
National Health
and Nutrition
Examination Survey

LABORATORY
PROCEDURES
MANUAL



April 2001

TABLE OF CONTENTS

For fast and easy navigation, press F5 to show Bookmarks

<u>Chapter</u>		<u>Page</u>
1	OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY	1-1
1.1	History of the National Health and Nutrition Examination Programs	1-1
1.2	Overview of the Current NHANES	1-3
1.2.1	NHANES Pilot and Dress Rehearsal	1-4
1.2.2	Data Collection for NHANES Main Survey	1-4
1.3	Sample Selection.....	1-6
1.4	Field Organization for NHANES.....	1-7
1.5	Exams and Interviews in the Mobile Examination Center (MEC)	1-10
1.6	Confidentiality and Professional Ethics.....	1-20
2	OVERVIEW AND LABORATORY TEAM RESPONSIBILITIES	2-1
2.1	Overview.....	2-1
2.2	The Laboratory Team	2-2
2.3	Tasks	2-2
2.4	Organization of the Laboratory.....	2-3
2.5	Tasks – Phlebotomy Room	2-4
2.6	Tasks – Workstation 1	2-4
2.7	Tasks – Workstation 2	2-6
2.8	Tasks – Workstation 3	2-7
3	BIOSAFETY	3-1
3.1	OSHA (Occupational Safety and Health Administration) Bloodborne Pathogens Regulations	3-1
3.2	Exposure Categories	3-1
3.3	Preventive Measures	3-1
3.3.1	Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections.....	3-2
3.4	Methods of Control.....	3-3
3.4.1	Engineering Control - Needle Precautions.....	3-4
3.4.2	Work Practice Controls - Personal Protective Equipment ..	3-5

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
3.5	Housekeeping.....	3-8
3.6	Identification of Infectious Waste.....	3-9
	3.6.1 Waste Management.....	3-9
	3.6.2 Infectious Waste Labels.....	3-9
	3.6.3 Handling, Transport, and Storage of Infectious Waste	3-10
3.7	Recordkeeping	3-10
3.8	References.....	3-12
4	VENIPUNCTURE.....	4-1
	4.1 Introduction.....	4-1
	4.2 Equipment and Supplies	4-3
	4.2.1 Inventory Procedures	4-4
	4.3 Session Preview, Show Results, and Room Log Reports	4-7
	4.4 Overview.....	4-12
	4.5 Gaining Cooperation.....	4-13
	4.5.1 Refusal Conversion	4-15
	4.6 Performing the Venipuncture on SPs Who Do Not Speak English	4-15
	4.7 Begin the Exam and Logon	4-17
	4.8 Open the Exam and Log the SP into the Exam.....	4-20
	4.9 The Phlebotomy Interview.....	4-22
	4.10 Administering the Fasting Questionnaire	4-31
	4.11 Venipuncture Procedures.....	4-38
	4.11.1 Preparation of the Puncture Site.....	4-38
	4.11.2 Venipuncture Technique for the Sherwood Kendall Monoject Angel Wing™ Blood Collection Set	4-40
	4.11.3 Venipuncture Technique for the Eclipse Multisample Needle	4-42
	4.11.4 Concluding the Venipuncture.....	4-43
	4.12 Pediatric Venipuncture	4-44
	4.13 Recording the Results of the Venipuncture Procedure	4-46
	4.14 Final Venipuncture Procedures.....	4-48
	4.15 Venipuncture Status.....	4-49
	4.16 Informed Consent Exclusions.....	4-53

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
4.17	Observations	4-56
4.18	Review an Exam	4-61
4.19	Phlebotomy Quality Control	4-67
4.20	Conducting the Venipuncture as Part of a Home Exam	4-70
	4.20.1 Introduction	4-70
	4.20.2 Equipment and Supplies	4-71
	4.20.3 Overview	4-72
	4.20.4 Preparing for the Home Exam - Printing Venipuncture Tube Labels and Collecting Supplies	4-73
	4.20.5 Conducting the Exam	4-92
	4.20.6 Entering Phlebotomy Home Exam Quality Control	4-93
4.21	Red Cross Procedures for Handling Vasovagal Reactions	4-98
4.22	How to Deal With System Failure	4-100
5	URINE SPECIMEN COLLECTION AND URINE PROCESSING AND STORAGE	5-1
	5.1 Introduction	5-1
	5.2 Supplies	5-2
	5.3 Document Urine Collection	5-3
	5.4 Urine Specimen Assays	5-13
	5.5 Urine Specimen Protocols	5-14
	5.6 Labeling Urine Processing Vessels	5-15
	5.7 Urine Specimen Processing	5-15
	5.8 Record the Results of Urine Specimen Processing	5-16
	5.9 Second Urine Samples	5-29
	5.10 Specimen Storage	5-30
	5.10.1 Opening New Containers	5-31
	5.10.2 Check Storage Containers	5-32
	5.11 Subsample and Session Previews	5-35
	5.12 How to Deal With System Failure	5-42
6	URINE PREGNANCY TEST	6-3
	I. Purpose and Principle of the Test	6-3
	II. Special Safety Precautions	6-4
	III. Computerization: Integrated Survey and Information System (ISIS)	6-5
	IV. Specimen Collection and Preparation	6-5

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	V. Procedure for Microscopic Examination	6-5
	VI. Reagents and Supplies	6-5
	VII. Calibration	6-7
	VIII. Assay Procedure	6-7
	IX. Reportable Range of Results.....	6-9
	X. Quality Control	6-9
	XI. Interpretation of Results and Remedial Action.....	6-24
	XII. Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions	6-39
	XIII. Reference Ranges	6-42
	XIV. Action Limits	6-43
	XV. Specimen Storage and Handling During Testing.....	6-43
	XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails.....	6-43
	XVII. Test Results Reporting System Protocol for Reporting Action Limits	6-43
	XVIII. Specimen Accountability and Tracking.....	6-43
	XIX. Quality Control Summary Statistics and Graphs	6-44
	XX. References.....	6-44
7	COMPLETE BLOOD COUNT (CBC)	7-1
	I. Purpose and Principle of Test	7-3
	II. Special Safety Precautions.....	7-5
	III. Computerization: Integrated Survey and Information System (ISIS).....	7-6
	IV. Specimen Collection and Preparation.....	7-6
	V. Procedure for Microscopic Examination	7-6
	VI. Reagents and Supplies	7-7
	VII. Calibration	7-10
	VIII. Assay Procedure	7-21
	IX. Beckman Coulter® Reportable Range of Results.....	7-35
	X. Quality Control	7-36
	XI. Interpretation of Results and Remedial Action.....	7-50
	XII. Limitations of Method: Specimen Rejection, Interfering Substances and Conditions	7-92
	XIII. Reference Ranges	7-94
	XIV. Action Limits	7-95
	XV. Specimen Storage and Handling during Testing	7-96
	XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails	7-96
	XVII. Test Results Reporting System: Protocol for Reporting Action Limits	7-97

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	XVIII. Specimen Accountability and Tracking.....	7-97
	XIX. Quality Control Summary Statistics and Graphs	7-97
	XX. References.....	7-97
8	BLOOD AND HIV URINE PROCESSING AND STORAGE	8-1
	8.1 Introduction.....	8-1
	8.2 Equipment and Supplies	8-1
	8.3 Protocols	8-2
	8.4 Labeling Vessels.....	8-8
	8.5 Blood Processing Age Specific Protocols.....	8-9
	8.6 Equipment.....	8-15
	8.6.1 Benchtop Centrifuges.....	8-15
	8.6.2 Laminar Flow Biological Safety Cabinet Operating Sequence	8-17
	8.7 Blood Processing Procedures.....	8-18
	8.7.1 Eppendorf Research Pro Pipettes	8-18
	8.7.2 Process the 3-mL and 5-mL EDTA Tubes.....	8-42
	8.7.3 Process the 3-mL Gray Tube for Glucose.....	8-45
	8.7.4 Process the 3-mL Blue Top Tube for Fibrin	8-46
	8.7.5 Process the 3-mL, 7-mL, and 15-mL Red Top Tubes for Pooled Sera.....	8-46
	8.7.6 Process the 10-mL Red Top Tube for Persis Pest and Phytoestro.....	8-48
	8.7.7 Process One 15-mL Red Top Tube for Clots.....	8-48
	8.7.8 Process the 8-mL ACD Tubes for WBC/DNA	8-49
	8.7.9 Reagent Processing and Preparation	8-49
	8.8 Record the Results of Specimen Processing.....	8-50
	8.9 Process HIV Urine.....	8-71
	8.10 Blood Specimen Storage.....	8-79
	8.10.1 Blood Specimen Storage Protocol.....	8-79
	8.10.2 Opening New Containers	8-81
	8.10.3 Check Storage Containers	8-82
	8.11 Subsample and Session Previews and Informed Consent Status Report	8-85
	8.12 Home Exam Blood Processing and Storage	8-92
	8.13 How to Deal With System Failure.....	8-99

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
9	PRINTING LABELS AND SPECIMEN SHIPMENT	9-1
9.1	Introduction.....	9-1
9.2	Equipment and Supplies	9-3
9.3	Print Vessel Labels and Label Blood-Processing Racks	9-4
	9.3.1 Print Vessel Labels Using the Print Labels Module.....	9-6
	9.3.2 Print Vessel Labels Using the Heads-up Display.....	9-23
	9.3.3 Print an Ad-Hoc Vessel Label Using the Heads-up Display	9-25
	9.3.4 Rescheduled Appointments.....	9-26
	9.3.5 Subsample and Session Previews Report.....	9-28
9.4	Regeneration of Data	9-33
9.5	Generate, Print, and Assign Container IDs or Labels	9-40
9.6	Trash Containers.....	9-52
9.7	Shipping Overview	9-55
9.8	Create FedEx Airbills	9-57
	9.8.1 Launch the FedEx Ship Application	9-57
	9.8.2 Create the Airbill.....	9-60
	9.8.3 FedEx Log.....	9-76
	9.8.4 Track Shipments.....	9-80
	9.8.5 Shipping Preferences.....	9-80
	9.8.6 Import FedEx Airbills	9-81
	9.8.7 Import Tracking Information and Export LAB Addresses	9-83
9.9	Create Airbills.....	9-85
9.10	Close Containers	9-92
9.11	Assign Containers to Shippers.....	9-96
9.12	Create Shipping Manifests.....	9-100
9.13	Packing Procedure for the Shippers.....	9-112
	9.13.1 Pack Boxed Specimens	9-117
	9.13.2 Pack Medium Shipping Containers for Frozen Shipment...	9-117
	9.13.3 Pack Small Shipping Containers for Frozen Shipment.....	9-117
	9.13.4 Pack Medium or Small Shipping Container for Refrigerated Shipment	9-118
	9.13.5 Pack a Medium or Small Shipper for Ambient Temperature Shipment.....	9-119
9.14	Label Shippers	9-119

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
10	QUALITY CONTROL AND QUALITY ASSURANCE - POLICIES AND PROCEDURES.....	10-1
	10.1 Safety	10-3
	10.1.1 Introduction.....	10-3
	10.2 Specimen Submission and Handling	10-3
	10.2.1 Introduction.....	10-3
	10.2.2 Identification of Specimens.....	10-4
	10.2.3 Questions on Specimen Submission and Handling.....	10-4
	10.3 Test Requisition	10-4
	10.3.1 Introduction.....	10-4
	10.3.2 Laboratory Tests.....	10-4
	10.3.3 Human Subjects Review	10-5
	10.4 Test Records	10-5
	10.4.1 Introduction.....	10-5
	10.4.2 Components of Test Records	10-5
	10.5 Test Report.....	10-6
	10.5.1 Introduction.....	10-6
	10.5.2 Review, Approval, and Release of Test Results	10-6
	10.5.3 List of Methods and Method Details.....	10-7
	10.5.4 Format of the Test Report	10-7
	10.5.5 Format for Laboratory Report Cover Letter.....	10-8
	10.5.6 Format for Listing of Laboratory Results	10-8
	10.6 Quality Control	10-8
	10.6.1 Introduction.....	10-8
	10.6.2 Method Specific QC Procedures.....	10-10
	10.6.3 QC Definitions	10-10
	10.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC.....	10-11
	10.6.5 Internal ("bench") QC	10-12
	10.6.6 Interlaboratory Quality Assurance Program (IQAP).....	10-13
	10.6.7 Proficiency Testing	10-13

TABLE OF CONTENTS (continued)

<u>Chapter</u>	<u>Page</u>
10.6.8 Calibration Verification	10-14
10.6.9 X _B Analysis	10-15
10.6.10 Linearity	10-16
10.6.11 Quality Control Records	10-16
10.7 Test Methods, Equipment, Reagents, Supplies, and Facilities	10-16
10.7.1 Introduction	10-16
10.7.2 Labeling of Reagents, Solutions, Supplies	10-17
10.7.3 Facilities	10-18
10.8 Analytical Procedure Manual	10-18
10.8.1 Introduction	10-18
10.8.2 Contents of the Analytical Procedure Documentation	10-18
10.8.3 Approval and Record Maintenance	10-19
10.8.4 Method Performance Specifications	10-19
10.9 Equipment Maintenance and Function Checks	10-20
10.9.1 Introduction	10-20
10.9.2 Temperature Monitoring	10-20
10.10 Calibration and Calibration Verification	10-22
10.10.1 Introduction	10-22
10.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites	10-22
10.11 Remedial Actions	10-23
10.11.1 Introduction	10-23
10.12 Integrated Survey Information System (ISIS)	10-23
10.12.1 Introduction	10-23
10.12.2 Integrated Survey and Information System Data Down Times	10-24
10.12.3 Maintenance of LAN Hardware	10-24
10.12.4 Backup Schedule of Integrated Survey and Information System Data	10-24

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
10.13	Communications and Complaints.....	10-24
	10.13.1 Introduction.....	10-24
10.14	Quality Promotion.....	10-25
	10.14.1 Introduction.....	10-25
10.15	Quality Assurance Program.....	10-26
	10.15.1 Introduction.....	10-26
	10.15.2 Quality Audit: Sample Person Test Management.....	10-27
	10.15.3 Quality Audit: Quality Control.....	10-27
	10.15.4 Quality Audit: Personnel.....	10-28
	10.15.5 Quality Assurance Review with Staff.....	10-29
10.16	Personnel Training and Evaluation.....	10-29
11	OPERATIONAL ISSUES.....	11-1
	11.1 Start of Stand Activities.....	11-1
	11.2 End of Stand Activities.....	11-4
	11.3 Inventory Procedures and Supplies.....	11-8
	11.4 Dry Run.....	11-12
	11.4.1 Phlebotomy Protocol and Procedures.....	11-13
	11.4.2 Urine Processing and Pregnancy Testing.....	11-15
	11.4.3 Hematology.....	11-24
	11.4.4 Blood Processing and Storage.....	11-24
	11.4.5 Shipping Dry Run Specimens.....	11-28
	11.5 Centrifuges – Equipment Maintenance.....	11-28
	11.6 Refrigerators and Freezers – Equipment Maintenance.....	11-29
	11.7 Use of the Temperature Recording Instrument.....	11-30
	11.8 Use of the Class II Type A Biological Safety Cabinet.....	11-32
	11.9 Ambient Air Temperature.....	11-33
	11.10 Laboratory Quality Control Module.....	11-34
	11.11 Unusual Occurrence Log.....	11-40
	11.12 Supply Use Control Log.....	11-43
	11.13 Eppendorf Pipette Care, Sterilization, Maintenance and Calibration.....	11-46

TABLE OF CONTENTS (continued)

List of Appendixes

<u>Appendix</u>		<u>Page</u>
A	PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS (VOC) STUDY	A-1
B	HAIR, MRSA, AND BACTERIAL VAGINOSIS PROCESSING, STORAGE, AND SHIPPING	B-1
C	LEAD DUST PROCESSING AND QUALITY CONTROL.....	C-1
D	INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS REGULATIONS	D-1
E	GLOSSARY OF TERMS	E-1

List of Figures

<u>Figure</u>		
2-1	Laboratory area	2-3
4-1	Floor plan for phlebotomy room.....	4-3
11-1	MEC trailer compartment maps.....	11-11

List of Exhibits

<u>Exhibit</u>		
1-1	Floor plan of the MEC	1-11
1-2	MEC exams and rooms	1-12
1-3	Examination components.....	1-15
4-1	Venipuncture protocol – primary.....	4-1
4-2	Venipuncture protocol – second exam.....	4-2
4-3	Venipuncture protocol – VIP guest.....	4-2

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-4	Venipuncture protocol – guest and surplus.....	4-2
4-5	Alternative venipuncture protocol - primary	4-2
4-6	Equipment and supplies - phlebotomy.....	4-4
4-7	Home exam venipuncture protocol.....	4-70
4-8	Home exam alternative venipuncture protocol.....	4-71
4-9	Equipment and supplies – home exam venipuncture.....	4-71
4-10	Phlebotomy worksheet – English Primary or Second Exam SP	4-101
4-11	Phlebotomy worksheet – Spanish Primary or Second Exam SP	4-102
4-12	Phlebotomy worksheet – English Home Exam SP	4-103
4-13	Phlebotomy worksheet – Spanish Home Exam SP.....	4-104
5-1	Equipment and supplies - urine processing and storage	5-2
5-2	NHANES urine processing protocol – primary	5-14
5-3	NHANES urine processing protocol – VIP guest.....	5-14
5-4	NHANES urine processing protocol – second exam.....	5-15
5-5	Storage protocol for urine	5-30
5-6	Workstation 2 worksheet	5-43
8-1	Non-consumable supplies for blood processing	8-1
8-2	Consumable supplies for blood processing.....	8-2
8-3	Primary SP's whole blood processing protocol.....	8-2
8-4	Primary SP's plasma processing protocol	8-3
8-5	Primary SP's serum, clot, and ACD processing protocol.....	8-3

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
8-6	Home exam blood whole blood processing protocol.....	8-4
8-7	Home exam plasma processing protocol	8-5
8-8	Home exam serum processing protocol.....	8-5
8-9	Second exam SP's whole blood processing protocol.....	8-5
8-10	Second exam SP's plasma processing protocol.....	8-6
8-11	Second exam SP's serum processing protocol	8-6
8-12	VIP guest's blood whole blood processing protocol	8-7
8-13	VIP guest's plasma processing protocol.....	8-7
8-14	VIP guest's serum processing protocol	8-7
8-15	Guest and surplus serum processing protocol.....	8-8
8-16	Blood processing protocol for primary SPs age 1-2 years.....	8-9
8-17	Blood processing protocol for primary SPs age 3-5 years.....	8-10
8-18	Blood processing protocol for primary SPs age 6-11 years.....	8-10
8-19	Blood processing protocol for primary SPs age 12+ years.....	8-11
8-20	Blood processing protocol for home exam age 50+ years.....	8-12
8-21	Blood processing protocol for second exam SPs age 12-69 years.....	8-12
8-22	Blood processing protocol for VIP guest age 1-2 years.....	8-13
8-23	Blood processing protocol for VIP guest age 3-5 years.....	8-13
8-24	Blood processing protocol for VIP guest age 6-11 years.....	8-14
8-25	Blood processing protocol for VIP guest age 12+ years.....	8-14
8-26	Blood processing protocol for guest and surplus age 1+ years.....	8-14

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
8-27	Storage protocol for blood and HIV urine	8-80
8-28	Workstation 1 worksheet	8-100
9-1	Shipping protocol.....	9-2
9-2	Supplies for labels/shipping.....	9-4
9-3	Contract laboratory addresses	9-112
9-4	Container protocol	9-121
9-5	FedEx Weekly Shipping List.....	9-123
11-1	Equipment and supplies	11-10
11-2	Dry run venipuncture protocol.....	11-13
11-3	Dry run urine processing protocol	11-20
11-4	Dry run processing protocol - whole blood	11-25
11-5	Dry run processing protocol - plasma	11-25
11-6	Dry run blood processing protocol - serum	11-26
11-7	Unusual Occurrence Log	11-42
11-8	Supply Use Control Log	11-45

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

Prepared by _____

Date Adopted _____

Approved by _____

Director

Signed _____

Director

Dated _____

Director

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

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7. COMPLETE BLOOD COUNT

Introduction

Perform a complete blood count (CBC) in duplicate on all Sample Persons (SPs) age 1 and older. Perform the CBC on the Beckman Coulter® MAXM. Run a CBC on home exam SP's EDTA blood tubes after returning to the MEC.

The three Coulter MAXMs serial numbers and system IDs are:

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

Purpose and Principle of Test

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

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

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

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

The MAXM measures these parameters in whole blood:

Cell	Parameter	Measured	Pulse size Wavelength Calculation	Reported Units
WBC	White Blood Cell Count	WBC bath	≥35 fL	n x 10 ³ cells/μL
RBC	Red Blood Cell Count	RBC bath	36 to 360 fL	n x 10 ⁶ cells/μL
Hgb	Hemoglobin Concentration	WBC bath	525 nm	g/dL

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

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

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

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

Special Safety Precautions

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

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

Computerization: Integrated Survey and Information System (ISIS)

The MAXM Data Management System (DMS) transmits individual SP results to the MEC automated ISIS system. Review all SP results at the Coulter DMS monitor. The hematology module in the laboratory application automatically receives the results or transmits them

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.

Specimen Collection and Preparation

Specimen collection

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

Specimen preparation

The blood specimen-processing technologist initially processes the tube by taking off whole blood for various tests. The blood specimen-processing technologist places the specimen on a rocker until the hematology technologist can perform the CBC. Run the CBC as soon as possible; there is no requirement to wait any length of time between drawing the blood and running the CBC.

Procedure for Microscopic Examination

Not Applicable - Do not prepare differential microscopic slides.

Reagents and Supplies

The MAXM DMS stores and maintains the lot numbers and expiration dates.

Reagents, controls and calibrators

Isoton III® -- PN 8546733 (20 L) -- an isotonic electrolyte

- Expires on expiration date printed on container

Beckman Coulter® Clenz -- PN 8546930 (5L) -- a cleaning agent that cleans and rinses diluter parts

- Expires 90 days after being opened and installed on the instrument

Lyse-S III® diff lytic reagent- PN 8546983 (1L) -- a lytic reagent used for the CBC mode

- Expires 60 days after being opened and installed on the instrument

Scatter Pak® -- PN 8546917

- Diff Lytic Reagent -- Erythrolyse II® erythrocyte lytic reagent
- Diff Leukocyte Preservative -- StabiLyse® leukocyte preservative
- Expires 60 days after being opened and installed on the instrument

Latron® Controls - PN 7546914 (5 x 16-mL)

- Expires 30 days after being opened

Latron® Primer - PN 7546915 (5 x 16-mL)

- Expires 30 days after being opened

5C® Cell Controls Tri Pack contains Normal, Abnormal I, Abnormal II - PN 7547001 (9 x 3.3-mL)

- Expires 13 days or 13 events after being opened

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

- Use at the start of each stand; expires 1 hour after being opened

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

- Use when calibrating with S-CAL for reproducibility study

Supplies

3-mL K₃ EDTA Becton Dickinson Hemogard Vacutainer® tube

Tube rocker

Clorox® Bleach, 5.25% Sodium Hypochlorite 1-800-292-2200

Bottled distilled water

Three 30 mL plastic containers with lid

Two one-liter containers with lid

Plastic squirt bottle

Cotton gauze pads

Three-hole paper punch

Notebook

Fujitsu printer ribbon

Flashlight

10-mL syringe with plastic tubing

Precision screwdriver set

Distilled water bottle

Disposable lab jacket – 48 inches long

Notes

If reagents become frozen in transit, mix thoroughly by inversion and let bubbles settle before use.

Do not place reagents on or near electric cords or lines to avoid electrical interference.

Calibration

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

Perform calibration:

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

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

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

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

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

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

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

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

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

Pre-calibration, reproducibility, and carryover check

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

Pre-calibration procedure

Bleach the aspiration system using the Clean Needle procedure.

Prepare a fresh bleach solution. Put one-mL Clorox bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.

Stop the system before it performs the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE**, [F3], Run. Press [F9] Stop.

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

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

Run 5C® cell controls.

Reproducibility check

Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Select [F5] to access options. Change [F5] Print: to none and [F6] Host to Off.

Use an unopened, normal-level, 5C®-cell control for reproducibility studies. Label the control vial with date and initial. Use of expired controls for this procedure is acceptable.

Select **SPECIAL FUNCTIONS, CALIBRATION, REPRODUCIBILITY** [Enter].

Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop.

Press [F6]. Press space bar to turn the DIFF ON. Press [Enter]. Press [F2] *START PRIMARY*.

Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.

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

Follow the directions listed in Section X for preparation and mixing the 5C®-cell control.

Cycle the sample 11 times. Do not use the bar code reader. Mix gently before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.

Check the results. Verify the average %CV does not exceed these limits:

- WBC 2.5%
- RBC 2.0%

- Hgb 1.5%
- MCV 2.0%
- Plt 5.0%
- MPV 3.0%

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

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

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

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

Notes

Be sure the PR↓ is on the status line before starting the reproducibility study.

Be sure to delete any data on the reproducibility screen before starting a new study.

On the reproducibility screen, use the %CV line for CBC parameters only and the Diff line for the DIFF parameters only.

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

Select **SPECIAL FUNCTIONS, CALIBRATION, and CARRYOVER**. Press [F2] *START PRIMARY*.

Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.

Use a routine 5-mL Vacutainer® EDTA (BD #369614) for the carryover check clean vials. Fill three separate vials with diluent, then cap.

Follow the screen directions. Cycle two vials of normal blood and three vials of diluent. Do not use the bar code reader. Insert the tube into the carousel when the green light appears.

Check the lower right corner of the screen for CARRYOVER ACCEPTABLE. If the result is not acceptable and the H flags appear next to the carryover value results, repeat the procedure. If results are still OUT, call the Beckman Coulter® representative.

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

Notes

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

Ignore count period (CP) voteouts on diluent runs.

Percent carryover is calculated by the formula.

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

CBC calibration with S-CAL® calibrator

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

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

Prepare the CBC calibration screen.

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

Enter the expiration date and the lot number.

Prepare and cycle the calibrator

Mix by hand as follows: Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.

Determine that all cells are uniformly distributed by inspecting the vial contents. If the cells are not totally distributed, repeat the mixing procedure. Use cotton gauze pads to remove the rubber stopper from the vial. Absorb any spray produced by pressure within the vial by using the gauze pads, avoiding accidental contact with the product.

With the pipette, fill each of two mixing tubes to within 1/4 inch of the top. Dispose of extra S-Cal. Set one of these tubes aside in a test tube rack. Do not refrigerate or place on rocker. Use Tube #1 for calibration and tube #2 is for verification if needed.

Cycle the first cap-pierceable calibrator 11 times. Do not use the bar code reader. Invert the vial and mix the S-CAL® calibrator before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.

After the cycles are complete, press [F4] Print to print the screen for the logbook. Press [F3] Run, [F9] STOP. Press [Esc.]

Assess the run

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

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

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

MPV ≤3.0

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

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

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

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

If both the FAC %DIFF and DELTA DIFF values for all parameters are less than or equal to these limits, **DO NOT calibrate: Press [F4] to print the screen for the logbook.**

If the FAC %DIFF or DELTA DIFF value of any of these parameters is greater than these limits continue with the next steps to verify the calibration.

To verify calibration:

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

Parameter	Calibrate if FAC %DIFF is:	Calibrate if DELTA DIFF is:
WBC	>1.25 but ≤5.00	>0.10 but ≤0.40
RBC	>0.70 but ≤2.00	>0.03 but ≤0.09

Hgb	>0.78 but ≤3.00	>0.10 but ≤0.40
MCV	>1.18 but ≤2.50	>1.00 but ≤2.00
Plt	>2.70 but ≤9.00	>6.0 but ≤20.0
MPV	>5.00 but ≤20.00	>0.50 but ≤2.00

If any value is outside these ranges, then, is *Select Function* displayed? If NO, press [F3] Run [F9] STOP [Esc]. If YES, Press [F5]. Choose SELECT PARAMETERS. Press [Enter]. Use the space bar to select YES for parameters that need adjusting, NO for others. Press [Esc]. Select TRANSMIT FACTORS. Press [Enter]. The following message appears: "WARNING -- DATA WILL BE CLEARED AFTER TRANSMISSION. DO YOU WANT TO PRINT DATA? Y/N" Select N since the values have already been printed.

Press [F3] Run [F2] START PRIMARY. Gently invert the second cap-pierceable vial of S-CAL® calibrator 8-10 times. Cycle the S-CAL® calibrator 11 times. Before each cycle, invert the vial and mix the S-CAL® calibrator. Check the FAC %DIFF and DELTA DIFF values results for all parameters against these limits (disregard minus signs) to be sure that they are below the lower limit.

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

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

Calibration terms and formulas

MEAN

- The average of the 10 S-CAL calibrator runs

NEW CAL FAC

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

OLD CAL FAC

- The current calibration factor

%CV

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

FAC % DIFF

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

DELTA DIFF

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

REF VALUES.

- The assigned value for each parameter.

Assay Procedure

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

Leave the instrument on and operate the MAXM with all panels closed. Check to make sure the date and time displayed are correct. To set date and time select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP, SET DATE/TIME**. Move the cursor and enter the correct date or time and press [Enter] or the arrow keys. Press [F10] to save and exit.

To begin Start Up, select **DILUTER FUNCTIONS, and START UP**. Press [Enter]. Follow the instructions on the screen.

After Start Up is complete, evaluate the display. Expired reagents and failed checks appear in red. Press [F2] to view detailed results. Make sure the Background and other Start Up results are within limits. Results outside limits turn red. Results automatically print. File in the logbook.

Review and verify sample analysis set up.

Select **SAMPLE ANALYSIS, RUN SAMPLE** [F3]. Sample mode? Press [F5] for options. Press the corresponding function key to enter specific options. Use [F6] to turn the Diff ON. Use [F5] to change XB and DB to ON, Print to NONE, Host to ON, and Display Only to OFF. Press [Esc] to exit.

Run controls

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

Run Sample Persons

Review the placement of the bar code on the sample tube to make sure it is parallel to the stopper and does not cover the bottom of the tube.

Run all samples in duplicate.

Run samples in the primary mode.

Check to verify connection and working order of the printer.

Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].

Is Sample Mode? Displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.

Press [F2] START PRIMARY.

Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep
-- Place the tube in the carousel. If the red light appears, wait and try reading the bar code label again.

Alternatively, cycle samples in the SECONDARY mode.

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

Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].

Is Sample Mode? displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.

Press [F3] SECONDARY.

Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep.
If the red light appears, wait and try reading the bar code label again.

Cycle the sample in the SECONDARY mode:

Mix the sample gently.

Open the tube and immerse the aspirator tip in the sample.

Press and release the sample bar.

Remove the sample when the instrument beeps.

Monitor the aperture-viewing screens for debris during the COUNT period.

Review data and transmit

Review the data using the criteria described in Section X.

Set host computer to \uparrow . Data from the Coulter DMS is automatically transmitted to the ISIS system.

Daily Shut Down

Shut down the instrument at the end of each day. Shut down the instrument for at least 30 minutes but less than 48 hours.

To begin shut down make sure the status line displays *Select Function*. Select **DILUTER FUNCTIONS** and **SHUT DOWN**. Press [Enter].

When it is time to use the instrument, perform Start Up. Results must be within tolerance.

Perform daily QC and operate as usual.

Prolonged Shut Down

If the instrument is going to be shut down for 48-72 hours, perform the following steps:

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

Perform Start Up to put diluent in the system.

Turn off the power.

When it is time to use the instrument, turn power on, and perform Start Up. Results must be within tolerance.

Perform daily QC and operate as usual.

If the instrument is going to be shut down for more than 72 hours, perform the following steps:

Place all reagent pickup tubes into distilled water.

Repeatedly perform Shut Down and Start Up procedures throughout the day.

Let distilled water remain in the reagent lines.

Turn off the power.

Place reagent caps on all open containers.

When it is time to use the instrument, turn on the power and place the reagent pickup tubes into the reagent containers, prime all reagents, and perform Start Up. Results must be within tolerance.

Perform daily QC and operate as usual.

Beginning and end of stand operations

Beginning of stand

Obtain one urine collection container or a 50-mL conical tube, seven 3 or 5-mL EDTA tubes (1 clean aspiration system, 3 reproducibility, 3 carryover), enough supplies to draw two 5-mL EDTA blood tubes, and a few plastic transfer pipettes.

Using all new containers of reagents, carefully unwrap and place all reagent pickup tubes in their appropriate container after pouring 30-mL Isoton® III into 30-mL plastic container. Use the Isoton® when performing the calibration carryover check. Handle reagent tubes by the

collar only to avoid contamination. Turn the power ON. Prime reagents through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**.

Perform the Start Up procedure. This should take approximately 5-6 minutes. Results should be within tolerance.

Contact the local Beckman Coulter® representative to perform an instrument verification procedure on set up day or as soon as possible.

Calibrate, perform, and verify QC checks according to procedure.

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

Select **SHIFT**

Move the cursor and set up the starting times for each shift and press [Enter] or the arrow keys. The system automatically calculates the end of the shift to prevent overlap.

Set shift 1 "Time" at 0600.

Set shift 2 "Time" at 1700.

Set shift 3 "Time" at 0558.

Press [F10] to save and return to the previous screen.

Select **REAGENTS** - Update reagent logs

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

Select **INSTITUTION**.

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

AA31227

AB08075

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

Select **COMMUNICATION DEF.** Enter the **SUPERVISOR PASSWORD, "super."** Select, **HOST COMPUTER DEFINITION.**

Use [Enter] or arrow keys to move to the appropriate field.

Type in the following information where necessary and use the space bar to choose between the responses.

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

Press [F10] to save and [Esc] to return to previous screen.

Select **Language.**

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

Select **IQAP ID#.**

Type in the IQAP number.

Enter 32979 1 T1 for instrument AA06042

32979 1 T2 for instrument AA31227

32979 1 T3 for instrument AB08075

Press [F10] to save and exit.

Select **SET DATE/TIME.**

Move the cursor and enter the correct date or time and press [Enter] or use the arrow keys. Press [F10] to save and exit.

Select **LYSE VOLUME**.

Press space bar to choose 1 L. Press [F10] to save and exit.

Select **OPTIMIZE HARD DISK**.

Type in the password "super" at the prompt and then press [Enter]. Use the spacebar to select YES. Press [F10] to save. Press [F9] to return to the main menu.

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

Select **DISPLAY FORMATS, REPORTING UNITS**.

Use the space bar to toggle to US 1. Press [F10] to save and [F9] to return to main menu.

Select **PRINT OPTIONS**.

Auto Print Format

Select **[GRAPHIC FORMAT]**

Ticket Options

Verify the following settings.

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

Spooler Priority

Leave **[AUTO PRINT]** as the default.

Graphic Options

Verify the following settings.

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

Optional Printer

Select "N."

Select **ACTION LIMITS** [Enter], **DEFINITIVE FLAG LIMITS** [Enter].

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

Select **ACTION LIMITS** [Enter], **HIGH/LOW FLAG LIMITS** [Enter].

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

Select **XB LIMITS**.

Enter target and limit percent values.

XB Limits

Target Limit %

MCV	88.5	3
MCH	29.5	3
MCHC	33.5	3

Press [F10] to save and exit.

End of stand

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

Review, print, and clear error file.

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

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

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

Perform Start-up.

Disable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTIONS, , FLUIDIC TESTS, and DISABLE REAGENT SENSORS**. Toggle through each reagent line using the space bar to change "ON" to "OFF."

Bleach the reagent lines.

Remove all reagent pickup tubes from the reagent containers. Dispose of all open containers. Wash and save the reagent collars.

Prepare a 25% solution of Clorox bleach (250-mL) and distilled water (750-mL) in one liter bottle. Place all reagent pickup tubes into the 25% bleach/distilled water solution. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL**. Press [Enter]. Repeat this procedure two more times.

Place all reagent pickup tubes into containers of distilled water.

Bleach the apertures and flow cell.

Mix 15-mL Clorox bleach and 15-mL distilled water in a plastic container.

Put 30-mL of distilled water in a second plastic container.

Open the front panel.

Select **DILUTER FUNCTIONS**, and **DISINFECT**. Press [Enter].

The instrument defaults to 15 minutes; stop the procedure after 3 minutes. Press [Enter].

Immerse the bleach probe in the bleach solution when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE BLEACH." Press any key. Aspirate all the bleach solution.

Immerse the bleach probe in the distilled water when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE WATER." Press any key. Aspirate all the distilled water. Stop the cycle after 3 minutes by pressing [F4].

Wait until the screen displays *Select Function* before touching any keys. When *Select Function* is displayed, continue with the following procedure.

Disinfect the needle. Bleach the aspiration system using the Clean Needle procedure.

Prepare a fresh bleach solution. Put one-mL Clorox bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.

Stop the system before beginning the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE**, [F3], Run. Press [F9] Stop.

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

Perform reproducibility in Primary and Secondary mode using this 1% bleach solution. Prepare a 1% bleach solution and fill one 5-mL EDTA blood tube with this solution. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press

space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY*. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select Primary and aspirate 3 samples of 1% bleach. Enter [F3]; sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of 1% bleach solution.

Rinse the reagent lines. Make sure all reagent lines are immersed in containers of distilled water. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL**. Press [Enter]. Repeat this procedure two more times.

Perform a Start Up. Make sure containers are full.

Perform reproducibility in Primary and Secondary mode by using distilled water. Fill one 5-mL EDTA blood tube with this distilled water. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY*. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Select Primary and aspirate three samples of distilled water. Enter [F3], sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of distilled water. Press [Enter].

Select **DILUTER FUNCTIONS, START-UP**. Press [Enter]. Perform one additional Start-Up procedure with the lines in the distilled water containers.

Cycle the instrument dry.

Remove all reagent pickup tubes from the distilled water containers.

Continue to cycle the instrument dry by priming air through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**. Repeat these actions at least three times.

Open front cover. Using hemostats, seal tubing with check valve coming out of the bottom of the sheath tank. Loosen the four large screws that hold the panel containing the sheath tank. Gently pull panel away from instrument. Trace two red wires from top of sheath tank to plastic electrical connection. Disconnect the junction. Insert paper clip into junction so that a circuit is formed on the instrument side of the connector. Do this by bending paper clip into a U and placing one end of paper clip into each of the open sockets on the instrument side of the junction. This will allow the instrument to Drain, Vent, and Shut Down without reagent. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTION**, and **DRAIN AND VENT**. Press [Enter.]

Select **DILUTER FUNCTIONS**, and **SHUT DOWN**. Press [Enter].

After cycles are complete, remove paper clip, reconnect junction, put panel back into instrument and tighten screws, then remove hemostats.

Enable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, FLUIDIC TESTS**, and **DISABLE REAGENT SENSORS**. Toggle through each reagent line using the space bar to change "No" to "Yes."

To protect the reagent pickup tubes from contamination, wrap them securely in paper towels. Allow air to continue to dry the tubes.

Turn off the power.

Rinse exterior of BSV with distilled water to remove built up Isoton and blue Clenz agent. Blot the BSV dry with lint free tissue. Do not use gauze.

Wash exterior of instrument with distilled water.

Empty waste and rinse container.

Blow air through the flow cell at the end of each stand. This is referred to as the Triple Transducer Module (TTM). Address questions to the service representative at 1-800-526-7694. Remove the 6-inch sample line to the flow cell at the mixing chamber. Connect a 10-mL syringe with tubing to the 6-inch line and force air into the line to remove ALL remaining liquid from the flow cell and the 6-inch sample line. Reconnect the sample line.

Beckman 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/dL	0 to 25.0	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10 ³ cells/ μ L	0 to 999	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

Quality Control

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

Principle - The Latron® control is a ready-to-use suspension of latex particles. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter.

Reagents - Latex particles suspended in a buffered bacteriostatic and fungistatic medium containing a surfactant.

Storage, handling, and stability -- Sealed vials are stable until their expiration date when stored and used at 2-30°C (35-86°F). Once open, date, and initial vials. Opened vials are stable for 30 days when stored at recommended temperatures. Keep vials tightly capped when not in use.

Indications of instability or deterioration -- Inability to recover expected results might indicate product instability or deterioration due to improper storage, handling, or contamination. Discard vial if debris is visible and put new vial into use.

Instructions for use -- Before running control, verify that a Start Up has been performed.

Run Latron® primer in the secondary mode. Select **CONTROLS**, then **CONTROL RUN** and press [Enter]. If the **LATEX FILE** does not appear, press [F2] File. Select the **LATEX FILE**. Press [Enter]. Press [F3] Run [F4] Primer. Cycle the primer by immersing the aspirator tip completely in the primer. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the primer. Remove vial when the audible "beep" occurs. Evaluate primer results. Results should be less than 500. Press [Esc] to remove the primer run.

Run the latex control. Mix a room-temperature control vial gently by inverting five (5) to eight (8) times. Be careful to avoiding foaming. When *Select Function* appears on the status line, press [F3]

Run, [F3] Control (SECONDARY). Cycle the control by immersing the aspirator tip completely in the vial. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the control. Remove vial when the audible "beep" occurs.

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

Bubbles in the flow cell or improper vial handling -- Rerun the primer and control.

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

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

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

Setting up a Latex control file

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

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

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

Principle - The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible.

Reagents -- 5C®-cell control consists of treated, stabilized human erythrocytes in an isotonic bacteriostatic medium. 5C®-cell control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes.

Storage, handling, and stability -- Store 5C®-cell control at 2-8°C. When stored at 2-8°C, sealed vials are stable at least until the expiration date shown on the Table of Expected Results. Note: The MCV and/or RDW parameters may show trending through the shelf life of the product. This is inherent to the product and is not an indicator of product stability. Date and initial open vials. Opened vials are stable for 13 days or 13 events when stored at 2-8°C.

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

Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (darkly colored supernatant) indicate product deterioration. However, a slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.

Instructions for use -- Remove 5C® cell control tubes from refrigerator and warm to ambient temperature for 10-15 minutes. After warming, mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube

and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.

Run the 5C®-cell control in the Primary Mode of the instrument. Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Is SAMPLE MODE displayed? If no, press [F9] STOP. Make sure the DIFF is on. If it is off, press [F6]. Press [F2] START PRIMARY. Complete the entire procedure and return the controls to the refrigerator within 30 minutes.

Identify the sample by holding the bar code label in front of the reader. Place the control in the carousel. Repeat for other levels of controls.

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

Improper mixing -- Follow instructions and rerun control.

Control files set-up incorrectly -- Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting, **SPECIAL FUNCTIONS, SET UP, CONTROL SET UP**.

Chance (statistical outlier) -- Rerun the control. If it is still out, continue with the following actions.

Change in the control -- Try another vial or level of control.

Instrument change -- Watch for normal sample flow. Call Beckman Coulter® representative to help troubleshoot abnormal operation.

Setting up a CBC/Diff control file

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

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

Using bar code scanner

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

Hold the wand like a pencil.

Place the wand in section 1, Lot No. Read this section first.

Gently slide the wand back and forth over the bar code until the instrument beeps. The lot number is now entered. Start and end each scan in the white space.

Beckman Coulter®'s expected ranges appear automatically when the control lot number is entered in an empty file.

Follow the same procedure for the expiration date and assigned values. (Values 2-10)

Manually select and enter Shift and Operator ID. Check all entries to make sure they are correct. Press [F10] to save and exit.

Manual entry

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

Control statistics and graphs

Use to review and print:

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

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

CBC/DIFF control review and report

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

Screen-specific function keys:

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

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

[F6] Remove/Restore
Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] restores the run and original statistics.

[F8] Delete File	Deletes the current control file. Displays a message " <i>You have asked to delete ENTIRE control file. Are you sure you want to delete?</i> " No. Press the space bar to select Yes or No.
[←] [→]	Press [←] or [→] to see parameters not currently displayed on the screen.
[F9] Menu	Displays the main menu.

Latex control review and report

Use this report to review and print control results and cumulative statistics and histograms for LATEX files. Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.

Screen-specific function keys:

Press [←]	to go back to DIFF Latex Control Review
[F2] File	Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].
[F4] Print	Prints the entire control on a graphic printer.
[F6] Remove/Restore	Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] again restores the run and original statistics.
[F8] Delete File	Deletes the current control file. Displays a message " <i>You have asked to delete ENTIRE control file. Are you sure you want to delete?</i> " No. Press the space bar to select Yes or No
[←] [→]	Press [←] or [→] to see parameters not currently displayed on the screen.
[F9] Menu	Displays the main menu.

Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Beckman Coulter®'s IQAP program. The IQAP program includes saving results of 5C® Cell controls, transferring them to a disk, and sending them to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure on the last day of each month, at the end of each stand, or when a lot expires.

Follow procedure for CBC/DIFF and Latex control review and report. After downloading and printing results, delete control files [F8].

Procedure to download IQAP files to diskette.

Slide the diskette into the drive with the arrow side up and pointed toward the drive in the Beckman Coulter® Data Management System. Gently push the diskette until it clicks into place.

Turn the computer OFF. Wait 15 seconds, and then turn the computer back ON. A screen will appear showing the Beckman Coulter® Corporation logo. To exit this screen, follow the instructions on the bottom left portion of the screen, and press [Esc].

The screen will indicate the process the system is performing. Read the instructions on the screen. When the process is complete, the DMS displays the list of possible files on the screen for review and selection. If some of the values are incorrect, edit or delete the fields on this screen. Any alteration to this screen will affect only data on the IQAP diskette, not in the MAXM computer.

FILE_NAME indicates the files by file number for downloading to the diskette.

- LOT_# indicates the type of control. Prefixes 86, 87, and 88 refer to 5C® Cell Controls.
- SHIFT refers to the shift designation selected for running the controls. Edit this field if necessary. Use arrow keys to position.
- START and END indicate beginning and end dates for each file. These fields are not editable.
- REPORT indicates whether IQAP will issue a report on the lot number.
- N_REC indicates the number of records found in the file.

Press [Esc] to leave this screen. If the IQAP# and Serial # are present and valid, the following screen message will appear, "Updating the IQAP Disk." After writing the control files to the diskette, a screen message will give instructions to follow. Follow these instructions and the computer will reboot to the routine program. To remove the diskette, press the eject button on the lower right of the diskette drive opening. Do not remove the diskette until the drive indicator light is off.

Label the diskette with the supplied IQAP ID label. Place the diskette in the pre-addressed mailer provided and send to the home office with the other end of stand documents. Do not place the label over the drive spindle or high-density hole.

X_B analysis

X_B analysis is a QC method monitoring instrument performance by tracking the MCV, MCH, and MCHC parameters of SP samples. These indices are very stable and show little variance between SP samples. This method displays the moving average of SP samples and compares it to established target values. Target values are MCV = 88.5 (FL), MCH = 29.5 (pg), and MCHC = 33.5. (g/dl or g/100mL) Review and print the X_B current batch at the beginning on each session when printing the 5C Cell control results. Review, print, and file the Coulter X_B current batch at the beginning of each session when printing the 5C Cell control results.

X_B batch means

Use to view the calculated means for the last batch of 20 SP results. The MAXM calculates MCV, MCH, and MCHC means. Review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Evaluate the percentage difference from the target limit to determine whether the batch is in or out of control. Select **SAMPLE ANALYSIS, X_B, and CURRENT X_B BATCH.** Press [F2] [F4]. Print and file in logbook.

To change the status of X_B, select [F5] Optns on the **RUN SAMPLES** screen.

Screen-specific function keys:

[F4] Print Prints the table.

[F6] Delete Last Batch

Deletes the last batch. Delete only if the batch is badly skewed because of non-random sampling or an instrument problem that it will adversely effect many later batches.

[F8] Delete Table

Deletes the entire table.

[←] [→]

Press [←] or [→] to see parameters not currently displayed on the screen.

[F9] Menu

Displays the main menu.

X_B Graphs

Review, print, file, and delete the Batch Means and graphs at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Select **SAMPLE ANALYSIS, X_B, X_B GRAPHS**, and [F4] to print. File in the logbook.

Proficiency testing

Evaluation and participation in the College of American Pathologist (CAP) proficiency-testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of 5 3-mL whole blood specimens. Follow all CAP instruction in preparing the materials before performing the test. Run specimens in a manner identical to routine specimens. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

Linearity for WBC, RBC, Hgb and Plt parameters

Lin-C™ (PN 7547065 - 5 x 3.3-mL) The Lin-C™ linearity controls verifies the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent.

OR

CAP Hematology Calibration Verification/Linearity Survey (LN9) - These materials are shipped twice per year and consist of 18 3-mL liquid specimens. Follow all CAP instructions in preparing and running the materials before performing the test. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

Run either the Lin-C™ or CAP LN9 survey material:

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

Principle - Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems. Controls contain one each of Ultra Low Range, Low Range, Mid Range, High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Beckman Coulter® system calibrates with S-CAL® calibrator.

Reagents - Lin-C™ controls consist of treated, stabilized, human erythrocytes in an isotonic bacteriostatic medium. Linearity controls also contain a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.

Storage, handling, and stability -- Ship Lin-C™ controls in thermally insulated containers designed to keep kits cool. Store Lin-C™ linearity controls between 2-8°C (35-46°F). Store vials in an upright position to achieve maximum product yield. Storage of the control product in a cap down position might require additional mixing or complete resuspension of cellular components.

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

Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (dark colored supernatant) indicates product deterioration. A slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.

Instructions for use -- Remove Lin-C™ controls from refrigerator and warm to ambient temperature for 10-15 minutes. After warming mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again. Controls expire 7 days after opening.

Turn the blood detectors off to analyze the Ultra Low Range. Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, BSV TESTS, and BLOOD DETECTOR ON/OFF**. Press [Enter]. Use space bar to select On or OFF. Press [Enter].

Disable the differential before analyzing Lin-C™ linearity controls. Is SAMPLE MODE displayed? If no, press [F9] STOP. Make sure the DIFF is off. If it is on, press [F6].

When analyzing Lin-C™ linearity controls, flags such as L, LL, H, HH, R, RR, *, *R, and *V will occur. Ignore these flags if a numerical result is obtained. When ---- (voteout), (incomplete computation) or ++++ (over range) flags occur, the sample should be repeated. Ignore Beckman Coulter® histogram differential flags and results.

Run the Lin-C™ controls in the Primary Mode of the instrument. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY**. Press [Enter]. Press [F2] START PRIMARY. Analyze controls six times and record the results for WBC, RBC, Hgb, and Plt parameters for each sample on the worksheet. Repeat flagged samples with non-numeric results.

Beckman Coulter® recommends that five sample results should be used to calculate the mean value. Use a minimum of three samples to calculate the mean when repetitive results with non-numeric values occur. Delete the first sample result. Plot mean recovered values on the Lin-C™ linearity control graphs.

Compare the mean value to the linearity control ranges listed on the Table of Expected Results on the package insert. Mean values should recover within the ranges. Use the ranges established by Beckman Coulter® Corporation as a guideline.

Plot the instrument background count as a zero value to extend the reportable range. Beckman Coulter® will prepare tabular summaries and graphic presentations of the data. Submit the top copy of the worksheet to IQAP at the following address:

Beckman Coulter® Corporation
IQAP (M/C 31 B04)
PO BOX 169015
Miami, FL 33116-9015

Interpretation of Results and Remedial Action

Sample Person hemoglobin and hematocrit review and remedial actions.

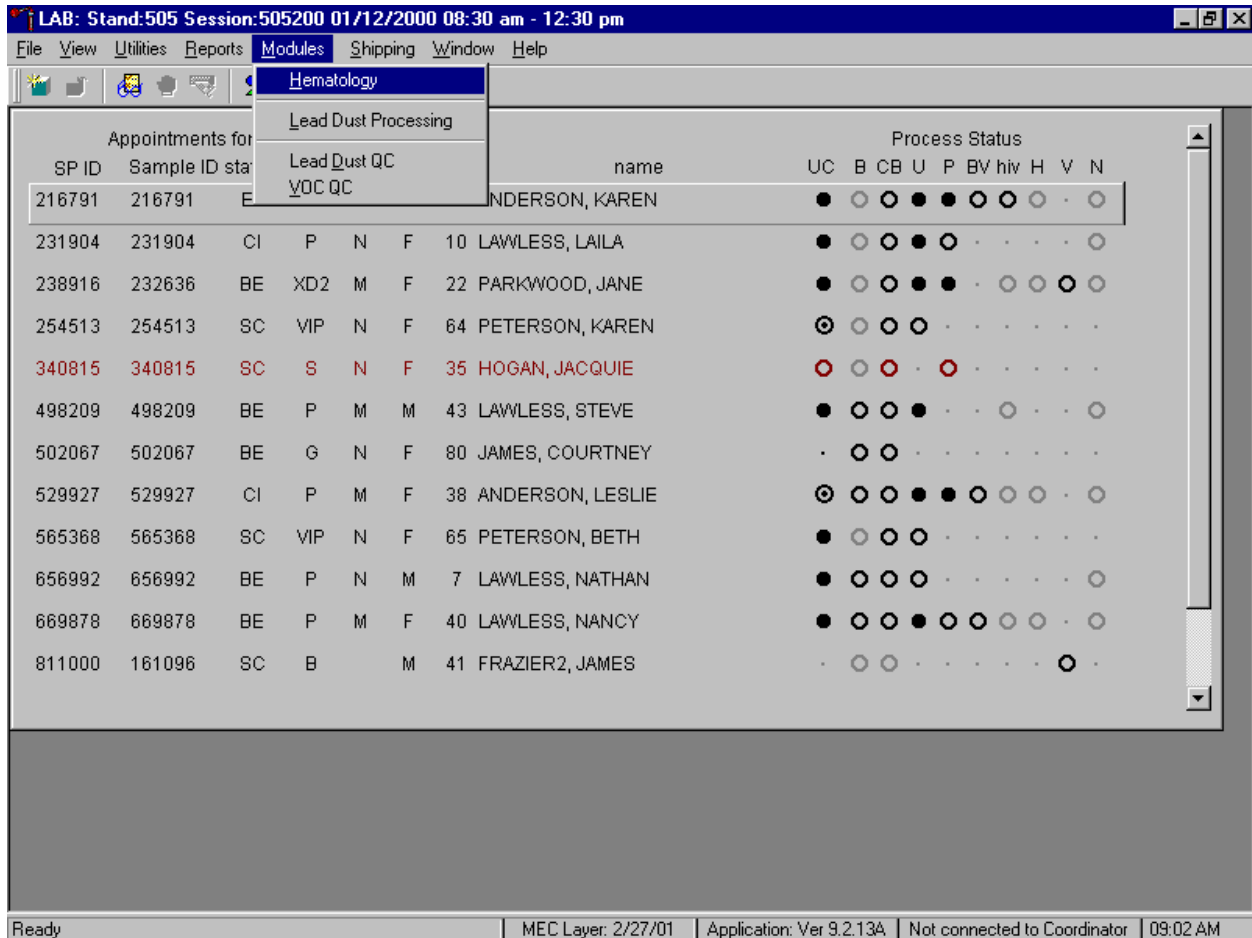
Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin.

Sample person parameter value review and remedial actions.

Access the Hematology module or reject a clotted blood tube.

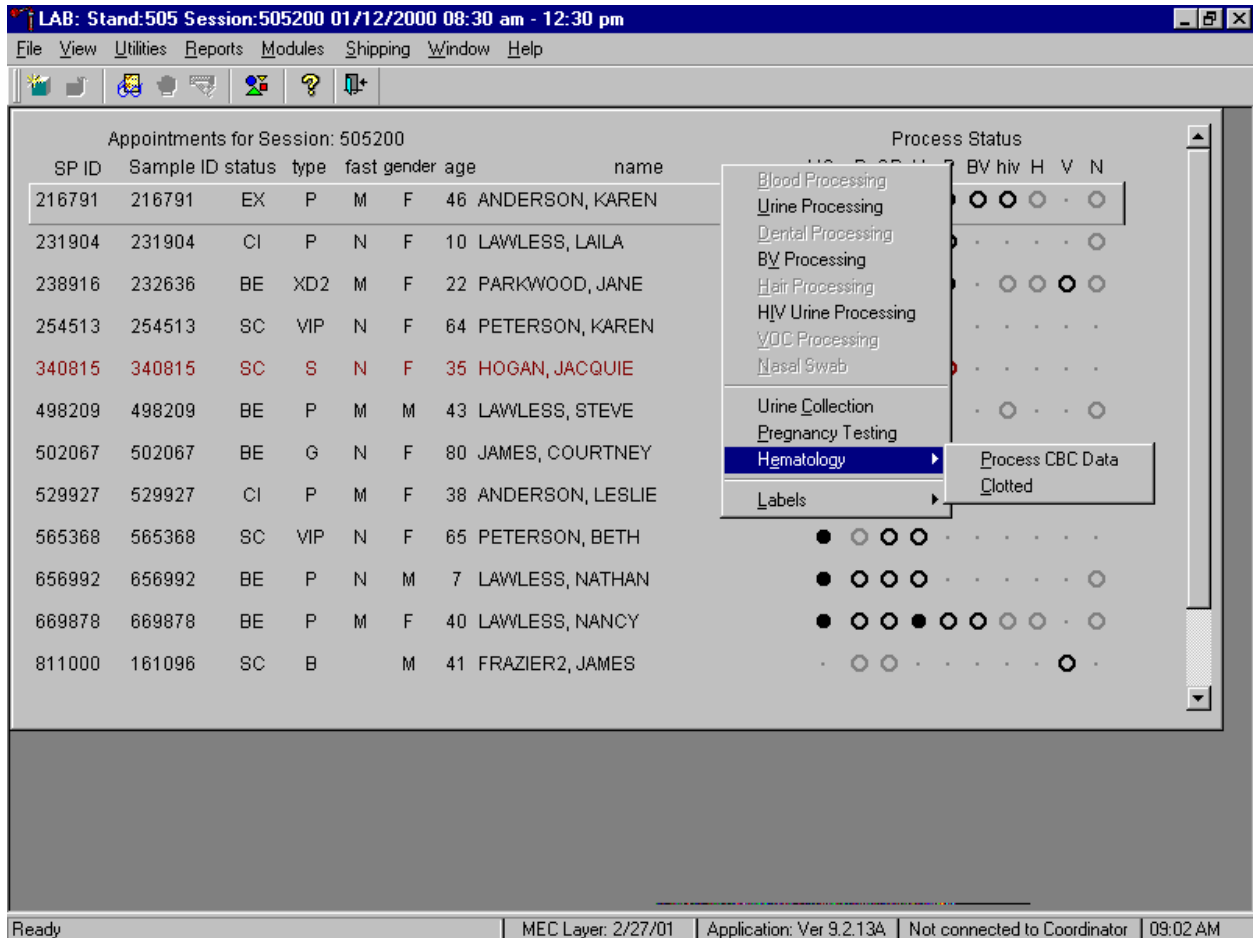
Make sure the Hematology module is open before running SP samples on the MAXM.

Open the Hematology module.



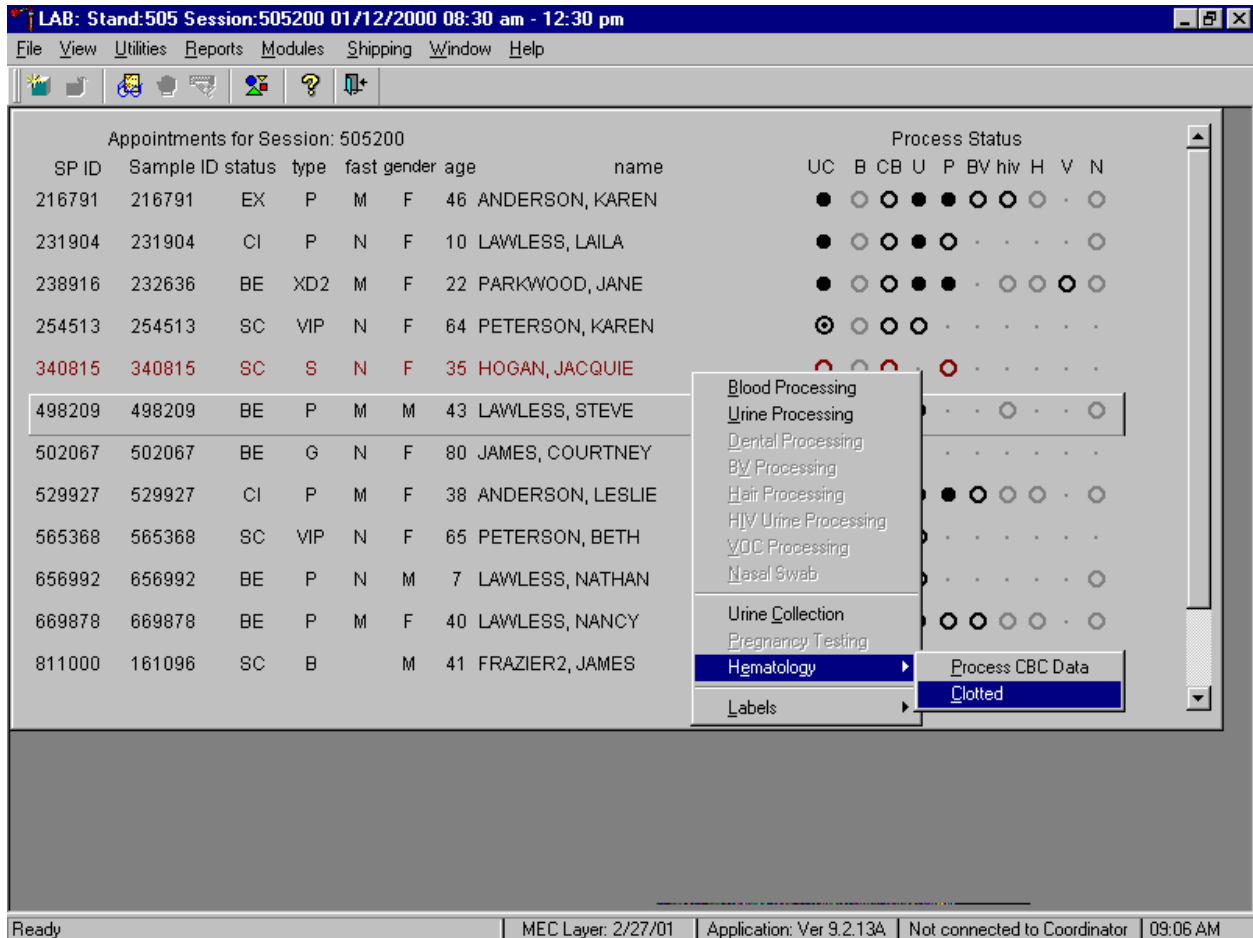
To open the Hematology module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Hematology}, and right click, or type [Alt][M/m], [H/h].

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



To access the Hematology module, use the mouse to direct the mouse arrow to any SP, right click, drag the mouse arrow to {Hematology}, and right click or right click and type [Shift] [E/e]. Alternatively, use the up and down keys to move up and down the list until a particular SP is highlighted, right click, drag the mouse arrow to {Hematology}, and right click or right click and type [Shift] [E/e].

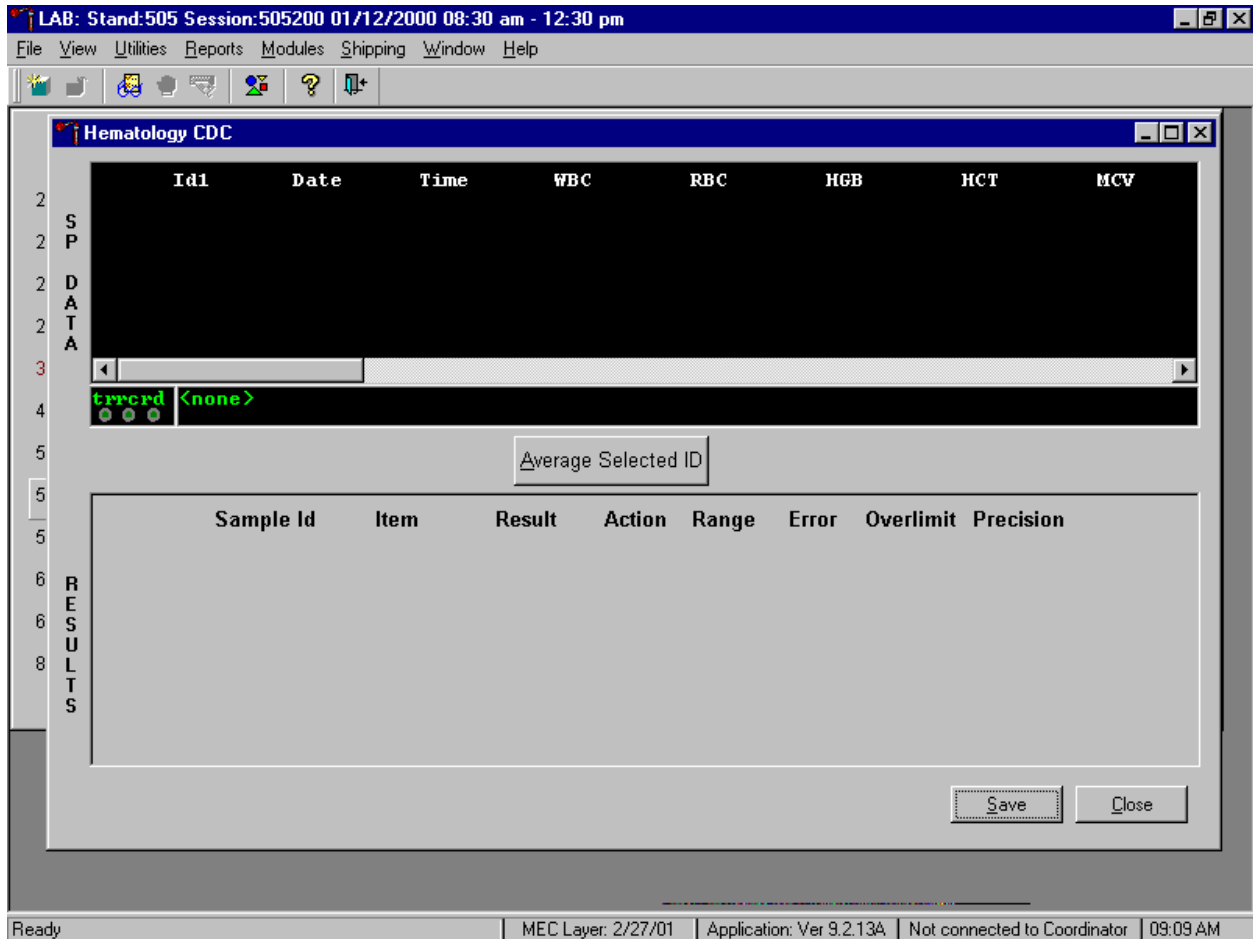
Either open the module or reject the specimen and attach a “clotted” comment to the record.



To complete opening or accessing the Hematology module, use the mouse to direct the mouse arrow to {Process CBC Data} and right click or type [P/p.] If the blood tube is clotted, use the mouse to direct the mouse arrow the exact SP’s line on the heads-up display, right click, drag the mouse arrow to {Clotted}, and right click or right click and type [Shift] [E/e] [C/c.] The record is marked as clotted in the database and the heads-up display updates to complete (the CB circle fills in.)

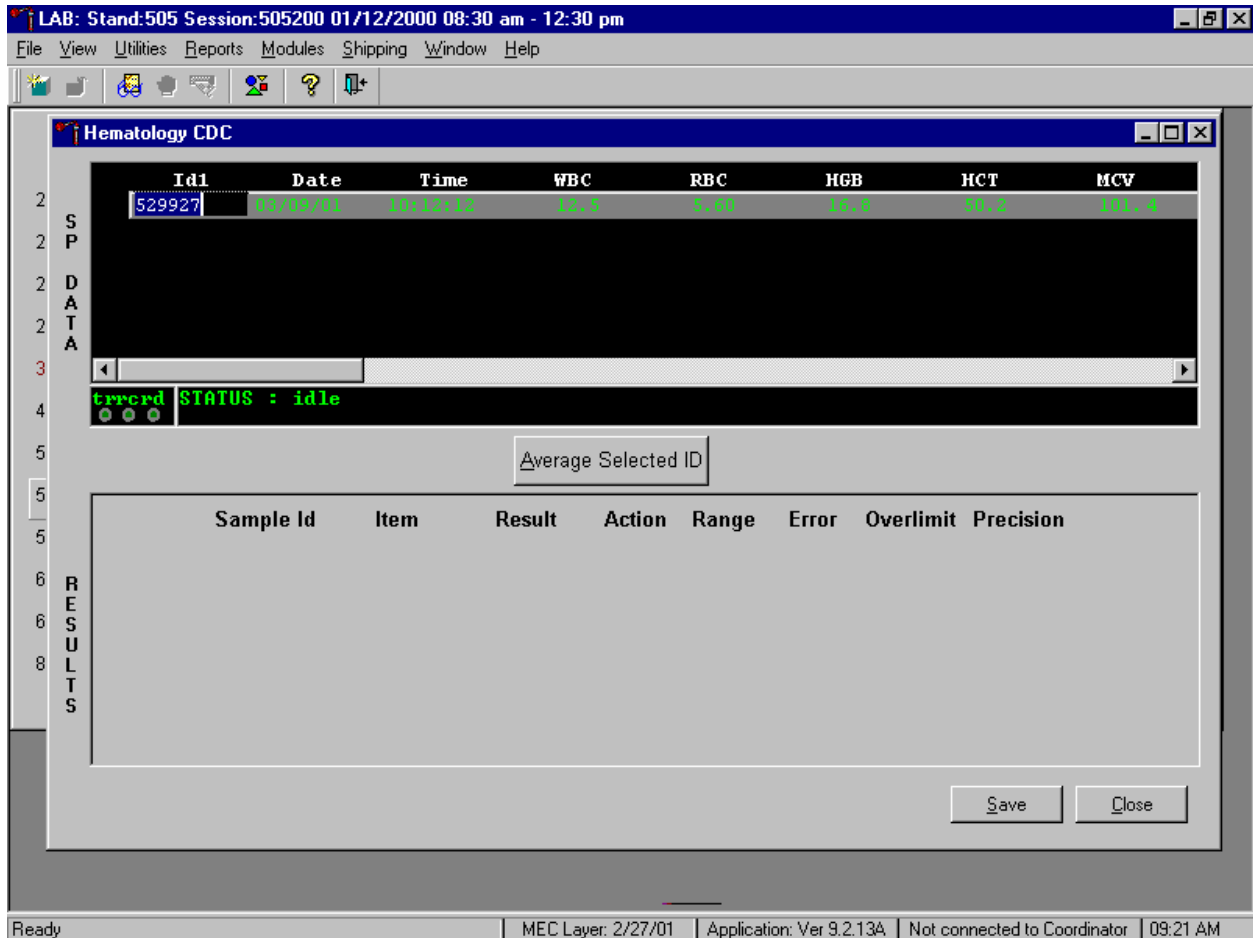
Hematology module overview.

Coulter automatically transmits results to the Laboratory application. Make sure the Beckman Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



SP data transmits to the hematology module and displays it in the top portion of the window, the SP Data section. This section includes the SP ID, the date and time the CBC was run, and columns for each individual parameter. The bottom portion of the window is the Results section. Results display after the Average Selected ID button is selected.

Review all Coulter data in the SP Data section after transmission.



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

The hematology Results section overview.

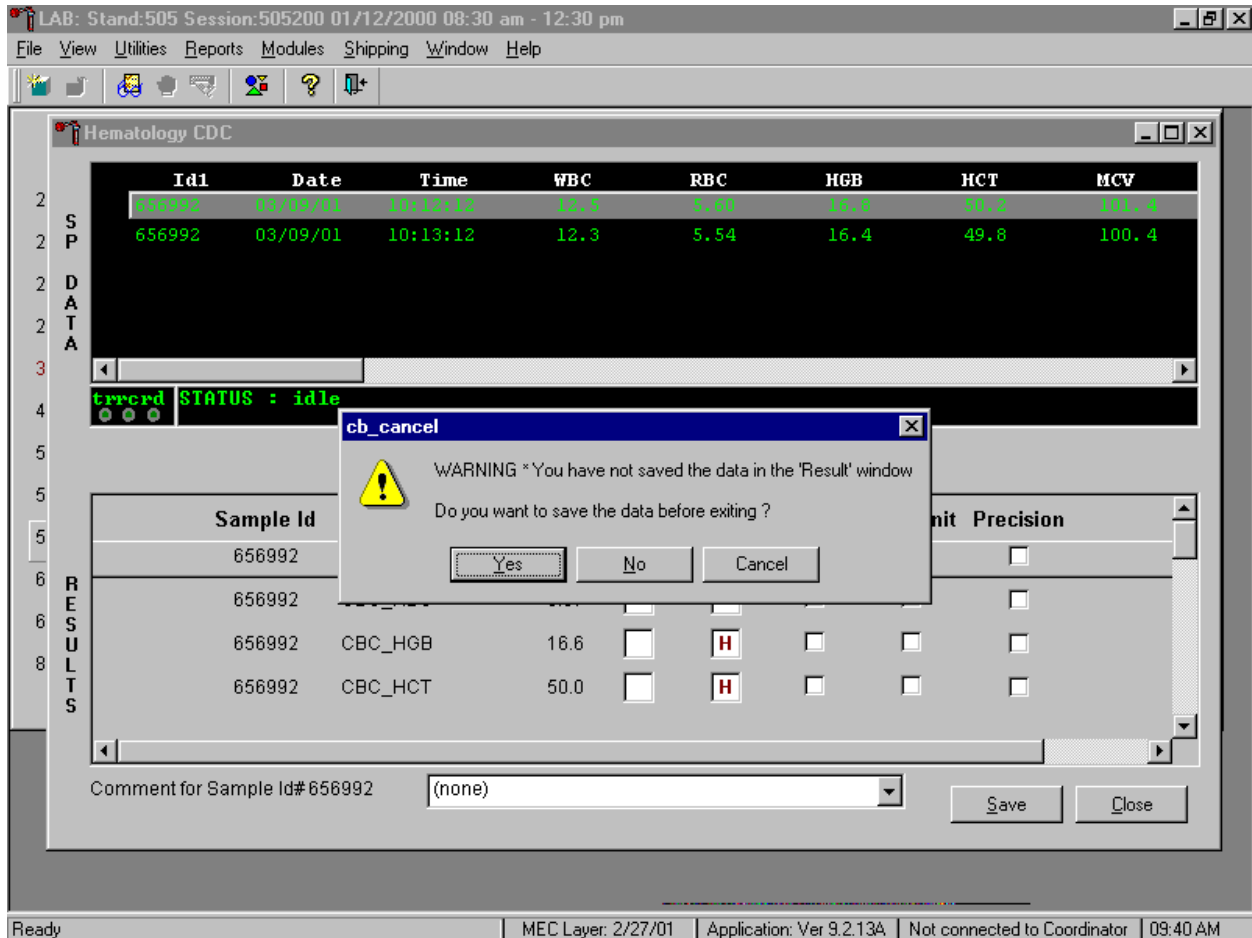
The screenshot shows the Hematology CDC software interface. At the top, a menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. Below the menu is a toolbar with various icons. The main window is titled 'Hematology CDC' and contains a data table with the following columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data row shows: 529927, 03/09/01, 10:12:12, 12.5, 5.60, 16.8, 50.2, 101.4. Below the table, there is a status bar showing 'errord STATUS : idle'. A button labeled 'Average Selected ID' is visible. The 'RESULTS' section contains a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data rows are: 529927, CBC_WBC, 12.5, [], [], [], [], []; 529927, CBC_RBC, 5.6, [], H, [], [], []; 529927, CBC_HGB, 16.8, H, H, [], [], []; 529927, CBC_HCT, 50.2, [], H, [], [], []. At the bottom, there is a comment field for Sample Id# 529927 with the text 'result based on single run' and buttons for 'Save' and 'Close'. The status bar at the very bottom shows 'Ready', 'MEC Layer: 2/27/01', 'Application: Ver 9.2.13A', 'Not connected to Coordinator', and '09:23 AM'.

The Result columns include Sample ID, Item (CBC parameter), Result (Coulter data for a single run or the ISIS averaged result for multiple runs), Action (CDC established critical limits), Range (CDC established reference ranges for both genders and 4 age groups), Error (Coulter transmitted instrument errors), Overlimit (Coulter transmitted result that exceeds the instrument's linearity limit), and Precision (CDC established values for the difference between any two runs.) Checkmarks display in boxes for parameters that have errors, are overlimit, or for those that exceed precision limits. 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, use the mouse to direct the mouse arrow to the vertical scroll bar at the right side of the Results section and drag the bar up or down. Alternatively, to view all the results, use the mouse to direct the mouse arrow to the small scroll arrows on the top and bottom edges of the vertical scroll bar, and left click. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit

and reference range flags. To save the result to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click or type [Shift] [C/c].

A warning text box displays if the Close button is selected before the results have been saved.

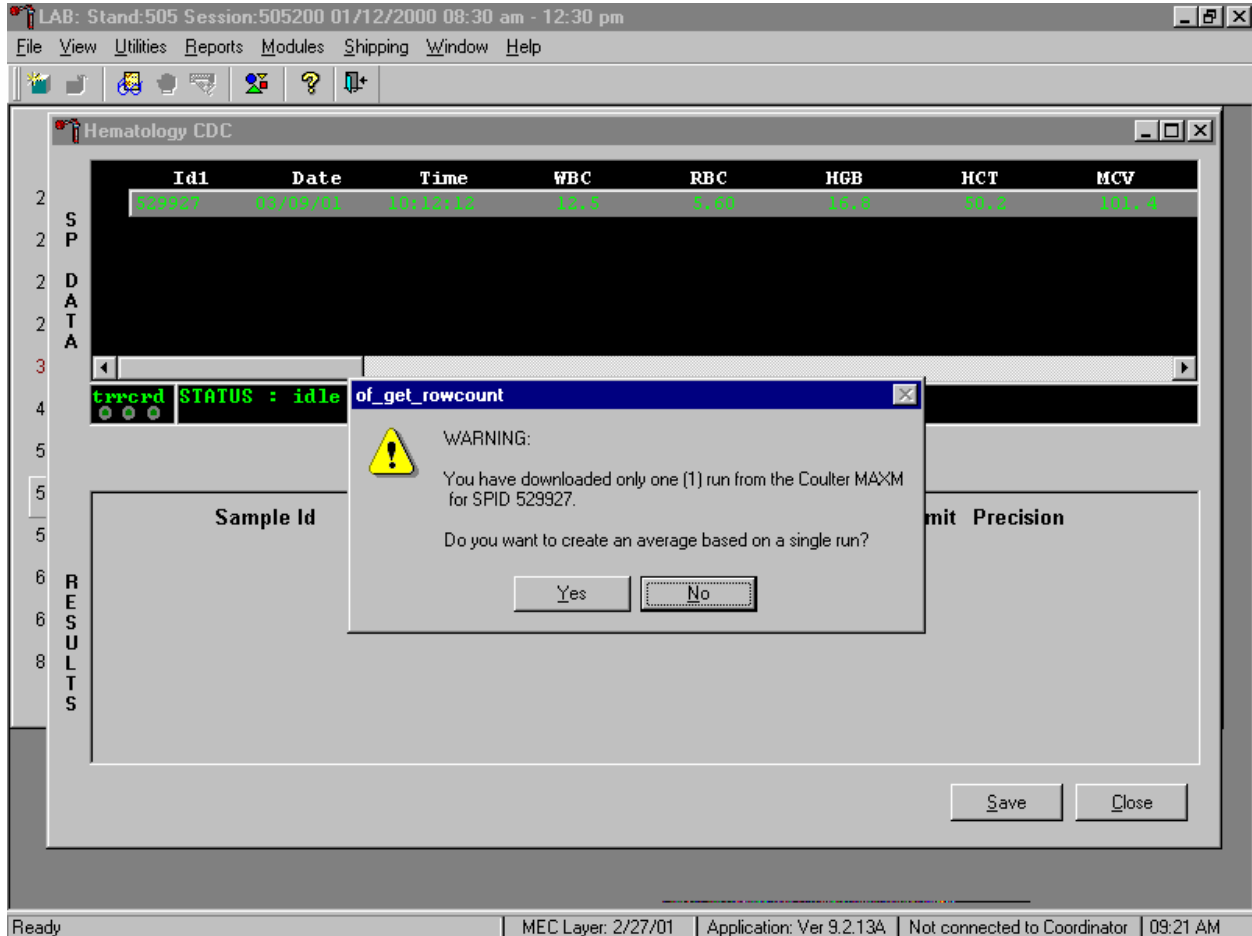


If the **Close** button is selected before the results are saved to the database, a warning message text box displays that states, "WARNING *You have not saved the data in the 'Result' window" and asks, "Do you want to save the data before exiting?" To record a "Yes" response, use the mouse to direct the mouse arrow to the **Yes** button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N/n]. To cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click. If a Yes response is recorded, the CBC results are saved to the database and erased. If a No response is recorded,

no results are saved to the database and the data in the Results section is erased. A Cancel response returns the screen to its previous state.

