

Store the Epicentre® Dacron swab in the assigned 9” x 12” plastic bag at room temperature; review the information in the HPV Processing window, and save the data to the database.

HPV: 446446

HPV processing

Tech ID: 1126	Sample ID: 446446	Name: CHAVEZ, ESPERANZA S	Gender: F	Age: 18
	SP ID: 446446	Appt Type: Primary	Fasting Req: No Fasting Required	

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
78	HPV	1.0	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No		0415803	1

Save OK Cancel

To record this action or save the data to the database, direct the mouse arrow to the Save button and left-click. To record this action or 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.

The process status circle in the heads-up display fills in completely for SPs whose vessel 78 is recorded as collected or Filled – Yes. Do not enter a result until the swab arrives in the laboratory. At the end of each session, review the results for each SP. **Access each record still enabled and enter the Filled — No result for all vessels for SPs for whom no swab was received, and choose the comment “no specimen received.”**

For vessels 78 and 140, perform container content verification on all vessels processed for each session. (For detailed instructions on this process, refer to Chapter 2.)

9.7 Specimen Storage

Record the processing result for the Epicentre® Dacron swab and store the swab in a 9” x 12” plastic bag at room temperature. Store vessels in numbered storage containers according to each vessel as indicated in Exhibit 9-7.

Store each vessel in the appropriate slot in the correct container immediately after processing. Check the slot assignment of containers associated with vessel 78 at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 9-7. Storage protocol for HPV

Shipping location	Vessel	Condition	Vessel storage
CDC/Human Papillomavirus Laboratory	78 HPV Swab, female	17-25 °C	9" x 12" plastic bag
CDC/Human Papillomavirus Laboratory	140 HPV Swab, male	Refrigerated	7" x 7" three-inch box

9.8 Shipping Procedures

Ship vessel 140 according to procedures described in Chapter 8. Ship vessel 78 according to procedures in Section 9.8.1. Place a barrier (newsprint/blue chuck) between the U-teks and the female swabs. Exhibit 9-8 illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Exhibit 9-8. Shipping protocol

Laboratory	Vessel	Test name	Vessel storage	Shipping frequency
CDC/Human Papillomavirus Laboratory	78	HPV Swab, female	Refrigerated	Weekly
CDC/Human Papillomavirus Laboratory	140	HPV Swab, male	Refrigerated	Weekly

9.8.1 Pack and Ship Vessel 78

- Place the plastic bag that contains the specimens into a biohazard bag and then into the large padded envelope.
- Place the padded envelope in the shipper with vessel 140. Place a barrier (blue chuck/newsprint) between the U-teks and the female HPV swabs.
- Place the appropriate shipping manifest in a 9" x 12" plastic bag and seal.
- Place a plastic envelope containing the appropriate shipping manifest into the shipper.

9.8.2 Label Shippers

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels.

Label all shippers with the appropriate warning labels as follows:

- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

9.9 How to Deal with System Failure

If the computer system fails, record results on a preprinted HPV Processing worksheet (Exhibit 9-9). Complete a Workstation 2 worksheet for each SP while processing the HPV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 9-9. HPV processing worksheet

HPV SWAB PROCESSING

SP ID _____

ID	Name	Ages/gender	Sample ml	Sample type	Filled ✓	Slot #
78	HPV Swab, female	14-59 females	1 swab	Epicentre® Dacron Swab		
140	HPV Swab, male	14-59 males	1 swab	Diagene Swab w/Transport Media		

THIS PAGE IS INTENTIONALLY LEFT BLANK.

10. 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 Manual.

10.1 Safety

10.1.1 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.

10.2 Specimen Submission and Handling

10.2.1 Introduction

The goal of specimen submission and handling is to optimize the accurate and reliable measurement of analytes of interest. Each analytical procedure used in NHANES is documented in the 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).

10.2.2 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 Sharpie 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.

10.2.3 Questions on Specimen Submission and Handling

The Lab Component Lead/Assistant Lead addresses questions concerning specimen collection, including handling and testing.

10.3 Test Requisition

10.3.1 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 8-13 who report that they are menstruating when asked during the home interview. If a urine pregnancy test is positive on any female SP aged 8-17 years, the urine test is repeated. The physician 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.

10.3.2 Laboratory Tests

The MEC physician reports “critical” or abnormally high CBC results to the SP. The report includes laboratory tests that will be performed. The MEC physician involved in the measurement may also confer with the SP to obtain any other pertinent information that might facilitate the laboratory measurement process.

10.3.3 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.

10.4 Test Records

10.4.1 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.

10.4.2 Components of Test Records

Test records include:

- Person performing the test (may be identified by initials or a unique four 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.

10.5 Test Report

10.5.1 Introduction

The laboratory Report of Findings, which gives the results of the tests performed on the mobile examination center (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.

10.5.2 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 are reported.

Review and approval of the CBC and urine pregnancy test results by the MEC physician are documented. Review by the MEC physician 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 physician with such results.

10.5.3 List of Methods and Method Details

NHANES maintains a Laboratory Procedures Manual (LPM), which includes detailed descriptions of each analytical procedure, including analytical sensitivity, specificity, and accuracy, interfering substances, and other information.

10.5.4 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.

10.5.5 Format for the Laboratory Report Cover Letter

An example of the laboratory report cover letter (Report of Findings) is available upon request.

10.5.6 Format for Listing of Laboratory Results

An example of the laboratory results is available upon request.

10.6 Quality Control

10.6.1 Introduction

Most quantitative analytical procedures involve several operations, or steps, and each operation is subject to some inaccuracy, imprecision, or to the possibility of a mistake. The immediate aim of quality control is to ensure that the analytical values produced by a clinical laboratory are sufficiently reliable for their intended purposes. A broader objective is to ensure that all laboratories produce analytical values that meet acceptable standards of precision and accuracy.

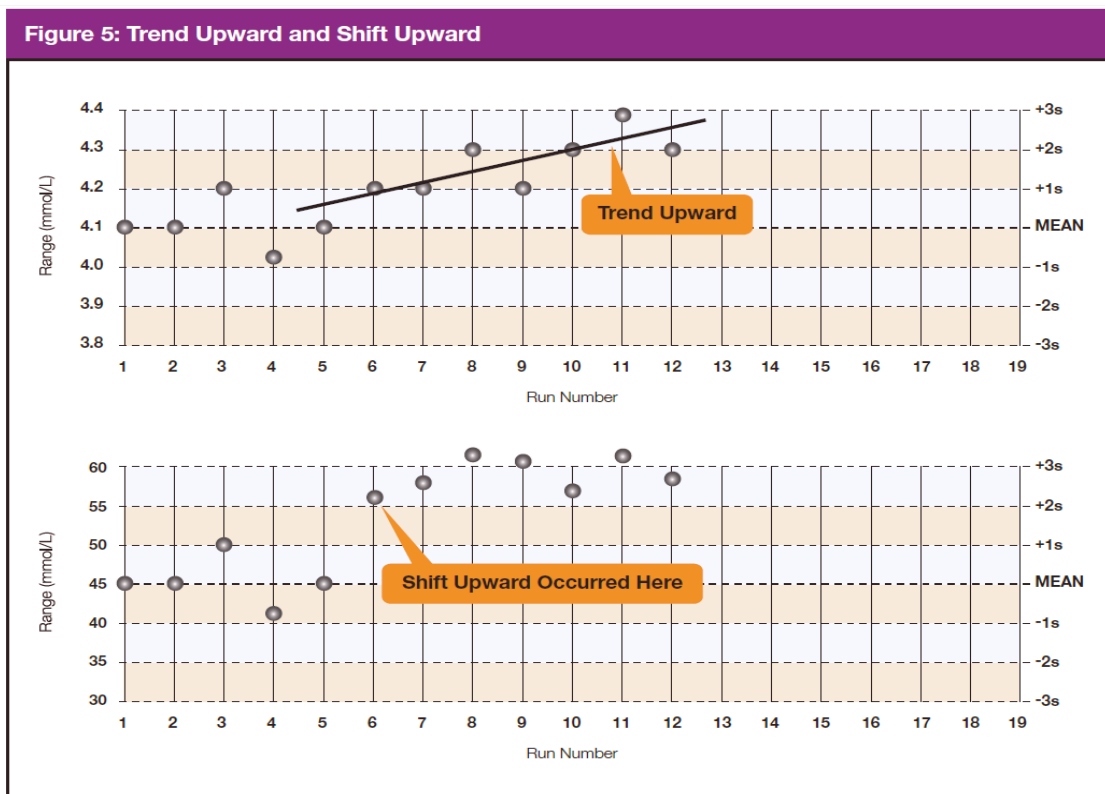
Quality control (QC) in laboratory medicine is the monitoring of the analytical measurement process to determine if it is performing correctly and patient results are reportable. The term “quality assurance” (QA) represents the entire process used to ensure with a specified degree of confidence that 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 10-1 presents examples of shifts and trends in QC data.

Exhibit 10-1. 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 technologist 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.

Quality assurance (QA) addresses all three phases of measurement: pre-analytic, analytic, and post-analytic. QC is therefore viewed here as one part of the overall QA process.

10.6.2 Method-Specific QC Procedures

Specific QC procedures exist for each analytical laboratory procedure in the LPM. The following are some general aspects of QC procedures.

10.6.3 QC Definitions

Internal (“Bench”) Quality Control

For purposes of this document, internal quality control 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.

10.6.4 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. Medical technologists perform instrument calibration.

Most laboratory quality control programs include running internal (“bench”) QC with each analytical run to ensure each analytical run is in control. 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.

10.6.5 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 and end of each session 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.

Standard 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.

10.6.6 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. Technologists 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 technologists 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 10-2 through 10-6).

Exhibit 10-2. 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.

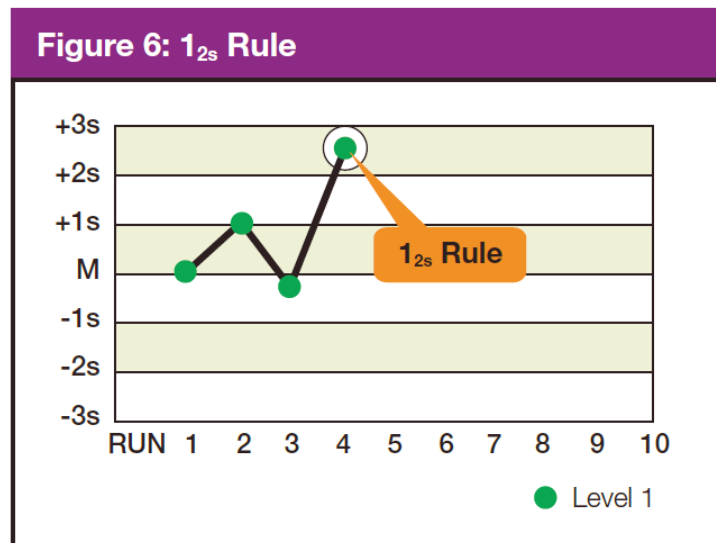


Exhibit 10-3. Westgard Rule 1_{3s}

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.

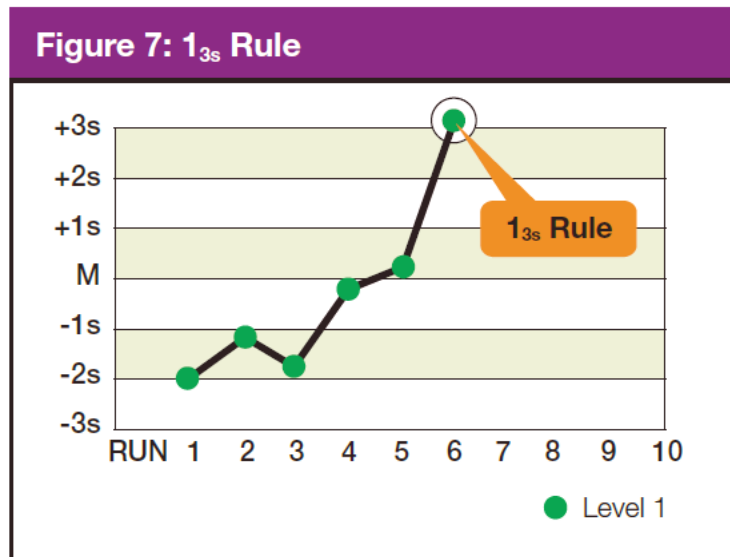


Exhibit 10-4. Westgard Rule 2_{2s}

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 are greater than 2 SD of control limits on the same side of mean within or across the run, with this rule.

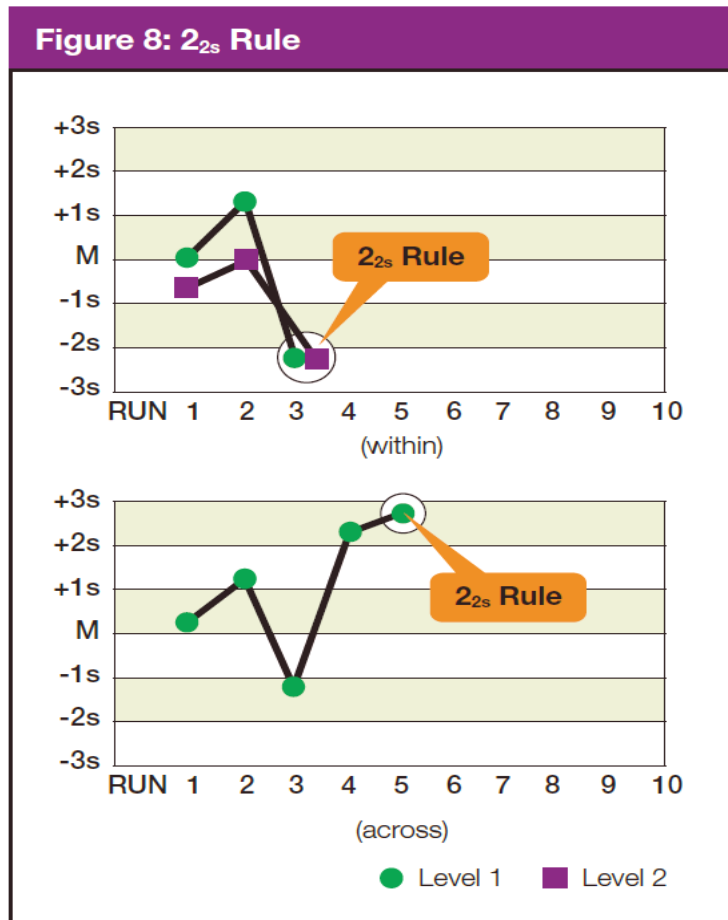
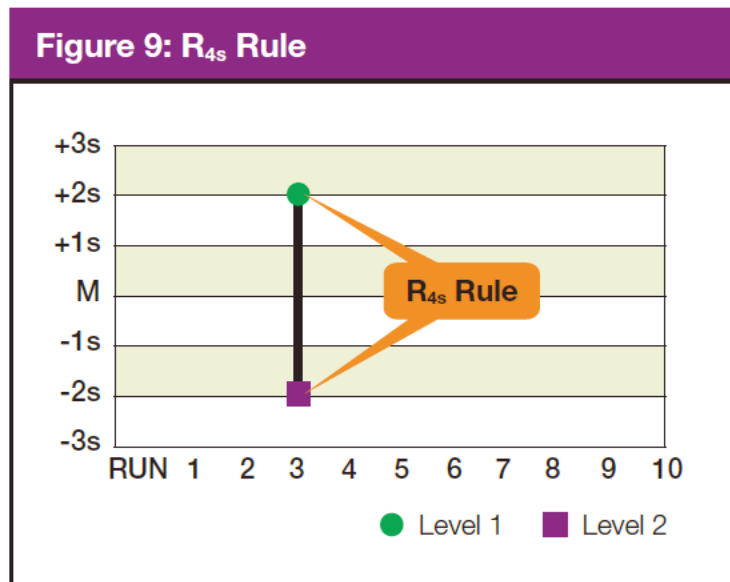


Exhibit 10-5. Westgard Rule R_{4s}

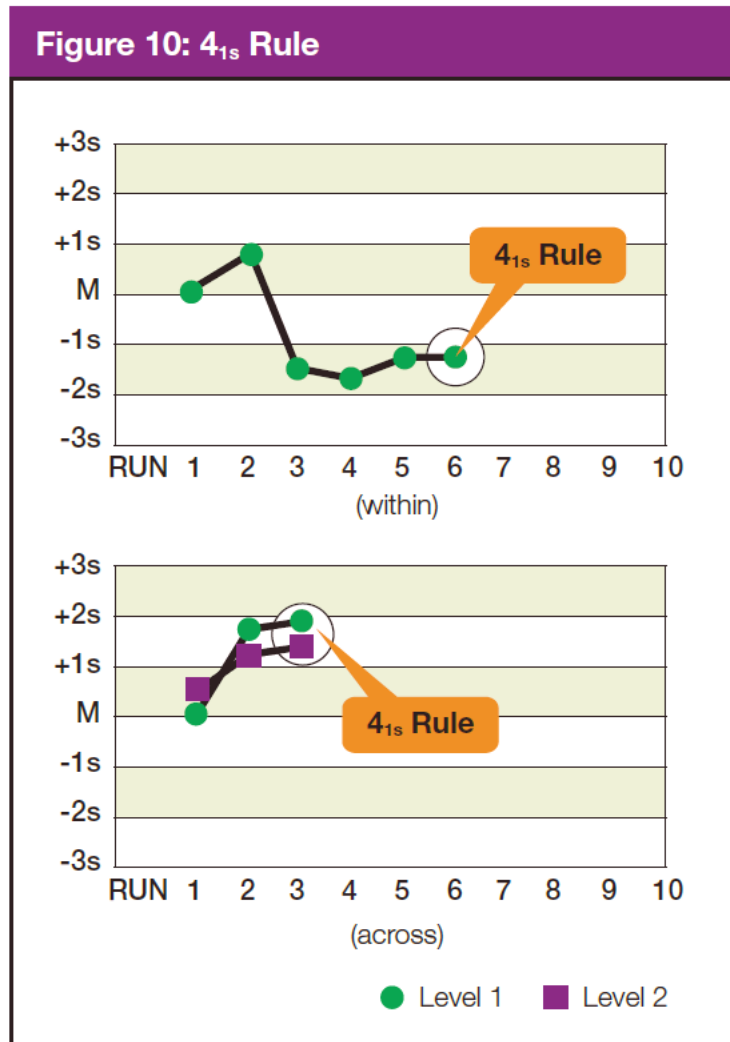
Rule R_{4s} . This rule rejects a run if there is at least a 4 SD difference between control values within a single run. For example, Level 1 control is +2.9 SD above the mean and Level 2 is -1.4 SD below the mean. The total difference between the two control levels is greater than 4 SD. This rule identifies 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 10-6. 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.



10.6.7 Calibration and Calibration Verification

10.6.7.1 Introduction

Calibration and calibration verification are specified in the documentation of the CBC analytical procedure in Chapter 6.

10.6.8 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, including the precision limits established to compare the duplicate runs of each sample.

After results have been evaluated and uploaded into the CAP online system, but while the samples are still fresh, other technologists 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 techs for the purposes of testing supervision and/or possible retraining of staff.

10.6.8.1 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 – Associate Service Fellow – Laboratory
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:
 - Data: Barcode – delete “Click Me” or “0000001” and type in proficiency sample number, i.e. FH6-01
 - Align: Center
 - Size: Medium

- Show Barcode Text: Below
- 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 labelmaker.
- 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).
- Menu
- Reporting
- 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

10.6.8.2 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 10-7). The percent difference will be calculated as $\text{absolute } (x_1 - x_2) / \text{mean } (x_1, x_2)$. 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 $\text{absolute } (x_1 - x_2)$. 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 10-7) will be used:

Exhibit 10-7. 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
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

10.6.9 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.

10.6.10 Linearity

The linearity controls verify the reportable range of Beckman Coulter hematology systems. Linearity is performed at installation, at least yearly, and whenever experiencing an altitude change of 1 mile or more between locations using 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.

10.6.11 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.

10.7 Test Methods, Equipment, Reagents, Supplies, and Facilities

10.7.1 Introduction

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the 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.

10.7.2 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, technologist's 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 technologist 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.

10.7.3 Facilities

Laboratories are arranged to ensure that adequate space, ventilation, and utilities are available for all phases of testing: pre-analytic, analytic, and post-analytic.

10.8 Analytical Procedure Manual

10.8.1 Introduction

All procedures performed in the 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.

10.8.2 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.

10.8.3 Approval and Record Maintenance

Each procedure is reviewed, approved, signed, and dated by the clinical consultant and technical supervisor and laboratory director of NHANES. Procedures are reapproved, signed, and dated if the director changes. Each change in a procedure is approved, signed, and dated by the current director. The procedure includes the dates of initial use and discontinuance, if discontinued. The procedure documentation is maintained for 7 years after discontinuance of the method.

10.8.4 Method Performance Specifications

Method performance specifications for each analytical method 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 the LPM 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, by comparing results on split samples with a method considered more definitive, or by analyzing a sample of persons ($n > 20$) and examining the measurement output searching for interference. The appropriate procedures for verifying analytical specificity will vary by analytical method. Substances 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.

10.9 Equipment Maintenance and Function Checks

10.9.1 Introduction

Laboratory equipment is checked regularly 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.

10.9.2 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.
- 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.

10.9.3 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 the medical technologists 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 medical technologists 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 10-8). Quality control temperature ranges have been established based on these recommendations.

Exhibit 10-8. 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 to 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 to 46°F)
Sure-Vue Urine Controls	2-8°C (36-46°F)	2-8°C (36-46°F)
QuantiFeron TB Blood Tube	4 to 25 C°	15-25°C (59-77°F)
BD Vacutainer 7mL Gray VOC	unknown CDC product	15-25°C (59-77°F)
BD Hemogard 2 mL Gray Top	4 to 30 C°	15-25°C (59-77°F)
BD Hemogard 3mL EDTA Lavender	4 to 30 C°	15-25°C (59-77°F)
BD Hemogard 4 mL EDTA Purple Top	4 to 25 C°	15-25°C (59-77°F)
BD Vacutainer 10mL Red Top	4 to 25 C°	15-25°C (59-77°F)
Covidien 7mL EDTA Lavender Top	0 to 40 C°	15-25°C (59-77°F)
Covidien 7mL Red Top	0 to 40 C°	15-25°C (59-77°F)

The following ranges have been established for monitoring instrument quality control (Exhibit 10-9).

Exhibit 10-9. 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 to 46°F)
Beckman centrifuge (room temperature)	-5 to +30°C (23-86°F)	15-25°C (62 to 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 to 41°F)	2-8°C (35 to 46°F)
LFBSC	0.450	0.350 to 0.550
Phlebotomy refrigerator	None	2-8°C (35 to 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 temperature for the -20°C Jewett model is -18 to -23°C. The range of allowable temperature 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.

10.9.4 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 LIS. A range of <80% is acceptable to operate the laboratory.

10.10 Troubleshooting

10.10.1 Introduction

Troubleshooting actions are taken and documented when:

- Test systems perform outside acceptable performance specifications. Troubleshooting is documented in the appropriate QC manual.
- 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 timeframe, 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 physician 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.

10.11 Integrated Survey Information System (ISIS)

10.11.1 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.

10.11.2 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.

10.11.3 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.

10.11.4 Backup Schedule of Integrated Survey Information System Data

ISIS data stored on LAN hard disk drives are backed up to tape once each weekday (Monday through Friday). If ISIS data are stored on local PC or minicomputer hard drives, they are archived to a second hard disk, tape, optical diskette, or CD-ROM at least once a week.