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, use the mouse to 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 MAXM for SPID XXXXXX" and asks, "Do you want to create an average based on a single run?" To record a "Yes" response, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Y/y]. To record a "No" response, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N/n], or press [Enter]. If a Yes response is recorded, the CBC results display in the bottom Results section of the window. A "No" response cancels the action and returns the window to its previous state.

For results where only one run was possible, the **Comment** box at the bottom of the window defaults to "result based on single run."

Running samples in duplicate.

Run all samples in duplicate and average the data.

The screenshot shows the Hematology CDC software interface. The main window displays a table of sample data with two duplicate entries for ID# 398087. Below the table is a status bar showing 'errord STATUS : idle'. A button labeled 'Average ID# 398087' is positioned above a results table. The results table has columns for Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The interface also includes a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a status bar at the bottom (Ready, MEC Layer: 2/27/01, Application: Ver 9.2.13A, Not connected to Coordinator, 09:18 AM).

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
398087	02/23/98	10:12:12	20.2	2.99	10.3	29.3	73.4
398087	02/13/99	10:14:42	20.4	3.00	10.3	20.3	73.4

errord STATUS : idle

Average ID# 398087

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
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Whenever a sample is run in duplicate, both results display in the SP Data section. To average these two results, use the mouse to direct the mouse arrow to **Average ID#XXXXXX** button and left click.

Results display in the lower section of the window.

The screenshot shows a software window titled "Hematology CDC" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area is divided into several sections:

- SP DATA:** A table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, MCV. It contains two rows of data for sample ID 656992.
- errord STATUS : idle** (with three status indicators)
- Average ID# 656992:** A text box containing the sample ID.
- RESULTS:** A table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, Precision. It lists four items: CBC_WBC, CBC_RBC, CBC_HGB, and CBC_HCT.
- Comment for Sample Id# 656992:** A dropdown menu showing "(none)".
- Buttons:** "Save" and "Close" buttons.

The status bar at the bottom shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:40 AM

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

CDC established precision limits:

Test	Precision Limits
WBC	0.4×10^3
RBC	0.1×10^6
Hgb	0.4 g/dL
MCV	2.2 fL
Plt	23×10^3
NE#	0.4×10^3
LY#	0.2×10^3
MO#	0.2×10^3
EO#	0.2×10^3
BA#	0.2×10^3

If RBC parameters are out of range, evaluate XB for a drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range, check the WBC scattergram for abnormal cell population(s).

Evaluate and save results when precision limits are not exceeded.

The screenshot shows the Hematology CDC software interface. At the top, the title bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC" and contains a data table with the following columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data is as follows:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

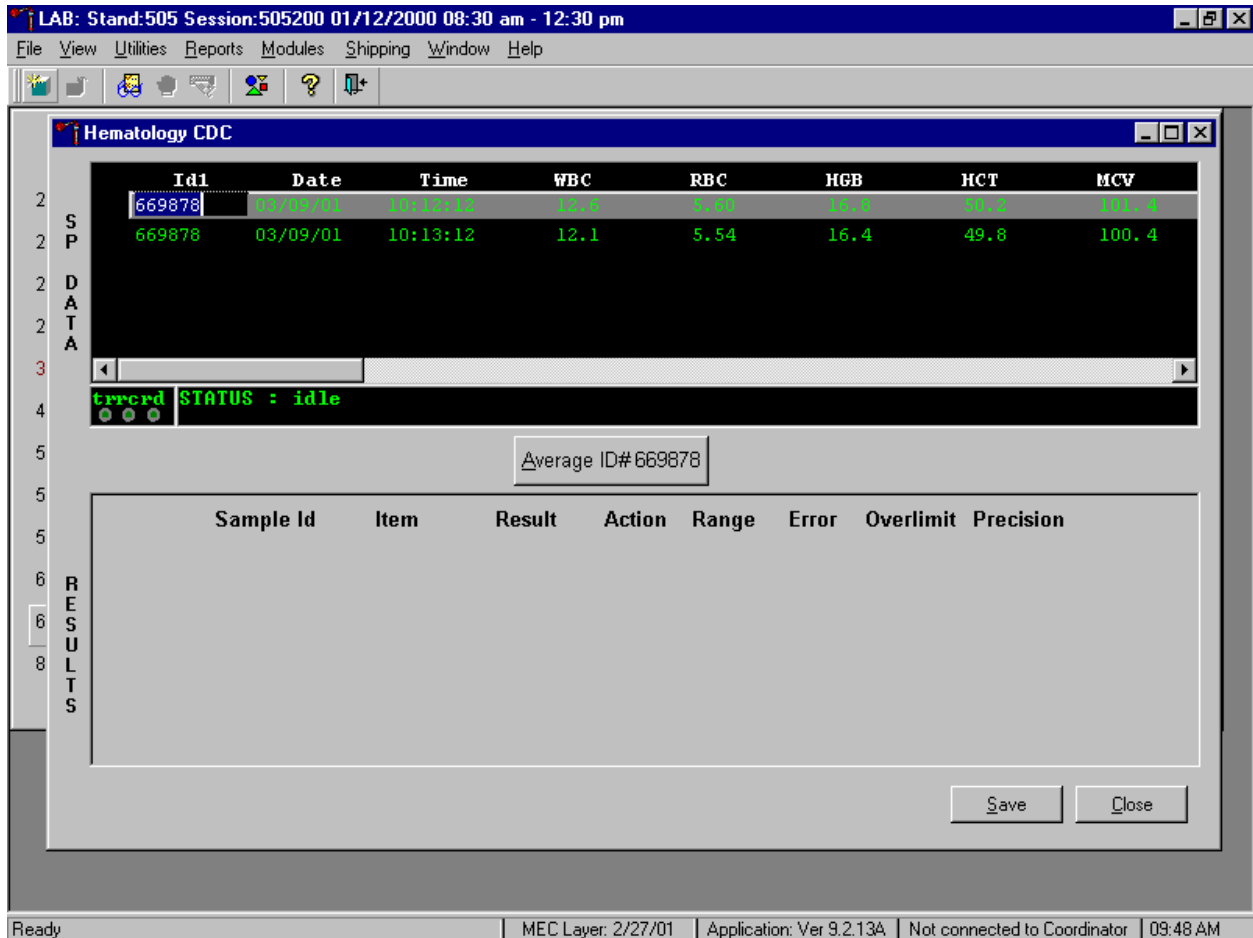
Below the data table, there is a status bar showing "errord STATUS : idle". A text box displays "Average ID# 656992". The "RESULTS" section contains a table with the following columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data is as follows:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
656992	CBC_WBC	12.4	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_RBC	5.57	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HGB	16.6	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
656992	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom of the "RESULTS" section, there is a text box for "Comment for Sample Id# 656992" with the value "(none)". To the right of the text box are "Save" and "Close" buttons. The status bar at the bottom of the window shows "Ready", "MEC Layer: 2/27/01", "Application: Ver 9.2.13A", "Not connected to Coordinator", and "09:40 AM".

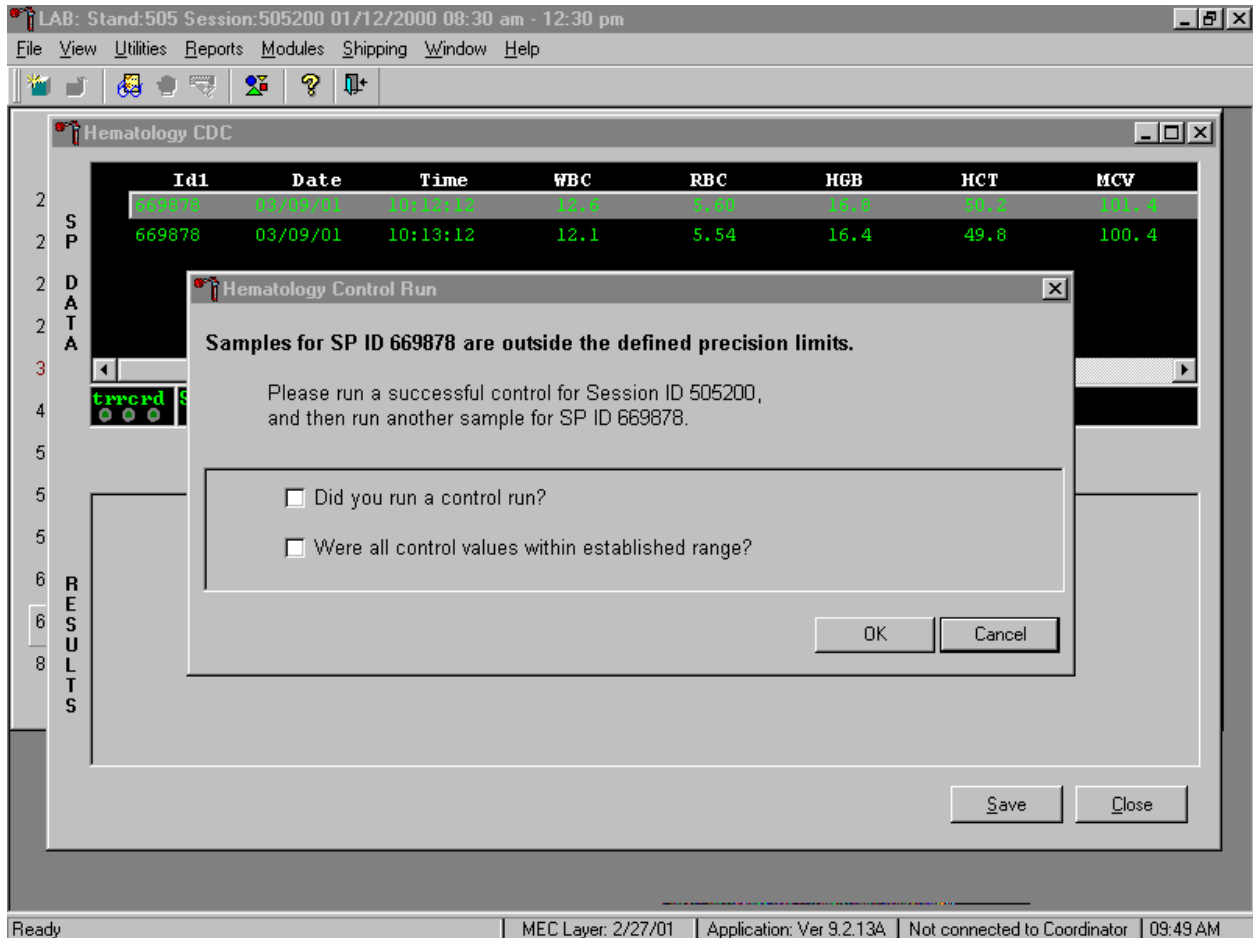
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [Shift] [C/c].

Average, evaluate, and rerun specimens that exceed precision limits.



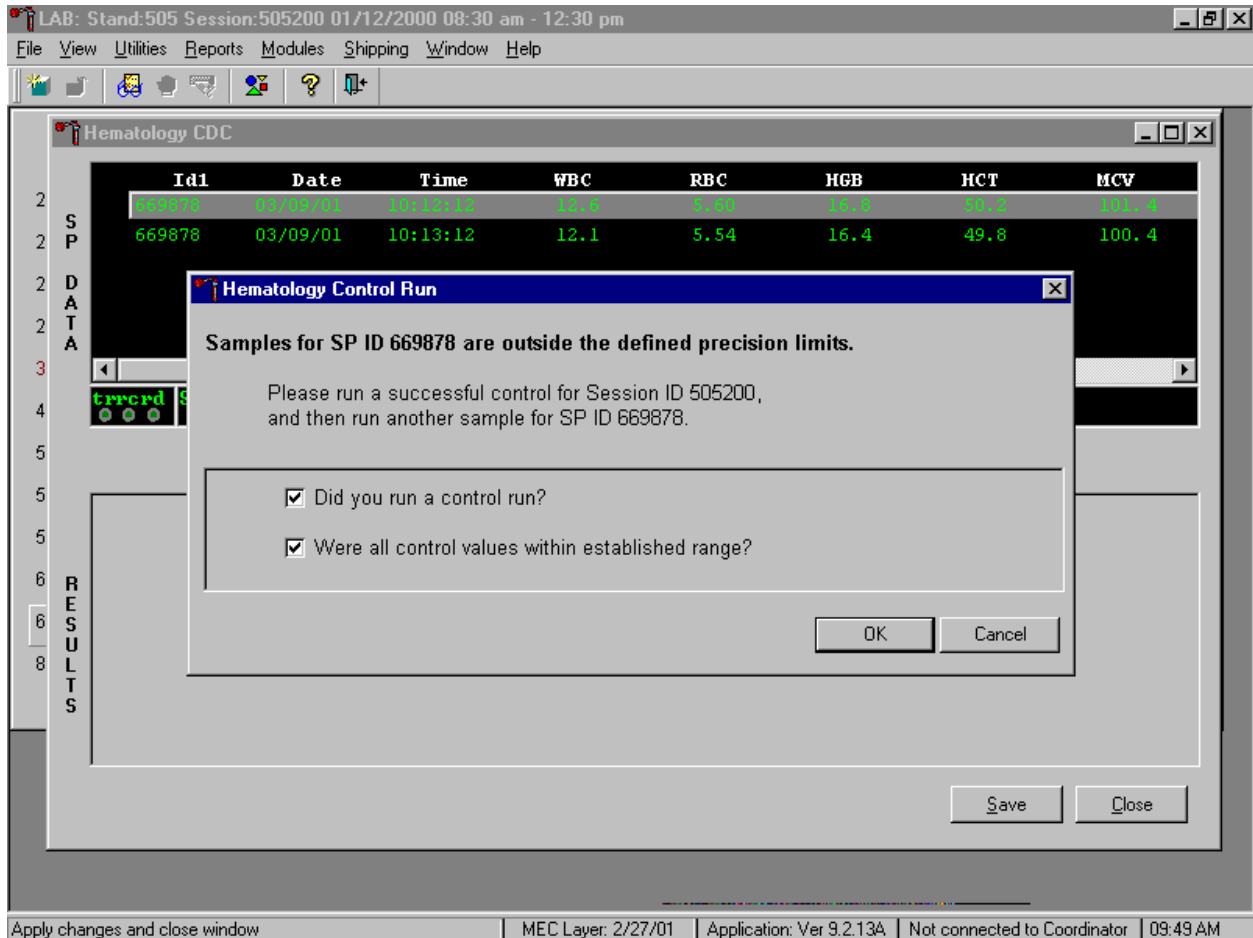
Average the two results by using the mouse to direct the mouse arrow to the **Average** **ID#XXXXXX** button and left click. If at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate it to determine if all control values fall within the 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." Run any one level of 5C Cell control and evaluate the results. Respond to the two questions, "Did you run a control run?" and "Were all control values within established range?" To confirm these actions, use the mouse to direct the mouse arrow to each of the two check boxes and left click to record the check marks.

Save the responses to the check box questions.



To save these responses to the database, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter], or to exit the Hematology Control Run window without saving the responses, use the mouse to direct the mouse arrow to the **Cancel** button and left click. As soon as the **OK** button is selected, the averages display in the Results section of the window.

Evaluate the results displayed in the Results section of the window.

The screenshot shows the Hematology CDC software interface. The main window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The interface is divided into several sections:

- SP DATA:** A table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, MCV.

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.6	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.1	5.54	16.4	49.8	100.4
- STATUS:** A small window showing "errord STATUS : idle".
- Average ID#669878:** A text box containing the sample ID.
- RESULTS:** A table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, Precision.

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Comment for Sample Id#669878:** A dropdown menu showing "(none)".
- Buttons:** "Save" and "Close" buttons.

The status bar at the bottom shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:50 AM

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. Use the scroll bar to view all results. When there are checkmarks in any of the Precision columns, meaning that the precision limit was exceeded, rerun the blood sample a third time. If there is insufficient blood to run the CBC a third time, save the result to the database. To save the results to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [Shift] [C/c].

Run the specimen a third time when any precision limit is exceeded.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

Hematology CDC

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

errord STATUS : idle

Average ID#669878

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

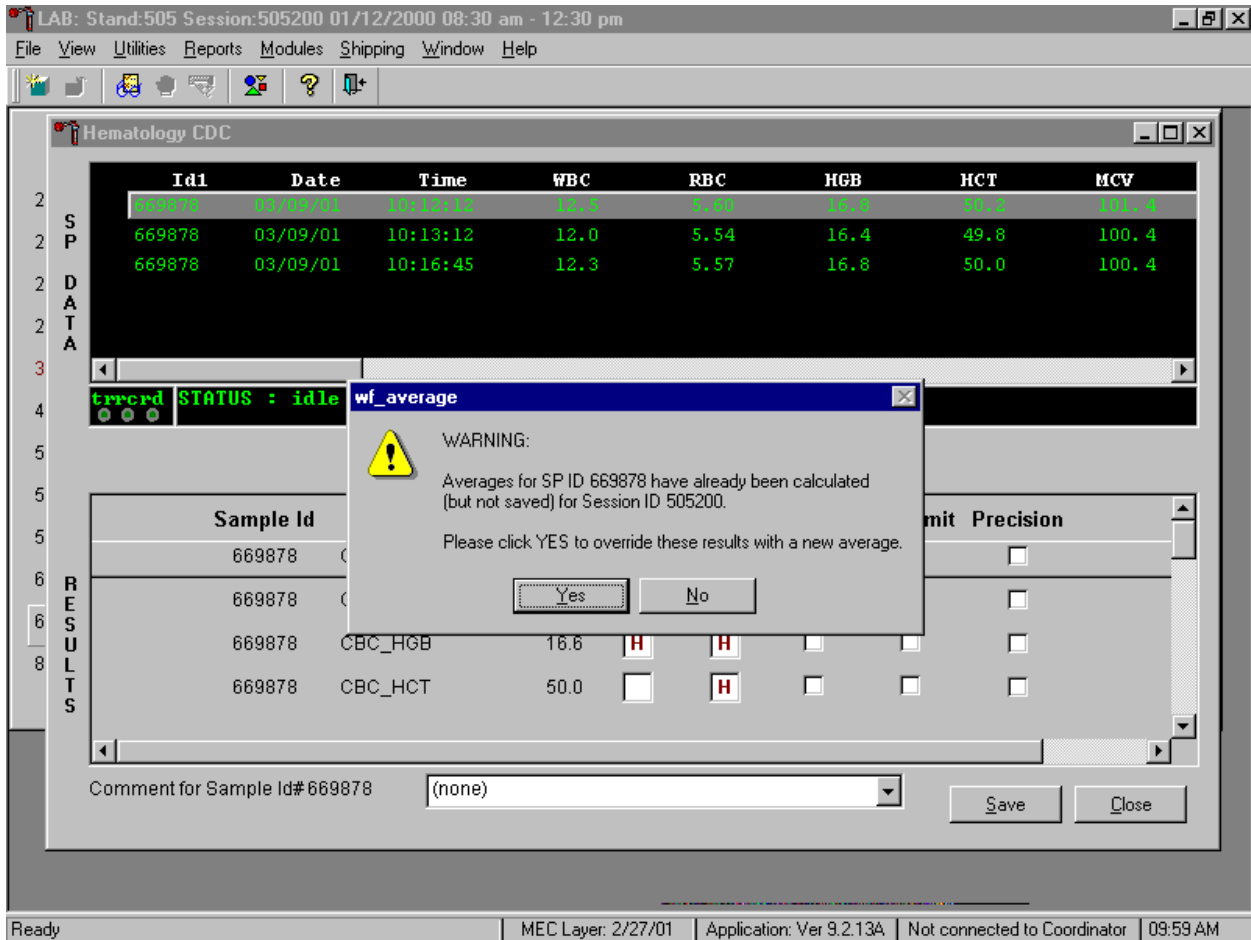
Comment for Sample Id#669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:58 AM

Run the blood sample a third time. Whenever a sample is run more than once, all results in the SP Data section are displayed. To re-average these results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click. The initial averaged result for parameters that do not exceed precision limits are fixed and are not recalculated.

Override the current averaged results for parameters that exceeded the precision limit with a new average.



Whenever a sample has previously been averaged, and a new average is calculated, a Warning message text box displays stating, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session ID XXXXXX." The text box instructs, "Please click YES to override these results with a new average." To override the current average with a new average (but for only those parameters that exceeded precision limits), use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Shift] [Y/y], or press [Enter]. To exit or return to the previous screen containing the previous averages, use the mouse to direct the mouse arrow to **No** button and left click, or type [Shift] [N/n].

Evaluate the new results.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hematology CDC

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

errord STATUS : idle

Average ID#669878

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id#669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM

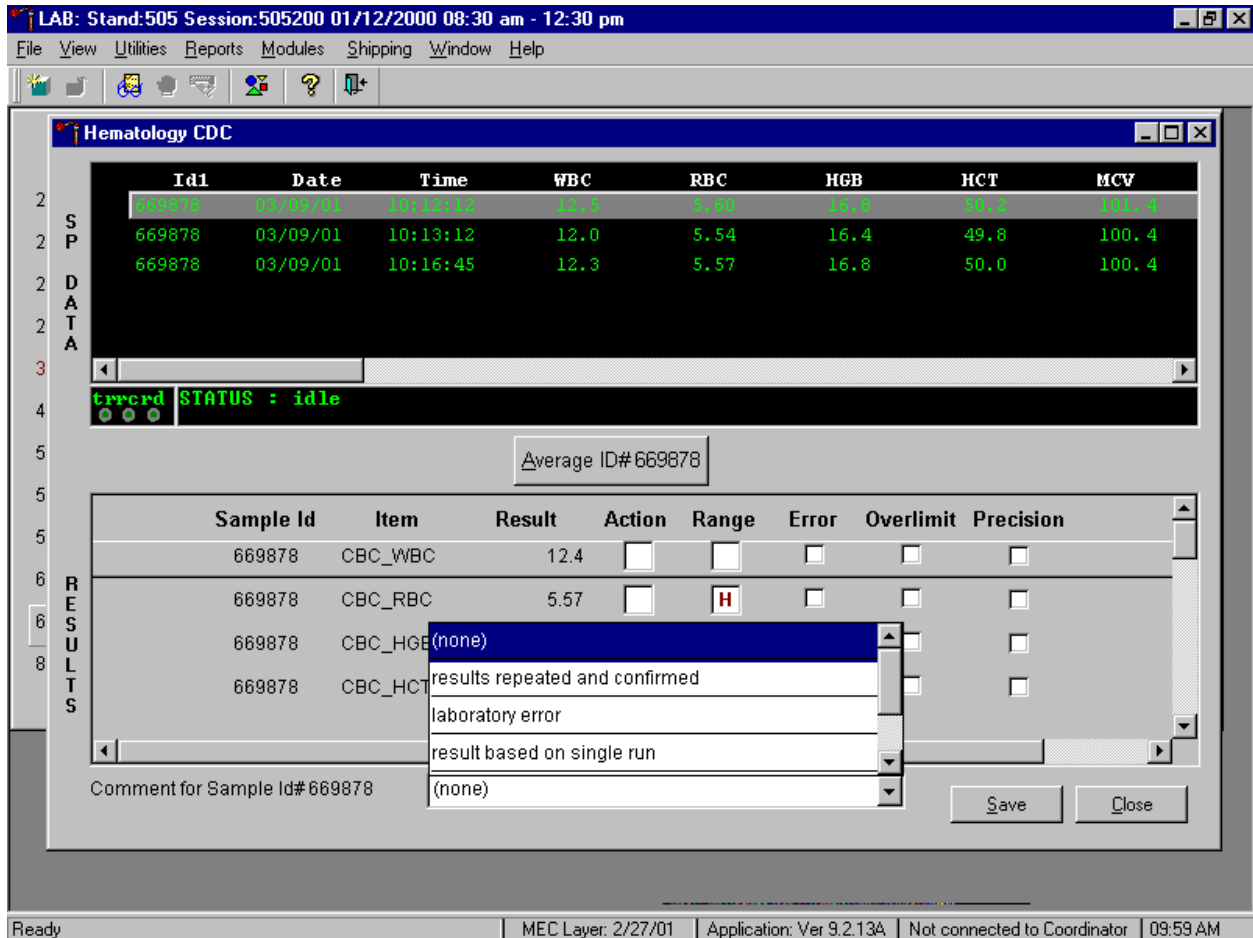
The first three runs are recalculated to find the closest two results for parameters where the difference between any two results exceeded its precision limits. If all parameters now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the result to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [Shift] [C/c].

If necessary, run the specimen a fourth time and evaluate.

If precision limits are still not met for any parameter, run the blood tube a fourth time. Re-average, evaluate, and save the results. If after four runs precision limits are still not met for any parameter, a comment is automatically attached to the results. Do not run a specimen more than 4 times.

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.



To attach a comment to the results in the database, use the mouse to direct the mouse arrow to the drop down list on the **Comment** box, left click to display the codes, drag the mouse arrow to the most appropriate choice, and left click. Alternatively, to record a comment, use the mouse to direct the mouse arrow to the drop down list on the **Comment** box, click to display the codes, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click.

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.

equipment failure	The Coulter malfunctioned.
laboratory error	There was a technologist error.
results based on single run	The quantity of specimen is insufficient to run it more than once.
no diff results/diff voteout	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 .

Save the result after attaching a comment.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC" and contains a data table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. Below this is a status bar showing "errord STATUS : idle". A button labeled "Average ID# 669878" is present. The "RESULTS" section contains a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. At the bottom, there is a comment field for "Sample Id# 669878" with the text "results repeated and confirmed" and "Save" and "Close" buttons.

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
669878	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
669878	03/09/01	10:13:12	12.0	5.54	16.4	49.8	100.4
669878	03/09/01	10:16:45	12.3	5.57	16.8	50.0	100.4

errord STATUS : idle

Average ID# 669878

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
669878	CBC_WBC	12.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_RBC	5.57	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HGB	16.6	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
669878	CBC_HCT	50.0	<input type="checkbox"/>	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comment for Sample Id# 669878: results repeated and confirmed

Save Close

Save changes | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM

Save the averaged result and update the comment, by using the mouse to direct the mouse arrow to the **Save** button and left click or type [Shift] [S/s]. To exit without saving any data to the database, use the mouse to direct the mouse arrow to the **Close** button and left click or type [Shift] [C/c].

Using alternative data manipulation choices.

Retain data for multiple SPs in the SP Data section of the window.

The screenshot shows the Hematology CDC software interface. The main window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window is titled "Hematology CDC".

The "SP DATA" section displays a table with the following data:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
529927	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4
656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

Below the table, the status is "errord STATUS : idle". A button labeled "Average ID# 565368" is visible. The "RESULTS" section is currently empty, with a header row: Sample Id, Item, Result, Action, Range, Error, Overlimit, Precision. At the bottom right of the results section are "Save" and "Close" buttons.

The status bar at the bottom of the window shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:11 AM

In general, run one SP in duplicate through the Coulter, average the result, and save the data to the database. The Hematology module will display data for multiple SPs in the SP Data section. Each individual SP's results or pairs of results are displayed in a different color. To select or highlight any one SP, use the mouse to direct the mouse arrow to the row containing the correct SP ID and left click.

Average the results for one SP at a time.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window displays a table of hematology data for sample ID 565368.

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
529927	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4
656992	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
656992	03/09/01	10:13:12	12.3	5.54	16.4	49.8	100.4

Below the table, the status is "errord STATUS : idle". A text box shows "Average ID# 565368". The Results section contains a table with the following data:

Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
565368	CBC_WBC	16.2	H	H	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
565368	CBC_RBC	3.64	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
565368	CBC_HGB	10.3	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
565368	CBC_HCT	29.3	<input type="checkbox"/>	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom, there is a "Comment for Sample Id# 565368" field with the value "(none)", and "Save" and "Close" buttons.

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, use the mouse to direct the mouse arrow to the **S**ave button and left click or type [Shift] [S/s]. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the **C**lose button and left click or type [Shift] [C/c]. If there are any Precision checkmarks, run a 5C Cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

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.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC" and contains a table of sample data. A context menu is open over the row for sample ID 565368, showing options: "Clear ID# 565368", "Clear All Downloads", "View Log For ID# 565368", "Save Averages", "Clear Averages", "Save & Exit", and "Clear & Exit". Below the table is a "RESULTS" section with a table of sample results and a "Comment for Sample Id# 565368" field.

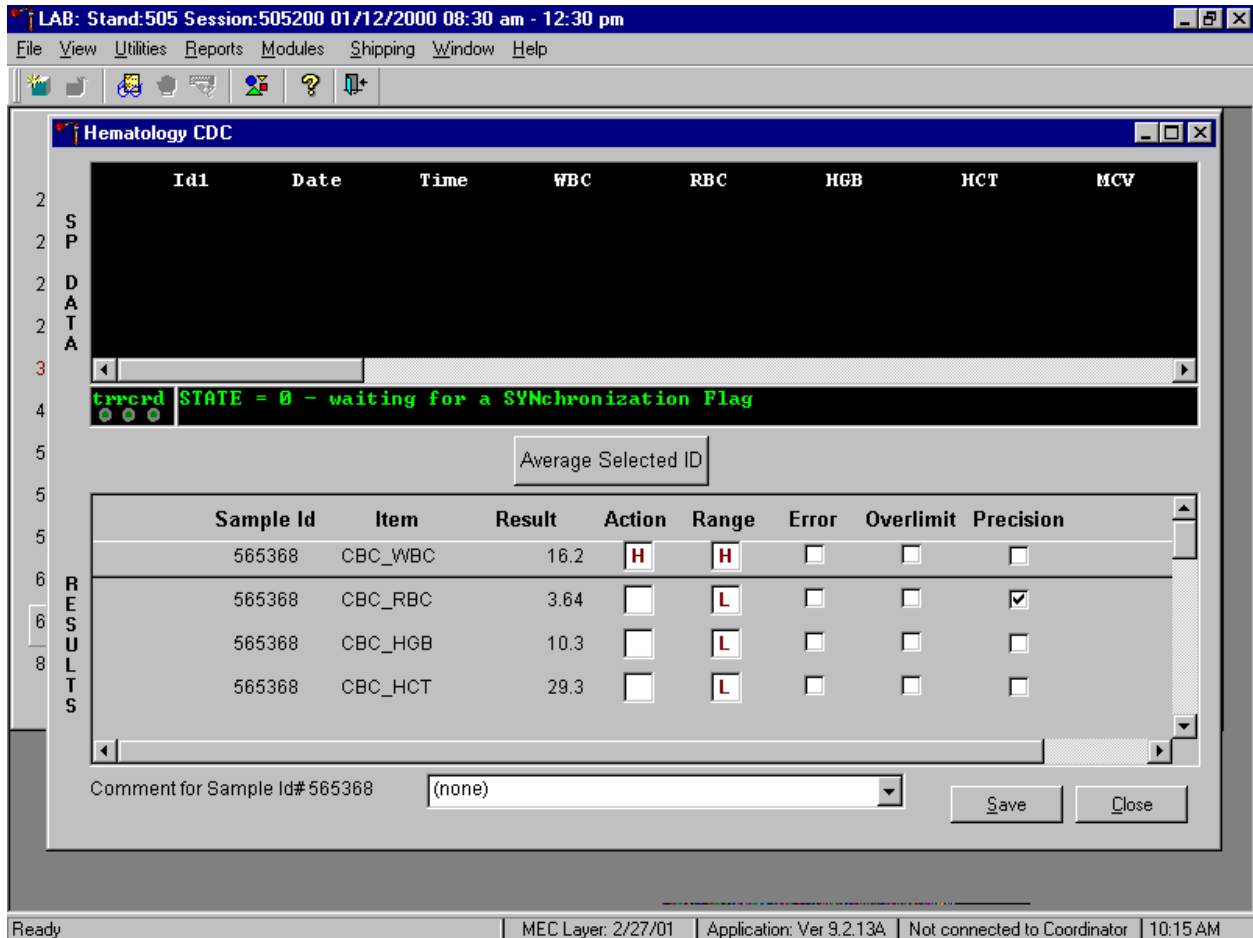
SP DATA	Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
2	529927	03/09/01	10:12:12	12.5	5.60	16.8	50.2	101.4
2	565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
2	565368	03/09/01	10:13:1			10.3	29.3	63.4
2	656992	03/09/01	10:12:1			16.8	50.2	101.4
2	656992	03/09/01	10:13:1			16.4	49.8	100.4

RESULTS	Sample Id	Item	Result	Action	Range	Error	Overlimit	Precision
5	565368	CBC_WBC	16.2	H	H			
6	565368	CBC_RBC	3.64		L			<input checked="" type="checkbox"/>
8	565368	CBC_HGB	10.3		L			
	565368	CBC_HCT	29.3		L			

Comment for Sample Id# 565368: (none)

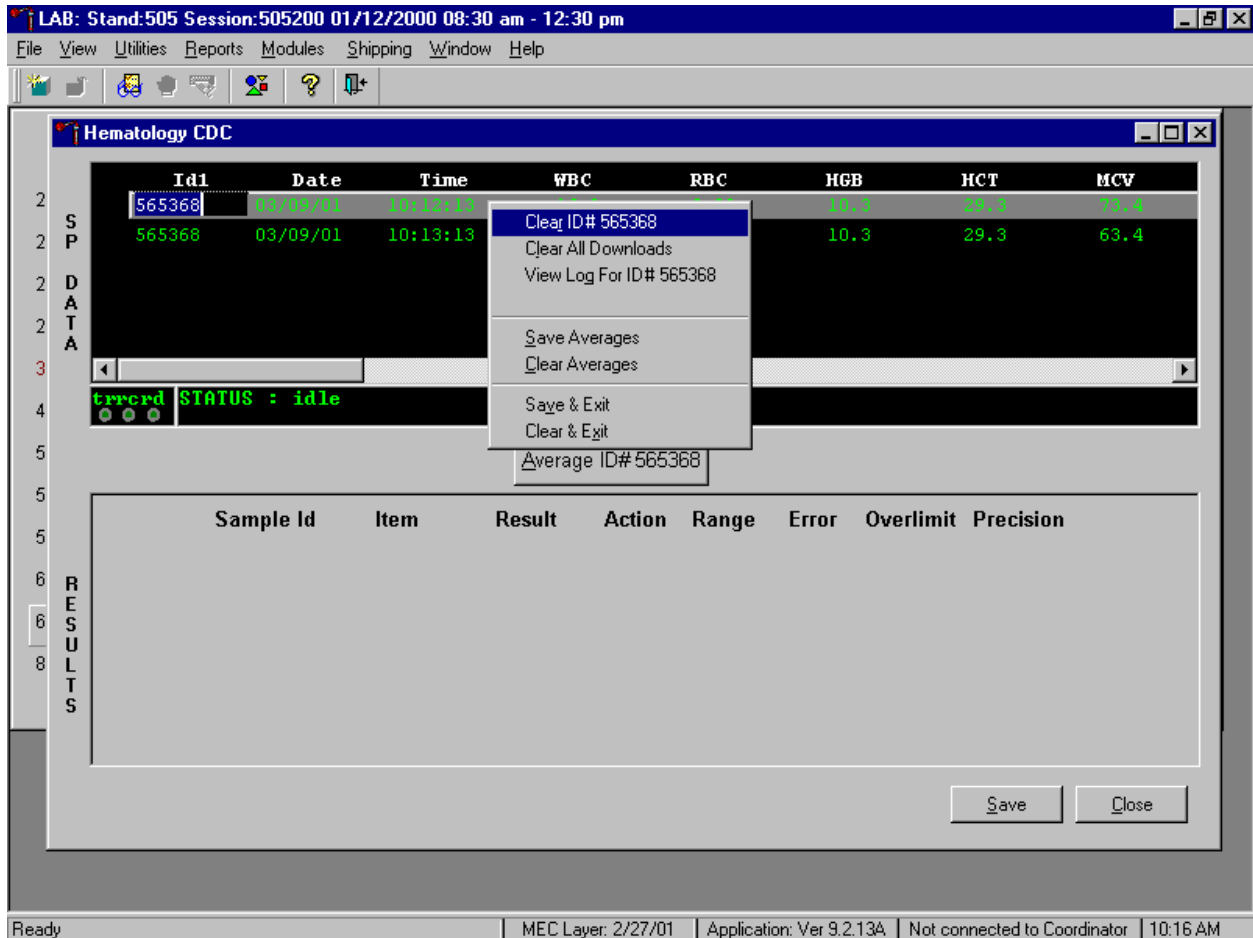
To clear all downloads from the SP Data section, use the mouse to direct the mouse arrow to any individual row in the SP Data section and right click to display the alternative data manipulation choices. To select "Clear All Downloads," drag the mouse arrow to {Clear All Downloads} and left click or type [Shift] [L/I].

Release the mouse button to clear all downloads.



All data in the SP Data section is erased but the last averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the hematology module, use the mouse to direct the mouse arrow to the **Close** button and left click or type [Shift] [C/c].

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



To clear the Coulter downloads for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear ID#XXXXXX }, and right or left click or type [Shift] [R/r]. Release the mouse button to clear this download. Retransmit, average, and save the data.

Clear only the averaged results for any SP using data manipulation choices.

The screenshot shows the Hematology CDC software interface. At the top, the title bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". A toolbar with various icons is located below the menu bar.

The main window is titled "Hematology CDC" and contains several sections:

- SP DATA:** A table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, MCV. It contains two rows of data for ID# 565368.
- STATUS:** A section showing "errord STATUS : idle" with three status indicators.
- RESULTS:** A table with columns: Sample Id, Item, Range, Error, Overlimit, Precision. It contains four rows of results for sample ID# 565368.
- Comment for Sample Id#565368:** A text field containing "(none)".

A context menu is open over the SP DATA table, listing the following options:

- Clear ID# 565368
- Clear All Downloads
- View Log For ID# 565368
- Save Averages
- Clear Averages** (highlighted)
- Save & Exit
- Clear & Exit

The bottom status bar shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:19 AM".

To clear the averaged results for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear Averages}, and right or left click or type [Shift] [C/c].

Release the mouse button to clear the results.

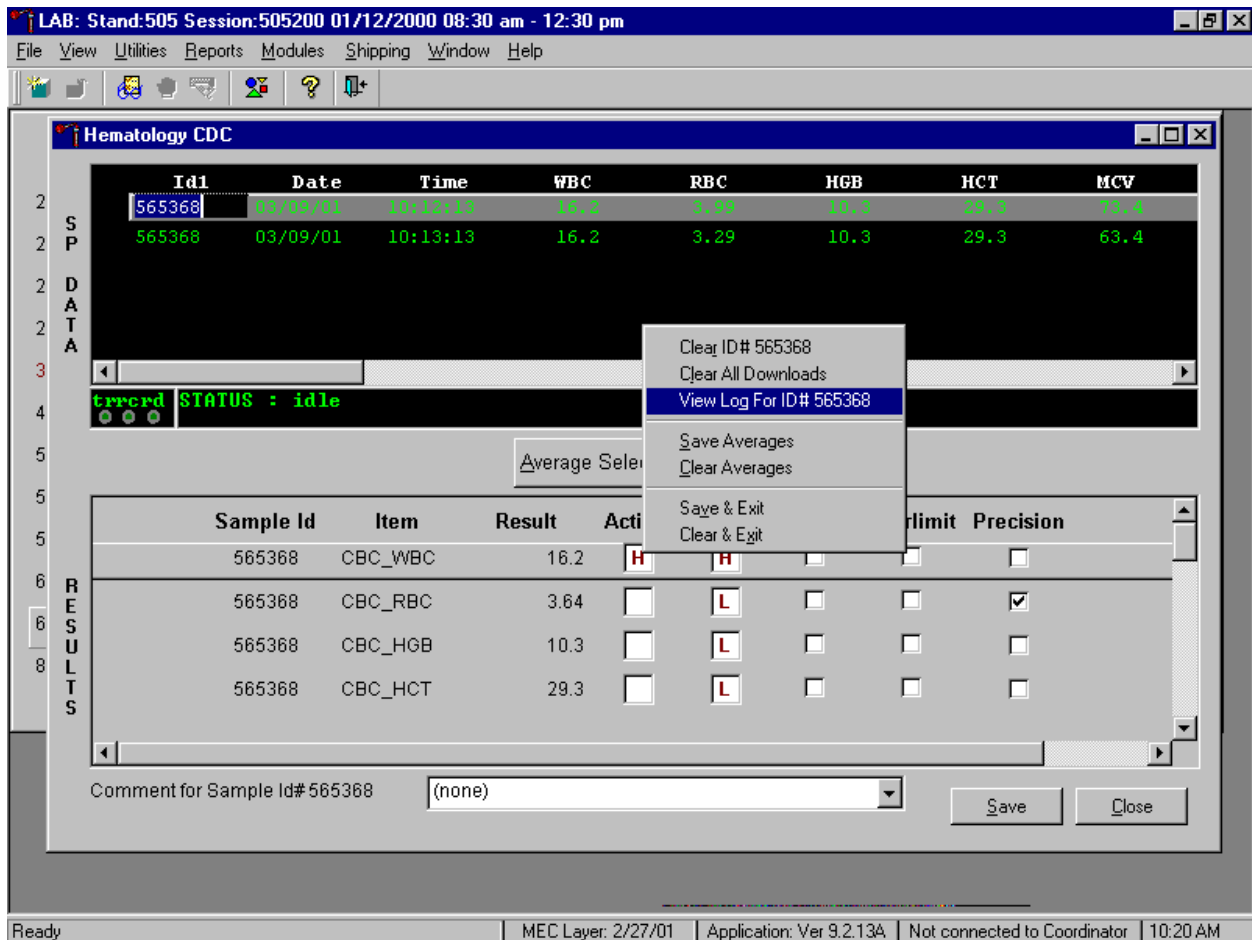
The screenshot shows the Hematology CDC software interface. The main window has a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The central area displays a table with the following data:

Id1	Date	Time	WBC	RBC	HGB	HCT	MCV
565368	03/09/01	10:12:13	16.2	3.99	10.3	29.3	73.4
565368	03/09/01	10:13:13	16.2	3.29	10.3	29.3	63.4

Below the table is a status bar showing "errord STATUS : idle". A button labeled "Average Selected ID" is positioned above a large empty box labeled "RESULTS". At the bottom right of the main window are "Save" and "Close" buttons. The system tray at the bottom shows "Ready", "MEC Layer: 2/27/01", "Application: Ver 9.2.13A", "Not connected to Coordinator", and "10:19 AM".

All results in the Results section of the window are erased. Re-average and save the data.

Use the "View Log for ID# XXXXXX" choice to view all Coulter data, averages, and precision limit values for any SP.



To view the detailed log for any one SP's result, use the mouse to direct the mouse arrow to the individual row in the SP Data section and right click to display the alternative data manipulation choices. Drag the mouse arrow to {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 screenshot displays a laboratory software interface. A central window titled "Lab" is open, showing a dialog box for "MAXM Download For ID#565368". The dialog contains the following text:

```

[PROCESSING OF AVERAGES FOR ID#565368]
sample_id:565368 age:65 gender:2
LBXWBCSI
  cmnt[1]: cmnt[2]:
  val[1]:16.20 val[2]:16.20
  dif[1]:.00 dif[2]: dif[3]: dif[4]: dif[5]: dif[6]:
  difcol[1]:1 difcol[2]:2
  average:16.20 diff:.00 limit:.40
  err.flag:FALSE over.flag:FALSE prec.flag:FALSE
  act.flag:H act l,h:3.00,16.00
  ref.flag:H mg l,h:3.90,12.50
LBXRBCSI
  cmnt[1]: cmnt[2]:
  val[1]:3.99 val[2]:3.29
  dif[1]:.70 dif[2]: dif[3]: dif[4]: dif[5]: dif[6]:
  difcol[1]:1 difcol[2]:2
  average:3.64 diff:.70 limit:.10
  
```

Below the dialog, a table of results is visible:

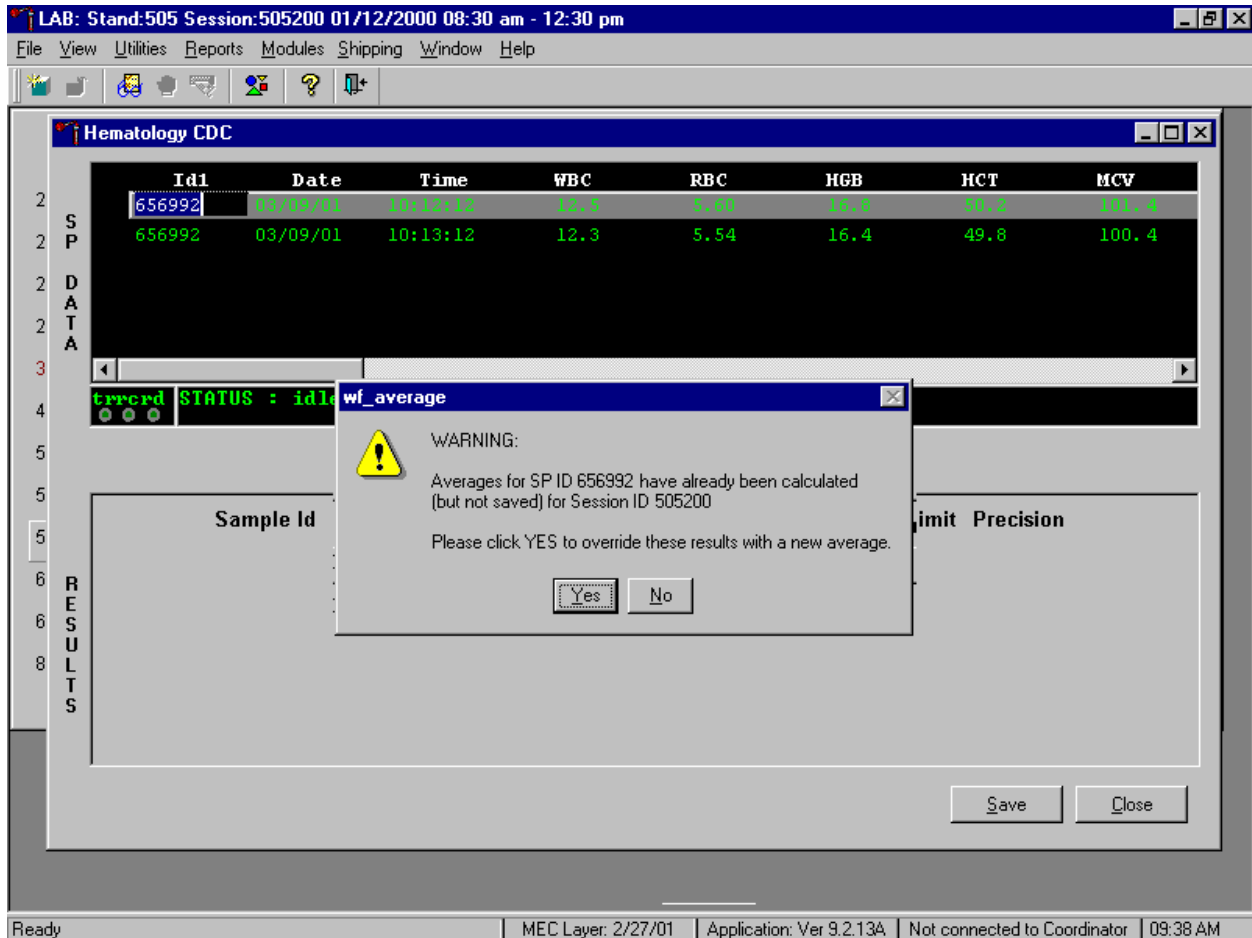
Sample ID	Parameter	Value	High (H)	Low (L)	Other	Print
565368	CBC_WBC	16.2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
565368	CBC_RBC	3.64	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
565368	CBC_HGB	10.3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
565368	CBC_HCT	29.3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

At the bottom of the dialog, there is a "Comment for Sample Id#565368" field with the value "(none)" and buttons for "OK", "Print", and "Reset". The status bar at the bottom of the application shows "Ready", "MEC Layer: 2/27/01", "Application: Ver 9.2.13A", "Not connected to Coordinator", and "10:20 AM".

The SP's log contains detailed information for each parameter and each run. When finished reviewing the information, use the mouse to direct the mouse arrow to the **OK** button to close the window. To print the log, drag the mouse arrow to the **Print** button and left click or type [Shift] [P/p]. To clear the log and close the screen, use the mouse to direct the mouse arrow to the **Reset** button and left click, or type [Shift] [R/r], or select [Enter].

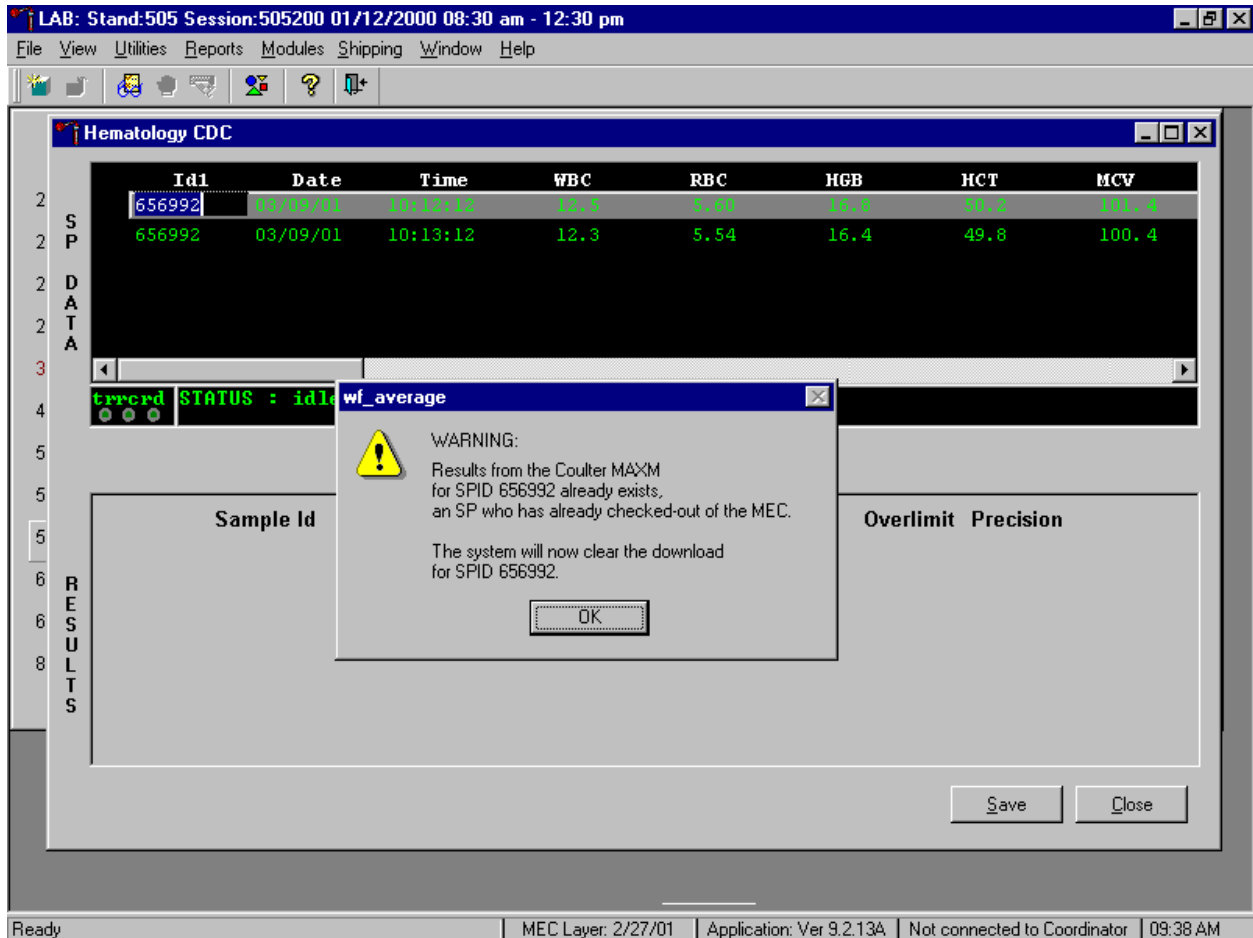
Re-averaging results.

Re-average a result that has or has not previously been saved to the database.



If a SP has not exited the MEC and the Report of Findings has not been printed, it is possible to retransmit and re-average the results for a SP and overwrite (save) the results in the database. A warning message text box displays when an attempt is made to save the data on a SP who has not exited the MEC or for whom a Report of Findings has not been printed. This text states, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session XXXXX. Please click yes to override these results with a new average." To override the previous results, use the mouse to direct the mouse arrow to the **Yes** button and left click or select [Enter] or type [Shift] [Y.] To remove the text box without overriding the previous results, use the mouse to direct the mouse arrow to the **No** button and left click, or type [Shift] [N].

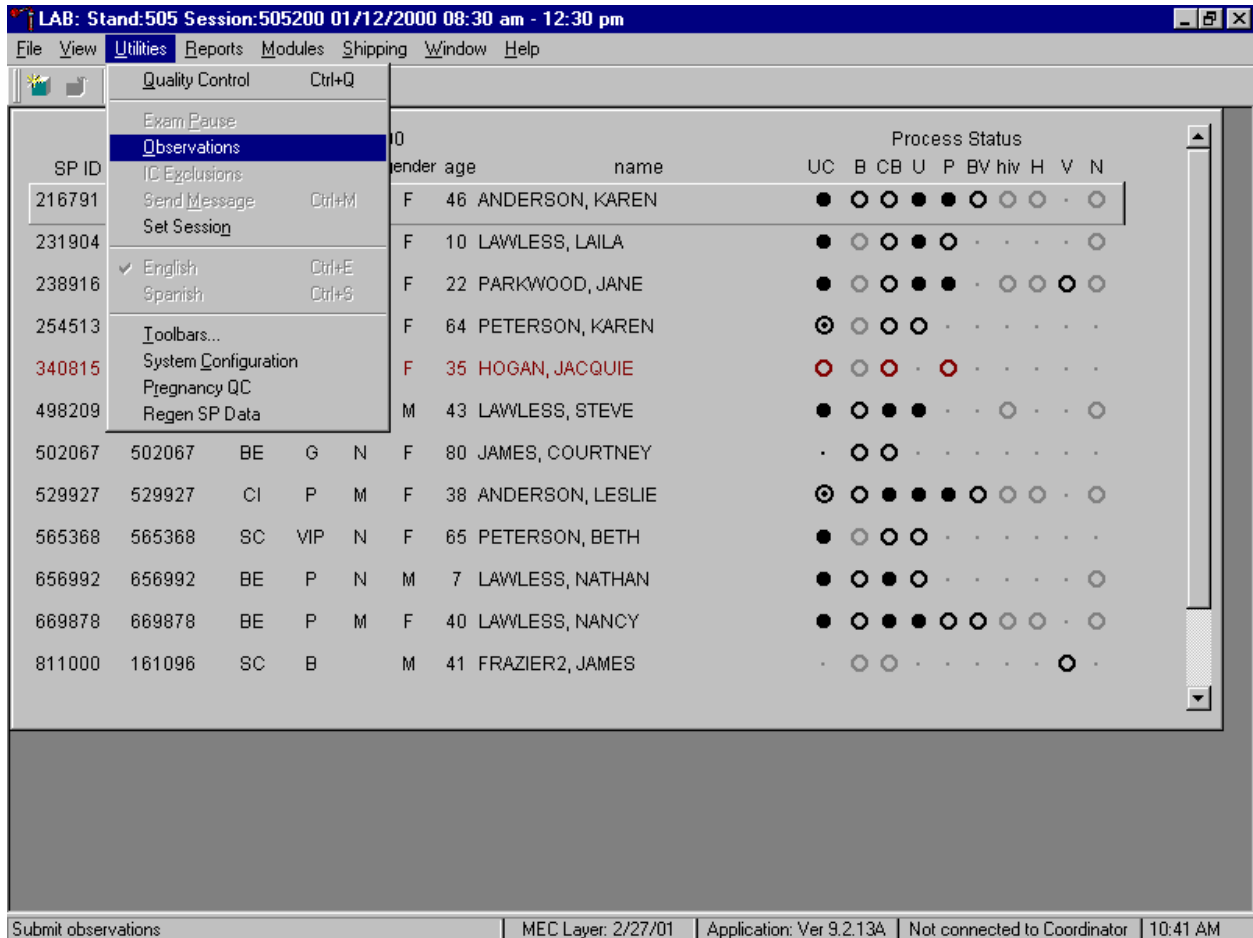
If the SP has exited the MEC or the Report of Findings has been printed, it is impossible to overwrite (save) the results in the database.



A warning message text box displays when an attempt is made to save the data on a SP either who has exited the MEC or for whom a Report of Findings has been printed. This text states, "Results from the Coulter MAXM for SPID XXXXXX already exist for an SP who has already checked out of the MEC. The system will now clear the download for SP ID XXXXXX." To remove the text box, use the mouse to direct the mouse arrow to the **OK** button and left click or type [Enter]. The downloaded data, including the results, are automatically erased.

Sending an observation to the physician.

Send an observation to the physician.



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

Select or highlight the correct SP.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N	
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	●	●	○	○	○	○	○	○
231904	231904	CI	P	N	F	10	LAWLESS, LAILA	●	○	○	●	○	○	○	○	○	○	○
238916	232636	SC	XD2	M	F	22												○
254513	254513	SC	VIP	N	F	64												○
340815	340815	SC	S	N	F	35												○
498209	498209	EX	P	M	M	43												○
502067	502067	BE	G	N	F	80												○
529927	529927	CI	P	M	F	38												○
565368	565368	SC	VIP	N	F	65												○
656992	656992	BE	P	N	M	7												○
669878	669878	BE	P	M	F	40												○
811000	161096	SC	B		M	41												○

Process Status

SP Observation

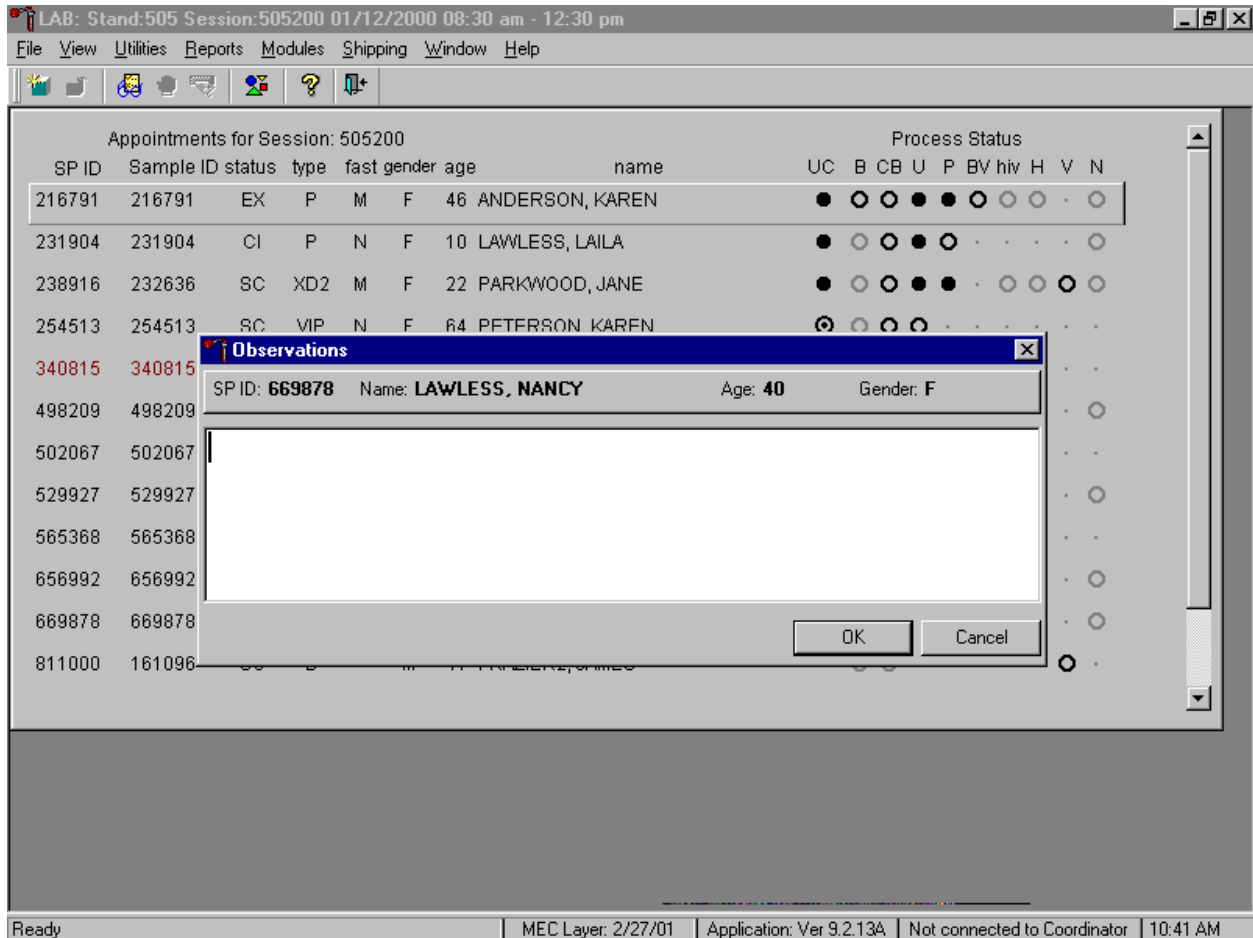
565368	PETERSON, BETH	65
254513	PETERSON, KAREN	64
502067	JAMES, COURTNEY	80
811000	FRAZIER2, JAMES	41
909333	AMIN2, MITUL	51
238916	PARKWOOD, JANE	22
865168	LAWLESS, SARA	1
231904	LAWLESS, LAILA	10
656992	LAWLESS, NATHAN	7
669878	LAWLESS, NANCY	40
498209	LAWLESS, STEVE	43

OK Cancel

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:41 AM

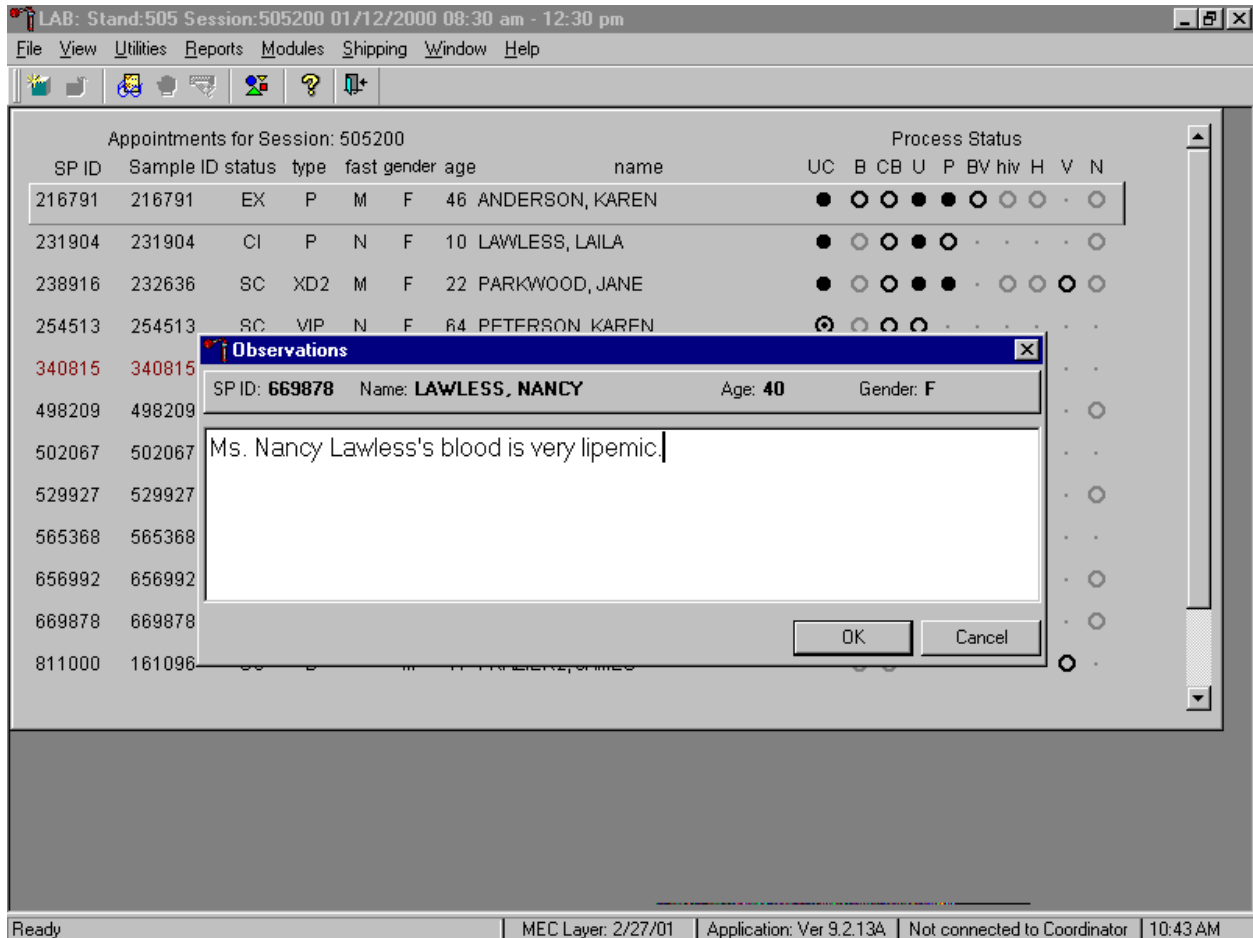
To select or highlight a SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to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

The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard.

Send the observation to the physician.



To send the observation to the physician, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

MAXM parameter codes

Review the message

The Beckman Coulter® MAXM uses triplicate counting with strict voting criteria. It has proprietary flagging algorithms to confirm parameter results before reporting. The instrument may not detect a transient or partial aperture blockage by any of these processes. A partial aperture blockage may cause erroneous results, such as, WBC count lower than what is present. Monitor the aperture-viewing screen when cycling specimens that are likely to contain fibrin or debris.

The MAXM displays abnormal parameter results for all cell populations and values. The following table describes the display and cause for the parameter codes.

Display	Cause
All Parameters	
"●●●●" for a single parameter result	Incomplete or abnormal computation
"●●●●" for all parameter results and PART.ASP message displayed	Sample integrity check failed, short sample or clot
"-----" for CBC parameter results, and no average histogram for the affected parameter If WBC is "-----", then LY#, MO#, NE#, EO# and BA# are "●●●●" If RBC is "-----", then MCH, MCHC, Hct are "-----"	Total voteout (none of the three counts agreed); Diff parameters do not vote out
"*V"	Single-count period voteout; May indicate an erroneous result due to aperture blockage or lack of mixing bubble

"V"	Appears next to parameter derived from the parameter with the single count period voteout
<p>"+++++" for parameter results</p> <p style="text-align: center;">IMPORTANT</p> <p>If the WBC, RBC, Hgb, or Plt result is +++++, run a blank cycle to prevent carryover to the next sample.</p>	<p>Result exceeds:</p> <p style="padding-left: 20px;">WBC $\geq 100.0 \times 10^3$ cells/μL</p> <p style="padding-left: 20px;">RBC $\geq 10.00 \times 10^6$ cells/μL</p> <p style="padding-left: 20px;">Plt $\geq 1000 \times 10^3$ cells/μL</p> <p style="padding-left: 20px;">MCV ≥ 1000</p> <p>If WBC is over range an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, MPV, Plt and Diff % results. Results for Diff% are dots (.....).</p> <p>If RBC is over range an R appears next to Hct, MCH, and MCHC results.</p> <p>If Hgb is over range an R appears next to MCH, and MCHC results.</p> <p>If MCV is over range an R appears next to Hct, MCHC, and RDW results.</p> <p>If Plt is over range an R appears next to WBC, Hgb, MCH, MCHC, diff# and Pct results.</p> <p>Data Base Query displays average values for over range WBC, RBC, or Plt. [F3] Results or [F3] Edit, beneath the definitive flag section. These values are for review only; do not report them.</p>
	<p style="text-align: center;">IMPORTANT</p> <p>Sample dilution may result in erroneous differential results.</p> <p>Set DIFF to OFF before cycling the diluted sample when WBC is over range.</p>

"???" for Diff results	Questionable data
Plt Parameter	
"R" next to Plt and MPV result	PDW >20% mode not between 3 and 15 fL, or non-positive curve detected, or Plt <20,000, or Total voteout of fitted curve, or WBC is over range.
RBC Parameters	
"R" next to RDW result	Excessive asymmetry in RBC histogram, or WBC or MCV over range.
"*R" next to MCV; also "R" next to RBC, Hct, MCH, MCH, RDW, Plt, and MPV	MCV below lower limit of <50 fL
WBC Parameters	
"*R" next to WBC; also "R" next to Diff numbers	Check of WBC lower threshold failed. Particles are present at the 35 fL threshold (Plt clump, giant Plt, nrbc, lyse resistant RBC, malarial parasites)
"R" next to Diff percentages and numbers	Low differential count statistics. These messages occur also: Population message: ABNORMAL WBC POP Suspect message: REVIEW SLIDE
":::" for Diff results	System detects a clog in the flow cell. There are three types of clogs: FC = Full Clog PC1 = Partial Clog 1 (partial clog in the flow cell or sample line) PC2 = Partial Clog 2 (partial clog in the sheath system)

Remedial action

Review the result for the affected parameter. Rerun the specimen if any of the parameter flags occurs.

MAXM 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.

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.

Limitations of Method: Specimen Rejection, Interfering Substances and Conditions

This method limits samples to human whole blood.

Specimen rejection

Reject clotted specimens and recollect.

Interfering Substances and Conditions

Since the Coulter directly measures RBC, WBC, Hgb, and Diff % it is most important to concentrate on analytes and substances that interfere with these parameters. The Coulter calculates HCT, MCH, MCHC, and DIFF # parameters. The Coulter derives MCV, RDW, PLT, and MPV from RBC or platelet histograms. The following are possible interfering substances or conditions:

- Abnormal BUN, glucose or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC count could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate CBC result carefully and report all parameters except the hemoglobin result
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

Reference Ranges

Males

Age in Years	1-5	6-18	19-65	66+
Test				
WBC (x 10 ³ µL)	4.3-14.1	3.7-11.9	3.9-12.1	3.9-12.3
RBC (x 10 ⁶ µL)	4.00 - 5.30	4.10-5.60	4.10-5.80	4.00-5.60
Hgb (g/dL)	10.5-13.7	11.5-16.3	12.7-17.1	11.0-16.8
HCT (%)	31.8-40.8	34.4-48.3	38.0-50.3	33.1-50.2
MCV (fL)	67.6-88.2	74.3-93.0	78.1-99.2	78.9-101.4
MCH (pg)	21.7-29.8	24.3-31.7	25.7-33.8	25.6-34.4
MCHC (g/dL)	31.5-35.0	31.9-35.1	32.0-35.3	31.8-35.1
RDW (%)	11.7-16.5	11.7-14.3	11.8-15.3	12.1-16.6
Plt (x 10 ³ µL)	224-568	194-477	157-414	138-407
MPV (fL)	6.3-9.3	6.6-9.9	6.8-10.4	6.7-10.6
LY (%)	24.5-70.0	20.0-56.6	17.8-51.8	13.0-48.3
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.4-70.5	33.2-74.7	39.7-77.3	44.7-81.9
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

Females

Age in Years	1-5	6-18	19-65	66+
Test				
WBC (x 10 ³ μL)	4.2-13.6	4.0-12.4	3.9-12.5	4.0-12.3
RBC (x 10 ⁶ μL)	3.90 - 5.20	3.90-5.20	3.70-5.20	3.50-5.20
Hgb (g/dL)	10.5-13.7	11.1-14.7	10.4-15.2	10.5-15.5
HCT (%)	32.0-40.6	33.4-43.4	32.0-45.0	32.0-46.0
MCV (fL)	69.0-88.6	74.5-93.9	73.4-98.3	79.7-100.2
MCH (pg)	22.3-30.1	24.2-31.8	23.2-33.3	25.9-33.8
MCHC (g/dL)	31.8-35.1	31.7-35.0	31.4-35.1	31.6-35.0
RDW (%)	11.4-15.4	11.6-14.8	11.8-16.6	12.0-16.1
Plt (x 10 ³ μL)	229-581	202-476	172-453	147-440
MPV (fL)	6.3-9.2	6.7-10.0	6.9-10.7	6.8-10.8
LY (%)	24.9-70.5	18.7-58.5	17.8-52.8	15.7-51.1
MONO (%)	0-12	0-12	0-12	0-13
NE (%)	21.3-69.3	32.9-77.2	39.6-77.8	42.0-79.8
EO (%)	0-10	0-11	0-8	0-8
BA (%)	0-2	0-2	0-2	0-2

Reference ranges for normal values were calculated from NHANES III data set using 95% reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

Action Limits

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

- WBC male and female (all ages) < or = to 3 x 10³ μL or > or = to 16.0 x 10³ μL
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL
- Hgb female (>6 years) <6.5 g/dL or >16.0 g/dL
- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL
- PLT male and female (all ages) <50 x 10³ μL or >800 x 10³ μL

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

Specimen Storage and Handling during Testing

Specimen storage

Store specimens capped and place on a rocker at room temperature until processed.

Run within 24 hours of drawing.

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.

Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are automatically brought to the physician's attention for a decision as to "course-to-follow."

Specimen Accountability and Tracking

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

Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 5C® Cell control results for bias and maintain results for the entire study period. Compare all three instruments CAP proficiency results.

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8. BLOOD AND HIV URINE PROCESSING AND STORAGE

8.1 Introduction

The purpose of blood specimen processing and storage is to process and allocate blood to storage vessels for transport to laboratories that conduct analysis of samples or store the specimens for future research. Processing includes centrifuging and storing blood collection tubes, aliquoting whole blood to storage vessels, centrifuging, separating, and aliquoting plasma and serum to storage vessels, performing a dilution, and storing the specimens.

Process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for primary SPs aged 18-49) and the SP has not refused the HIV test.

8.2 Equipment and Supplies

The blood processing area includes two under-counter refrigerators, four under-counter freezers, two refrigerated centrifuges, two data terminals, a laminar flow hood, and two specimen rockers. This area also includes counter space for processing blood. Store extra supplies for processing in cabinets and the trailer compartments.

Exhibit 8-1. Non-consumable supplies for blood processing

Blood processing template (12+)	Blood processing template (1-2/3-5/6-11)
One Eppendorf pipette 100-5000 μ L	Two Eppendorf pipette 50-1000 μ L
One Eppendorf pipette 5-100 μ	Pipette charging stand
One pipette battery	50-mL graduated cylinder
Nalge 13mm half rack	Nalge 16mm half rack
Nalge 16mm full rack	Bottled distilled water
Cube rack – 4 way flipper rack	Styrofoam rack

Exhibit 8-2. Consumable supplies for blood processing

Ascorbic acid 0.5 gm per vessel	Wooden applicator sticks
Cotton swabs	Eight gallon biohazard sharps container
Biohazard bags 25 x 35	Biohazard bags 19 x 23
Kimwipes	Bench Kote paper
Pipette tips 1000 µL	Pipette tips 200 µL
Pipette tips 5-mL	Lab marker – fine
5-mL cryovial sterile	14-mL snap cap test tube
Conical tube 50-mL	2-mL cryovial sterile
2-mL cryovial non-sterile	Caps for 2-mL cryovial
Serum filters 13mm x 4 inches	Serum filters 16mm x 6 inches
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 cardboard box with 9 x 9 cardboard grid
5.25 x 5.25 x 3.0 inch cardboard box without grid	Three inch 5 x 5 cardboard grid
5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert	Nonsterile, powder-free, latex (non-latex for use by latex allergic staff) gloves -- small, medium, large

8.3 Protocols

Exhibits 8-3 through 8-5 illustrate the primary SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-3. Primary SP's whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	1-11 12+	0.3 0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	3+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1-5 16-49 women	0.5 1.0	Whole blood	EDTA	2-mL	
6	CD4	18-49	0.5	Whole blood	EDTA	2-mL	

Exhibit 8-4. Primary SP's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
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7	Homocys/MMA	3+	1.0	Plasma	EDTA	2-mL	Plasma must be off the cells within 30 minutes.
8	Xtra Plasma	6+	0.5	Plasma	EDTA	2-mL	
9	Glucose	12+	0.5	Plasma	Gray	2-mL	Morning SPs only.
10	Fibrin	40+	1.0	Plasma	Blue	2-mL	

Exhibit 8-5. Primary SP's serum, clot, and ACD processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	1-2 3+	1.3 1.2	Serum	Red	2-mL	
68	Ferritin	1+	0.3	Serum	Red	2-mL	
12	Fol/B12	3-5 6+	0.8 1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	3+	0.5	Serum	Red	2-mL	
14	Hepatitis	2-5 6+	0.2 1.5	Serum	Red	2-mL	
15	Vit A/E/Car	3-11 12+	0.3 0.4	Serum	Red	2-mL	
16	Rub/Mea/Var	6-49	0.4	Serum	Red	2-mL	
17	Cotinine	3-11 12+	1.5 2.0	Serum	Red	2-mL	
18	Biochem	12+	0.8	Serum	Red	2-mL	
19	Bn Alk Phos	8+	0.5	Serum	Red	2-mL	
20	Crypto	6-11 12-49	0.2 0.5	Serum	Red	2-mL	
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	Serum	Red	2-mL	
22	HIV	18-49	0.5	Serum	Red	2-mL	
23	Insul/Cpep	12+	1.0	Serum	Red	2-mL	Morning SPs only.
24	HSV	14-49	0.5	Serum	Red	2-mL	
74	Syphilis	18-49	0.5	Serum	Red	2-mL	
75	PSA	40+ Males	1.0	Serum	Red	2-mL	
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	
26	Selenium	3-11	0.3	Serum	Red	2-mL	
27	Latex	12-59	0.5	Serum	Red	2-mL	
28	TSH/Thyrox	12+	1.0	Serum	Red	2-mL	
70	Vitamin D	6+	0.5	Serum	Red	2-mL	

Exhibit 8-5. Primary SP's serum, clot, and ACD processing protocol (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
64	Phytoestro	12+	4.0	Serum	10-mL Red	5-mL	Process separately. Decant this aliquot.
32	Xtra Sera	6+	0.5	Serum	Red	2-mL	
33	Xtra Sera	6+	0.5	Serum	Red	2-mL	
34	Xtra Sera	6+	0.5	Serum	Red	2-mL	
35	Xtra Sera	12+	0.5	Serum	Red	2-mL	
36	Xtra Sera	12+	0.5	Serum	Red	2-mL	
37	Xtra Sera	12+	0.5	Serum	Red	2-mL	
38	Xtra Sera	12+	0.5	Serum	Red	2-mL	
39	Xtra Sera	12+	0.5	Serum	Red	2-mL	
40	Xtra Sera	12+	0.5	Serum	Red	2-mL	
41	Xtra Sera	12+	0.5	Serum	Red	2-mL	
42	Xtra Sera	12+	0.5	Serum	Red	2-mL	
43	DNA	20+	17.0	Clot	One 15-mL Red	14-mL	
44	WBC/DNA	20+	Whole blood	ACD tube	8-mL ACD	8-mL	
71	WBC/DNA	20+	Whole blood	ACD tube	8-mL ACD	8-mL	

Exhibits 8-6 through 8-8 illustrate the home exam SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-6. Home exam blood whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	50+	0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	50+	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	50+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	50+	0.4	Whole blood	EDTA	2-mL	

Exhibit 8-7. Home exam plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
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7	Homocys/MMA	50+	1.0	Plasma	EDTA	2-mL	Tube must be kept at 4-8°C.
10	Fibrin	50+	1.0	Plasma	Blue	2-mL	

Exhibit 8-8. Home exam serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	50+	1.2	Serum	Red	2-mL	
68	Ferritin	50+	0.3	Serum	Red	2-mL	
12	Fol/B12	50+	1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	50+	0.5	Serum	Red	2-mL	
14	Hepatitis	50+	1.5	Serum	Red	2-mL	
15	Vit A/E/Car	50+	0.4	Serum	Red	2-mL	
18	Biochem	50+	0.8	Serum	Red	2-mL	
21	Lipids	50+	2.0	Serum	Red	2-mL	

Exhibits 8-9 through 8-11 illustrate the second exam SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-9. Second exam SP's whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	12-69	0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	12-69	0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	12-69	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12-69	0.4	Whole blood	EDTA	2-mL	

Exhibit 8-10. Second exam SP's plasma processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
7	Homocys/MMA	12-69	1.0	Plasma	EDTA	2-mL	Plasma must be off the cells within 30 minutes.
9	Glucose	12-69	0.5	Plasma	Gray	2-mL	Morning SPs only.
10	Fibrin	12-69	1.0	Plasma	Blue	2-mL	

Exhibit 8-11. Second exam SP's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	12-69	1.2	Serum	Red	2-mL	
68	Ferritin	12-69	0.3	Serum	Red	2-mL	
12	Fol/B12	12-69	1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
13	CRP/Hpylori	12-69	0.5	Serum	Red	2-mL	
15	Vit A/E/Car	12-69	0.4	Serum	Red	2-mL	
16	Rub/Mea/Var	12-49	0.4	Serum	Red	2-mL	
17	Cotinine	12-69	2.0	Serum	Red	2-mL	
18	Biochem	12-69	0.8	Serum	Red	2-mL	
19	Bn Alk Phos	12-69	0.5	Serum	Red	2-mL	
21	Lipids	12-69	2.0	Serum	Red	2-mL	
23	Insul/Cpep	12-69	1.0	Serum	Red	2-mL	Morning SPs only.
75	PSA	40+ Males	1.0	Serum	Red	2-mL	
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	
27	Latex	12-59	0.5	Serum	Red	2-mL	
70	Vitamin D	12-69	0.5	Serum	Red	2-mL	

Exhibits 8-12 through 8-14 illustrate the VIP guest's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-12. VIP guest's blood whole blood processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	Whole blood	EDTA	2-mL	
2	Ery Proto	1-11 12+	0.3 0.4	Whole blood	EDTA	2-mL	
3	RBC Folate	3+	0.1	Whole blood	EDTA	2-mL	
4	Glycohem	12+	0.4	Whole blood	EDTA	2-mL	
5	Mercury	1-5 16-49 women	0.5 1.0	Whole blood	EDTA	2-mL	

Exhibit 8-13. VIP guest's plasma processing protocol

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

Exhibit 8-14. VIP guest's serum processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
11	Iron/TIBC	1-2 3+	1.3 1.2	Serum	Red	2-mL	
68	Ferritin	1+	0.3	Serum	Red	2-mL	
12	Fol/B12	3-5 6+	0.8 1.3	Serum	Red	2-mL	Do not allow protracted exposure to sunlight, which degrades Folate.
15	Vit A/E/Car	3-11 12+	0.3 0.4	Serum	Red	2-mL	
18	Biochem	12+	0.8	Serum	Red	2-mL	
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	Serum	Red	2-mL	
23	Insul/Cpep	12+	1.0	Serum	Red	2-mL	Morning SPs only.
25	FSH/LH	35-60 Females	0.8	Serum	Red	2-mL	

Exhibit 8-15 illustrates the guest and surplus protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-15. Guest and surplus serum processing protocol

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

8.4 Labeling Vessels

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

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

- Styrofoam rack
- Age appropriate processing template
- Storage vessels of the following sizes
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, person type, and subsample selection. When possible, prepare the racks at least one day before the SP arrives for the MEC examination.

Before each session, the technologist at workstation 3 prints all labels for all SPs, distributes the labels and labels the blood processing racks. The correct bar-coded labels automatically print for each SP based on the SP's age, sex, person type, and subsample selection.

While the technologist assigned to shipping is responsible for labeling the vessels and setting up the blood processing racks, it is the blood-processing technologist's responsibility to verify that each vessel has the correct label before filling. Do not rely only upon memory or the positioning of the vessels in a rack to indicate which vessels to fill. Always double check:

- The SP's ID number on the bar-coded label
- The vessel number on the label
- The adhesion quality of the labels
- That specimens are not missing labels or incorrectly labeled

Save and recycle unused vessels:

- If the SP does not show up for the appointment, it is possible they will reschedule
- Store the SPs labels in a zip closable bag until the end of the stand
- If the SP has not shown up by the end of the stand, recycle the unused vessels

8.5 Blood Processing Age Specific Protocols

Exhibits 8-16 through 8-19 illustrate the blood processing vessels for each primary SP.

Exhibit 8-16. Blood processing protocol for primary SPs age 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	1-2	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	1-2	0.3	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	1-2	1.3	Serum	3-mL Red	2-mL
68	Ferritin	1-2	0.3	Serum	3-mL Red	2-mL
14	Hepatitis	2	0.2	Serum	3-mL Red	2-mL

Exhibit 8-17. Blood processing protocol for primary SPs age 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.5	Whole blood	5-mL EDTA	2-mL
7	Homocys/MMA	3-5	1.0	Plasma	5-mL EDTA	2-mL
11	Iron/TIBC	3-5	1.2	Serum	7-mL Red	2-mL
68	Ferritin	3-5	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	3-5	0.8	Serum	7-mL Red	2-mL
13	CRP/Hpylori	3-5	0.5	Serum	7-mL Red	2-mL
14	Hepatitis	3-5	0.2	Serum	7-mL Red	2-mL
15	Vit A/E/Car	3-5	0.3	Serum	7-mL Red	2-mL
17	Cotinine	3-5	1.5	Serum	7-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	7-mL Red	2-mL
26	Selenium	3-5	0.3	Serum	7-mL Red	2-mL

Exhibit 8-18. Blood processing protocol for primary SPs age 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	6-11	0.6	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	6-11	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
7	Homocys/MMA	6-11	1.0	Plasma	5-mL EDTA	2-mL
8	Xtra Plasma	6-11	0.5	Plasma	5-mL EDTA	2-mL
11	Iron/TIBC	6-11	1.2	Serum	15-mL Red	2-mL
68	Ferritin	6-11	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	6-11	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	6-11	0.5	Serum	15-mL Red	2-mL
14	Hepatitis	6-11	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	6-11	0.3	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	6-11	0.4	Serum	15-mL Red	2-mL
17	Cotinine	6-11	1.5	Serum	15-mL Red	2-mL
19	Bn Alk Phos	8-11	0.5	Serum	15-mL Red	2-mL
20	Crypto	6-11	0.2	Serum	15-mL Red	2-mL
21	Lipids	6-11	1.5	Serum	15-mL Red	2-mL
26	Selenium	6-11	0.3	Serum	15-mL Red	2-mL
70	Vitamin D	6-11	0.5	Serum	15-mL Red	2-mL
32	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL
33	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL
34	Xtra Sera	6-11	0.5	Serum	15-mL Red	2-mL

Exhibit 8-19. Blood processing protocol for primary SPs age 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
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1	Lead/Cad	12+	0.5	Whole blood	First 5-mL EDTA	2-mL
2	Ery Proto	12+	0.4	Whole blood	First 5-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	First 5-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	First 5-mL EDTA	2-mL
5	Mercury (females)	16-49	1.0	Whole blood	First 5-mL EDTA	2-mL
6	CD4	18-49	0.5	Whole blood	First 5-mL EDTA	2-mL
7	Homocys/MMA	12+	1.0	Plasma	Second 5-mL EDTA	2-mL
8	Xtra Plasma	12+	0.5	Plasma	Second 5-mL EDTA	2-mL
9	Glucose (morning only)	12+	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	40+	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	12+	1.2	Serum	15-mL Red	2-mL
68	Ferritin	12+	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12+	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	12+	0.5	Serum	15-mL Red	2-mL
14	Hepatitis	12+	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12+	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	12-49	0.4	Serum	15-mL Red	2-mL
17	Cotinine	12+	2.0	Serum	15-mL Red	2-mL
18	Biochem	12+	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	12+	0.5	Serum	15-mL Red	2-mL
20	Crypto	12-49	0.5	Serum	15-mL Red	2-mL
21	Lipids	12+	2.0	Serum	15-mL Red	2-mL
22	HIV	18-49	0.5	Serum	15-mL Red	2-mL
23	Insul/Cpep (morning only)	12+	1.0	Serum	15-mL Red	2-mL
24	HSV	14-49	0.5	Serum	15-mL Red	2-mL
74	Syphilis	18-49	0.5	Serum	15-mL Red	2-mL
75	PSA (males)	40+	1.0	Serum	15-mL Red	2-mL
25	FSH/LH (females)	35-60	0.8	Serum	15-mL Red	2-mL
27	Latex	12-59	0.5	Serum	15-mL Red	2-mL
28	TSH/Thyrox	12+	1.0	Serum	15-mL Red	2-mL
70	Vitamin D	12+	0.5	Serum	15-mL Red	2-mL
29	Persis Pest	12+	4.0	Serum	10-mL Red	5-mL
64	Phytoestro	12+	4.0	Serum	10-mL Red	2-mL
32	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
33	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
34	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
35	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
36	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
37	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
38	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
39	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL

Exhibit 8-19. Blood processing protocol for primary SPs age 12+ years (continued)

40	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
41	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
42	Xtra Sera	12+	0.5	Serum	15-mL Red	2-mL
43	DNA	20+	One	Clot	15-mL Red	14-mL
44	WBC/DNA	20+	ACD	Whole blood	8-mL ACD	8-mL ACD
71	WBC/DNA	20+	ACD	Whole blood	8-mL ACD	8-mL ACD

Exhibit 8-20 illustrates blood-processing vessels for each home exam SP.

Exhibit 8-20. Blood processing protocol for home exam age 50+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	50+	0.5	Whole blood	First 5-mL EDTA	2-mL
2	Ery Proto	50+	0.4	Whole blood	First 5-mL EDTA	2-mL
3	RBC Folate	50+	0.1	Whole blood	First 5-mL EDTA	2-mL
4	Glycohem	50+	0.4	Whole blood	First 5-mL EDTA	2-mL
7	Homocys/MMA	50+	1.0	Plasma	Second 5-mL EDTA	2-mL
10	Fibrin	50+	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	50+	1.2	Serum	7-mL Red	2-mL
68	Ferritin	50+	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	50+	1.3	Serum	7-mL Red	2-mL
13	CRP/Hpylori	50+	0.5	Serum	7-mL Red	2-mL
14	Hepatitis	50+	1.5	Serum	7-mL Red	2-mL
15	Vit A/E/Car	50+	0.4	Serum	7-mL Red	2-mL
18	Biochem	50+	0.8	Serum	7-mL Red	2-mL
21	Lipids	50+	2.0	Serum	7-mL Red	2-mL

Exhibit 8-21 illustrates the blood processing vessels for each second exam SP.

Exhibit 8-21. Blood processing protocol for second exam SPs age 12-69 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	12-69	0.5	Whole blood	5-mL EDTA	2-mL
2	Ery Proto	12-69	0.4	Whole blood	5-mL EDTA	2-mL
3	RBC Folate	12-69	0.1	Whole blood	5-mL EDTA	2-mL
4	Glycohem	12-69	0.4	Whole blood	5-mL EDTA	2-mL
7	Homocys/MMA	12-69	1.0	Plasma	Second 5-mL EDTA	2-mL
9	Glucose (morning only)	12-69	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	40-69	1.0	Plasma	3-mL Blue	2-mL
11	Iron/TIBC	12-69	1.2	Serum	15-mL Red	2-mL

Exhibit 8-21. Blood processing protocol for second exam SPs age 12-69 years (continued)

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
68	Ferritin	12-69	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12-69	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	12-69	0.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12-69	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	12-49	0.4	Serum	15-mL Red	2-mL
17	Cotinine	12-69	2.0	Serum	15-mL Red	2-mL
18	Biochem	12-69	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	12-69	0.5	Serum	15-mL Red	2-mL
21	Lipids	12-69	2.0	Serum	15-mL Red	2-mL
23	Insul/Cpep (morning only)	12-69	1.0	Serum	15-mL Red	2-mL
75	PSA (males)	40-69	1.0	Serum	15-mL Red	2-mL
25	FSH/LH (females)	35-60	0.8	Serum	15-mL Red	2-mL
27	Latex	12-59	0.5	Serum	15-mL Red	2-mL
70	Vitamin D	12-69	0.5	Serum	15-mL Red	2-mL

Exhibits 8-22 through 8-25 illustrate the blood processing vessels for each VIP guest.

Exhibit 8-22. Blood processing protocol for VIP guest age 1-2 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	1-2	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	1-2	0.3	Whole blood	3-mL EDTA	2-mL
5	Mercury	1-2	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	1-2	1.3	Serum	3-mL Red	2-mL
68	Ferritin	1-2	0.3	Serum	3-mL Red	2-mL

Exhibit 8-23. Blood processing protocol for VIP guest age 3-5 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	3-5	0.3	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	3-5	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	3-5	0.1	Whole blood	3-mL EDTA	2-mL
5	Mercury	3-5	0.5	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	3-5	1.2	Serum	7-mL Red	2-mL
68	Ferritin	3-5	0.3	Serum	7-mL Red	2-mL
12	Fol/B12	3-5	0.8	Serum	7-mL Red	2-mL
15	Vit A/E/Car	3-5	0.3	Serum	7-mL Red	2-mL
21	Lipids	3-5	0.2	Serum	7-mL Red	2-mL

Exhibit 8-24. Blood processing protocol for VIP guest age 6-11 years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	6-11	0.6	Whole blood	3-mL EDTA	2-mL
2	Ery Proto	6-11	0.3	Whole blood	3-mL EDTA	2-mL
3	RBC Folate	6-11	0.1	Whole blood	3-mL EDTA	2-mL
11	Iron/TIBC	6-11	1.2	Serum	15-mL Red	2-mL
68	Ferritin	6-11	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	6-11	1.3	Serum	15-mL Red	2-mL
15	Vit A/E/Car	6-11	0.3	Serum	15-mL Red	2-mL
21	Lipids	6-11	1.5	Serum	15-mL Red	2-mL

Exhibit 8-25. Blood processing protocol for VIP guest age 12+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	12+	0.5	Whole blood	5-mL EDTA	2-mL
2	Ery Proto	12+	0.4	Whole blood	5-mL EDTA	2-mL
3	RBC Folate	12+	0.1	Whole blood	5-mL EDTA	2-mL
4	Glycohem	12+	0.4	Whole blood	5-mL EDTA	2-mL
5	Mercury	16-49	1.0	Whole blood	5-mL EDTA	2-mL
9	Glucose (morning only)	12+	0.5	Plasma	3-mL Gray	2-mL
11	Iron/TIBC	12+	1.2	Serum	15-mL Red	2-mL
68	Ferritin	12+	0.3	Serum	15-mL Red	2-mL
12	Fol/B12	12+	1.3	Serum	15-mL Red	2-mL
15	Vit A/E/Car	12+	0.4	Serum	15-mL Red	2-mL
18	Biochem	12+	0.8	Serum	15-mL Red	2-mL
21	Lipids	12+	2.0	Serum	15-mL Red	2-mL
25	FSH/LH (females)	35-60	0.8	Serum	15-mL Red	2-mL

Exhibit 8-26 illustrates the blood-processing vessel for each guest and surplus.

Exhibit 8-26. Blood processing protocol for guest and surplus age 1+ years

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type
18	Biochem	12+	0.8	Serum	3-mL Red	2-mL

8.6 Equipment

8.6.1 Benchtop Centrifuges

Each laboratory contains two benchtop refrigerated Beckman GS-6R centrifuges.

The centrifuge has the following safety features:

- An imbalance detector triggers an automatic shutdown if rotor loads are severely out of balance.
- A safety-lock mechanism and secondary manual latch prohibit opening the centrifuge door during a run until the rotor is virtually stopped.
- A lockout system requires the door to be closed and latched before the centrifuge will start.
- An anchoring system secures the centrifuge in place. Anchoring systems reduce the possibility of injury or damage that could result from centrifuge movement in case of a major rotor mishap.

The control panel is mounted at an angle on the centrifuge front for easy visibility and access. The control panel has the following features:

- Power - This rocker switch, labeled I (ON), and O (OFF), controls electrical power to the centrifuge. The chamber door cannot be opened unless the power is turned ON.
- Door - When pressed to the OPEN position, this switch releases the latch mechanism and allows the door to be opened when the secondary manual latch lever is switched to UNLOCK (the rotor must be stopped and the power switched on).
- Brake - Use this switch to select the brake mode used during deceleration. Set the position to HIGH or LOW. The HIGH break position activates the dynamic and the electromechanical disk breaking. Dynamic breaking starts immediately after the timer turns the rotor off. At 1600 rpm the disk break engages, and remains on until the speed reaches 400 rpm, followed by dynamic breaking alone to 50 RPM. At 50 rpm, all breaking stops and the rotor coasts to a stop.
- Time - This knob may be set for any run time between 2 and 30 minutes in 1-minute increments. During a run, the timer rotates back to zero, at which point the centrifuge begins deceleration. A HOLD setting enables longer-duration runs - the centrifuge will

run until turned off. Stop runs at any time by turning the knob to OFF. Set appropriate time and temperature for each tube as follows:

- | | | | |
|---|--------------------------------|------------|------------------|
| - | 5-mL EDTA | 10 minutes | 4-8°C |
| - | 3-mL gray | 10 minutes | 17-25°C or 4-8°C |
| - | 3-mL blue | 10 minute | 17-25°C or 4-8°C |
| - | 3-mL, 7-mL, 10-mL or 15-mL red | 15 minutes | 17-25°C |
- Speed and ACCU-SET - Use this knob to set the drive speed, in 200-rpm increments, up to 8000 rpm. For precise adjustments, the ACCU-SET button can be pressed as the speed knob is turned until the desired speed appears on the RPM display. ACCU-SET can be adjusted at any time during a run. Set the speed at 2,900 rpm.
 - RPM - During the run, the display indicates the actual rotor speed to the nearest increment of 10 rpm.
 - Temperature - Use this knob to set operating temperature. The dial is marked from -10 to +40°C in 1°C increments. Set the refrigerated centrifuge at 4°C and the room temperature centrifuge at 22°C. The display indicates the temperature (+/-2°C) within the bowl in increments of 1°C.

Run Procedure:

1. Press the POWER to switch to ON.
2. Move the door latch lever to UNLOCK. Press the DOOR switch to OPEN and lift the centrifuge door up; it will remain in the open positions.
3. Load the Aerosolve canisters symmetrically. If only two canisters are being run, place the canisters in opposite buckets; and place two empty buckets for balance in the other two buckets. If only three canisters are required, balance tubes in empty canister across from third canister.
4. Close the centrifuge door and push firmly down on it until hearing a clicking or latching sound. Move the secondary latch lock to LOCK position.
5. Set the TEMPERATURE knob to the required run temperature.
6. Set the run speed using the following procedure:
 - Press the small ACCU-SET button in; rotate the SPEED dial until the required speed shows on the display.
 - While holding the ACCU-SET button in, rotate the SPEED dial until the required speed shows on the display.
 - When the selected speed is displayed, release the ACCU-SET button.
7. Select the HIGH brake position for the EDTA, gray, and blue top tubes and select the LOW brake for the red top tubes.

8. Turn the timer to the required time. The centrifuge will start. As the run begins, acceleration control protects delicate gradients; when the rotor speed reaches about 200 rpm, full acceleration to set speed occurs.
9. To end a run in progress for any reason:
 - Turn the timer knob to OFF. The door interlock system keeps the door latched until the rotor has virtually stopped.
 - After the rotor stops spinning move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
10. After the rotor stops spinning move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
11. After completing a run, unload the canisters.

Leave the door open in order to prevent chamber icing.

8.6.2 Laminar Flow Biological Safety Cabinet Operating Sequence

- Turn on the cabinet blower and lights, check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the magnehelic gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the biomedical engineer. Record the pressure reading and any comments in the Laboratory QC module.
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.
- Disinfect the interior of the workspace by wiping it down with a 1% solution of bleach and water (1:100).
- Place a disposable paper blotter on the work surface. Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange and separate clean and contaminated materials.
- Wait 2-3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all "loose" contamination.
- Wear a long sleeved laboratory coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect hands and arms from viable agent contamination. Wash hands with soap and water before and after working in the cabinet.
- After completing work, leave the blower on for 2-3 minutes to purge the unit.

- Decontaminate interior surfaces after removal of all specimens and biohazard waste by wiping them with a 1% solution of bleach and water (1:100).
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

8.7 Blood Processing Procedures

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 1:100 bleach solution.

Decontaminate racks and template by soaking in 1% bleach solution at the end of each session. Place on blotter to air dry.

8.7.1 Eppendorf Research Pro Pipettes

Pipette whole blood and pooled serum and make dilutions using the Eppendorf Research Pro pipettes. Pipette plasma using plastic transfer pipettes.

The MEC laboratory has 4 Eppendorf Research pro electronic pipettes: one 5-100 μ L, two 50-1000 μ L, and one 100-5000 μ L. The lab also uses 100 μ L and 1000 μ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- ◆ Use the one 5-100 μ L pipette in the standard (PIP) mode and set the volume to 100 μ L. Use this dedicated pipette to aliquot the whole blood for the RBC folate, vessel 3.
- ◆ Use one of the two 50-1000 μ L pipettes in the standard (PIP) mode and set the volume to 1000 μ L. Use this dedicated pipette to aliquot the ascorbic acid for RBC folate, vessel 3.
- ◆ Use the second 50-1000 μ L pipette in the FIX mode. Set the five fixed volumes to 300 μ L, 400 μ L, 500 μ L, 600 μ L, and 1000 μ L. Use this pipette to aliquot all whole blood

tests, except the RBC folate, and pooled serum volumes that match the five volume settings.

- ◆ Use the second 50-1000 μL pipette and the 100-5000 μL pipette in the DIS mode. Set the DIS volume on the 50-1000 μL to 100 μL . Set the DIS volume on the 100-5000 μL to 500 μL . Use these pipettes to aliquot pooled serum.
- ◆ Use the 100-5000 μL pipette in the FIX mode. Set the five fixed volumes to 1000 μL , 2000 μL , 3000 μL , 4000 μL , and 5000 μL . Use this pipette to aliquot pooled serum volumes that match the five volume settings.
- ◆ Use the 100-5000 μL pipette in the ADS mode. Program this mode in slot 2. Set the volume to 500 μL and the interval to 1 second. Use this pipette to aliquot pooled serum.
- ◆ Use the 100-5000 μL pipette in the SD mode. Set the volumes to match the age-specific processing protocols. Set program 1 to match the adult profile for vessels 11-70. Set program 3 to match the child's profile age 1-2. Set program 4 to match the child's profile age 3-5. Set program 5 to match the child's profile age 6-11. Use this pipette to aliquot pooled serum.

Pipette	Tip	Mode	Volume	Matrix
*5-100 μL	200 μL	PIP	100 μL	Whole blood
*50-1000 μL	1000 μL	PIP	1000 μL	Ascorbic acid
50-1000 μL	1000 μL	FIX	300 μL 400 μL 500 μL 600 μL 1000 μL	Whole blood Pooled serum
50-1000 μL	1000 μL	DIS	100 μL	Whole blood Pooled serum

Pipette	Tip	Mode	Volume	Matrix
100-5000 μL	5000 μL	FIX	1000 μL 2000 μL 3000 μL 4000 μL 5000 μL	Pooled serum
100-5000 μL	5000 μL	DIS	500 μL	Pooled serum
<i>100-5000 μL</i>	<i>5000 μL</i>	<i>ADS</i>	<i>500 μL</i> <i>1 second</i>	<i>Pooled serum</i>
<i>100-5000 μL</i>	<i>5000 μL</i>	<i>SD</i>	<i>Program 1 – Adult</i> <i>Program 3 – Child 1-2</i> <i>Program 4 – Child 3-5</i> <i>Program 5 – Child 6-11</i>	<i>Pooled serum</i>

Italic = Pipette's primary program

* Dedicated pipette for Vessel 3 RBC Folate dilution

8.7.1.1 Safety Precautions, Handling, Care and Maintenance, Battery, Technical Data

Before using the Research pro for the first time, please read the entire operating manual.

Observe the following points:

Handling

- ✓ Use the Research pro only when a pipette tip is attached.
- ✓ Do not lay down the Research pro when a filled pipette tip is attached.
- ✓ After liquid has been aspirated, press the Actuate key only when you are sure the liquid shall 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 shall be dispensed correctly.
- ✓ Emergency stop: pressing the Reset key can stop a moving piston.
- ✓ Operate the Research pro at temperatures between 15°C and 40°C. Operate at a maximum humidity of 80% at a temperature up to 31°C.

Care and maintenance

- ✓ Do not clean the display or any of the labeling using acetone or aggressive solutions.
- ✓ Do not allow any liquid to enter the device.

- ✓ Authorized service personnel may carry out repairs only.
- ✓ Use original spare parts and accessories (battery, pipette tips) only.

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 the battery to be exposed to any metallic surfaces.
- ✓ Dispose of used batteries as special waste.
- ✓ Never charge the Research pro without a battery.
- ✓ Before storing the Research pro for a long period, remove the battery.

Technical Data

Single Channel Pipette

Volume Range μL	Step size μL	Color code	Pipette tip	Test volume	Inaccuracy %	Imprecision %
5-100	0.1	Yellow	200 μL	100 μL	± 0.8	≤ 0.2
50-1000	1	Blue	1000 μL	1000 μL	± 0.6	≤ 0.2
100-5000	10	Violet	5-mL	500 μL 5000 μL	± 3.0 ± 0.6	≤ 0.6 ≤ 0.15

The technical data is valid only when the Research pro is used with Eppendorf pipette tips.

Test conditions in accordance with DIN 12650 for piston-stroke pipettes with an air cushion by means of a standardized fine balance with a moisture trap. Number of determination: 10; degassed distilled water, $20^{\circ}\text{C} - 25^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$; maximum speed; standard operation; prewetted pipette tip; dispensing onto inside of tube; due to possible evaporation; check volumes $\leq 10 \mu\text{L}$ immediately after aspiration.

Battery

Nickel-metal hydride battery pack, 1,200 mAh/2.4 V with reversible overcurrent and overtemperature protection. Charging time: approximately 9.5 hours for a fully discharged battery. Overcharging protection is included with the pipette.

Power Unit

Input voltage, country-specific: 230 V \pm 10%, 50/60 Hz; 115 V \pm 10%, 60 Hz; 100 V \pm 10%, 50/60 Hz. Output voltage: 9 V DC; 200 mA (1.8 VA)

Delivery Package

The Research pro 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:

- Charging stand with separate power unit;
- Special tool(s) according to pipette type;
- Operating manual with measuring protocol and CE conformity assurance document; and
- Ni-MH battery pack.

Inserting the battery

Charge the battery in the pipette. Charging may only be carried out 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 two or three complete charging/discharging cycles have been completed.

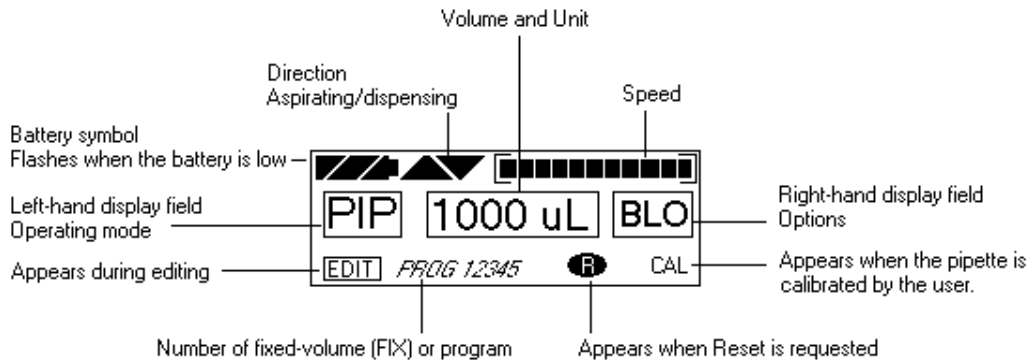
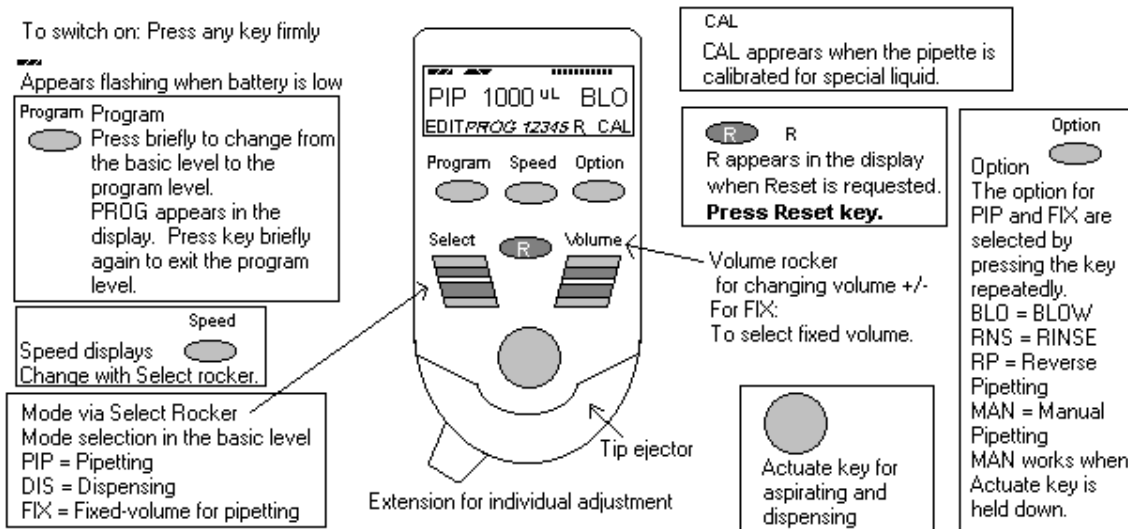
For charging purposes, place the pipette in the charging stand.

During the start and termination of the charging process, "CON" appears briefly on the left-hand side of the display. The display is switched on during the charging process. The battery symbol appears in a rolling form. 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. To increase the charging capacity, the battery should be discharged until the flashing battery symbol appears. To avoid accidental discharge, remove the battery from the Research pro during extended periods of non-use. In this case, all data remains stored.

8.7.1.2 Operating Principle

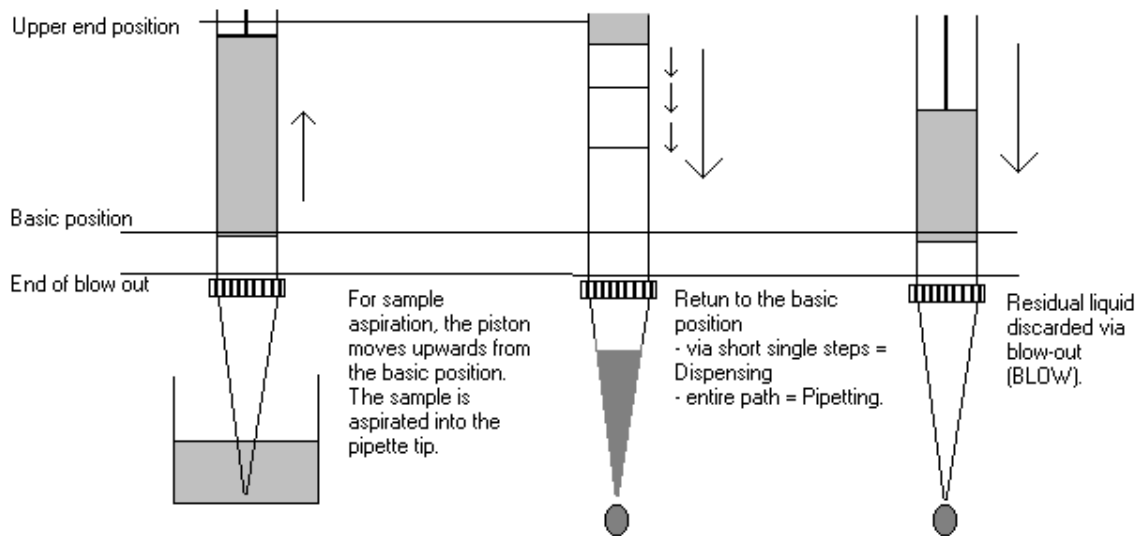
Display and Keypad

- To switch on: Press any key firmly.
- To switch off: It does so automatically after 10 minutes of non-use.



8.7.1.3 Unit's Functions

The Research pro is a microprocessor-controlled pipette, which executes the piston movement with the aid of a stepper motor. The power supply is a rechargeable nickel-metal hydride battery.



Dispensing and Reverse Pipetting require a different basic position than that for Pipetting. *The request to change the basic position is accomplished by selecting the Reset button.*

Ejector with extension

The force translation of the ejector for pipette tips ensures that the tips are ejected very easily. The extension can be individually adjusted to accommodate left- and right-handed users as well as different hand sizes. *Select the desired setting by simply sliding the extension into the position as required.*

Hook on the hand rest

Loosening the screw enables the hook on the rear of the pipette to be adjusted to suit all hand sizes. This can be done easily with a small Phillips screwdriver.

Contact surface on the read of the pipette

Both upper surfaces are required for charging the nickel-metal hydride 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 to acknowledge that the keypad has been pressed.

- Slightly higher tone to indicate that the function for which the key has been pressed cannot be executed.
- Louder tone to indicate that the piston movement has ended.
- Louder tone to indicate that a specific sequence of steps (e.g., dispensing) has ended.
- Louder tone to indicate 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 (see Sec. 5.11).

8.7.1.4 Mode of Operation

If the display of the Research pro is dark, activate the pipette by pressing any key firmly. If the pipette has not been used for a long period, a motor reset is executed after it has been activated.

- Attach an Eppendorf pipette tip to the Research pro. The color-coding of the 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 - and as little as possible into the liquid. Following aspiration, remove the pipette tip from the liquid after the acoustic signal has been emitted. If the air bubbles have been aspirated, repeat this process.
- Never lay the pipette down when the tip is filled.
- To dispense the liquid, position the pipette tip against the side of the aspirating vessel.
- Discard the pipette tip by pressing the Eject key, attach a new tip and reaspirate liquid.

Essential operating information

The following sections contain systematic explanations of the operating procedure. It is essential to work through these sections with the pipette in your hand.

If a Reset is requested in the display, a piston movement always accompanies this Reset request. For this reason, please ensure that any residual liquid in the pipette tip is dispensed beforehand. A Reset can also be used to empty the pipette tip and to end an operating process. If you quit an input field during programming (e.g., changing the speed) using Reset, the changes that have been made are not stored. The Reset button can also act as an emergency stop function.

Reset



Motor
reset

If the Reset key (**R**) is held down until the piston movement begins and R appears in the display, a motor reset is carried out. This motor reset guarantees that the piston movement is correct. This reset lasts for approximately 10 seconds.

Please refer to the following illustrations when going through each operation.

Program



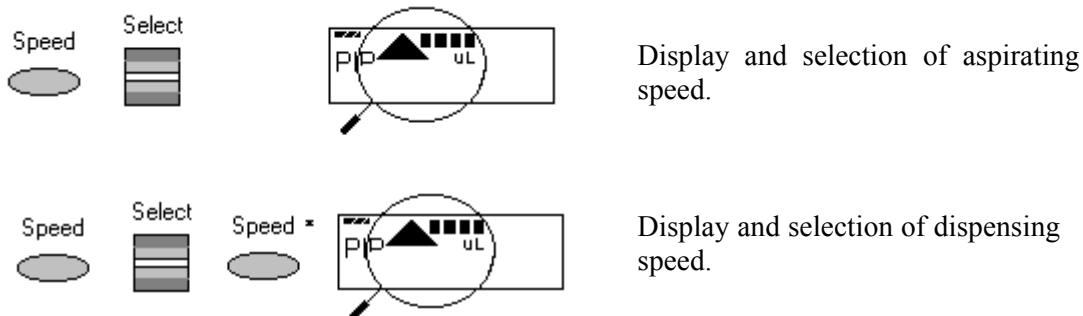
The Research pro has two operating levels. The basic modes for pipetting (PIP and FIX) and (DIS) are accessed in the first level by pressing the Select rocker. **PROG** appears in the display by pressing the "Program" key. You are now in the second level. Using the Select rocker, select from the five available program slots. To quit this level, press the "Program" key briefly and PROG will disappear from the display.



If the piston movements appear in the display without any volumes, this indicates a process that is not connected to liquid aspiration or dispensing.

Aspirating and dispensing speeds

The selected speed can be viewed by pressing the Speed key several times. The speed is changed as follows:



- This procedure does not have to be completed using the Speed key. Any key, with the exception of Reset, may be used. At the same time, pressing the key executes the respective key function.
- The direction of the arrow for speed flashes in this input field.
- The speed can be altered before every dispensing or aspiration.
- Important - High speeds have a much lower current consumption than low speeds.

8.7.1.5 Pipetting in the Standard Mode (PIP) *[use this mode for whole blood RBC folate (5-100 μ L pipette) and ascorbic acid (50-1000 μ L pipette)]*

In the Standard mode, blowout is executed automatically when liquid is dispensed. The standard mode is recommended for rapid series pipetting with aqueous solutions.

Programming - PIP	
Step 1	Select the Pipetting mode "PIP." Use the Select rocker switch to move up and down through the three modes (PIP, DIS, and FIX) until the "PIP" choice appears in the left-hand side of the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i>
Step 2	Select the volume. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 5-100- μ L pipette and 1000 μ L for the 50-1000- μ L pipette is reached. If necessary, press the Option key several times until the right-hand side of the display is blank. (Do not use the BLO, RNS, RP, or MAN options.)
Pipetting Procedure	
Step 1	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip.
Step 2	Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button.
Step 3	The pipette is ready to aspirate again if the Aspirating arrow in the display points up.

8.7.1.6 Pipetting with a Preselected Fixed (FIX) Volume *(use this mode for aliquoting whole blood volumes 300, 400, 500, 600, and 1000 μ L - 50-1000 μ L pipette and for pipetting pooled serum volumes 1000, 2000, 3000, 4000, and 5,000 μ L - 100-5000 μ L pipette)*

FIX is used to rapidly set and recall five frequently used pipette volumes. Five FIX volumes are predefined in the pipette. FIX volumes can be changed via programming.

Programming FIX fixed volumes

Step 1	Select the Pipetting mode "FIX." Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the "FIX" choice appears in the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i>
Step 2	Hold down the Program key until EDIT appears in the lower left hand corner of the display. The volume flashes.
Step 3	Select the first memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #1 is displayed.
Step 4	Select the volume for memory slot #1. Use the Volume rocker to move the number (volume) up and down until the number (volume) 300 μ L for the 5-1000- μ L pipette or 1000 μ L for the 100-5000 μ L pipette is reached.
Step 5	Select the next (second) memory slot for purposes of changing the volume. Select the second memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #2 is displayed.
Step 6	Select the volume for memory slot #2. Use the Volume rocker to move the number (volume) up and down until the number (volume) 400 μ L for the 5-1000- μ L pipette or 2000 μ L for the 100-5000 μ L pipette is reached.
Step 7	Select the next (third) memory slot for purposes of changing the volume. Select the third memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #3 is displayed.
Step 8	Select the volume for memory slot #3. Use the Volume rocker to move the number (volume) up and down until the number (volume) 500 μ L for the 5-1000- μ L pipette or 3000 μ L for the 100-5000 μ L pipette is reached.
Step 9	Select the next (fourth) memory slot for purposes of changing the volume. Select the fourth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #4 is displayed.
Step 10	Select the volume for memory slot #4. Use the Volume rocker to move the number (volume) up and down until the number (volume)

	600 μL for the 5-1000- μL pipette or 4000 μL for the 100-5000 μL pipette is reached.
Step 11	Select the next (fifth) memory slot for purposes of changing the volume. Select the fifth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #5 is displayed.
Step 12	Select the volume for memory slot #5. Use the Volume rocker to move the number (volume) up and down until the number (volume) 1000 μL for the 5-1000- μL pipette or 5000 μL for the 100-5000 μL pipette is reached.
Step 13	End the programming. Press the Program key to stop programming. Alternatively, to stop programming and aspirate the volume of liquid in the display, press the Aspirate button. EDIT and the flashing volume disappear from the display.
Pipetting Procedure	
Step 1	Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until FIX displays.
Step 2	Select one of the 5 programmed fixed volumes. Select the correct memory slot. Use the Volume rocker to move the volume number up and down until the correct choice displays.
Step 3	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip.
Step 4	Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button.
Step 5	The pipette is ready to aspirate again if the Aspirating arrow in the display points up.

8.7.1.7 Dispensing (DIS) (use this mode to pipette 100 μL whole blood and/or pooled serum - 50-1000 μL pipette and 500 μL pooled serum 100-5000 μL pipette)

During this procedure, the aspirating liquid is dispensed in partial steps. As with "Reverse Pipetting," slightly more liquid is aspirated than is necessary for the sum of the dispensing steps. The maximum number of dispensing steps per filling of the pipette tip is displayed in the right hand side of the display. The maximum number of dispensing steps is calculated by the pipette and is based on the dispensing volume and the pipette tip. For example, if the dispensing volume is set at 100 μL and the pipette tip is 1000 μL then there are 10 dispensing steps. If the dispensing volume is set at 500 μL and the pipette tip is 5000 μL , then there are also 10 dispensing steps.

Programming DIS	
Step 1	Select the Pipetting mode "DIS." Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the "DIS" choice appears in the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i>
Step 2	Select the volume per dispensing step. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 50-1000- μL pipette or 500 μL for the 100-5000 μL pipette is reached.
Step 3	Select the aspirating speed using the Speed key and the Select rocker. Press the Speed key then use the Select rocker to move the speed indicator all the way to the right. When finished, press the Speed key. The pipette is ready for entry of the dispensing speed.
Step 4	Select the dispensing speed. Use the Select rocker to move the speed indicator all the way to the right. Press the Speed key to exit.
Pipetting Procedure	
Step 1	Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until DIS displays.
Step 2	Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip. (If R appears in the display: Press the R key briefly.)
Step 3	Place the pipette tip against the side of the first receiving vessel. Make sure the Dispensing arrow in the display points down. To

	dispense the first aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one number.
Step 4	Place the pipette tip against the side of the second receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the second aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one more number.
Step 5	Continue dispensing until the dispensing step number reaches 0. A special acoustic signal is emitted.
Step 6	Complete the "blank" step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.
Step 6	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 7	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

8.7.1.8 Notes on the Programs

1. To reach the programming level, press the Program key briefly.
2. PROG appears in the display together with a memory slot number from 1 to 5.
3. With the aid of the Select rocker, five programs can be shown in the left-hand side of the display.

4. To program the five memory slots, it is possible to select from seven different program sequences:
- PIP = Pipetting
As per PIP outside program level. The complete sequence with volume, option, and speeds is programmed in one memory slot.
 - SP = Sequential Pipetting
Up to five different pipette steps can be linked to each other. Volume, option, and speeds are defined for each pipetting sequence.
 - DIS = Dispensing
As per DIS outside the program level. The complete procedure is programmed in one memory slot with dispensing volume, dispensing steps, and speeds.
 - SD = Sequential Dispensing
Up to 20 dispensing steps can be defined. Each dispensing step may have a different partial volume. The total volume may exceed the filling level of a pipette tip. This means that new liquid for the pipette tip must be aspirated during the dispensing procedure. Only one aspirating and dispensing speed is defined for all dispensing steps.
 - ADS = Automatic Dispensing
With the Actuate key held down, all dispensing strokes are executed automatically with the same volume and in a user-defined rhythm (.01-10.0 seconds). Automatic dispensing may be interrupted by releasing the Actuate key. Apart from this, the procedure is identical to the DIS function.
 - DIL = Diluting
During the diluting process, a diluent, then an air bubble, and finally a sample are aspirated into the pipette tip. The user defines the diluent volume and the sample volume. The air bubble is dependent on the sample volume and is always specified by the program. Selecting a pipetting option can dispense the entire contents of the pipette tip. Depending on the pipette used, the dilution ratio is between approximately 1:2 and approximately 1:20.
 - SDI = Serial Diluting
For serial diluting, a defined volume of liquid is aspirated into the pipette tip. This liquid is dispensed and then mixed with a specific liquid volume by means of a programmable mixing process (volume, mixing cycles). Pressing the Actuate key separately starts the mixing process (MIX).

EDIT

1. If PROG is in the display, holding down the Program key can open the programming level. The Program key must be held down until the word EDIT appears in the display in front of PROG 1-5. Systematically, programming is explained in the following subsection.
2. If the programming of a program sequence is quit by pressing Reset, the entries for the program sequence are not stored.
3. The same program sequence - with, for example, different volumes or options - can be stored in several memory slots. It would therefore be possible for different pipetting sequences to be stored permanently in the program level.
4. Programming sequences can be overwritten at any time under EDIT (Hold down the Program key). During the programming process, the entry that is to be defined flashes in the display. Selections are made using the Select rocker. Volumes are selected using the Volume rocker.
5. Data is stored by pressing the Actuate key (ENTER function).
6. Options and speeds can be selected in the programming level by using the Select rocker or by using the Option and Speed key. We recommend that you read these sections before you start programming. The following sections on programming for pipetting contain only a description of operation using the rockers. Programming and execution of the other programs is contained in Part B of this manual.

8.7.1.9 Introduction – 6 Additional Program Sequences

During programming (EDIT and PROG in display), the Speed and Option keys and the Volume rocker can also be used. This enables users to skip backwards and forwards during the program sequence.

When the programs are executed (only PROG is in the display), the Speed and Option keys and the Volume rocker are blocked.

If only parts of the program have been changed, programming can be ended prematurely by pressing the Program key briefly.

If a memory slot is quit using Reset before programming has been completed, the changes that have not been carried out for this memory slot are not saved. EDIT disappears from the display.

8.7.1.10 SD = Sequential Dispensing (*use this mode to pipette the 4 age-specific (1-2, 3-5, 6-11 and 12+) serum protocols - 100-5000 μ L pipette)*)

The sequential dispensing program can be used when different volumes of a solution have to be dispensed consecutively. Up to 20 steps can be defined. If the sum of the dispensing steps is larger than the volume of the pipette tip, the procedure for normal dispensing is applicable when a liquid is aspirated repeatedly.

Programming SD	
Step 1	Select the programming mode. Press the Program key. PROG appears in the display.
Step 2	Select the memory slot number 1. Use the Select rocker to move up and down through the 5 program numbers until “1” is selected.
Step 3	Hold down the Program key until EDIT appears in the display.
Step 4	Select the SD program. Use the Select rocker to move through the programming choices until “SD” appears in the display. Press the Actuate key.
Step 5	Determine the dispensing steps 1-20. Use the Select rocker to move the number up or down until the number 19 is displayed. Press the Actuate key to store the number of steps in the program.
Step 6	Select and store the volume for the first dispensing step. Use the Select or Volume rocker to move the number up or down until the number 1000 is displayed. Press the Actuate key to store the volume for step 1.
Step 7	Continue programming the remaining 18 steps and volumes for the 12+ protocols.
Step 8	Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program.
Step 9	Programming is complete. The display should show: “SD 500 μ L 19”

Pipetting Procedure	
Step 1	The necessary or largest possible amount of serum is aspirated. Aspirate the serum. Make sure the direction of the aspirating arrow is pointed up. Press the Actuate key once. The pipette will aspirate 1000 μL .
Step 2	Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward.
Step 3	Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 1000 μL aliquot. The dispensing step counter (number) on the right-hand side of the display counts down one number.
Step 4	Place the pipette tip against the side of the second receiving vessel.
Step 5	Continue dispensing the remaining aliquots until the (number) on the right-hand side of the display reaches 0. If a slot in the processing rack is empty, dispense the aliquot back into the pooled serum vessel.
Step 6	Complete the "blank" step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.
Step 6	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 7	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

Continue programming the remaining program slots, age-specific protocols, and volumes.

8.7.1.11 ADS = Automatic Dispensing (*use this mode to repetitively pipette 500 μL pooled serum - 100-5000 μL pipette*)

The automatic dispensing function allows a single volume to be dispensed repetitively with a predetermined time interval of between 0 and 10 seconds.

Programming ADS	
Step 1	Select the programming mode. Press the Program key. PROG appears in the display.
Step 2	Select the memory slot number 2. Use the Select rocker to move up and down through the 5 program numbers until “2” is selected.
Step 3	Hold down the Program key until EDIT appears in the display.
Step 4	Select the ADS program. Use the Select rocker to move through the programming choices until “ADS” appears in the display. Press the Actuate key.
Step 5	Select and store the dispensing volume. Use the Select or Volume rocker to move the number until 500 is displayed. Press the Actuate key to store the volume in the program.
Step 6	Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key, then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program.
Step 7	Reduction of the dispensing steps. The total number of dispensing steps displays in the right-hand side of the display. Do not use the Select rocker to change this number. The pipette has calculated the number of dispensing steps based on the aspirating volume and the size of the pipette tip. Press the Actuate key to store the number of calculated dispensing steps and to move to the final programming step, setting the dispensing frequency.
Step 8	Set the dispensing frequency. Use the Select rocker to move the number of seconds (SEC) up or down until 1 is displayed before SEC in the display. Press the Actuate key to store this frequency in the program.
Step 9	Programming is complete. The display should show: “ADS 500 μ L 10”
Pipetting Procedure	
Step 1	Aspirate the serum. Make sure the direction of the aspirating arrow is pointed upward. Press the Actuate key once. The pipette will aspirate 5000 μ L.
Step 2	Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward. Press the Actuate key once. Dispensing is carried out while the Actuate key is held down. An acoustic signal is

	emitted after the dispensing step. To Interrupt the action, release the Actuate key.
Step 3	Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 500 μL aliquot or to automatically pipette sequential 500 μL aliquots, <u>hold the actuate key down</u> . The dispensing step counter (number) on the right-hand side of the display counts down one number. As soon as you hear the acoustic signal, move the pipette tip to the next vessel.
Step 4	Place the pipette tip against the side of the second receiving vessel.
Step 5	Continue dispensing 500 μL aliquots until the (number) on the right-hand side of the display reaches 0.
Step 6	Complete the "blank" step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted.
Step 6	Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released.
Step 7	The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display.

8.7.1.12 Device Parameters

Trained personnel may change device parameters only after a thorough inspection.

Device parameters are made up of the following:

- BE1 To switch on/off the acoustic signal for the keypad (short beep).
- BE2 To switch on/off the second acoustic signal for the end position of the dispensing piston, for warning and for confirmation (different beeps).
- CAL To alter the calibration data μL , axle section (b) and gradient (m).
- OPT Option for volume restriction

When the 200 µL tips are used with the 300-µL pipettes (limit: 200 µL).
 With "RP" and "DIS" when filtertips are used.

INI To initialize the original pipette data upon delivery.

The device parameters can all be found on one list. The Actuate key functions as an Enter key. After Enter has been pressed, the next line appears in the display.

If the device parameter is quit using the Reset, the setting that was made prior to change is valid.

To access the device parameters	With the pipette switched on, press both the Speed and Option keys briefly at the same time.
To switch off/on acoustic signal for the keypad	Use the Select rocker to move through the selections until "BE 1" is displayed in the left side of the display window. Press the Actuate key.
To switch on/off (on), second acoustic signal	Use the Select rocker to move through the selections until "BE 2" is displayed in the left side of the display window. Press the Actuate key.
To exit the device parameters	Press the Actuate key when "INI" is displayed in the left side of the display window.
To initialize the pipette and to erase all settings	Using "ENTER", access "INI" in device parameters. Hold down the Program key. Initialization is completed when the device parameter "INI" disappears from the display.

8.7.1.13 Care, Sterilization, Maintenance, and Ordering Information

The outside of the pipette can be wiped with a moist cloth. The use of water with 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 60% Isopropanol.

If the pipette is very contaminated or if very aggressive chemicals are dispensed, the lower half of the Research pro should be disassembled. The individual parts are rinsed in distilled water and then dried. The piston is then lightly lubricated using silicone grease.

After opening the pipette, please check that the piston is correctly positioned. A motor reset must also be executed. The motor reset is triggered by holding down the Reset key until **R** appears in the display.

Sterilization

Only the lower half of the pipette can be disassembled. The individual parts of the lower part must be disassembled as separate pieces. Please review the diagrams on page 27 of the Instruction Manual before attempting to disassemble any pipette.

To loosen the lower part of the pipette for all pipettes except the 5,000 μL :

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the lower part using the key. During disassembly, do not damage the piston!
3. Unscrew the piston. If necessary, first loosen the piston at the upper end using flat nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000 μL pipette:

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the cylinder. The piston is held in place magnetically. During reassemble, do not damage the piston!
3. Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000 μL piston as shown in the diagram on page 27 of the Instruction Manual. Check that the dispensing function of the pipette is working correctly.

Maintenance

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced completely. The process for replacing the seals in the lower part is described in Part B: “Ordering information/service parts.” The Service Department may carry out maintenance on the Research pro. Contact Brinkmann Instruments at 800-645-3050 Ext 404.

A complete list of troubleshooting information is included on pages 28 and 29 of the Instruction Manual.

Ordering information

Item	Size	Part number
Eppendorf Research pro	5-100 μL	2246-136-2
Eppendorf Research pro	50-1000 μL	2246-138-9
Eppendorf Research pro	100-5000 μL	2246-139-7
Charging stand	Four pipettes	2246-155-9
Pipette Tips		
Bulk-packaged, in bags	5-mL	2235-081-1
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	200 μL	2249-002-8
Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips	1000 μL	2249-006-1
Additional accessories		
Spare Ni-MH battery, 1,200 mAh		2246-701-8

Page 102 in the Instruction Manual contains a complete list of additional parts and accessories.

- Use the dedicated 5-100 μL and the dedicated 50-1000 μL Eppendorf Research pro pipettes and trace metal free pipette tips to aliquot whole blood and perform the dilution for RBC Folate using 1.0-uL ascorbic acid.
 - Pipetting Procedure
 1. Using the pipette tip dispenser tray, press the pipette nozzle firmly into a fresh tip.
 2. Aspirate and dispense the whole blood, serum, and ascorbic acid using procedures described in Section 8.7.
 3. Place the tip against the inner wall of the cryovial as close to the bottom as possible.
 4. Discard the tip in the sharps container.
 5. Cover the pipette tips at the end of each session to prevent contamination.

8.7.2 Process the 3-mL and 5-mL EDTA Tubes

Use the well-mixed lavender 3-mL and 5-mL EDTA tubes for the hematology profile (CBC) and certain blood tests. The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation.

8.7.2.1 Process the 3-mL or 5-mL EDTA Tube for Lead/Cad, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4

The hematology technologist runs the CBC on the room temperature 3-mL or 5-mL EDTA tube after the blood-processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4 vessels. If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury), or vessel 6 (CD4); process vessel 2 (Ery Proto) and attach the comment, "Clotted." If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad) and 5 (Mercury) was pipetted, do not process these two vessels and add the comment "laboratory error." Continue to pipette the whole blood for vessels 2, 3, 4, and 6 even if the CBC was run before the whole blood was pipetted.

Complete the following process for all SPs.

- The blood-processing technologist initially processes the 3-mL or 5-mL EDTA tube.
 - Invert the appropriate EDTA tube several times to remix contents thoroughly.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.3-mL whole blood for vessel 1 (Lead/Cad) on primary SPs and VIP guests ages 1-5 into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.6-mL whole blood for vessel 1 (Lead/Cad) on primary SPs and VIP guests ages 6-11 into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to transfer 0.5-mL whole blood for vessel 1 (Lead/Cad) on primary, home, and second exam SPs and VIP guests age 12+ into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.3-mL whole blood for vessel 2 (Ery Proto) on primary SPs and VIP guests ages 1-11 into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to pipette 0.4-mL whole blood for vessel 2 (Ery Proto) on primary, home, and second exam SPs and VIP guests age 12+ into a 2-mL vessel.
 - Use trace metal free pipette tips and the dedicated 5-100 μ L Eppendorf pipette to pipette 0.1-mL whole blood for vessel 3 (RBC Folate) on primary, home, and second exam SPs and VIP guests age 3+ into a 2-mL vessel. Do not prewet the pipette tips. Dilute the whole blood with ascorbic acid. Use trace metal free pipette tips and the dedicated 50-1000 μ L Eppendorf pipette to immediately pipette 1.0-mL ascorbic acid into the 2-mL vessel. Mix well. Refrigerate L-ascorbic acid diluent when not in use. Discard unused diluent at end of each stand.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 4 (Glycohem) on primary, home, and second exam SPs and VIP guests into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 5 (Mercury) on primary SPs and VIP guests ages 1-5 into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 1.0-mL whole blood for vessel 5 (Mercury) on female primary SPs and female VIP guests ages 16-49 into a 2-mL vessel.
 - Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 6 (CD4) on primary SPs ages 18-49 into a 2-mL vessel.

- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.
- Place the EDTA tube on a hematology rocker until the hematology technologist performs the CBC.

Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 2-mL EDTA blood tube at room temperature for no more than 24 hours. After 24 hours, the blood will undergo changes that will render the WBC, RBC, HgB, and HCT results inaccurate.

8.7.2.2 Process Second 5-mL EDTA Tube for Plasma for Homocys/MMA and Extra Plasma

Process the second 5-mL EDTA tube for Homocys/MMA and Xtra Plasma immediately and centrifuge at 4-8°C or refrigerate the tube until it can be centrifuged. Remove the plasma from the cells within 30 minutes. Red blood cells synthesize homocysteine, which results in a 10% increase after 30 minutes. After 1 hour, the increase in homocysteine is 2-16%, after 2 hours 11-30%, after 4 hours 23-35%, and after 6 hours 22-42%.

- Place the tube in the centrifuge carrier of the refrigerated tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Immediately centrifuge the remaining whole blood from the first 5-mL EDTA tube or the whole blood in the second 5-mL EDTA tube at 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 7 (Homocys/MMA) and vessel 8 (Xtra Plasma.)
- Use a calibrated plastic transfer pipette to aliquot at least 1.0-mL plasma for vessel 7 (Homocys/MMA) on primary and second exam SPs age 3+ and home exam SP's age 50+ into a 2-mL vessel.
- Use a calibrated plastic transfer pipette to aliquot at least 0.5-mL plasma for vessel 8 (Xtra Plasma) on primary SPs age 6+ into a 2-mL vessel.
- If there is excess plasma, add 1.0-mL to vessel 7 and any remainder to vessel 8.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.3 Process the 3-mL Gray Tube for Glucose

Centrifuge and separate the plasma from the 3-mL gray top tube as soon as possible. Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 3-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (Glucose.)
- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 9 (Glucose) on primary and second exam SPs and VIP guests age 12+ into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.4 Process the 3-mL Blue Top Tube for Fibrin

Centrifuge and separate the plasma from the 3-mL blue top tube as soon as possible. Process the specimen even if the contents of the tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 3-mL blue tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 10 (Fibrin.)
- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 1.0-mL for vessel 10 (Fibrin) on primary and second exam SPs age 40+ and home exam SPs age 50+ into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.5 Process the 3-mL, 7-mL, and 15-mL Red Top Tubes for Pooled Sera

- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in each 3-mL, 7-mL, and 15-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.

If the serum in any one red top tube from a SP is grossly hemolyzed, do not pool it with serum from the remaining tubes. Reserve it for the storage vessels 32-42.

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

- Use a serum separator to remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard. Do not touch the serum separator to the clot barrier.
- Label the 50-mL conical tube with SP ID # label. Pool all clear sera. For each SP pool the serum from all red top tubes by decanting the separated serum into the 50-mL polypropylene tube. Hold the tube and the separator level while decanting the serum. Be careful to avoid introducing any cellular debris. Reserve one 15-mL tube for the DNA vessel 43. Discard the other original tubes and separators in a sharps container.
- Securely close the 50-mL polypropylene tube and mix its contents by gentle inversion.
- Confirm that all vessels have the correct information with the appropriate SP's bar-coded ID label before filling them.
- Use the 100-5000 Eppendorf® pipette and 5-mL pipette tips to aliquot the serum.
- Using clear serum only, fill as many vessels as possible in the priority order shown in Section 8.5. Exhibits 8.16 – 8.26 describe the order of allocation and specific procedures to follow for each person type and vessel.
- If excess serum remains after completing the entire protocol, add an additional 1.5-mL serum beginning with vessel 32 and continuing through vessel 42 until the serum is exhausted. If extra serum remains, continue to top off the other serum vessels beginning with vessel 11 until the serum is exhausted.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.
- If the serum cannot be aliquoted immediately, refrigerate it at 4°C for no more than 4 hours.

8.7.6 Process the 10-mL Red Top Tube for Persis Pest and Phytoestro

- Do not substitute any other red top tube for these vessels; this tube is prescreened by the CDC for these tests.
- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in the 10-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
- Use a serum separator to carefully remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flowthrough may occur. Do not touch the serum separator to the clot barrier.
- Aliquot the serum immediately by pouring the serum for vessels 29 (Persis Pest) or 64 (Phytoestro) on primary SPs age 12+ into a 5.0-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.7 Process One 15-mL Red Top Tube for Clots

- After decanting and processing the sera from one 15-mL red top tube, discard the serum separator(s), and loosen the remaining clot with a wooden stirring rod.
- Decant the loosened clot for vessel 43 (DNA) on primary SPs age 20+ into a 14-mL vessel.
- Discard the empty red top tube and the wooden stirring rod in a sharps container.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.8 Process the 8-mL ACD Tubes for WBC/DNA

Process the two 8-mL ACD tubes 44 and 71 (WBC/DNA) on primary SPs age 20+. Keep the tube upright at room temperature. Label and verify that a minimum of 6-mL of blood is in the tube by comparing the volume in the tube to a calibrated tube. Do not expose tubes to extreme temperatures.

- Mix the blood by gently inverting the tubes 5-6 times.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately at room temperature as outlined in Section 8.10.

8.7.9 Reagent Processing and Preparation

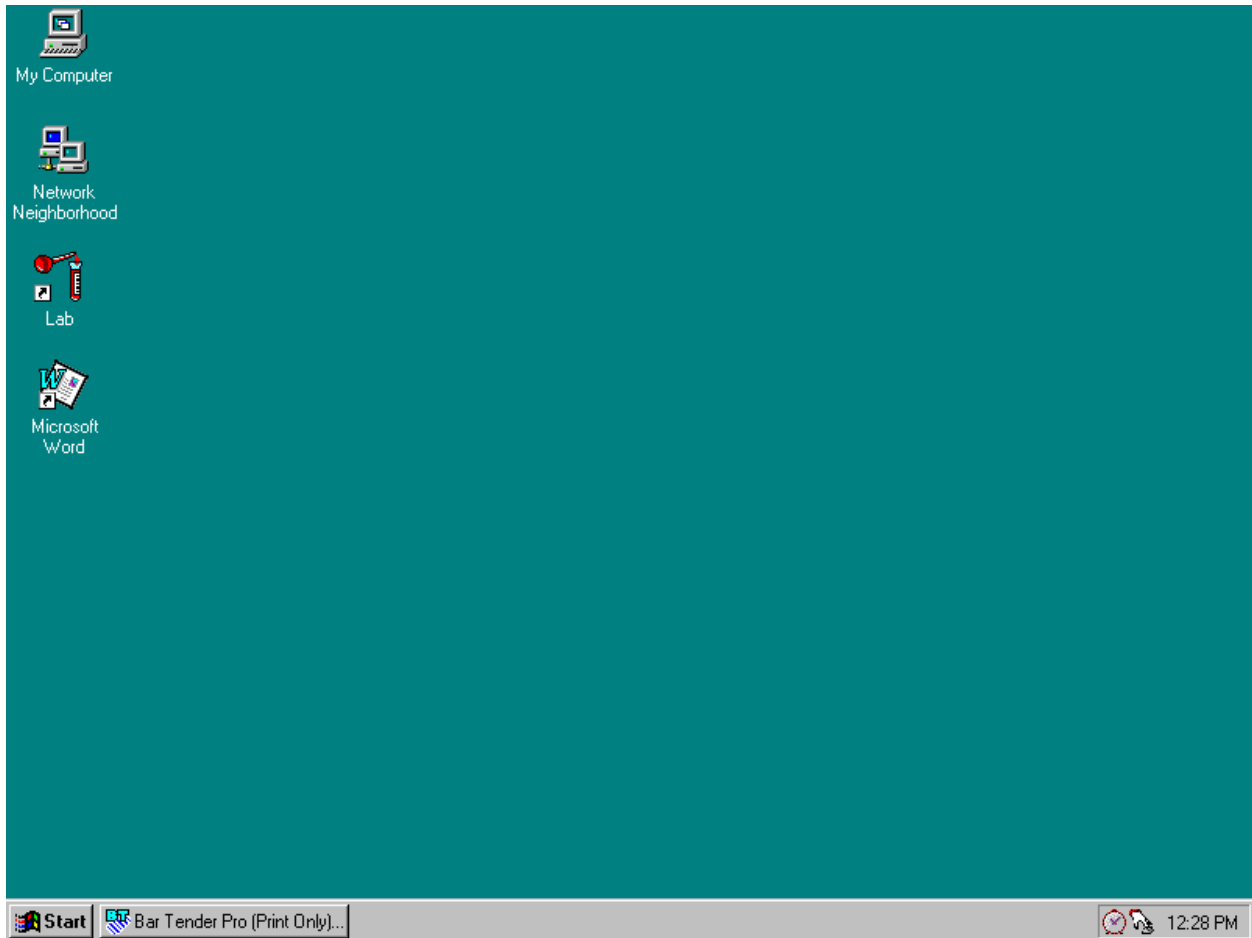
The Centers for Disease Control and Prevention supplies premeasured 1% ascorbic acid (AA) for the RBC Folate assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use calibrated MLA pipettes to make the dilution. Add 1.0-mL ascorbic acid to 0.1-mL whole blood for the RBC Folate assay. Mix by gentle inversion.

- The ascorbic acid powder is in a 50-mL Falcon tube. Dissolve the powder in 50-mL of distilled water using a graduated cylinder to measure the water and mix gently. Prepare this reagent weekly. Date and label the Falcon tube. If the powder appears discolored or the solution appears cloudy, discard and prepare fresh reagent. If no bottled distilled water is available, use tap water. Record the reagent in the Supply use Control Log each time it is prepared.
- Refrigerate the prepared reagent at the end of each day to maintain its stability and bring the reagent back to room temperature the next day.

8.8 Record the Results of Specimen Processing

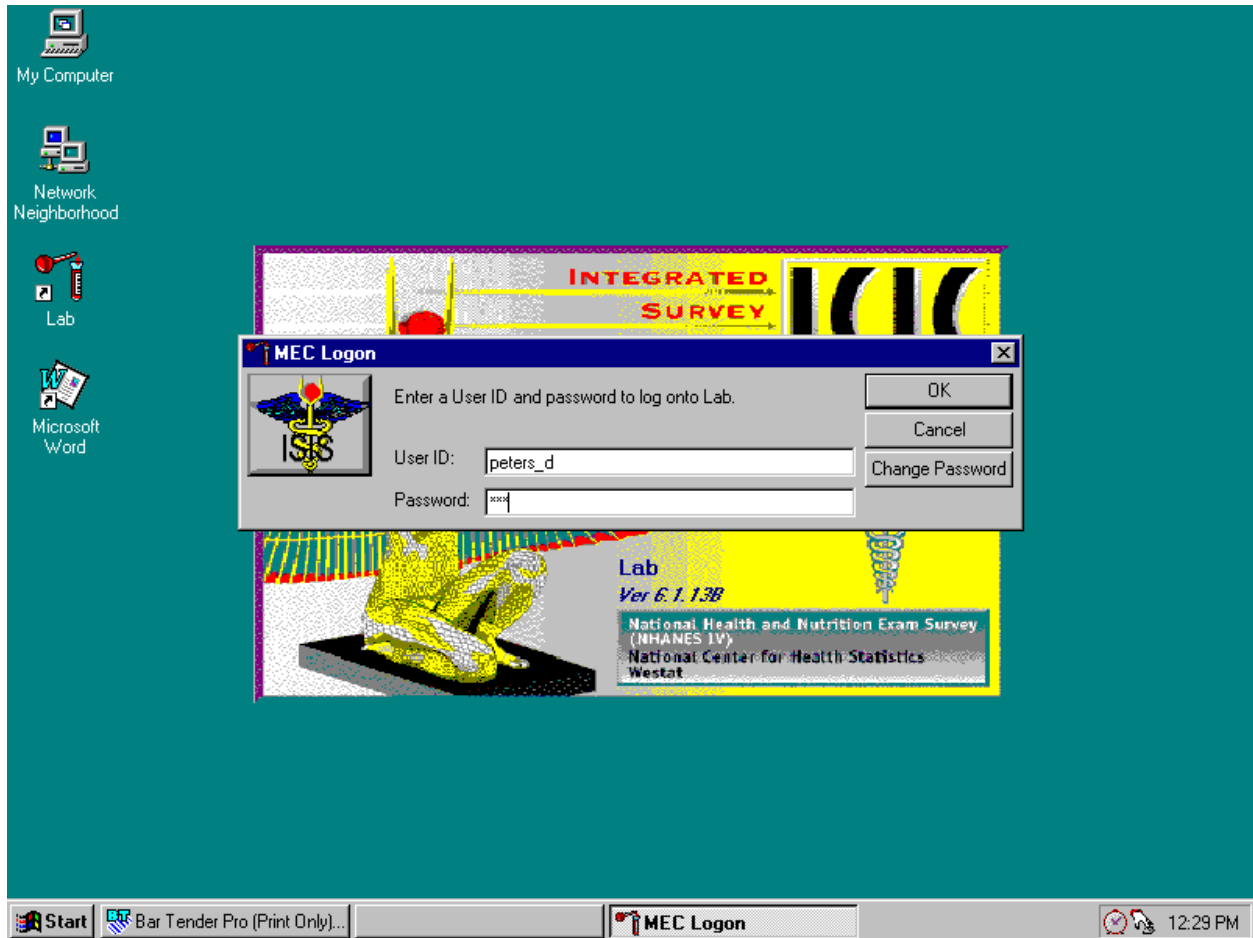
After filling or processing the whole blood, plasma, serum, clot vessels and/or the ACD tubes for each SP, use the Blood Processing module to enter the blood processing results.

Open the Laboratory application.



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

Log onto the laboratory application.



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

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

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status											
								UC	B	CB	U	P	BV	hiv	H	V	N		
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●	●	.	●	.
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	.	.	.	●	.
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	●	●
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	●	●	●	●
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	●
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	●	●	●
811000	161096	SC	V		M	41	FRAZIER2, JAMES	.	●	●	●	.
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	●	●	●	.	●	.

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 11:38 AM

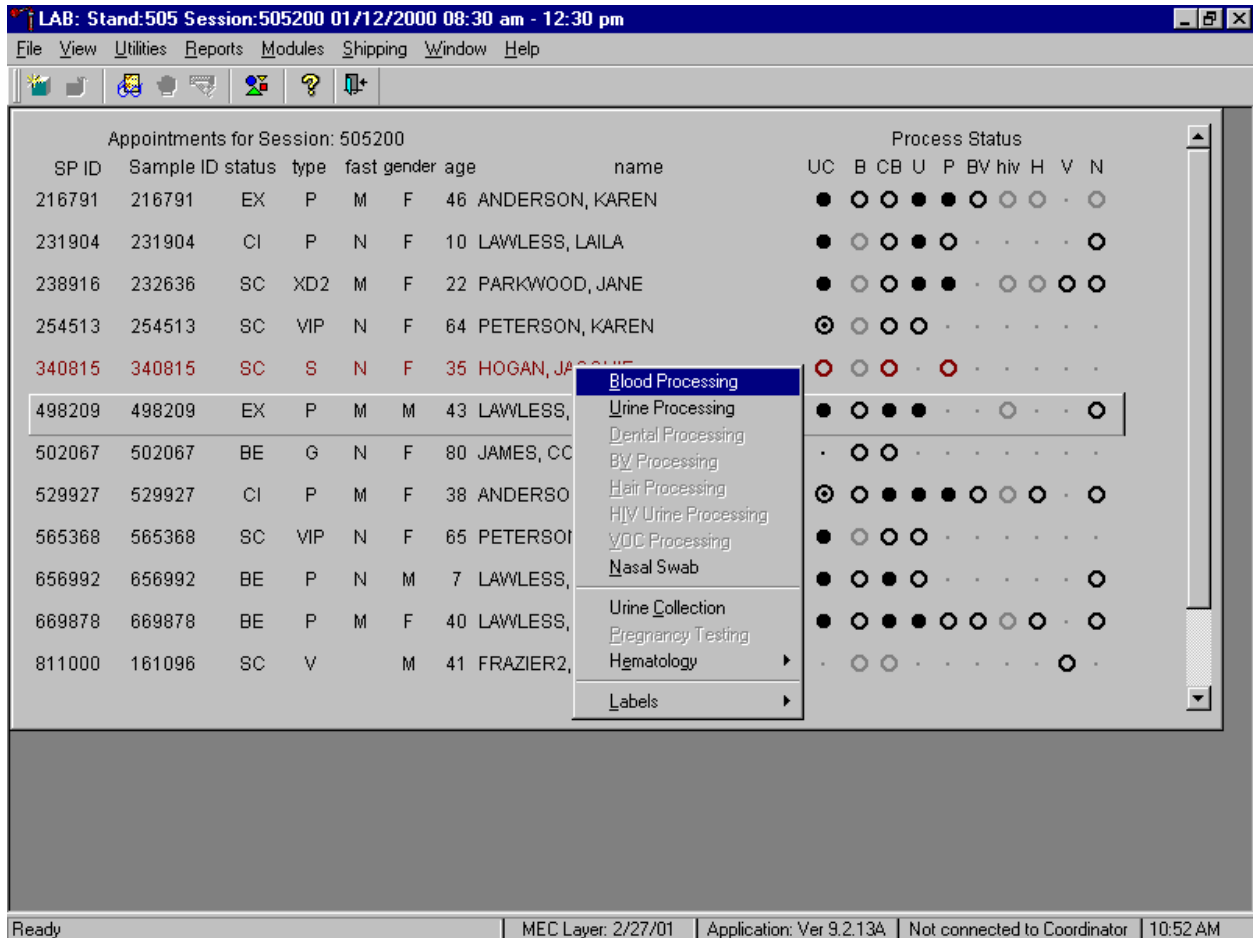
The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run, V=VOC), fast (M=morning, A=afternoon, E=evening, N=none), 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), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible for a module when the process status is •. The SP is eligible for a module but no results have been recorded when the process status is ○. The SP is eligible for a module and some results have been recorded when the process status is ◐. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●. The SP is eligible for a module but the process status is O until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from O to ●. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from O to ●. The process status updates and changes after each result is saved.

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

To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down. Alternatively, to view all SPs use the mouse to direct the mouse arrow to the bottom of the heads-up display, right click, and drag the display up or down.

Select the correct SP and access the Blood Processing module.



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

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

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The main area displays a table of appointments for session 505200. A dialog box titled "Blood Processing" is overlaid on the table, displaying an error message: "* ERROR * No Blood Processing Labels Printed for Sample_ID 285851." with an "OK" button.

Appointments for Session: 505200								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●	●	.	●
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	.	.	●
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	●	●
529927	529927	CI	P	M	F	30	ANDERSON, LEQUE	●	●	●	●	●	●	●	●	●	●
565368	565368	SC	VIP	N			
656992	656992	SC	P	N			
669878	669878	BE	P	M			
811000	161096	SC	V				
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	●	●	●	.	●
909333	140929	SC	V		F	51	AMIN2, MITUL	●	●	●	.	●	●

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

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

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status													
								UC	B	CB	U	P	BV	hiv	H	V	N				
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	●	●	○	○	○	○	○	○	○	○	○
231904	231904	CI	P	N	F	10	LAWLESS, LAILA	●	○	○	●	○	○	○	○	○	○	○	○	○	○
238916	232636	SC	XD2	M	F	22	PARKWOOD, JANE	●	○	○	●	●	○	○	○	○	○	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○	○	○	○	○	○	○	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	○	○	○	○	○	○	○	○	○	○	○	○	○	○
498209	498209	EX	P	M	M	43	LAWLESS, STEVE														
502067	502067	BE	G	N	F	80	JAMES, COURTNEY														
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE														
565368	565368	SC	VIP	N	F	65	PETERSON, BETH														
656992	656992	BE	P	N	M	7	LAWLESS, NATHAN														
669878	669878	BE	P	M	F	40	LAWLESS, NANCY														
811000	161096	SC	V		M	41	FRAZIER2, JAMES														

Context Menu:

- Blood Processing
- Urine Processing
- Dental Processing
- BY Processing
- Hair Processing
- HIV Urine Processing
- VOC Processing
- Nasal Swab
- Urine Collection
- Pregnancy Testing
- Hematology
- Labels

Sub-menu (selected):

- All
- Blood
- Dental
- Hair
- BY Processing
- Home
- Pregnancy
- Urine
- VOC
- Nasal Swab
- Regenerate Labels

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:54 AM

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

The SP's blood processing screen displays.