10.12 Communications and Complaints

10.12.1 Introduction

Good communication between the laboratory and persons reviewing laboratory analyses is essential for proper use of laboratory results. NHANES encourages collaborative relationships between technologists and physicians utilizing laboratory data. This collaborative interaction is the primary mechanism by which NHANES evaluates the effectiveness of laboratory protocols and other laboratory communications. If the laboratory has a persistent problem with meeting laboratory criteria (e.g., inadequate amount of specimen), the MEC manager, technical supervisor, or laboratory director will discuss the problem with the person in a collaborative spirit. 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 his or her 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 him or her. 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.

10.13 Quality Promotion

10.13.1 Introduction

High-quality laboratory results are generated when all phases of the measurement process (i.e., pre-analytic, analytic, and post-analytic) are conducted properly. Factors that promote high quality results include:

- Competent, well-trained, and motivated laboratory staff;
- Quality laboratory facilities;
- Well-maintained, high-quality laboratory equipment;
- High-quality laboratory analytical methods; and
- Clear commitment of management to quality laboratory results.

NHANES is committed to supporting each of these factors to enhance quality.

10.14 Quality Assurance Program

10.14.1 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 included the following requirements:

- All data are released in a timely manner relative to its intended use. All CBC results are provided to the SP in a preliminary Report of Findings when the SP checks out of the MEC. If the results are not available by the time the SP checks out of the MEC, they are reviewed by the MEC physician as soon as they are available, and the SP is notified by 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 study participant. Mailing labels are printed, the mailing label is matched to the final Report of Findings, and the final Report of Findings is inserted into the envelope. NCHS monitors communications from SPs who report that they have received the incorrect Report of Findings.
- All results are generated based on results stored in the database. The ISIS system prohibits the MEC technologist from changing data in the database after the SP has checked out of the MEC or if the MEC Report of Findings has been printed. All subsequent copies of results should match the original results. If any result is ever changed in the database, a back-end editing request system form is submitted, tracked, and maintained by ISIS.
- A comprehensive security system guards against unauthorized access. A complete description of this system is maintained by and is available through NCHS.

The basic mechanism for the QAP is the quality audit. The quality audit is conducted by the NHANES technical supervisor or laboratory director, who maintains documentation of the results of the quality audits, including remedial actions taken to address conditions that merited corrective action.

The QAP audits are reviewed monthly during the NCHS-Westat Laboratory Quality Assurance meeting.

10.14.2 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.

10.14.3 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.

10.14.4 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 audit the documentation of personnel training and evaluation to check whether the analyst has been appropriately evaluated in the last year (or 6 months if in the first year performing a new method). The evaluation criteria are described in the Personnel Training and Evaluation section of the LPM (Chapter 10, Section 10.15). The technical supervisor maintains documentation of the results of the audit.

10.14.5 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)	1	5.7

10.14.6 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% 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% of the total sample volume requires a plan of corrective action and follow-up.

10.14.7 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. Medical technologists are required to send an observation through ISIS to the physician for any participant parameters flagged as extremely high or low. The physician documents discussion with the participant and may refer the participant to a clinical physician 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 addressed immediately by the Laboratory Component Lead.

10.14.8 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 the 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.

10.14.9 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 are immediately notified via email of any occurrences so 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.

10.14.10 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 that no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

10.15 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 six months afterward for the first year. Assessments are performed annually thereafter. The evaluation shall consist 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).

10.16 Competency Assessment

10.16.1 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 reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

10.16.2 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 10-10). 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 10-10. 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 10-10 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	Completed 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

THIS PAGE IS INTENTIONALLY LEFT BLANK.

11. Operational Issues

11.1 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 reception area until set-up day. On set-up day, the supplies are put away in the laboratory and mobile examination center (MEC) trailer compartments.

While advance arrangement staff may assist in completing some set-up activities, the phlebotomists and medical technologists are responsible for most set-up activities. On set-up day, the phlebotomists will complete the set-up activities for phlebotomy and medical technologists 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, medical technologists will handle the following tasks:

- Perform maintenance on and test the functionality of all instruments and equipment.
- Complete the inventory sheet, note deficiencies in the inventory, and then give 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.
- Document instrument and equipment malfunctions in the Troubleshooting Log if applicable.
- Mark and store 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 medical technologists will handle separately within each work area are described in further detail in Sections 11.1.1 and 11.1.2.

11.1.1 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 $\geq 80\%$ 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).
 - 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.
 - Turn on the refrigerator in phlebotomy (done by FES).
 - Verify the refrigerator's operation.
 - Clean the refrigerator.
 - Check the function of the telephone intercom (done by FES).
 - Clean all work surfaces and storage areas.
 - 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;
- Prepare blood tube racks according to the protocol for each SP;
- Perform venipunctures;
- Label and pass tubes to laboratory;
- Assist in WS1 if needed;
- 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;
- Clean all surfaces, storage areas, and phlebotomy chair
- 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. The EOS transfer inventory sheet will be used to indicate which items were sent back to the warehouse (refer to Section 11.3.6).
 - QuantiFeron TB Blood Tubes – keep original box blue & white-KEEP original cardboard boxes that the kits come in and ship the partial trays back in those boxes so the warehouse has the lot number.
 - BD Vacutainer 7mL Gray VOC
 - BD Hemogard 2 mL Gray Top
 - BD Hemogard 3mL EDTA Lavender
 - BD Hemogard 4 mL EDTA Purple Top
 - BD Vacutainer 10mL Red Top

- **Note:** The EOS transfer inventory sheet will be used to indicate which items were sent back to the warehouse (refer to Section 11.3.6). Send Phlebotomy Refusal Spreadsheet to Home Office Staff;
- Secure all supplies and equipment for transport.

11.1.2 Medical Technologists' and Facilities and Equipment Specialists Responsibilities

Laboratory

Medical technologists' responsibilities include the following tasks:

- Inventory consumables and non-consumables (see Section 11.3.5 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 before flushing the eyewash unit.
 - Flush until water runs clear (at least 1-2 minutes).
 - Reinsert the filter 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 portable phone and ensures it is charging (technologist in Workstation 3 or WS 3).
- 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. If the surface and storage areas were not cleaned and disinfected at the end of the previous stand, then clean and disinfect them at the start of the current stand.
- Stock and organize supplies.
- Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC.
- 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 readings and activities in the Laboratory QC module.
- Call FedEx to check availability (1-800-463-3339).

Duties by workstation are presented in Section 11.1.3.

11.1.3 Workstation Responsibilities for the Team

Workstation 1

Setup

- Print inventory sheets.
- Count previous inventory before counting the new start-of-stand (SOS) inventory;
- Assist in recording new inventory and putting all the supplies away.
- Count, cut open, and store all shippers in the designated belly compartments.
- Organize the laboratory belly compartments using personnel identified to be able to carry heavy loads (the “Muscle”). These personnel will remove shippers from the belly of the trailer and inventory the contents within.
- Place receive date stickers on all reagents and on 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 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 when are the last available pickup times Monday thru Friday, as well as the weekend; and
- Ask if there is a local facility accepting dangerous goods (e.g., dry ice for late dropoff)
- Make racks for the dry run session (with the assistance of the phlebotomist). For dry run SPs, put a yellow cryodot on when labeling the vessels for that session.
- 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 and HPV oral rinse labels in WS 3).
- Make any newly appointed SP racks or pull any rescheduled racks that have been added to the current session.
- Process blood for first 45 minutes of each session.
- Incubate TB samples. Centrifuge and store refrigerated after incubation.
- Make all racks for each upcoming session (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 technologist is responsible for phlebotomy.

- Check the informed consent status throughout the session and add yellow dots to the affected vessels for those SPs that refuse future studies. Let the WS 3 technologist know of a “yes” informed consent status so the extra urine sample vessels can be discarded for that SP.
- If time permits, prepare Class 9 labels for the next stand. Give the labels to the chief technologist for transport to 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: make airbills and return packets.
- Process salt samples.

Shipping Day

- Work morning session in Workstation 3.
- Pull and label shippers.
- Assign containers to shippers.
- Perform functions of the “**outside person.**” Pack all frozen containers into shippers with dry ice.
- Have the evening session **off!**

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. 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

- Count existing inventory in Workstation 2 (WS 2).
- Assist in recording new 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 to remove any debris present using Terri-wipes.
- Set up pipettes, 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

- Report to work 45 min after the start of the session (with the exception of dry run, **everyone reports to work at 8:30 a.m.**).

- Process blood specimens (whole blood, plasma, and serum).
- Complete container mapping (**after each session**). Verify cryodots have been applied to dry run, all 1- to 2-year-olds, guests, and non-consented SP's for future studies.
- Verify that red caps have been applied to 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. Discard those supplies at the End of Stand.
- Record WS 2 inventory.
- Clean Eppendorf Pipettes.
- Tear down and clean centrifuges.
- Wipe down the mini vortex with a Sani-Cloth Plus; store for transport.
- Tear down and clean the laminar flow hood.
- On shipping days perform functions of the “**inside person**.” Pack up all refrigerated shippers and HPV swabs; assemble frozen packages for outside shipping person).
- Clean freezer #4 and refrigerator #2.
- Tear down workstation (shut down and secure computer, turn off the UPS, strap down printer, unplug Dymo printer and scanners [store in phlebotomy bin] and wipe down workstation countertop).

- 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.
- Count existing inventory in WS 3.
- Place receive date on all reagents and consumables with expiration dates and/or lot numbers.
- Rotate stock based on expiration dates.
- Record new 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.

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:** Latron and 6C controls; **Second Session:** 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, incubator temp, 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 volatile organic compounds and male and female human papillomavirus (HPV) swabs.
- Process VOC tubes.
- Process Genetics tubes.
- Process HPV oral rinse samples.
- Perform container mapping (**after each session**).
- 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 Nalge 13mm and 16 mm half racks), centrifuge cups, and rocker pads at the end of the week.
- Perform weekly DxH maintenance.
- Process water samples of those SP's that have completed a MEC exam.

Shipping Day

- Take the morning session **off!**
- Come in at 12:15 p.m. and help wrap any containers, if applicable.
- Shipping should be completed by the “**inside person.**” Pack up all refrigerated shippers and HPV swabs; assemble frozen packages for outside shipping person).
- Call FedEx and schedule a pickup.
- Label new containers and put them into their respective freezers or refrigerators.
- Wait for the scheduled FedEx pickup.
- Work the evening session.

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-View hCG Urine Control Set-Do not send back opened controls-discard.
 - Coulter Latron CP-X control- Discard if it has a short expiration date.
 - Coulter 6C cell Control-Discard if it has a short expiration date.
 - 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 11.3.6).

- 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 study manager at the home office.
- 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. Discard those supplies at the End of Stand.
- Record WS 3 inventory.
- **Wash everything**, including all racks (Nalgene cryovial racks and Nalge 13 mm and 16 mm half and full racks), centrifuge cups, and rocker pads, and all Tupperware. Unplug scale, clean platform and remove. Place cone on platform head. Place all in hard case, then store case in a cabinet.
- Clean freezer #3 and refrigerator #1.
- 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.
- 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.

11.1.4 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**.

11.2 Additional End-of-Stand Activities

At the end of a stand, shut down all equipment and inventory all supplies. On teardown day, the phlebotomist and medical technologists will work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Lock all cabinets and drawers. Safely discard all biohazardous waste. Repack the Mettler Toledo scale in the blue carrying case.

11.2.1 Packing the Phlebotomy Room

- Phlebotomists' responsibilities include the following tasks:
 - Inventory consumables and non-consumables (see Section 11.3.5 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 stand of the current MEC.
 - Package and send the applicable Vacutainer® tubes that will not expire before the next Stand to the warehouse.
 - The applicable phlebotomy collection tubes will be sent back to the warehouse in order to maintain the manufacturer's recommended temperature range for the medical devices. 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 if ensure that the original plastic wrapping is kept 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 all juices that have not been refrigerated and crackers in drawers. Discard any loose juices (not in original eight-pack wrapping). Discard and do not inventory any juice packs or crackers that will expire before the start to 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.

11.2.2 Packing the Laboratory

- Medical technologists' responsibilities include the following tasks:
 - Close and ship all containers to appropriate contract laboratories.
 - Inventory consumables and non-consumables. Discard and do not inventory any consumables that will expire before the next session of the current MEC. This may be done 1 to 2 days before teardown, if usage on the last days is accounted for.
 - Package and send the supplies described earlier in this chapter to the warehouse.
 1. Pack supplies using procedures described in Chapter 8.
 - Discard Coulter cleaner and diluent.

- Perform the Beckman Coulter® end-of-stand procedures as described in Chapter 6; these include the following:
 1. Review and then export to a CD the Event, Data Summary, Maintenance, and Audit logs on the Coulter. Clear the logs after exporting.
 2. Review and then export the (IQAP) files to a second CD.
 3. Print Latron and 6C Cell control cumulative statistics (files) and graphs.
 4. Export Patient Log (database) to a third CD.
 5. Clean the DxH aspiration probe and STM.
 6. Clean exterior of the instrument and handheld barcode scanner using Sani-Cloths.
- 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.
- Turn off all freezers and refrigerators by flipping the corresponding wall switch to the left of the units. Turn off after all shipping is complete.
- Clean refrigerators and freezers with Sani-Cloths or Bleach Rite solution.
- 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. See Section 11.12 for detailed instructions.
- Clean and power down the LFBSC.
- 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.
- 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.
- Tape to counter or clip all computer cables to secure.
- 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 then lock.
- Clean all counters and the LFBSC with Sani-Cloths.
- Remove all trash, and place regular waste cans flat on their side under a counter. Remove all biohazard waste.
- After DxH has been shutdown 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.

11.2.3 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 log book).

11.3 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.

11.3.1 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 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 creates chaos with the Inventory Management System.
- 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 his or her component counts.

11.3.2 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 are 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 Inventory Management System.

- 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.

- 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.

11.3.3 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 is to 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 use “inventory/supplies” for the type of UFO entry.
- In the description field, the MEC staff member will request the supply(s) 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, write “Nothing needed” in the description field.
- **Do not** request items in the UFO that are not on the component inventory list.
- **Do not** request changes to set par levels in mid-stand UFOs.
- **Do not** 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.

11.3.4 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 bring each item back 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 are 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 technician conducts the tasks listed below:

- Reconcile the inventory for each item.
- Verify the previous EOS count 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.
- Writes the physical count on hand to the right of the ship-to stand count box (per item), if there is a discrepancy.
- Removes the excess from a component (leaving par) and returns 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, have the MEC manager 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. Give the excess inventory and the Transfer Inventory Sheet to the MEC manager to ship 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.

11.3.5 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. 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., physician medical kit supplies, stopwatches, thermometers, CPR masks).

11.3.6 Shipping Inventory Back to the Warehouse

When shipping inventory back to the warehouse, please use the Transfer Inventory to Warehouse Sheet, which is found on the portal and can be printed by the MEC manager. 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. Give the items to be returned along with the Transfer Inventory to Warehouse Inventory Sheet to the MEC manager to ship 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.

11.3.7 Tracking Expired and Broken Inventory

Complete the Delete Expired/Broken Inventory Report when inventory has expired and must be destroyed 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 have expired or broken, and which are 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 (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 chief medical technologist and the phlebotomist are responsible for notifying the MEC manager if additional supplies are needed during the stand. However, each technologist and phlebotomist is responsible for identifying any potential shortage of supplies at each workstation. Contact the warehouse manager directly at 301-212-3759.

11.4 Dry Run Session

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 volunteer—the original SP ID and a second unique sample ID. Document the results of the dry run session the same way as an actual session except enter the results twice: first using the SP ID and second using the sample ID.

Procedures

- Collect the amount of blood specified in the Dry Run Venipuncture Protocol. This amount is less than the blood required from a routine examinee.
- Prepare split samples for each volunteer.
 - Collect 6 ml of urine and process as specified in Dry Run Urine Processing Protocol. Process the blood as directed in the protocols. Store these split samples and ship them to contract laboratories for analysis with the first routine shipment.

11.4.1 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 four 2-ml ethylene diamine-tetracetic acid (EDTA), two 2-ml gray tubes, two lavender 7 mL top tube, and four 15-ml red-top tubes. If the last digit is an even number,

the volunteer’s protocol includes two 2-ml ethylene diamine-tetracetic acid (EDTA), two 2-ml gray tubes, two lavender 7 mL top tube, and four 15-ml red-top tubes.

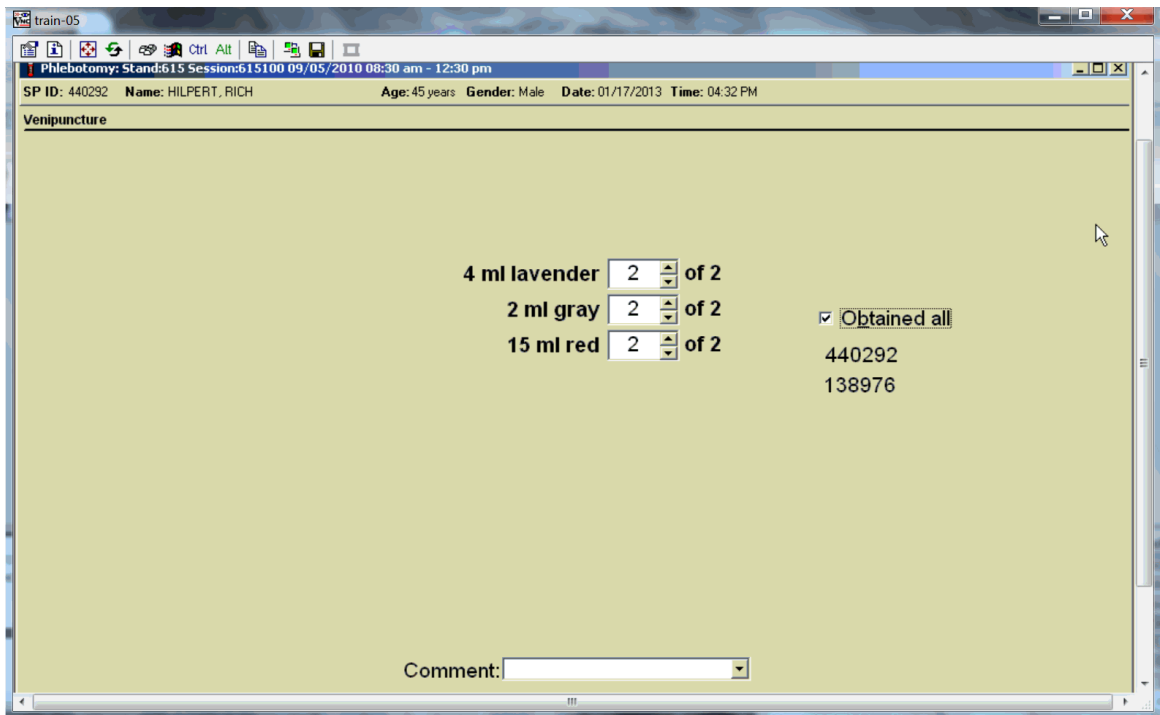
Exhibit 11-1. Dry run venipuncture protocol

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	2	2
7-ml EDTA	2	2
15-ml red	4	4

On dry run day, the phlebotomist refers to the following instructions to conduct the phlebotomy procedures:

- Access the phlebotomy application; open the exam, and wand the dry run volunteer into the component.
- Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 3.
- Perform the venipuncture using procedures described in Chapter 3.

The correct venipuncture protocol automatically displays. Note that there are two IDs—a SP ID (110355) and a Sample ID (616625). Both IDs display under the “Obtained all” check box.



Enter the venipuncture results using procedures described in Chapter 3. 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:

- Place one label with the original SP ID on one of the two 4-ml EDTA tubes and the other labels with the sample ID on the other 4-ml EDTA tubes.
- Place one label with the original SP ID on one of the two 7-ml EDTA tubes and the other labels with the sample ID on the other 7-ml EDTA tubes.
- Place the label with the original SP ID on one tube of the pair of 2-ml gray tubes and the label with the sample ID on the other 2-ml gray tubes.
- Place the label with the original SP ID on two 15-ml red tubes and the label with the sample ID on the other 15-ml red tubes.

For dry run volunteers with the SP ID and sample ID ending in an even number:

- Place one label with the original SP ID on one of the two 4-ml EDTA tubes and the other label with the sample ID on the other 4-ml EDTA tubes.
- Place one label with the original SP ID on one of the two 7-ml EDTA tubes and the other label with the sample ID on the other 7-ml EDTA tubes.
- Place the label with the original SP ID on one tube of the pair of 2-ml gray tubes and the label with the sample ID on the other 2-ml gray tubes.
- Place the labels with the original SP ID on two of the four 15-ml red tubes and the labels with the sample ID on the other two 15-ml red tubes.

11.4.2 Dry Run Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window.

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC	F	M
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	○	○	-	○	○	○	-	-

Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique sample ID.

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. Assemble and label the blood processing racks for each dry run volunteer using procedures described in Chapter 8.

Review the laboratory heads-up display. Use the heads-up display to view the modules for which the dry run volunteer is eligible and the current process status.

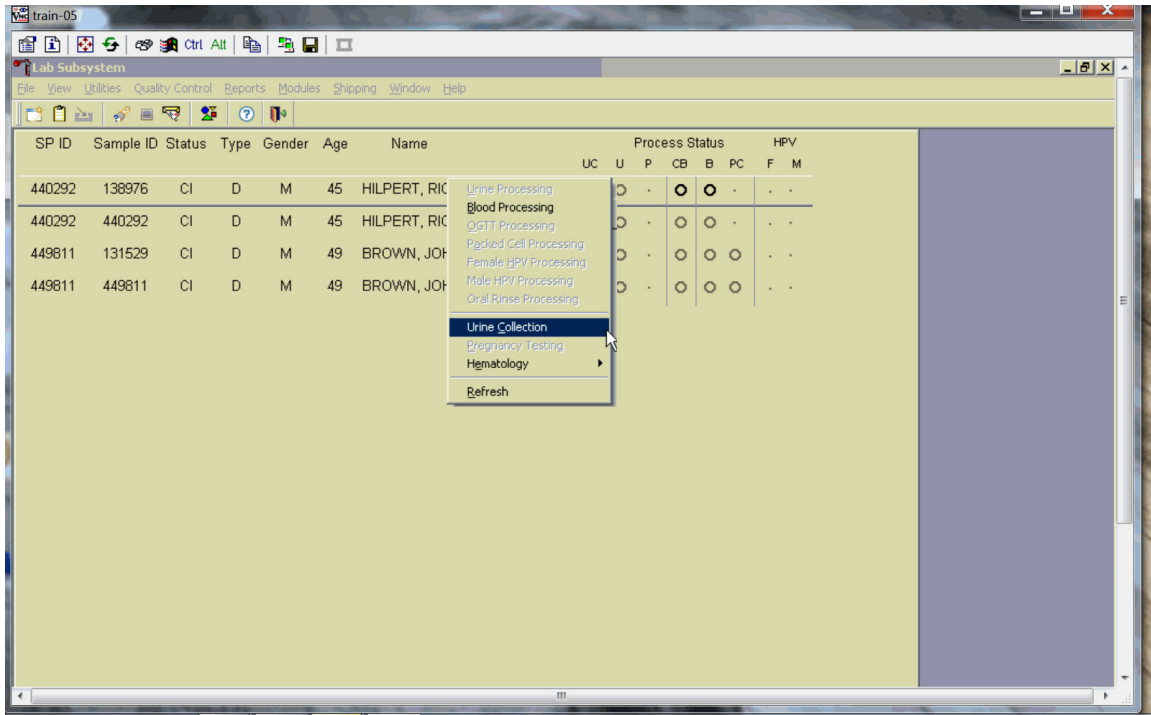
SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status							
							UC	U	P	CB	B	PC	HPV F	HPV M
440292	138976	CI	D	M	45	HILPERT, RICH	-	○	-	○	○	-	-	-
440292	440292	CI	D	M	45	HILPERT, RICH	○	○	-	○	○	-	-	-
449811	131529	CI	D	M	49	BROWN, JOHN	-	○	-	○	○	○	-	-
449811	449811	CI	D	M	49	BROWN, JOHN	○	○	-	○	○	○	-	-

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 one urine collection result and one pregnancy test are required for each dry run volunteer when the SP ID and Sample ID end in an odd or even digit.