Appointments for Session: 505200 Process Status

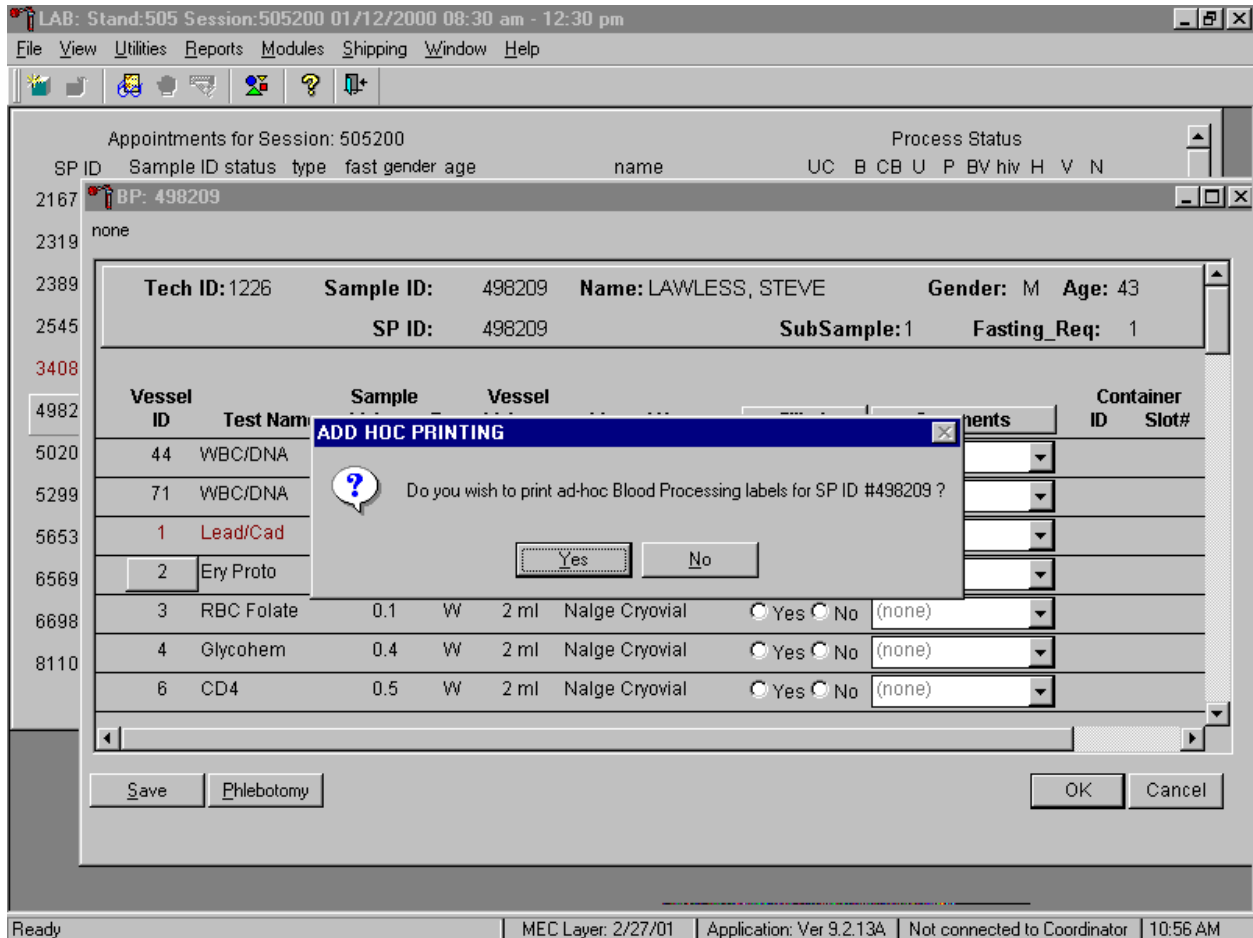
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
2167	BP: 498209																
2319	none																
2389	Tech ID: 1226		Sample ID: 498209		Name: LAWLESS, STEVE			Gender: M		Age: 43							
2545	SP ID: 498209			SubSample: 1		Fasting_Req: 1											
3408																	
4982	Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#							
5020	44	WBC/DNA	8	T	8 ml	ACD	<input type="radio"/> Yes <input type="radio"/> No	(none)									
5299	71	WBC/DNA	8	T	8 ml	ACD	<input type="radio"/> Yes <input type="radio"/> No	(none)									
5653	1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)									
6569	2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)									
6698	3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)									
8110	4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)									
	6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)									

Save Phlebotomy OK Cancel

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:56 AM

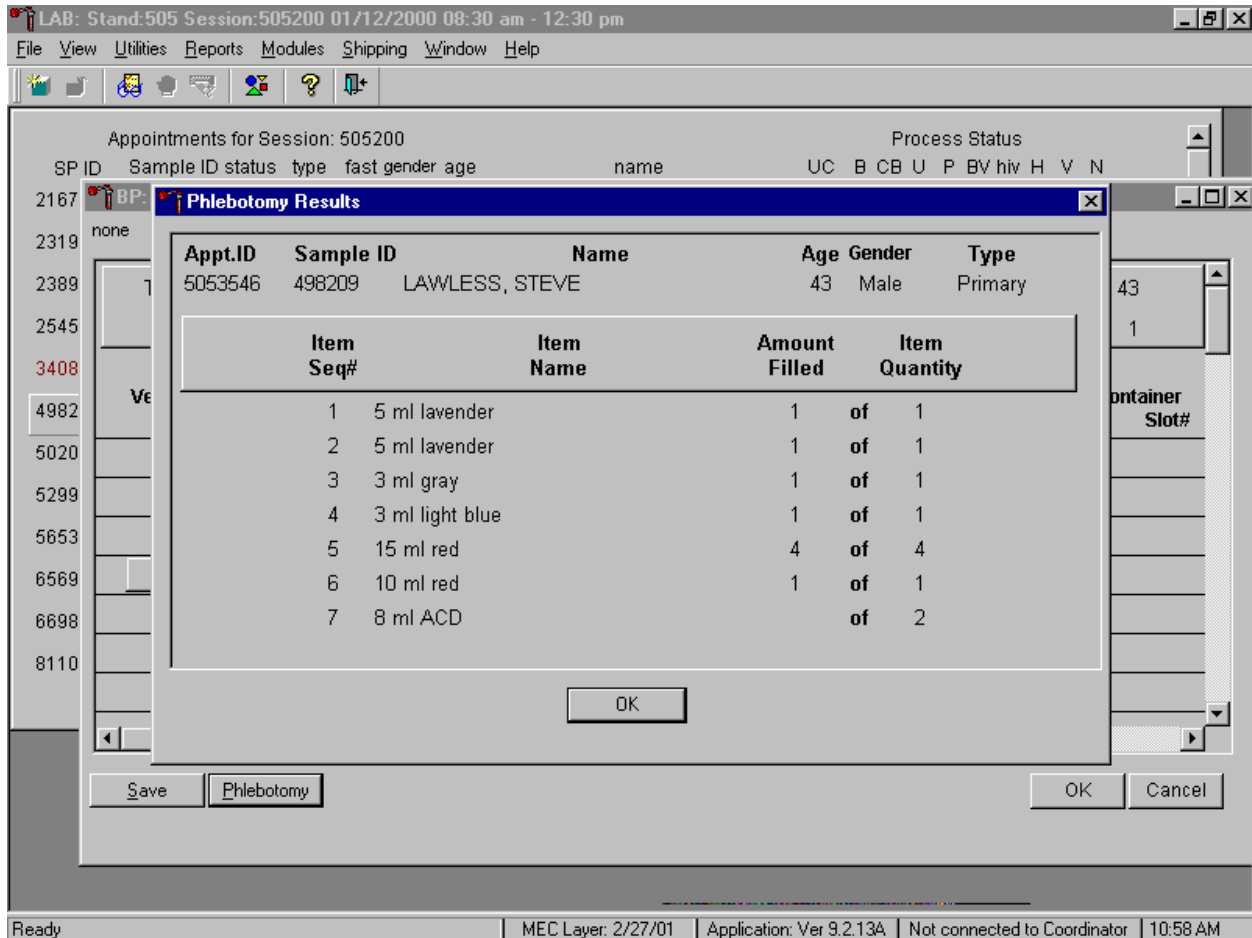
The blood processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Sample Volume, Type (blood tube, whole blood, plasma, serum, clots), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons. Vessels that require sterile 2-mL cryovials are displayed in red.

Print an ad hoc label for any individual vessel.



To print an ad hoc label for one vessel, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the text box request. To print the label and remove the text box, use the mouse to direct the mouse arrow to the **Yes** button and left click, type [Y/y], or select [Enter.] The label prints on the label/ship printer. To remove the text box without printing a label, use the mouse to direct the mouse arrow to the **No** button and left click or type [N/n].

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the bar code label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



To review the phlebotomy results, use the mouse to direct the mouse arrow to the **Phlebotomy** button on the blood processing screen and left click or type [Shift] [P/p.] 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."

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

Process Status

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N	
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	○	○	○	○	○	○	○	○

BP: 498209

none

231904

238916

254513

340815

498209

502067

529927

565368

656992

669878

811000

Tech ID:1226	Sample ID:	Name:	Gender:	Age:	SP ID:	SubSample:	Fasting_Req:
498209	498209	LAWLESS, STEVE	M	43	498209	1	1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	4
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	5
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305921	15
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305908	14
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:59 AM

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."

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BP: 498209

none

Tech ID:1226 Sample ID: 498209 Name: LAWLESS, STEVE Gender: M Age: 43
 SP ID: 498209 SubSample:1 Fasting_Req: 1

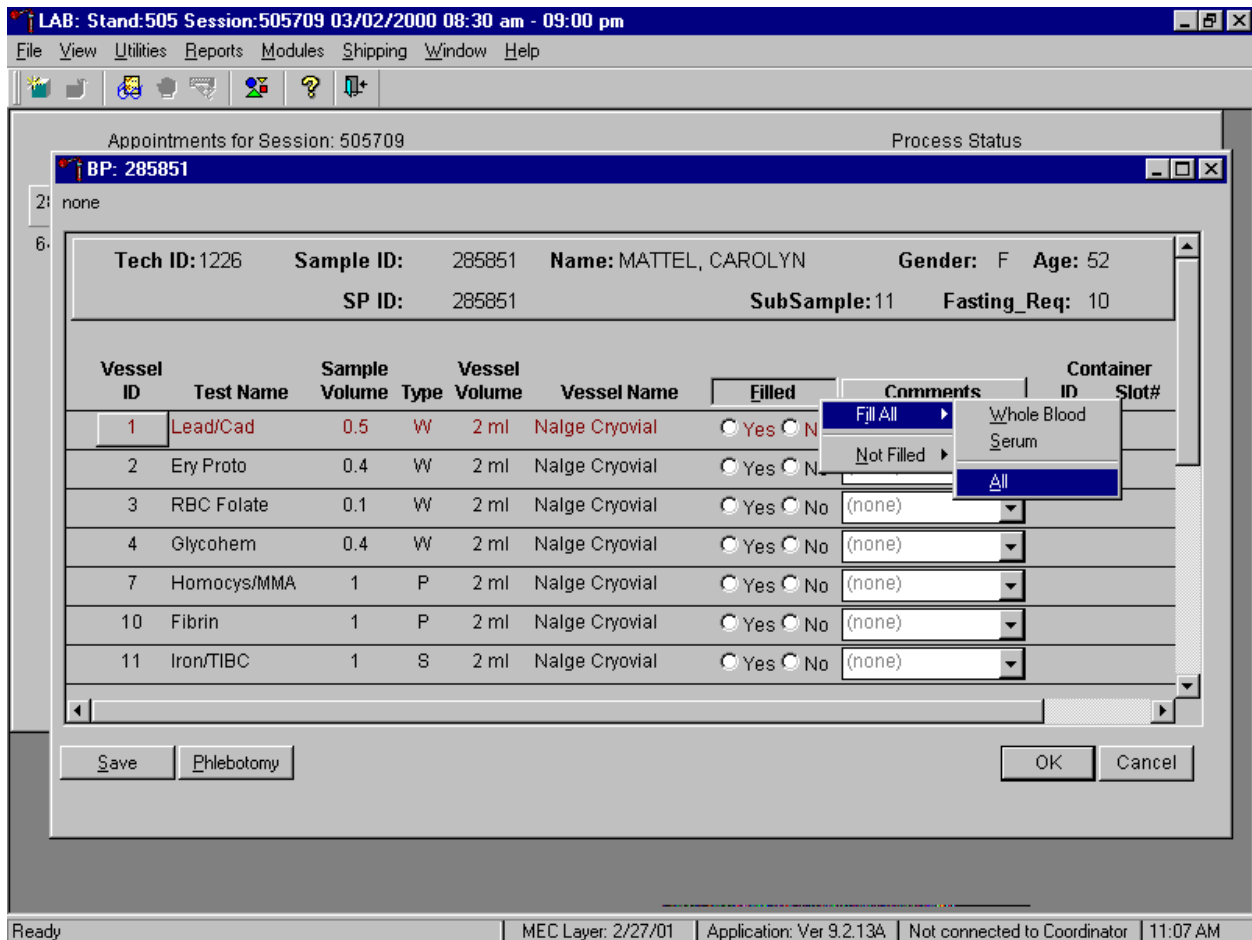
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	10
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	11
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305921	19
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305908	18
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Ready MEC Layer: 2/27/01 Application: Ver 9.2.13A Not connected to Coordinator 11:08 AM

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" or selectively mark whole blood or serum vessels as Filled – "Yes."



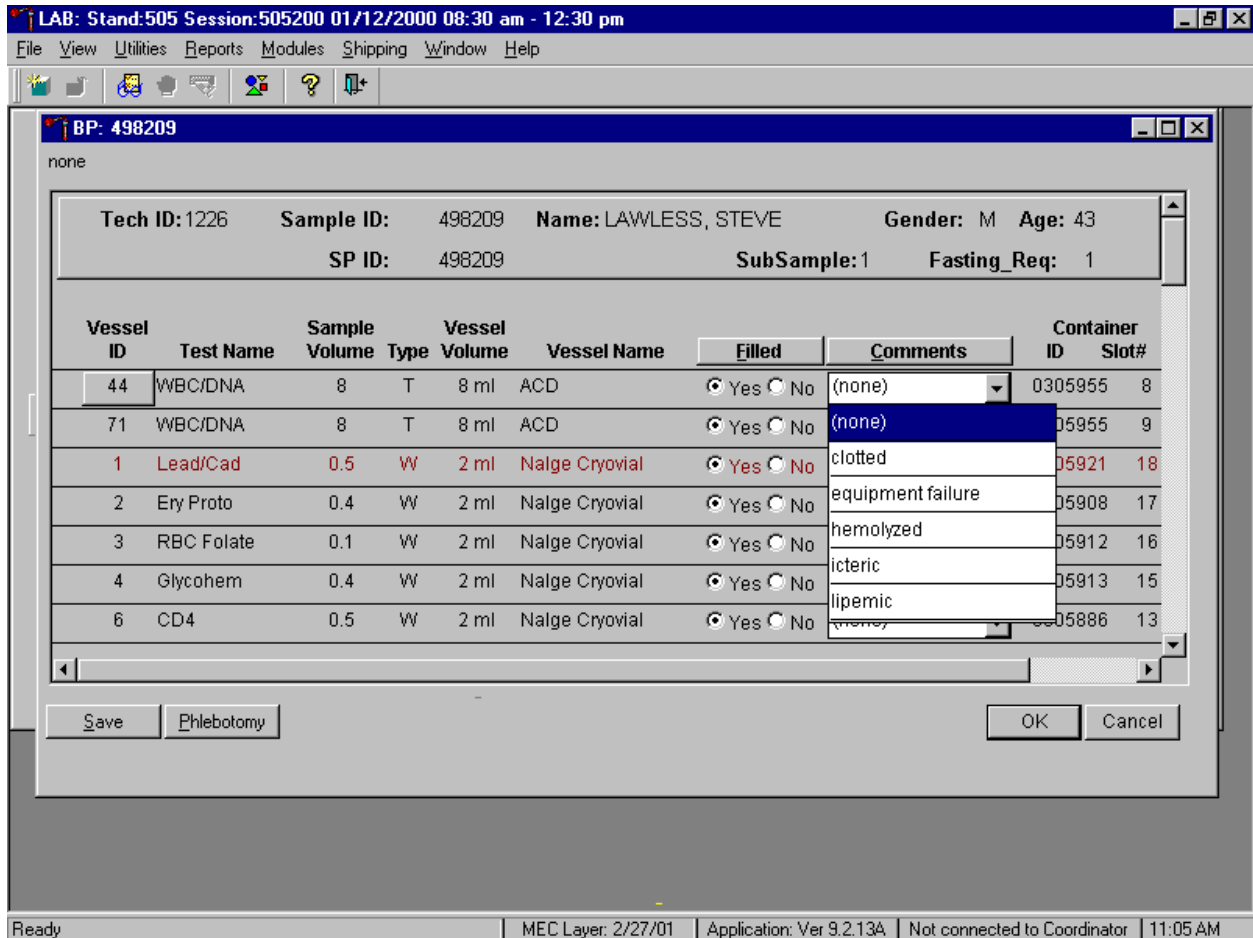
To collectively mark all vessels as Filled - "Yes," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {All}, and left click. To collectively mark all whole blood vessels as Filled - "Yes," use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, 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," 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 {Serum}, and left click. As each vessel is marked as "Filled," it is automatically assigned to a slot in an existing (open) container. All plasma and clot vessels and the ACD tubes must be marked individually.

Alternatively, to collectively mark all vessels as Filled - "Yes," type [Shift] [F/f], [I/I], and [A/a.] To collectively mark all whole blood vessels as Filled - "Yes," type [Shift] [F/f], [I/I] and [W/w.] To collectively mark all serum vessels as Filled - "Yes," type [Shift] [F/f], [I/I], and [S/s.]

Quality comment codes are available to describe the quality of the specimen.

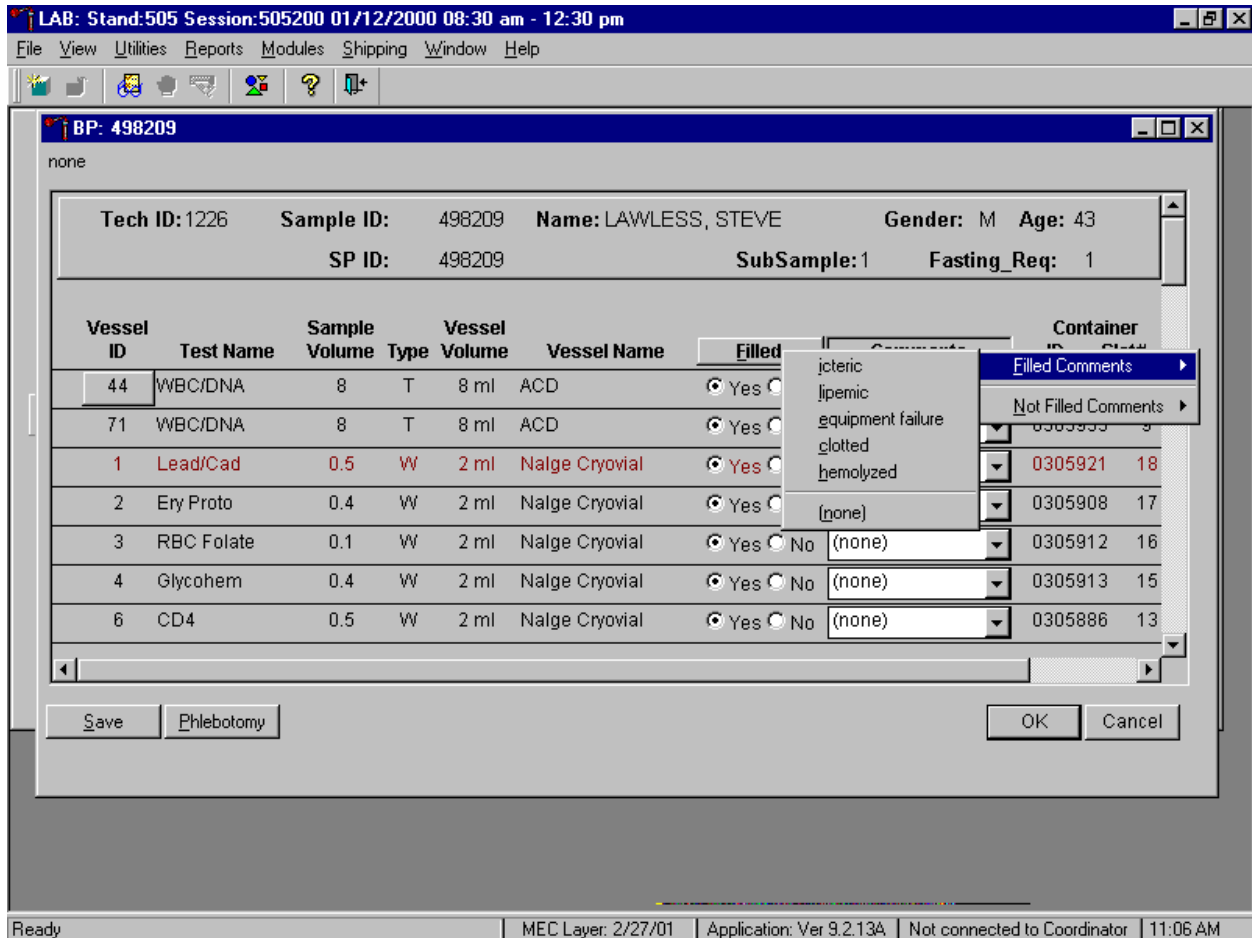
Comment for filled vessels	Use when:
icteric	There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible "jaundice" color when the concentration of bilirubin is above 430 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.
equipment failure	Pipettes are malfunctioning.
clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture (<i>in vivo</i> hemolysis) or during the analytic procedure (<i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 mg/L.

Attach a comment to an individual filled vessel.



To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop down list under the **Comments** button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (i, l, e, c, h.)

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. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h.)

All plasma and clot vessels and the ACD tubes must be marked individually. All Vessels marked as Filled – "No" require a comment or explanation.

Enter comment codes to describe the reasons why a vessel is marked as Filled – "No," or why the protocol is incomplete.

Comment for not filled vessels	Use when:
container discarded	Do not use this comment.
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 consequently, excluded from HIV or genetic testing.

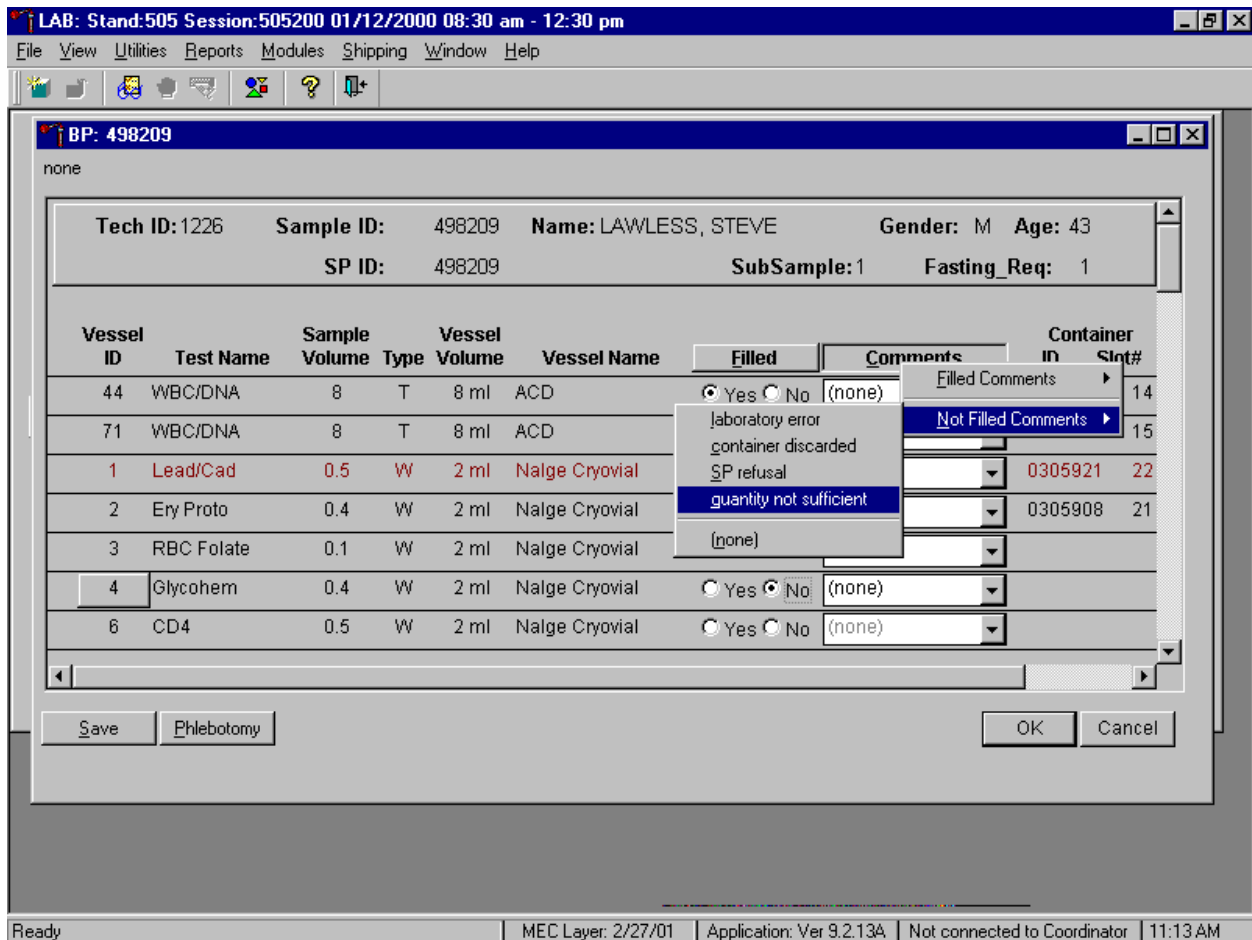
Attach a comment to an individual Filled – "No" vessel.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The main window is titled "BP: 498209" and displays patient information: Tech ID: 1226, Sample ID: 498209, Name: LAWLESS, STEVE, Gender: M, Age: 43, SP ID: 498209, SubSample: 1, Fasting_Req: 1. Below this is a table of vessels with columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled status, Comments, Container ID, and Slot#. A dropdown menu is open for the "Comments" column of vessel 3, showing options: (none), container discarded, laboratory error, quantity not sufficient, and SP refusal. Buttons for "Save", "Phlebotomy", and "Cancel" are visible at the bottom of the window. The system tray at the bottom shows "Ready", "MEC Layer: 2/27/01", "Application: Ver 9.2.13A", "Not connected to Coordinator", and "11:10 AM".

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	12
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	13
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305921	20
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305908	19
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	container discarded		

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. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

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. Alternatively, to collectively attach the same comment to all vessels marked as Filled - "No" type [Shift] [C/c], [N/n], and the first letter of the desired choice (l=laboratory error, s= SP refusal, q=quantity not sufficient.).

Every SP who has any vessel filled must have vessel 1 marked as filled.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BP: 216791

none

Tech ID:1226 Sample ID: 216791 Name: ANDERSON, KAREN Gender: F Age: 46
 SP ID: 216791 SubSample:1 Fasting_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	16
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	17
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305921	24
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	clotted		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	empty vial		
5	Mercury	1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	equipment failure		

Save Phlebotomy Cancel

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:25 AM

Mark vessel 1 as Filled – “Yes,” even if the blood is clotted but do not fill the vessel. Attach the comment, “empty vial” to this vessel. To attach the comment “empty vial” to this 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 {empty vial}, and left click.

If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury), or vessel 6 (CD4). Process vessel 2 (Ery Proto) but attach the comment, "Clotted."

BP: 216791
none

Tech ID: 1226 Sample ID: 216791 Name: ANDERSON, KAREN Gender: F Age: 46
SP ID: 216791 SubSample: 1 Fasting_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	16
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	17
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	clotted	0305921	24
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	clotted	0305908	23
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
5	Mercury	1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Ready MEC Layer: 2/27/01 Application: Ver 9.2.13A Not connected to Coordinator 11:28 AM

If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad) and 5 (Mercury) was pipetted, do not process these two vessels. Continue to pipette the whole blood for vessels 2, 3, 4 and 6 even if the CBC was run before the whole blood was pipetted. Attach the comment "laboratory error."

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

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BP: 498209

none

Tech ID: 1226 Sample ID: 498209 Name: LAWLESS, STEVE Gender: M Age: 43
 SP ID: 498209 SubSample: 1 Fasting_Req: 1

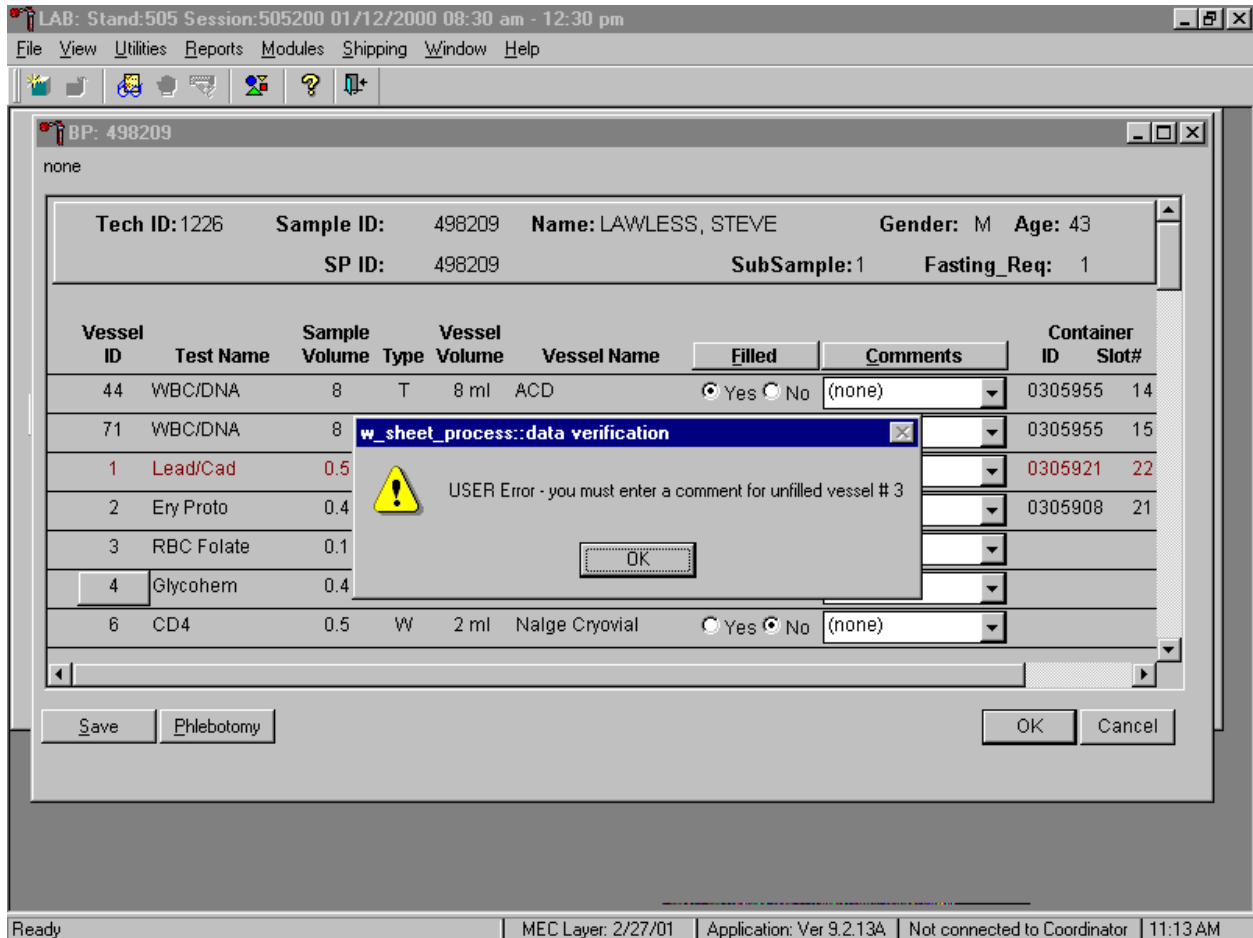
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
44	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	10
71	WBC/DNA	8	T	8 ml	ACD	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305955	11
1	Lead/Cad	0.5	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305921	19
2	Ery Proto	0.4	W	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	0305908	18
3	RBC Folate	0.1	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
4	Glycohem	0.4	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
6	CD4	0.5	W	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save Phlebotomy OK Cancel

Ready MEC Layer: 2/27/01 Application: Ver 9.2.13A Not connected to Coordinator 11:08 AM

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

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

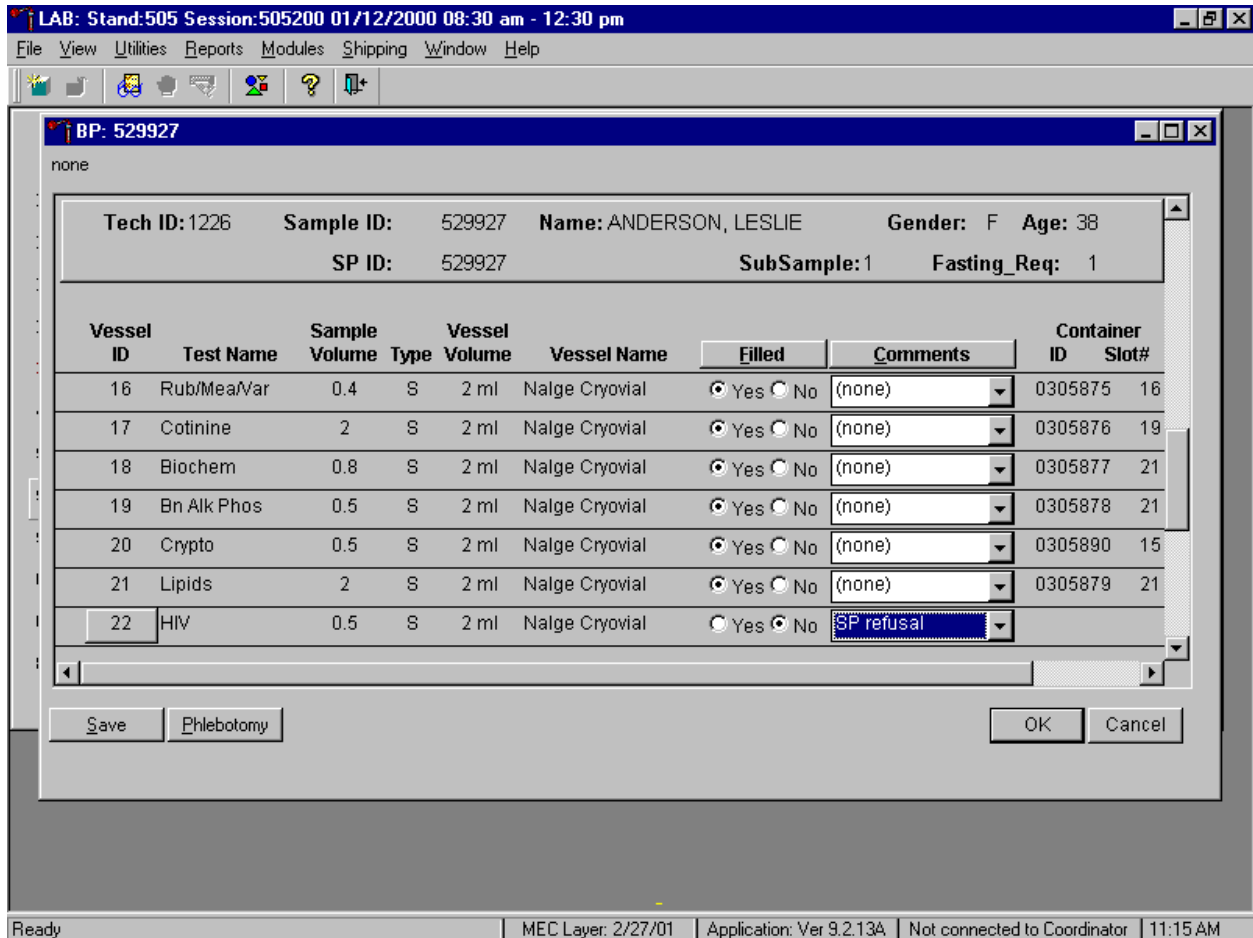


If the **Save** or the **OK** button is selected and all vessels are not marked as either Filled - "Yes" or Filled - "No," a warning message box displays requesting a comment for each unfilled vessel. To remove the warning message box, use the mouse to direct the mouse arrow to the **OK** button and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

8.9 Process HIV Urine

At the end of each session, process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for SPs 18-49) and the primary SP has not refused the HIV test. Record and save to the database, the HIV vessel 22 result.

If the quantity of serum is insufficient and the SP has not refused the test, mark vessel 22 as Filled – “No.”



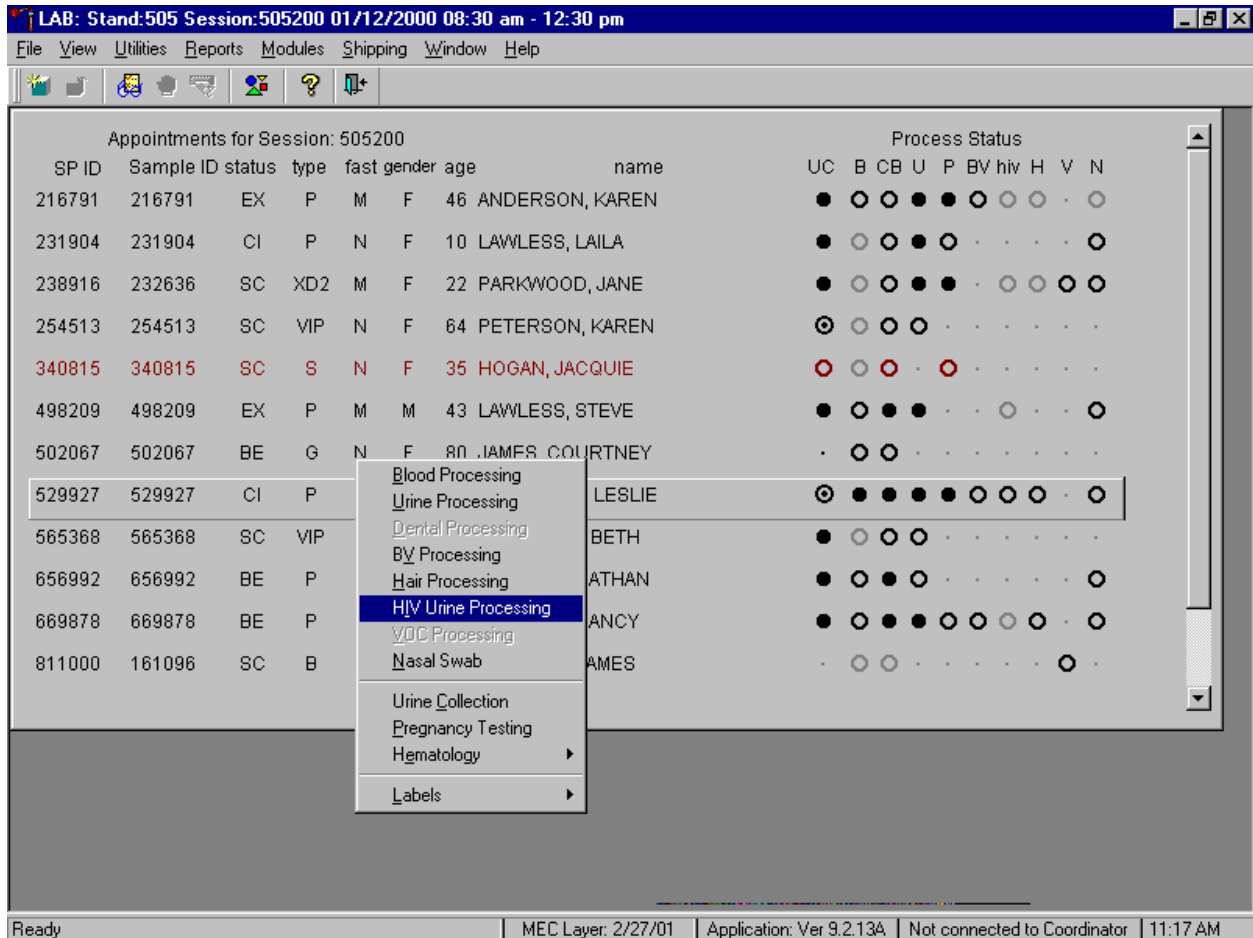
Once the blood processing result for vessel #22 (HIV) is Filled - "No" and the result is saved to the database, the HIV Urine Processing module becomes enabled.

Select the correct SP from the heads-up display.

Appointments for Session: 505200								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	●	●	○	○	○	○	○
231904	231904	CI	P	N	F	10	LAWLESS, LAILA	●	○	○	●	○	○	○	○	○	○
238916	232636	SC	XD2	M	F	22	PARKWOOD, JANE	●	○	○	●	●	○	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○	○	○	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	○	○	○	○	○	○	○	○	○	○
498209	498209	EX	P	M	M	43	LAWLESS, STEVE	●	○	●	●	○	○	○	○	○	○
502067	502067	BE	G	N	F	80	JAMES, COURTNEY	○	○	○	○	○	○	○	○	○	○
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	○	●	●	●	●	○	○	○	○	○
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	○	○	○	○	○	○	○	○	○
656992	656992	BE	P	N	M	7	LAWLESS, NATHAN	●	○	●	○	○	○	○	○	○	○
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	○	●	●	○	○	○	○	○	○
811000	161096	SC	V		M	41	FRAZIER2, JAMES	○	○	○	○	○	○	○	○	○	○

The process status hiv circle changes from gray to black when an SP is eligible for the HIV urine vessel.

Access the HIV Urine Processing module.



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

The HIV Urine Processing screen displays.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

HIV: 529927

none

Tech ID: 1226 Sample ID: 529927 Name: ANDERSON, LESLIE Gender: F Age: 38
 SP ID: 529927 SubSample: 1 Fasting_Req: 1

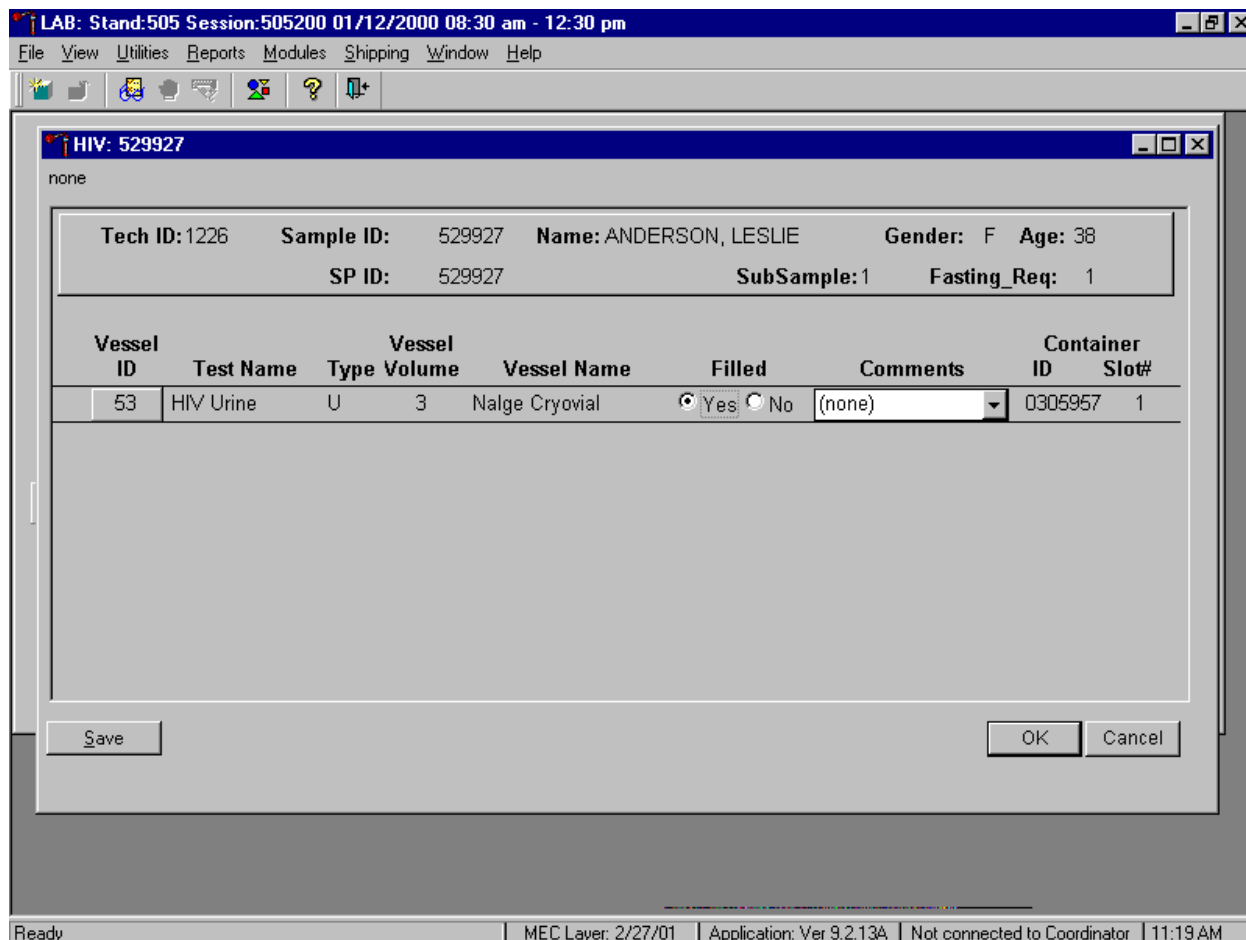
Vessel ID	Test Name	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

Ready MEC Layer: 2/27/01 Application: Ver 9.2.13A Not connected to Coordinator 11:17 AM

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

Mark the vessel as Filled – “Yes” or Filled – “No.”



To mark the HIV urine 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 this vessel is marked as Filled – "Yes," it is automatically assigned to a slot in an existing (open) container. To mark the HIV urine vessel as not collected or Filled - "No," use the mouse to direct the mouse arrow to the center of the "No" radio button and left click.

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

The screenshot shows a software window titled "HIV: 529927" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area contains patient information and a table of vessels.

none

Tech ID: 1226	Sample ID: 529927	Name: ANDERSON, LESLIE	Gender: F	Age: 38
	SP ID: 529927	SubSample: 1	Fasting_Req: 1	

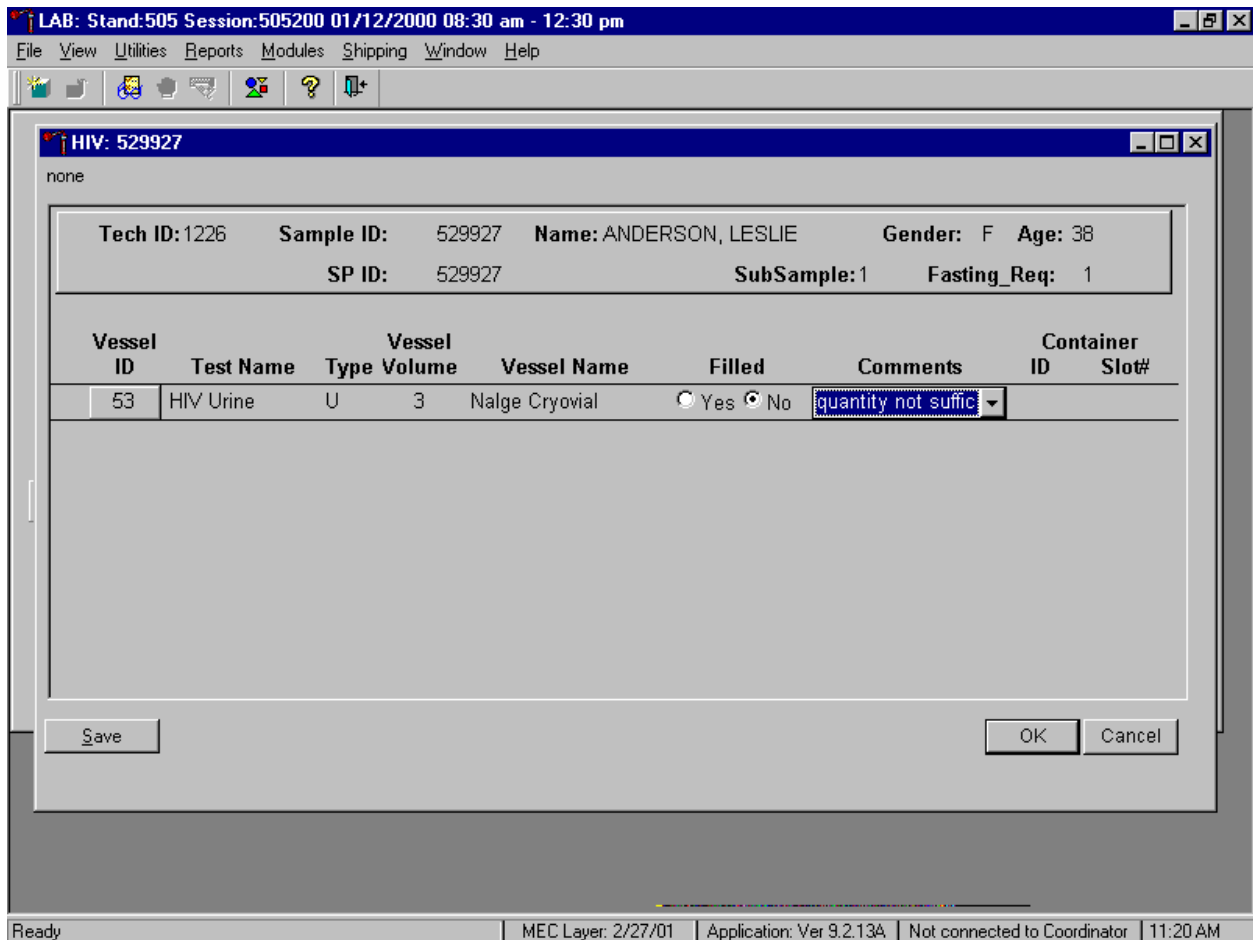
Vessel ID	Test Name	Vessel Type	Volume	Vessel Name	Filled	Comments	Container ID	Slot#
53	HIV Urine	U	3	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none) (none) blood present	0305957	1

Buttons: Save, OK, Cancel

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:20 AM

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

If this vessel is marked as Filled "No," the comment "quantity not sufficient" is automatically entered in the Comments column.



Review the information in the urine-processing window and save the data to the database. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **S**ave button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

8.10 Blood Specimen Storage

8.10.1 Blood Specimen Storage Protocol

Fill the blood vessels, enter the blood and HIV urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 8-27.

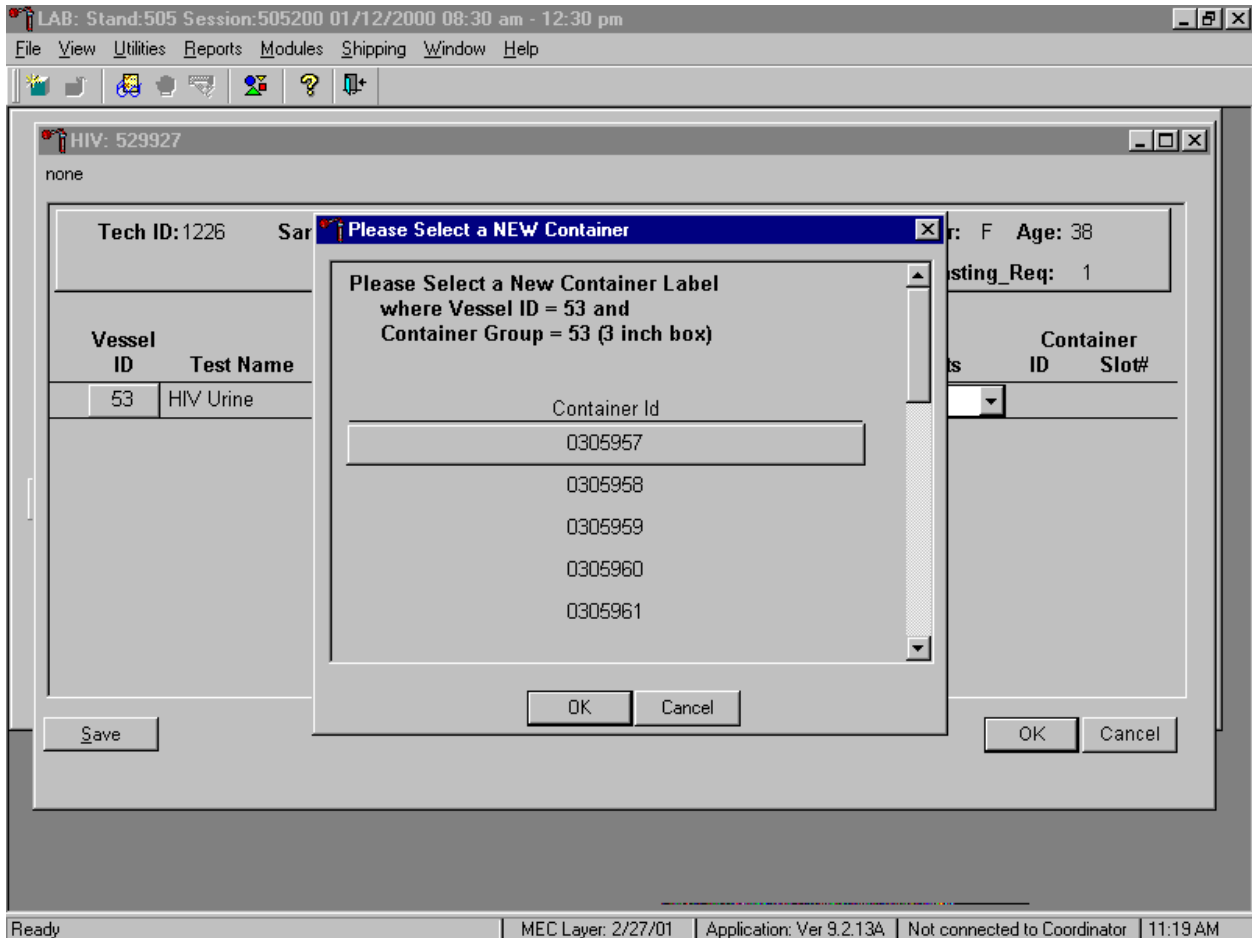
At the beginning of each stand, generate and print a series of bar coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process "opens" a storage box. Each vessel is assigned to a specific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

Exhibit 8-27. Storage protocol for blood and HIV urine

Shipping Location	Vessels	Conditions	Vessel Storage
CASPIR	1 Lead/Cad	Frozen	9 x 9 two inch box
CASPIR	2 Ery Proto	Frozen	9 x 9 two inch box
CASPIR	3 RBC Folate	Frozen	9 x 9 two inch box
University of Missouri	4 Glycohem	Refrigerated	9 x 9 two inch box
CASPIR	5 Mercury	Frozen	9 x 9 two inch box
CASPIR	6 CD4	Frozen	9 x 9 two inch box
CASPIR	7 Homocys/MMA	Frozen	9 x 9 two inch box
CASPIR	8 Xtra Plasma	Frozen	9 x 9 two inch box
University of Missouri	9 Glucose	Frozen	9 x 9 two inch box
University of Washington	10 Fibrin	Frozen	9 x 9 two inch box
CASPIR	11 Iron/TIBC	Frozen	9 x 9 two inch box
CASPIR	Ferritin	Frozen	9 x 9 two inch box
CASPIR	12 Fol/B12	Frozen	9 x 9 two inch box
University of Washington	13 CRP/Hpylori	Frozen	9 x 9 two inch box
CDC/NCID/Hepatitis Reference	14 Hepatitis	Frozen	9 x 9 two inch box
CASPIR	15 Vit A/E/Car	Frozen	9 x 9 two inch box
California Dept of Health Services	16 Rub/Mea/Var	Frozen	9 x 9 two inch box
CASPIR	17 Cotinine	Frozen	9 x 9 two inch box
Coulston Foundation	18 Biochem	Refrigerated	9 x 9 two inch box
University of Washington	19 Bn Alk Phos	Frozen	9 x 9 two inch box
CDC/Div of Parasitic Diseases	20 Crypto	Frozen	9 x 9 two inch box
Lipoprotein Analytical Laboratory/JHU	21 Lipids	Frozen	9 x 9 two inch box
CDC/NCID/AIDS Division	22 HIV	Frozen	9 x 9 two inch box
University of Missouri	23 Insul/Cpep	Frozen	9 x 9 two inch box
Emory University	24 HSV	Frozen	9 x 9 two inch box
CDC DASTLR/NCID	74 Syphilis	Frozen	9 x 9 two inch box
University of Washington	75 PSA	Frozen	9 x 9 two inch box
Coulston Foundation	25 FSH/LH	Frozen	9 x 9 two inch box
CASPIR	26 Selenium	Frozen	9 x 9 two inch box
CDC/Hospital Infections Program	27 Latex	Frozen	9 x 9 two inch box
Coulston Foundation	28 TSH/Thyrox	Frozen	9 x 9 two inch box
CASPIR	70 Vitamin D	Frozen	9 x 9 two inch box
CASPIR/Dr. Wayman Turner	29 Persis Pest	Frozen	9 x 9 three inch box
CASPIR/Dr. Charles Dodson	64 Phytoestro	Frozen	9 x 9 three inch box
CASPIR	32-42 Xtra Serum	Frozen	9 x 9 two inch box
CASPIR	43 DNA	Frozen	5 x 5 three inch box
Molecular Biology Branch	44 & 71 WBC/DNA	Room temperature	5 x 5 five inch box
CDC/NCID/AIDS Division	53 HIV Urine	Refrigerated	9 x 9 three inch box

8.10.2 Opening New Containers

When a container is full, the container will automatically "close." Open a new container to replace the closed container.

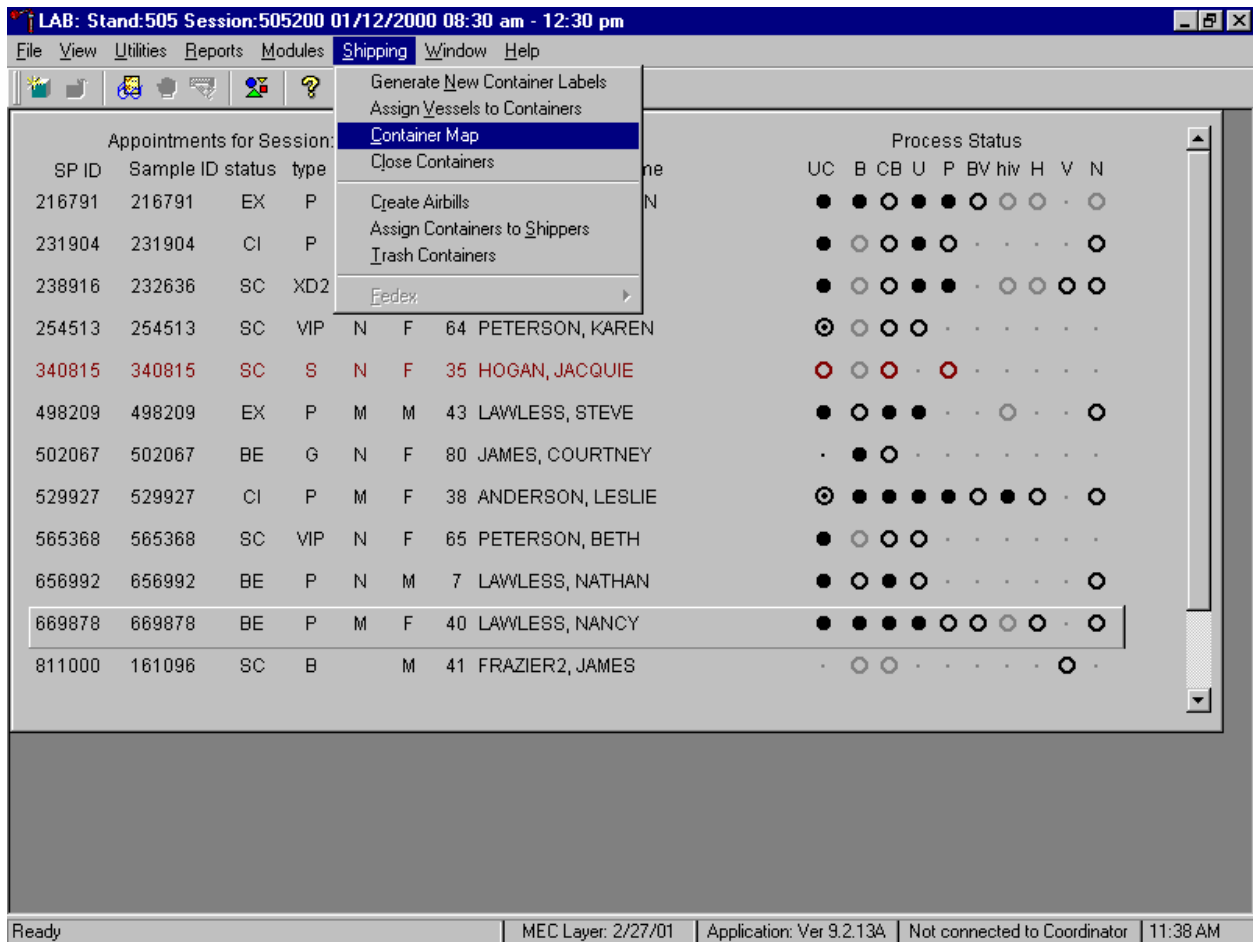


When a container is full, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left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

8.10.3 Check Storage Containers

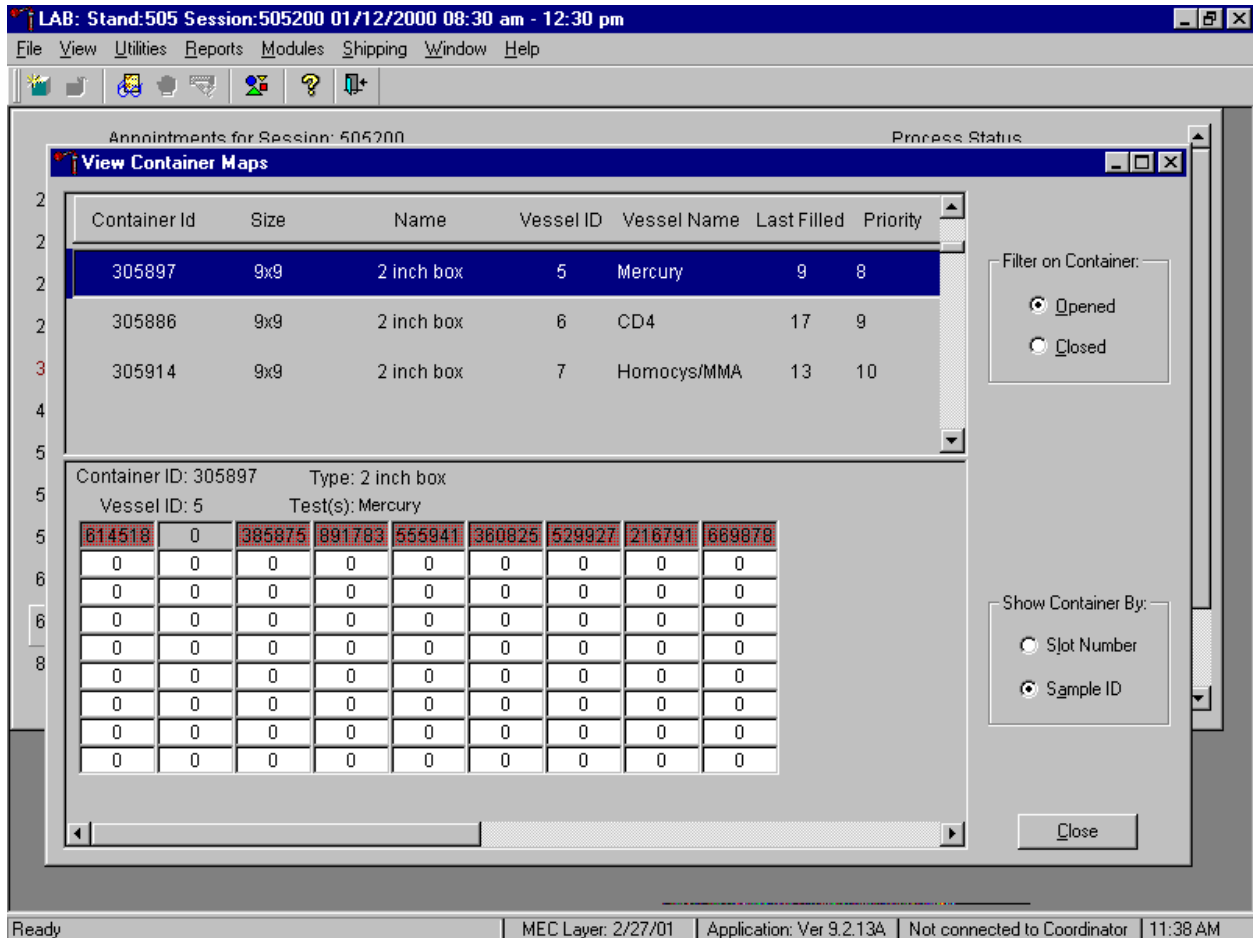
Check the slot assignment of containers associated with vessels 1-29, 43-44, 68, 70, 74-75, and 71 at the end of each session.

Access the Container Map report.



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

Verify the contents of each container against the container map.

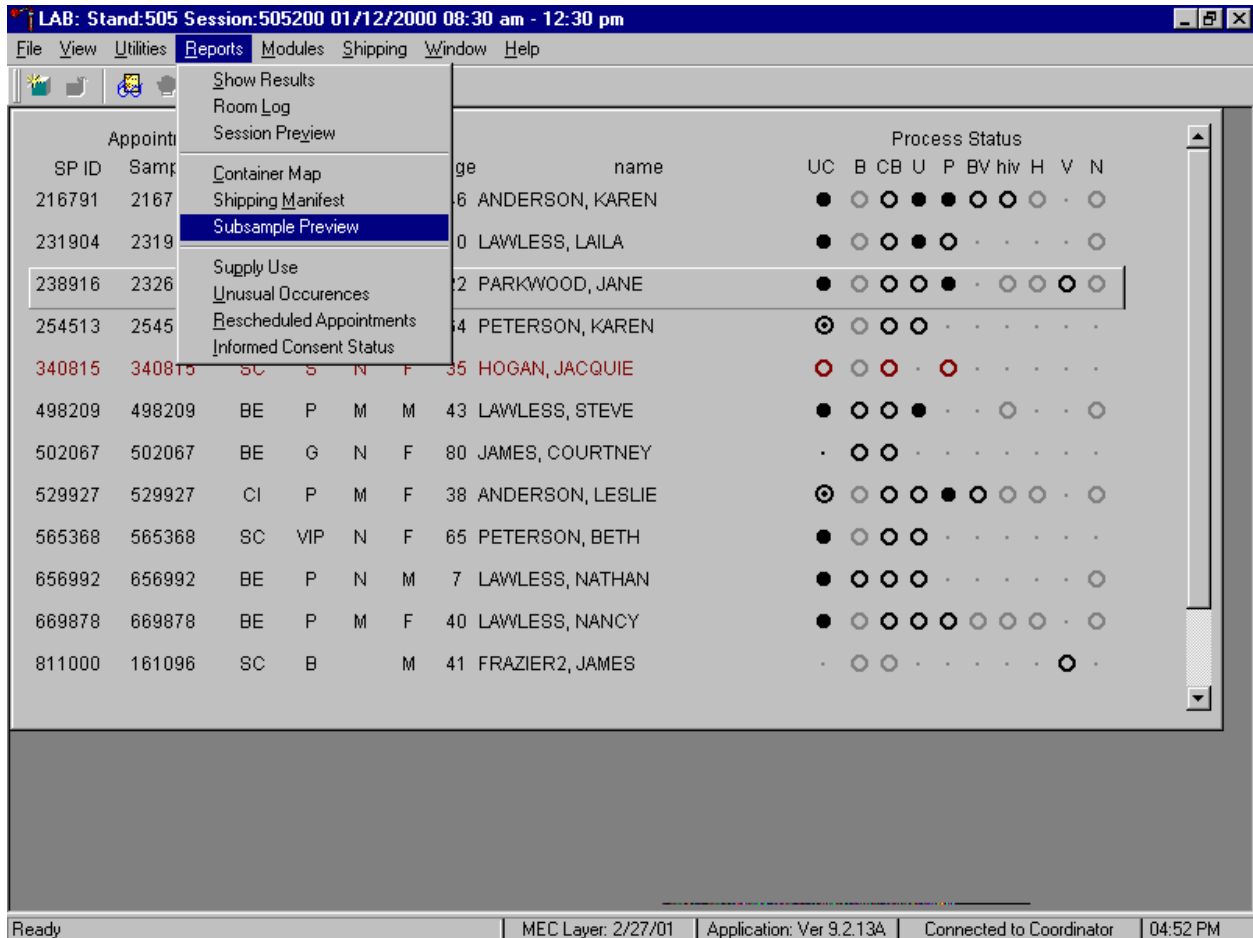


- Set the Filter on Container to "Opened" by using the mouse to direct the mouse arrow to "Opened" and left click.
- Set the Show Container By to "Sample ID" by using the mouse to direct the mouse arrow to "Sample ID" and left click.
- Highlight or select the first container ID for vessel 1 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 45.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining blood and urine HIV containers.

- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

8.11 Subsample and Session Previews and Informed Consent Status Report

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



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

Review the Subsample Preview.

Appointments for Session: 505200

Process Status

Subsample Report for Session 505200

Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
5053546	498209	LAWLESS, STEVE	M	43	1	Dioxins
					1	Heavy Metals
5053547	669878	LAWLESS, NANCY	F	40	1	Audiometry
					1	Dioxins
					1	DIMES-In person
					1	Heavy Metals
5053548	216791	ANDERSON, KAREN	F	46	1	Dioxins
					1	Heavy Metals
5053549	231904	LAWLESS, LAILA	F	10	1	EPA Priority Pesticide
					1	Organophosphate Pesticide
					1	DIMES-Telephone
					1	Urinary Iodine
5053550	529927	ANDERSON, LESLIE	F	38	1	CIDI
					1	DIMES-In person

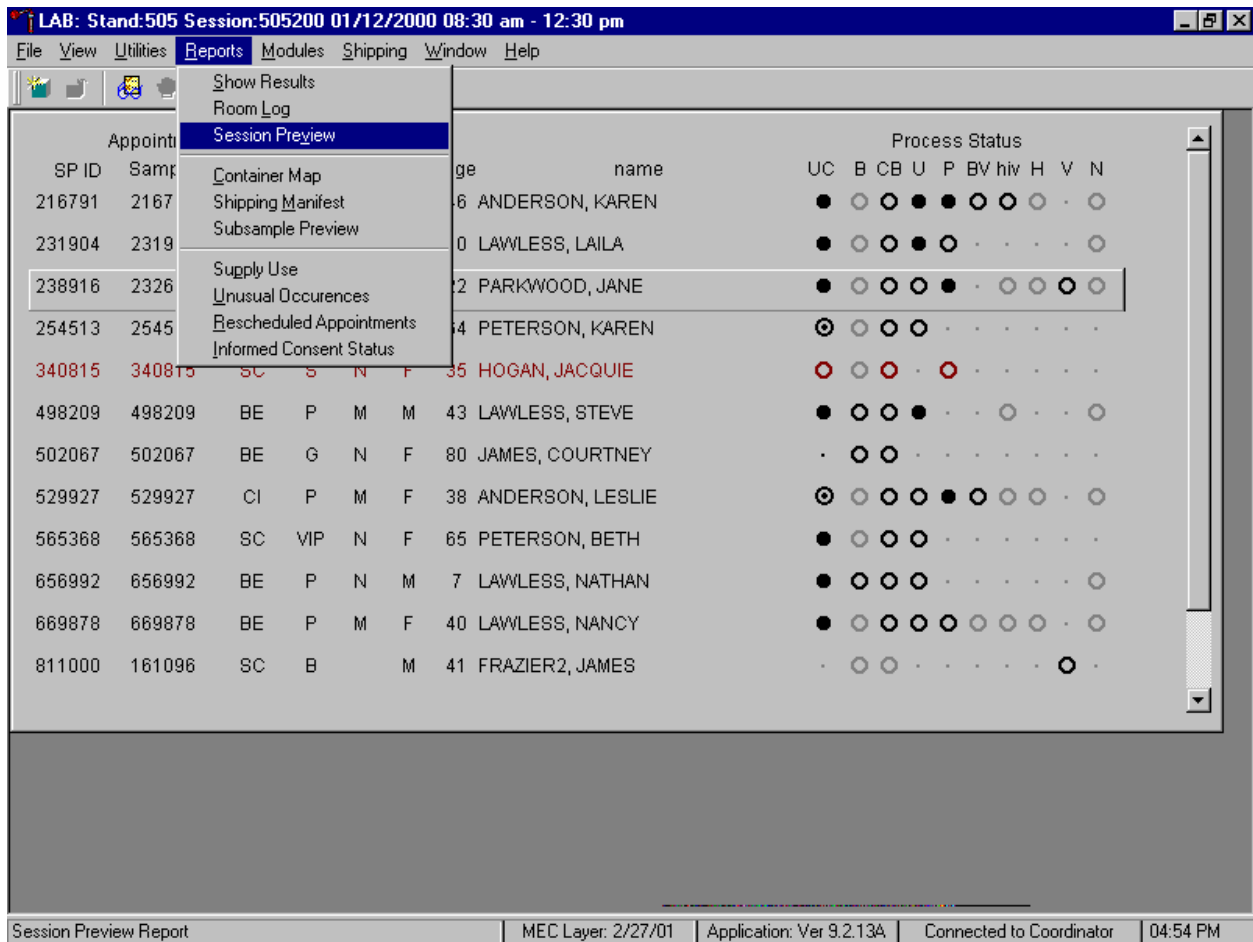
3/8/01

Page 1 of 2

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 04:53 PM

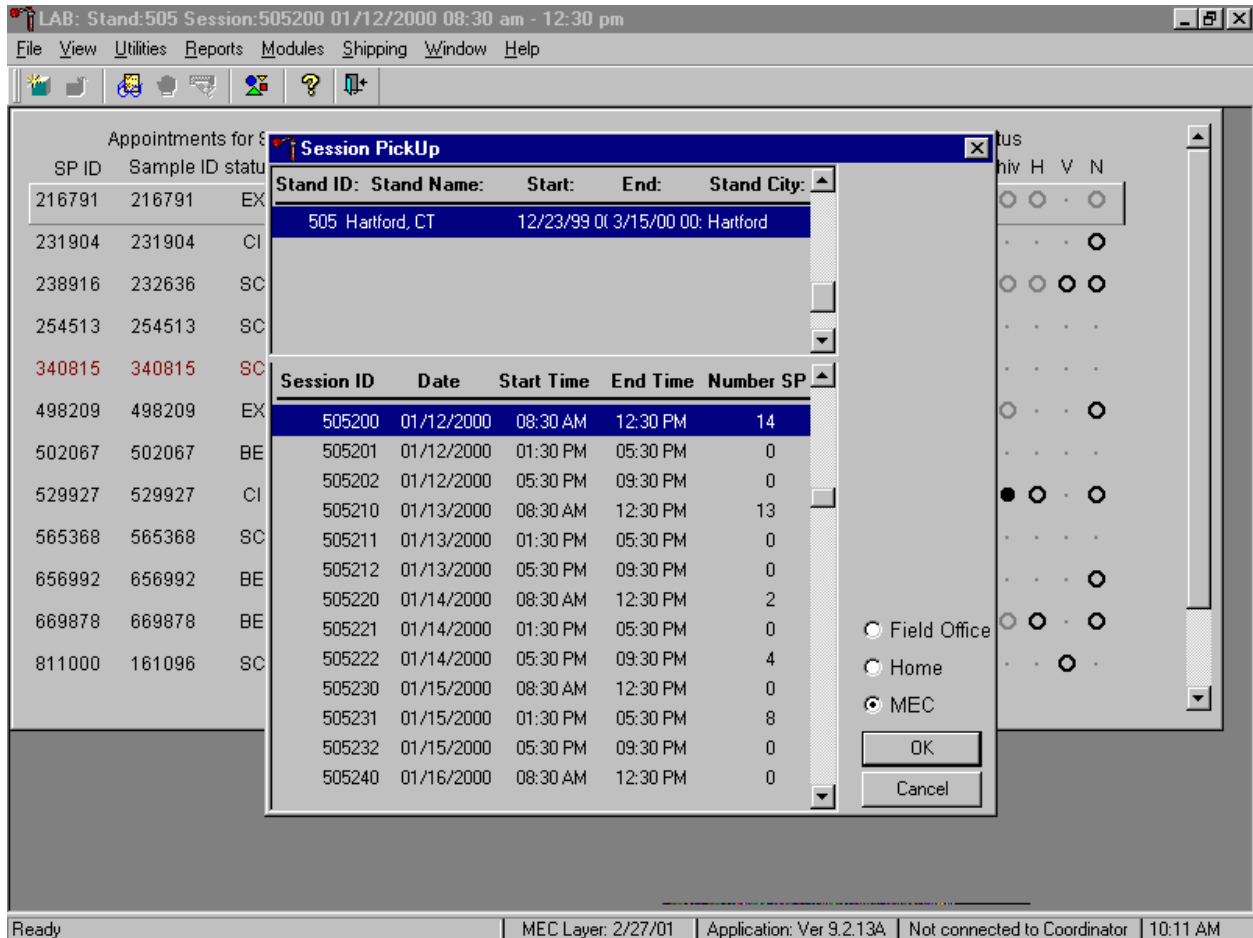
The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible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

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



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

Select the session.



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

The Session Preview Report displays.

Session Preview Report 03/08/01 16:55
Stand: 505

Session: 505200 01/12/2000 08:30 AM - 12:30 PM

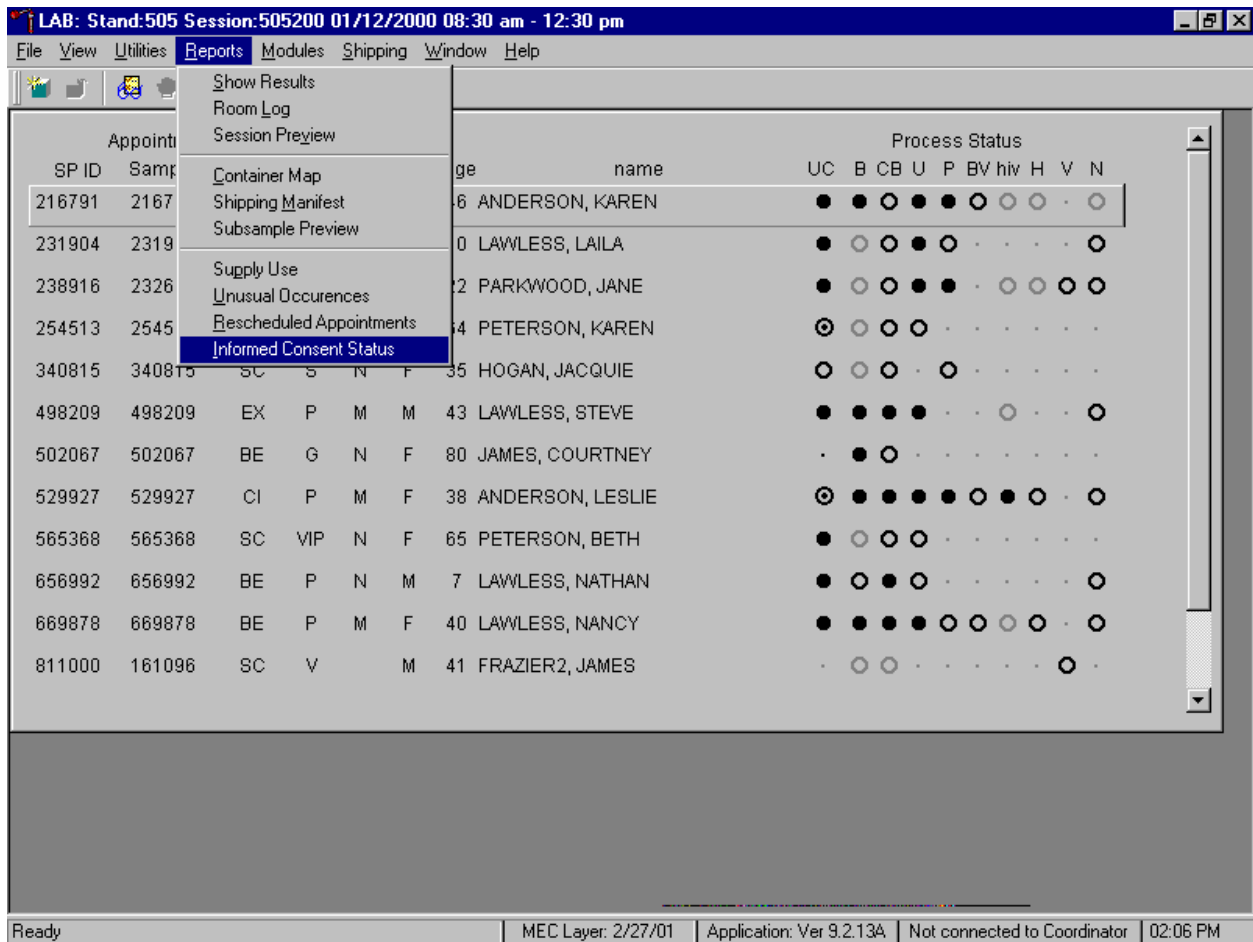
SP	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
505-00-0000-00-00 254513	VIP Guest	KAREN PETERSON	64 years	Female		
505-00-0000-00-00 565368	VIP Guest	BETH PETERSON	65 years	Female		
505-00-0000-00-00 502067	Guest	COURTNEY JAMES	80 years	Female		
505-01-0002-04-17 811000	TB & VOC	JAMES FRAZIER2	41 years	Male		
505-01-0002-04-20 909333	VOC	MITUL AMIN2	51 years	Female		
505-04-0016-15-01 238916	2nd Exam	JANE PARKWOOD	22 years	Female		

Page 1 of 3

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 04:55 PM

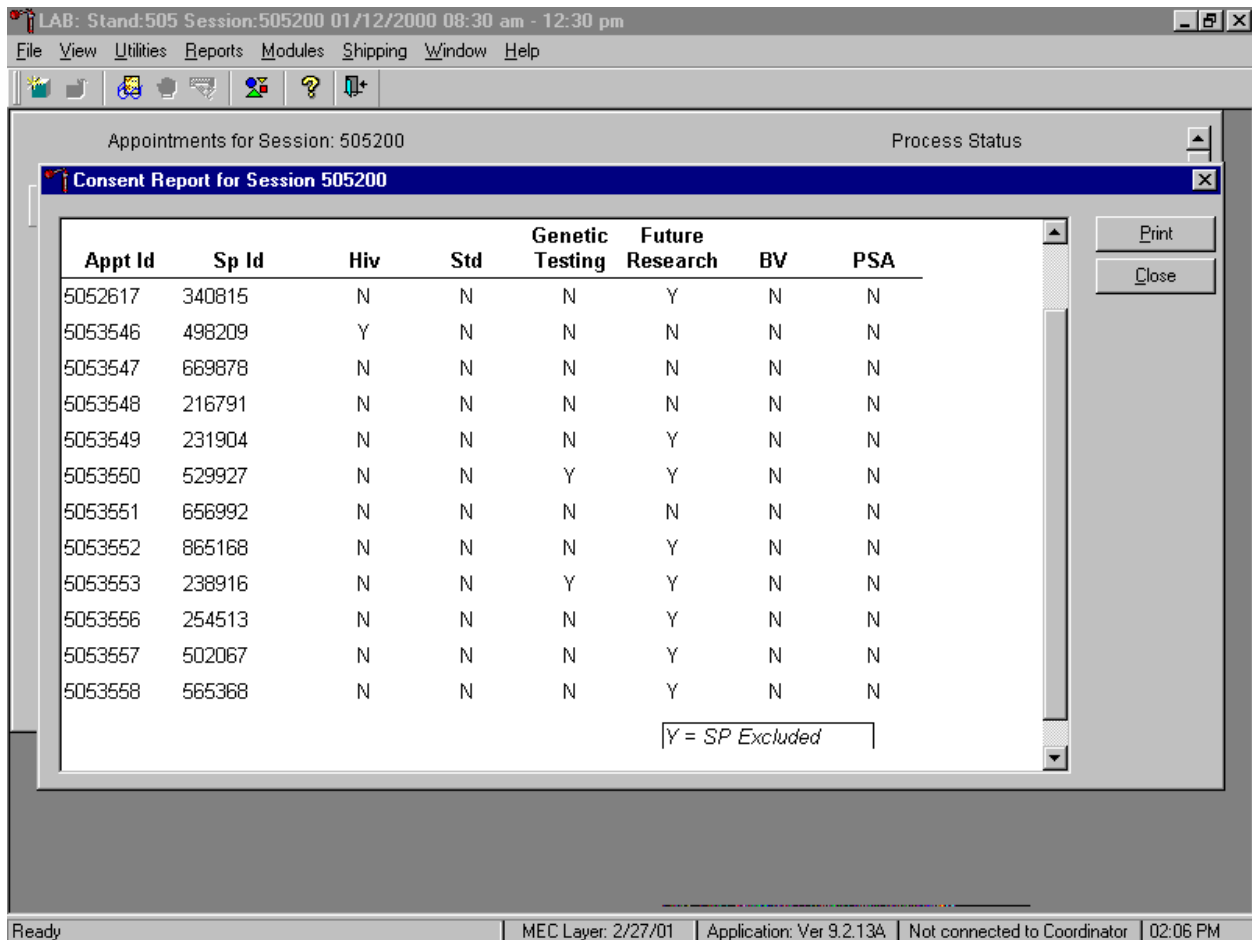
The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last) Age, Gender and any special considerations or consent comments. A blue asterisk in front of their name indicates SPs eligible for the VOC component.

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



To access the Informed Consent Status report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Informed Consent Status} and left click or type [Alt] [R/r], [I/i].

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



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

- hiv (vessels 22 – serum, 53 - urine)
- std (vessels 22 – HSV, 46 – Chlam/GC, 74 – Syphilis)
- genetic testing (vessels 44 and 71 – ACD tubes, 43 – clot)
- future research (vessels 8 – plasma, 32-42 – serum, 51-52 – urine)
- BV (vessel 72 – bacterial vaginosis, 73 – *T. vaginalis*)
- PSA (vessel 75)

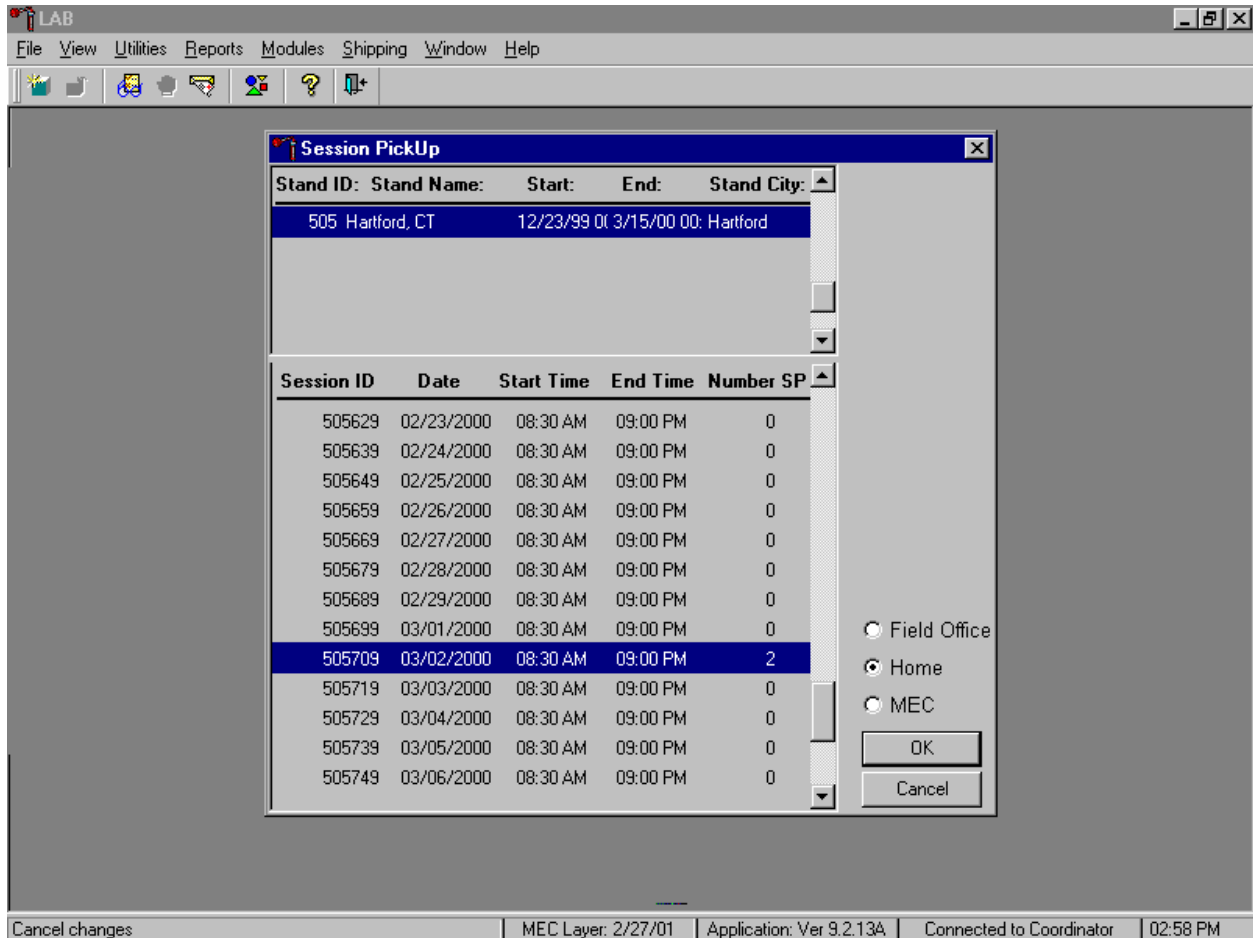
The status is “Y” or “yes” if the SP is excluded and “N” if the SP is not excluded.

8.12 Home Exam Blood Processing and Storage

The home examiner collects blood on home exam SPs, then transports the blood to the MEC and processes the blood in the MEC. Processing includes centrifuging blood collection tubes, aliquoting whole blood to storage vessels, centrifuging, separating, and aliquoting plasma and serum to storage vessels, performing a dilution and storing specimens. The home examiner uses all the routine laboratory supplies, processing equipment, and processing and storage protocols. Exhibits 8-6 through 8-8 illustrate the home exam SP's protocol for blood processing.

Log onto the laboratory application. Open the laboratory application. Sign onto the computer terminal if the staff is not conducting a MEC session.

Select the correct filter and session if the staff is not conducting a MEC session.



To select the correct filter, use the mouse to direct the mouse arrow to the Home radio button and right click to pick up (or filter on) home exam sessions. To select or highlight the correct home session, use the mouse to direct the mouse arrow to the correct session date, time, and right click. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

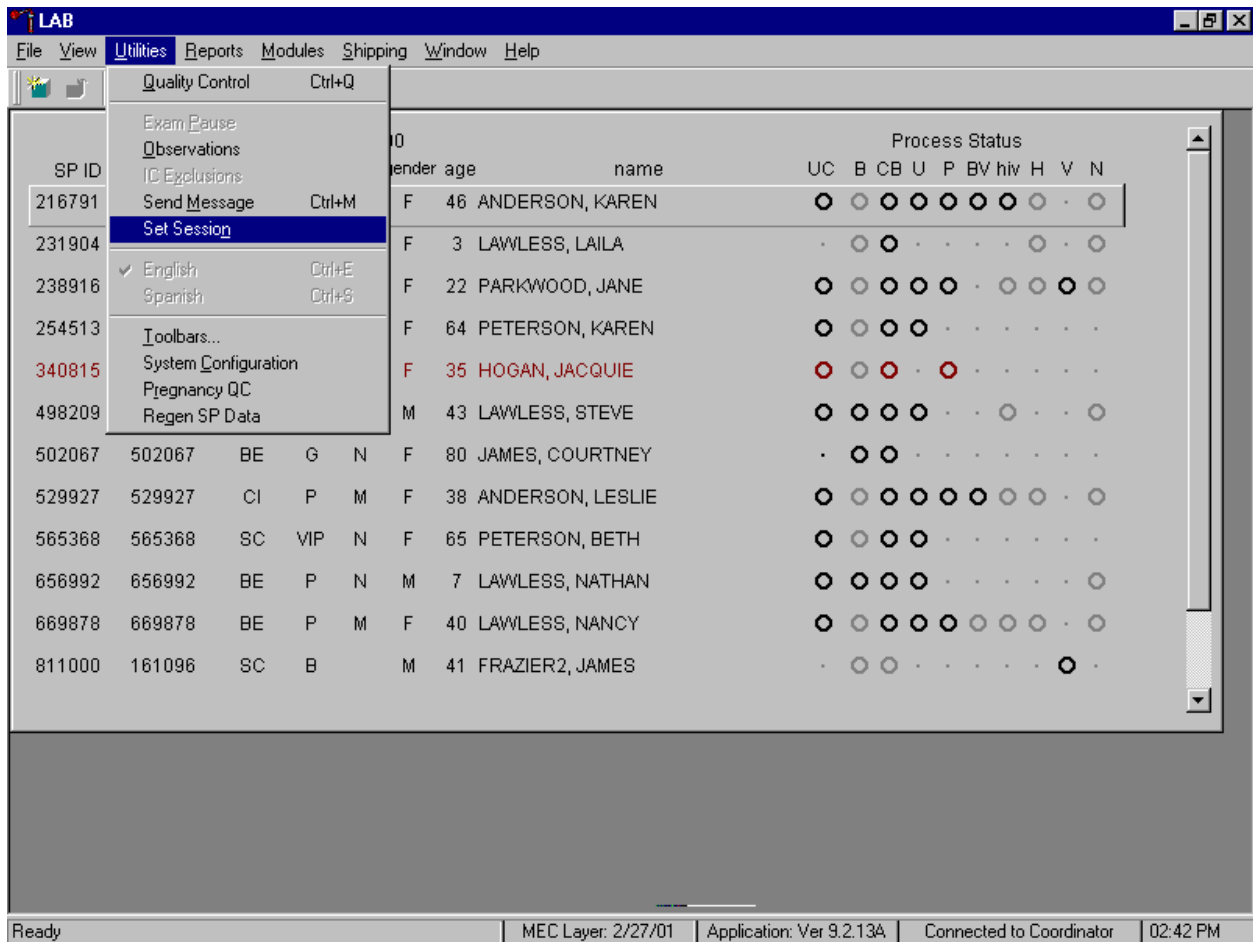
If the staff is conducting a MEC session, the laboratory application will default to the current MEC session.

Appointments for Session: 505200								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●	●	.	●
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●
498209	498209	BE	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	.	.	●
502067	502067	BE	G	N	F	80	JAMES, COURTNEY	.	●	●
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	.	●
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●
656992	656992	BE	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	●
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	.
811000	161096	SC	B		M	41	FRAZIER2, JAMES	.	●	●	●

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 02:42 PM

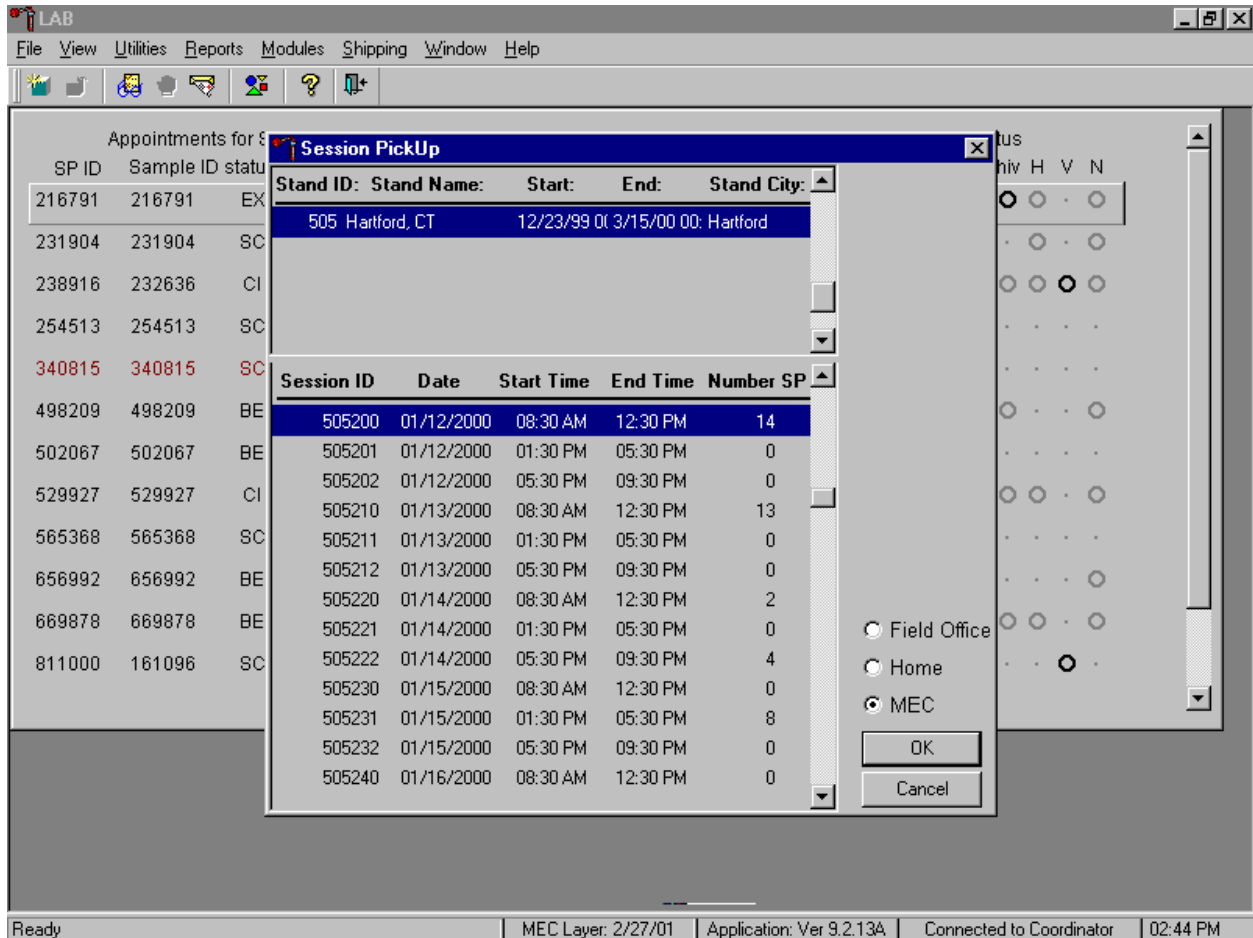
It is acceptable to set the session to a home exam session during a MEC session. Set only one computer terminal to access the MEC session and a second terminal to access a home session.

Use the Set Session laboratory module to access a home examination session when the staff is conducting a MEC session.



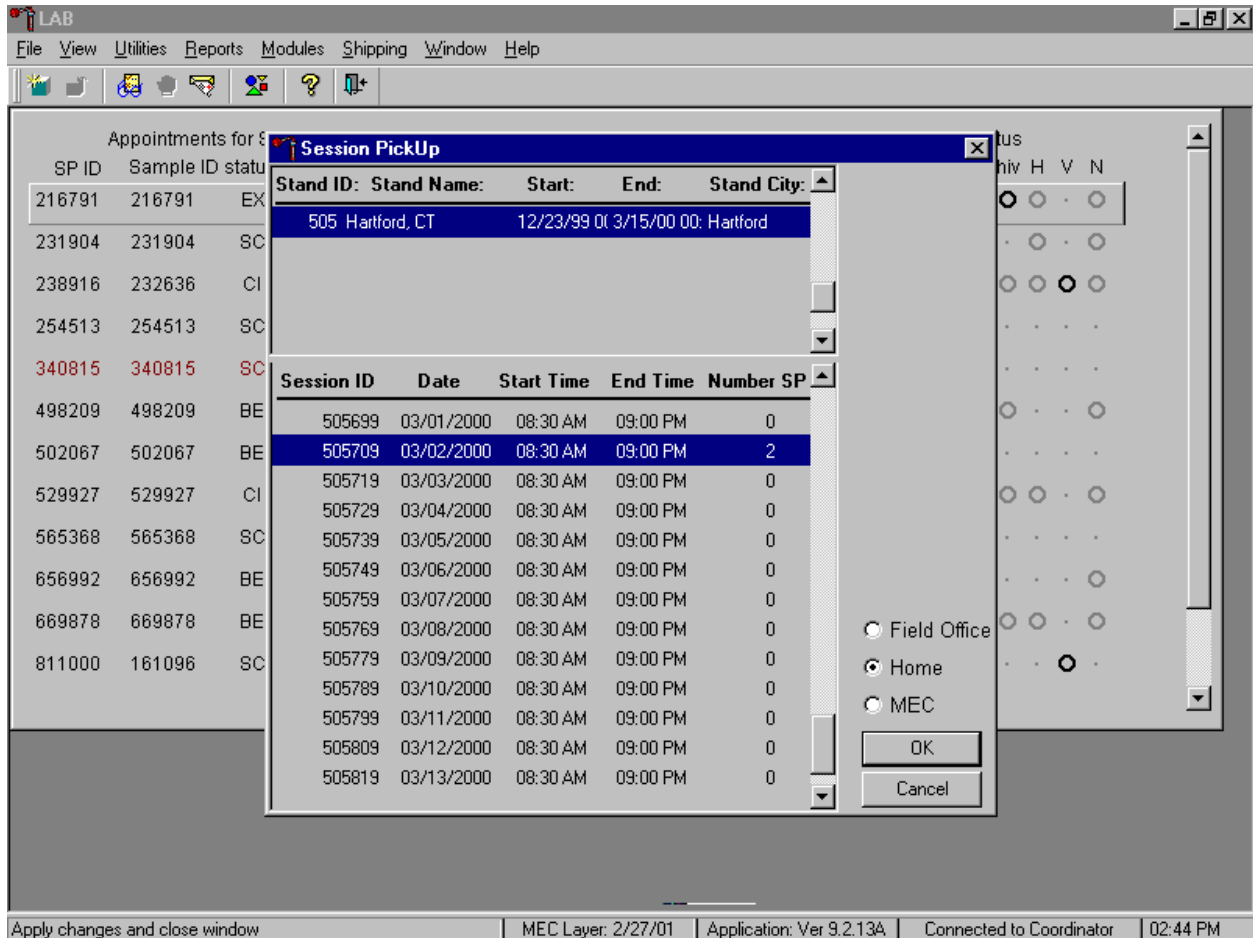
To access a home examination session when the staff is conducting a MEC session, use the mouse to direct the mouse arrow to the {Utilities} module in the top tile bar, drag the mouse arrow to {Set Session}, and left click or type [Alt] [U/u], [N/n.]

Select the correct Session Pickup filter.



The Session Pickup list displays. To filter on home examination sessions, and not MEC sessions, use the mouse to direct the mouse arrow to the Home radio button and left click.

Select the correct home exam session.



To select or highlight the correct home session, use the mouse to direct the mouse arrow to the correct session date and time. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The selected home exam session displays.

Appointments for Session: 505709								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
285851	285851	EX	H	10	F	52	MATTEL, CAROLYN	.	●	●	○
641596	641596	EX	H	10	M	58	MITCHELL, STUART	.	●	●	○

Review the heads-up screen. Verify that the home examination SP(s) is (are) scheduled into this session and that the exam status is EX or “examined.” Use the heads-up display to view the home exam SPs, the modules for which they are eligible and their current process status, and to print blood processing labels.

The Heads-up display lists home exam SPs scheduled for the session. It lists the SP ID, Sample ID, Status (SC=scheduled, EX=examined), Type (H=home exam), fast (N=none), Gender, Age, and Name (last then first.)

The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible for a module when the process status is •. The SP is eligible for a module but no results have been recorded when the process status is ○. The SP is eligible for a module and some results have been recorded when the process status is ◐. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●. The SP is eligible for a module but the process status is O until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from O to ○. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from O to ○. The process status updates and changes after each result is saved.

Print labels for an SP, access the blood-processing screen and process, store the vessels, and record the processing results using procedures described in Sections 8.7, 8.8, and 8.10.

8.13 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 1 Blood Processing and HIV Urine Processing Worksheet (Exhibit 8-28). Complete a Workstation 1 worksheet for each SP while processing the blood and HIV urine specimens. Enter the results after the system is operational.

Exhibit 8-28. Workstation 1 worksheet

BLOOD PROCESSING AND HIV URINE PROCESSING

SP ID _____

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>QNS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
1	Lead/Cad	1-5 6-11 12+	0.3 0.6 0.5	WB				
2	Ery Proto	1-11 12+	0.3 0.4	WB				
3	RBC Folate	3+	0.1	WB				
4	Glycohem	12+	0.4	WB				
5	Mercury	1-5 16-49	0.5 1.0	WB				
6	CD4	18-49	0.5	WB				
7	Homocys/MMA	3+	1.0	P				
8	Xtra Plasma	6+	0.5	P				
9	Glucose	12+	0.5	P				
10	Fibrin	40+	1.0	P				
11	Iron/TIBC	1-2 3+	1.2 1.0	S				
68	Ferritin	1+	0.3	S				
12	Fol/B12	3-5 6+	0.8 1.3	S				
13	CRP/Hpylori	3+	0.5	S				
14	Hepatitis	2-5 6+	0.2 1.5	S				
15	Vit A/E/Car	3-11 12+	0.3 0.4	S				
16	Rub/Mea/Var	6-49	0.4	S				
17	Cotinine	3-11 12+	1.5 2.0	S				
18	Biochem	12-150	0.8	S				
19	Bn Alk Phos	8+	0.5	S				
20	Crypto	6-11 12-49	0.2 0.5	S				

Exhibit 8-28. Workstation 1 worksheet (continued)

ID	Name	Ages	Sample mL	Sample Type	Filled ✓	Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i>	Not Filled Comments <i>QNS</i> <i>SP Refusal</i> <i>Lab Error</i>	Slot #
21	Lipids	3-5 6-11 12+	0.2 1.5 2.0	S				
22	HIV	18-49	0.5	S				
23	Insul/Cpep	12+	1.0	S				
24	HSV	14-49	0.5	S				
74	Syphilis	18-49	0.5	S				
75	PSA	40+	1.0	S				
25	FSH/LH	35-60	0.8	S				
26	Selenium	3-11	0.3	S				
27	Latex	12-59	0.5	S				
28	TSH/Thyrox	12+	1.0	S				
70	Vitamin D	6+	0.5	S				
29	Persis Pest	12+	4.0	S				
64	Phytoestro	12+	4.0	S				
32	Xtra Sera	6+	0.5	S				
33	Xtra Sera	6+	0.5	S				
34	Xtra Sera	6+	0.5	S				
35	Xtra Sera	12+	0.5	S				
36	Xtra Sera	12+	0.5	S				
37	Xtra Sera	12+	0.5	S				
38	Xtra Sera	12+	0.5	S				
39	Xtra Sera	12+	0.5	S				
40	Xtra Sera	12+	0.5	S				
41	Xtra Sera	12+	0.5	S				
42	Xtra Sera	12+	0.5	S				
43	DNA	20+	17.0	C				
44	WBC/DNA	20+	8.0	WB				
71	WBC/DNA	20+	8.0	WB				
53	HIV Urine	18-49	5.0	U				

WB = Whole Blood P = Plasma S = Serum C = Clot U = Urine

9. PRINTING LABELS AND SPECIMEN SHIPMENT

9.1 Introduction

Labels are essential to the laboratory component. Labels support each SP's unique processing protocol. When blood tube labels, vessel labels, and pregnancy test labels are generated, the laboratory record is created. This record forms the basis for each SP's data in the database. Container labels are generated and assigned to vessel storage containers and allow a processed sample to be tracked from MEC processing through contract laboratory receipt.

The technologists ship biological specimens to a variety of contract laboratories in double-sided Styrofoam and corrugated cardboard shippers using dry ice or wet ice (refrigerant packs). Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 9.1, the Shipping Protocol, illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Ship packages using FedEx. The chief medical technologist is responsible for contacting FedEx at the start of each stand to determine availability. The MEC manager contacts the dry ice company at each stand to establish a contact but the chief medical technologist arranges for the delivery of dry ice on shipping days. It is the chief medical technologist's responsibility to confirm the arrangements for shipping and dry ice delivery with the MEC manager at the beginning of each stand.

The chief medical technologist works with the MEC manager and the home office to determine exactly which days to ship specimens to the contract laboratories. As a rule, pack and ship most specimens once a week during MEC split exam sessions. The only exception is the 8-mL ACD genetic tube; these tubes are shipped within 48 hours of collection, whenever possible. All specimens should arrive at the destination the day after shipping. The next-day limitation may conflict with off days, holidays, and vacations. If a conflict with the shipping schedule, working schedule, or the contract laboratory schedule occurs, consult the MEC manager and the home office.

Exhibit 9-1. Shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Blood				
CASPIR	Lead/Cad	Frozen	9 x 9 two inch box	Weekly
CASPIR	Ery Proto	Frozen	9 x 9 two inch box	Weekly
CASPIR	RBC Folate	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Glycohem	Refrigerated	9 x 9 two inch box	Weekly
CASPIR	Mercury	Frozen	9 x 9 two inch box	Weekly
CASPIR	CD4	Frozen	9 x 9 two inch box	Weekly
CASPIR	Homocys/MMA	Frozen	9 x 9 two inch box	Weekly
CASPIR	Xtra Plasma	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Glucose	Frozen	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	Fibrin	Frozen	9 x 9 two inch box	Weekly
CASPIR	Iron/TIBC	Frozen	9 x 9 two inch box	Weekly
CASPIR	Ferritin	Frozen	9 x 9 two inch box	Weekly
CASPIR	Fol/B12	Frozen	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	CRP/Hpylori	Frozen	9 x 9 two inch box	Weekly
CDC/HRL (Hepatitis Reference Lab)	Hepatitis	Frozen	9 x 9 two inch box	Weekly
CASPIR	Vit A/E/Car	Frozen	9 x 9 two inch box	Weekly
California Dept of Health Services	Rub/Mea/Var	Frozen	9 x 9 two inch box	Weekly
CASPIR	Cotinine	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	Biochem	Refrigerated	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	Bn Alk Phos	Frozen	9 x 9 two inch box	Weekly
CDC/Div of Parasitic Diseases	Crypto	Frozen	9 x 9 two inch box	Weekly
Lipoprotein Analytical Lab Johns Hopkins University	Lipids	Frozen	9 x 9 two inch box	Weekly
CDC/NCID AIDS Division	HIV - serum	Frozen	9 x 9 two inch box	Weekly
University of Missouri (Columbia School of Medicine)	Insul/Cpep	Frozen	9 x 9 two inch box	Weekly
Emory University (School of Medicine)	HSV	Frozen	9 x 9 two inch box	Weekly
CDC DASTLR/NCID	Syphilis	Frozen	9 x 9 two inch box	Weekly
University of Washington (Immunology Division)	PSA	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	FSH/LH	Frozen	9 x 9 two inch box	Weekly
CASPIR	Selenium	Frozen	9 x 9 two inch box	Weekly
Hospital Infections Program/CDC	Latex	Frozen	9 x 9 two inch box	Weekly
Coulston Foundation	TSH/Thyrox	Frozen	9 x 9 two inch box	Weekly
CASPIR	Vitamin D	Frozen	9 x 9 two inch box	Weekly
CASPIR/Dr. Wayman Turner	Persis Pest	Frozen	9 x 9 three inch box	Weekly

Exhibit 9-1. Shipping protocol (continued)

Location	Vessels	Conditions	Vessel storage	Shipping frequency
CASPIR/Dr. Charles Dodson	Phytoestro	Frozen	9 x 9 three inch box	Weekly
CASPIR	Xtra Sera	Frozen	9 x 9 two inch box	Weekly
CASPIR	DNA	Frozen	5 x 5 three inch box	Weekly
CDC/MBB (Molecular Biology Branch)	WBC/DNA	Room temperature	5 x 5 five inch box	48 hours
Urine				
University of Minnesota (School of Medicine)	Alb/Creat	Frozen	9 x 9 three inch box	Weekly
CDC/NCID/NCHSTP	Chlam/GC	Frozen	9 x 9 three inch box	Weekly
University of Washington (Immunology Division)	NTX	Frozen	9 x 9 two inch box	Weekly
CASPIR	Urn Iodine	Frozen	9 x 9 three inch box	Weekly
CDC/Dr. Dana Barr	Prior Pest	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	Organophos	Frozen	5 x 5 three inch box	Weekly
CASPIR	Urn Merc	Frozen	9 x 9 three inch box	Weekly
CASPIR	Heavy Metal	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	Urn Phytoes	Frozen	5 x 5 three inch box	Weekly
CDC/Dr. Dana Barr	PAH	Frozen	9 x 9 three inch box	Weekly
CDC/Dr. John Brock	Phthalates	Frozen	9 x 9 three inch box	Weekly
CASPIR	Xtra Urine	Frozen	9 x 9 three inch box	Weekly
CDC/NCID AIDS Laboratory	HIV	Refrigerated	9 x 9 three inch box	Weekly

9.2 Equipment and Supplies

Exhibit 9-2 contains a list of label/shipping supplies.

Exhibit 9-2. Supplies for labels/shipping

Small Styrofoam shippers (14x 14 x 10)	Medium Styrofoam shippers (16 x16 x 15.5)
U-TEK Reusable Refrigerant Packs Large	U-TEK Reusable Refrigerant Packs Small
5-mL cryovial sterile	2-mL cryovial sterile
14-mL snap cap test tube	2-mL cryovial non-sterile
Conical tube 50-mL	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 cardboard box with 9 x 9 cardboard grid
5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert	Scale
5.25 x 5.25 x 3.0 inch cardboard box without grid	Three inch 5 x 5 cardboard grid
Bitran bag 12 x 12	Zip closable bags – Quart size
Absorbent sheets (2 x 2)	Rubber bands
Large padded envelope	Newsprint paper
Cryo gloves	Full face shield
Hammer	Dry ice scoop
Tape gun	Packaging tape 2”
Biohazard label	Refrigerate Do Not Freeze label
Keep Frozen label	Avery 5160 labels
Label Datamax (1.125”)	Printer ribbon, Datamax (thermal transfer)
Sheet-fed laser labels	Wipes, Terri 13” x 18”
FedEx large boxes	FedEx preprinted return labels - FO
Clear FedEx label pouches	FedEx preprinted return labels - Warehouse
FedEx Class 9 label	FedEx preprinted return labels - Blank
Toner cartridge (HP Laser Jet 4000)	Lab jackets (Petite, Lg, X-Lg)

9.3 Print Vessel Labels and Label Blood-Processing Racks

Before each session, the technologist at workstation 3 prints all labels for all SPs assigned to a session. The correct bar coded labels automatically print for each SP based on the SP's age, sex, person type, and subsample selection. Print blood tube, pregnancy, urine processing, and blood processing labels for all SPs in the MEC or home exam session. The phlebotomist, home examiner, and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks.

Distribute labels and assemble blood-processing racks:

- Place pregnancy and urine labels at workstation 2 in the laboratory.

Save and recycle unused vessels:

- If the SP does not show up for the appointment, it is possible they will reschedule.

- Store the SP's vessels and labels in a zip closable bag until the end of the stand.
- If the SP has not shown up by the end of the stand, recycle the unused vessels.

Assemble blood-processing racks:

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

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

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

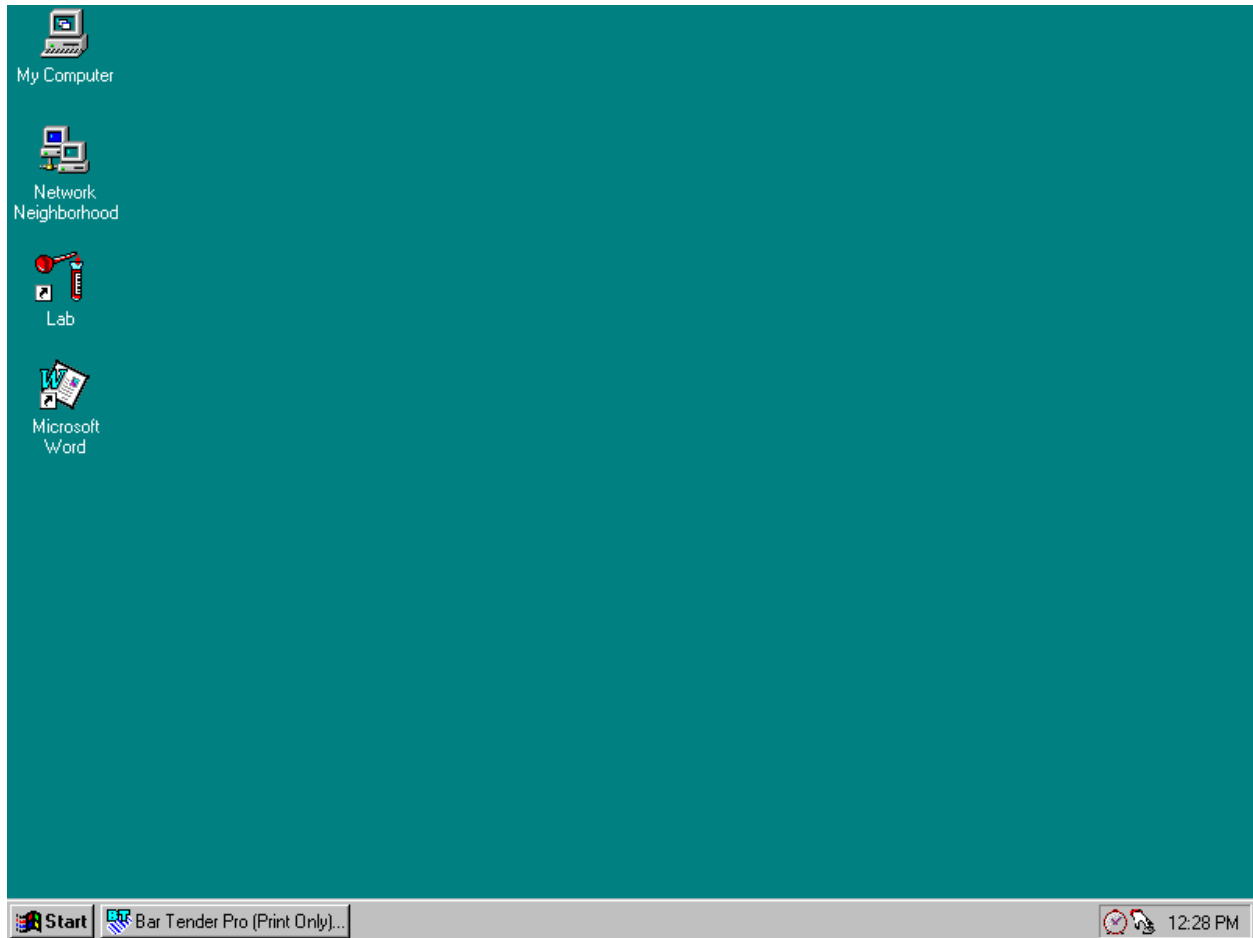
- Styrofoam rack
- Age appropriate processing template
- Storage vessels of the following sizes:
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The set-up of the rack depends on the subject's age, sex, person type, and subsample selection. When possible, prepare the racks at least one day before the SP arrives for the MEC examination.

- Place the prelabeled blood processing racks in the laboratory at the start of each session.

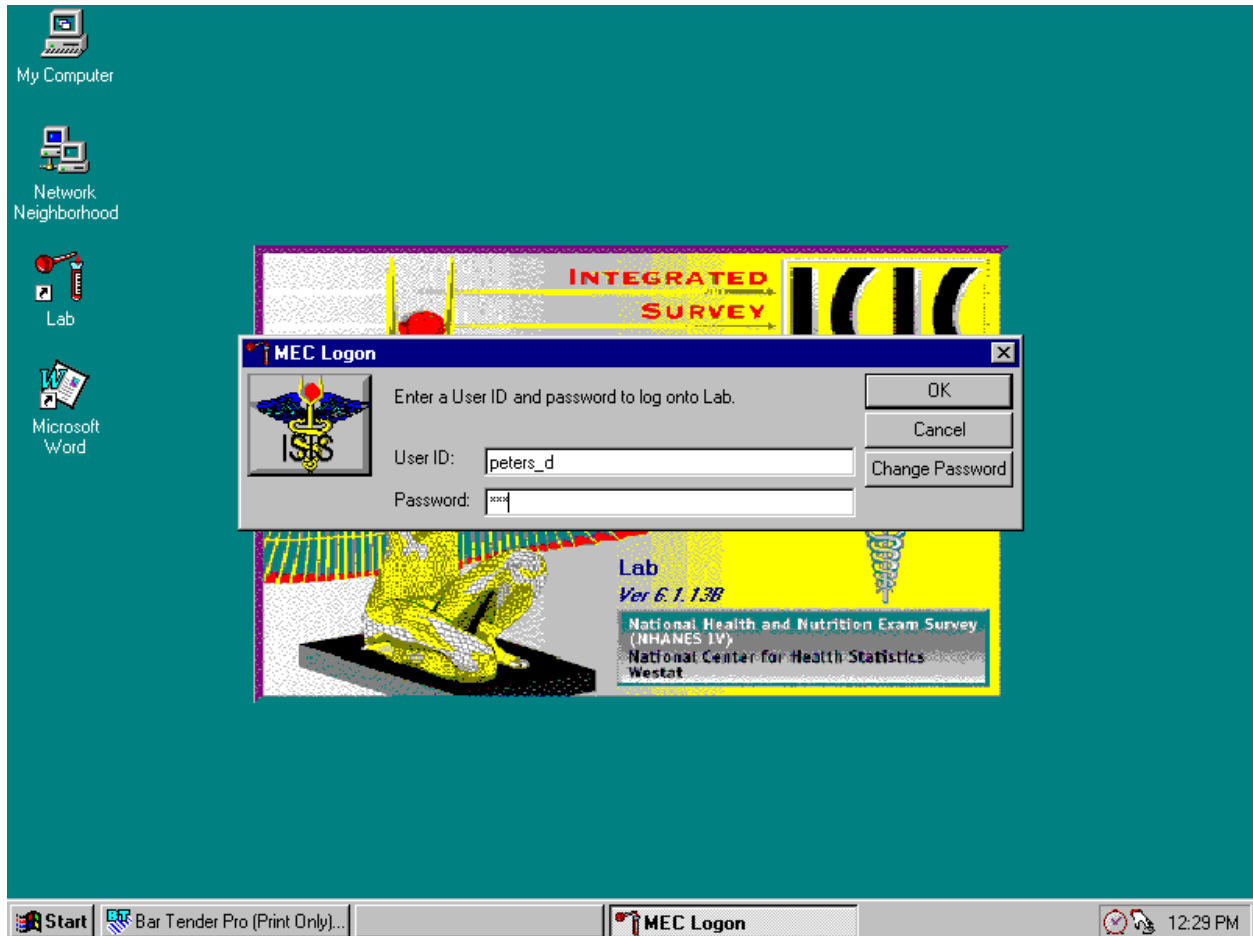
9.3.1 Print Vessel Labels Using the Print Labels Module

Open the Laboratory application.



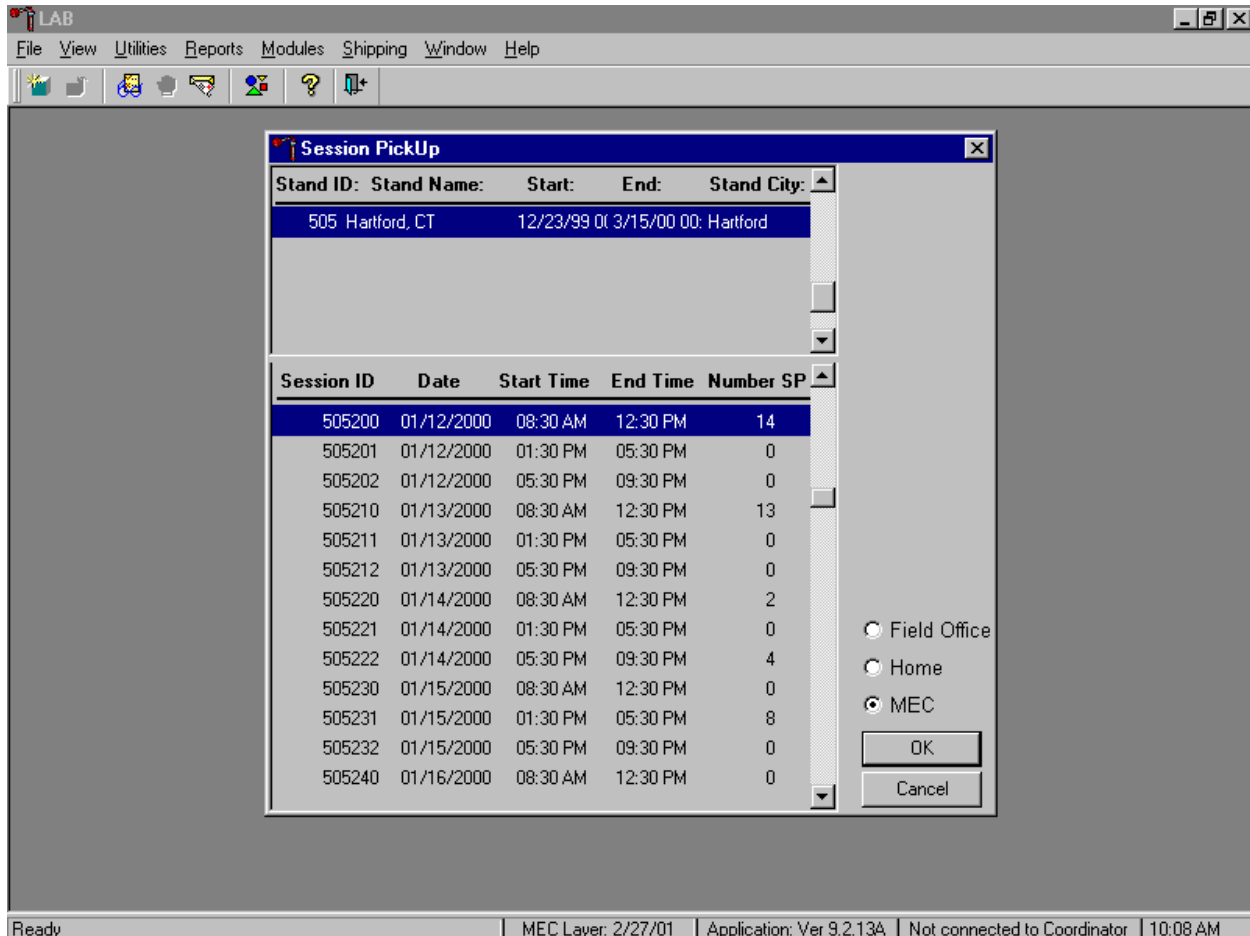
To open the Laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Log onto the computer terminal.



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

Select the correct filter and session if the MEC is not conducting a session.



The Session Pickup window displays. To select the correct filter, use the mouse to direct the mouse arrow to the MEC or Home radio button and right click to pick up (or filter on) either MEC or home exam sessions. The current stand is displayed in the top section of the window. To select or highlight the correct MEC or home session, use the mouse to direct the mouse arrow to the correct session, date, and time, and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter]. The heads-up screen displays. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and right click.

The laboratory heads-up screen displays.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

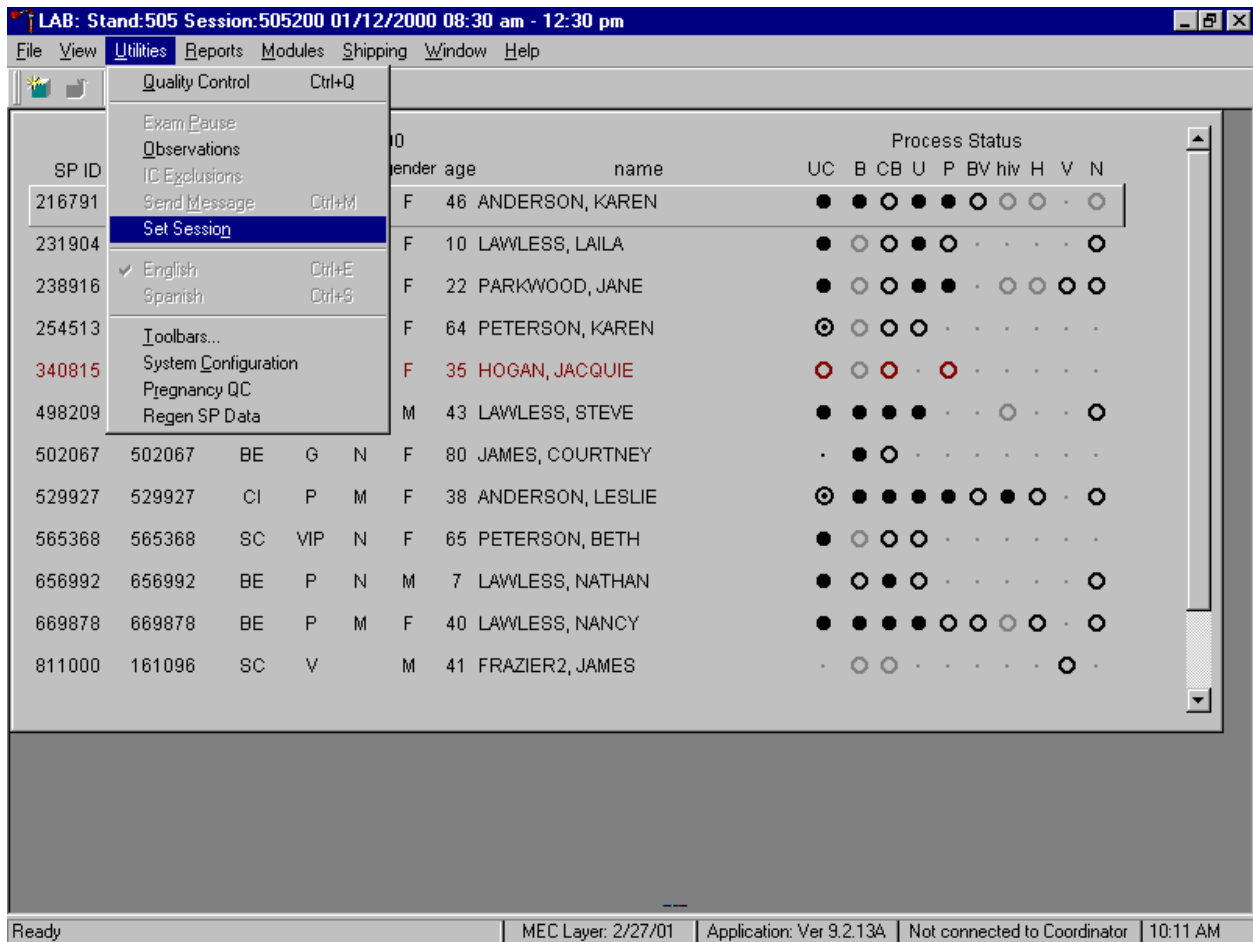
Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status												
								UC	B	CB	U	P	BV	hiv	H	V	N			
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	●
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	●	●
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	●	●	●	●	●
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	●
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	●	●	●	●
811000	161096	SC	V		M	41	FRAZIER2, JAMES	.	●	●	●
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	●	●	●

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 11:38 AM

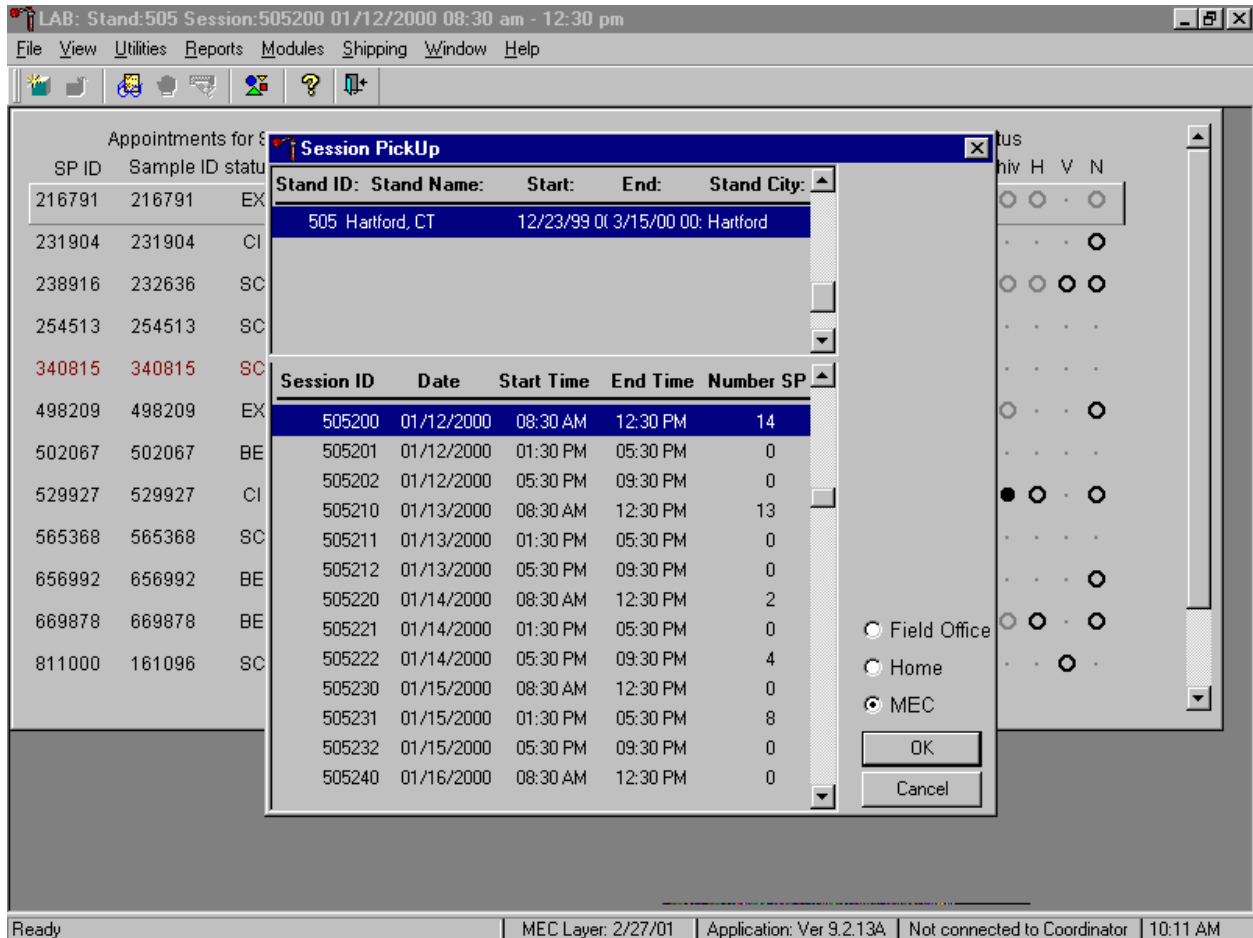
After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays. If the MEC session is in process, the laboratory application defaults to the current MEC session heads-up screen.

Use the Set Session laboratory module to access a different MEC or home examination session.



To access a different MEC or home examination session, use the mouse to direct the mouse arrow to the {Utilities} module in the top menu bar, drag the mouse arrow to {Set Session} and left click, or type [Alt] [U/u], [N/n]. The Session Pickup window displays.

Select a different filter and/or session type.



To select a different filter, use the mouse to direct the mouse arrow to the MEC or Home radio button and left click to pick up (or filter on) either MEC or home exam sessions. The current stand is displayed in the top section of the window. To select or highlight a different MEC or home session, use the mouse to direct the mouse arrow to the correct session date and time and left click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the **OK** button and right click or press [Enter]. The heads-up screen displays. To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

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

Appointments for Session: 505200								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	○	○	○	○	○	○	○
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	○	○	○	.	○
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	○	○	○	○	○	.	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	○	○	○	.	○
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	○	○	○	○	.	.	○	.	.	○
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	○	○
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	○	○	○	○	○	○	○	○	.	○
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	○	○	○	○
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	○	○	○	○	○
669878	669878	CI	P	M	F	40	LAWLESS, NANCY	○	○	○	○	○	○	○	○	○	.
811000	161096	SC	V		M	41	FRAZIER2, JAMES	.	○	○	○	.
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	○	○	○	.	○
909333	140929	SC	V		F	51	AMIN2, MITUL	○	○	○	.	○	.	.	.	○	.

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run, V=VOC), fast (M=morning, A=afternoon, E=evening, N=none), 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), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible for a module when the process status is . The SP is eligible for a module but no results have been recorded when the process status is ○. The SP is eligible for a module and some results have been recorded when the process status is ◐. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●. The SP is eligible for a module but

the process status is O until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from O to **O**. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from O to **O**. The process status updates and changes after each result is saved.

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

To view all SPs, the modules for which they are eligible, and their process status, use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down. Alternatively, to view all SPs use the mouse to direct the mouse arrow to the bottom of the heads-up display, right click, and drag the display up or down.

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

LAB: Stand:505 Session:505709 03/02/2000 08:30 am - 09:00 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505709

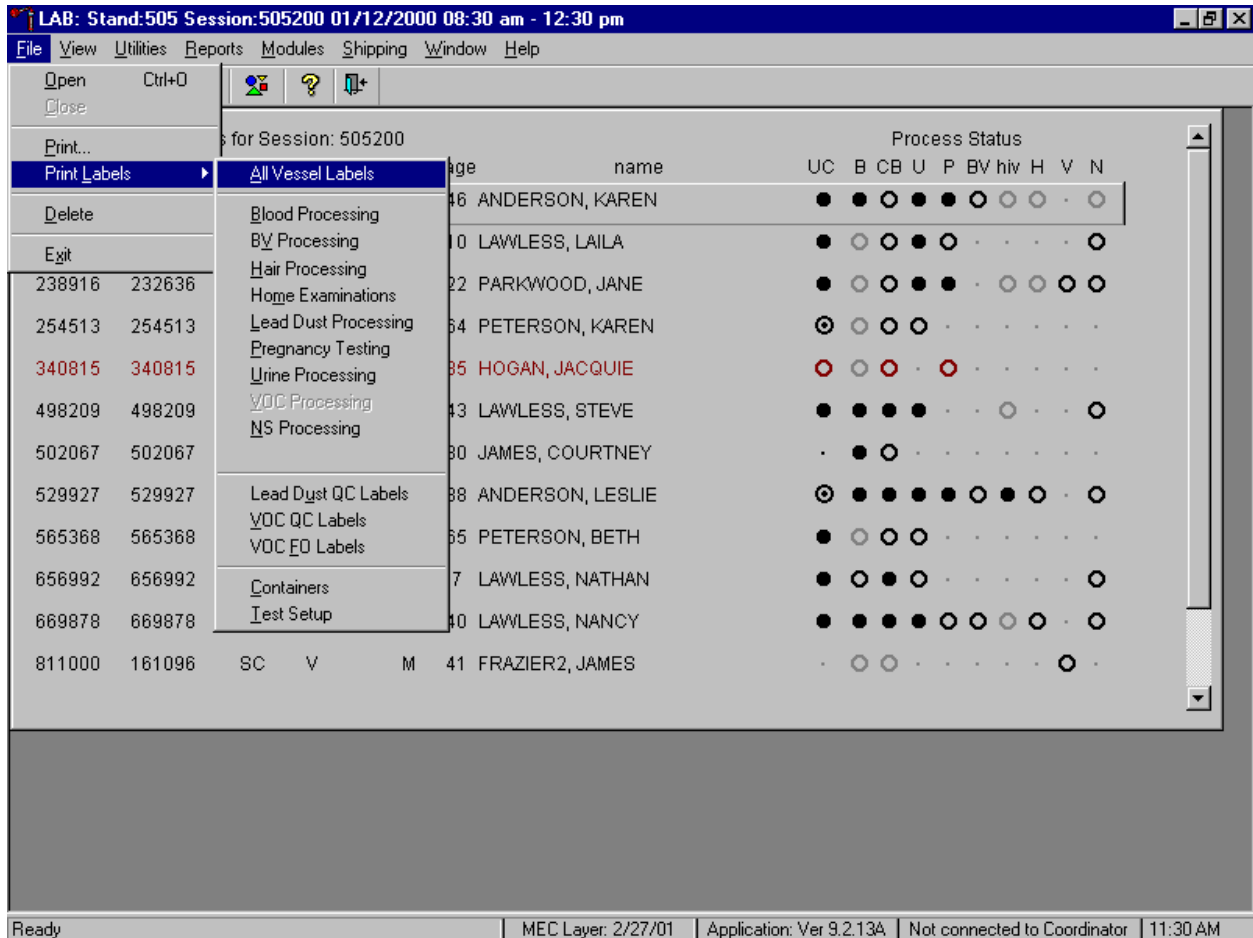
SP ID	Sample ID	status	type	fast	gender	age	name	Process Status										
								UC	B	CB	U	P	BV	hiv	H	V	N	
285851	285851	EX	H	10	F	52	MATTEL, CAROLYN	.	●	●	○
641596	641596	EX	H	10	M	58	MITCHELL, STUART	.	●	●	○

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:06 AM

The Home Exam heads-up display lists home exam SPs scheduled for the session. It lists the SP ID, Sample ID, Status (SC=scheduled, EX=examined), Type (H=home exam), fast (N=none), Gender, Age, and Name (last then first.)

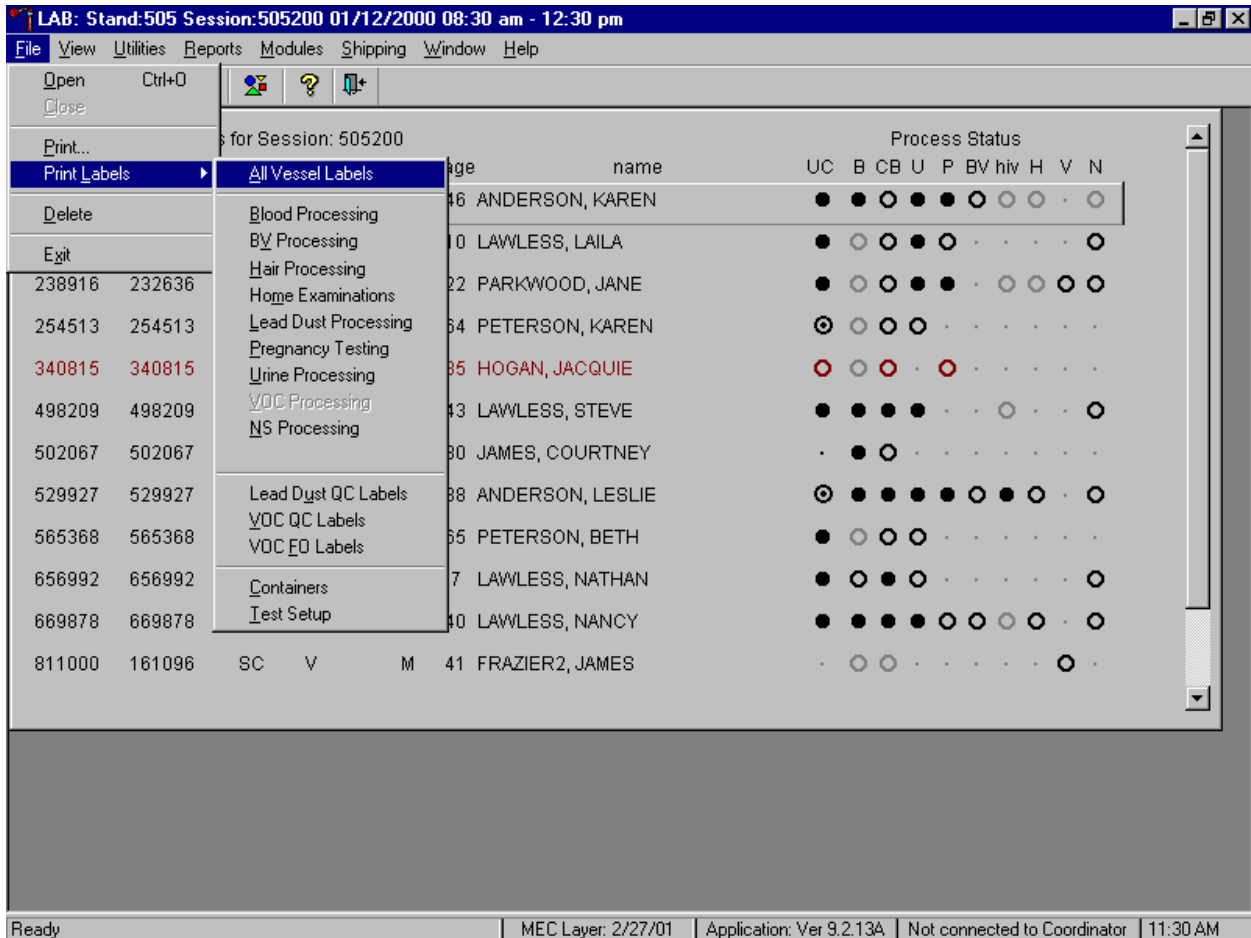
The home exam SP is ineligible for all modules except blood processing and CB (complete blood count).

Print vessel labels.



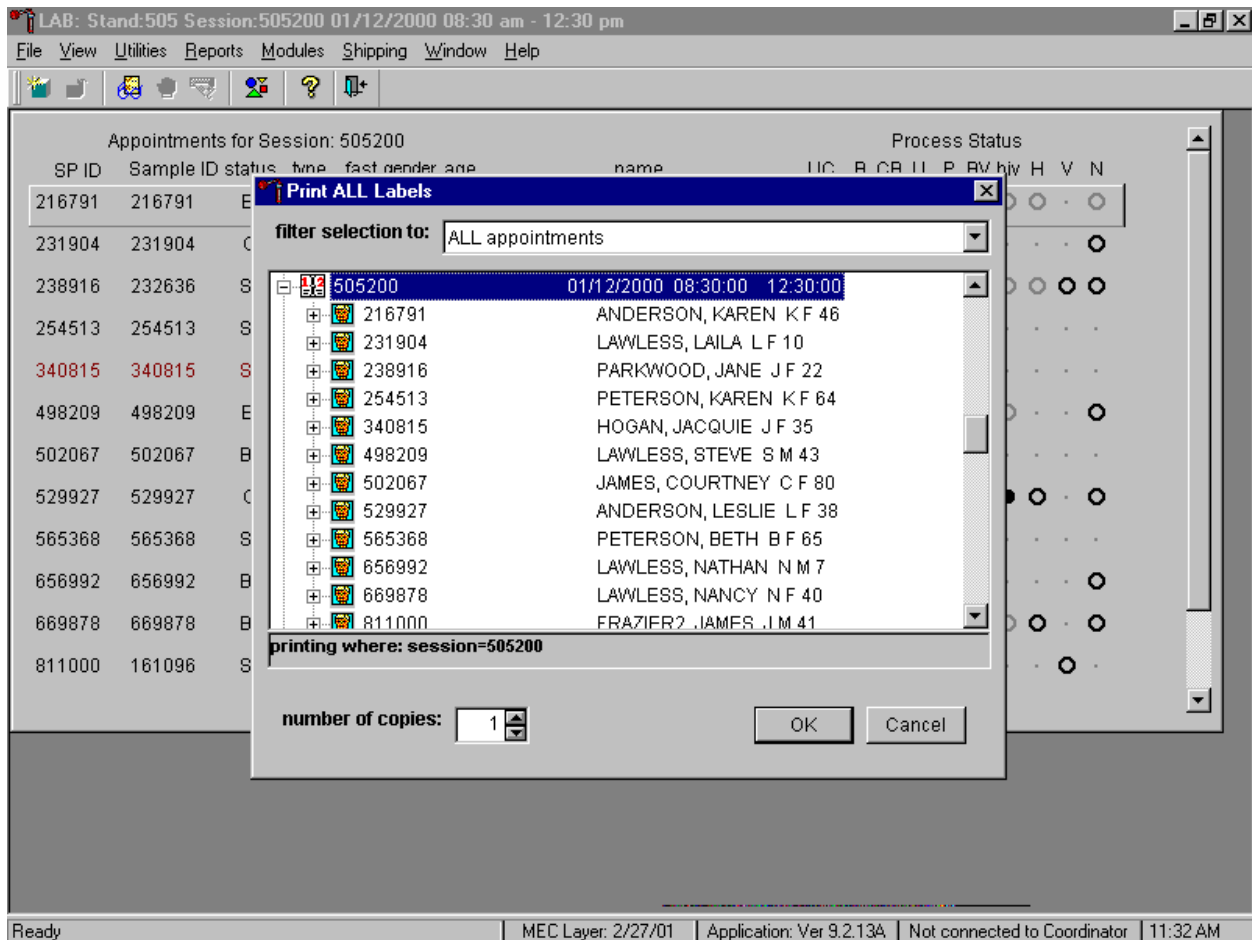
It is possible to (1) print labels for all modules (blood, urine, pregnancy, dental, hair, home, pregnancy and urine), or individual modules; (2) print labels for all SPs in a session or individual SPs; or (3) print labels for ALL appointments, appointments NOT previously printed, or appointments PREVIOUSLY printed.

Print vessel labels for all modules.



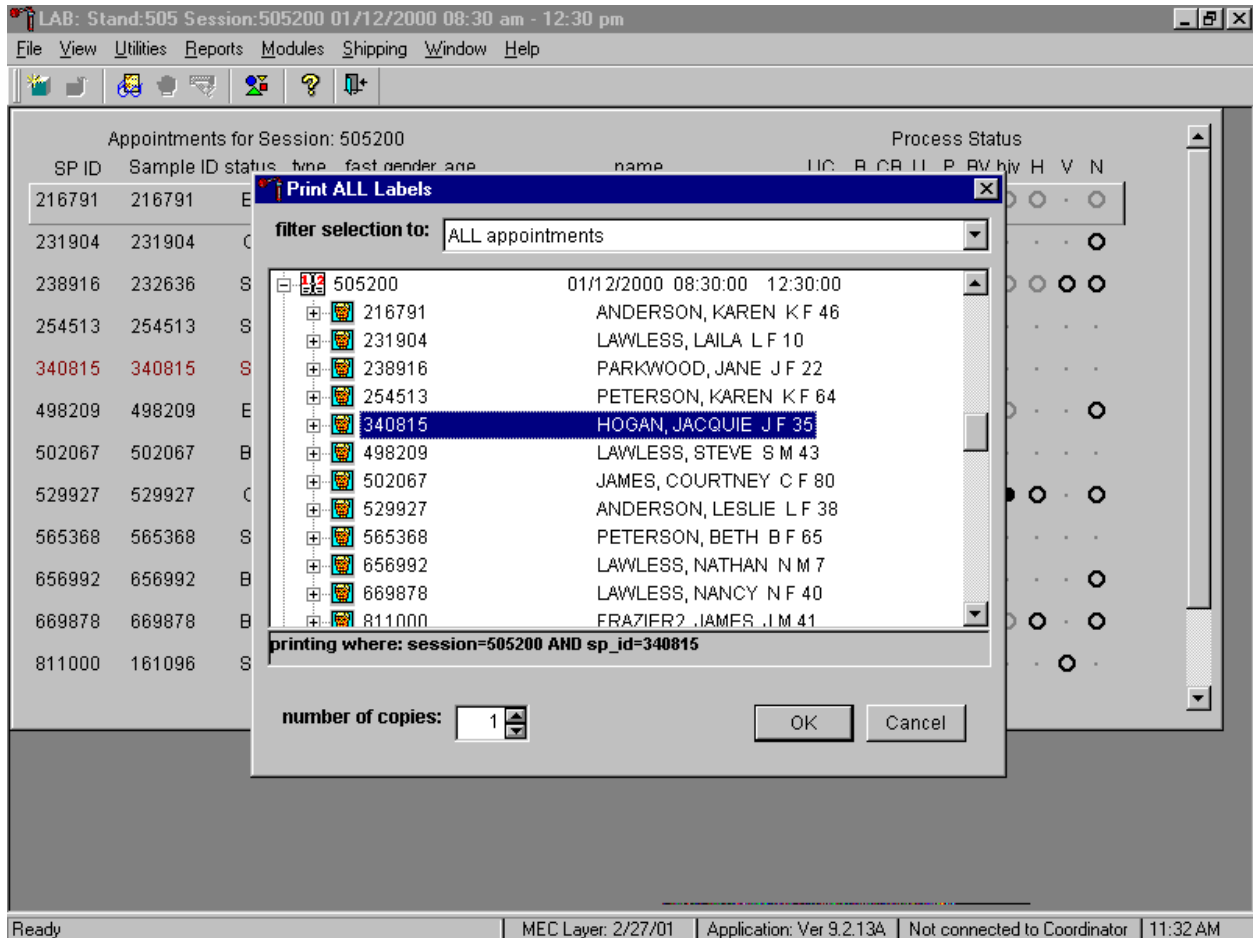
To print vessel labels for all modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {All Vessel Labels} and left click or type [Alt] [F/f], [L/l], [A/a]. Selecting {All Vessel Labels} prints a complete set of blood processing, urine processing, pregnancy testing, BV, hair, and nasal swab labels. The Print All Labels window displays.

Use the Print All Labels window to print vessel labels for all modules for all SPs in either a MEC or home exam session.



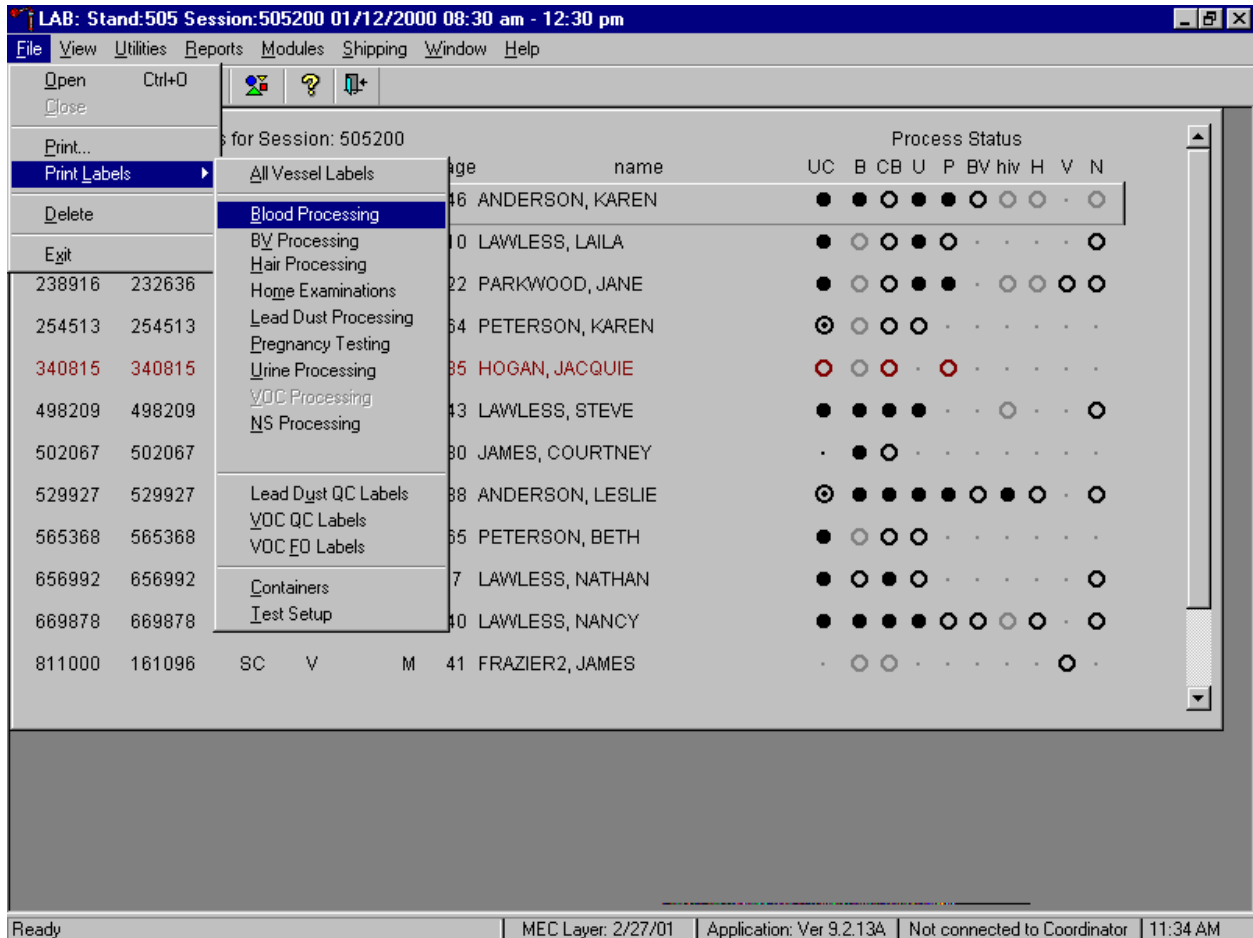
To print vessel labels for all modules for all SPs in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the "number of copies" spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Print vessel labels for all modules for one SP in a MEC or home exam session.



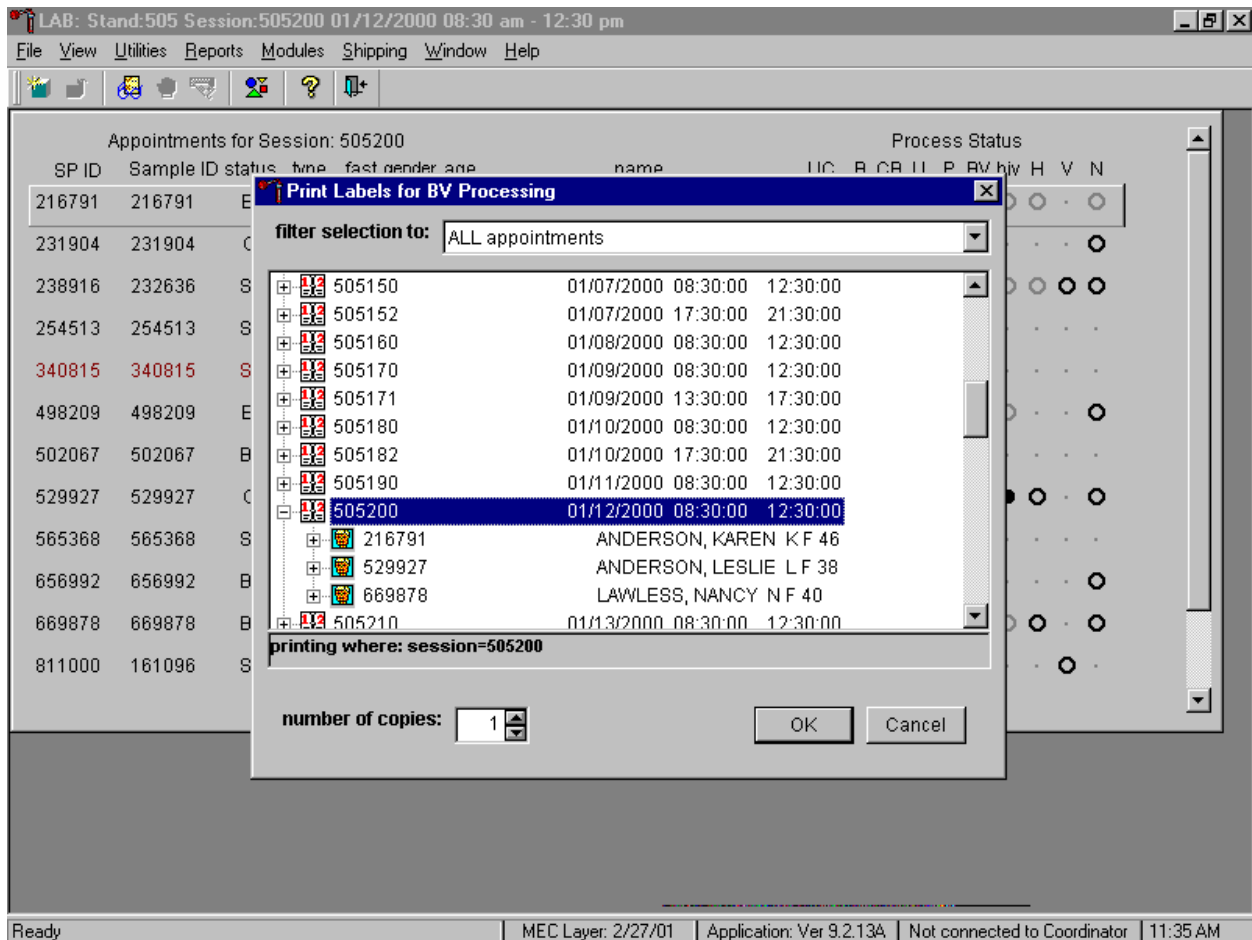
To print vessel labels for all modules for one SP in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the "number of copies" spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Print labels for one specific module for all SPs or one SP in a MEC or home exam session.