Collect 6-ml urine from all dry run volunteers. The MEC coordinator will instruct each volunteer to void as soon as he or she feels able to provide a urine specimen. The coordinator or local assistant transports the initial specimen to the laboratory. All dry run volunteers are eligible for at least one urine test.

Place the urine collection cup on the scale and scan in the urine collection specimen barcode as described in Chapter 4, Section 4.4.

Document the urine collection in the laboratory application.



To select the correct dry run volunteer's record, locate the record in the heads-up display that contains the urine collection circle. To access the urine collection module, use the up and down keys to move up and down the list until the correct record is highlighted or drag the mouse arrow to the correct volunteer and right-click. Continue by dragging the mouse arrow to Urine Collection, then left-click.

The urine collection window displays.

Urine Collection Verification: 430010

Sp ID	Sample ID	Name	Gender	Age
119114	119114	RAMOS, STEPHEN	M	72
281786	281786	RAMOS, MARTIN	M	42
350948	350948	RAMOS, JACKSON	M	74
412754	412754	DEMARCO, JILL	F	25
439242	439242	DEMARCO, LEANNE	F	49
454419	454419	DEMARCO, NAOMI	F	48
565311	565311	RAMOS, LEONARD	M	67

SP ID: 119114 NAME: RAMOS, STEPHEN AGE: 72 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	<input type="text"/>	<input type="text"/>	(none)	(none)	<input type="checkbox"/>

Total Collected:
Total Required: 3

The top of the urine collection window contains columns for the SP ID, sample ID, person name (last, first), gender, and age. The row for checked-in SPs is indicated in black, while SPs who have not checked into the MEC session are gray. Only dry run volunteers who have checked into the MEC session are available for processing. SPs who have a urine collection ready for verification display in blue. Use the scroll bar to view all SPs scheduled into the session.

Verify the sufficiency of the quantity of urine received in the laboratory. Use the measuring tool to verify the amount of urine reported from the scale.

Urine Collection Verification: 430010

Sp ID	Sample ID	Name	Gender	Age
119114	119114	RAMOS, STEPHEN	M	72
281786	281786	RAMOS, MARTIN	M	42
350948	350948	RAMOS, JACKSON	M	74
412754	412754	DEMARCO, JILL	F	25
439242	439242	DEMARCO, LEANNE	F	49
454419	454419	DEMARCO, NAOMI	F	48
565311	565311	RAMOS, LEONARD	M	67

SP ID: 119114 NAME: RAMOS, STEPHEN AGE: 72 Gender: M

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	138	12/13/2008 09:30 AM	Yes	(none)	<input type="checkbox"/>

Total Collected: 138
Total Required: 3

New Collection Save Cancel

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 protocol requirement, the application will automatically insert “QNS” in the Status result text field and “quantity not sufficient” in the Comment Code text box.

Urine Collection Verification: 430000

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date:Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>

Total Collected: 3
Total Required: 4

A QNS status immediately prompts and notifies the coordinator to ask the SP for an additional urine sample.

A second instance of urine collection for the first QNS sample or third instance of urine collection for the second QNS sample will appear below the current sample.

Urine Collection Verification: 430000

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input type="checkbox"/>

Total Collected: 28
Total Required: 4

New Collection Save Cancel

If the quantity of urine collection meets the requirement of the urine protocol, the application will automatically select a status of “Yes,” and no additional collections will appear.

Evaluate the quantity of urine received in the laboratory. Compare the number displayed in the Total Collected line and the actual volume of urine in the cup.

Urine Collection Verification: 430000

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input type="checkbox"/>

Total Collected: 28
Total Required: 4

New Collection Save Cancel

Adjust the volume (ml) if necessary by directing the mouse arrow to the text box under the Volume (ml) column. Right-click on the text box to enable the cursor. 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."

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each dry run volunteer. Enter "No" in the Status Result Field for all volunteers who have

not produced a urine sample. Record a result other than “(none)” for all records. Record a comment for all insufficient urine collections.

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.

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date/Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input checked="" type="checkbox"/>

Total Collected: 28
Total Required: 4

New Collection Save Cancel

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

Verify the results of the urine collection.

Urine Collection Verification: 430000

Sp ID	Sample ID	Name	Gender	Age
110355	110355	TRAHERNE, MADELINE	F	22
196285	196285	TRAHERNE, MARCUS	M	35
250071	250071	TRAHERNE, SIMON	M	14
623489	623489	TRAHERNE, GEORGE	M	18
634819	634819	TRAHERNE, BRIDGET	F	27
653143	653143	TRAHERNE, FRANKLIN	M	92
660895	660895	TRAHERNE, EMILY	F	17

SP ID: 110355 NAME: TRAHERNE, MADELINE AGE: 22 Gender: F

Collection	Volume (mL)	Collection Date:Time	Status	Comment Code	Verified
1	3	12/15/2008 09:10 AM	QNS	quantity not suffic	<input checked="" type="checkbox"/>
2	25	12/15/2008 10:30 AM	Yes	(none)	<input checked="" type="checkbox"/>

Total Collected: 28
Total Required: 4

New Collection Save Cancel

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

To save a result to the database without exiting the module or removing the window, direct the mouse arrow to the “Verify” check box. Left-click on the check box. Alternately, direct the mouse arrow to the “Save” button and left-click or press [Enter] when it is highlighted. To save a result to the database and exit the module and remove the window, direct the mouse arrow to the “OK” button and left click. To exit the module and remove the window without saving any information to the database, direct the mouse arrow to the “Cancel” button and left-click. To exit the module or close the window after saving results to the database, and without recording any further actions, direct the mouse arrow to the Close Window button and left-click.

11.4.3 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—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).

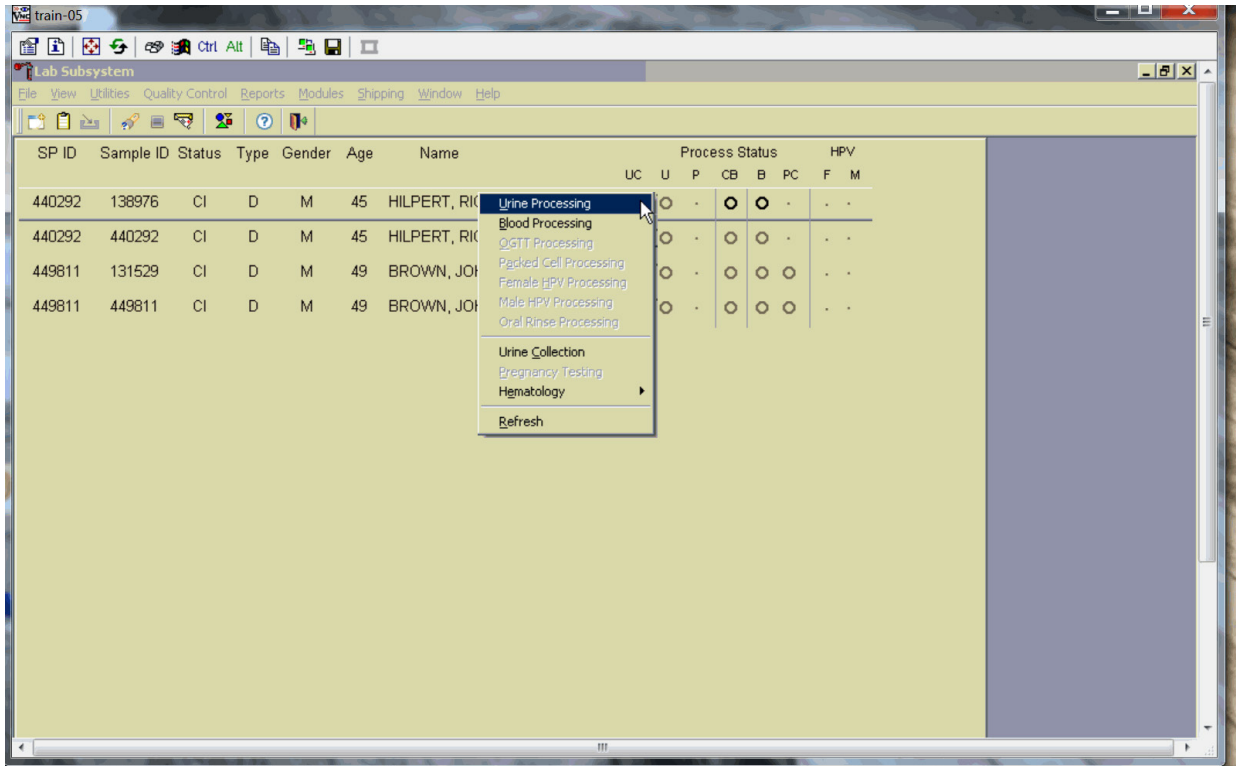
Exhibit 11-2. Dry run urine processing protocol

ID	Assay	Sample size ml	Vessel
45	Alb/Creat	3	5-ml cryovial

Procedures for Dry Run Volunteers

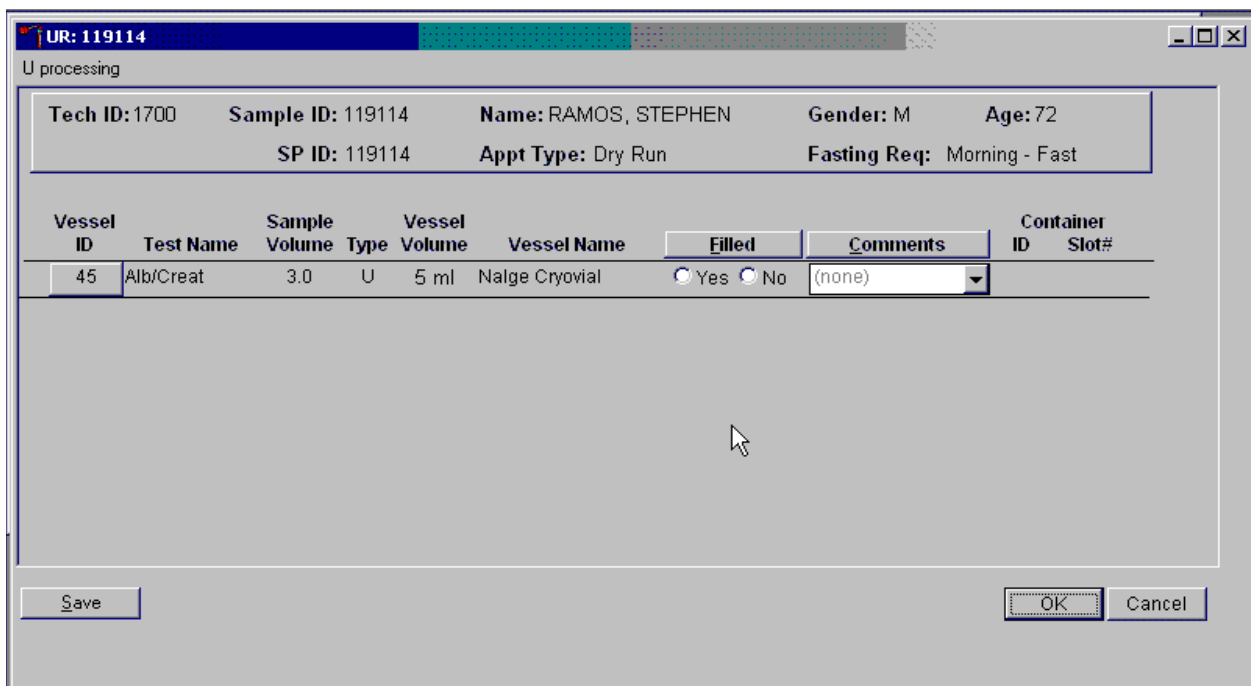
- Label one 5-ml cryovial for the first test—#45. Label one tube with the volunteer's original SP ID. Label the other tube with the volunteer's sample ID.
- Aliquot 3-ml of urine into each of the two #45 vessels using a large plastic transfer pipette.
- Enter the results of urine processing for the original 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.



To access the Urine Processing module, direct the mouse arrow to the correct volunteer, right-click, drag the mouse arrow to Urine Processing, and right-click.

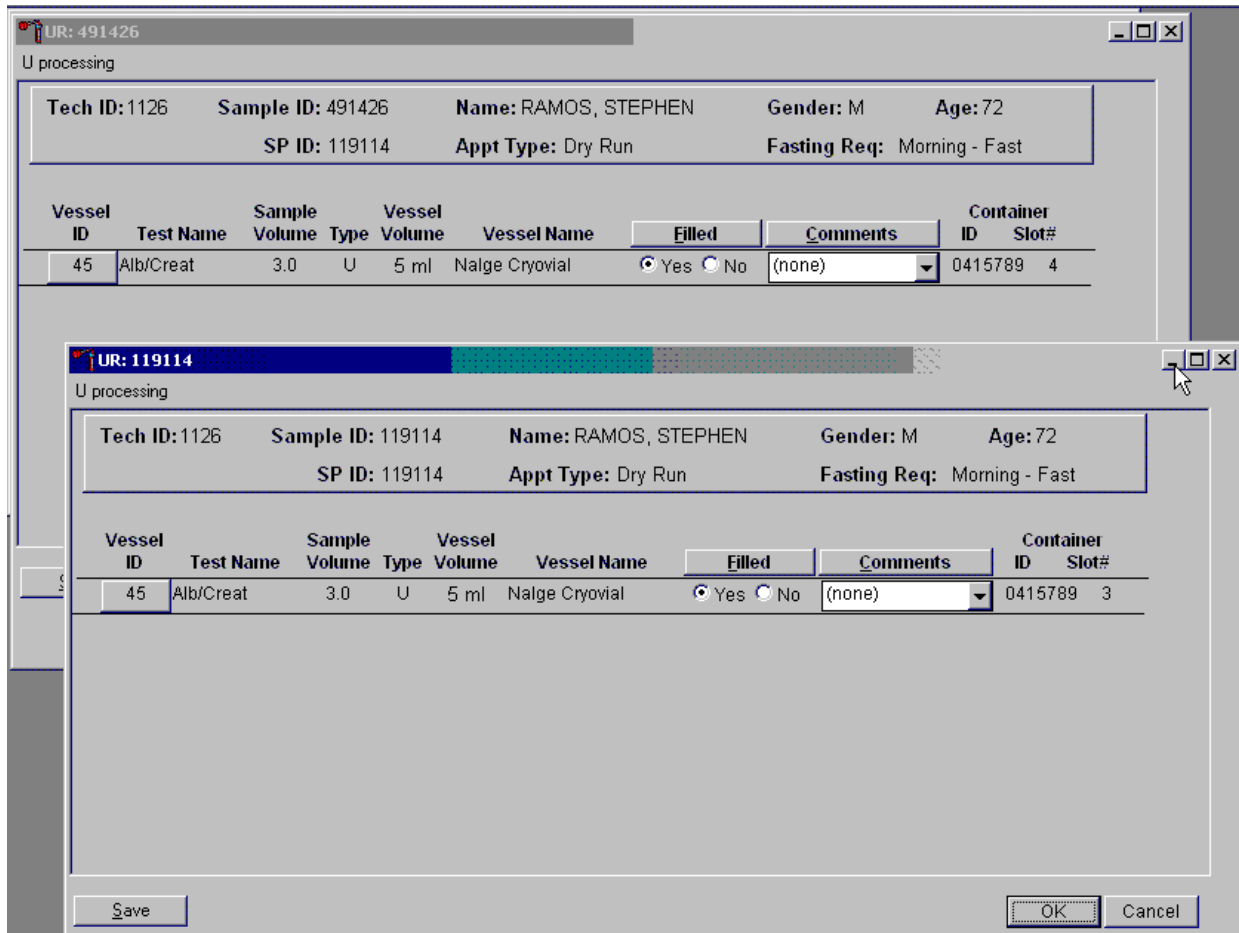
The volunteer's urine processing screen displays.



To mark an individual urine vessel as collected or Filled – Yes, direct the mouse arrow to the “Yes” radio button and left-click. As each vessel is marked as Filled – Yes, it is automatically assigned to a slot in an existing (open) container. To mark an individual urine vessel as not collected or Filled – No, use the mouse to direct the mouse arrow to the “No” radio button and left-click. As each vessel is marked as Filled – No, the comment, “quantity not sufficient” is automatically entered in the Comments column. To collectively mark all vessels as Filled – Yes, use the mouse to direct the mouse arrow to the Filled button above the radio buttons, left-click, and drag the arrow to {Fill All} and left-click. To mark all vessels as Filled – No, direct the mouse arrow to the “Filled” button above the radio buttons, left-click, drag the mouse arrow to {Not Filled All}, and left-click.

Use the quality comment code to indicate if blood is present. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save 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, 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, direct the mouse arrow to the Cancel button, and left-click.

Access the sample ID record on the heads-up display and record the processing results.



Remember to process vessels in pairs and, if the quantity of urine is insufficient to fill both vessels, do not record either vessel as filled. Store the vessels in a manner identical to vessels processed during a regular session.

Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Mark out the SP name with a marker. Flush the sink with water. Discard urine cup in the trash.

The urine-processing technologist performs the pregnancy test on female dry run volunteers aged 8 to 59 years and documents the results following the procedures described in Chapter 5.

11.4.4 Dry Run Hematology

The medical technologist at Workstation 3 runs two CBCs, in duplicate, for each dry run volunteer from the 4 mL EDTA tubes. The technologist in Workstation 2 processes whole blood from the

7 ml EDTA tubes according to the whole blood processing protocol (see Exhibit 11-3). 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 7.

Exhibit 11-3. Dry run processing protocol—whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad/HG/Se/Mn	Both	0.4	Whole blood	7-ml EDTA	2-ml
3	RBC Folate	Even	0.1	Whole blood	7-ml EDTA	2-ml
4	Glycohem	Odd	0.4	Whole blood	7-ml EDTA	2-ml
5	Mercury		0.5	Whole Blood	7-ml EDTA	2-ml
88	Acrylamide	Odd	1.6	Packed cells	7-ml EDTA	2-ml
221	RBC Folate Forms	Both	1.1	Packed Cells	7-ml EDTA	2-ml
222	Fatty Acids	Both	1.6	Packed Cells	7-ml EDTA	2-ml

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 7.

11.4.5 Dry Run Blood Processing and Storage

Print blood-processing labels using procedures described in Chapter 8. There are two sets of labels for each dry run volunteer; one set of labels contains the SP ID and the second set contains the sample ID. 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+.

Treat each set of venipuncture tubes and pre-labeled blood processing racks as two independent and separate dry run volunteers. Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID, and then process the second set of venipuncture tubes and blood processing vessels using the sample ID.

For volunteers who’s SP ID and sample ID ends in an odd digit, process one of the 7-ml EDTA tubes for Lead/Cad/HG/Se/ Mn, glycohemoglobin, and acrylamide. For volunteers who’s SP ID and sample ID ends in an even digit, process one of the 7-ml EDTA tubes for Lead/Cad/HG/Se/Mn, 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	OddEven	0.7	Serum	15-ml Red	2-ml
118	Thyroid Panel	Both	1.0	Serum	15- ml Red	2-ml
99	Ferritin	Odd	0.4	Serum	15- ml Red	2-ml
122	HAV	Even	1.0	Serum	15-ml Red	2-ml
17	Cotinine	Even	1.8	Serum	15-ml Red	2-ml
21	Lipids	Both	1.0	Serum	15-ml Red	2-ml
11	Iron/TIBC/% saturation	Even	0.5	Serum	15-ml Red	2-ml
18	Biochem	Both	0.5	Serum	15-ml Red	2-ml
23	Insulin	Odd	1.0	Serum	15-ml Red	2-ml
13	CRP	Even	0.3	Serum	15-ml Red	2-ml

- Fill each vessel as described in the blood processing protocol.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID. Continue to use the labeled vessels in the prepared rack.
- Process the second set of venipuncture tubes and blood processing vessels using the sample ID. Continue to use the labeled vessels in the prepared rack.
- Use the same techniques for spinning and separating the blood as described in Chapter 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. Record the blood processing results.

B processing

Tech ID: 1756	Sample ID: 503985	Name: DR6, SP6	Gender: M	Age: 19
	SP ID: 503985	Appt Type: Dry Run	Fasting Req: Morning - Fast	

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 type="radio"/> Yes <input type="radio"/> No			
4	Glycohem		0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
9	Glucose		0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
136	Se/Cu/Zn		1.0	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
70	Vit D/FA	●	0.7	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
21	Lipids	●	1.5	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
18	Biochem		0.8	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
23	Insulin		1.0	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
118	Thyroid		1.0	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
127	IgA-TTG/EMA		0.5	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
137	TST		0.5	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			
110	Folate 1		0.7	S	2 m	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No			

BP: 103733

B processing

Tech ID: 1756	Sample ID: 103733	Name: DR6, SP6	Gender: M	Age:
	SP ID: 503985	Appt Type: Dry Run	Fasting Req: Morning -	

Vessel ID	Test Name	CAP	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments
1	PbCadHgSeMn		0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
4	Glycohem		0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
9	Glucose		0.5	P	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
136	Se/Cu/Zn		1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
70	Vit D/FA	●	0.7	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
21	Lipids	●	1.5	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	
18	Biochem		0.8	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	

Enter results for the vessels where both vessels are filled for the whole blood, plasma, and serum protocol. Enter the results of blood processing using the correct sample ID and SP ID numbers and procedures described in Chapter 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.

11.4.6 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 8.

11.5 Centrifuges Allegra X-15R—Equipment Maintenance

The medical technologists are responsible for inspecting the centrifuges at the beginning of each stand, and inspecting and cleaning the centrifuges at the end of each stand and whenever necessary.

Clean the interior of the chamber with a mild soap, as time permits. Rinse thoroughly and dry completely.

11.5.1 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.

- 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.

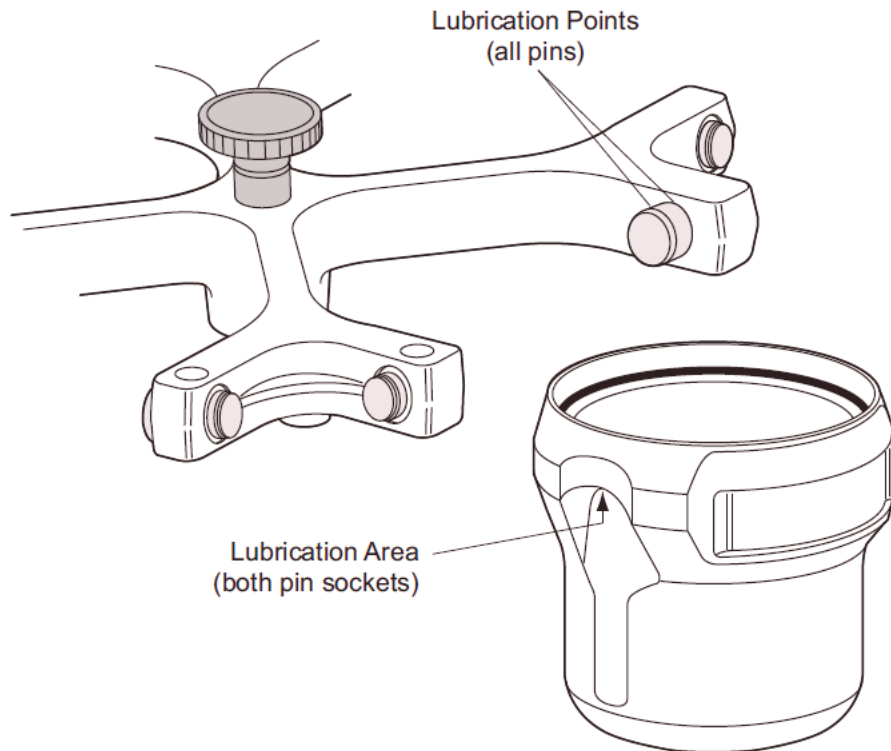
11.5.2 Rotor Care and Maintenance

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 11-5).
- Allow the lubricant to dry for at least 5 minutes before installing the rotor in a centrifuge.

Store the rotor inside of the foam-lined bin, at the end of stand. 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.

Exhibit 11-5. Lubrication points



11.5.3 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, clean the rotor and components immediately 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.

11.5.4 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.

11.5.5 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.



The NCHS biomedical engineer certifies both centrifuges annually. 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.

11.6 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. 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.

11.7 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 the following: 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 facilities and equipment specialist 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 xxxxxx” 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 medical technologist should contact the MEC manager.

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 in the refrigerator, freezer, or next to the room temperature digital thermometer. The same thermometer can be used for the refrigerators and room temperature checks.
- Allow the thermometer to remain in the environment for 2 hours to equilibrate. Avoid opening and closing the refrigerator and freezer doors during this time.
- After 2 hours, 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.

11.8 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 (see Exhibit 11-6). The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and the technologist. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

Installation, Certification, and Maintenance

The NCHS biomedical engineer arranges 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. Lift the front glass and wash both the interior and exterior glass with Windex. Remove all contents from the interior of the cabinet. Remove and wash the front grill with Sani-Cloth Plus cloths or Bleach-Rite. 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 each session.

Document all unscheduled maintenance for the LFBSC in the automated Unusual Field Occurrence utility.

Exhibit 11-6. 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 11-6. 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 11-6. 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.

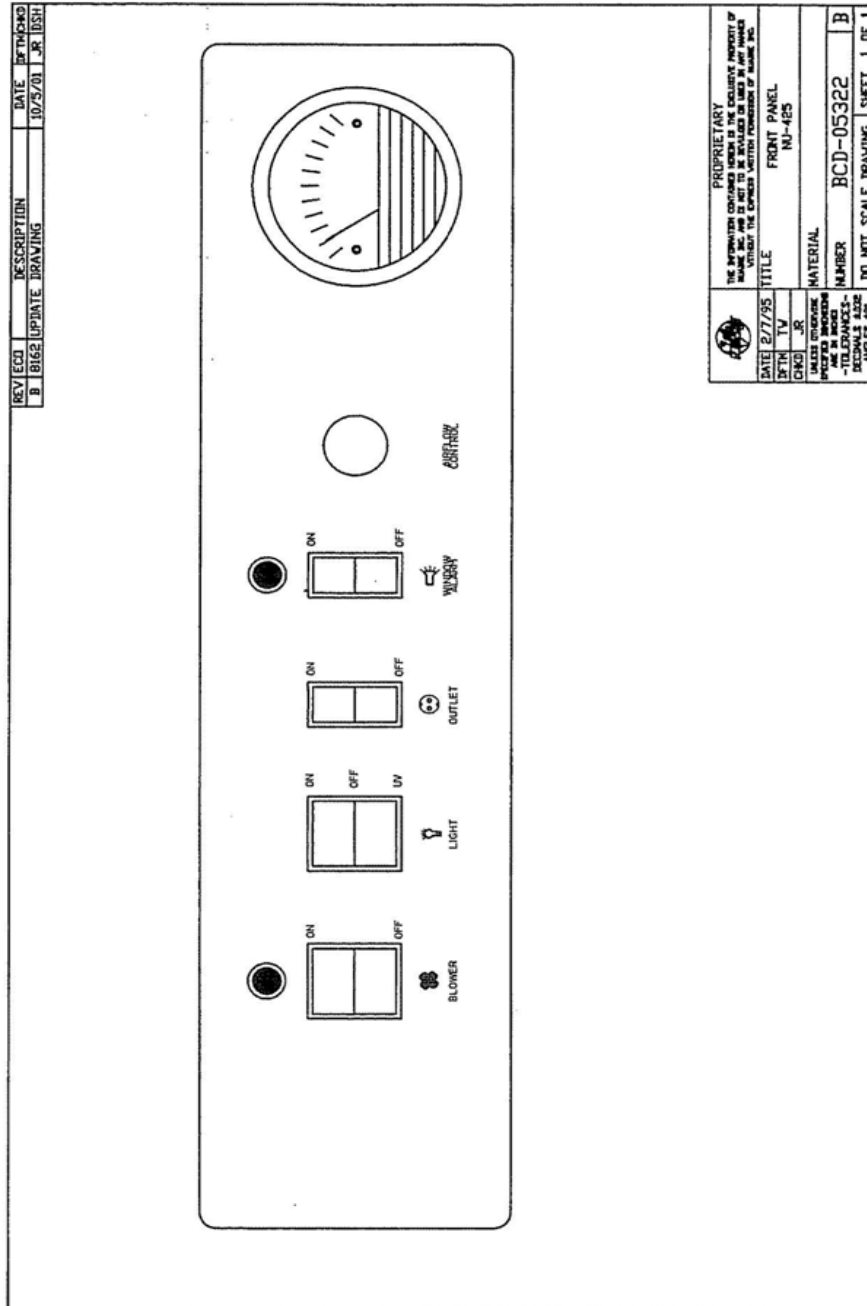


Exhibit 11-6. Operating the laminar flow biological safety cabinet (continued)

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 11-6. Operating the laminar flow biological safety cabinet (continued)

1.1.11 Convenience/Accessory Outlet

A convenience/accessory outlet is located in the upper left hand corner in back of 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.

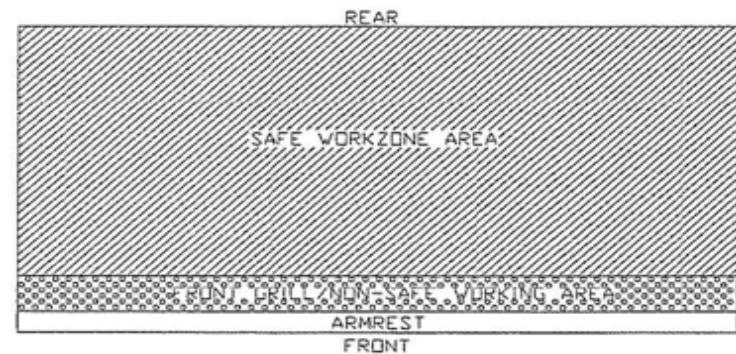
Procedure protocols defined in terms of the barrier or control concepts unique to LFBSC must be developed to obtain a maximum potential for safety and protection. The pre-planning necessary to develop these protocols is based on several fundamental considerations, each of which will contribute to optimum benefits from the equipment:

- Know your “safe working area.”
- Minimize disruption of “air curtain.”
- Minimize room activity.
- Use unidirectional airflow.
- Employ aseptic techniques.

Exhibit 11-6. Operating the laminar flow biological safety cabinet (continued)

1.2.1 Know Your “Safe Working Area”

The LFBSC safe working area is basically the worktray or depressed area. All work should be performed on or above the worktray. 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, 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 completely 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 11-6. 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.

Exhibit 11-6. Operating the laminar flow biological safety cabinet (continued)

1.2.5 Employ Aseptic Technique

The operator must not assume an attitude of “let the cabinet do it” when performing procedures within a LFBSC. Properly balanced and properly used cabinets will do an excellent job of controlling airborne contamination and containing viable agents, but the cabinet will not eliminate contact transmission of contamination. Normal laboratory contamination control procedures and basic aseptic techniques are necessary to obtain maximum benefit from the cabinet. For example, open bottle, tube or flask mounts should be kept as parallel as possible to the downflow to minimize capture of chance particulates. This precaution is merely an extension of good aseptic technique as practiced on open bench tops. The good laboratory practices designed to minimize creation and/or release of aerosols to the environment should not be discontinued.

Items of equipment in direct contact with the etiologic agent must remain in the cabinet until enclosed or until surface-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.

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.

Exhibit 11-6. Operating the laminar flow biological safety cabinet (continued)

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 Wipedown

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.

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.

Exhibit 11-6. Operating the laminar flow biological safety cabinet (continued)

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 Wipedown

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 cabinet as a depository for excess laboratory equipment during periods of non-operation.

Exhibit 11-6. 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 foot rest. 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 effect work zone.

Exhibit 11-6. 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 of time.
- After the specified contact time, wipe up excess disinfectant.

11.9 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 wall thermometers for damage at the beginning of each stand. Notify the warehouse manager of any damage and request a new monitor.

The allowable ambient temperature range for the laboratory is 15°C to 25°C (59°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 MEC manager immediately. If using the portable air conditioner, document use for each session by way of a UFO.

11.10 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.

11.11 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 with Windex. 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.

11.11.1 Initial Scale Interface Setup

1. Press and hold 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 the scale on:

1. The scale application is turned on via the computer.
2. Touching the scale plate.
3. Pressing the on/off button.

This scale has no warm-up time and zeroes itself each time it turns on. So to wake it up via touching the scale plate, do not place urine on plate until it has zeroed itself.

11.11.2 Scale Setup

- Open the blue carrying case.
- Remove scale from case and place on the counter next to the barcode scanner.
- Verify that the scale is free of dust and debris. Clean scale with Windex and lint-free clothes.

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. It looks like this:



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.

11.11.3 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 scale. Slide weigh pan back into slot in lid of carrying case. Remove the protective cone cover from the carrying case and place 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.

11.12 Eppendorf Pipette Care, Sterilization, Maintenance, and Calibration

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.

11.12.1 Care and Maintenance

- Never use corrosive cleaning fluids, strong solvents, or abrasive polishes.
- 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.

11.12.2 Disinfecting

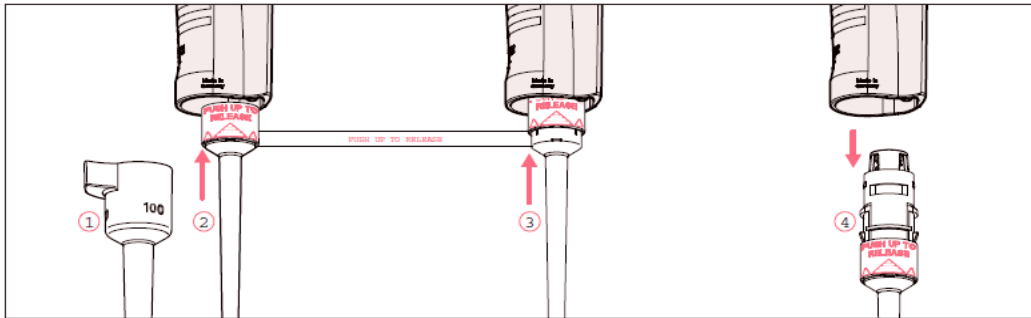
- Carefully wipe off the outer surfaces, tip cone, and ejector sleeve with a disinfectant, such as 70 percent alcohol solution or a Sani-Cloth.

11.12.3 Xplorer Pipette Assembly and Disassembly

Exhibit 11-7 presents information and diagrams on this process.

Exhibit 11-7. Explorer pipette assembly and disassembly for pipettes < 5ml

7.5.1.1 Removing the lower part

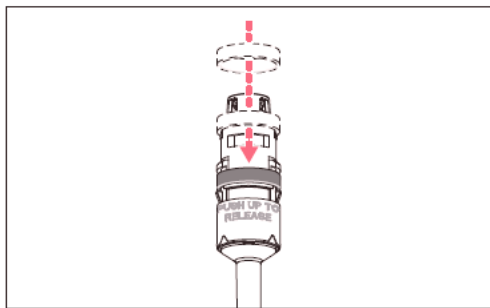


1. Keep the ejector pressed and remove the ejector sleeve ①.
2. ② and ③: On the lower part, slide the ring marked "PUSH UP TO RELEASE" up by about 5 mm until the lower part comes off.
3. ④: Remove the lower part from the upper part.

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 11-7. Explorer pipette assembly and disassembly for pipettes < 5ml (continued)

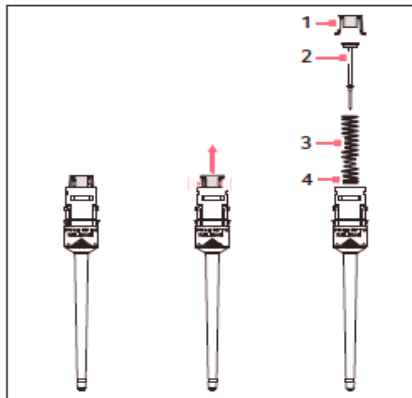
7.5.1.4 Opening and assembling the lower part ($\leq 1000 \mu\text{L}$)

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.

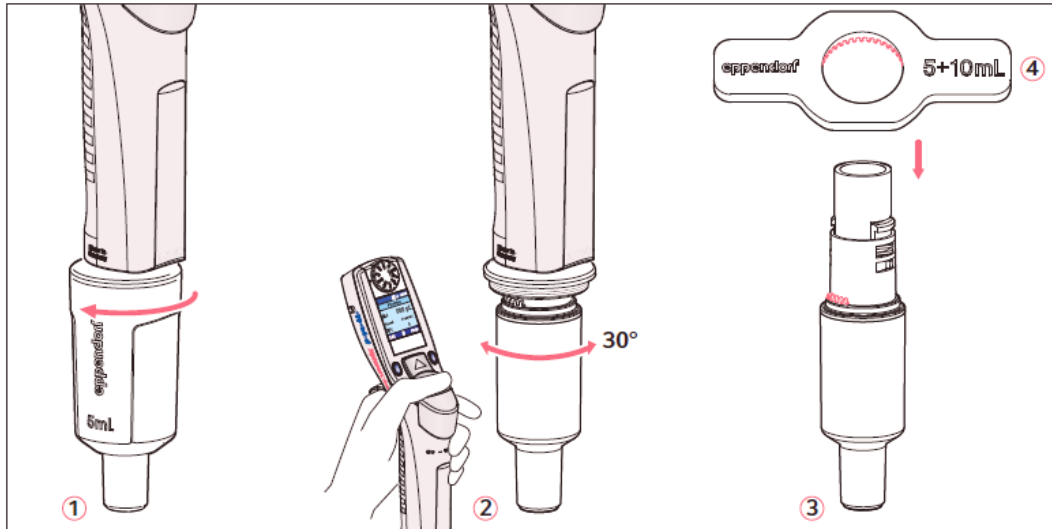
Assembling the lower part

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 11-7. Explorer pipette assembly and disassembly for pipettes < 5ml (continued)

7.5.2 5 mL and 10 mL single-channel

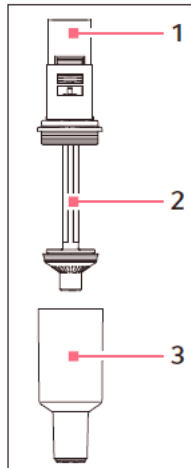
The piston must be in its basic position before separating the lower and upper part. Press the rocker down to move the piston to its basic position.



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 11-7. Explorer pipette assembly and disassembly for pipettes < 5ml (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.

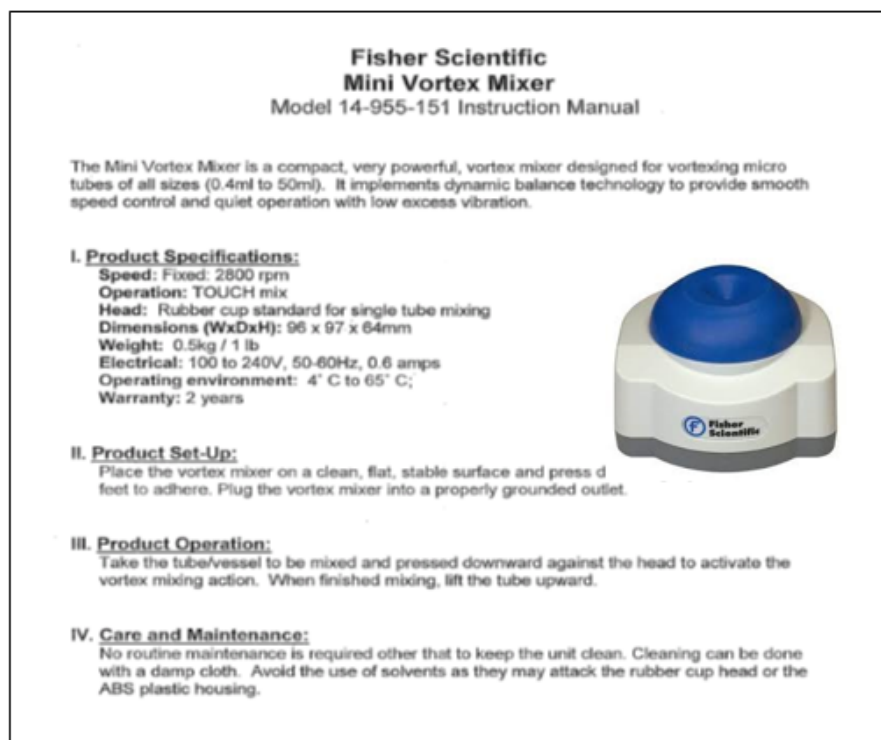
i For replacing an ejector sleeve, the 5 mL and 10 mL sizes are delivered with an ejector sleeve and ejector carrier. The lower part must be removed in order to install a new ejector carrier.

Yearly Calibration

The Eppendorf Xplorer Plus pipettes are calibrated on an annual basis, 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 over to the home office to the study manager of the laboratory component.

11.13 Mini Vortex Mixer Care and Storage

The Fisher Scientific Mini Vortex Mixer is to be used inside the LFBSC to mix the MPA with serum for preservation of Vitamin C levels. 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.



11.14 Heratherm™ Compact Microbiological Incubator

The Thermo Heratherm IMC18 portable incubator has a temperature setting range of 17°C to 40°C. This incubator works with 12V DC power and also AC/DC power with the included adaptor.

Connect the incubator to power a source and push the button to turn the incubator ON. Push the button to select the desired temperature. The unit may take up to 2 hours to equilibrate to 37°C

This unit will be monitored and documented each session in the Quality Control record under Daily QC. The acceptable temperature range has been set to 37°C +/- 1°C. A 24 hour digital timer on the power strip will be used with this unit to shut the unit off after the 16-hour incubation period has elapsed.

Record the temperature of the incubator at the start of each session. To record the temperature, access (click) the quality control menu to show the drop down menu. Select quality control and then the daily tab. Record the temperature for the incubator.

11.15 Laboratory Quality Control Module

Document the following items in the Laboratory QC module based on the frequency described in the following table (Exhibit 11-8).

Exhibit 11-8. 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 weight +/- 6.0 g	594 to 606
Remove filter from and flush eyewash for 1-2 minutes	Yes

Exhibit 11-8. Laboratory QC table (continued)

Item	Acceptable result
Daily	
Centrifuge #1 refrigerator temperature reading	4 °C to 8 °C
Centrifuge #2 refrigerator temperature reading	4 °C to 8 °C
LFBSC magnahelic gauge readings	0.050 to 0.550
Workstation 2 room temperature reading	15 °C to 25 °C
Workstation 3 room temperature reading	15 °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	36-38 °C
Weekly	
HMX Latron and 6C Cell Control QC data transmitted?	Yes
Remove filter from and flush eyewash for 1-2 minutes	Yes
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
LFBSC cleaned	Yes
Coulter printouts sent to home office	Yes
DxH Latron and 6C Cell Control QC data transmitted?	Yes
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.

Access the Laboratory QC module.

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"/>	-
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"/>	-	-	-
525757	525757	SC	P	M	3	LAST NAME, PAT M	<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"/>	-	-	-
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"/>	-
836040	836040	SC	P	M	54	TORRES, LUCAS T	<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"/>

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.

Lab Sink					
<input checked="" type="checkbox"/> Start of Stand	<input type="checkbox"/> Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> End of Stand	<input type="checkbox"/> Yearly	<input type="checkbox"/> NCHS QC
QC Check	Done	Result	Comment		
Centrifuge 1 Refrigerator Temperature Reading (2 to 8°C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>		
Centrifuge 2 Refrigerator Temperature Reading (2 to 8°C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>		
LFBSC guage reading (0.050 to 0.550)	<input type="checkbox"/>	<input type="text"/> w.g.	<input type="text"/>		
Workstation 2 room temp reading (15 to 30°C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>		
Workstation 3 room temp reading (15 to 30°C)	<input type="checkbox"/>	<input type="text"/> degrees C	<input type="text"/>		
Lab Humidity Reading (<80%)	<input type="checkbox"/>	<input type="text"/> enter %	<input type="text"/>		
Class F2 twenty gram weight +/- 0.2 g	<input type="checkbox"/>	<input type="text"/> enter weight	<input type="text"/>		

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the Done column, and left-click to insert a check mark. Press Tab or Enter to move to the Result text box.

Enter the response or reading in the Result text box.

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	
LFBSG 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	

OK Cancel

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 check mark on the top of the file header indicates that all QC activities associated with that requirement were successfully recorded and saved to the database.

Lab Shipping

Start of Stand
 Daily
 Weekly
 End of Stand
 Yearly
 NCHS QC

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)	

OK Cancel

11.16 Unusual Field Occurrence

Document any unusual occurrence using the Unusual Field Occurrence (UFO) utility. The hard-copy Unusual Occurrence Log (see Exhibit 11-9) 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 the serial number of the instrument.

Exhibit 11-9. 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.

11.17 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.

11.17.1 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 are 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 he 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 technologists 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; (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 with the remaining freezer are located on the bottom. Refrigerators and freezers are numbered according to which port they are in on the TempGuard system. Freezers are numbered 3 to 6 and the refrigerators are numbered 1 and 2. Port 7 is for room temperature monitoring. Refrigerant gel packs are stored in the 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 (vessel 54, 119), swabs (vessel 140), HPV oral rinse (vessel 129), TB tubes (vessels 223-226), 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.

11.17.2 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 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 medical technologist or any of the staff medical technologists 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.

11.17.3 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.

THIS PAGE IS INTENTIONALLY LEFT BLANK.

12. HPV Oral Rinse Processing

12.1 Introduction

The overall goal of collecting an oral rinse is to perform the first population-based study of oral human papillomavirus (HPV) infection to determine the prevalence and type distribution of infection and to investigate the demographic and behavioral factors associated with infection.

Testing for 37 types of HPV will be accomplished by means of a multiple polymerase-chain reaction (PCR) assay targeted to the L1 region of the viral genome, using PGMY09/11 L1 primer pools and primers for Beta globulin followed by hybridization to a linear probe array (Roche Molecular).

The HPV oral rinse is collected by the dentist during the oral health exam on primary study participants (SPs) aged 14-59. The SP is asked to swish a 10-ml sample of Scope mouthwash (or a sterile saline solution if preferred by the SP) in his or her mouth and then expectorate the sample into a sterile collection cup. The cap is secured on the cup, a label is attached, and the sample is then taken to the mobile examination center (MEC) laboratory for processing.