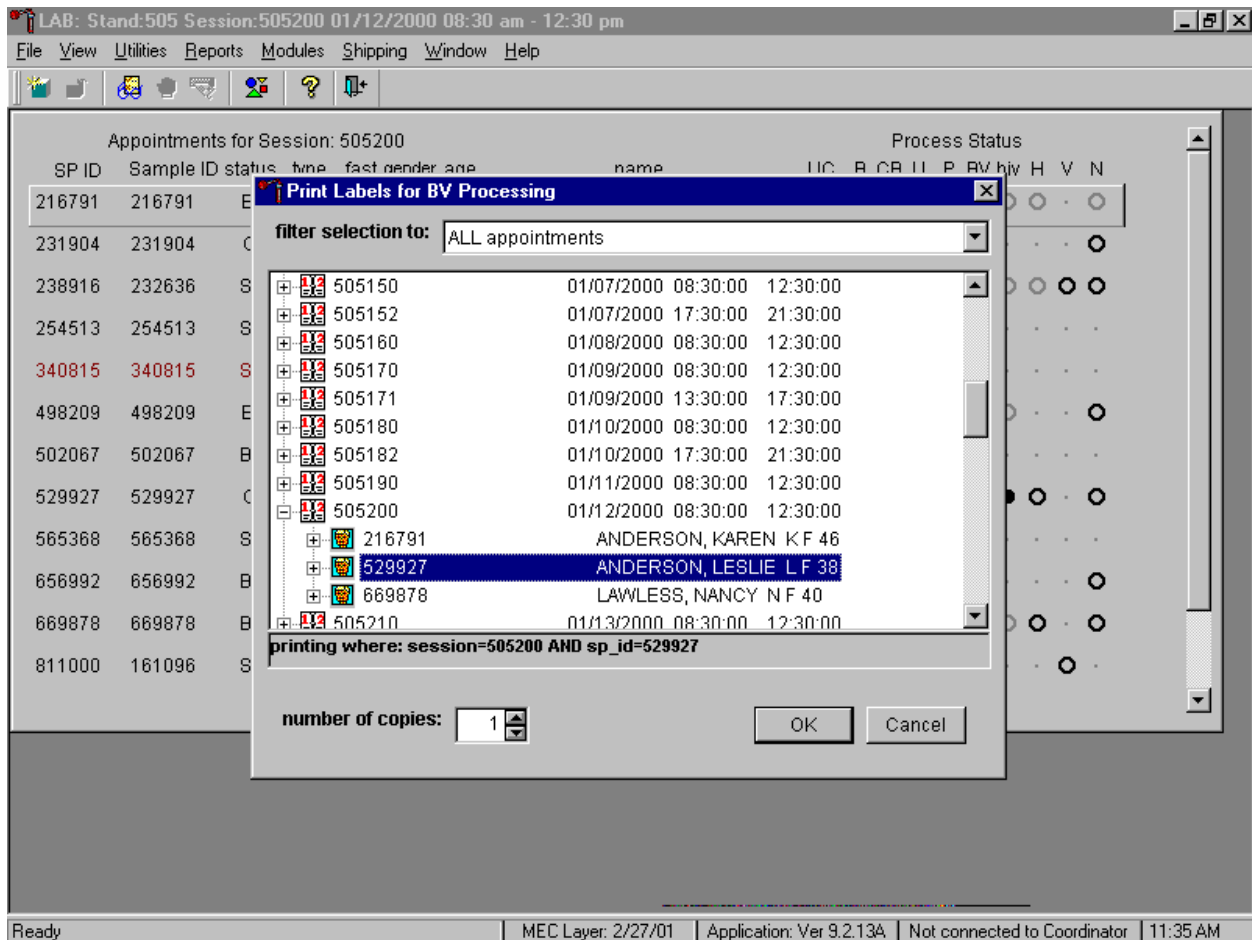
To print labels for one specific module, use the mouse to direct the mouse arrow to {File} and left click, drag the mouse arrow to {Print Labels}, then to {Blood Processing}, {BV Processing}, {Hair Processing}, {Home Examinations}, {Pregnancy Testing}, {Urine Processing}, or {NS Processing} and left click. Alternatively, to print labels for one specific module, type [Alt] [F/f], [L/l], then identify the module by typing [B/b]{Blood Processing}, [V/v] {BV Processing}, [H/h]{Hair Processing}, [M/m]{Home Examinations}, [P/p]{Pregnancy Testing}, [U/u]{Urine Processing} or [N/n] {NS Processing}. The Print Labels window displays.

Print vessel labels for one specific module for all SPs in either a MEC or home exam session.



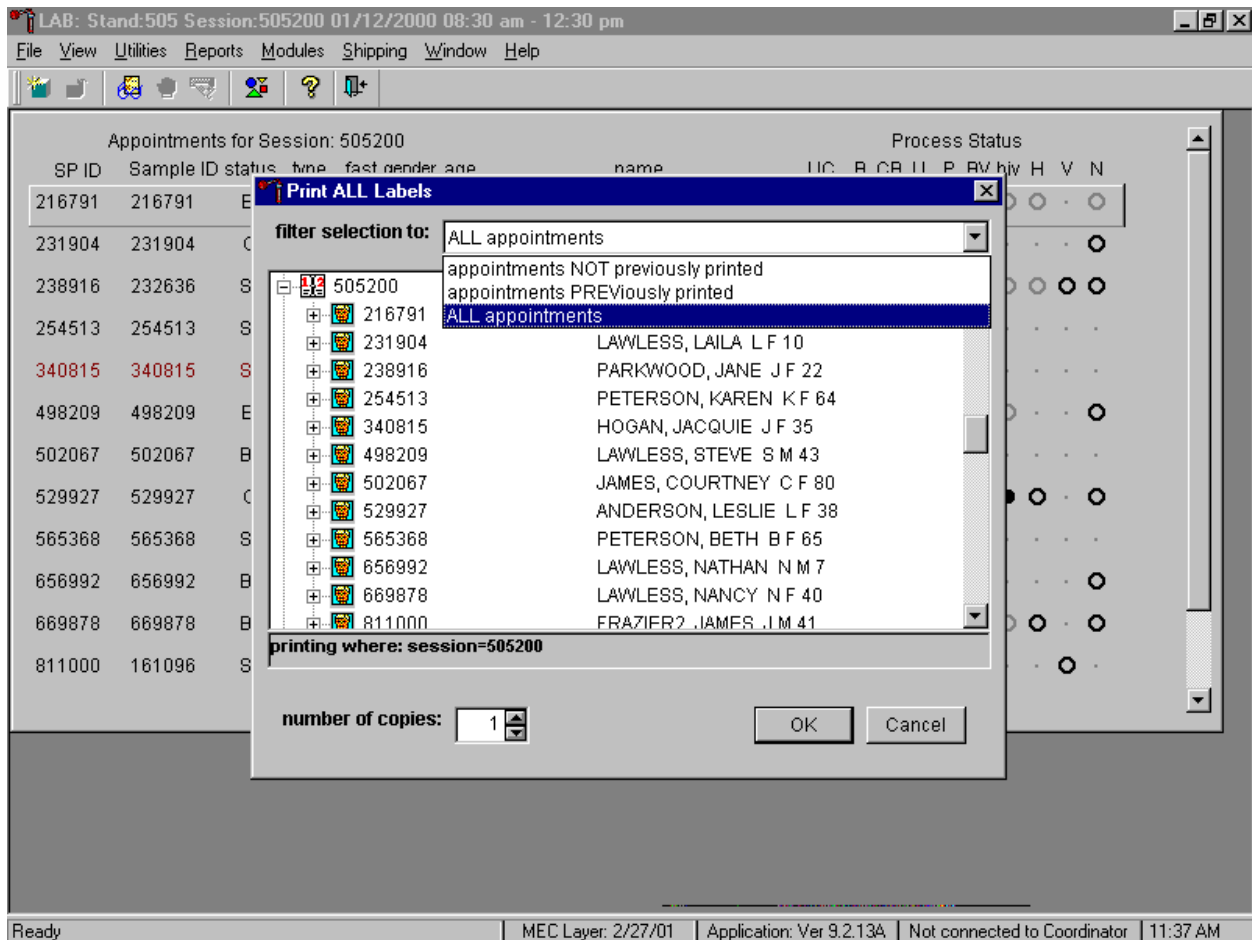
To print vessel labels for one specific module for all SPs in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the "number of copies" spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Print vessel labels for one specific module for one SP in either a MEC or home exam session.



To print vessel labels for one specific module for one SP in either a MEC or home exam session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the "number of copies" spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels use the mouse to direct the mouse arrow to the **Cancel** button and left click.

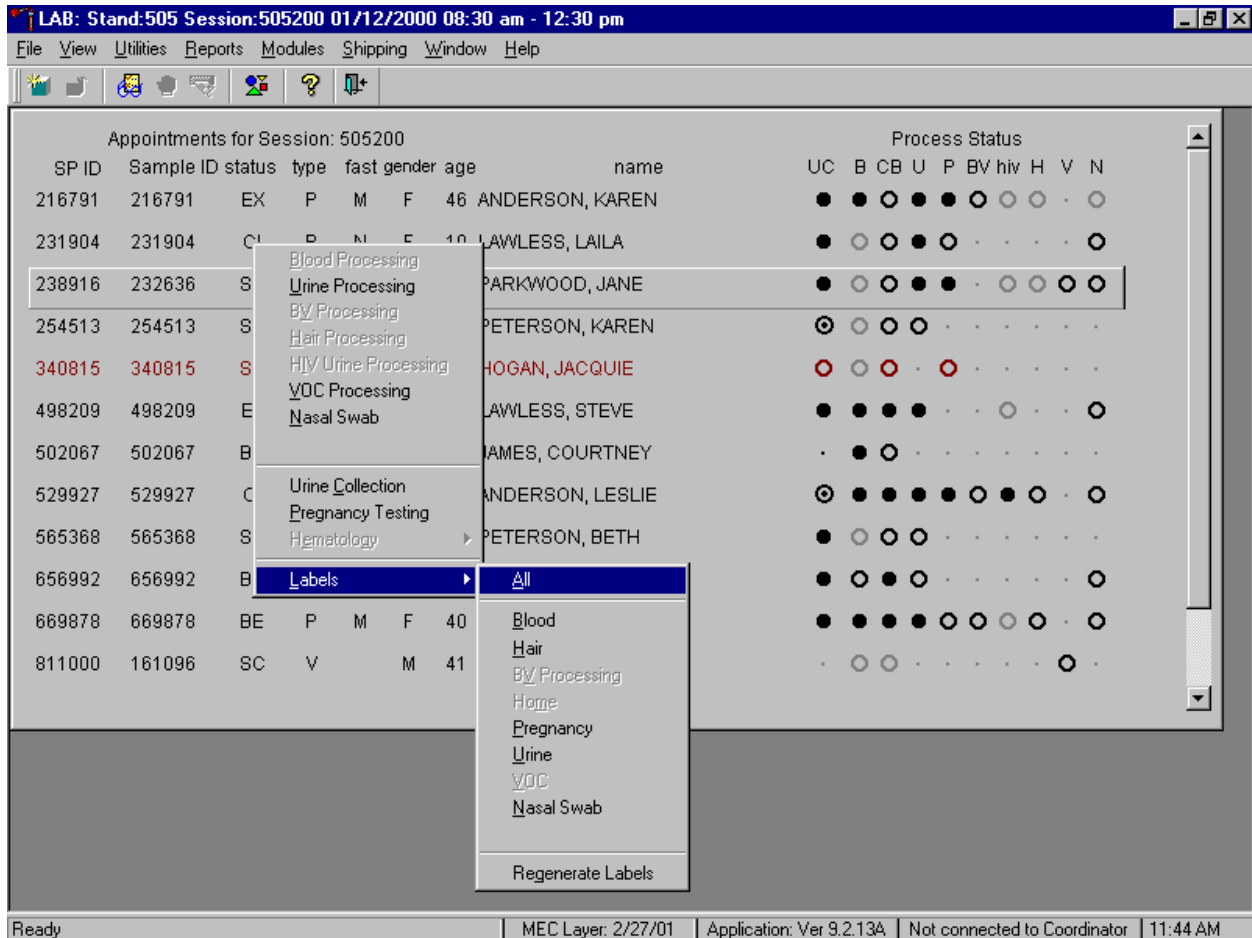
It is also possible to print labels for specific SPs using criteria such as "appointments NOT previously printed," or "appointments PREVIOUSLY printed" by using a filter.



The default filter selection is "ALL appointments." To select or change a filter, use the mouse to direct the mouse arrow to the drop down list on the "Filter Selection to:" box and drag the mouse arrow to "Appointments NOT previously printed," "Appointments PREVIOUSLY printed," or "All appointments" and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the "number of copies" spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

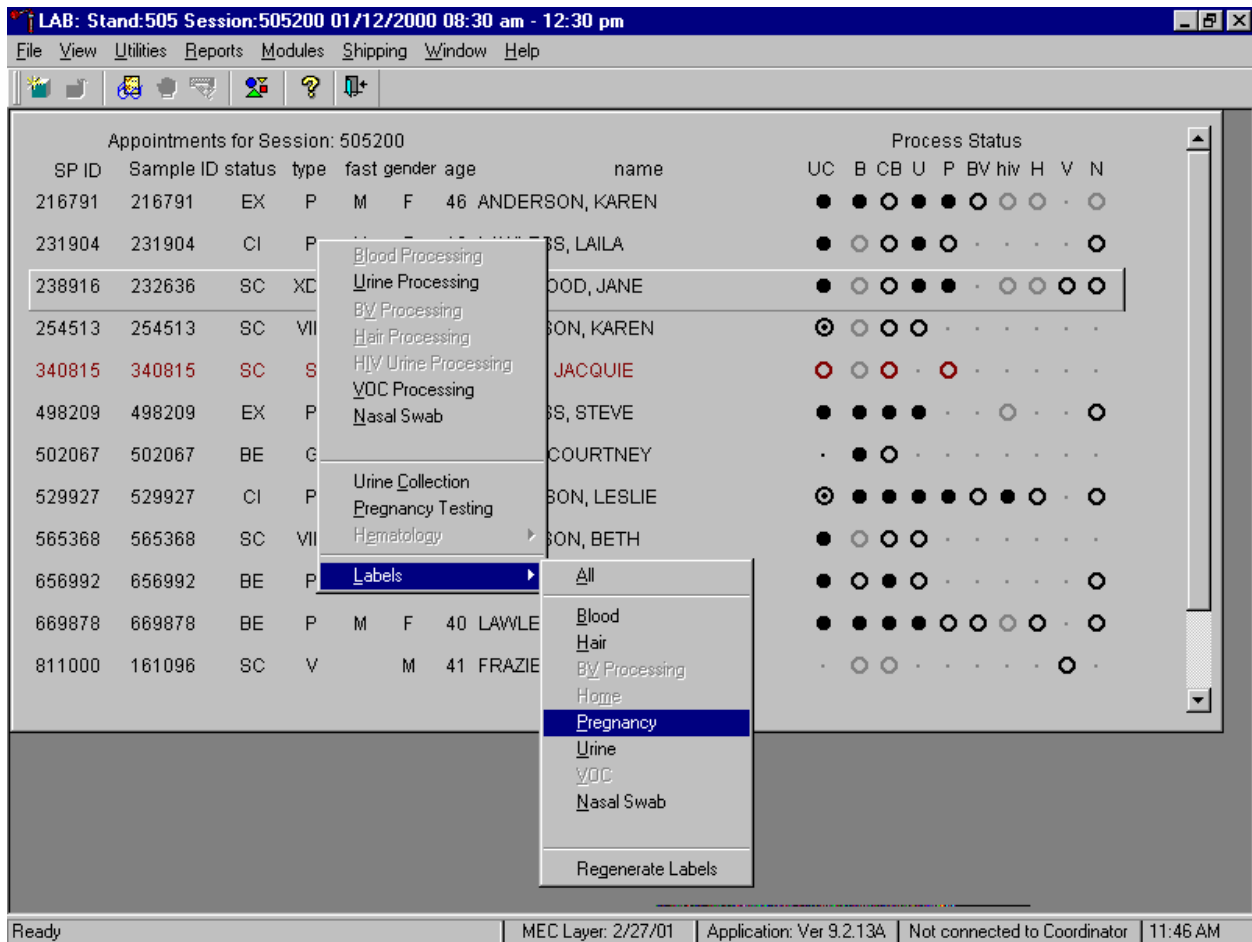
9.3.2 Print Vessel Labels Using the Heads-up Display

Print labels for a particular MEC or home exam SP using the heads-up display. Print labels for all modules or for a specific module.



To print labels for all modules for a particular MEC or home exam SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to {All} and left click or use the mouse to direct the mouse arrow to the correct SP, right click and type [L/l], [A/a]. Labels print in the label/ship area.

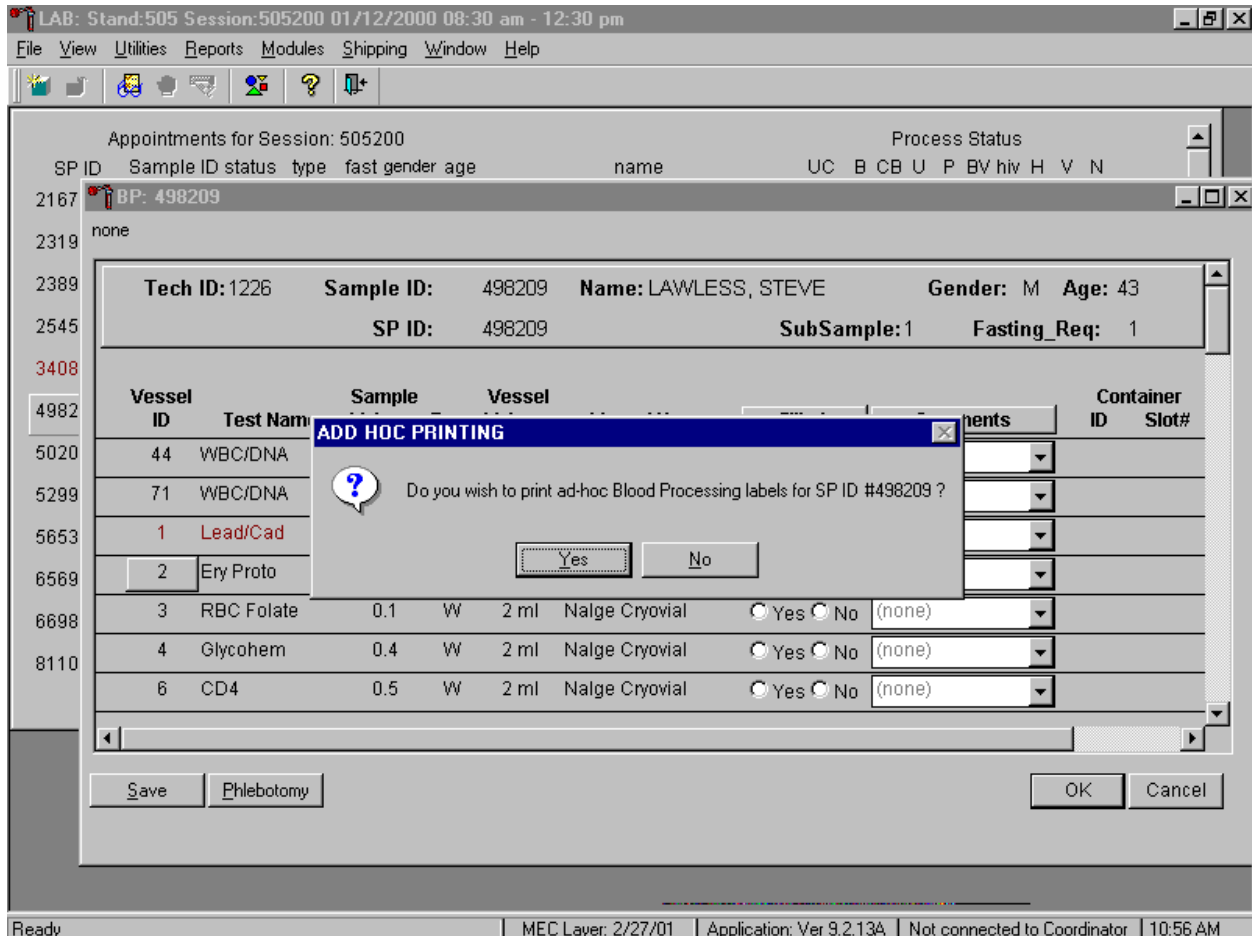
Print labels for one module for a particular MEC or home exam SP using the heads-up display.



To print labels for one module (Blood, Hair, BV processing, Home, Pregnancy, Urine, Nasal Swab) for a particular MEC or home exam SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to the specific module and left click, or use the mouse to direct the mouse arrow to the correct SP, right click and type [L/l], and the first letter of the module name. Labels print in the label/ship area.

9.3.3 Print an Ad-Hoc Vessel Label Using the Heads-up Display

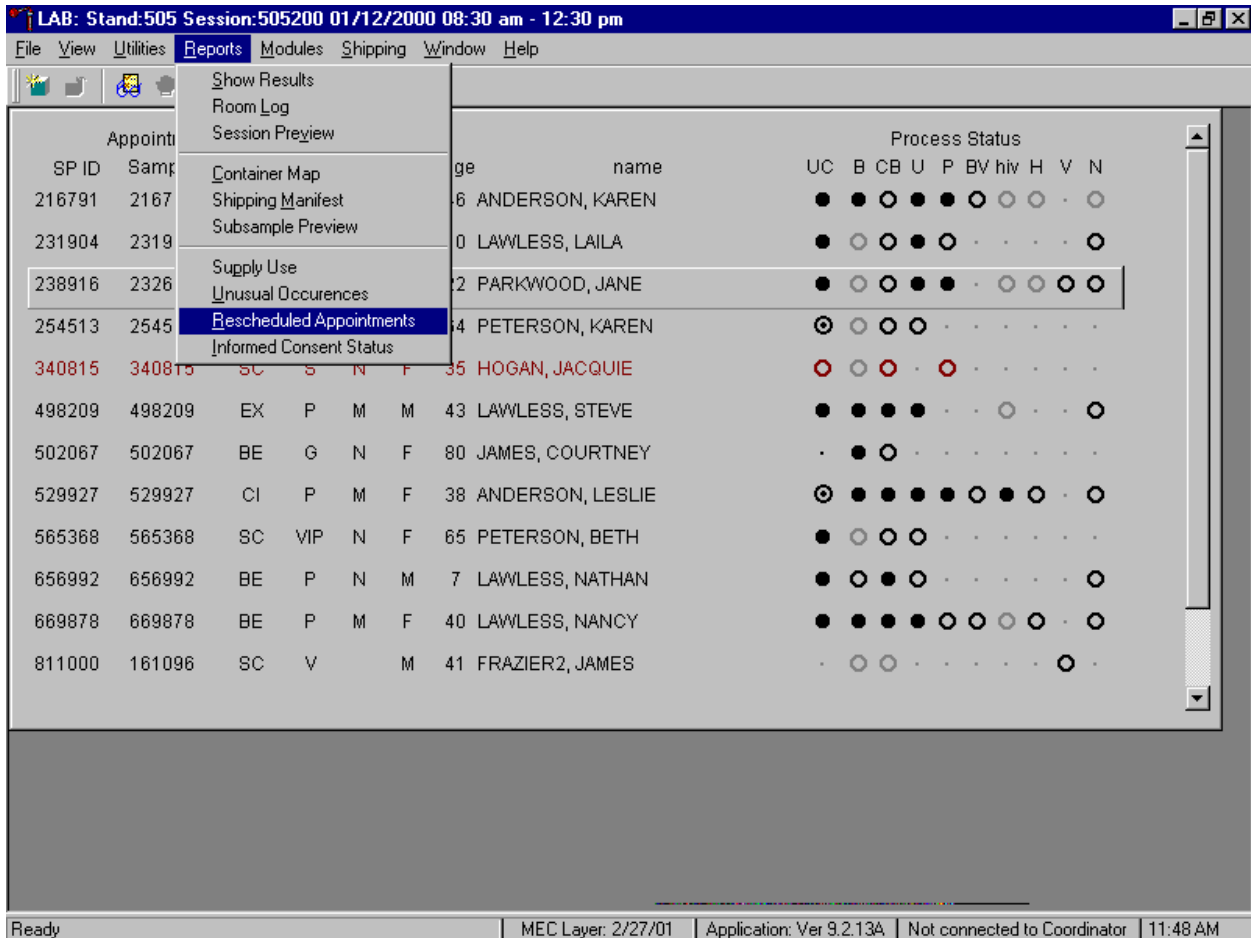
Print an ad-hoc label for any individual vessel.



To print one ad-hoc label for any one vessel, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the message text box request. To print the label and remove the message text box, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y] or select [Enter]. To remove the message text box without printing a label, use the mouse to direct the mouse arrow to the **No** button and left click or type [N/n].

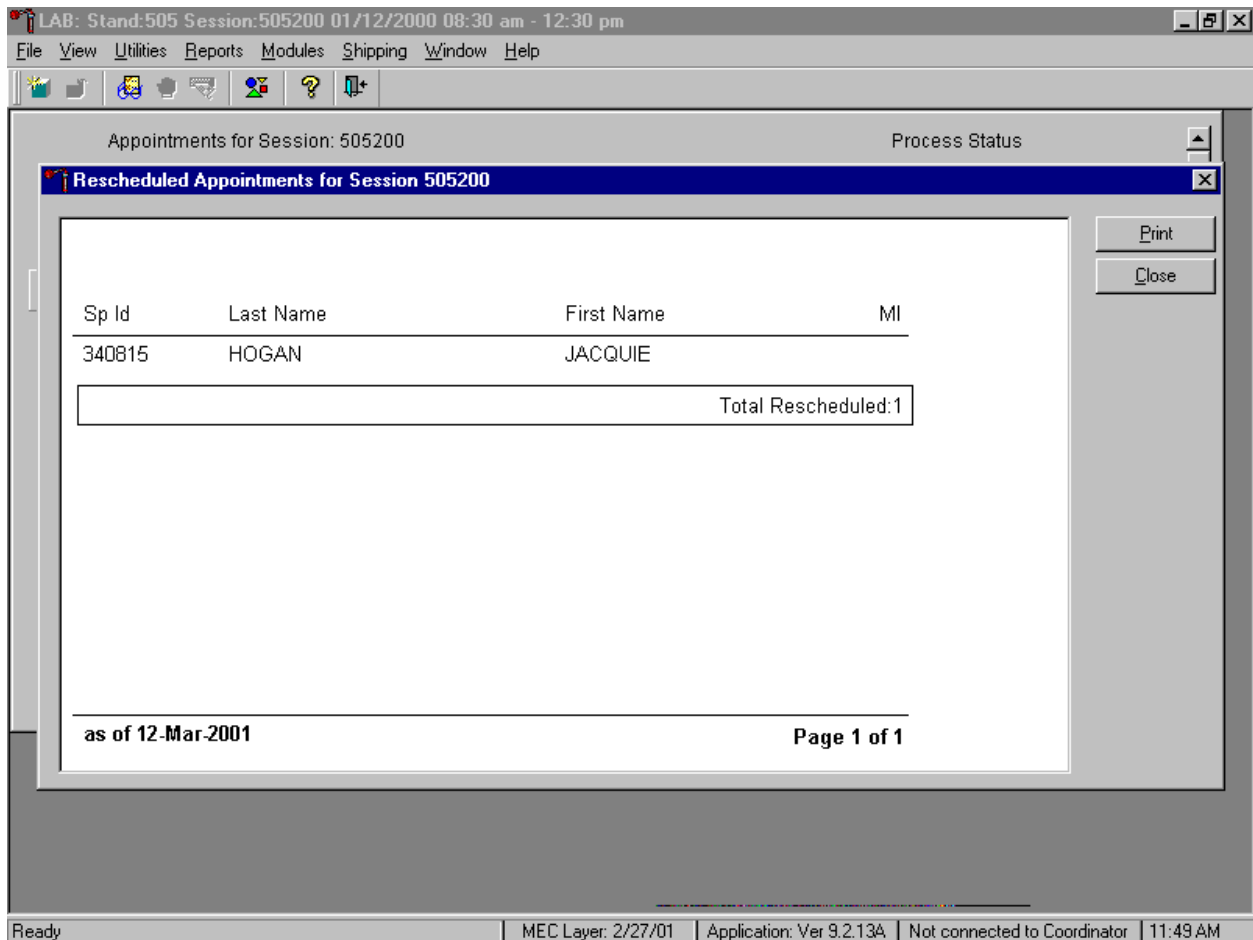
9.3.4 Rescheduled Appointments

If the SP does not show up for a MEC exam or the home exam is cancelled, it is possible they will reschedule. Previously generated labels and vessels may be stored in individual zip closable bags. At the beginning of each session, use the Rescheduled Appointments report to view a list of rescheduled SPs.



To access the Rescheduled Appointments report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, left click, drag the mouse arrow to {Rescheduled Appointments} and left click or type [Alt] [R/r], [[R/r].

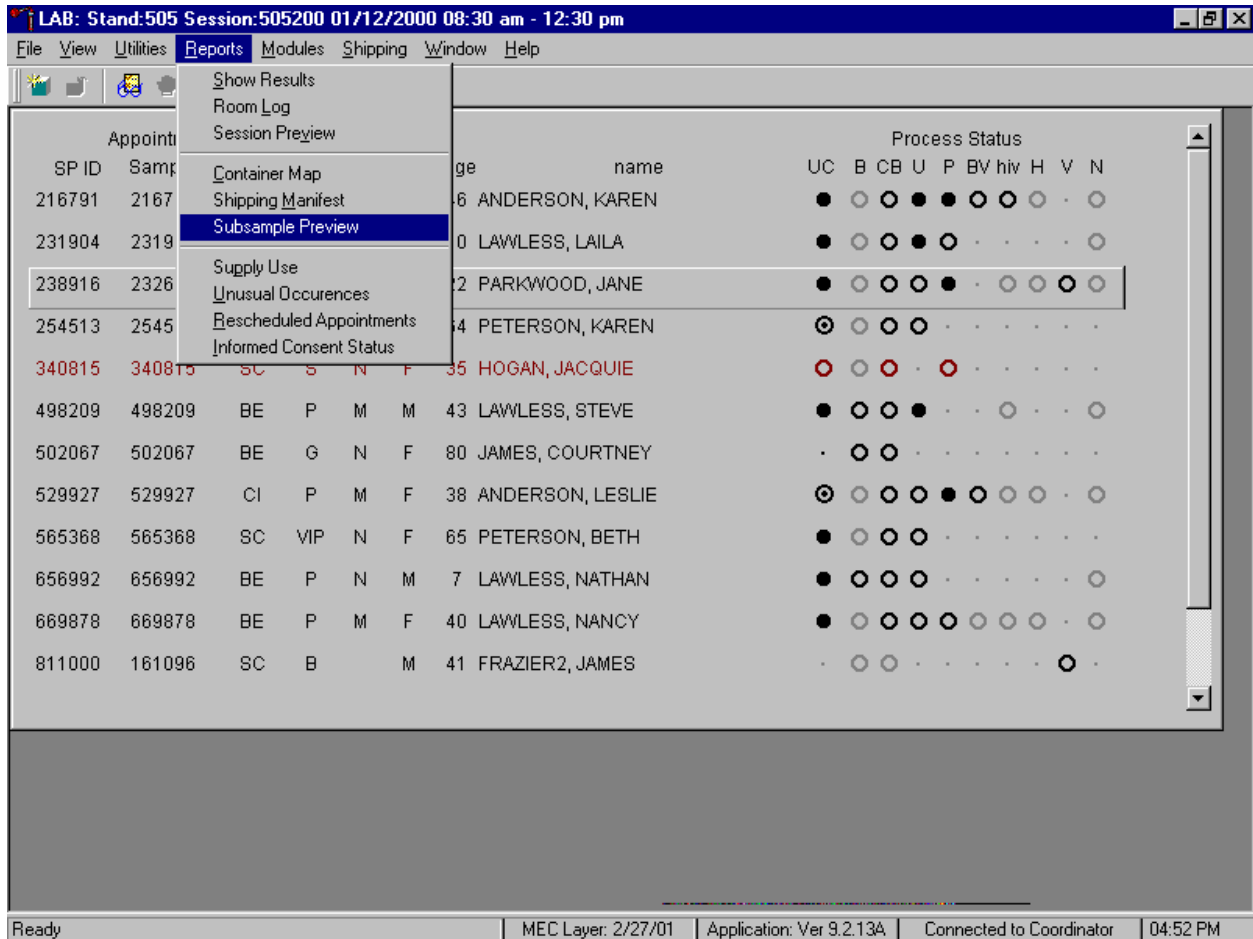
The Rescheduled Appointments report listed the rescheduled SPs or displays a message text box displays indicating that no appointments have been rescheduled for the current session.



To close the report, use the mouse to direct the mouse arrow to the **C**lose button and left click or type [Enter]. If no appointments have been rescheduled for the current session, the Rescheduled Appointments message text box displays the following message, “None of the appointments for Session IDXXXXXX have been identified as Rescheduled.” To remove the message text box, use the mouse to direct the mouse arrow to the **O**K button and left click, or select [Enter].

9.3.5 Subsample and Session Previews Report

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



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

Review the Subsample Preview.

Appointments for Session: 505200

Process Status

Subsample Report for Session 505200

SPs Selected for Subsamples in Session 505200

Appt.ID	SP ID	Person Name	Gender	Age	Type	Subsample Description
5053546	498209	LAWLESS, STEVE	M	43	1	Dioxins 1 Heavy Metals
5053547	669878	LAWLESS, NANCY	F	40	1	Audiometry 1 Dioxins 1 DIMES-In person 1 Heavy Metals
5053548	216791	ANDERSON, KAREN	F	46	1	Dioxins 1 Heavy Metals
5053549	231904	LAWLESS, LAILA	F	10	1	EPA Priority Pesticide 1 Organophosphate Pesticide 1 DIMES-Telephone 1 Urinary Iodine
5053550	529927	ANDERSON, LESLIE	F	38	1	CIDI 1 DIMES-In person

3/8/01

Page 1 of 2

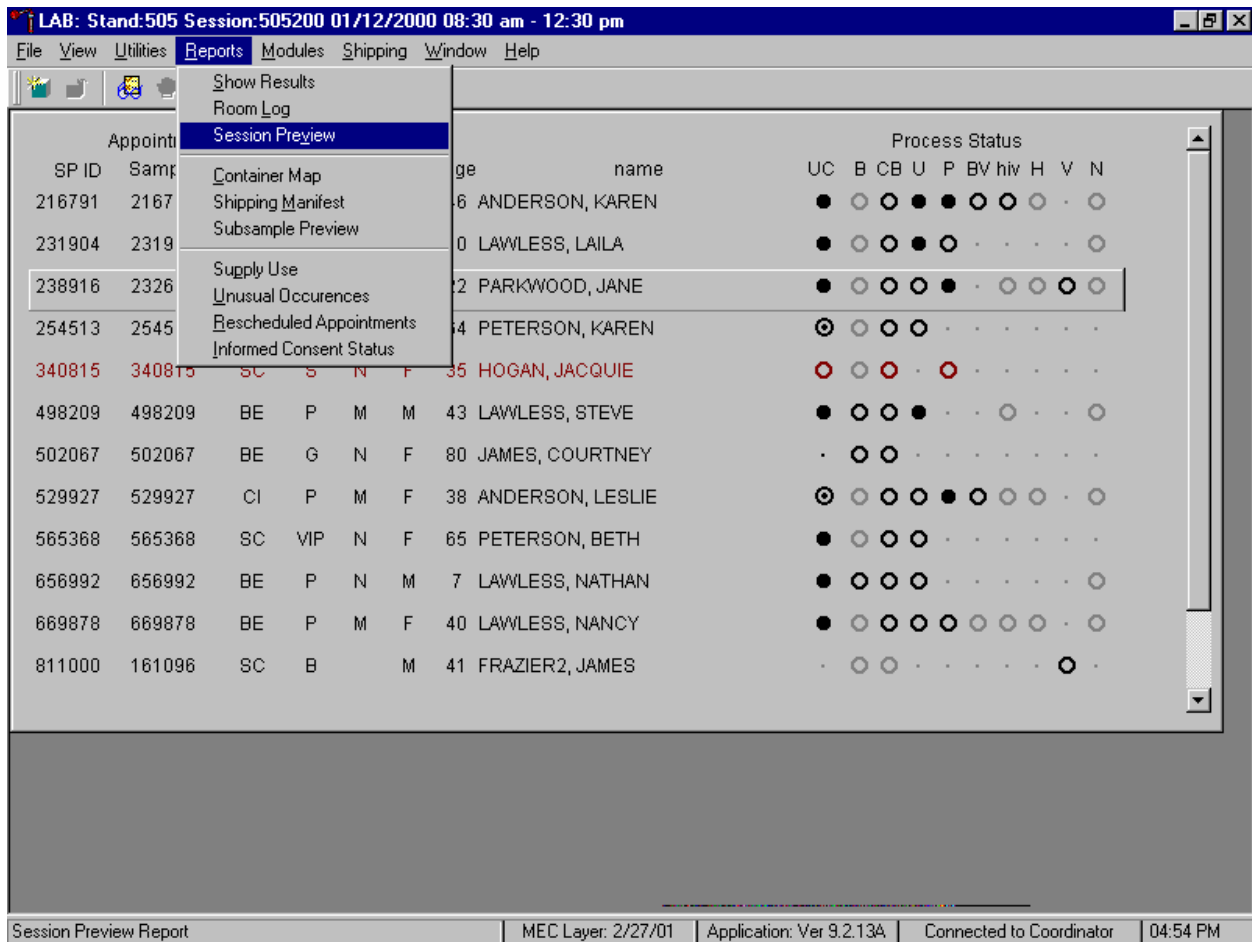
Print

Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 04:53 PM

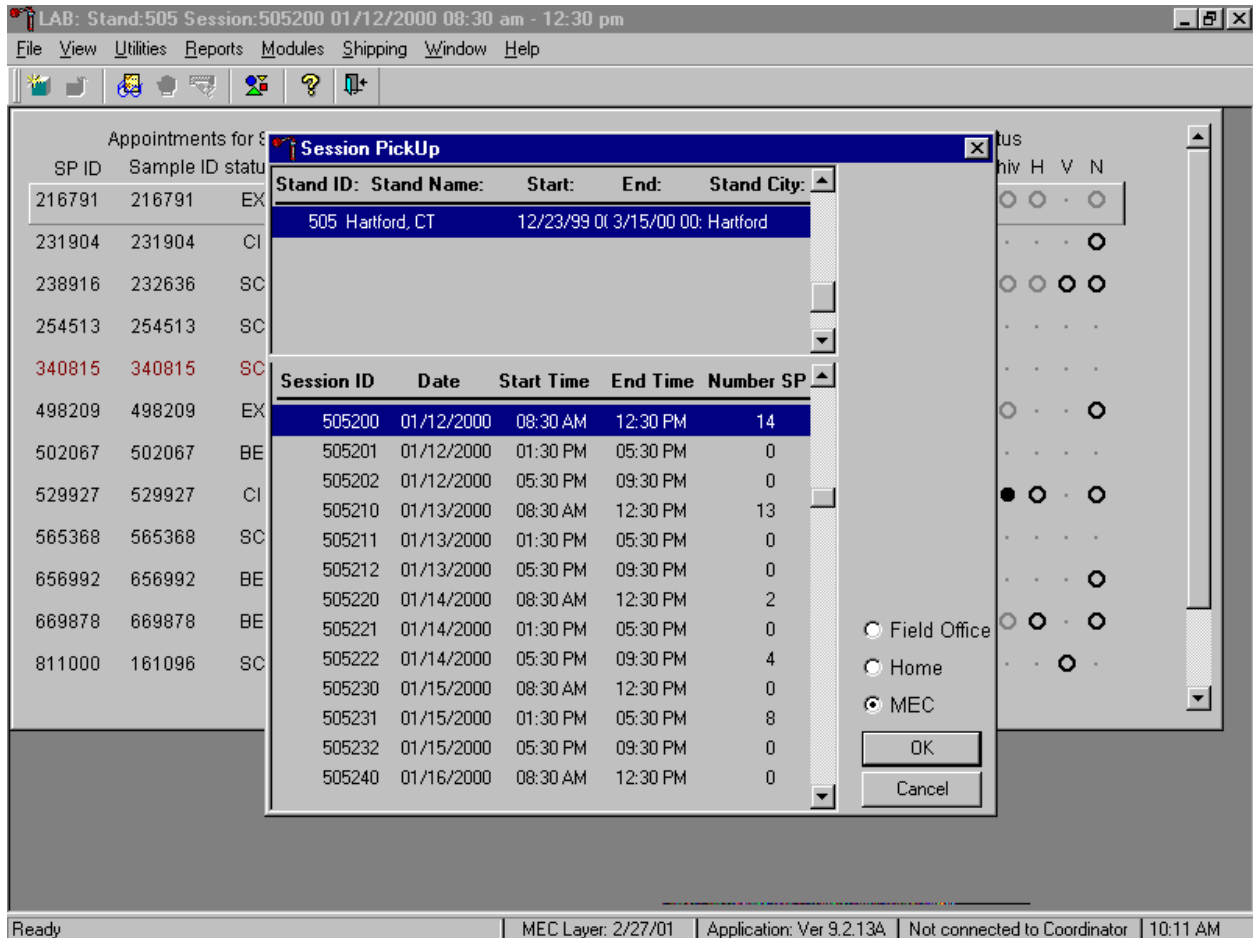
The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible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

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



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

Select the session.



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

The Session Preview Report displays.

Session Preview Report 03/08/01 16:55
Stand: 505

Session: 505200 01/12/2000 08:30 AM - 12:30 PM

SP	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
505-00-0000-00-00 254513	VIP Guest	KAREN PETERSON	64 years	Female		
505-00-0000-00-00 565368	VIP Guest	BETH PETERSON	65 years	Female		
505-00-0000-00-00 502067	Guest	COURTNEY JAMES	80 years	Female		
505-01-0002-04-17 811000	TB & VOC	JAMES FRAZIER2	41 years	Male		
505-01-0002-04-20 909333	VOC	MITUL AMIN2	51 years	Female		
505-04-0016-15-01 238916	2nd Exam	JANE PARKWOOD	22 years	Female		

Page 1 of 3

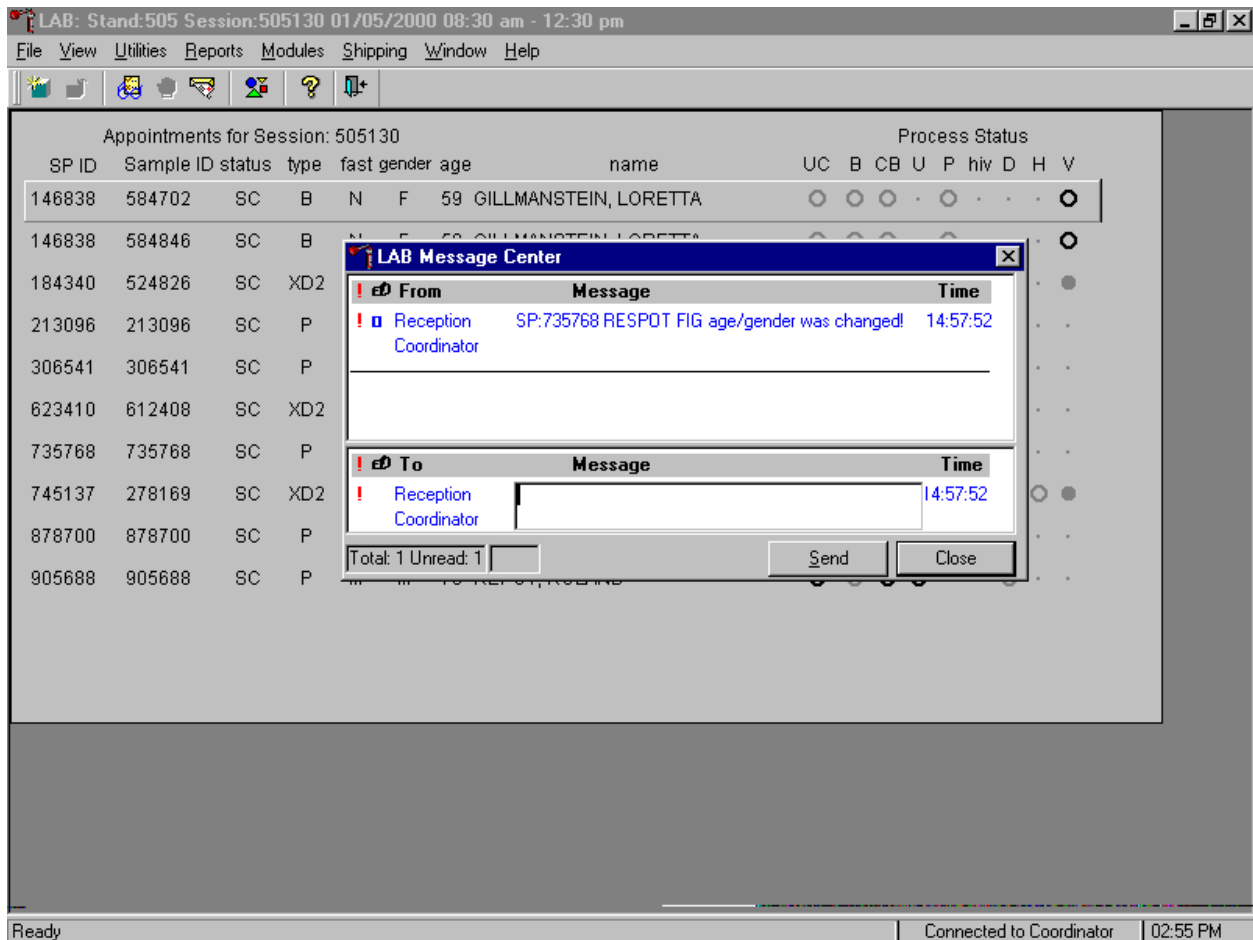
Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 04:55 PM

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

9.4 Regeneration of Data

Processing protocols are SP specific and are based on the age and gender information obtained during the home interview. Protocols are also dependent on session times and person type. Labels are based on the SP's unique protocol. When labels are generated, the laboratory record is created. If the age or gender information obtained during the home interview is incorrect, or the session time or person type changes, the processing protocol may be affected. If the incorrect information is corrected before labels are generated, no action is necessary. If the incorrect information is corrected after the labels have been generated (and laboratory record created), the color of the SP's row on the heads-up display turns red.

If the coordinator changes an SP's age and/or the gender, a message center text box displays on all three laboratory terminals.



Review the information. To send a response to the coordinator, type the text of the response into the lower Message text box, use the mouse to direct the mouse arrow to the **Send** button, and left click, or type [S/s]. To close the Message Center text box without responding to the message, use the mouse to direct the mouse arrow to the **Close** button and left click, type [C/c], or select [Enter].

Regenerate the data for each MEC or home exam SP indicated in red on the heads-up display.

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●	●	.	●
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	.	.	●
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	●	●
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	.	●
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	●
669878	669878	CI	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	.
811000	161096	SC	V		M	41	FRAZIER2, JAMES	.	●	●	●	.
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	●	●	●	.	●
909333	140929	SC	V		F	51	AMIN2, MITUL	●	●	●	.	●	.	.	.	●	.

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 11:31 AM

Do not process the SP's specimens if the line on the heads-up display is red.

Select the correct SP and regenerate the data.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status													
								UC	B	CB	U	P	BV	hiv	H	V	N				
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	●	●	○	○	○	○	○	○	○	○	○
231904	231904	CI	P	N	F	10	LAWLESS, LAILA	●	○	○	●	○	○	○	○	○	○	○	○	○	○
238916	232636	SC	XD2	M	F	22	PARKWOOD, JANE	●	○	○	●	●	○	○	○	○	○	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○	○	○	○	○	○	○	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	○	○	○	○	○	○	○	○	○	○	○	○	○	○
498209	498209	EX	P	M	M	43	LAWLESS, STEVE														
502067	502067	BE	G	N	F	80	JAMES, COURTNEY														
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE														
565368	565368	SC	VIP	N	F	65	PETERSON, BETH														
656992	656992	BE	P	N	M	7	LAWLESS, NATHAN														
669878	669878	BE	P	M	F	40	LAWLESS, NANCY														
811000	161096	SC	V		M	41	FRAZIER2, JAMES														

Context Menu:

- Blood Processing
- Urine Processing
- BV Processing
- Hair Processing
- HIV Urine Processing
- VOC Processing
- Nasal Swab
- Urine Collection
- Pregnancy Testing
- Hematology
- Labels

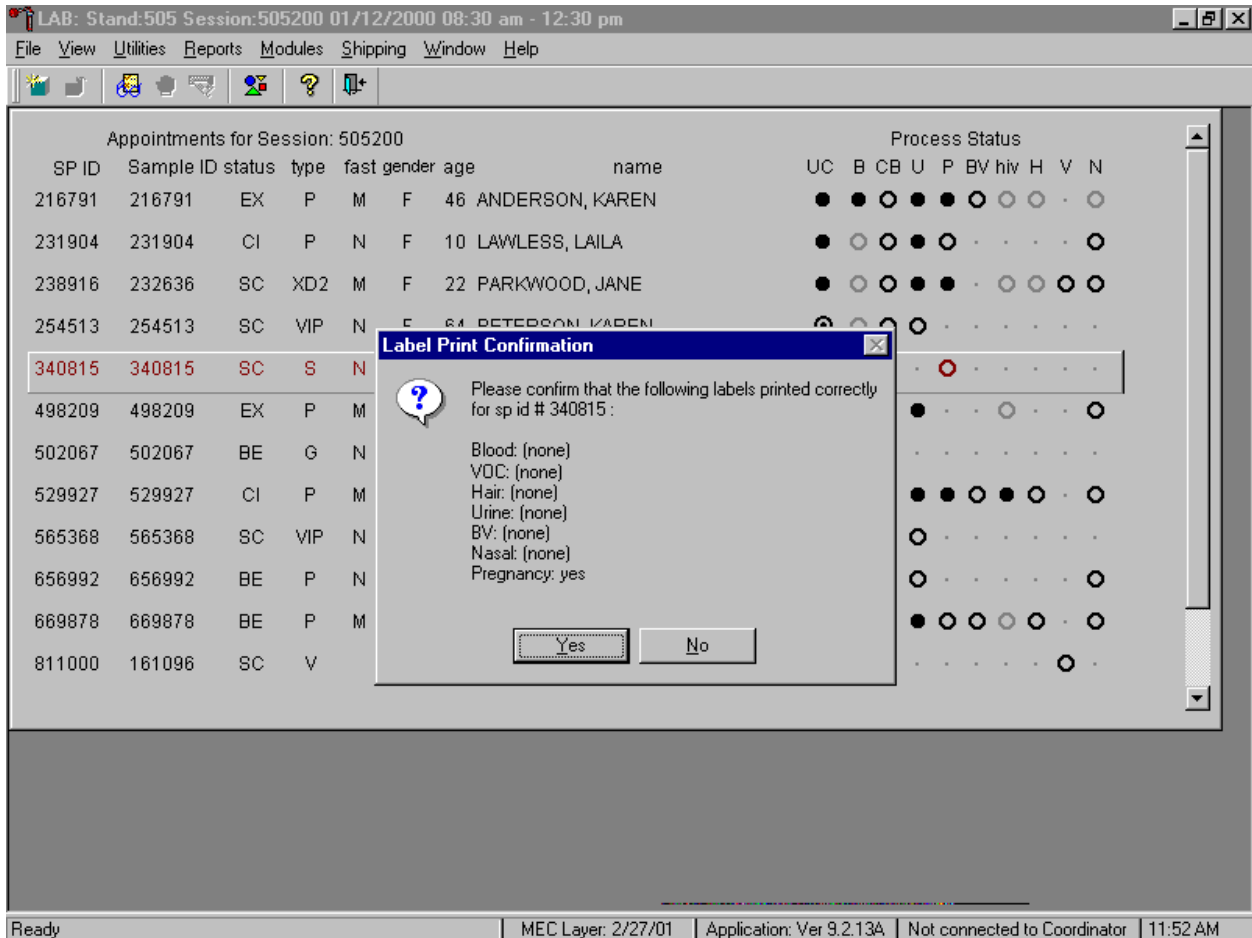
Sub-menu:

- All
- Blood
- Hair
- BV Processing
- Home
- Pregnancy
- Urine
- VOC
- Nasal Swab
- Regenerate Labels

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:54 AM

To regenerate the data for the SP, drag the mouse arrow to the SP's row, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and left click. Alternatively, use the up and down keys to move up and down the list until the correct SP is selected or highlighted, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and right click.

New labels print.



New labels print for vessels that are in addition to the existing vessels. The Label Print Confirmation message text box displays and asks, "Please confirm that the following labels printed correctly for sp id # xxxxxx:

Blood:

VOC:

Hair:

Urine:

BV:

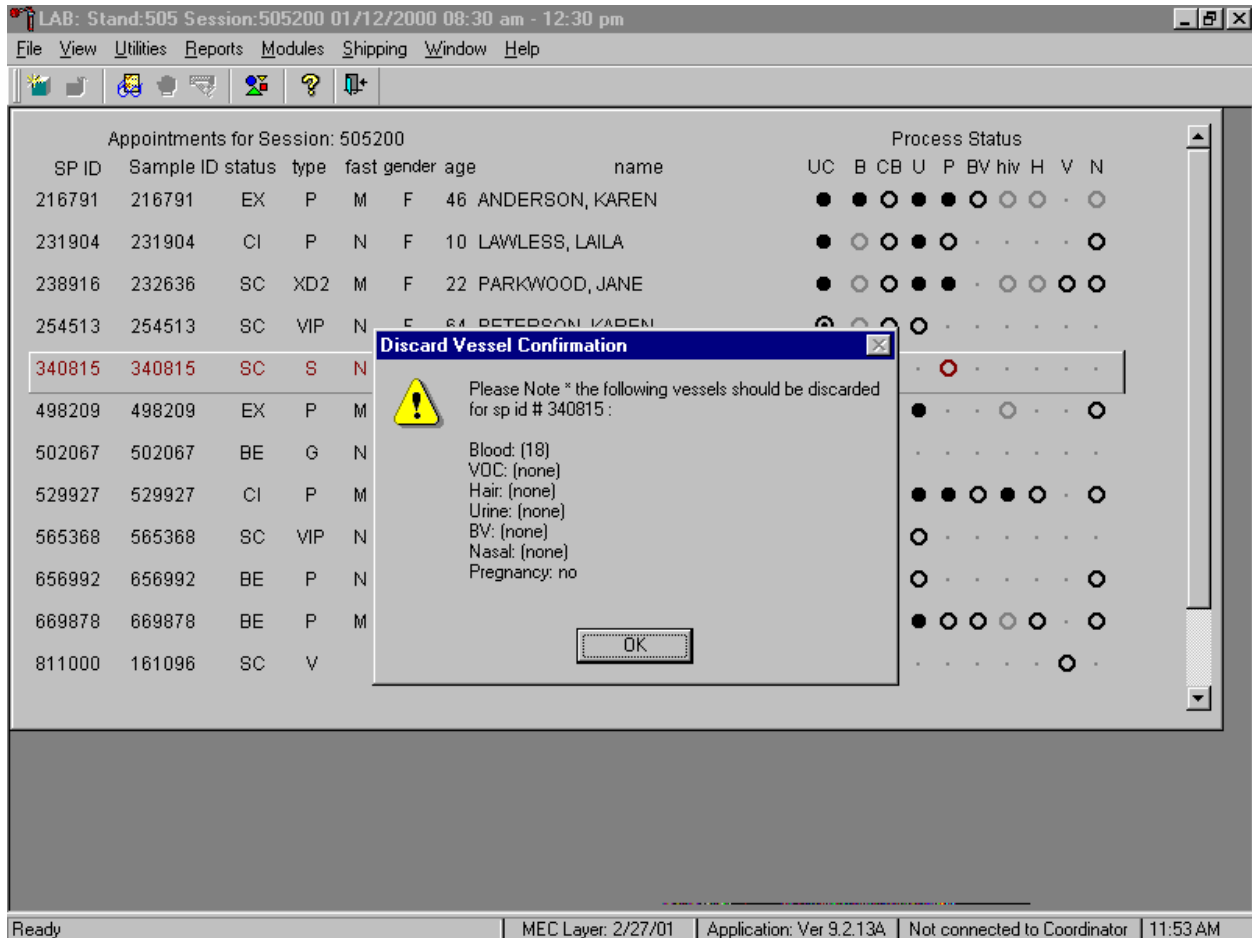
Nasal:

Pregnancy:

Examine the new printed labels and compare them to the list presented on the Label Print Confirmation message text box. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y/y], or select [Enter]. To respond negatively to

the message, use the mouse to direct the mouse arrow to the **No** button and left click or type [N/n]. If a negative response is recorded, labels reprint.

The Discard Vessel Confirmation message text box displays.



The Discard Vessel Confirmation message text box displays and states, "Please Note *the following vessels should be discarded for sp id # xxxxxx:

Blood:

VOC:

Hair:

Urine:

BV:

Nasal:

Pregnancy:

Discard (destroy) the vessels and labels indicated in the message. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the **Yes** button and left click or type [Enter].

Allow the heads-up screen to update.

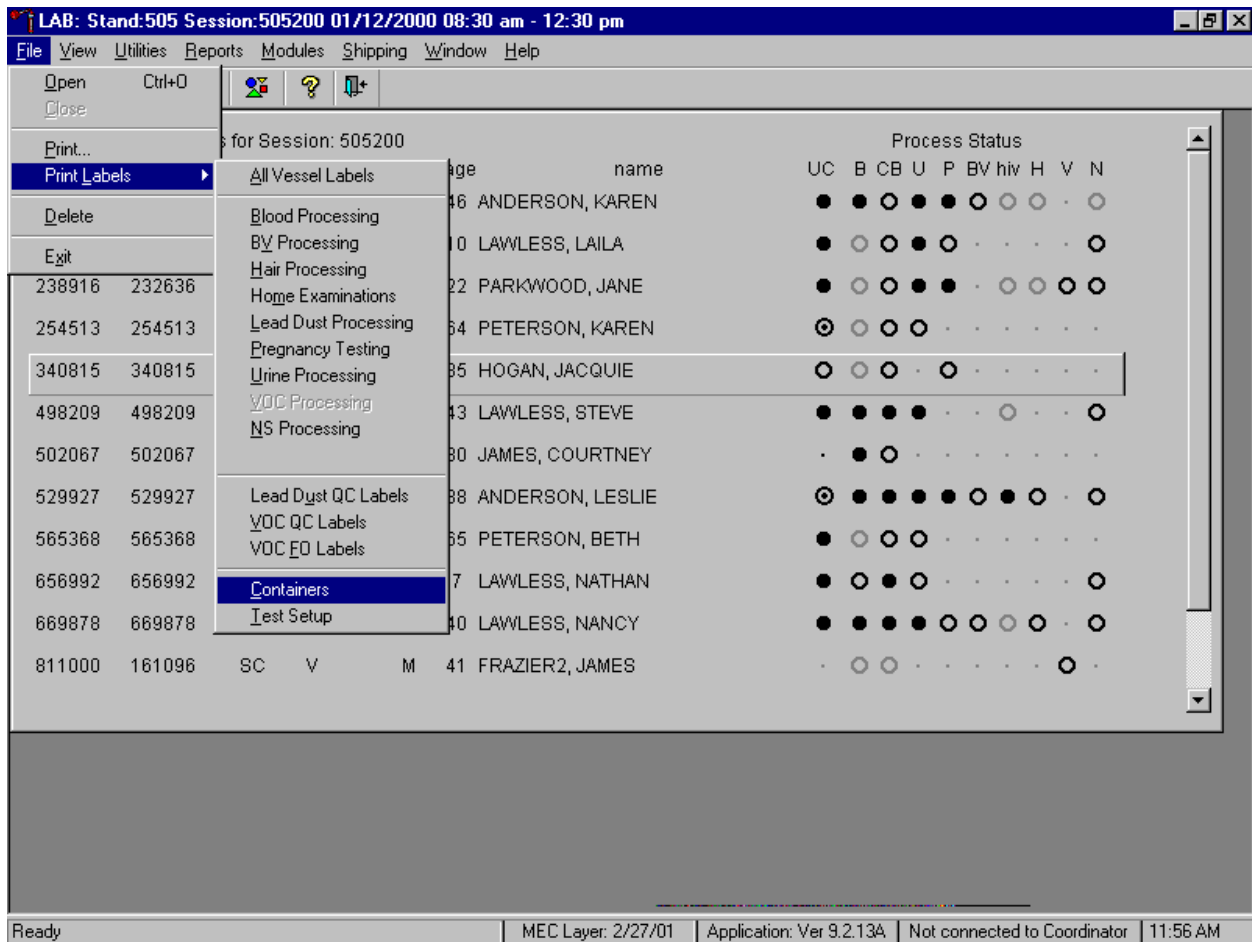
Appointments for Session: 505200								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	○	●	●	○	○	○	○	○
231904	231904	CI	P	N	F	10	LAWLESS, LAILA	●	○	○	●	○	○	○	○	○	○
238916	232636	SC	XD2	M	F	22	PARKWOOD, JANE	●	○	○	●	●	○	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○	○	○	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	○	○	○	○	○	○	○	○	○	○
498209	498209	EX	P	M	M	43	LAWLESS, STEVE	●	●	●	●	○	○	○	○	○	○
502067	502067	BE	G	N	F	80	JAMES, COURTNEY	○	●	○	○	○	○	○	○	○	○
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	○	●	●	●	●	○	●	○	○	○
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	○	○	○	○	○	○	○	○	○
656992	656992	BE	P	N	M	7	LAWLESS, NATHAN	●	○	●	○	○	○	○	○	○	○
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	●	●	●	○	○	○	○	○	○
811000	161096	SC	V		M	41	FRAZIER2, JAMES	○	○	○	○	○	○	○	○	○	○

Allow the heads-up display to update before proceeding. After the screen updates, the SP's row turns from red to black.

9.5 Generate, Print, and Assign Container IDs or Labels

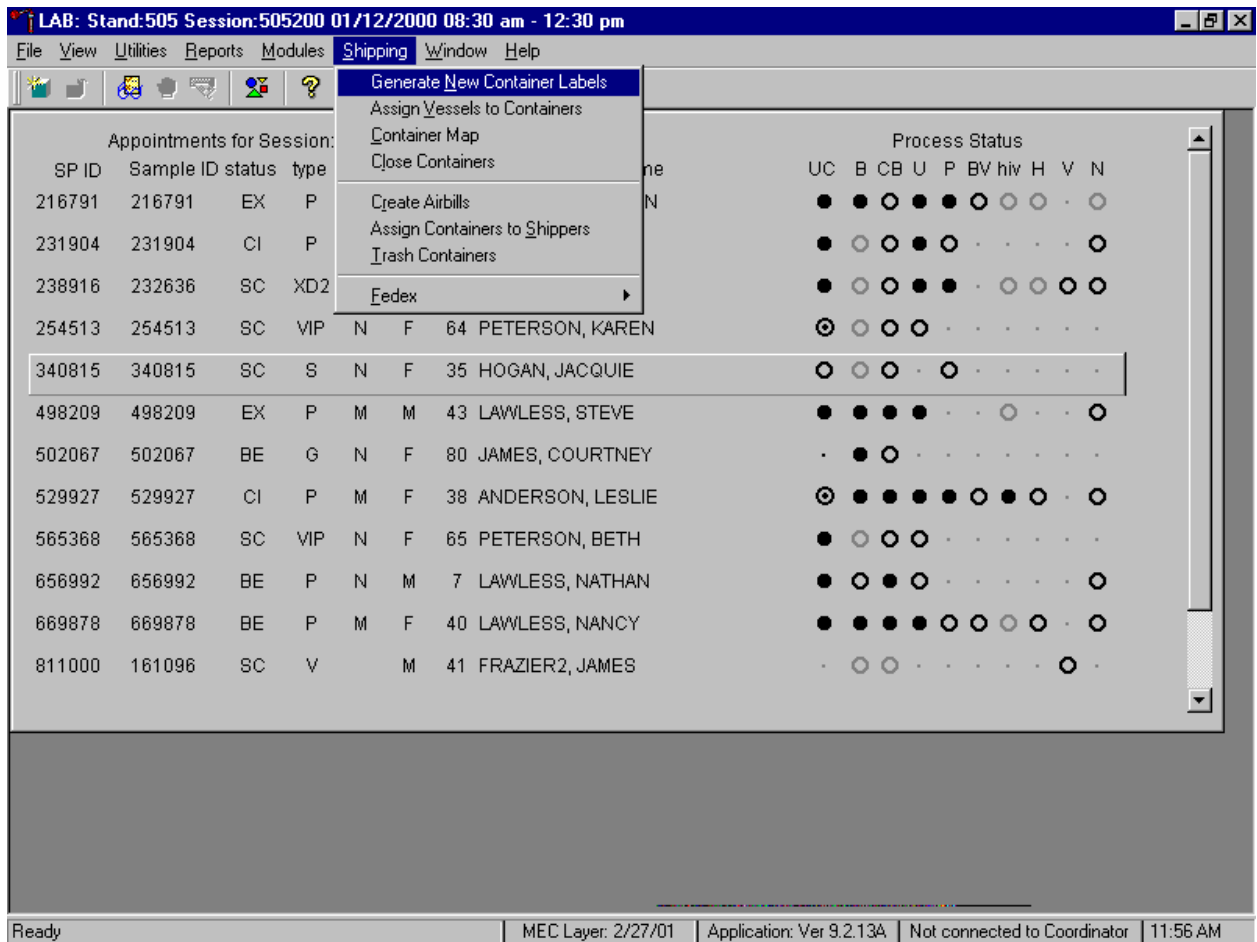
Store processed vessels and biological samples in boxes or bags (containers.) Generate container labels with unique IDs. At the beginning of each stand, specify the initial number of container IDs to generate or print, then assign or associate a container ID with a vessel.

At the beginning of each stand, specify the initial number of container IDs to generate or as needed, specify an additional number of container IDs, using the Print Labels module.



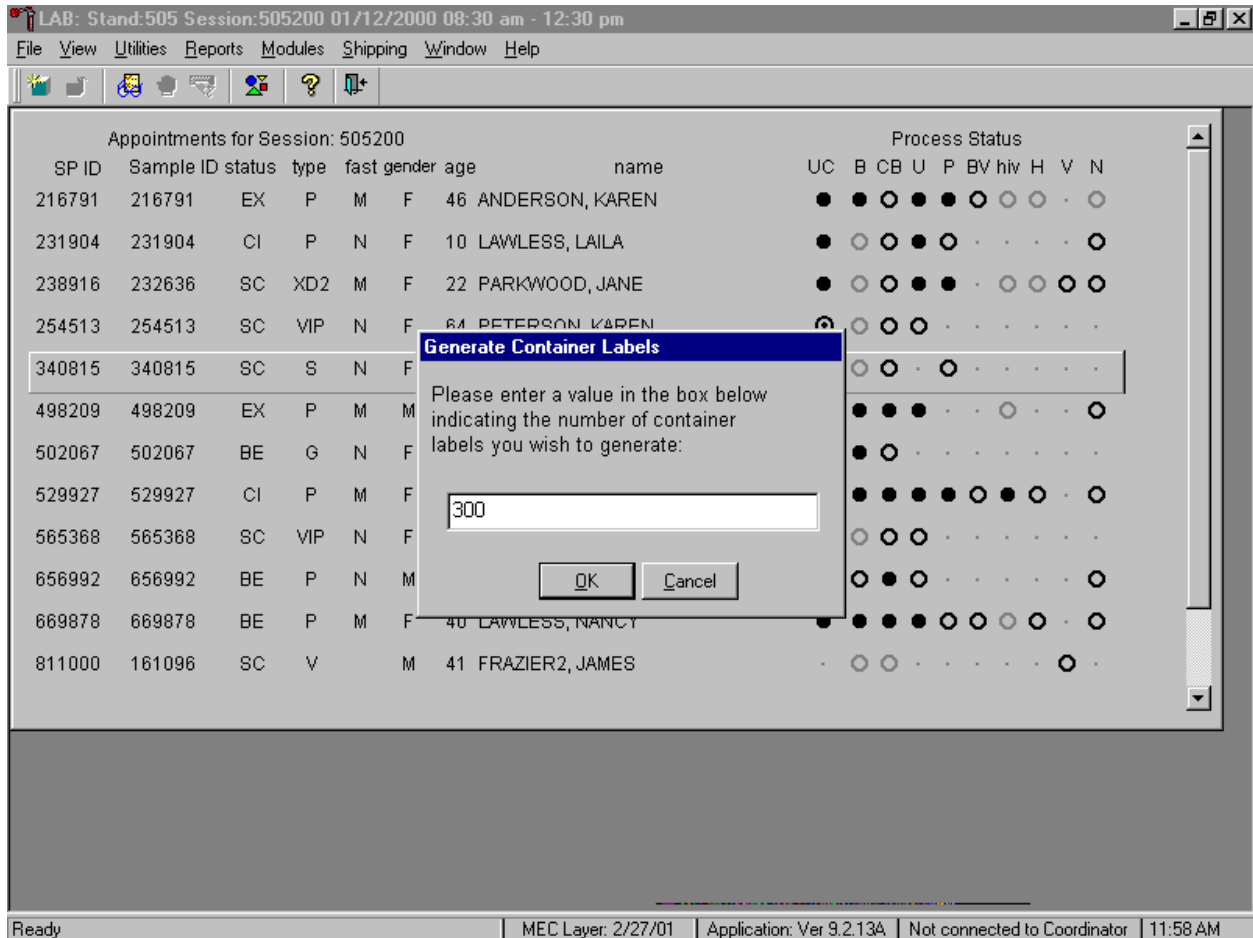
To generate new container IDs or labels using the Print Labels module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, then drag the mouse arrow to {Print Labels}, {Containers}, and left click or type [Alt] [F/f], [L/l], [C/c].

At the beginning of each stand, specify the initial number of container IDs to generate or as needed, specify an additional number of container IDs, using the Shipping module.



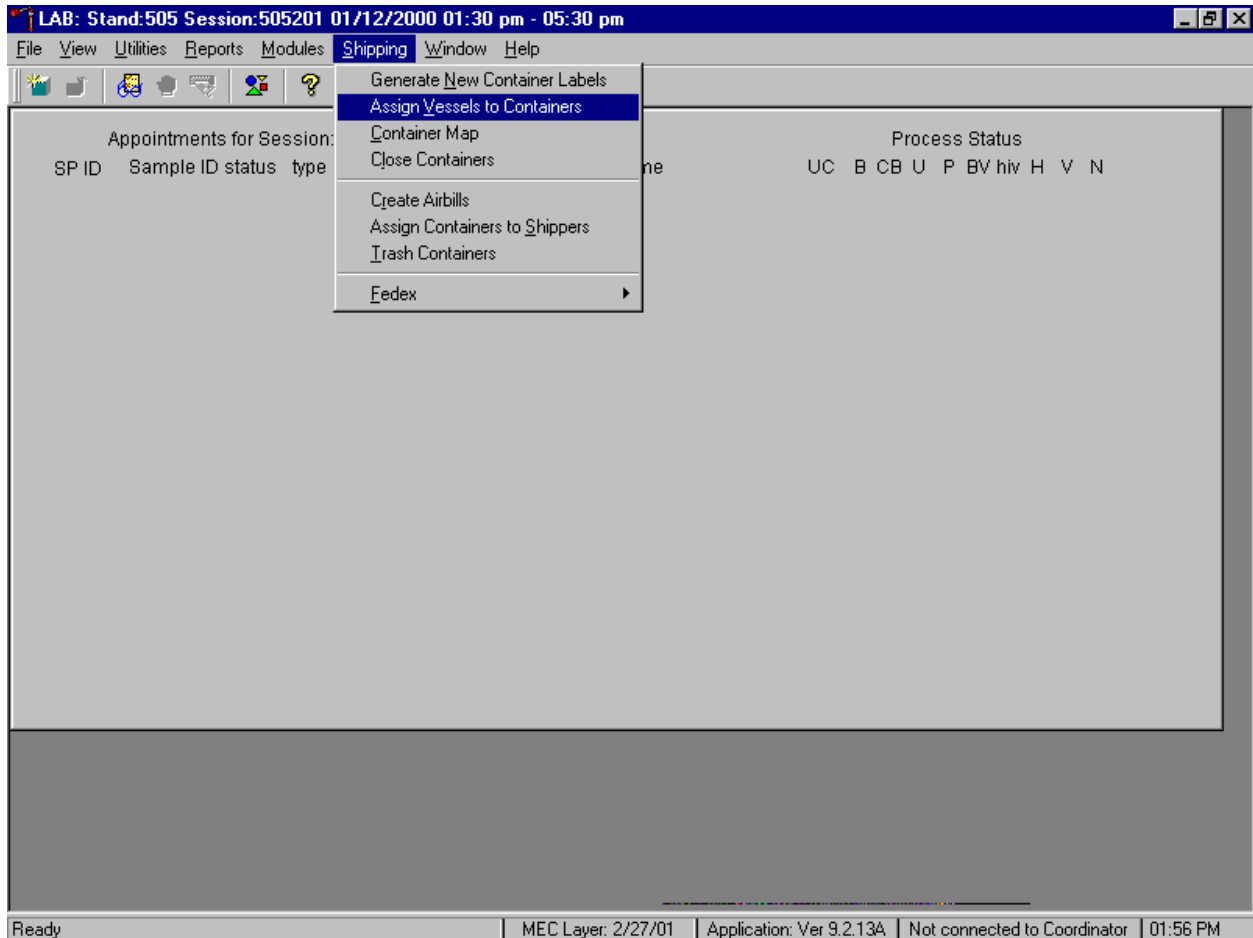
To access the Generate New Container Labels module, use the mouse to direct the mouse arrow to {Shipping} in the menu bar and left click, drag the mouse arrow to {Generate New Container Labels}, and left click or type [Alt] [S/s], [N/n].

Specify the initial or additional number of container labels.



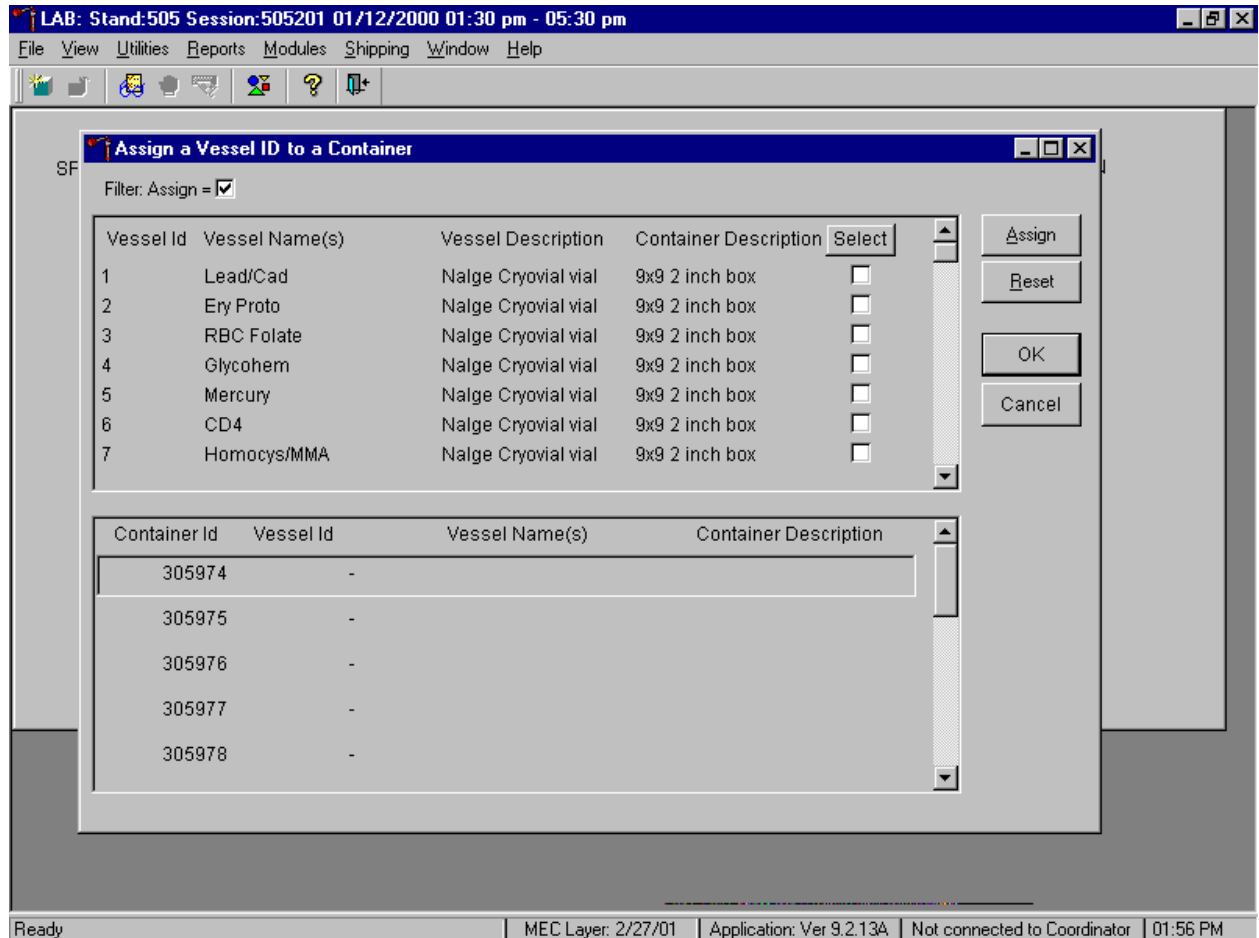
The Generate Container Labels text box displays. The number defaults to 24. At the start of each stand, specify the initial number of labels as 300; type this number into the box using the keyboard. To print the labels and remove the Generate Container Labels text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or type [O/o], or select [Enter]. To cancel these actions and remove the Generate Container Labels text box, use the mouse arrow to direct the mouse arrow to the **Cancel** button and left click, or type [C/c]. Each stand is allocated a maximum of 750 labels.

Access the Assign Vessels to Containers module.



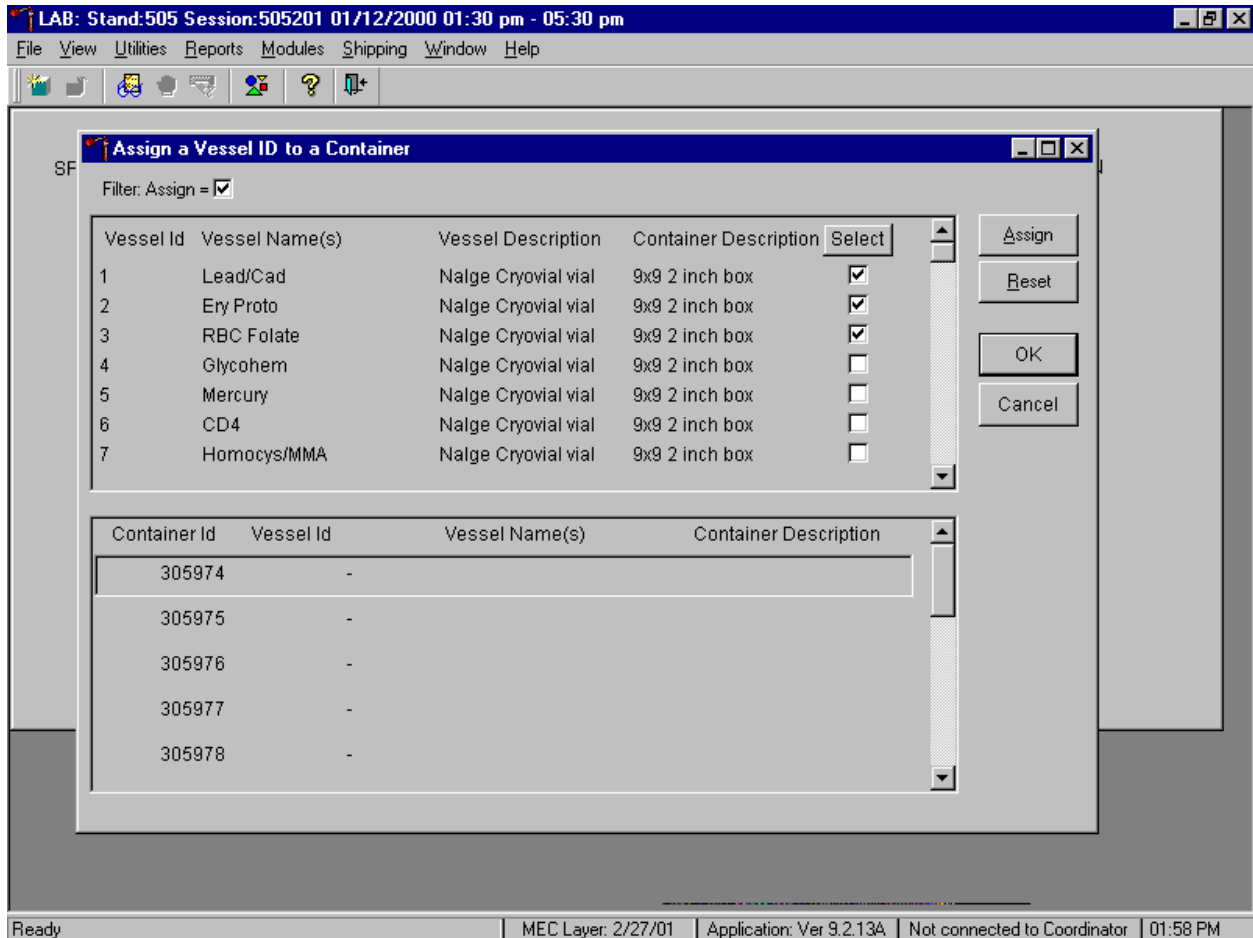
To access the Assign Vessels to Containers module, use the mouse to direct the mouse arrow to {Shipping} and left click, drag the mouse arrow to {Assign Vessels to Containers}, and left click or type [Alt] [S/s], [V/v].