The dentist places the cup in the MEC laboratory in the same area as the urine collection samples. The HPV oral rinse samples are easily distinguishable from the urine collection samples by the color of the sample (blue-green unless the clear sterile saline solution is used) and the collection cup (clear and cylindrical with a green screw-on cap), which is much smaller than the urine collection cup.

The MEC laboratory technologists process the sample by transferring the HPV oral rinse from the collection cup to a 14-ml Falcon screw-on cap tube. It is critical to transfer the entire sample from the collection cup to the processing vessel. The technologists use the Oral Rinse (OR) Processing module to document collection status. All SPs are listed on one screen so the samples can be batch processed. The technologist should make sure that the cap is tightly secure to prevent leakage during shipment.

The samples are stored refrigerated at -2-8°C and shipped weekly to

Lab 37
CDC/Human Papillomavirus Laboratory
1600 Clifton Road, MSG-41 Bldg. 23, Rm 4-409
Atlanta GA 30329
(404) 639-2187

12.2 Supplies

The supplies needed for HPV Rinse processing and storage are listed in Exhibit 12-1.

Exhibit 12-1. Equipment and supplies – HPV Rinse processing and storage

14-ml Falcon tube	Small Styrofoam shipper (14 x 14 x 12)
Three-inch 5 x 5 cardboard grid	STP-310 Pressure vessel
Absorbent sheets (2 x 2)	Plastic bag 9" x 12"
Packaging tape 2"	Refrigerated Paks
Overpack label	
Rubber bands	

12.3 Protocol

Exhibit 12-2 illustrates the SP's protocol for HPV Rinse processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 12-2. HPV Rinse processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Appointment type
129	HPV Rinse	14-59	1	Oral rinse	14-ml Falcon tube	Primary only

12.4 Labeling Vessels

The dentist prints the label for the specimen cup. The medical technologist assigned to workstation 1 prints the **vessel** labels for all eligible SPs and places these labels at workstation 3.

12.5 HPV Rinse Protocol

Process the oral rinse for HPV Rinse. Verify that the specimen container is labeled correctly and that the label is legible.

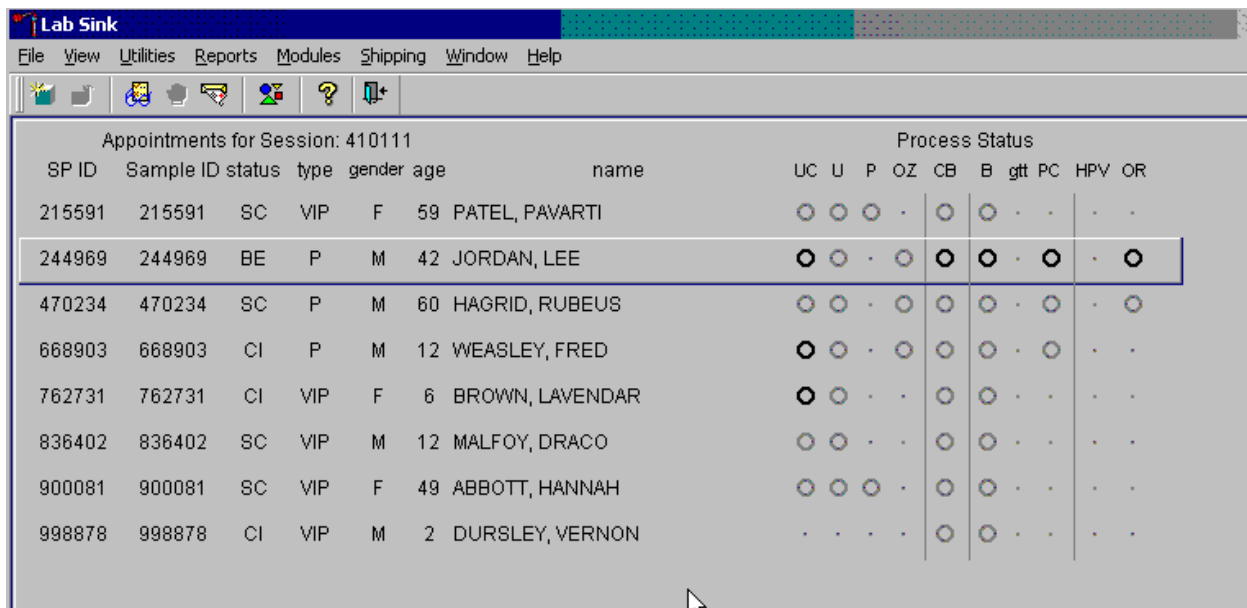
Access the OR Processing module for all SPs.

- Vessel 129 – HPV Rinse
 - Verify that the SP ID on the label matches the SP ID on the processing screen.

- Label the 14-ml Falcon tube.
 - Pour the oral rinse from the specimen container into the Falcon tube.
 - Screw the cap firmly on the Falcon tube.
 - Record the processing results in the OR Processing module.
 - Store the vessel in a three-inch-tall foam box with a 5 x 5 grid.
 - Store the container in the refrigerator.
 - Ship refrigerated on a weekly basis.

12.6 Record Processing Results

Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status. Record oral rinse processing results for vessel 129 using the OR Processing module.



Appointments for Session: 410111							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	gtt	PC	HPV	OR
215591	215591	SC	VIP	F	59	PATEL, PAVARTI	○	○	○	○	○	○	○	○	○	○
244969	244969	BE	P	M	42	JORDAN, LEE	●	○	○	○	○	○	○	○	○	○
470234	470234	SC	P	M	60	HAGRID, RUBEUS	○	○	○	○	○	○	○	○	○	○
668903	668903	CI	P	M	12	WEASLEY, FRED	○	○	○	○	○	○	○	○	○	○
762731	762731	CI	VIP	F	6	BROWN, LAVENDAR	○	○	○	○	○	○	○	○	○	○
836402	836402	SC	VIP	M	12	MALFOY, DRACO	○	○	○	○	○	○	○	○	○	○
900081	900081	SC	VIP	F	49	ABBOTT, HANNAH	○	○	○	○	○	○	○	○	○	○
998878	998878	CI	VIP	M	2	DURSLEY, VERNON	○	○	○	○	○	○	○	○	○	○

The OR module is grayed out until at least one SP has had the oral rinse collected in the oral health component. Once one SP has the oral rinse marked as collected, the processing circle for that SP turns black.

Select the correct SP and access the OR Processing module.

Appointments for Session: 410111							Process Status									
SP ID	Sample ID	status	type	gender	age	name	UC	U	P	OZ	CB	B	ggt	PC	HPV	OR
215591	215591	SC	VIP	F	59	PATEL, PAVARTI										
244969	244969	BE	P	M	42	JORDAN, LEE										
470234	470234	SC	P	M	60	HAGRID, RUBEUS										
668903	668903	CI	P	M	12	WEASLEY, FRED										
762731	762731	CI	VIP	F	6	BROWN, LAVENDY										
836402	836402	SC	VIP	M	12	MALFOY, DRACO										
900081	900081	SC	VIP	F	49	ABBOTT, HANNAH										
998878	998878	CI	VIP	M	2	DURSLEY, VERNON										

- Urine Processing
- Blood Processing
- OGTT Processing
- Packed Cell Processing
- HPV Processing
- Oral Rinse Processing
- Urine Collection
- Pregnancy Testing
- Osmolality
- Hematology
- Refresh
- Labels

To access the OR module, use the mouse to direct the arrow to the SP on the heads-up display, left-click, drag the mouse arrow to Oral Rinse Processing, and right-click.

Record the vessel 129 processing results in the Oral Rinse window. All SPs are included in the same window but are listed separately by row.

Oral Rinse

Oral Rinse

Tech ID: 1126	Test Name: HPV Rinse	Total Volume: 14 ml
Vessel ID: 129	Vessel Name: 17 x 100	Sample Volume: 10.0

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		
470234	HAGRID, RUBEUS	M	60	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		

The Oral Rinse window lists the vessel requirements across the top. SPs are listed separately in rows. The upper section of the Oral Rinse window contains the following information: Tech ID, Vessel

ID (129), Test Name (HPV Rinse), Vessel Name (17 x 100), Total Volume (14 ml), and Sample Volume (10.0). The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled Yes and No (radio buttons), Comments (text box), and a Container ID/Slot #. Use the Save button to save the results to the database. Use the OK button to save the results to the database and close the module. Use the Cancel button to close the window without saving any data to the database.

Record oral rinse processing results for each SP. Individually mark “Yes” for each vessel in the “Filled” column.

The screenshot shows a software window titled "Oral Rinse". At the top, there are fields for "Tech ID: 1126", "Vessel ID: 129", "Test Name: HPV Rinse", "Vessel Name: 17 x 100", "Total Volume: 14 ml", and "Sample Volume: 10.0". Below these fields is a table with the following columns: Sample ID, Person Name, Gender, Age, Filled, Comments, Container ID, and Slot#. The table contains two rows of data, both of which are currently grayed out. The first row is for Sample ID 244969, Person Name JORDAN, LEE, Gender M, Age 42, Filled (Yes/No radio buttons), Comments (none), Container ID 0415882, and Slot# 1. The second row is for Sample ID 470234, Person Name HAGRID, RUBEUS, Gender M, Age 60, Filled (Yes/No radio buttons), Comments (none), Container ID, and Slot#. At the bottom of the window are buttons for "Save", "OK", and "Cancel".

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0415882	1
470234	HAGRID, RUBEUS	M	60	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Only SPs who have had the oral rinse marked as collected in the Oral Health application are eligible to be processed. Once the sample is collected, the row changes from gray to black, indicating that the SP is ready to be marked as processed. To mark an individual 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, it is automatically assigned to a slot in an existing (open) container.

There are no quality comment codes available to describe the quality of the specimen or to explain why a vessel is marked as not filled.

Record oral rinse processing results for each SP. Individually mark each vessel as Filled–“No.”

Oral Rinse

Tech ID: 1126 Test Name: HPV Rinse Total Volume: 14 ml
 Vessel ID: 129 Vessel Name: 17 x 100 Sample Volume: 10.0

Sample ID	Person Name	Gender	Age	Filled	Comments	Container ID	Slot#
244969	JORDAN, LEE	M	42	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
470234	HAGRID, RUBEUS	M	60	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		

Save OK Cancel

To mark vessel 129 as not collected or Filled–“No,” direct the mouse arrow to the center of the “No” radio button and left-click. Vessels marked as “No” do not require a comment.

Continue to enter results as vessels are processed. Review the information in the OR Processing window and save the data to the database.

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, direct the mouse arrow to the “Save” button and left-click. To record this action or to save this 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.

12.7 Specimen Storage

Record the processing result for the HPV Rinse and store the vessel in a three-inch-tall foam container with a 5 x 5 grid. Store the container in the refrigerator. See Exhibit 12-3 for the shipping protocol.

Check the slot assignment of containers associated with vessel 129 at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 12-3. Storage protocol for HPV Rinse

Shipping location	Vessel	Condition	Vessel storage
Lab 37 CDC/Human Papillomavirus Laboratory 1600 Clifton Road MSG-41, Bldg. 23, Rm 4-409 Atlanta, GA 30329 (404) 639-2187	129 HPV Rinse	Refrigerated	5 x 5 three-inch foam box

12.8 Shipping Procedures

Secure the top of the cardboard box to the bottom with a rubber band. Place one absorbent sheet under the rubber band. Place the container in a plastic biohazard bag. Remove as much air as possible and seal the bag. Place the wrapped container into the large 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 refrigerator. Place the container the shipper with vessel 78 and 144. Place the appropriate shipping manifest in a 9" x 12" plastic bag and seal. This container is shipped weekly. Exhibit 12-4 lists the shipping criteria.

Exhibit 12-4. Shipping protocol

Laboratory	Vessel	Test name	Vessel storage	Shipping frequency
Lab 37 CDC/Human Papillomavirus Laboratory 1600 Clifton Road MSG-41, Bldg. 23, Rm 4-409 Atlanta, GA 30329 (404) 639-2187	129	HPV Rinse	Refrigerated	Weekly

12.9 How to Deal with System Failure

If the computer system fails, record results on a preprinted HPV Oral Rinse Processing worksheet (Exhibit 12-5). Complete a workstation 2 worksheet for each SP while processing the HPV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 12-5. HPV Oral Rinse Processing worksheet

HPV ORAL RINSE PROCESSING

SP ID _____

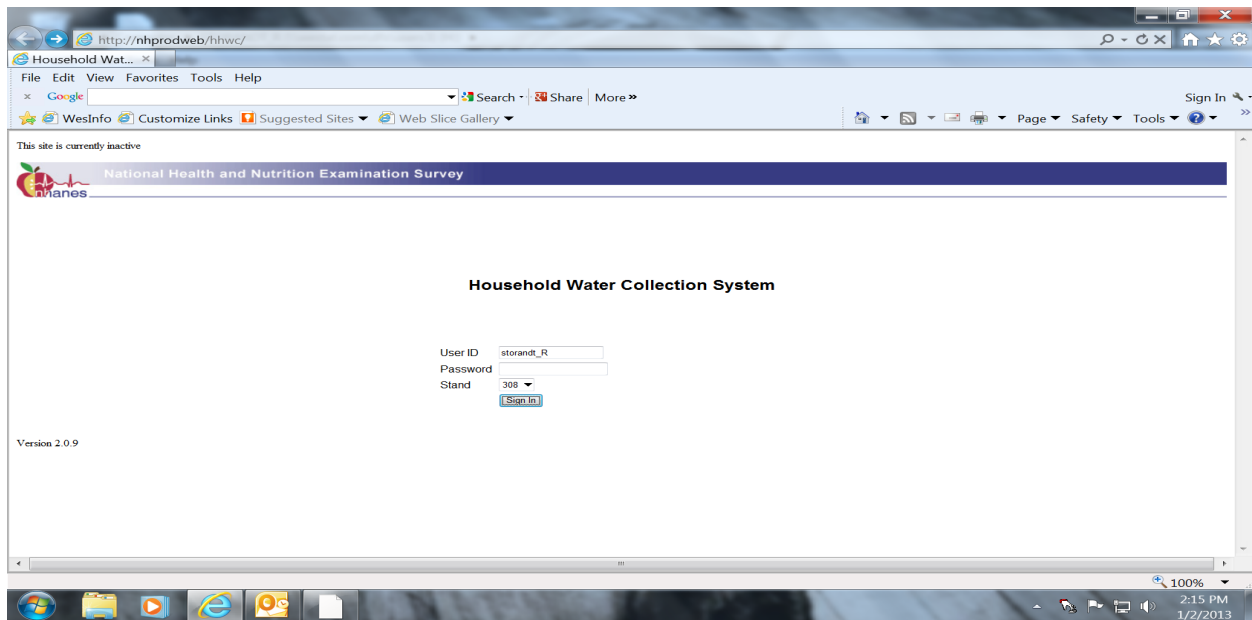
ID	Name	Ages	Sample ml	Sample type	Filled ✓	Slot #
129	HPV Rinse	14-59	1 oral rinse	10-ml		

13. Household Water Sample Processing

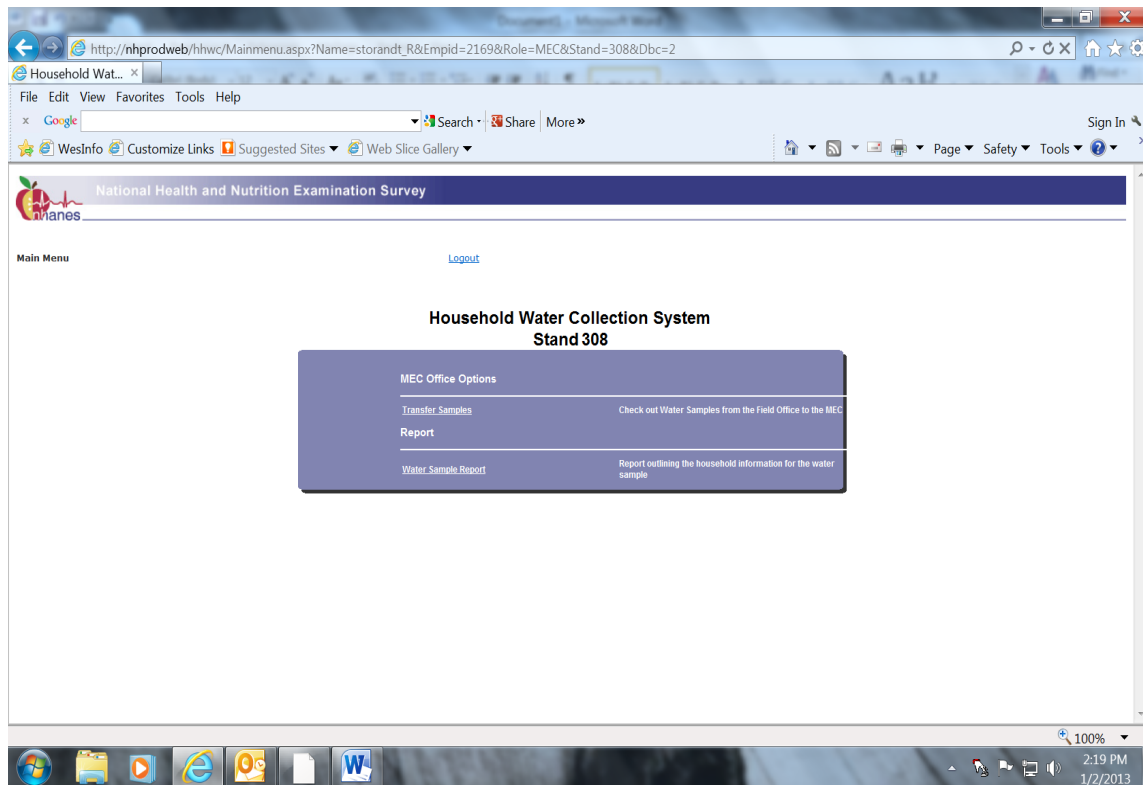
13.1 Receipt of Household Water

After obtaining water samples, the household interviewers drop them off at the field office (FO); the MEC manager or chief technologist then retrieves the samples to take back to the MEC. The MEC manager or chief technologist will use the household water application at the field office to document that the sample has been transferred to MEC personnel.

Log in to the household water application at the field office, shown below.

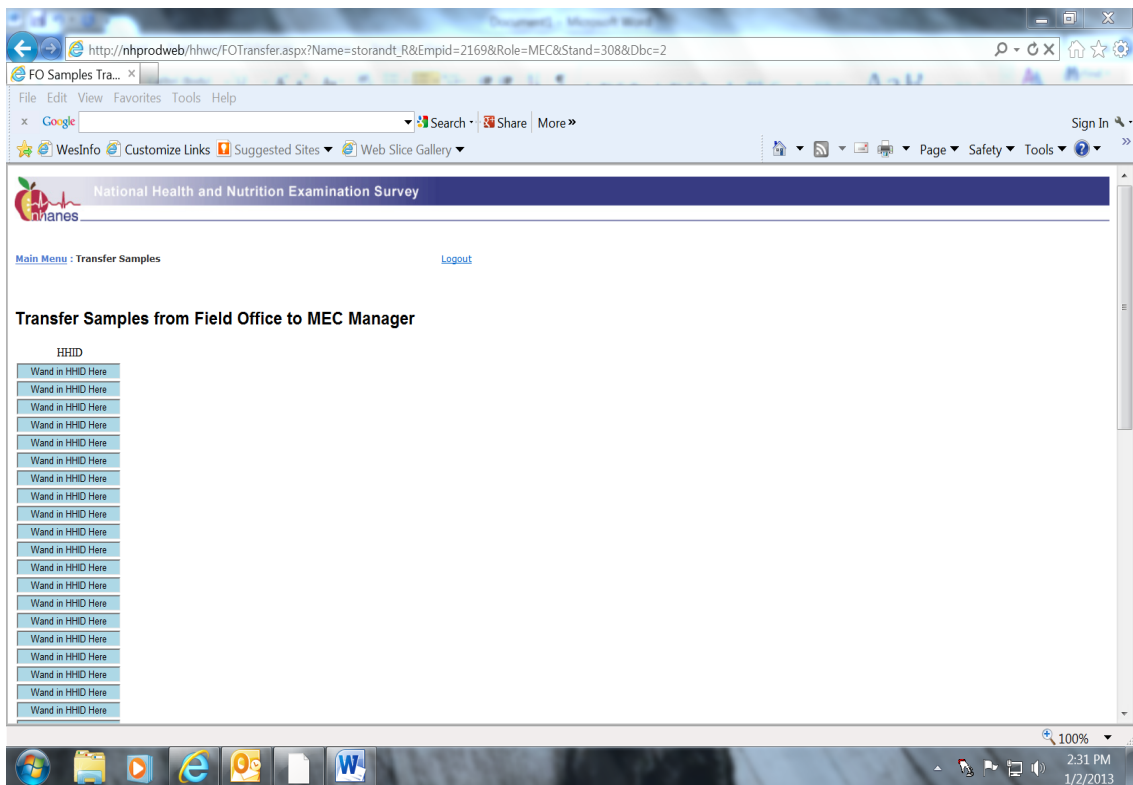


This will display the Household Water Collection System, shown below.



Click on “Transfer Samples.”

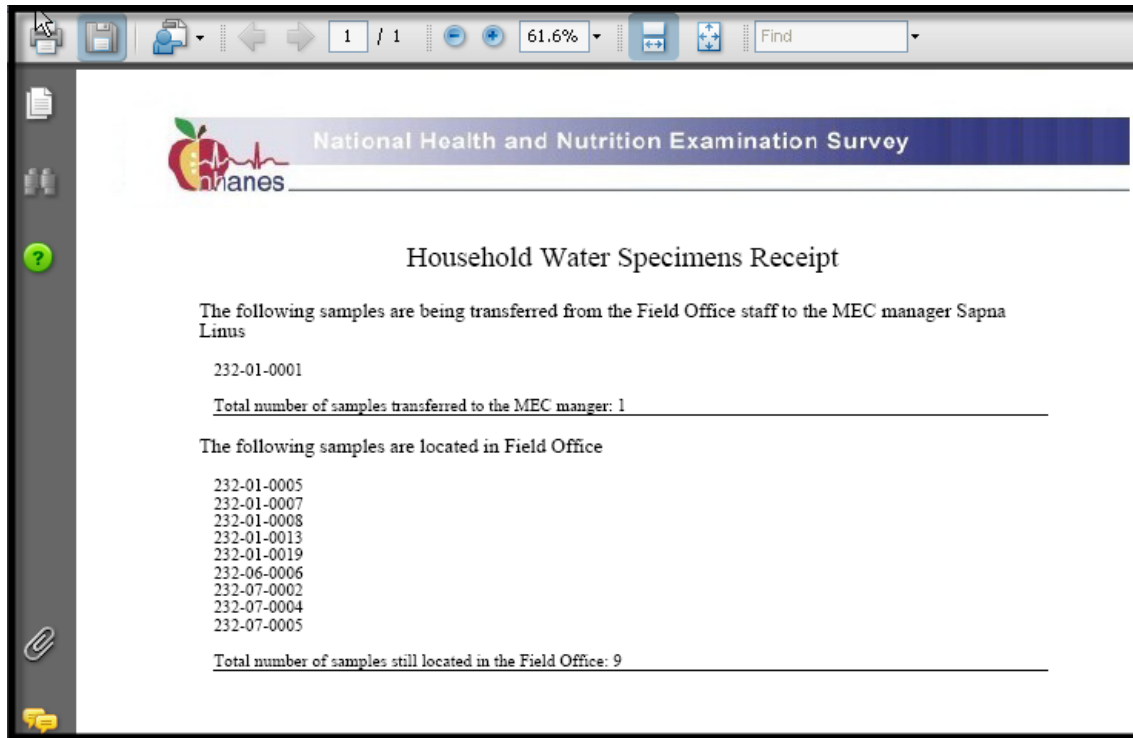
Scan in the barcodes from the water samples. The system will automatically populate the barcode information into one of the fillable field columns as shown in the picture below.