The Assign a Vessel ID to a Container window displays.



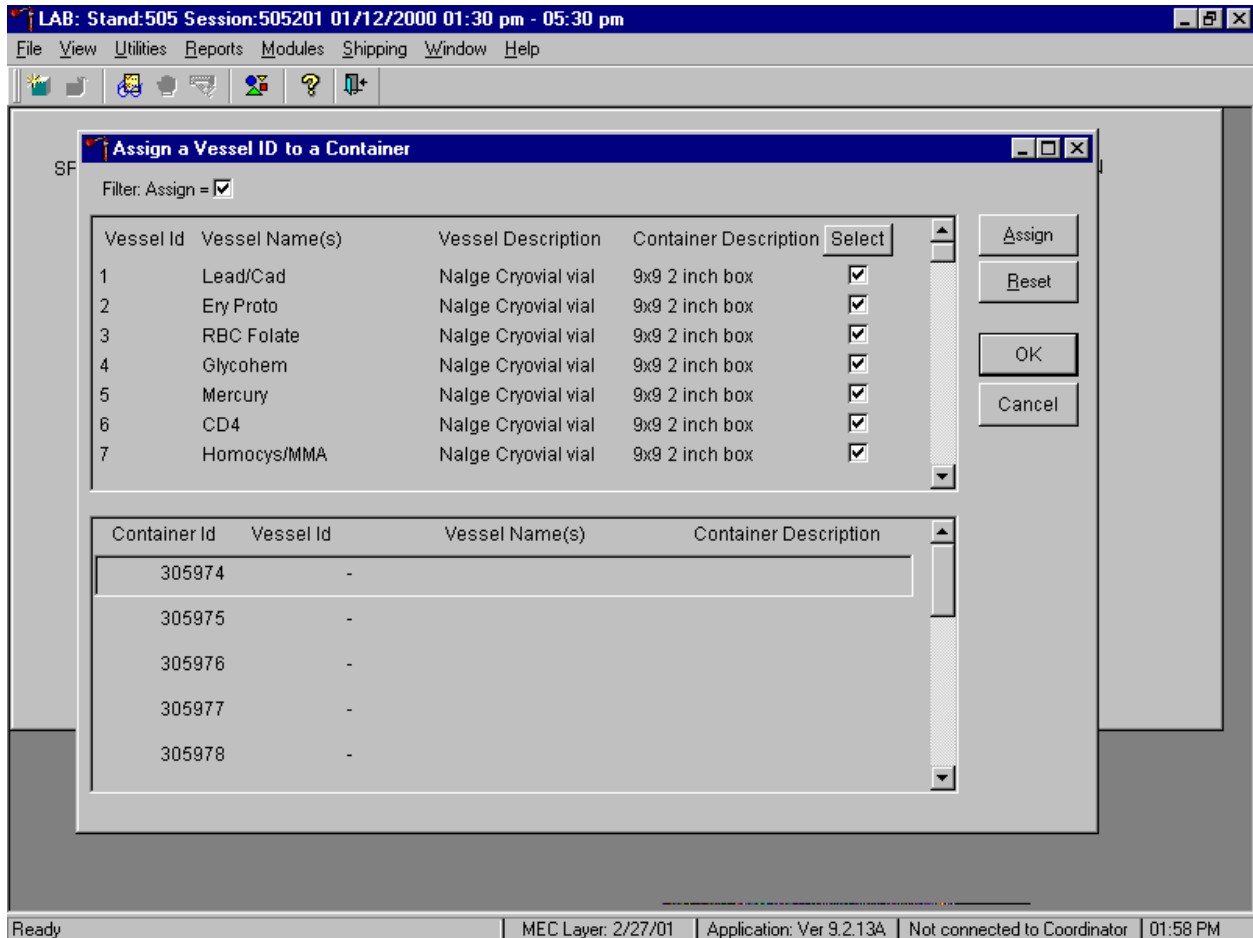
The top half of the Assign a Vessel to a Containers window contains a complete list of Vessel IDs, Vessel Names, Vessel Descriptions, Container Descriptions, and Select check boxes. Use the vertical scroll bar to view all rows.

Individually mark vessels for container ID assignment.



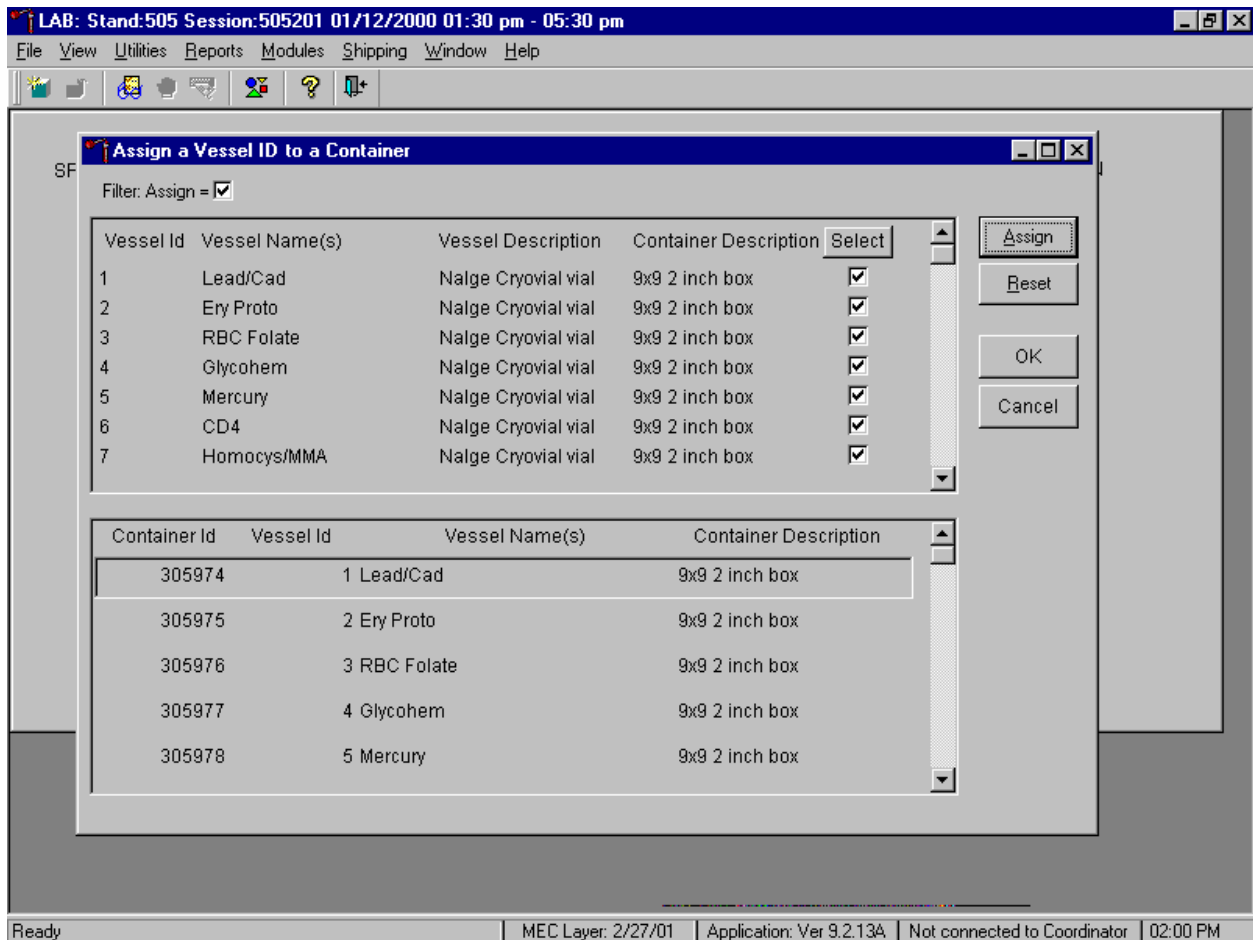
To individually mark or identify a vessel as requiring container ID assignment, use the mouse to direct the mouse arrow to an individual "Select" check box and left click.

Mark or select all vessels for container ID assignment.



To mark all vessels for container ID assignment, use the mouse to direct the mouse arrow to the Select button and left click. Check marks fill in all the check boxes.

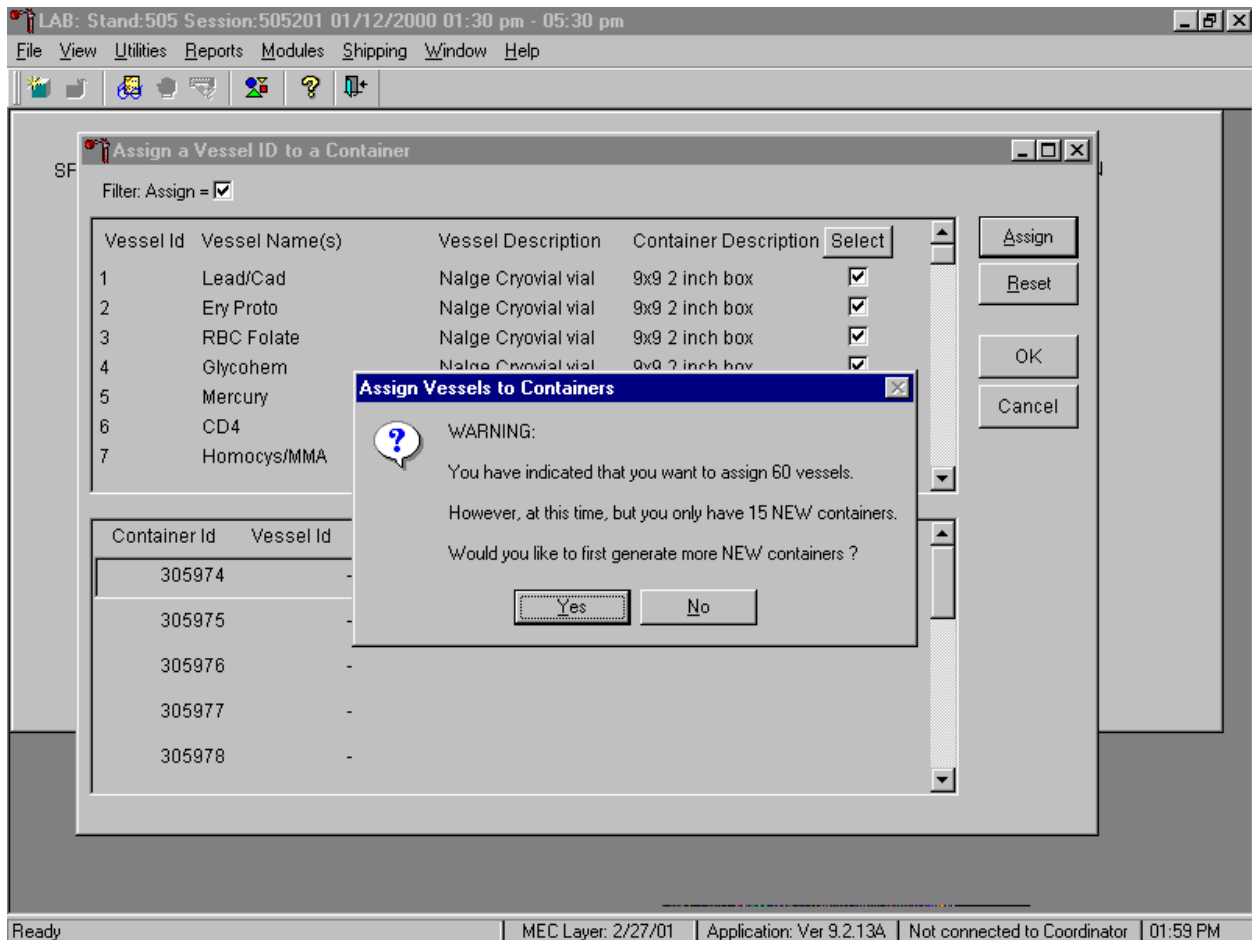
Once the vessels are marked with a check mark or selected for container assignment, they are ready for automatic assignment. Each vessel is assigned a unique container ID.



The lower section of the Assign a Vessel ID to a Container window contains a list of available (generated) Container IDs, and columns for Vessel id, Vessel Name(s) and Container description.

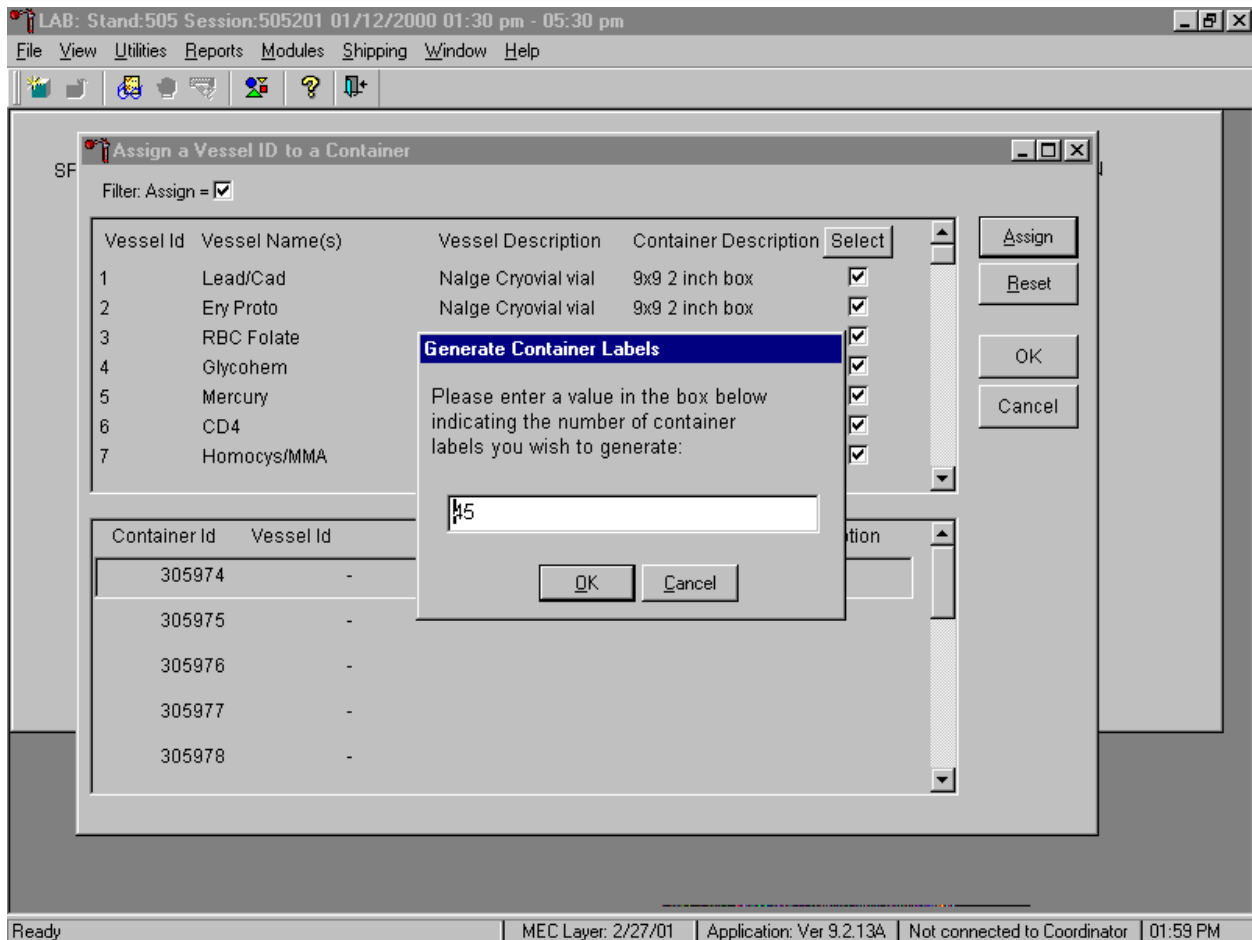
To automatically assign vessels to containers, use the mouse to direct the mouse arrow to the **Assign** button and left click, or press [Enter]. All marked vessels are assigned sequentially to the generated (available) container IDs.

If there are insufficient container labels available to assign a container ID to each check marked vessel, a warning message text box displays.



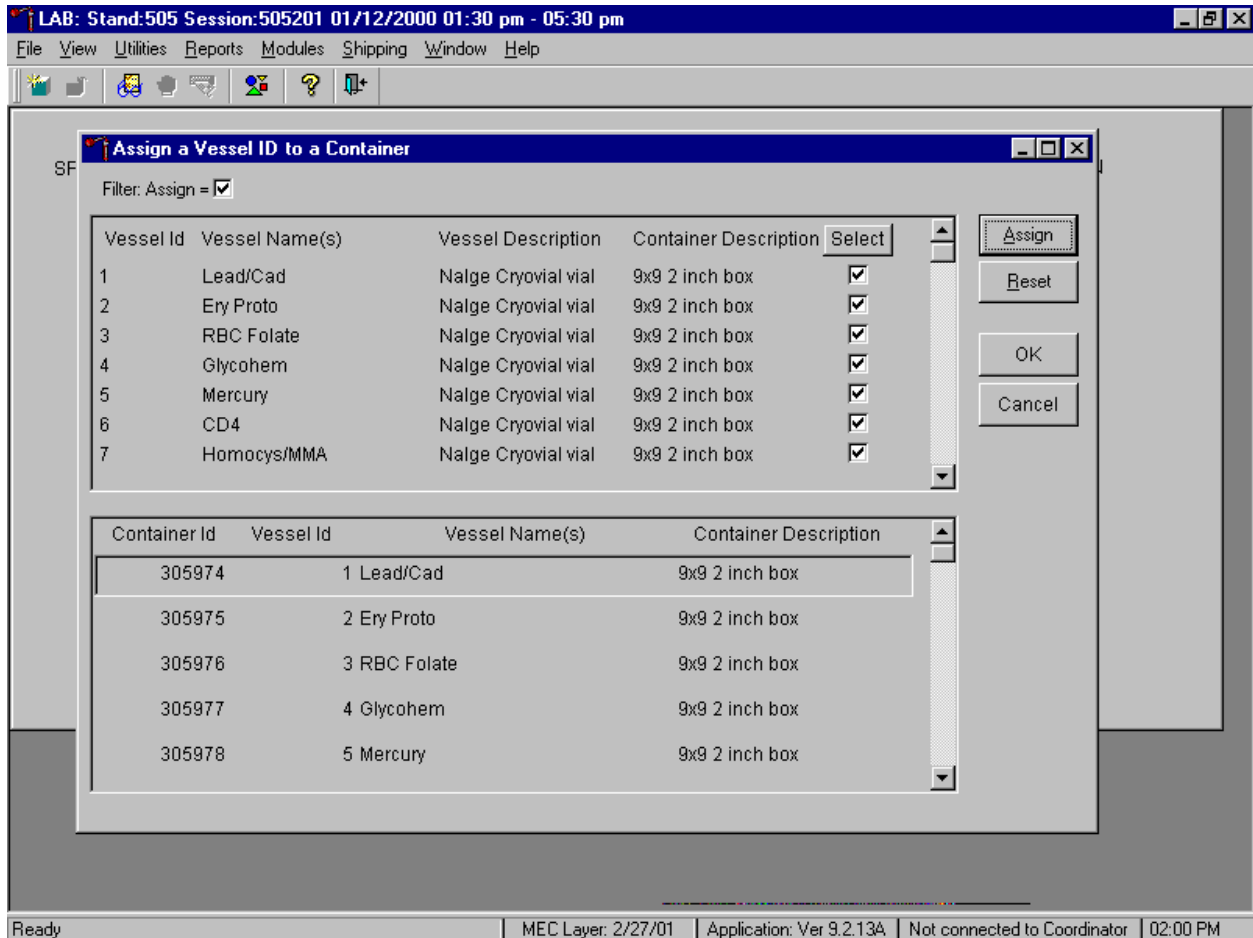
The warning message text box reports the number of check-marked vessels (those ready for assignment), and the difference between the number of check-marked vessels and the number of available container IDs. The text box provides an opportunity to create new container IDs without exiting the module. To create the additional number of container IDs necessary to complete the assignment process, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y/y], or select [Enter]. To decline the opportunity to create additional container IDs, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N/n].

If the response to the previous warning message text box is "Yes," the Generate Container Labels text box displays.



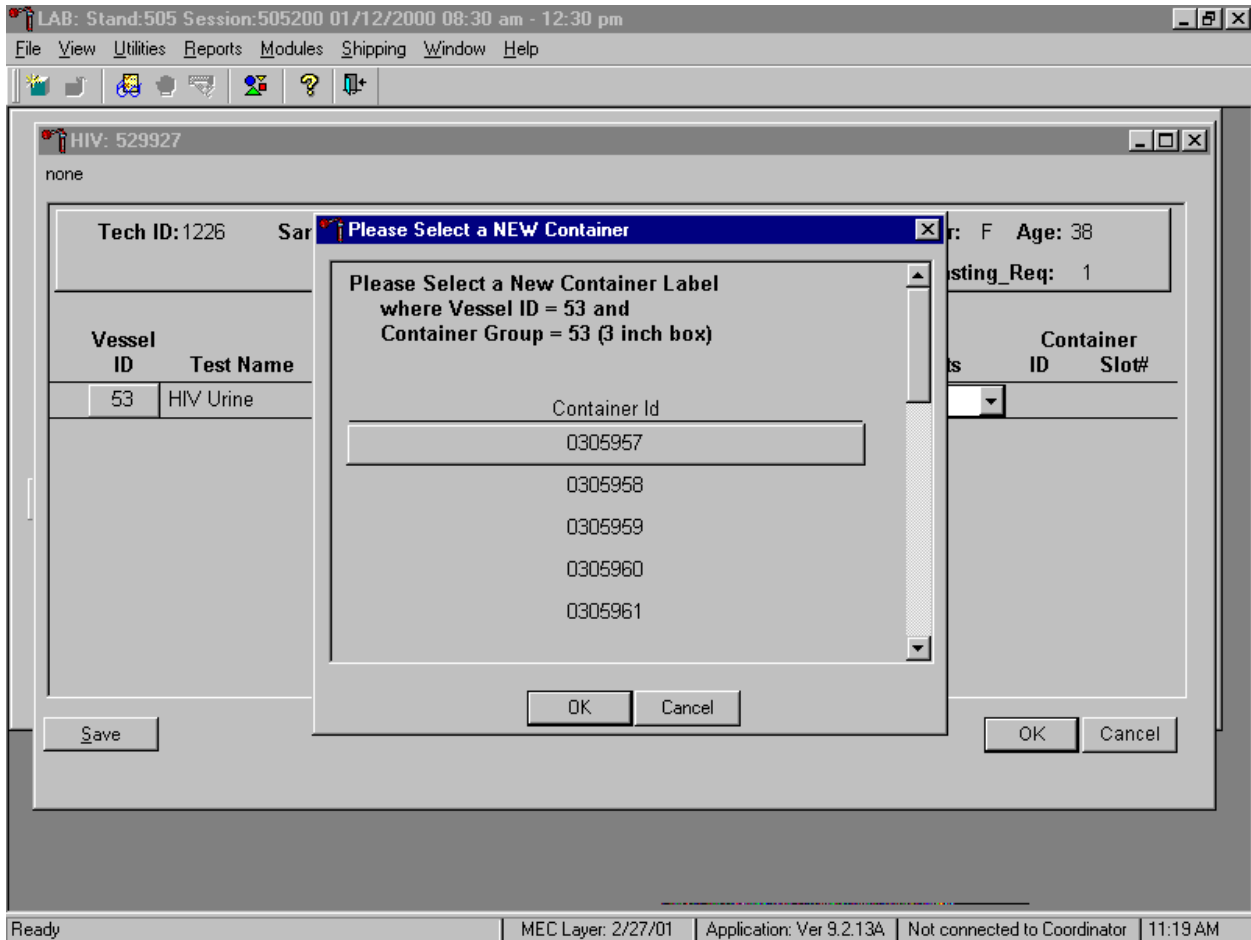
The Generate Container Labels message text box fills in with the exact number of container IDs necessary to complete the assign containers to vessel request. To create these additional container IDs, use the mouse to direct the mouse arrow to the **OK** button and left click, or type [O/o], or type [Enter]. To remove the text box without creating new container IDs, use the mouse to direct the mouse arrow to the **Cancel** button and left click, or type [C/c]. To change the number of labels in the text box, type a different number in the space using the keyboard, then select the **OK** button.

Complete the assignment process.



After reviewing the screen, affix the designated (assigned) container ID label to a container of the correct type and manually write the test/vessel ID on the container. To accept and register the assignments, use the mouse to direct the mouse arrow to the **OK** button and left click. To erase all assignments and restart the process, use the mouse to direct the mouse arrow to the **Reset** button and left click, or type [Shift] [R]. To exit the module without recording any actions to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

When a container is full, the container will automatically "close." Open a new container to replace the closed container.

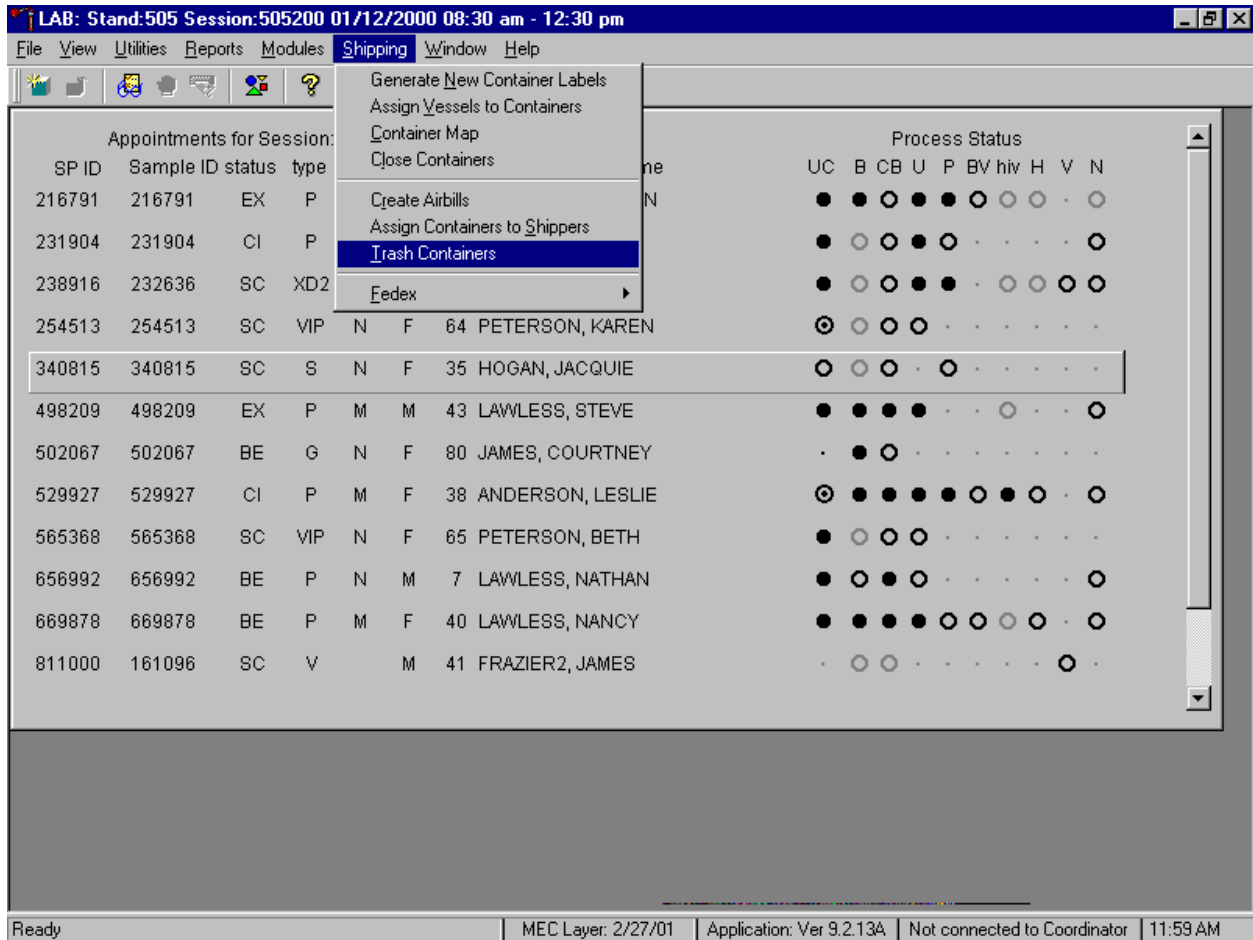


When a container is full, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left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

9.6 Trash Containers

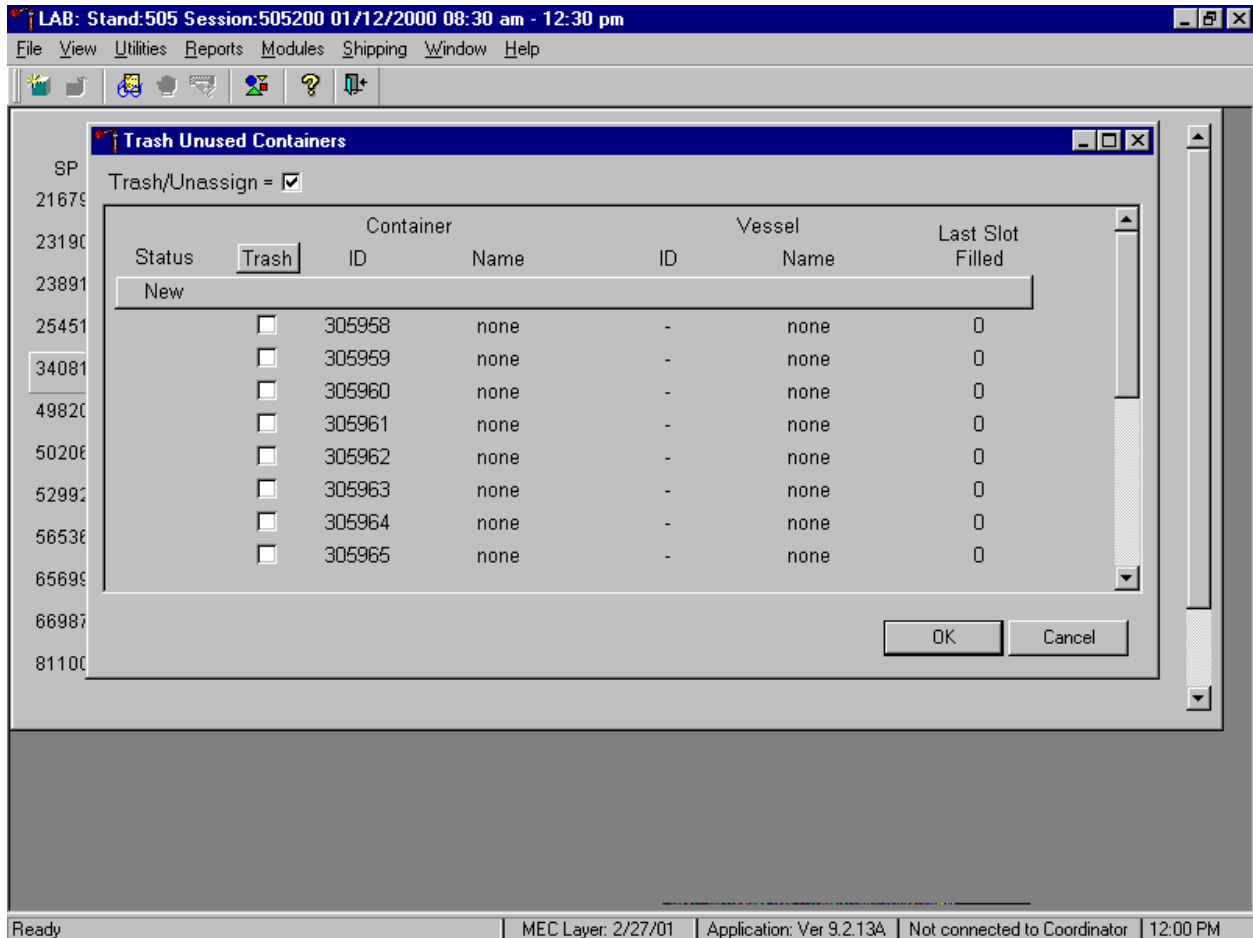
Each stand is allocated a maximum of 750 container IDs.

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



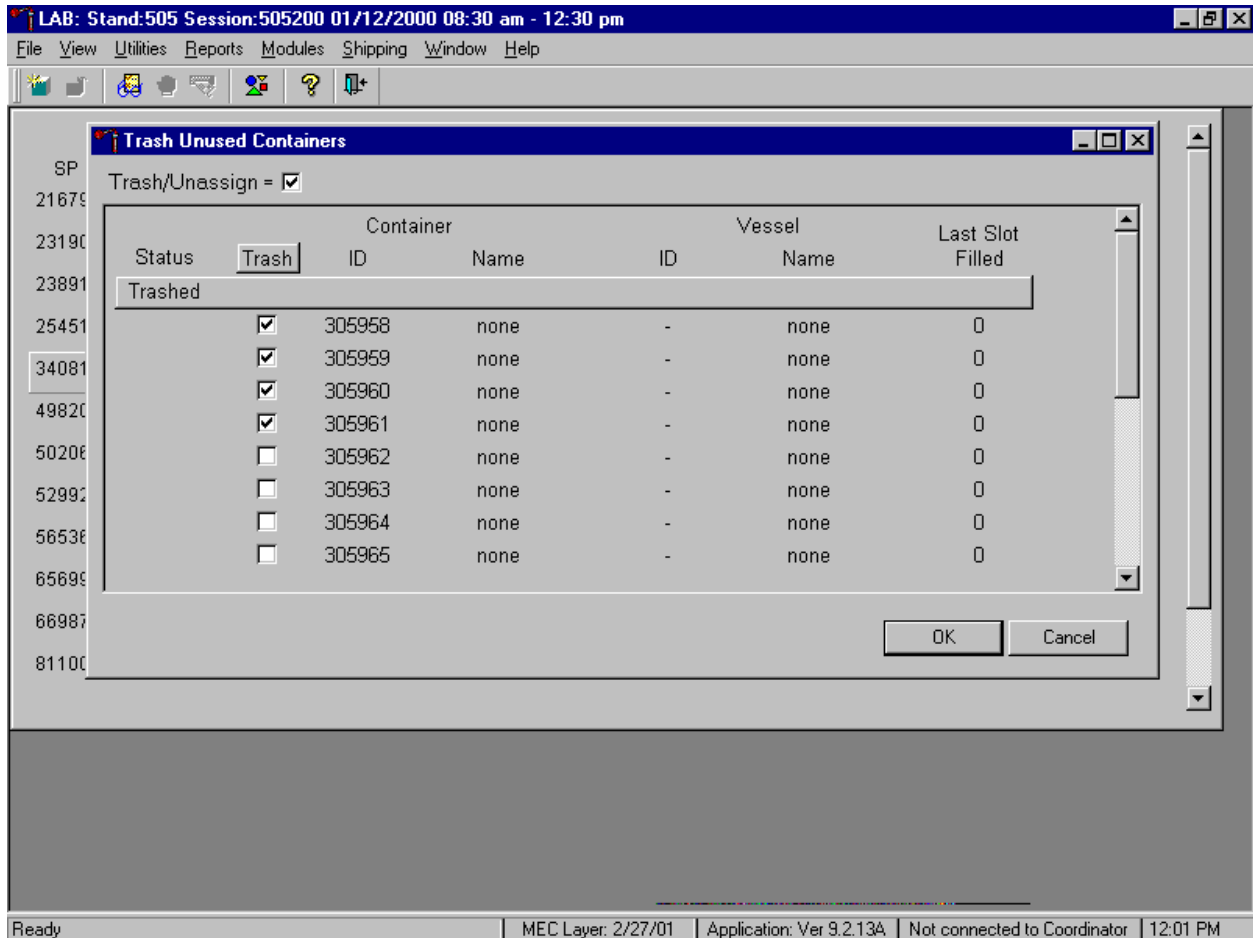
To access the Trash Containers module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Trash Containers}, and left click, or type [Alt] [S/s], [T/t].

The Trash Unused Containers window displays.



The status of each container ID is "New." To individually mark the container IDs for deletion, use the mouse to direct the mouse arrow to the check boxes and individually left click on specific boxes or, to mark all outstanding container IDs for deletion, use the mouse to direct the mouse arrow to the **Trash** button and left click.

As the container IDs are marked for deletion, the status changes from "New" to "Trashed."



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

9.7 Shipping Overview

The integrity of laboratory specimens is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and 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 FedEx priority overnight.

Overnight delivery by FedEx can be delayed due to a weekend or holiday. This extraordinary circumstance usually occurs at the end of a stand or just before vacation. In any case, all specimens must be shipped before vacations. In extreme heat, take the following actions:

- Consider using medium shippers instead of small shippers for all laboratories east of the Mississippi when shipping from areas west of the Mississippi and for all laboratories west of the Mississippi when shipping from areas east of the Mississippi. Substitute a larger shipper when shipping specimens in extreme summer heat or whenever professional judgement dictates added precautions.
- Use dry ice in blocks instead of pellets since blocks sublime at a slower rate.
- Increase the number of refrigerant packs from four to at least six per shipper. Use the smallest shipper possible for these specimens.

The shipping technologist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other medical technologists, the phlebotomist and the home examiner assist in performing each of the steps listed below to complete the shipping procedures.

At the start of each stand, the laboratory staff creates labels with the current MEC address to use on the Class 9 labels.

- On the day before or the morning of a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software.
- Prepare the Class 9 labels for shipment with dry ice.
- On the morning of a shipping day, close all containers, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.

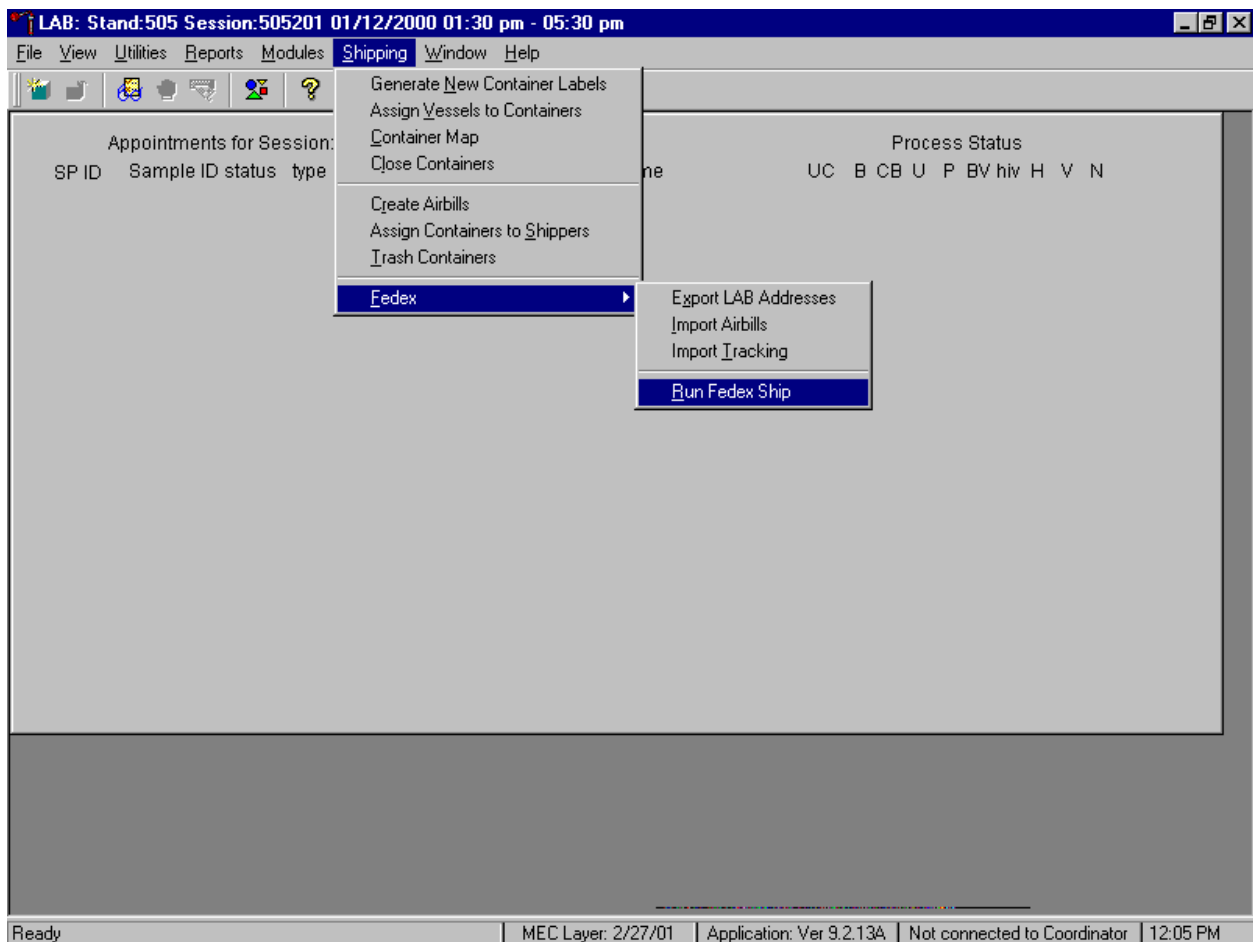
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted "warning" labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of dry ice or refrigerant packs as appropriate.
- Place the appropriate paper manifest and the FedEx return airbill in a 12 x 12 plastic bag and place the plastic bag on top of the Styrofoam shipper lid.
- Label each shipper with the appropriate FedEx label and warning labels.
- When the contract laboratory personnel receive the shippers, they unpack the specimens and return the shippers and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

9.8 Create FedEx Airbills

9.8.1 Launch the FedEx Ship Application

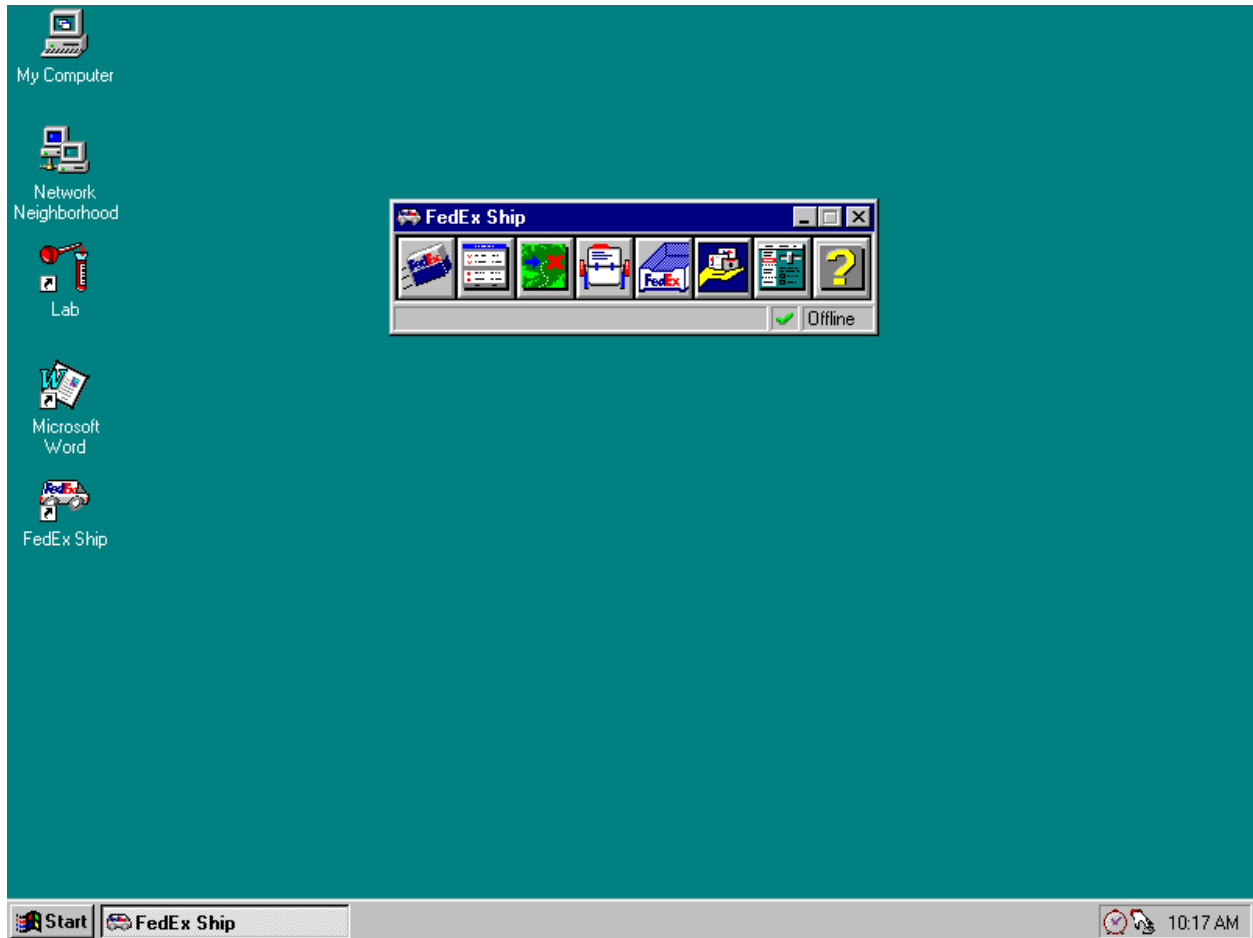
In advance of the shipping day, create one airbill using FedEx Ship software for each shipper. Create five or six airbills for CASPIR, two airbills each for Coulston Foundation and the University of Missouri; create one airbill for the frozen shipper and the other airbill is for the refrigerated shipment. It may be necessary to create two airbills for the CDC/NCID AIDS laboratory.

Launch the FedEx Ship software.



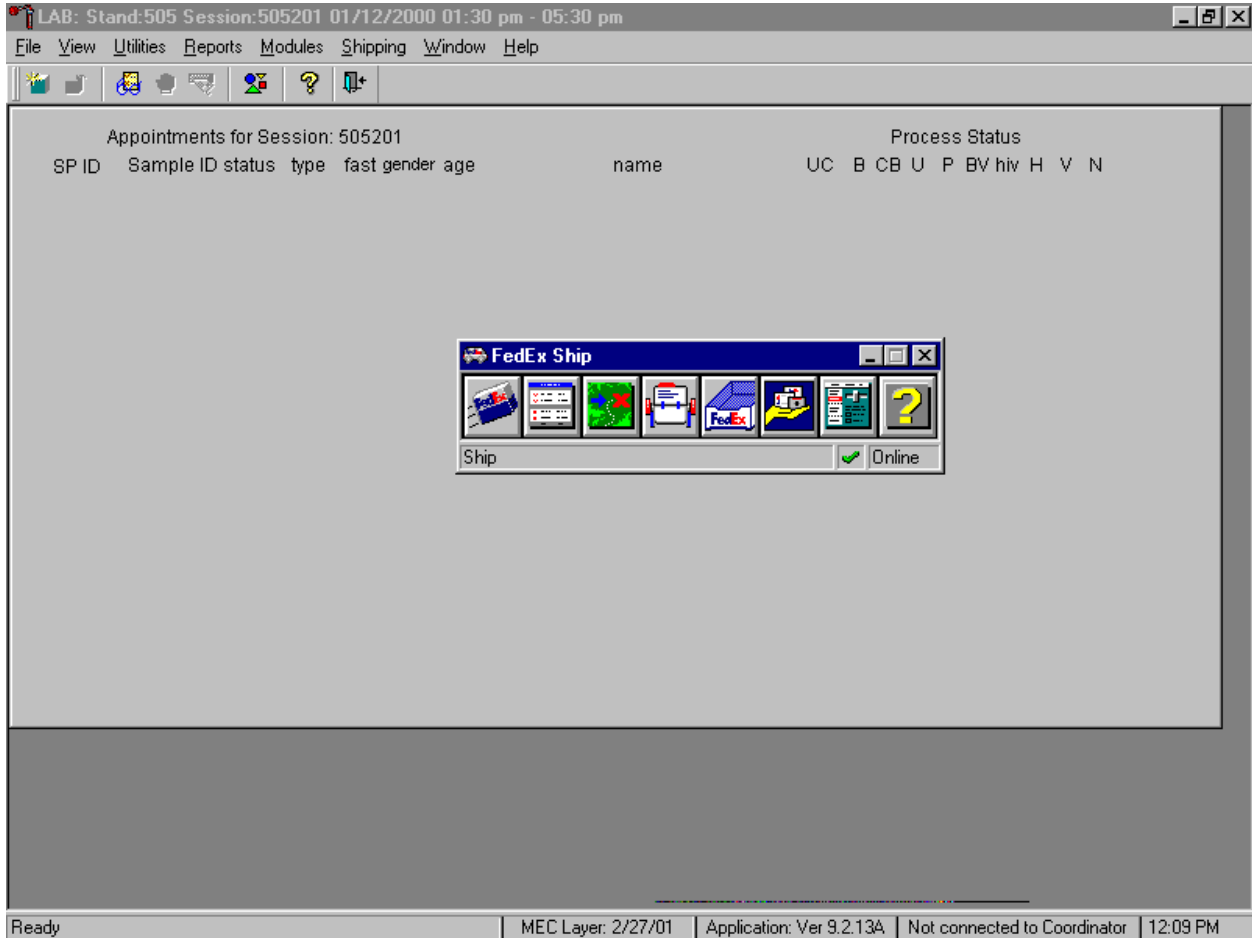
To launch the FedEx Ship software from within the laboratory application, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {FedEx}, then to {Run FedEx Ship}, and left click, or type [Alt] [S/s], [F/f], [R/r].

Alternatively, launch FedEx Ship software from the desktop.



To launch the FedEx Ship application from the desktop, use the mouse to direct the mouse arrow to the FedEx icon on the desktop and double click.

The FedEx Ship toolbar displays. Use the first four icons to create airbills. The first icon represents the shipping function, the second ICON represents the log, the third icon represents the tracking function, and the fourth icon represents the address book.



To select a function, use the mouse to direct the mouse arrow to the icon and left click.

9.8.2 Create the Airbill

Click on the Ship icon in the navigator bar to display the Ship window.

LAB: Stand:505 Session:505201 01/12/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

Ship Window Documents Help

Appointme
SP ID Sample

Address
Billing
Services
Special
Int'l Svcs

Recipient Sender

Name: []
Company: []
Address: []
Suite: []
City: []
State: []
Zip: []
Phone: [] - ext: []
Country: United States [v]
Residential:
Email ID: []
 Send e-forms
Address...

B Lindstrom
(301) 738-8324
Westat
MECLab
1650 Research Boulev...
WB248
Rockville, MD 20850

Date: 3/12/01
Account #: 129015748
Man Wgt: 1 LBS
Dimmed:

To:

FedEx

Service: Priority Overnight
Packaging: FedEx Letter
Billing: Bill Sender
Special: Drop

OK, Ship Now
OK, Ship Another
Close

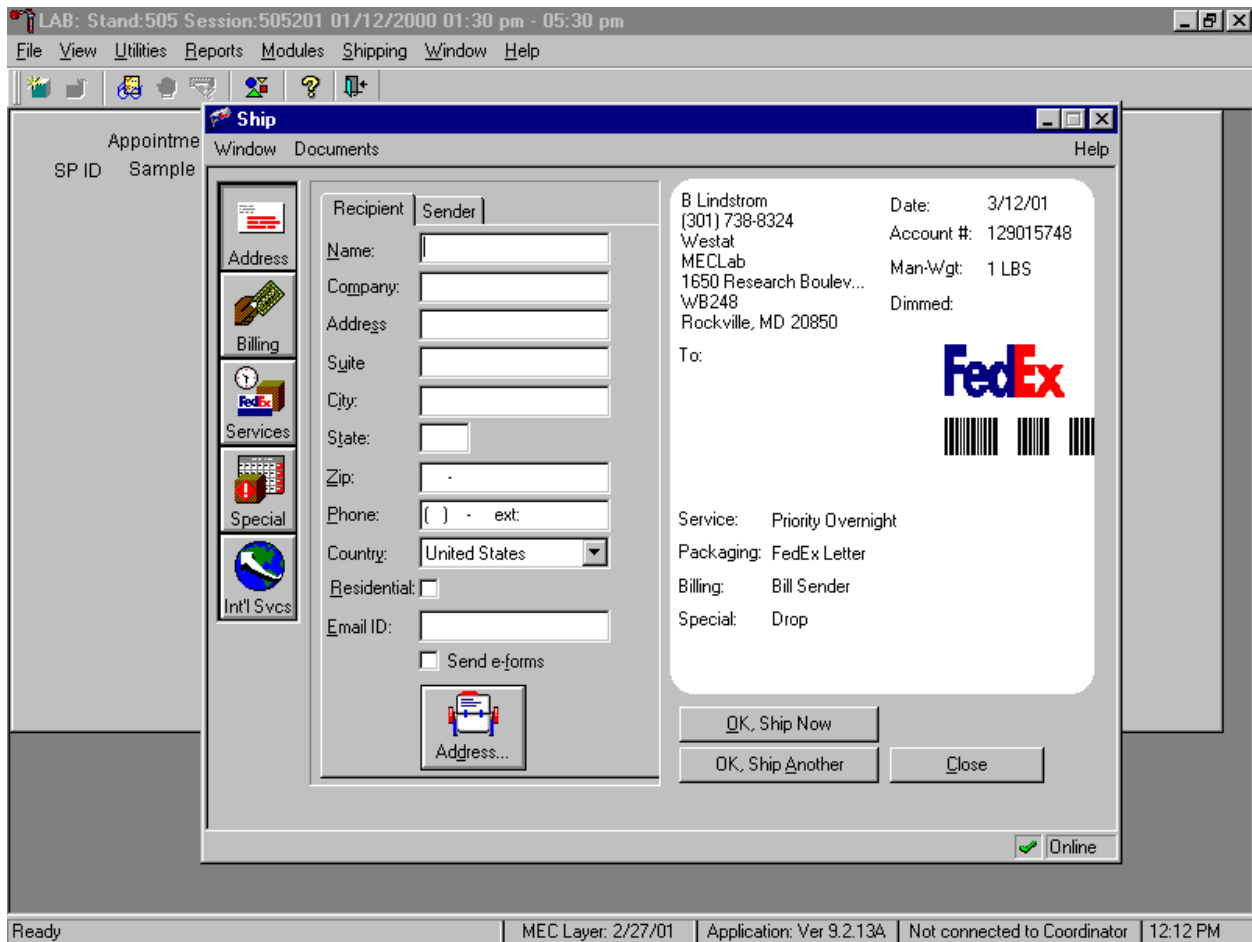
Online

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 12:12 PM

The window displays a blank form for entering recipient information. The right side of the window incorporates the shipment information in an on-screen version of the shipping label.

Each shipper must have a separate label. Enter shipment information for more than one shipment at one time by using the **OK, Ship Another** button. Enter shipment information for several shipments while in the Ship window. Preparing a shipment involves entering and verifying shipment information, sending shipment information to FedEx, and printing the shipping label and placing it on the shippers that make up the shipment. The following sections explain how to complete these tasks.

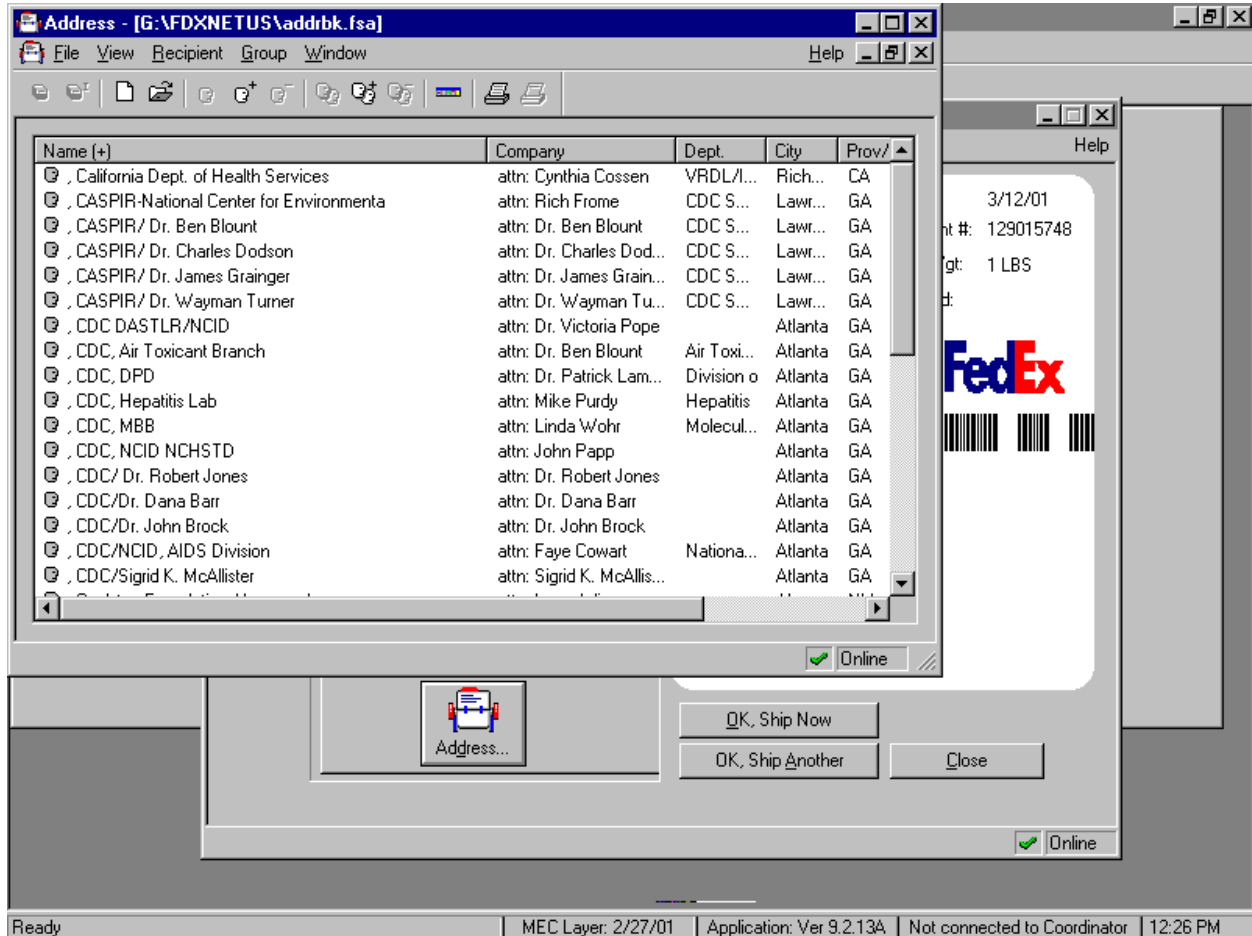
Begin entering the shipment information. To display the ship window, use the mouse to direct the mouse arrow to the navigator bar and click on the Ship icon. FedEx displays the Ship window.



The FedEx Ship window includes tabs for the Recipient and Sender.

Enter the recipient's name, company, full address, and telephone number by using the Address book.

The address book stores names and addresses of laboratories to which shipments are sent. Records are imported directly from the database tables. Do not change or edit this information unless authorized by the technical supervisor at the home office.



Use the address book to quickly select address information for creating shipping labels. This can be done several ways and from different places within FedEx Ship.

To open the address book from the ship window, click on the address book icon on the recipient page in the ship window. Select a record. Click the ship to icon on the toolbar. FedEx Ship automatically enters the name and address information into the recipient page of the ship window. Alternatively, start typing the recipient's name in the recipient page in the ship window. FedEx Ship

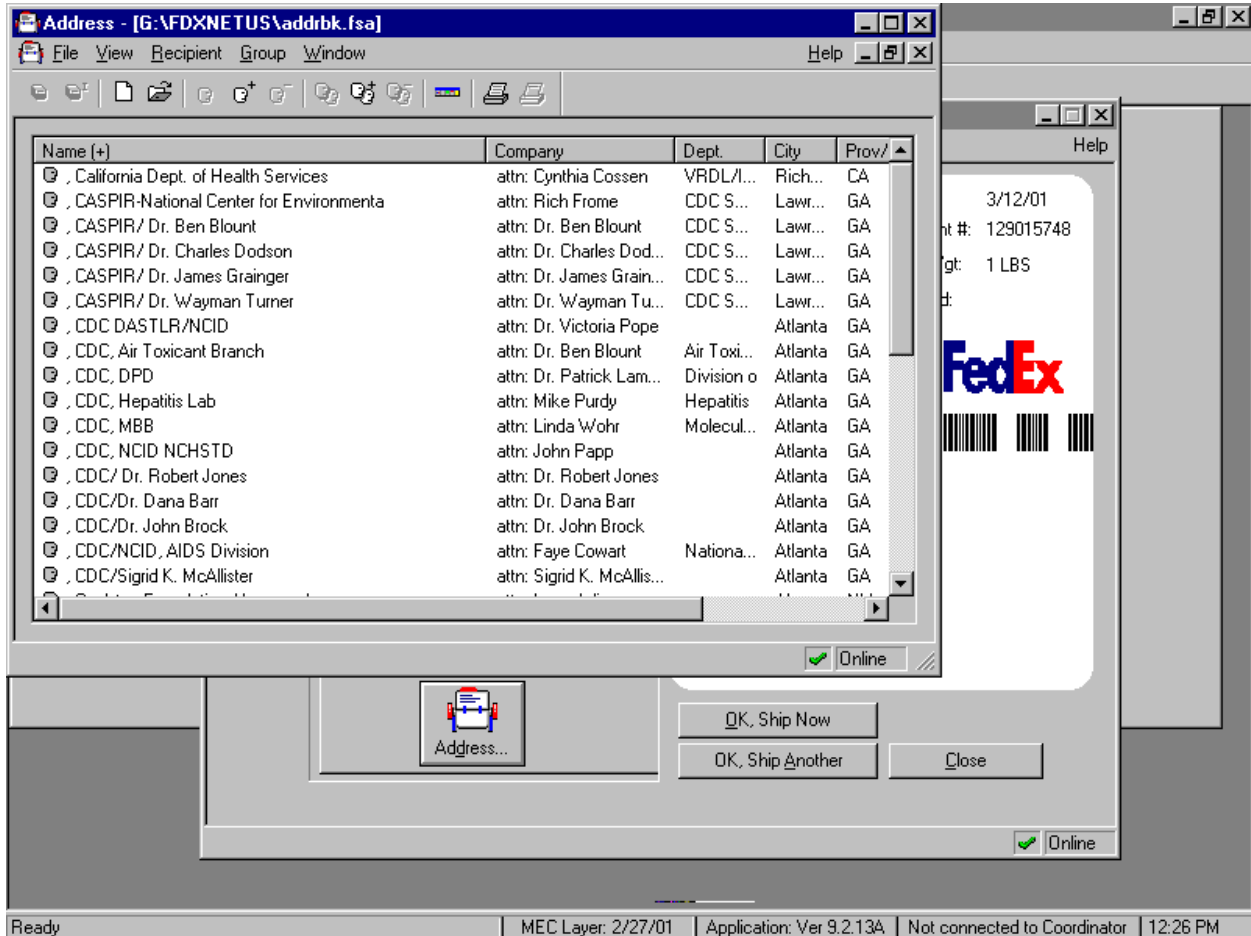
searches the address book and, if it finds a match, completes the name and address information from the address book.

To open the address book from the FedEx Ship navigator bar, click the address book icon to open the address book window. Select a record, and then click Ship To icon on the toolbar.

Windows desktop allows FedEx to display the FedEx navigator bar, the ship window, and the address book window simultaneously.

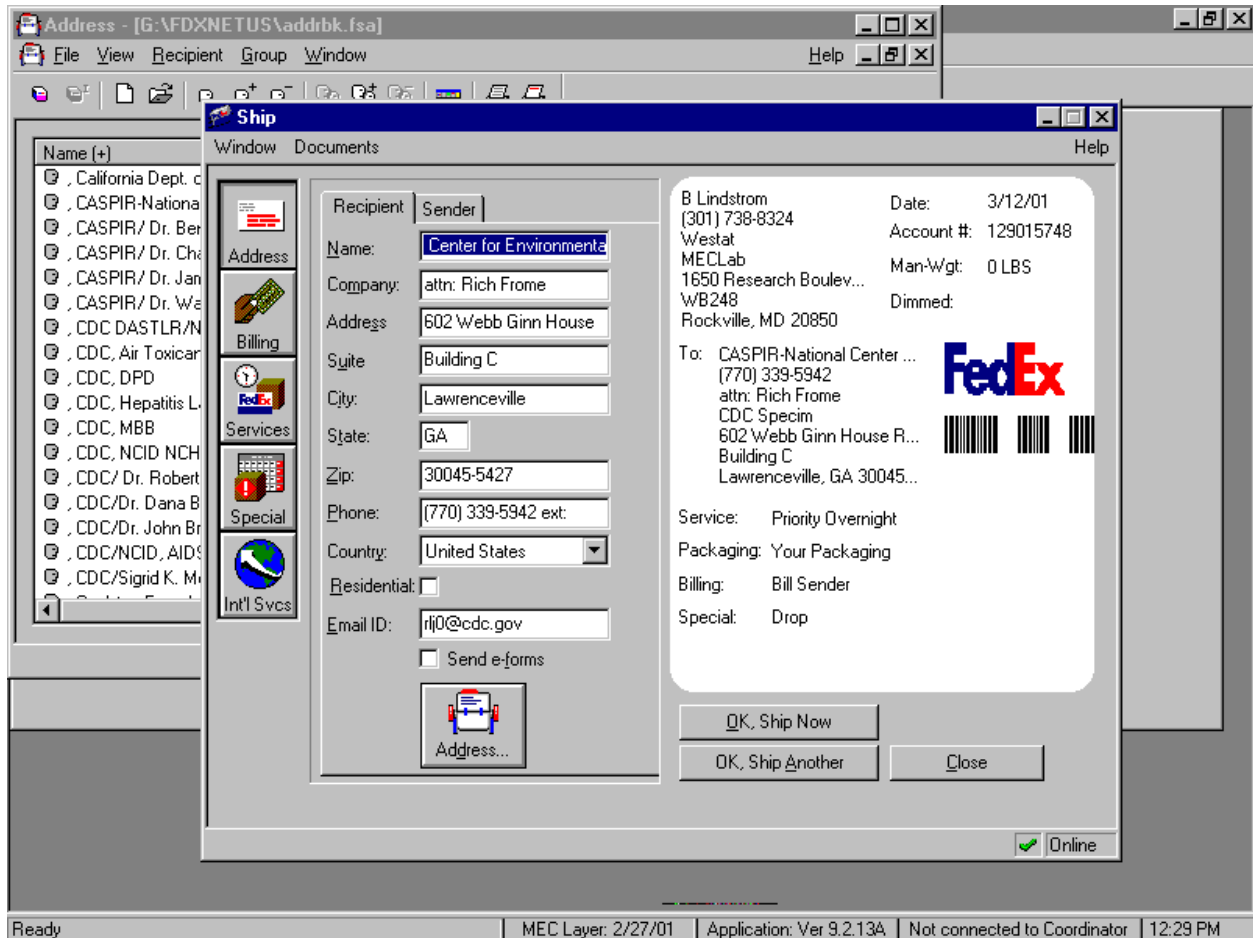
To open the address book window from the navigation bar, drag and drop a record from the address book window onto the ship icon in the navigator bar, or drag and drop a record from the address book window into the recipient page of the ship window.

Drag and drop a recipient's address information.



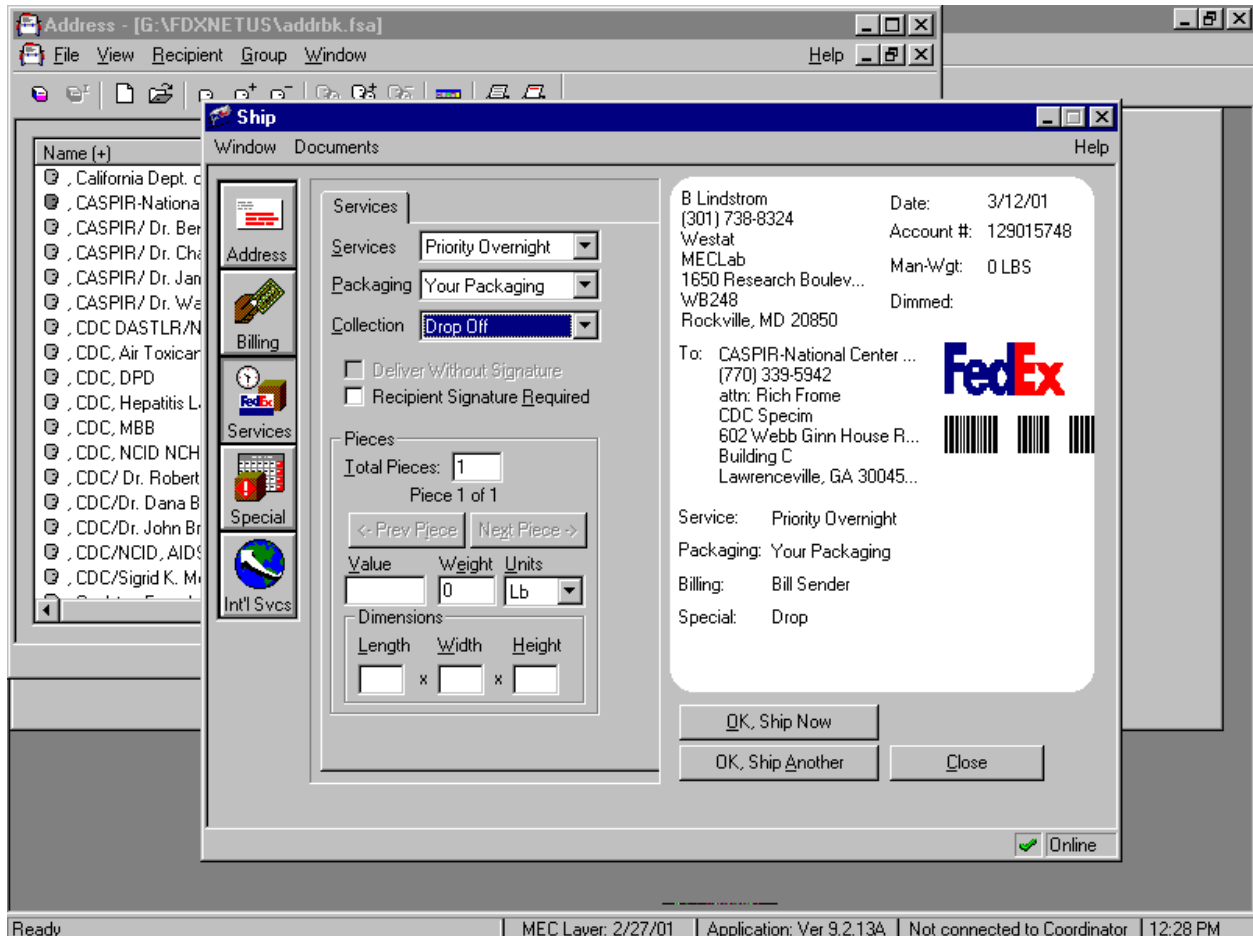
To access the address book, use the mouse to direct the mouse arrow to the address icon on the bottom of the ship window. The address book displays. Stagger the ship and the address book windows. To drag and drop the selection from the address book to the ship window, use the mouse to direct the mouse arrow to the desired laboratory, left click, continue to hold the mouse button down, drag the entity to the ship window and release the mouse button. The recipient's information is entered into the ship recipient text boxes.

Verify the sender and recipient's information.



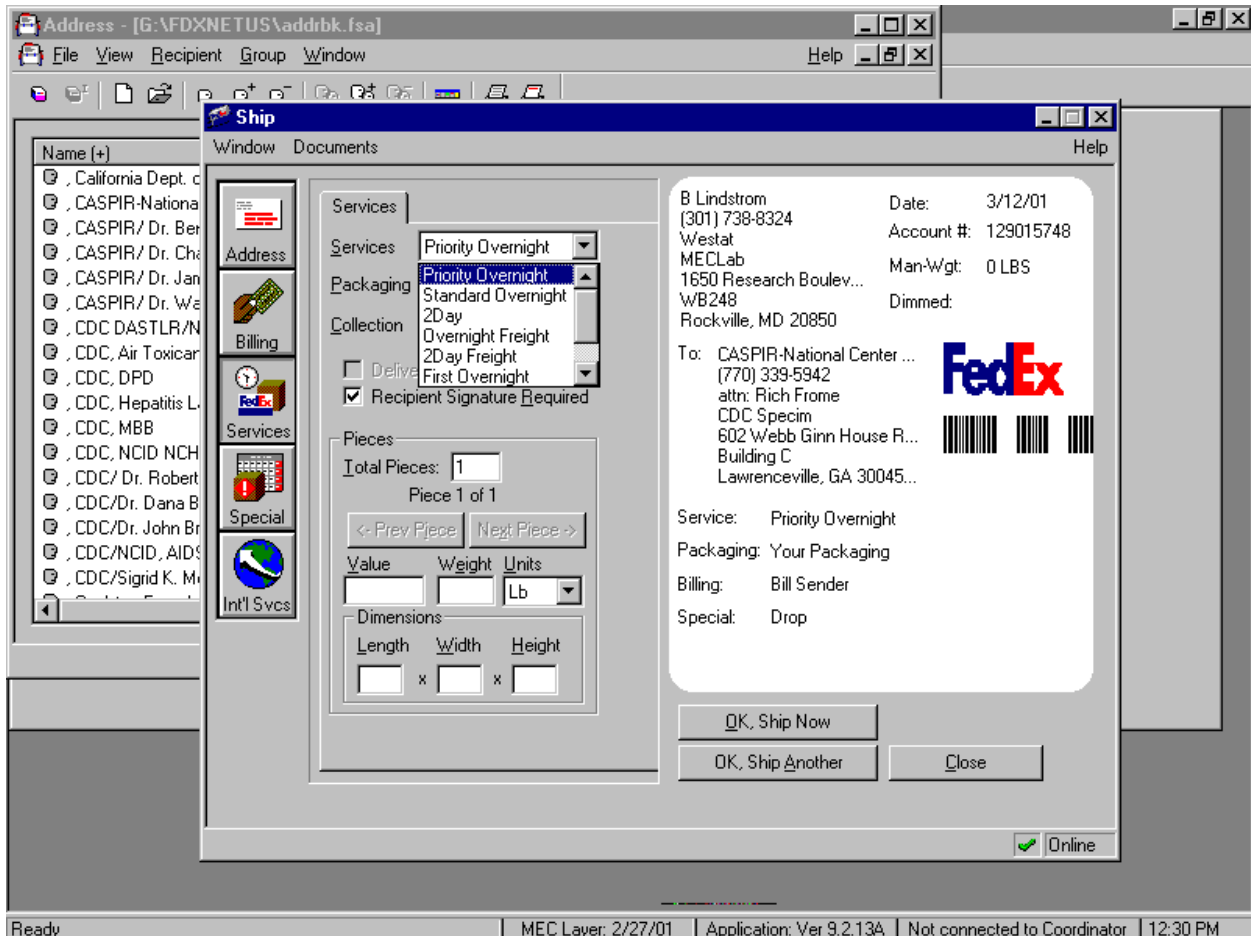
Verify the sender and recipient information shown on the screen label. Contact the data manager to make any changes.

Verify the services or select different services.



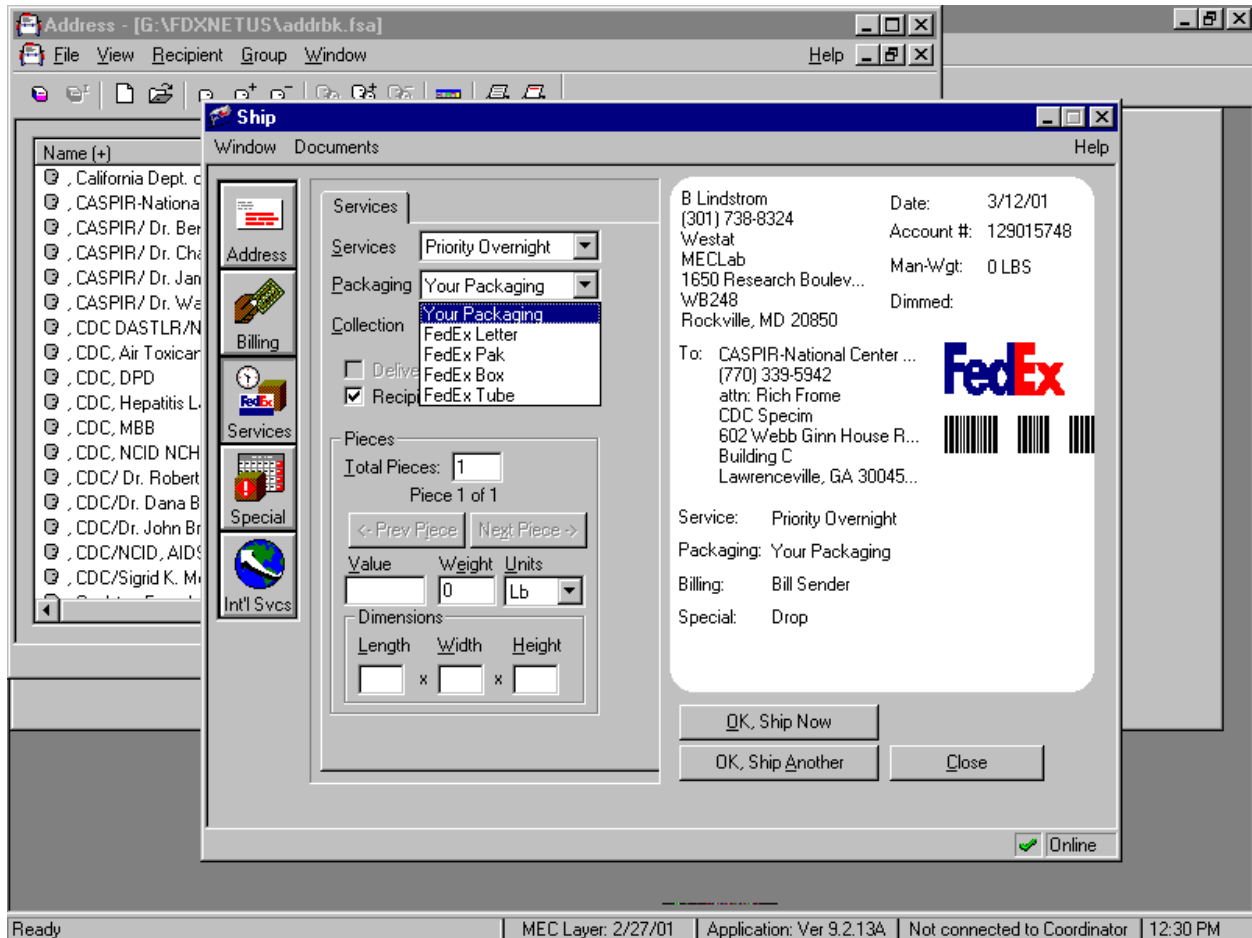
To review the previous service choices or to select new choices, use the mouse to direct the mouse arrow to services icon located on the left side of the window.

Choose the type of FedEx service as Priority Overnight or accept the default.