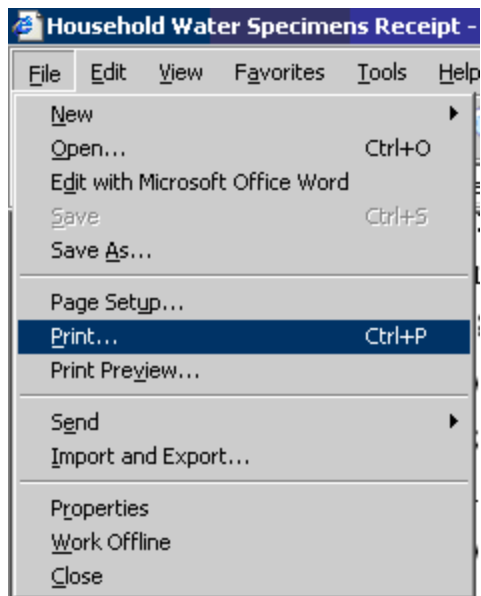
When finished scanning, select the Release button at the bottom of the page.

- The Release button on the transfer page is not activated until the household IDs are entered in the correct format.
- The system will not release a sample to the MEC if it has not already been receipted in the system by the field office or if the sample has already been released to the MEC.
- The system reconciles the sample received at the MEC with the ones received at the field office and creates and displays a Household Water Specimens Receipt report, shown below.

A PDF report is generated after the sample has been “Released” to the MEC. Users can save or print this PDF for future reference.



To print this report, select File,



Log out when finished.

Use any of the six filtering criteria to modify the data displayed in the report. By default, the report will initially display all the records. Use the filters to select by:

- Household ID: List of all processed samples
- Sample Status: Missing, Received
- Sample Location: FO, Interviewer, MEC
- Sample Collected By: List of all assigned interviews

After selecting the desired filter options, select the Filter button to view the modified report. It is also possible to sort by clicking on the column name.

The report contains a list of records based on the filtering criteria and initially displays by household ID. Selecting the “+” sign next to the household ID reveals the entire list of SPs in that household.

Print out the report and take a copy of it along with the samples back to the MEC. The report will be sent at the end of stand to the home office to be filed and saved by the Laboratory Component Lead.

13.2 Processing

The household interviewers label the fluoride water kit with a paper label containing the household ID. They write the collection date and time on the label of the water collection kit. This date and time are also captured and stored in the database when the interviewer marks the sample as collected.

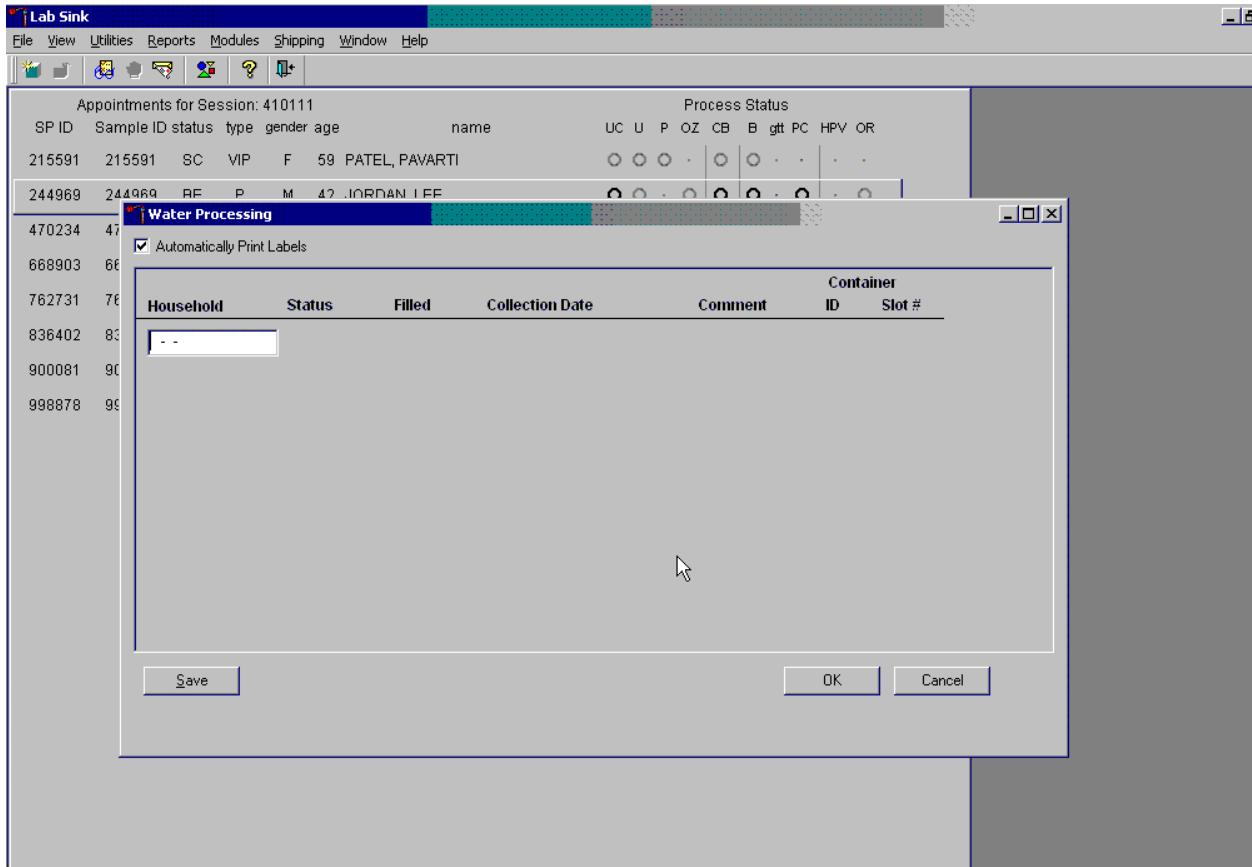
Access the Household Water module by selecting “Household Water” from the Modules tab, shown below.

The screenshot displays a software application window titled "Stand:615 Session:615810 11/15/2010 08:30 am - 12:30 pm". The application has a menu bar with options: File, View, Utilities, Quality Control, Reports, Modules, Shipping, Window, and Help. The "Modules" menu is open, showing "Hematology" and "Household Water" (which is selected). Below the menu is a table with the following data:

SP ID	Sample ID	Status	Type	Gender	Age	Name	Process Status						HPV		
							UC	U	P	CB	B	GTT	PC	F	M
329869	329869	SC	P	F	73	HOWARD, CLAIRE S	○	○	-	○	○	○	-	-	-
386827	386827	SC	P	F	13	DEEGAN, DOUG	○	○	○	○	○	○	-	-	-
499508	499508	SC	P	M	10	DEEGAN, MARK	○	○	-	○	○	-	-	-	-
767995	767995	SC	P	F	19	NAME, LAST M	○	○	○	○	○	-	○	-	○
836040	836040	SC	P	F	57	TORRES, LUCAS T	○	○	○	○	○	-	○	-	○
849425	849425	SC	P	M	16	CAMPBELL, VINNIE N	○	○	-	○	○	○	-	○	○
919919	919919	SC	P	M	83	PAYNE, IMAL	○	○	-	○	○	○	-	-	-

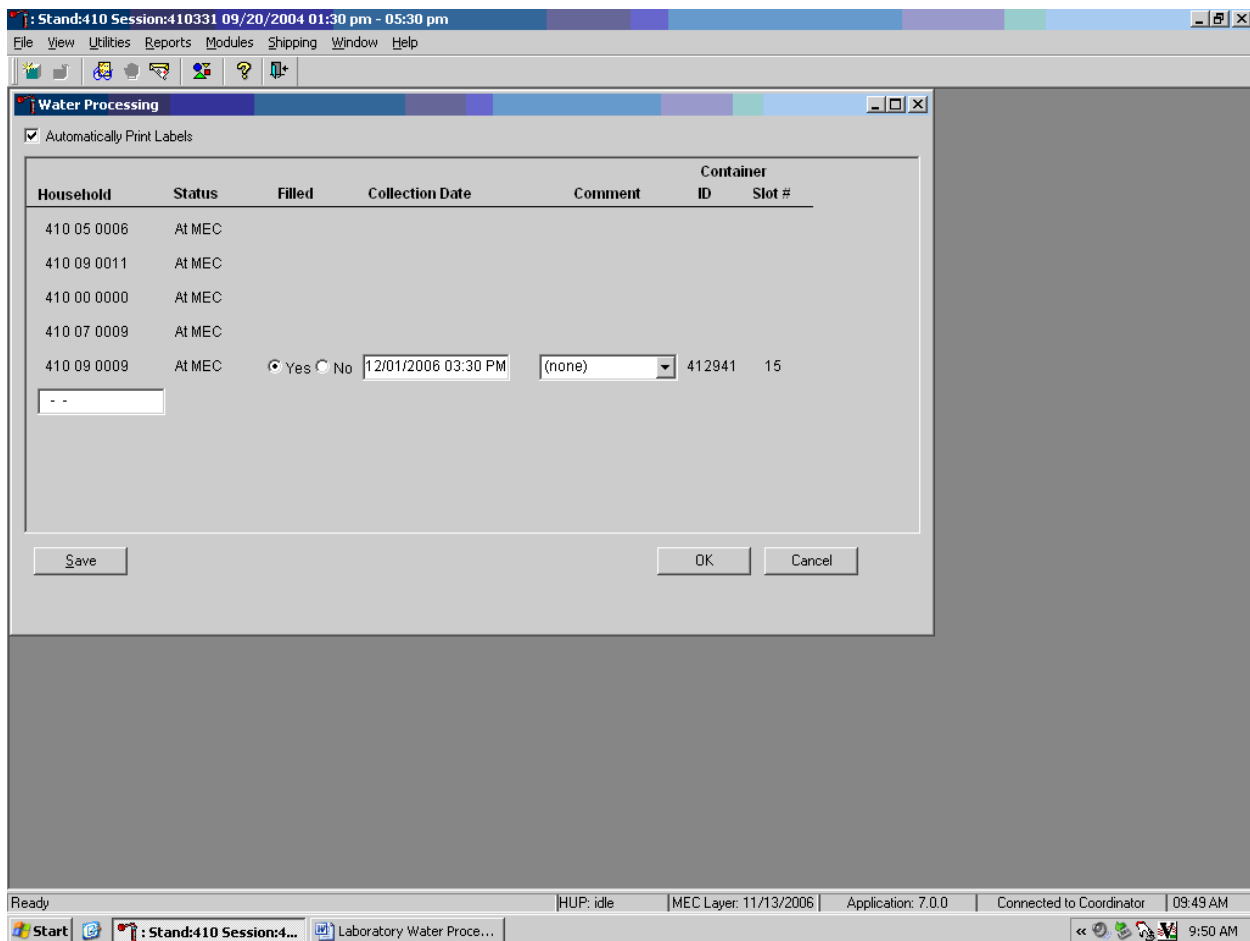
The taskbar at the bottom shows the system is "Ready", the user is "HUP: idle", the date is "8/26/2015", and the time is "2:31 PM". The taskbar also includes icons for "Start", "NHANES - Lab Vessel Pri...", and "Stand:615 Session:6...".

The water processing window then displays, as shown below.



The water processing window includes an Automatically Print Labels check box, a blank Household text box, columns for Status, Filled, Collection Date, Comments, Container ID and Slot #, and Save, OK, and Cancel buttons. The Automatically Print Labels check box will default to checked; do not change this.

Use the barcode gun to scan the household ID barcode for every water sample.



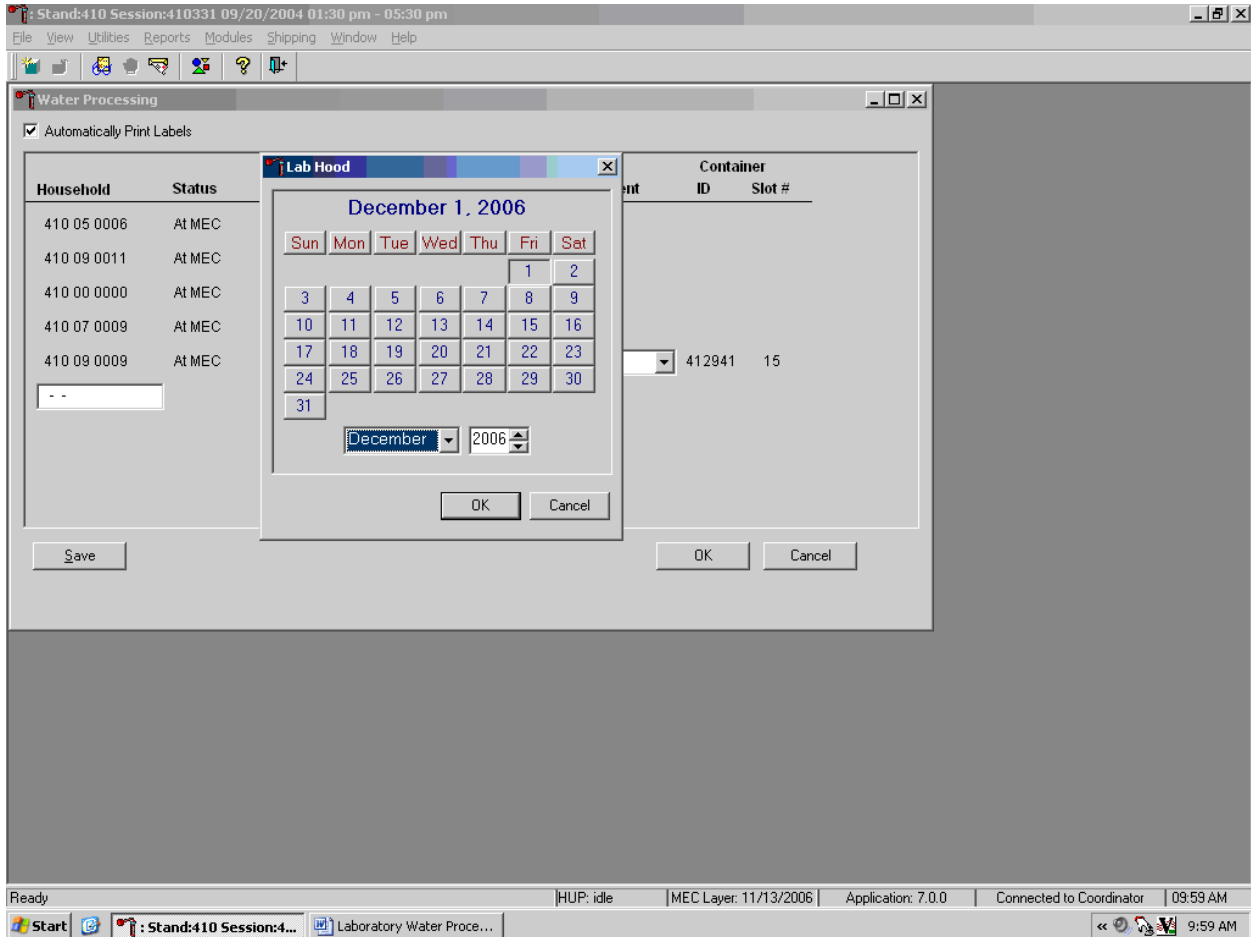
As each barcode is read, the status or current location of the sample is displayed:

- At MEC = sample is at the MEC but no one from the household has been examined.
- At FO = sample has been receipted at the field office but has not been transferred to the MEC.

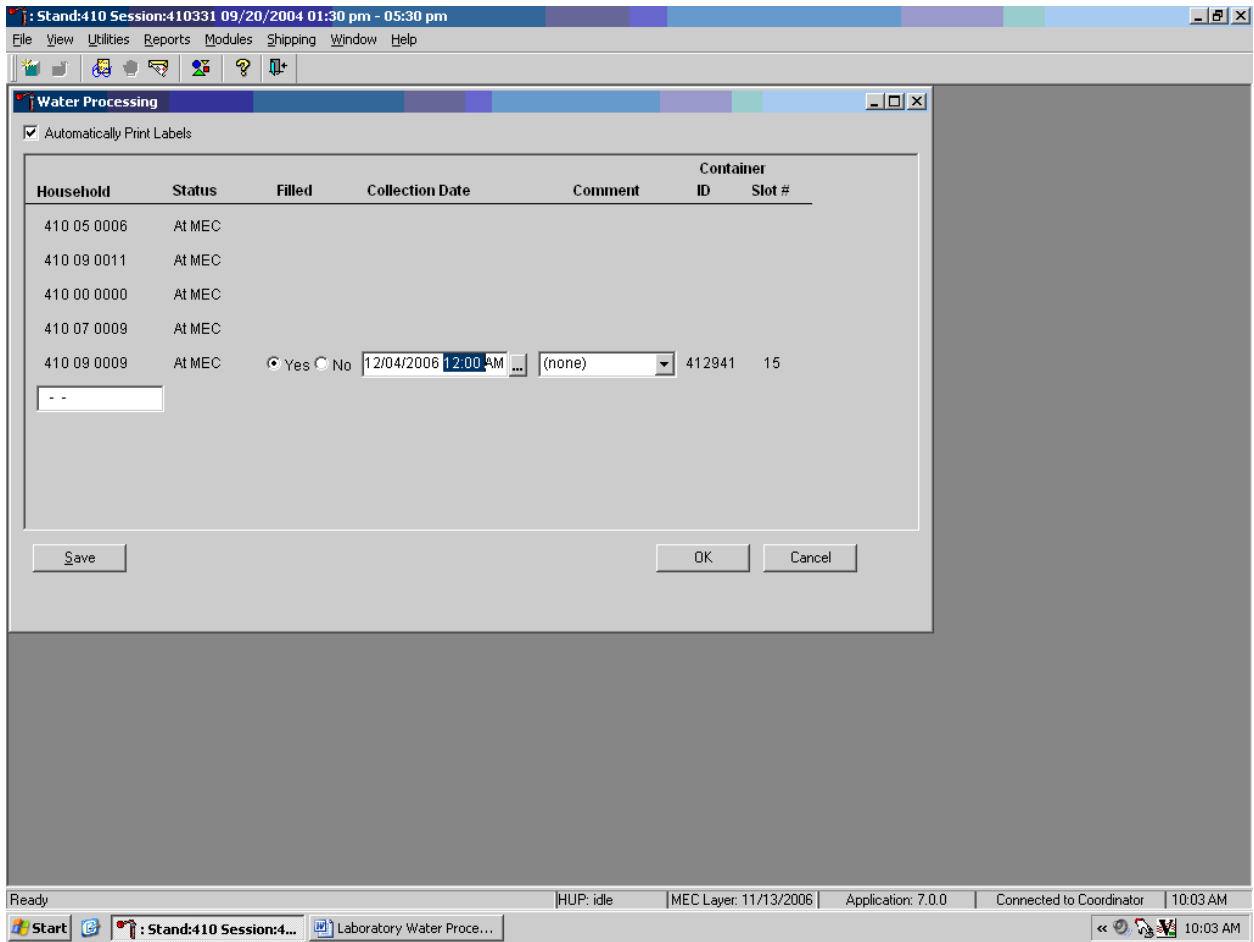
If the sample is at the MEC and someone from the household has checked in, the “Filled” radio button will be filled in, the collection date and time will be displayed, the comment box will default to blank, and the container ID and slot number will be assigned and displayed as shown above. A label will automatically print on the Dymo printer. This label contains a household ID barcode, an Astro ID barcode, and the words “HH Water” on the top.

Verify the collection date and time in the system with the date and time written on the outside of the plastic collection bag.

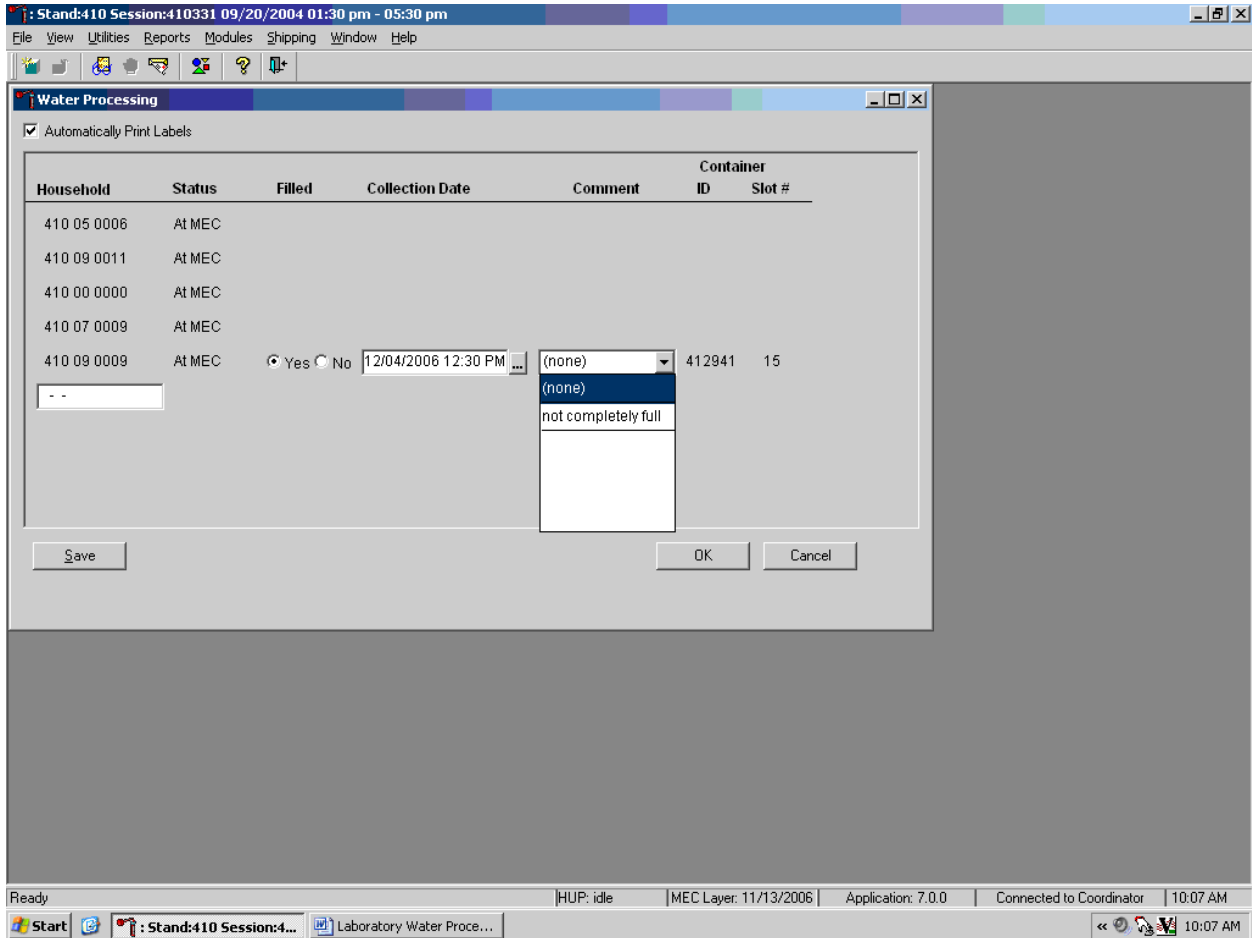
To change the collection date or time, place the cursor in the Collection Date and Time text box. An ellipse icon will display. Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format or use the calendar to enter the date. To access the calendar, select the ellipse icon and use the drop-down list to select the correct month (use the scroll bar if necessary). Then select the day on the displayed month and use the up-down controls on the spin box to select the year. Then select OK. To exit the calendar function, select the Cancel button.



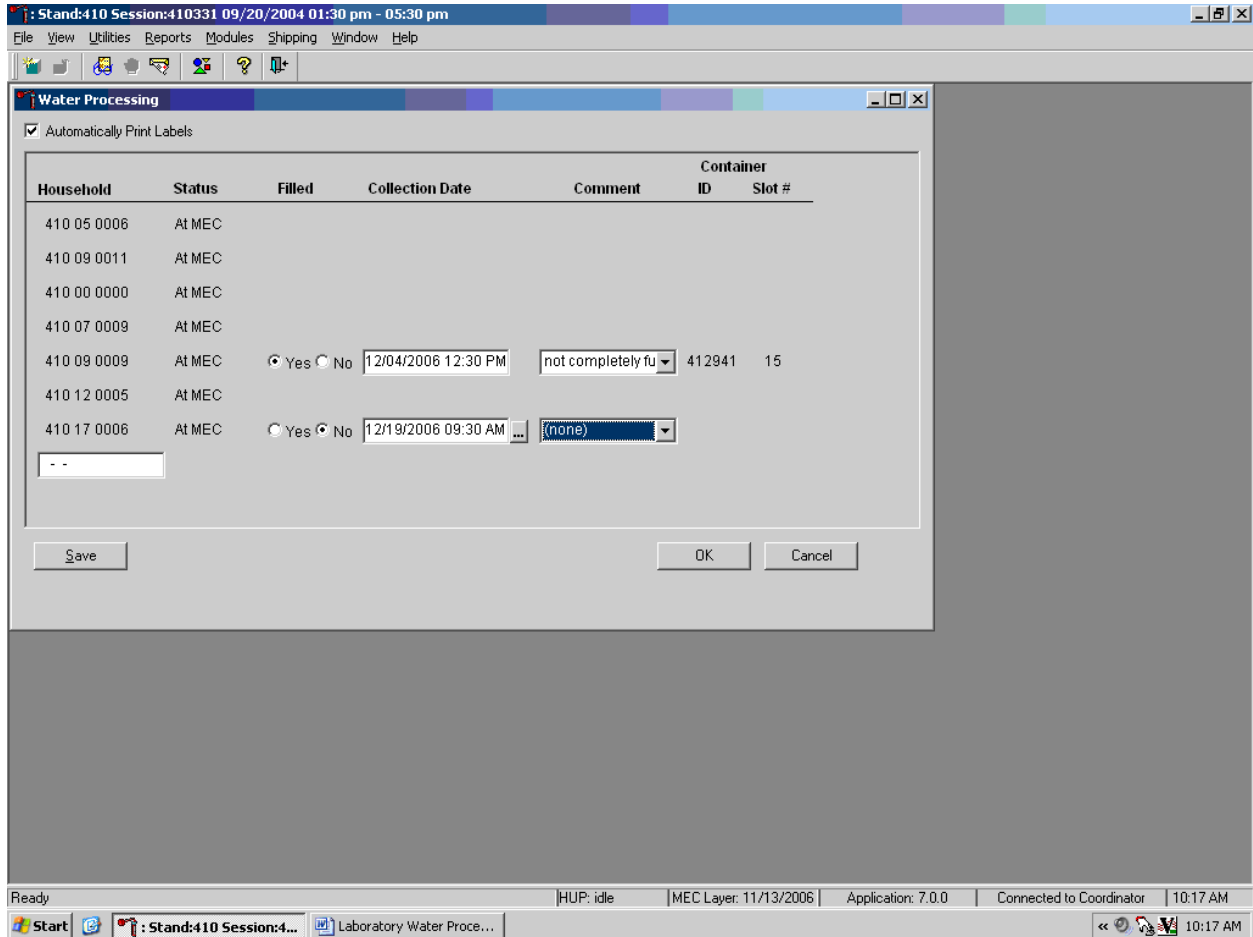
To correct the time, select the time (HH:MM) and double-click to highlight, as shown below. Use the numeric keyboard keys to type the correct hour and minutes and to indicate AM or PM.



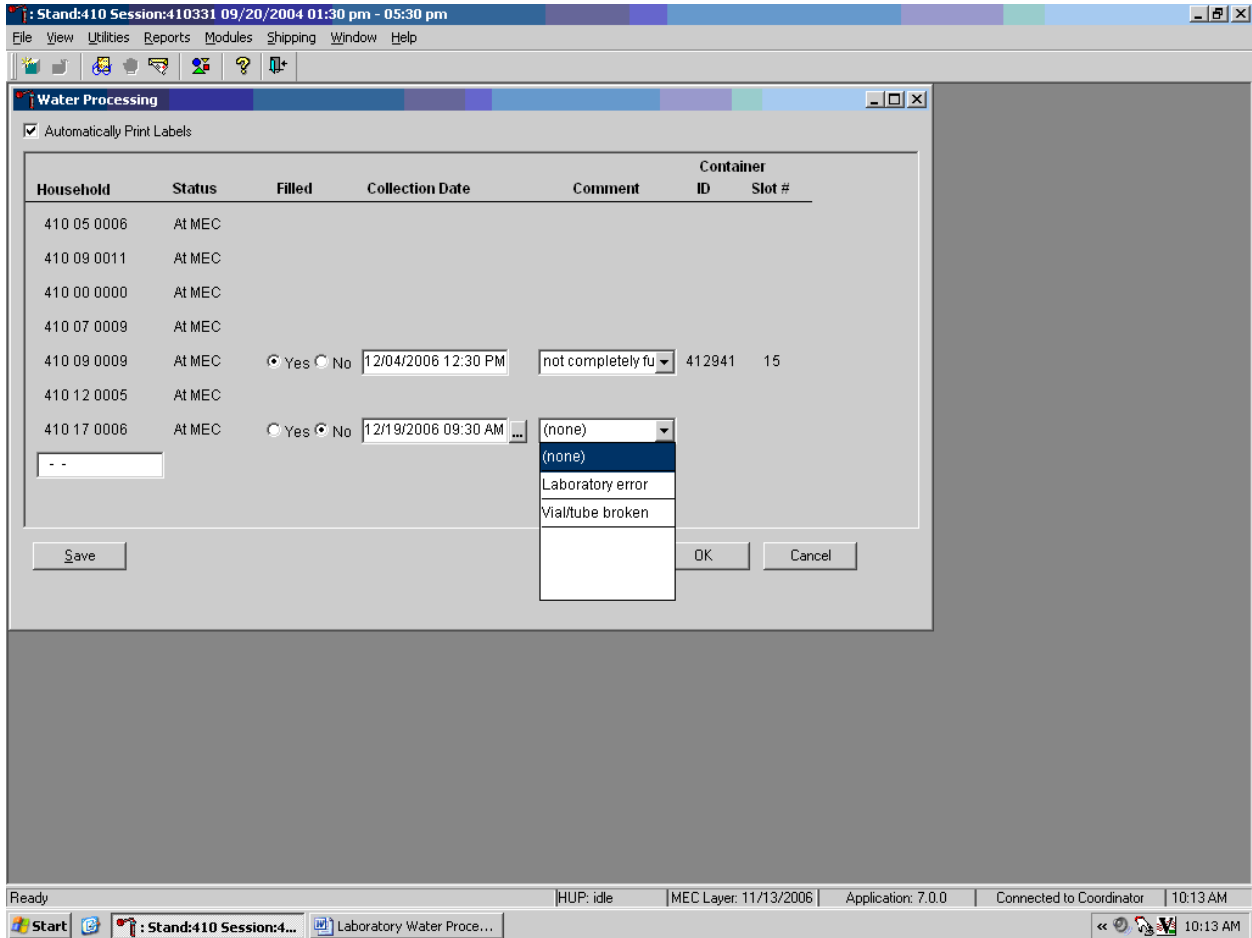
Add a “not completely full” comment to any sample that does not have water filled to the top of the vial. Use the drop-down arrow on the right side of the Comment text box and select “not completely full,” as shown below.



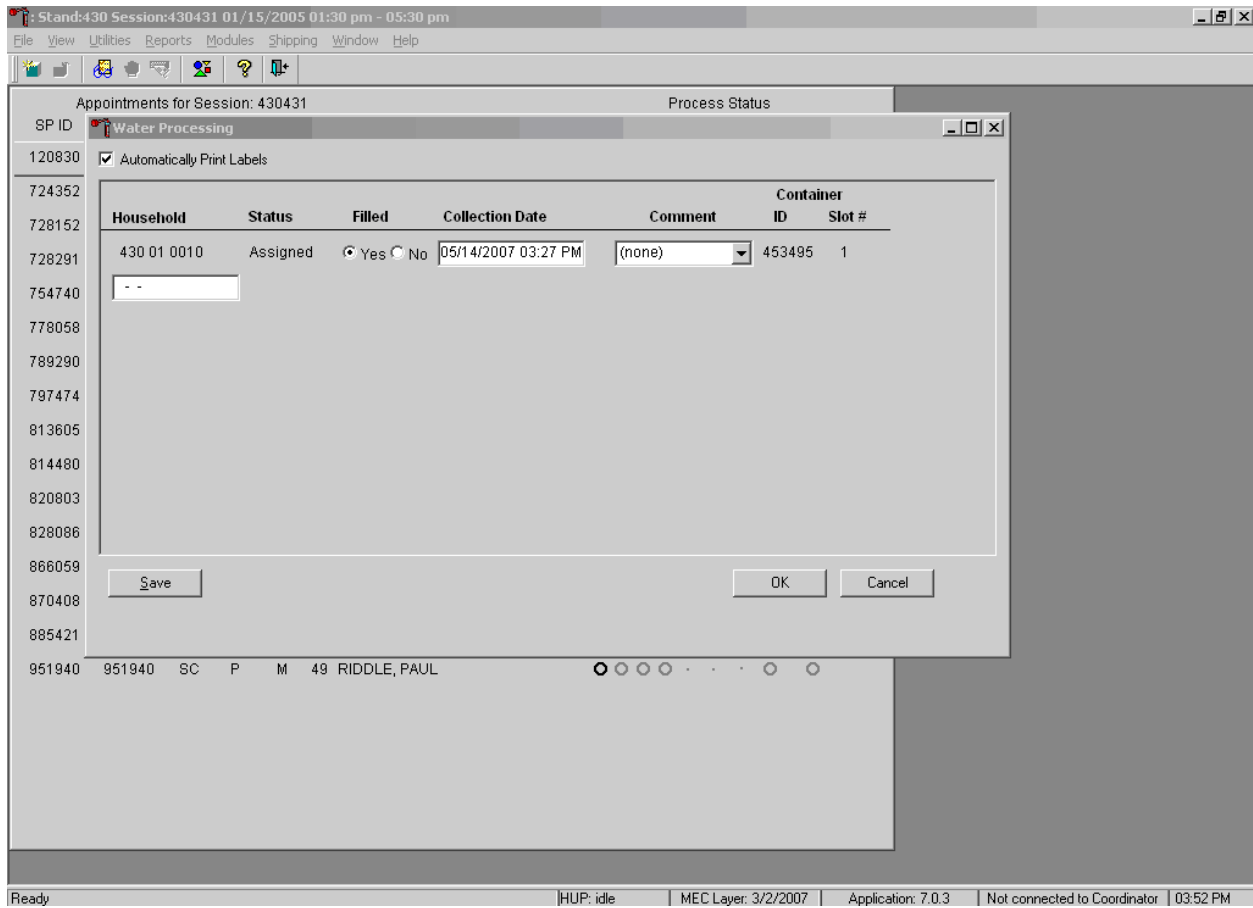
All samples that meet the processing criteria are automatically marked as Filled “Yes.” To change to Filled “No,” select the “No” radio button, as shown below. Use “No” for a sample that has been collected, delivered to the MEC, and an SP from the household has been checked in, but the vial has broken or there has been a laboratory error.



Add a comment to indicate why a sample is marked as Filled “No.” Use the drop-down menu on the right side of the Comment text box to select “Laboratory Error” or “Vial/tube broken,” as shown below.

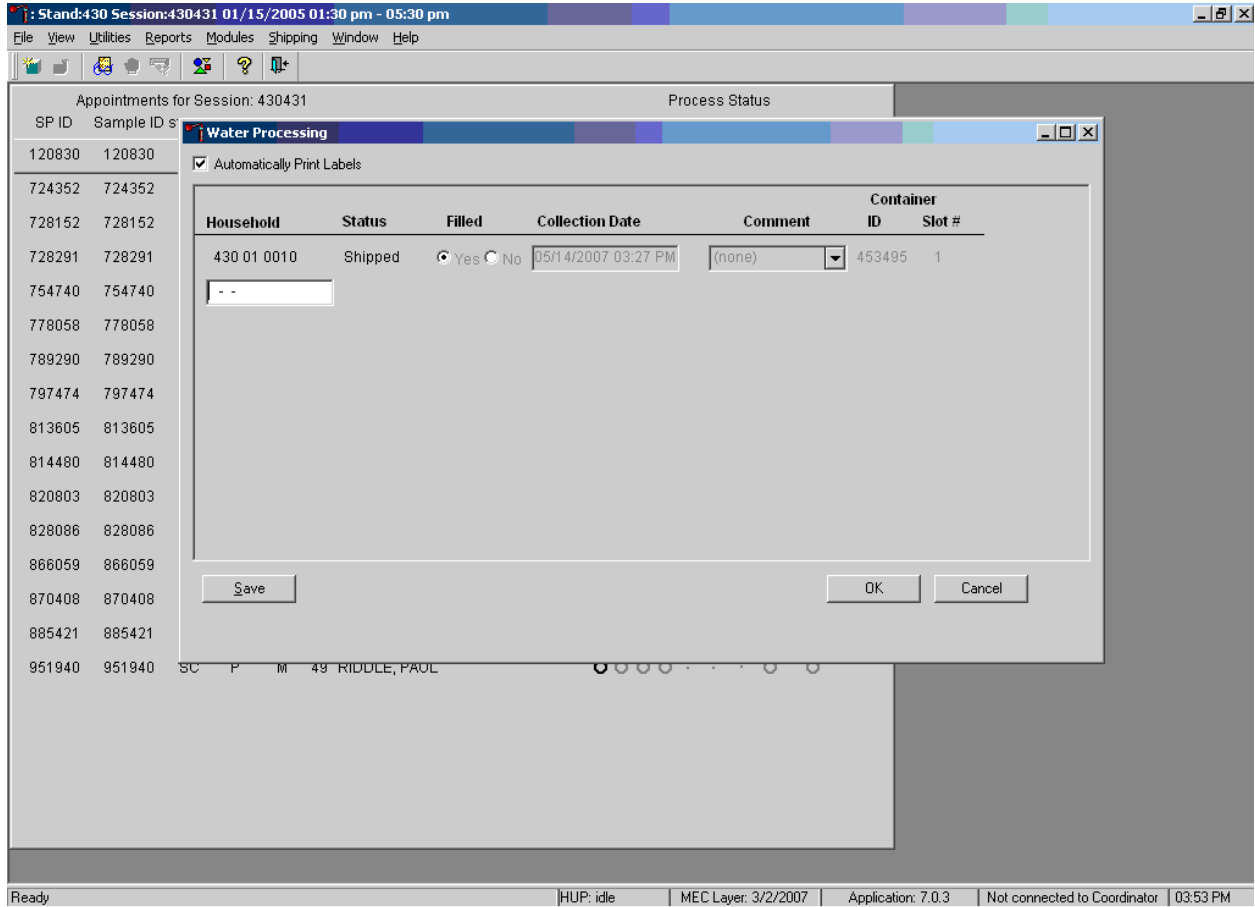


Water samples cannot be processed more than once. If a barcode is accidentally scanned more than once during the processing session, the Status field will display “Assigned,” as shown below.



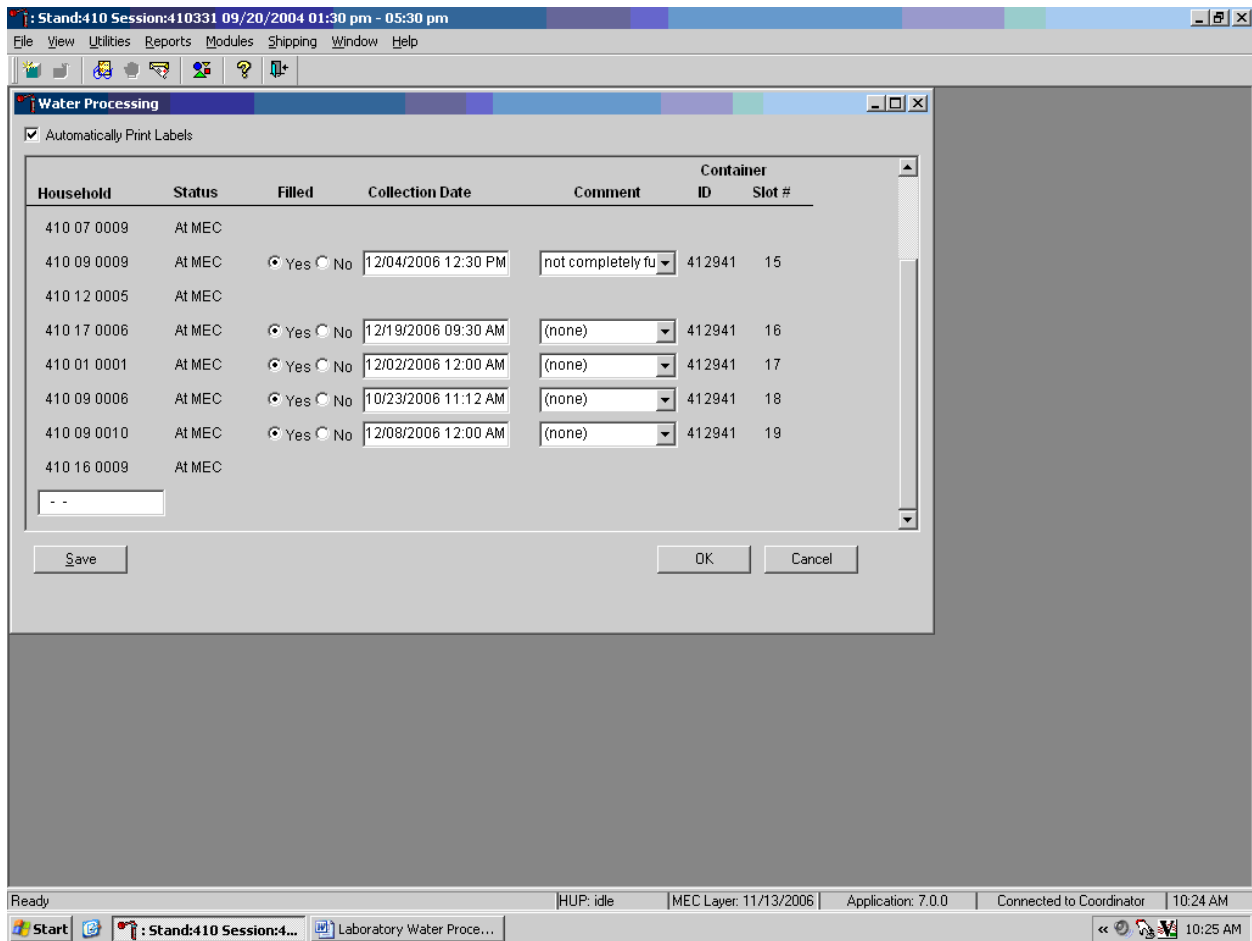
All samples that meet the processing criteria are automatically marked as Filled “Yes.”

If the sample has not been shipped, the record will be editable. If the sample has been shipped the record status will display “Shipped.” The record will appear grayed out and cannot be modified, as shown below.



To continue, scan another water vial or select the Cancel or OK button.

Continue to process all samples stored in the refrigerator, as shown below.



Store each vessel in the correct slot in the correct container. To record these actions or save this data to the database, select the Save button. Then select OK.

Verify the contents of the container by using the content container verification module found on the laboratory's Shipping tab. Ship the water samples according to the NHANES protocol.

Store the household water samples according to the protocol. The container protocol (Exhibit 13-1) illustrates the specifications for the storage of the household water samples.

Exhibit 13-1. Container protocol

Vessel ID	Test ID/name	Sample type	Vessel type	Vessel storage	Storage unit
144	Fluoride	Water	10-mL plastic	5 x 5 3" box	Refrigerator #2

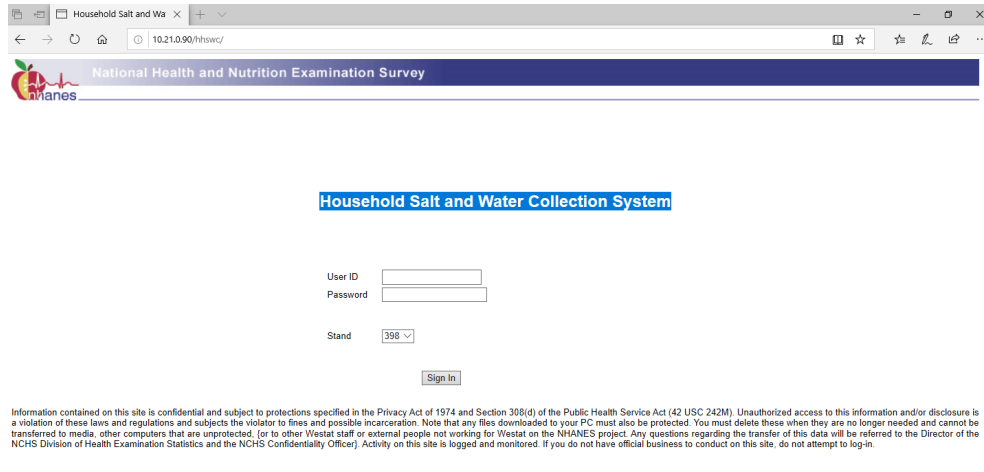
Send the sample on ice packs to Lab 6 – CDC Repository (CBR) 602 Webb Gin House Road Bldg C, Lawrenceville, GA 30045.

14. Household Salt Sample Processing

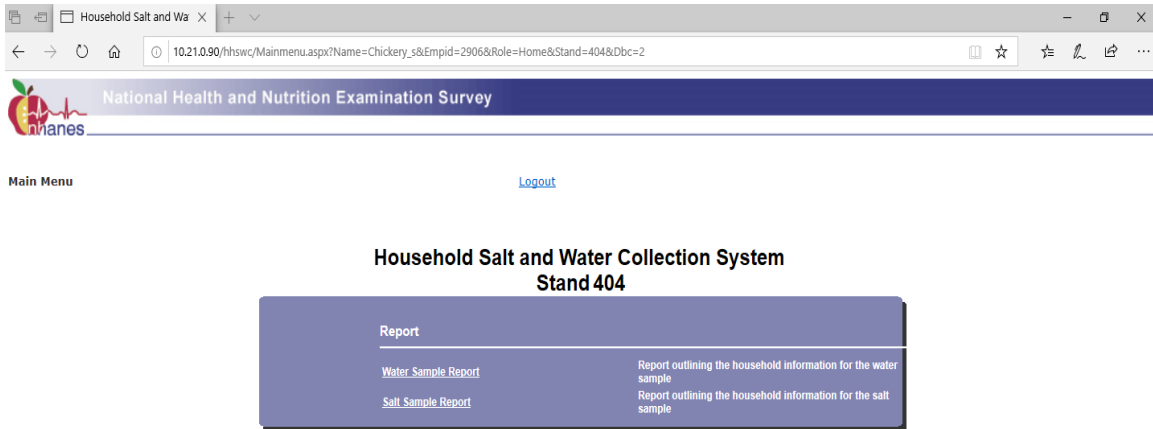
14.1 Receipt of Household Salt

The household interviewers after obtaining salt samples drop them off at the Field Office (FO) in order for the MEC Manager or Chief Technologist to come retrieve them to take back to the MEC. Prior to taking the samples, the responsible retriever will use the Household Salt and Water Collection System at the FO to fill out the chain of custody to indicate in the system that the sample has been transferred to MEC personnel.

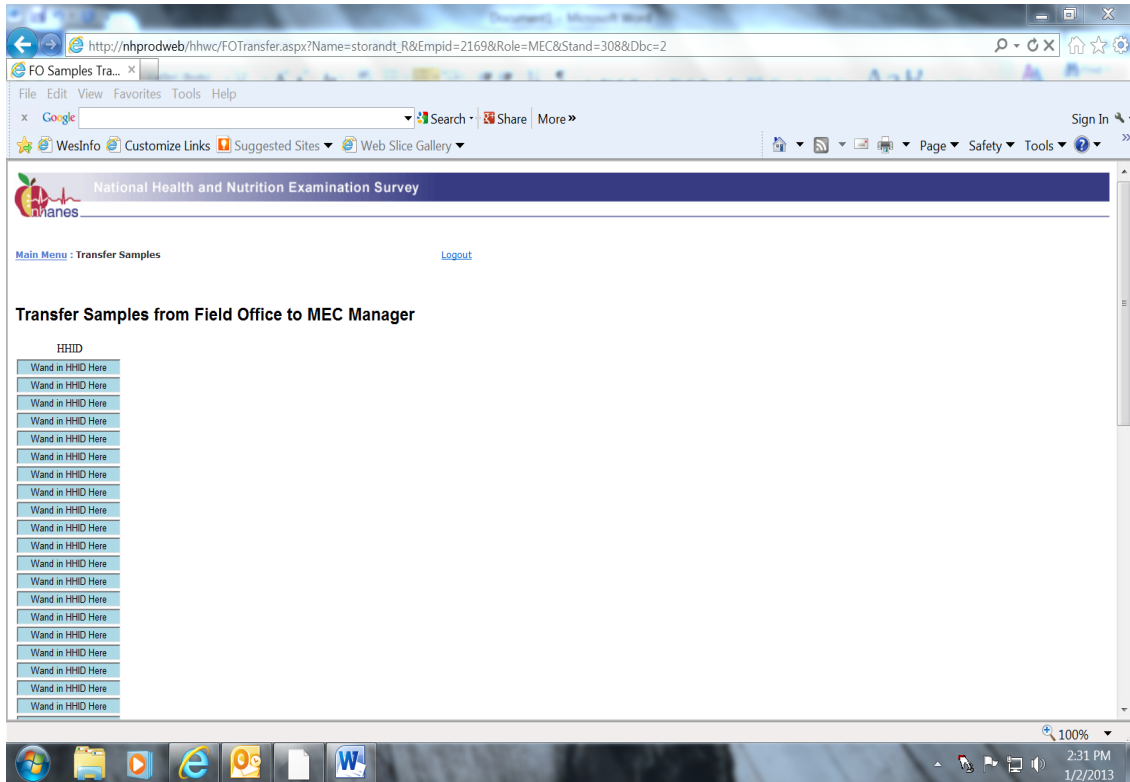
Log In to the Household Salt and Water Collection System at the FO



This will bring up the Household Salt and Water Collection System



Click on Transfer Samples



Scan in the barcodes from the salt samples.

When finished scanning select the Release button at the bottom of the page.

1. The “Release” button on the “Transfer Page” is not activated until the Household IDs are entered in the correct format.
2. The system will not release a sample to the MEC if it has not already been receipted into the system by the Field Office or if the sample has already been released to the MEC.
3. The system reconciles the sample received at the MEC with the ones received at the FO and creates and displays a Salt Specimens Receipt report.

A pdf report is generated after the sample has been “Released” to the MEC. The Users can save or print this pdf for future reference. To print this report select File, then Print from the top tool bar.

Logout when finished.

Use any of the six filtering criteria to modify the data displayed in the report. By default, the report will initially display all the records.

Use the filters to select by:

1. Household ID: List of all processed samples.
2. Sample Status: Missing, Received.
3. Sample Location: FO, Interviewer, MEC.
4. Sample Collected By: List of all assigned interviews.

After selecting the desired filter options, click on the Filter button to view the modified report. It is also possible to sort by clicking on the column name.

The report contains a list of records based on the filtering criteria and initially displays by household ID. Selecting the “+” sign next to the household ID reveals the entire list of SPs in that household.

To print the report, select “File” and “Print” from the top menu.

Take a copy of report along with the samples back to the MEC.

The copy of the report will be sent at the end of stand back to the home office to be filed and saved by the laboratory component lead.

14.2 Processing

The household interviewers label the outside of the salt kit with a paper label containing the Household ID. They write the collection date, time, and any observations, such as possible contamination, on the label that is located on the outside of the water collection kit. The date and time are also captured and stored in the database when the interviewer marks the sample as collected.

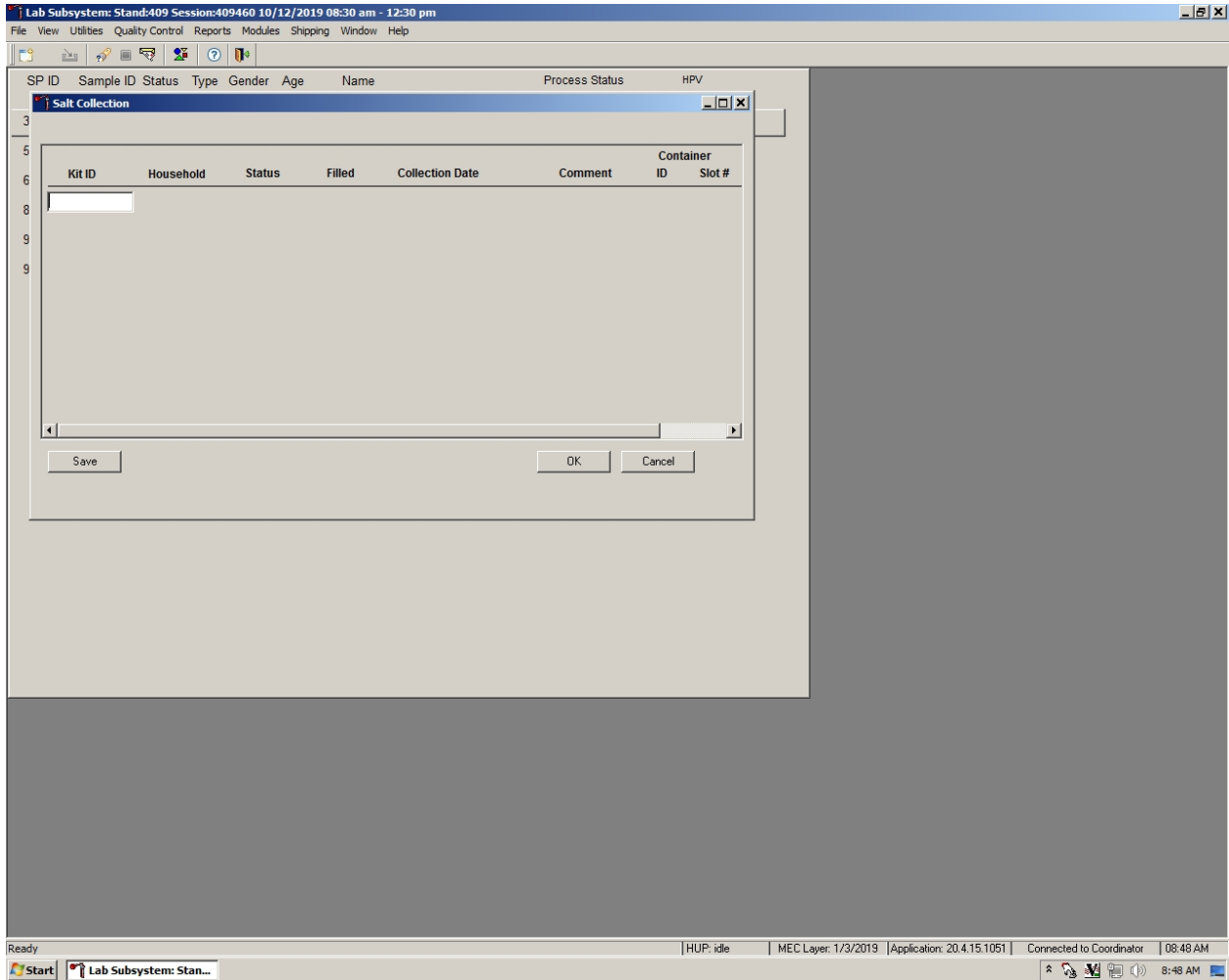
Access the Salt module.

To access the {Salt} module, use the mouse to direct the mouse arrow to {Modules} and left click.

The screenshot shows the 'Lab Sink' application window. The 'Modules' menu is open, displaying options: Hematology, Household Water, Household Salt (highlighted), and TB Processing. The main window contains a data table with columns for SP ID, Sample ID, Status, Type, G, and Name. To the right of the table are columns for Process Status (UC, U, P, CB, B, PC) and HPV (F, M, OR). Each cell in these columns contains a radio button or a dash.

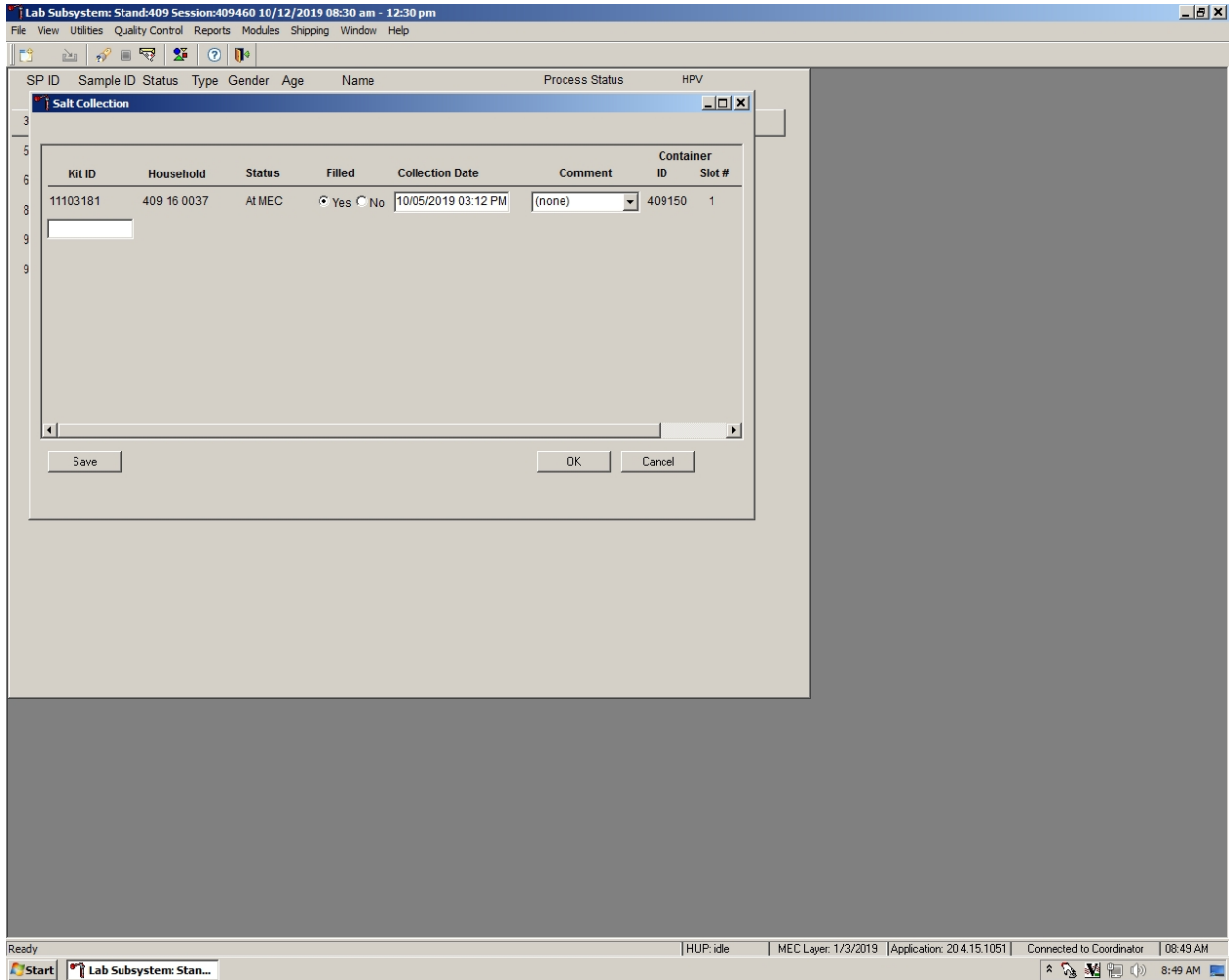
SP ID	Sample ID	Status	Type	G	Name	UC	U	P	CB	B	PC	F	M	OR
218716	218716	EX	P	M	40 TEST 12, TEST 12	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>
490416	490416	NS	P	M	12 TEST 11, TEST 11	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-
504260	504260	NS	P	F	11 TEST 7, TEST 7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-
506544	506544	EX	P	M	20 GAVIRIA, DAVID	<input checked="" type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-
601513	601513	NS	P	F	16 TEST 10, TEST 10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	<input type="radio"/>
908695	908695	NS	P	F	10 TEST 9, TEST 9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	-	-	-

The Salt Collection window displays.

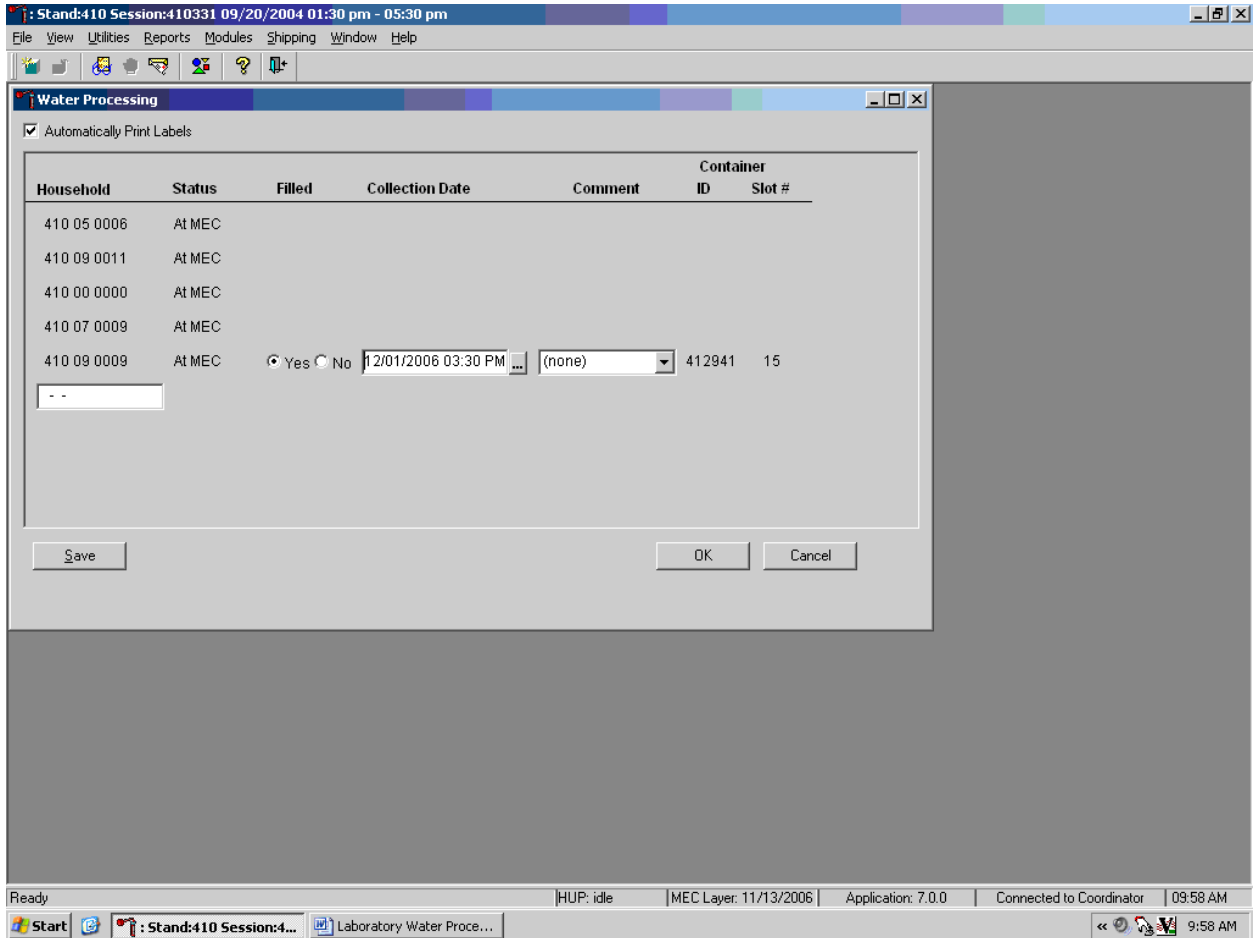


The Salt processing window includes a blank Kit ID, a blank Household text box, columns for Status, Filled, Collection Date, Comments, Container ID and Container Slot, and Save, OK, and Cancel buttons.

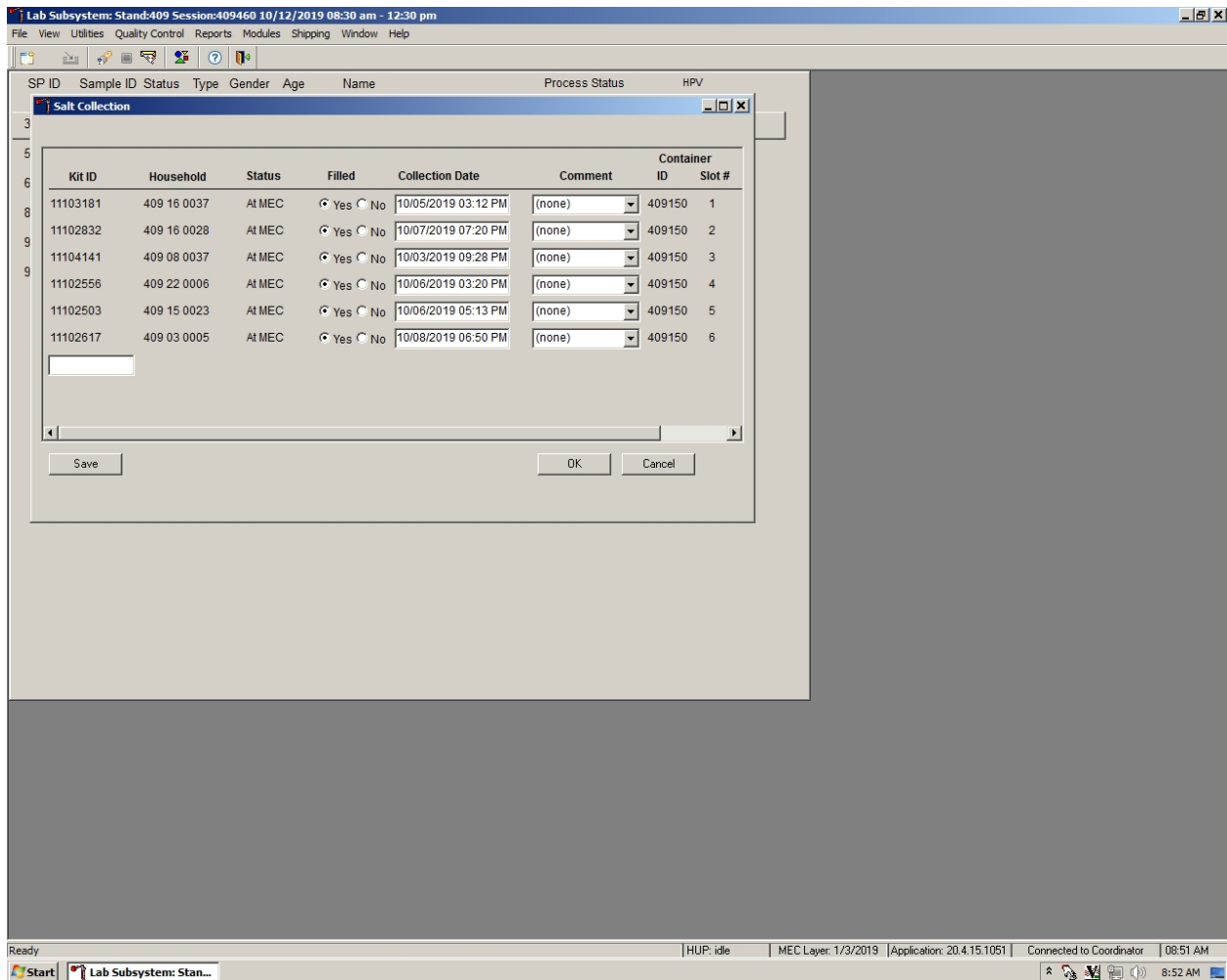
Use the bar code gun to scan the Kit ID bar code on the front of every salt sample.



As each bar code is read, the status or current location of the sample is displayed.



All samples that meet the processing criteria are automatically marked as Filled “Yes.”



To change the Filled “Yes” to Filled “No,” use the mouse to direct the mouse arrow to the “No” radio button and right click. Enter Filled "No" for a sample that has been collected and delivered to the MEC for an SP who has been checked in, but the vial has been broken or there has been a laboratory error. Add a comment to indicate the reason why a sample is marked as Filled “No.”

To select a comment for a Filled “No” sample, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the Comment text box and left click. Drag the mouse arrow to “Laboratory Error” or “Vial/tube broken” and left click.

If the household interviewer indicated there was possible contamination of the sample, select the down arrow in the comment block and select the comment for possible contamination.

Salt samples cannot be processed more than once.

If a bar code is accidentally scanned more than once during the processing session, the Status field will display “Assigned”. If the sample has not been shipped, the record will be editable. If the sample has been shipped the record status will display “Shipped.” The record will appear greyed out and cannot be modified. To continue, scan another salt vial or select the Cancel or OK button. Continue to process all samples.

14.3 Storage and Shipping

Store each container in the correct slot in the correct container. To record these actions or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the Cancel button and left click.

Verify the contents of the container, by using the content container verification module found on the laboratories shipping tab on the head’s up display. Ship the salt samples according to the NHANES protocol.

Store the Salt samples according to the protocol. The container protocol (Exhibit-14-1) illustrates the specifications for the storage of the salt samples.

Exhibit 14-1. Container protocol

Vessel ID	Test ID/name	Sample type	Vessel type	Vessel storage	Storage unit
227, 228	Iodine, Salt	Salt	15 mL HDPE Container	5 x 5 3 inch box	Room Temp

Send the sample on ice packs to Lab 6 – CDC Repository (CBR) 602 Webb Gin House Road Bldg C, Lawrenceville, GA 30045.