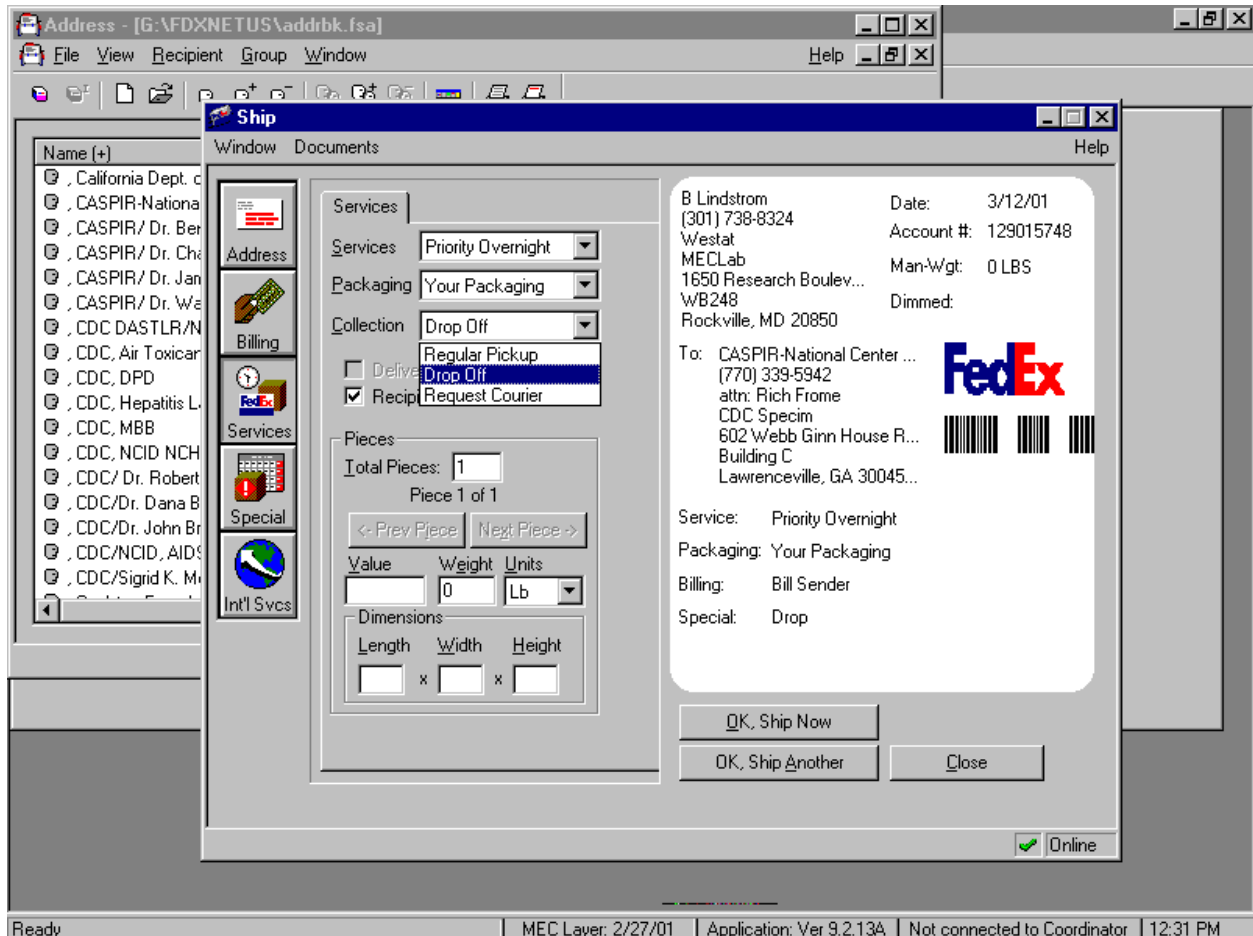
To select the priority overnight option, use the mouse to direct the mouse arrow to the drop down arrow on the right side of the services text box, left click and drag the mouse arrow to {Priority Overnight}.

Select the type of packaging as Your Packaging.



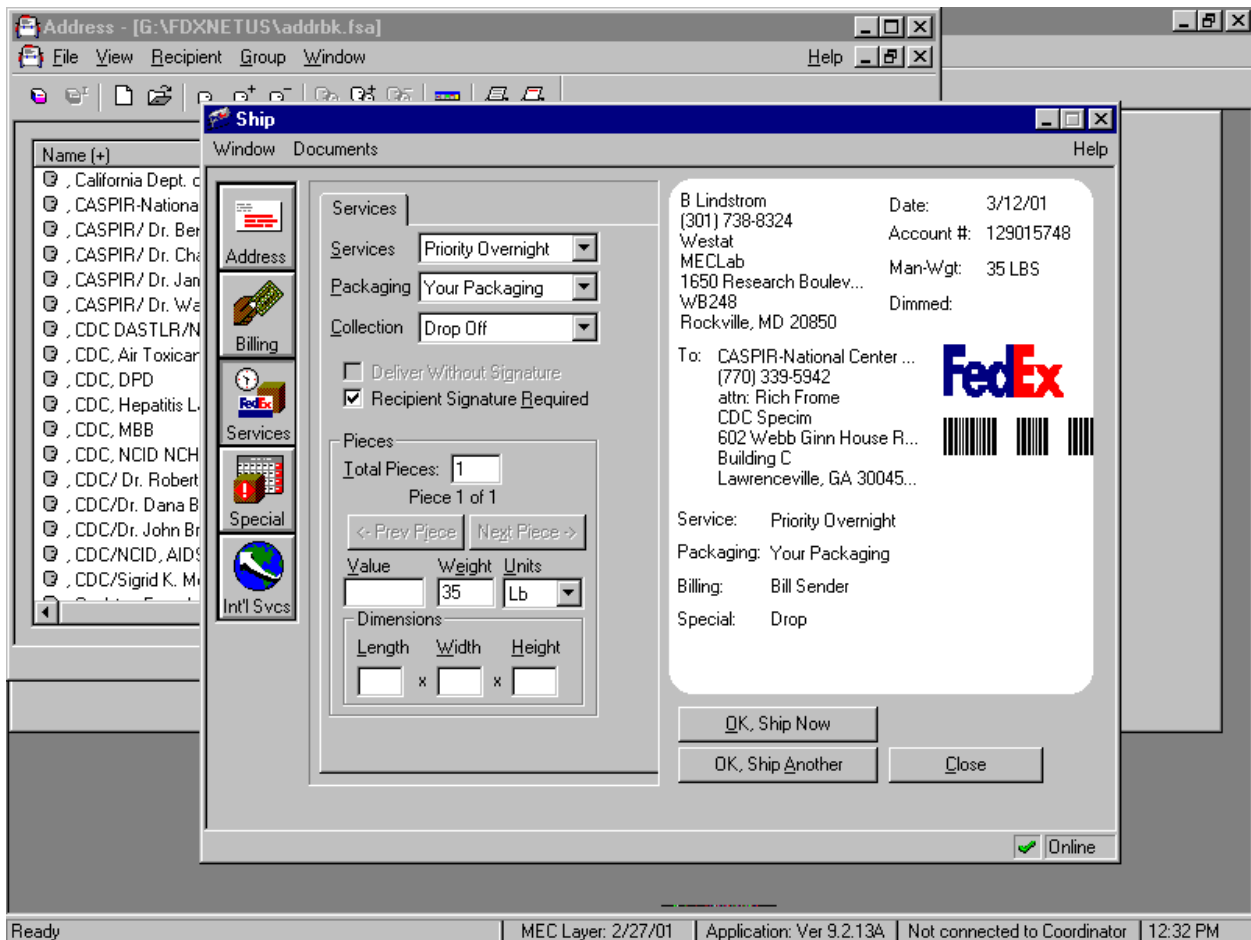
To select your packaging option, use the mouse to direct the mouse arrow to the drop down arrow on the right side of the packaging text box, left click and drag the mouse arrow to {Your Packaging}.

Select the collection type as drop off.



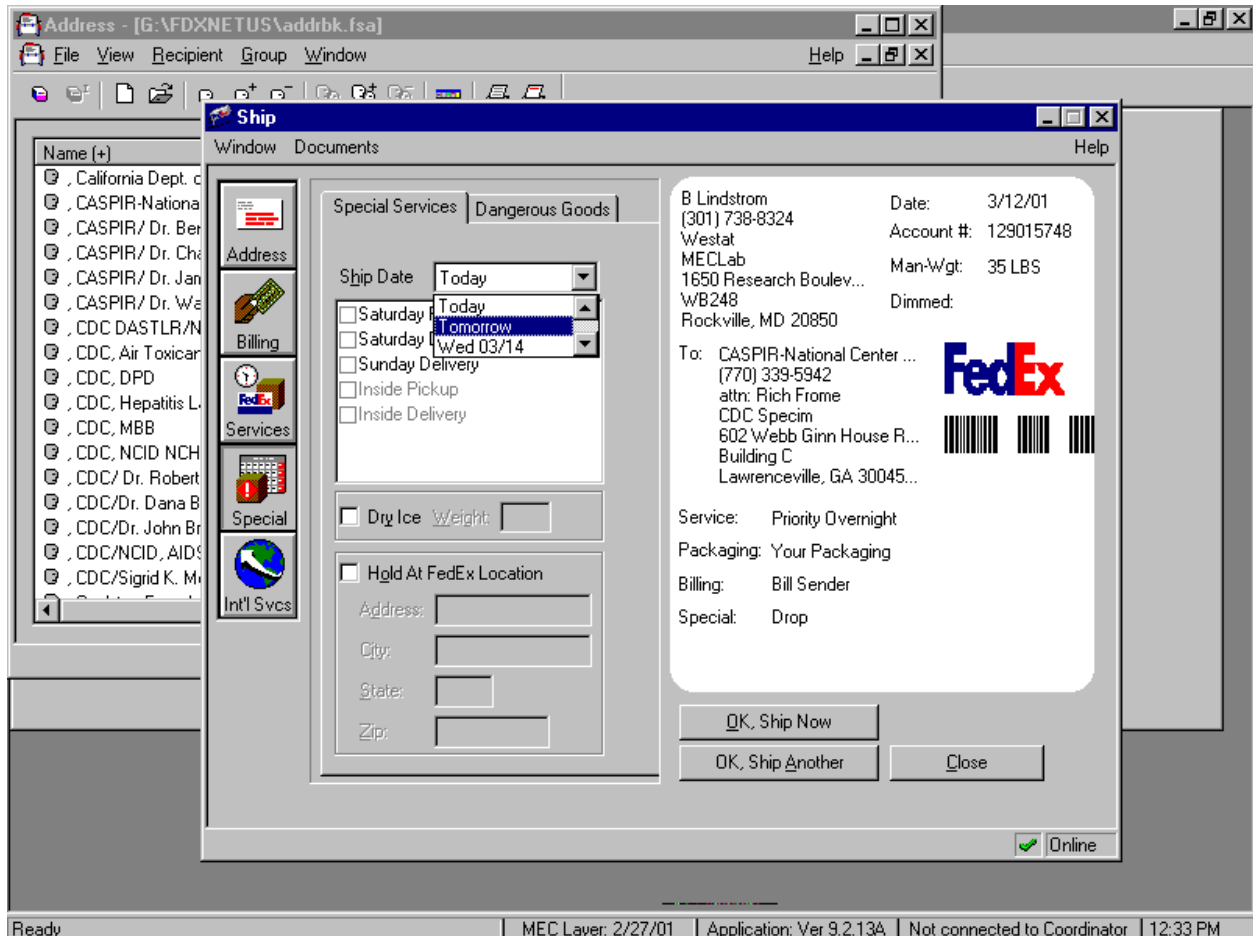
To select the collection type or pick up option, use the mouse to direct the mouse arrow to the drop down arrow on the right side of the collection text box, left click and drag the mouse arrow to {Drop Off}.

Enter the total number of pieces as one and enter the package weight for each shipment. Use the FedEx laminated shipping list to determine the weight for each laboratory's shipper.



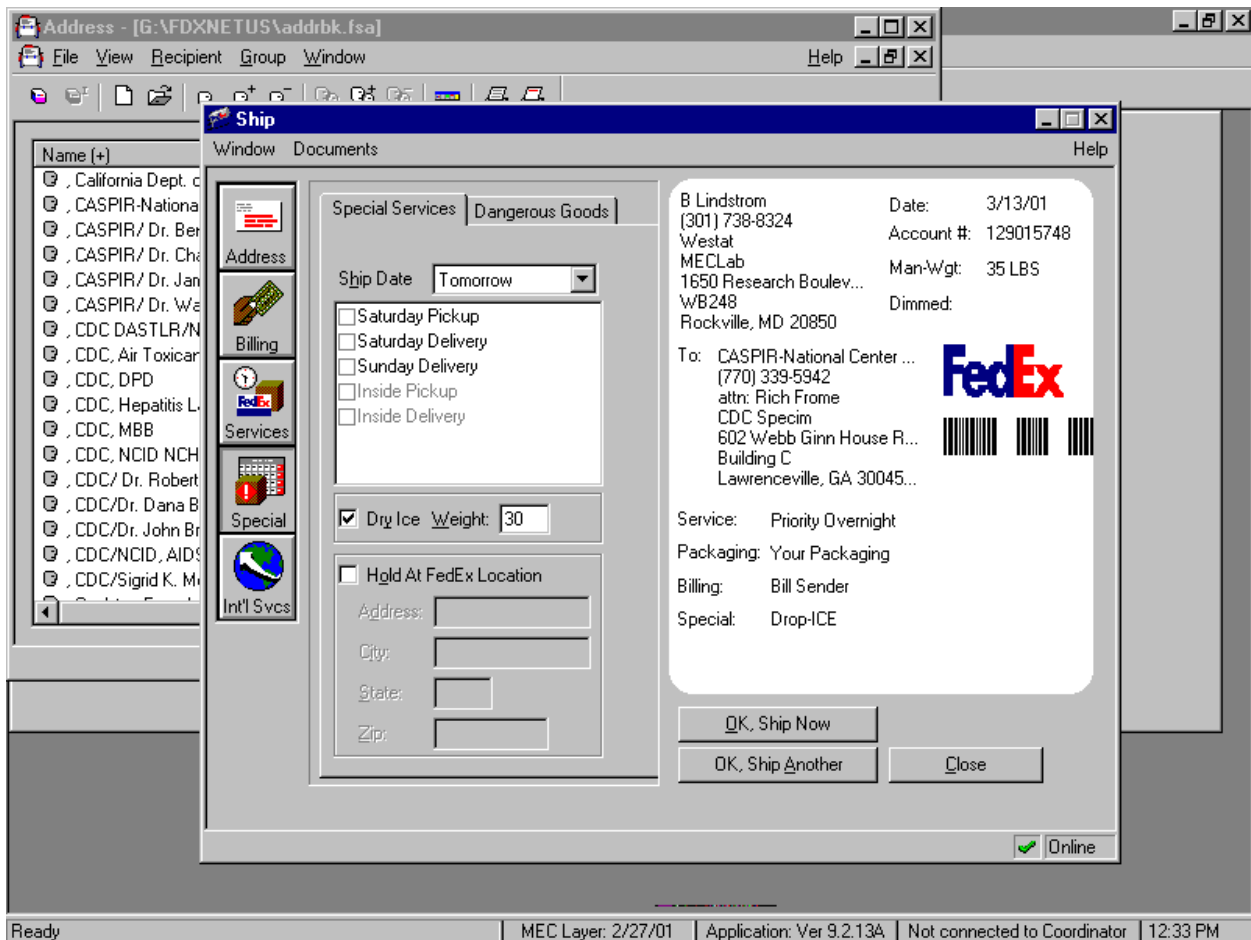
To enter the number of packages, [Tab] to the Total Pieces text box and type the number one (1). To enter the package weight, use the mouse to direct the mouse arrow to the weight text box and type the number using the keyboard's keys.

Select the Special icon to select the actual shipping date.



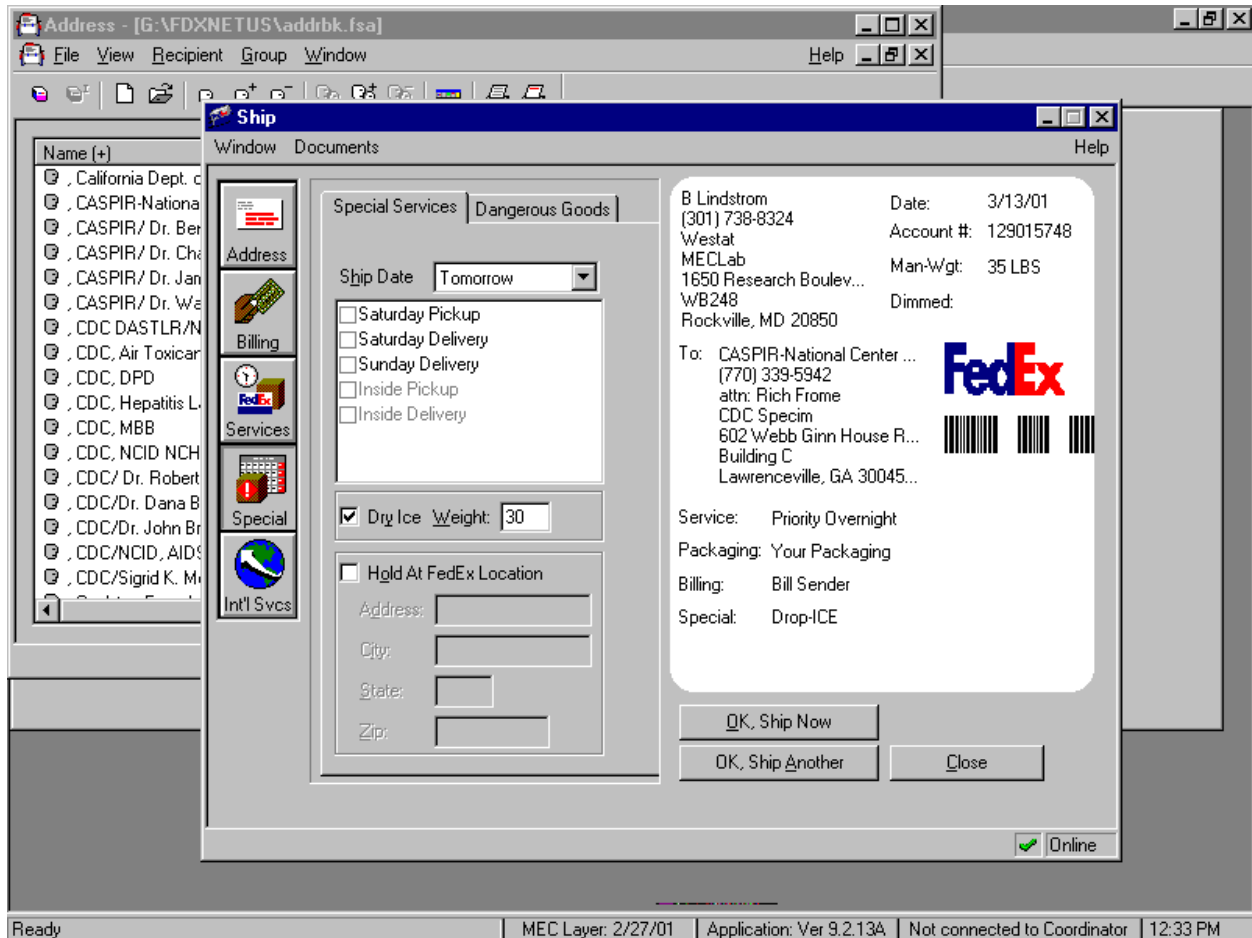
To access the Special choices, use the mouse to direct the mouse arrow to special icon located on the left side of the window. To select today, tomorrow, or the next day (displayed as a date), use the mouse to direct the mouse arrow to the drop down arrow on the right side of the Ship date text box, left click, and drag the mouse arrow to {Today}, {Tomorrow} or the next day.

Select the Special icon to enter the weight of dry ice for shipments containing dry ice. Use the FedEx laminated shipping list to determine the weight of dry ice for each laboratory's shipper.



To indicate that the shipment contains dry ice, use the mouse to direct the mouse arrow to the checkbox to the left of dry ice and left click to record a checkmark. Select [Tab] to move to the dry ice weight text box and use the keyboard keys to type the number (weight of the dry ice.)

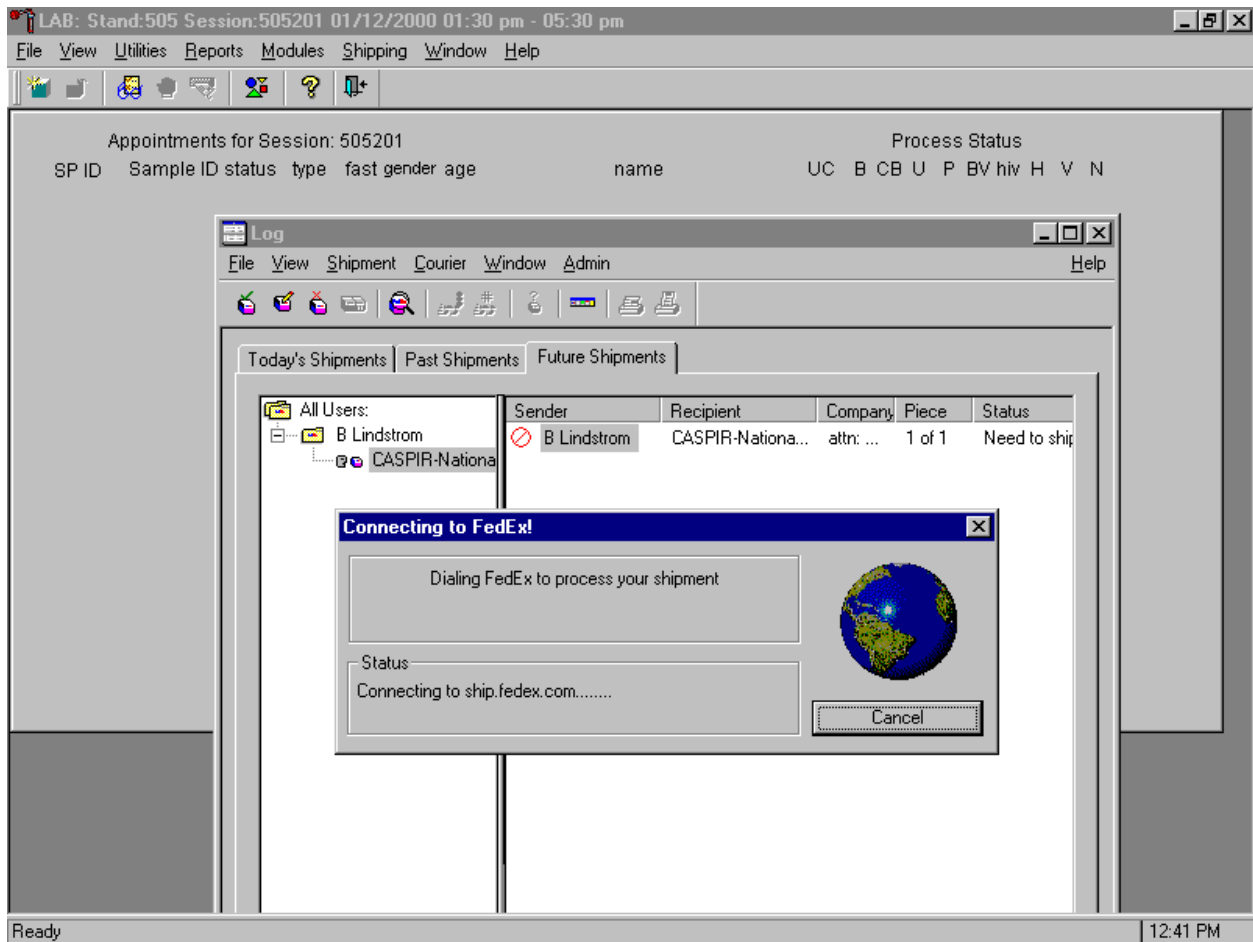
Create another airbill or connect to FedEx to transmit the information.



When finished entering all the information for a shipment in the Ship window, finish processing the shipment, enter the information for another shipment, or save the shipment information and complete the process at a later time.

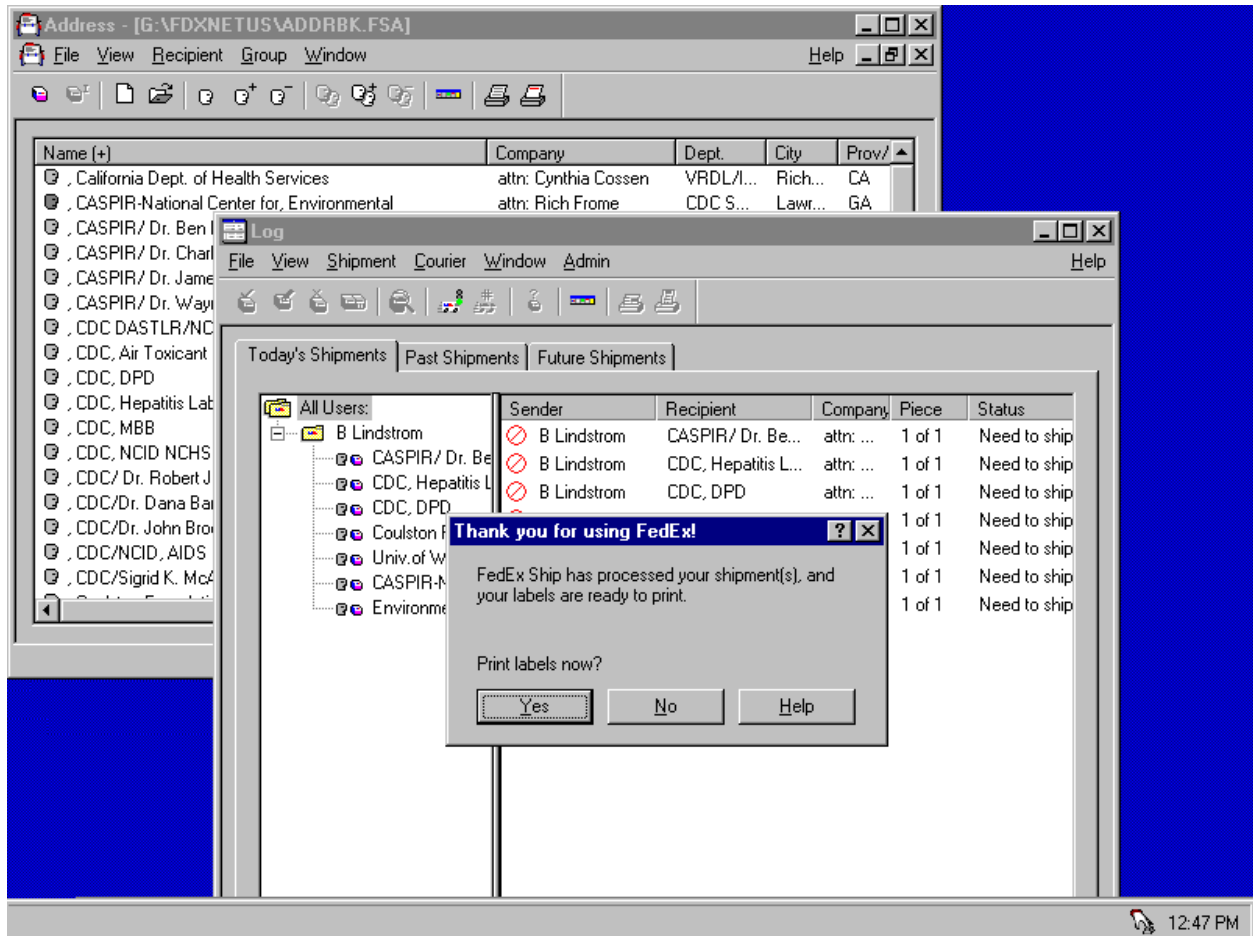
- To complete the session, click the **OK, Ship Now** button.
- To prepare another shipment, click the **OK, Ship Another** button. FedEx Ship automatically saves the shipment information in the Log, then displays a blank Ship window, ready for the next shipment's information.

Send shipment information to FedEx.



The modem automatically dials FedEx, transmits the shipment information, and logs out. When complete, print the labels for the shipment(s).

Print the shipping label.



After sending the information to FedEx, print the shipping label for each piece in the shipment. Print the labels immediately, as a reminder to label the package. To print the label(s) for the shipment:

1. Click the **Yes** button when FedEx displays the "Print Labels Now?" message. FedEx Ship displays a Print dialog box.
2. Click **OK**. Make sure the printer is using 8.5" x 11" paper in tray 2 of the Label/Ship printer.
3. After the label is printed, fold the paper in half and insert it into a FedEx clear plastic pouch.
4. Peel the backing off the pouch and place the adhesive side on the top of the plastic pouch.

The shipment processing is complete once a shipment is processed and the label is printed and attached to the piece. The shipment is ready for pickup by a FedEx courier.

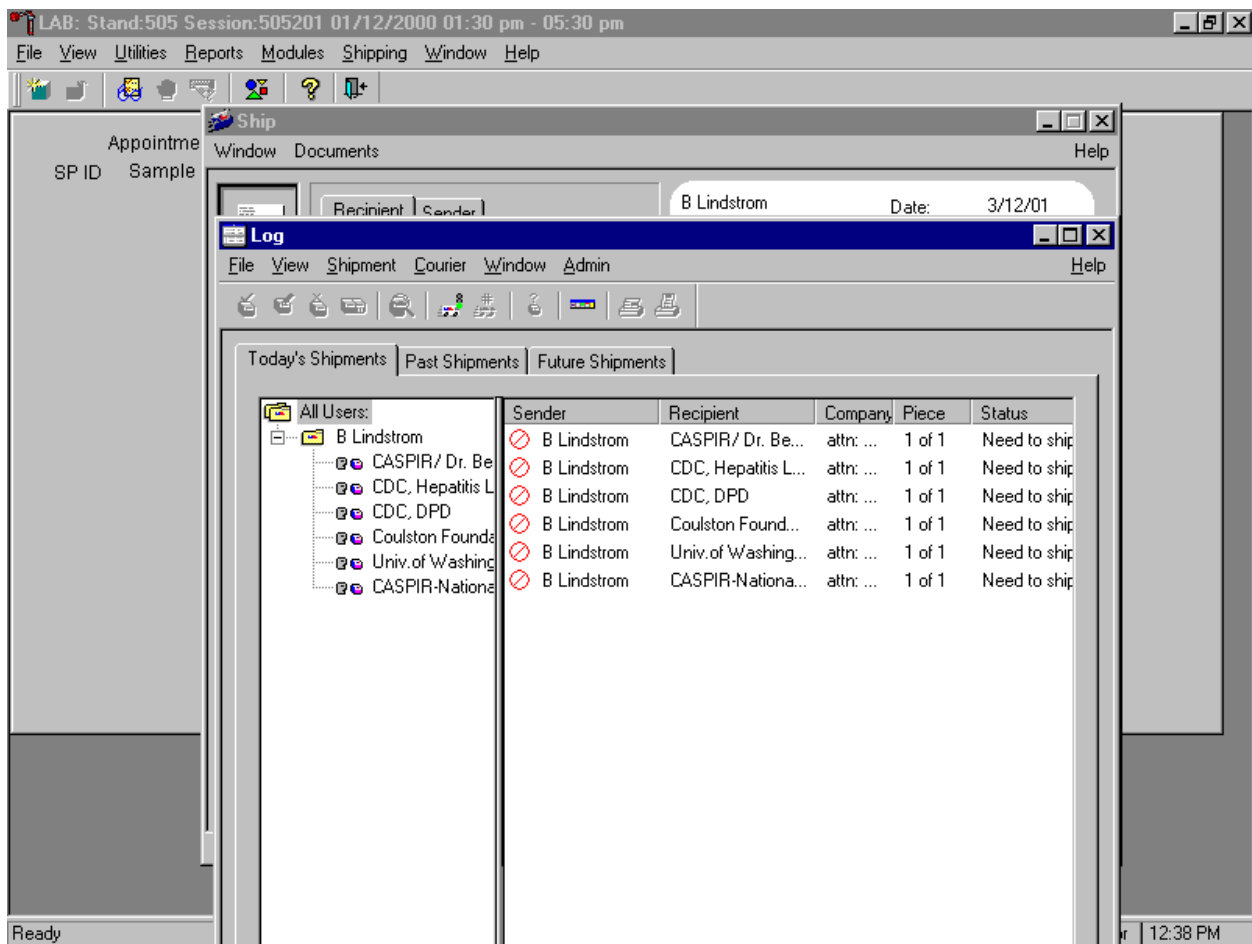
9.8.3 FedEx Log

The Log is a central work area that maintains records of shipment, tracks remaining activities for pending shipments, and maintains a history of previous shipments.

The Log:

- Modifies shipments (edit shipment information)
- Repeats previous shipments
- Cancels shipments
- Views today's, past, and future shipments
- Views the courtesy rate quote (the shipment's receipt)
- Prints shipping labels and receipts
- Requests courier pickup
- Processes incomplete shipments
- Tracks shipments

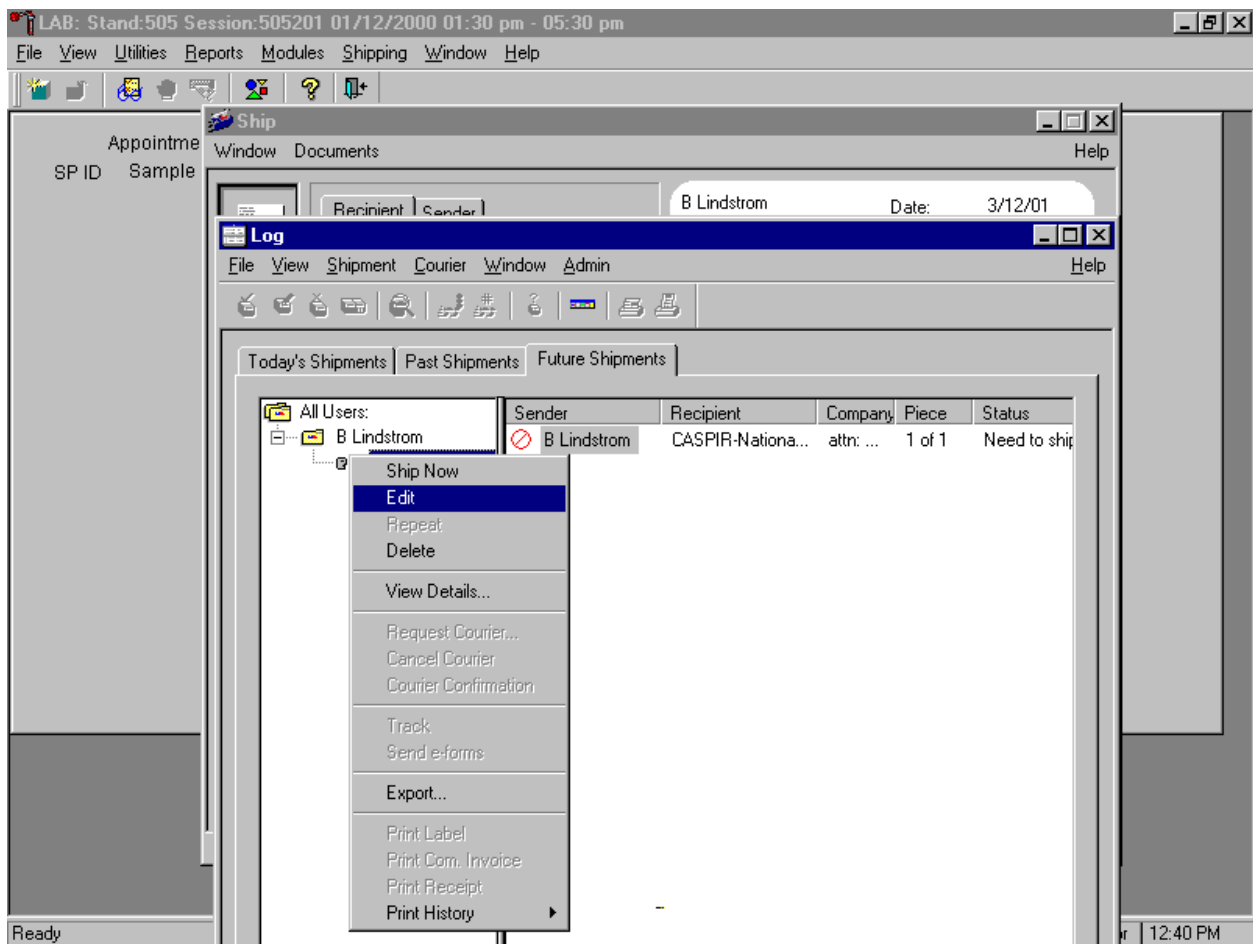
The Log window displays shipments in three pages: Today's Shipments, Past Shipments, and Future Shipments. Select the tab that corresponds to the shipment in question.



The Today's Shipment page displays all shipments entered today (and shipped from previous days that are still unprocessed). If a shipment in the Today's Shipment page requires further processing, the status column indicates the steps required to complete the shipment. The Past Shipment page displays shipments shipped before today's date. The Future Shipment page displays shipments entered and processed but not shipped.

Today's shipments include shipments that have been shipped today and pending shipments. Shipments remain in the Today's Shipment list until they are completed. To view today's shipments, click the Log icon in the FedEx navigator bar. The Log window displays with the Today's Shipment page active. To see more of the information in any of the columns, position the cursor over a column border and click and drag the border.

To view a summary of the shipment information, select the shipment from the list and choose Show Details from the Shipment menu, or click the View Details icon on the toolbar.



To edit shipment information, select the shipment from the list and choose Edit Shipment from the Shipment menu, or click the edit Shipment icon on the toolbar. To print labels, select the shipment from the list and choose Print/Print Label from the File menu, or click the Print Label icon on the toolbar. To cancel a shipment, select the shipment from the list and choose Delete Shipment from the Shipment menu, or click the Delete Shipment icon on the toolbar.

Past Shipment

FedEx automatically transfers all completed shipments from Today's Shipments to Past Shipments the day after shipping. Any incomplete shipments remain on the Today's' Shipment page until they are processed. To view past shipments, click on the Log icon in the FedEx Ship navigator bar. The Log window displays with the Today's Shipment page active. Click the Past Shipments tab. FedEx

displays previous shipments in the Past Shipments page. To display the information for a shipment or track a shipment, select a shipment and choose the operation from the pull-down menus or toolbar icons.

To view a shipment's details, select the shipment from the list and choose Show Details from the Shipment menu. The Shipment Details window displays showing the tracking number and courtesy rate quote.

To copy or repeat a shipment, select the shipment from the list and choose Repeat Shipment from the Shipment menu. FedEx displays the receipt page with all the information from the previous shipment filled in. Make any changes. When ready to send the shipment, follow the instructions for "Sending Shipment Information to FedEx."

To print detail, summary, and historical reports, select the shipment(s) from the list and choose Print/Print History from the file menu. From the Print History sub-menu, select the report: Detail History, Summary by Date, Summary by Recipient, or Summary by Reference.

To export historical information from the Log to a spreadsheet or database program, see the online help topic "Exporting Information from the Log."

Future Shipments

Shipments scheduled for a future date appear in the Future Shipments page of the Log until the shipping day. FedEx automatically transfers all shipments from Future Shipment to the Today's Shipment page on the day they are scheduled to be shipped. Incomplete shipments remain on the Today's Shipment page until completed. The Future Shipment page in the Log allows all the same functions as the Today page with the exception of requesting a courier.

To view future shipments, click the Log icon in the FedEx navigator bar. The Log window displays with Today's Shipment page active. Click the Future Shipment tab. Select a shipment and choose the required operation from the pull-down menu.

9.8.4 Track Shipments

FedEx automatically assigns a tracking number to the shipment. FedEx Ship can track the delivery status of a shipment at any time using this tracking number.

Track shipments from the Track window. After FedEx Ship obtains the latest delivery information from FedEx, it places the shipment status information in the Track window. If the package has been delivered, the delivery confirmation displays on the screen. If the shipment was sent over 14 days ago, FedEx provides only the final delivery information. Final delivery information is retained for 120 days.

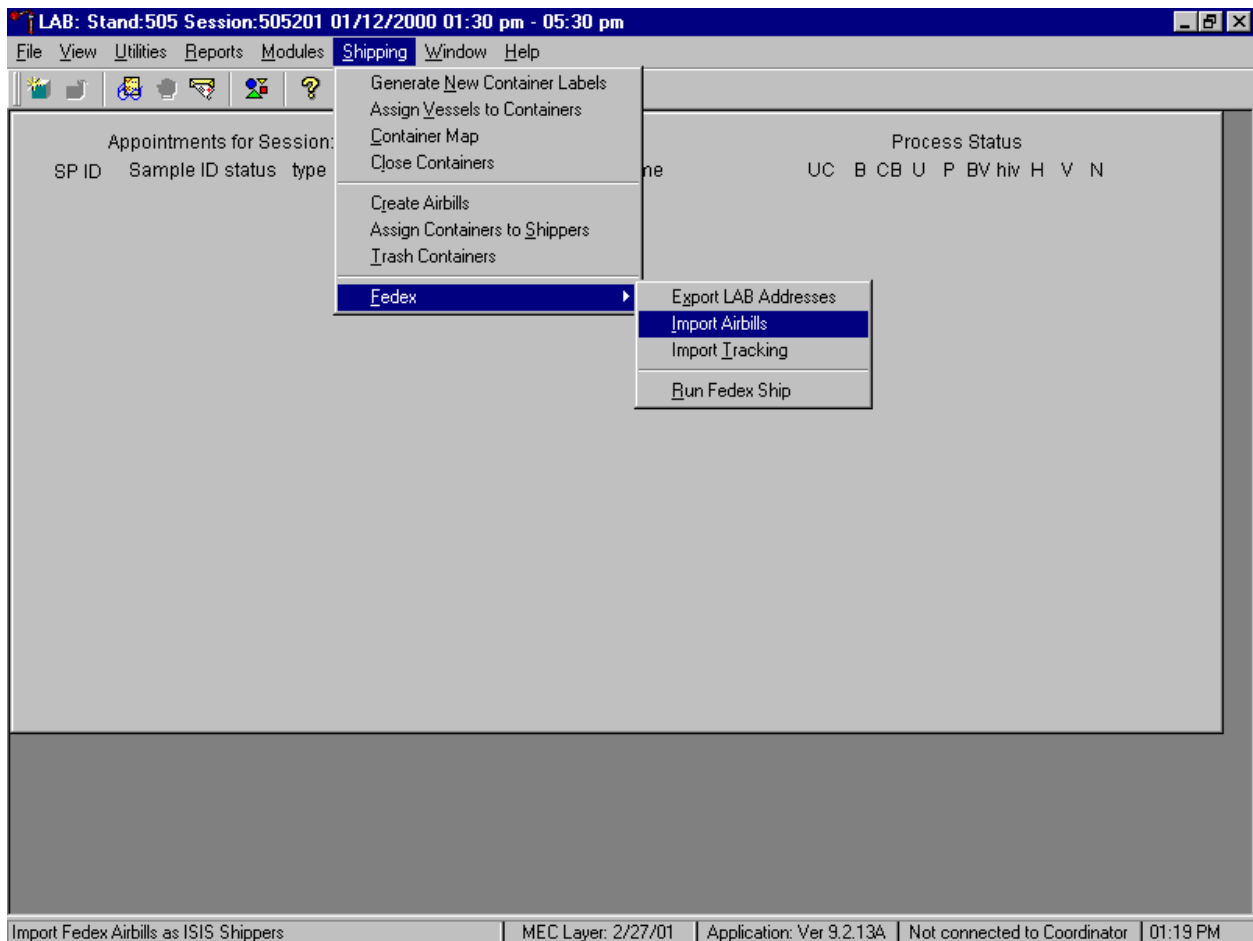
The Track window provides up-to-the-minute location and delivery of shipments. Use this feature to find out when, where, and to whom the package was delivered. Generally, access the past shipments in the log. Select the shipment(s), right click, and drag the mouse arrow to {Track now}. Click the OK button after receiving the information from FedEx. All shipments that match the entered tracking numbers will be tracked and displayed in the log. To view details about a shipment, select the shipment and click the Show detail icon on the toolbar. The Detailed Tracking Information displays detailed tracking information about the shipment.

9.8.5 Shipping Preferences

The Settings Window allows customization to reflect preferences. The data manager uses this window to specify preferences for services, packaging, and shipment collection method.

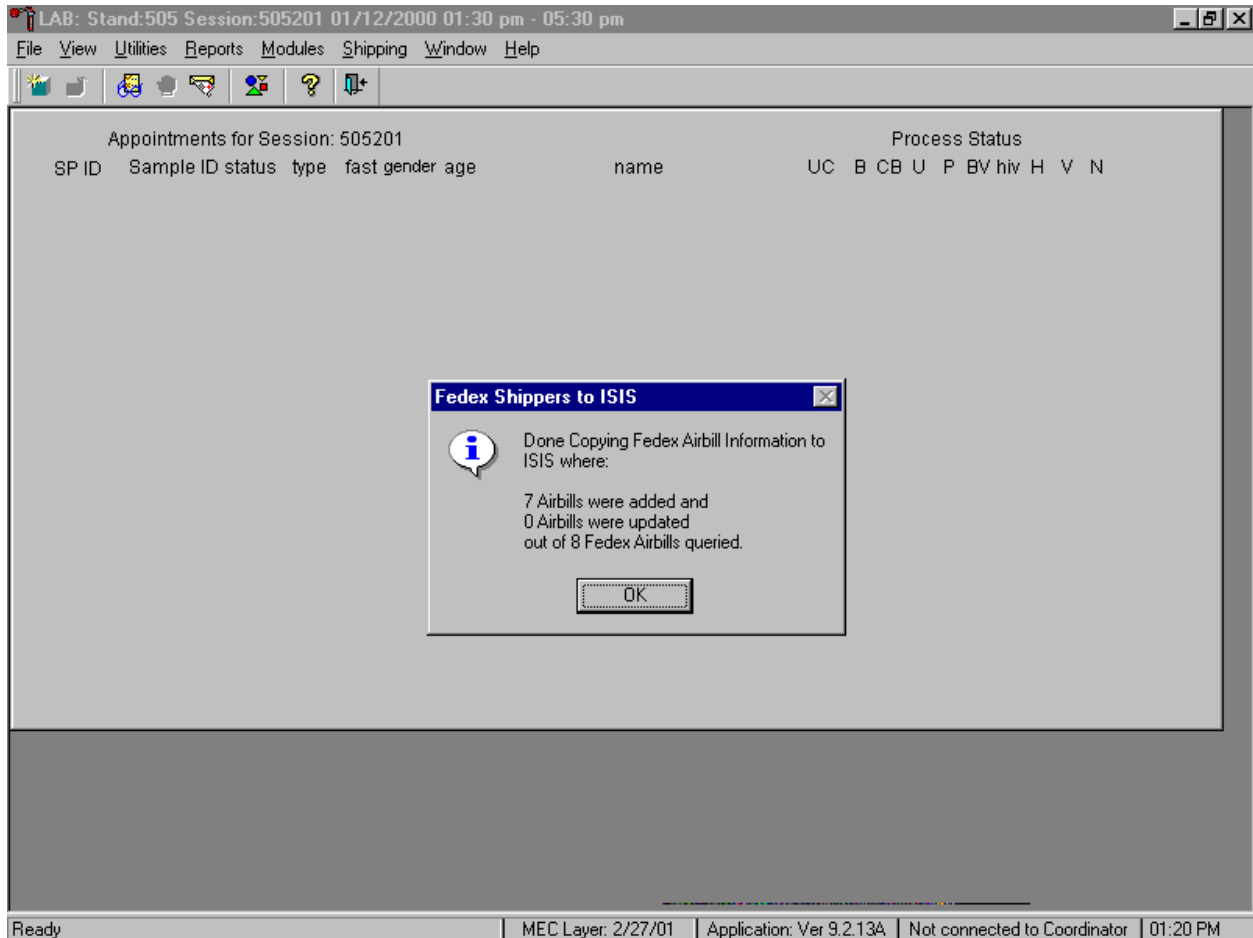
9.8.6 Import FedEx Airbills

Import FedEx airbills.



To import FedEx airbills, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Fed Ex}, then to {Import Airbills} and left click, or type [Alt] [S/s], [F/f], [I/i].

Airbills are now accessible from within the Shipping module.

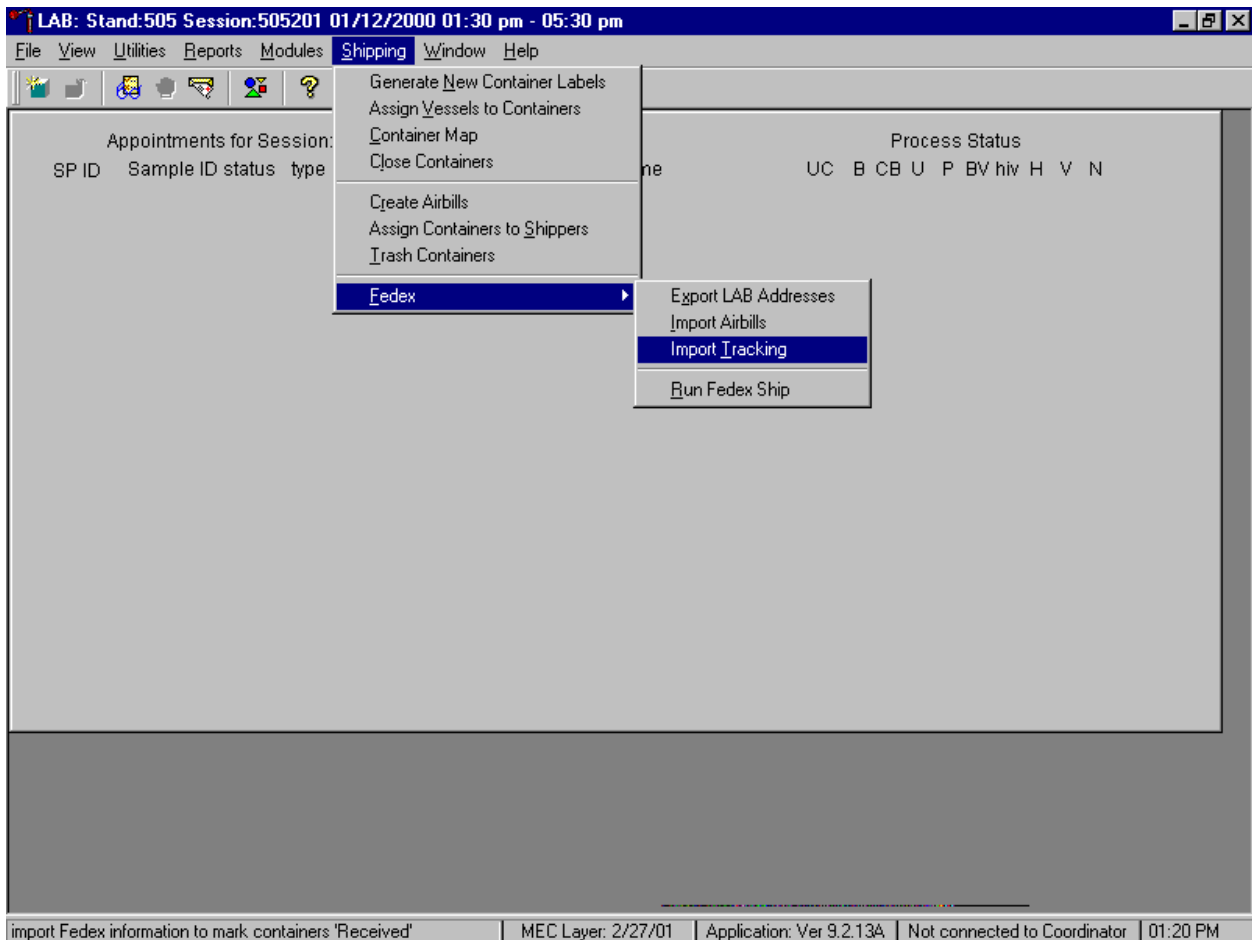


A FedEx Shippers to ISIS informational message text box displays indicating the number of airbills added, updated, and queried. To close this box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

9.8.7 Import Tracking Information and Export LAB Addresses

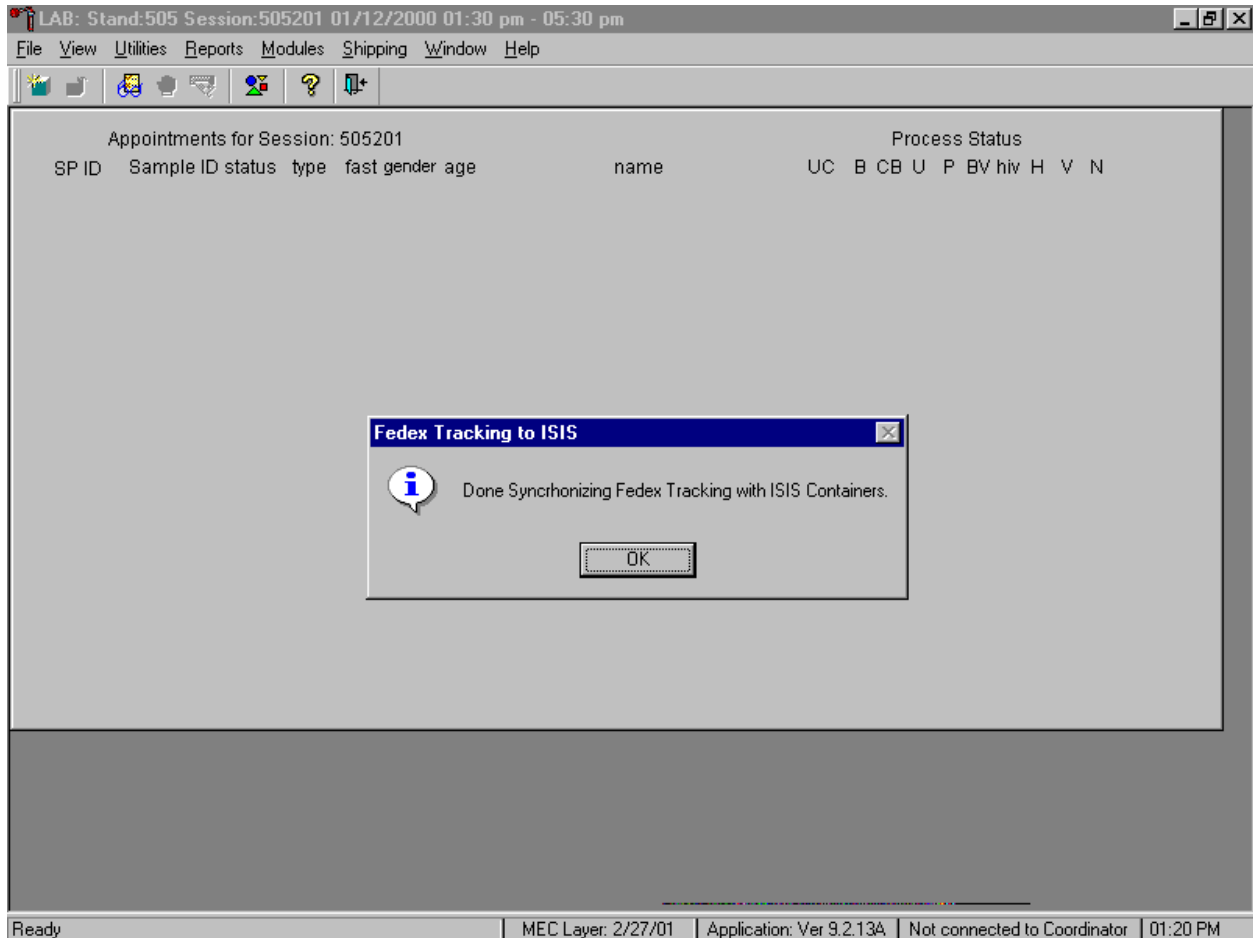
The data manager is the only individual authorized to export LAB addresses from the database tables into FedEx Ship.

Import FedEx tracking information into the laboratory application daily. This mandatory maintenance function allows FedEx to synchronize tracking information with the laboratory application.



To import tracking information from FedEx, use the mouse to direct the mouse arrow to {Shipping} and left click, drag the arrow to {Fed Ex}, then to {Import Tracking} and left click, or type [Alt] [S/s], [F/f], [T/t].

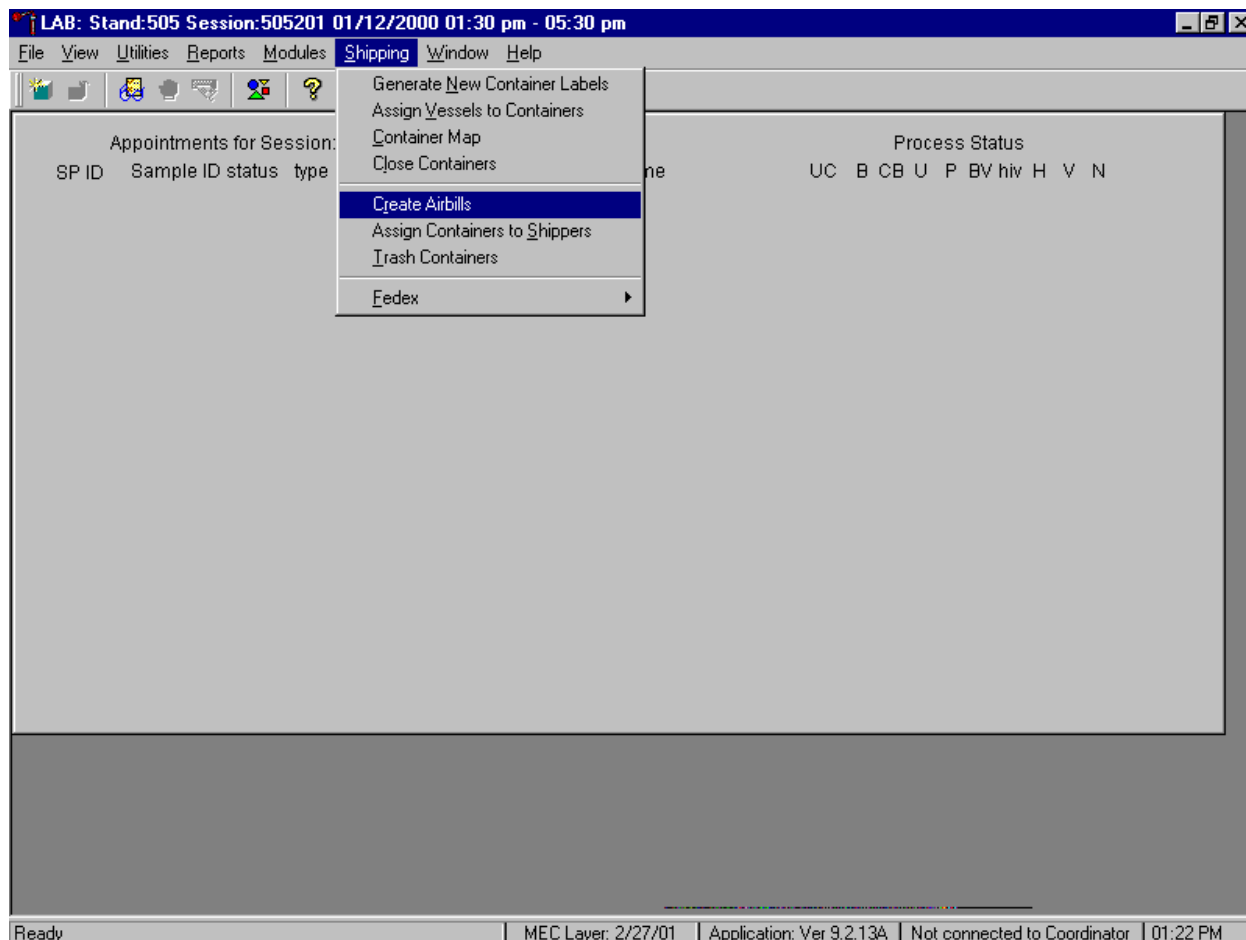
An informational message text box displays.



A FedEx Tracking to ISIS informational message text box confirms the transfer of tracking information. To close this box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

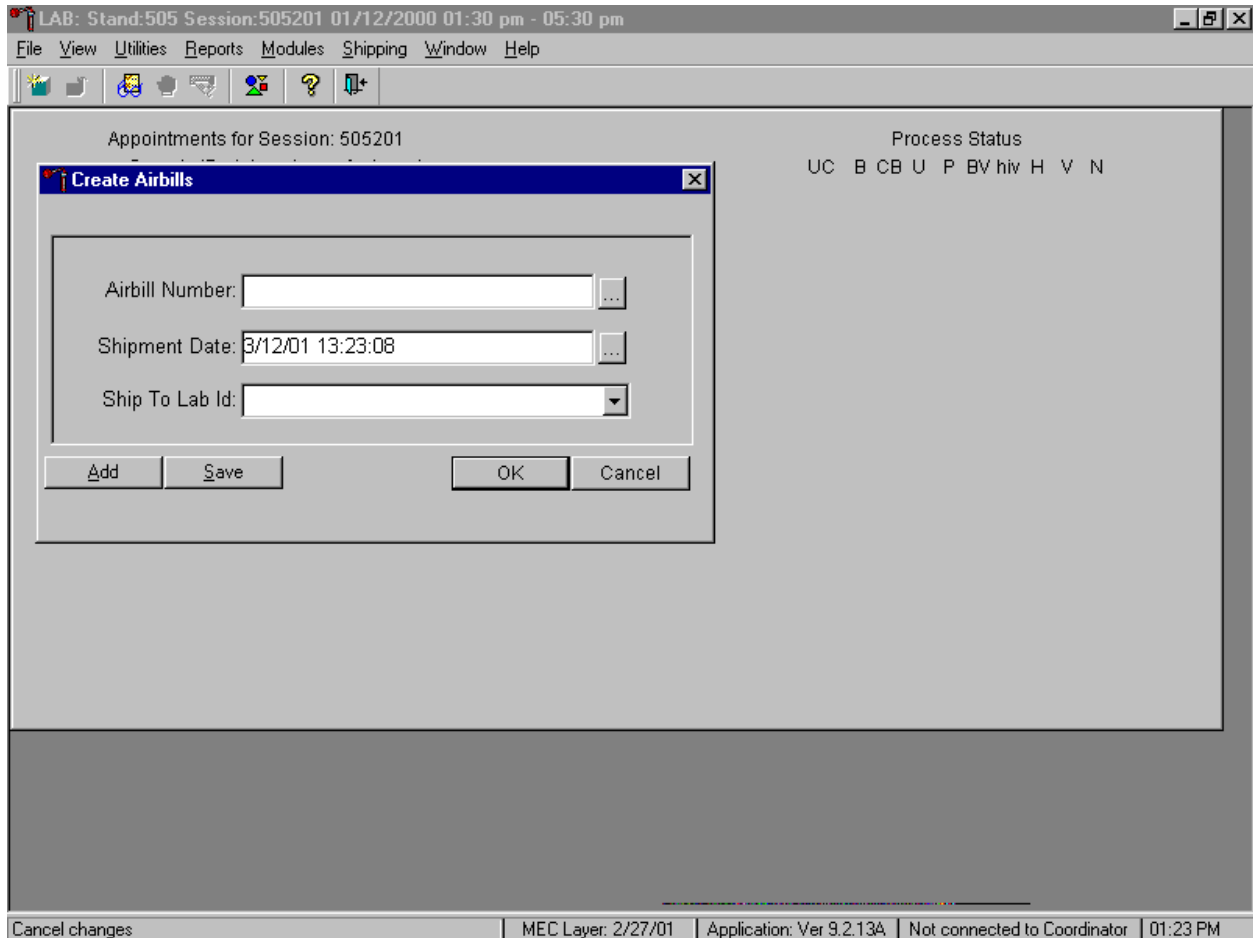
9.9 Create Airbills

Manually create airbills when FedEx Ship is inoperable or edit existing airbills using the Create Airbills module. Access the Create Airbills module.



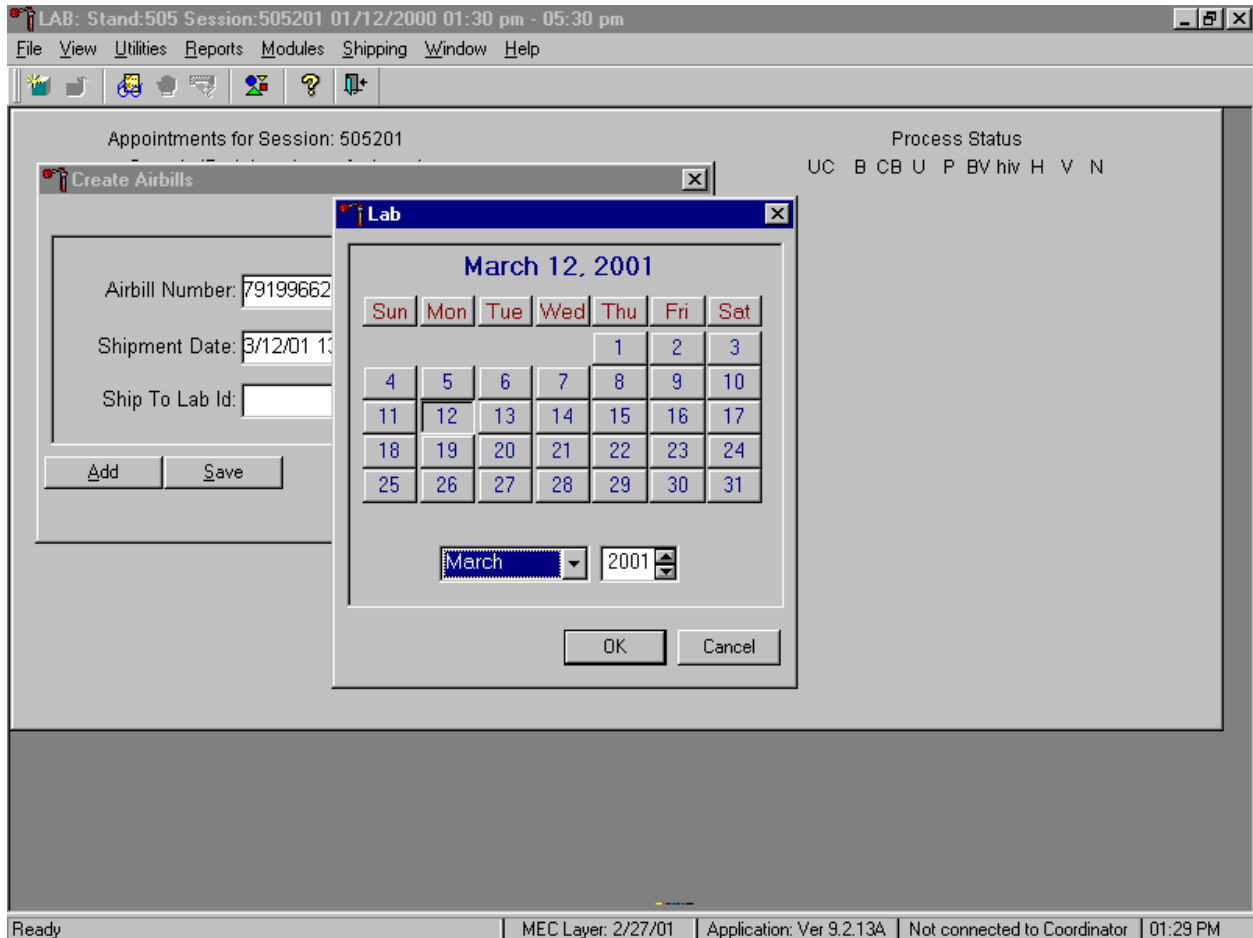
To access the Create Airbills module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Create Airbills} and left click, or type [Alt] [S/s], [R/r].

The Create Airbills window displays.



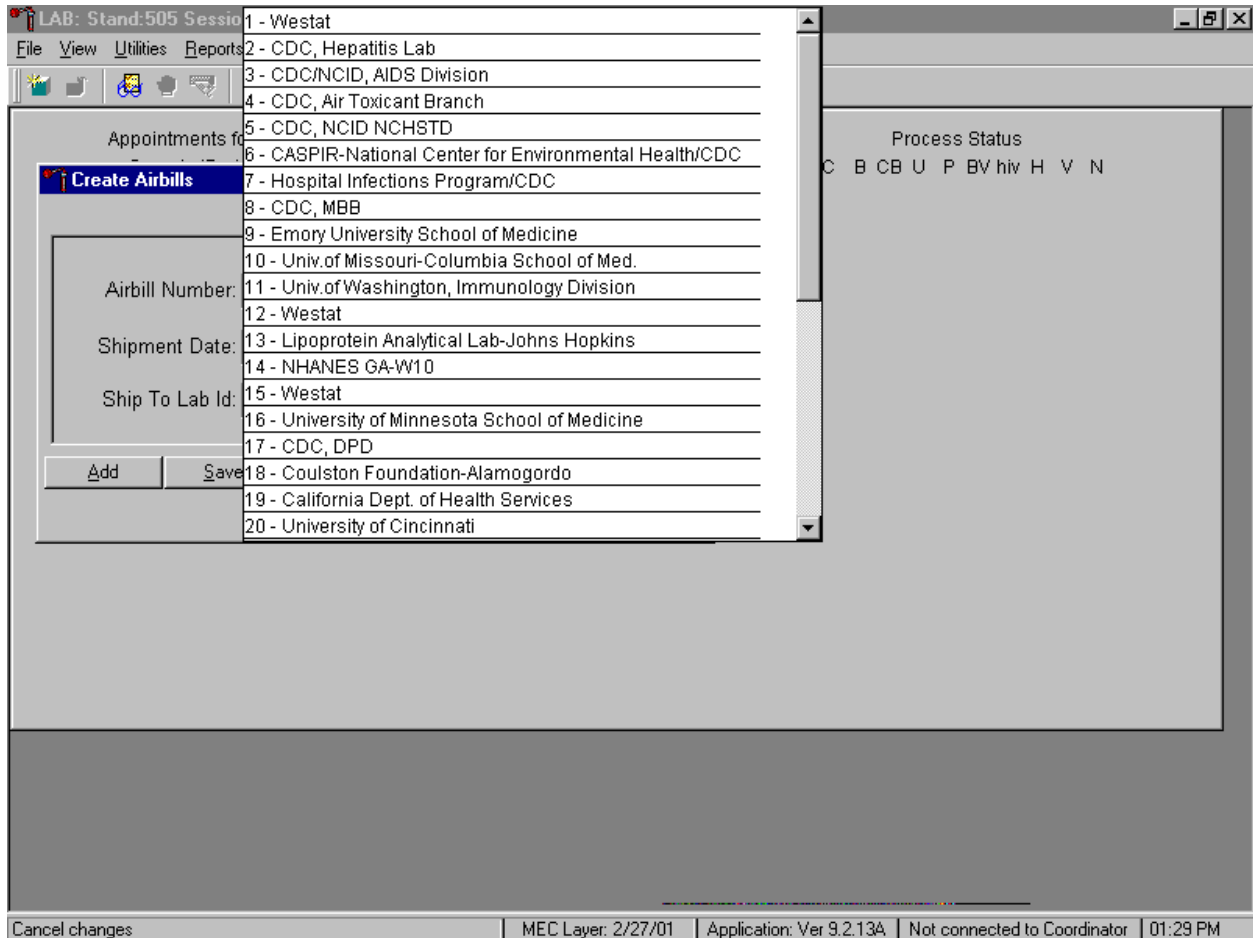
To manually create an airbill, type a FedEx airbill number (from a blank FedEx airbill) into the Airbill Number text box. The Shipment Date defaults to today's date and time. To enter a different date, access the calendar by using the mouse to direct the mouse arrow to the ellipsis button on the right side of the Shipment Date box and left click to display the calendar.

The calendar displays.



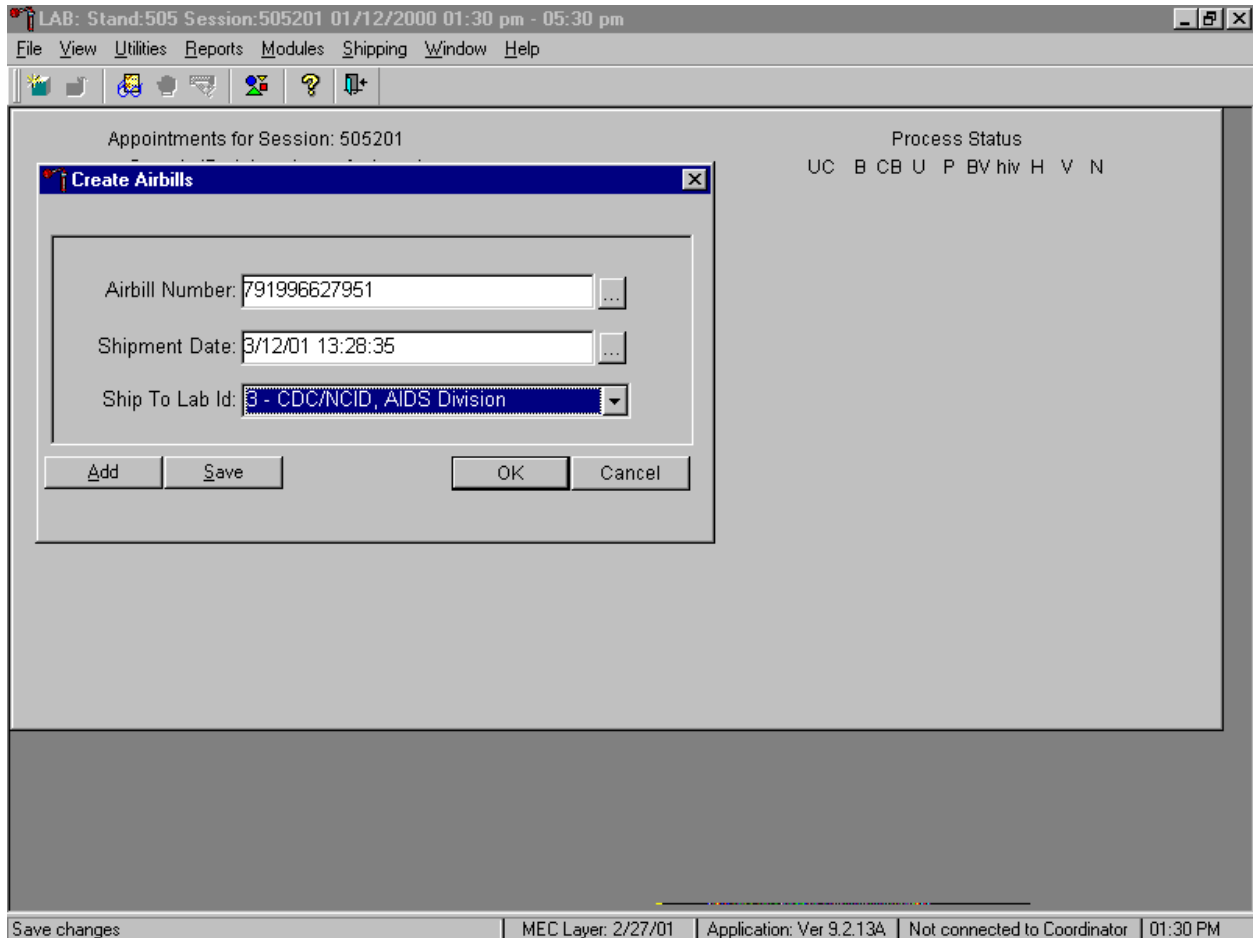
To select or specify a date, use the mouse to direct the mouse arrow to the month drop down list, drag the arrow to the correct month (use the vertical scroll bar if necessary) and left click. Select the correct day by using the mouse to direct the mouse arrow to the correct day on the displayed month and left click. Correct the year by using the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer the day, month, and year into the date space and to exit the calendar window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar window without entering or transferring a date into the date space, use the mouse to direct the mouse arrow to **Cancel** button and left click.

Associate a specific laboratory with each airbill.



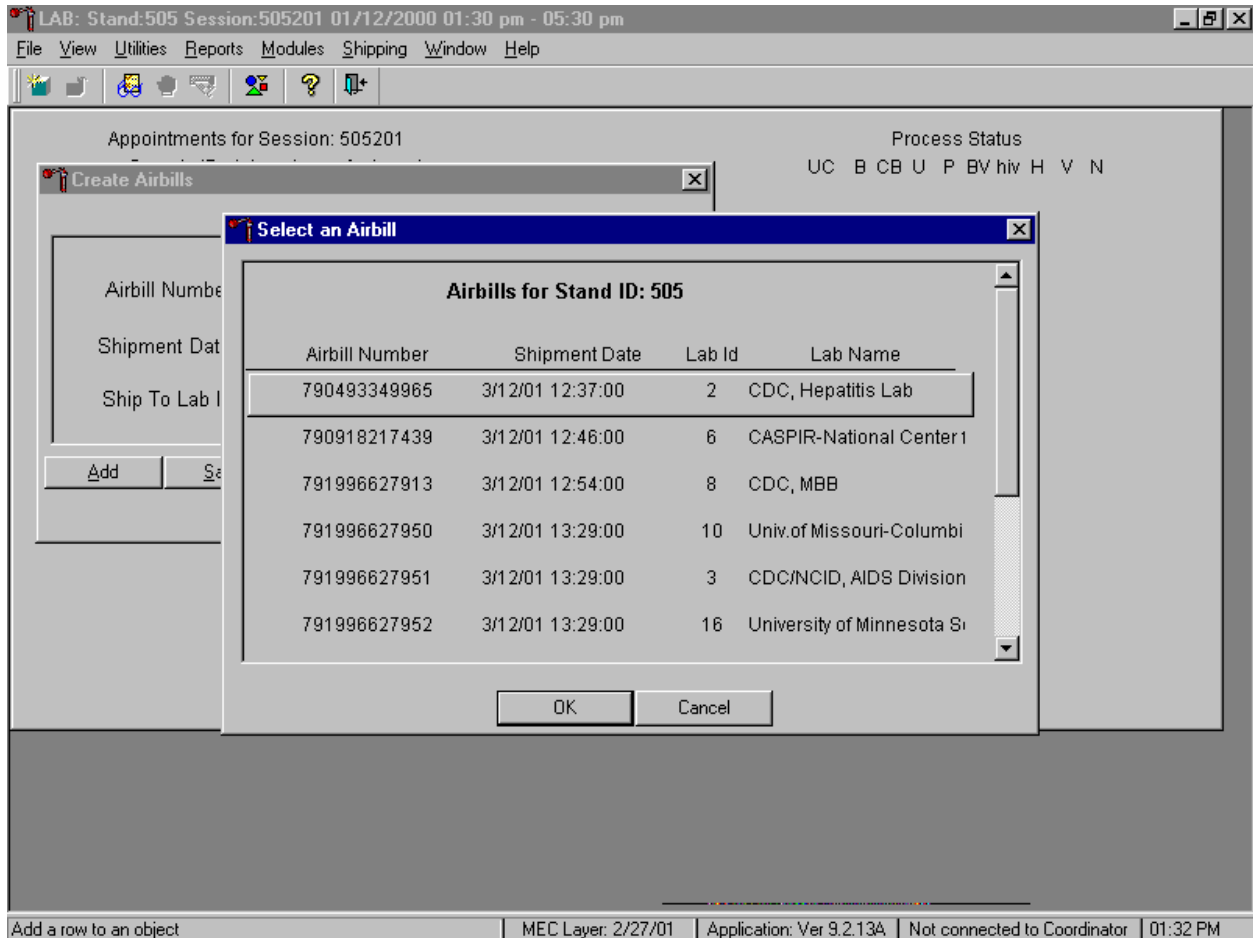
To display the list of contract laboratories and to select one laboratory, use the mouse to direct the mouse arrow to the drop down list on the right side of the Ship To Lab ID box, left click, drag the arrow to the correct laboratory, and left click. To view all the choices, use the mouse to direct the mouse arrow to the vertical scroll bar, right click, and drag the bar up or down.

Save the information or continue creating additional airbills.



To complete this process of associating a specific laboratory with this airbill number and date, use the mouse to direct the mouse arrow to the **S**ave button and left click, or type [Shift] [S/s]. To continue creating additional airbills, and to save the current airbill, use the mouse to direct the mouse arrow to the **A**dd button and left click, or type [Shift] [A/a]. To record or save the information and exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click, or select [Enter]. To exit the module without recording or saving the information, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

Use the Create Airbill module to edit an existing airbill.



To select an existing airbill to edit, type the existing FedEx airbill number into the "Airbill Number" text field, or use the mouse to direct the mouse arrow to the ellipsis button on the right of the Airbill Number box and left click to display existing airbills. To select an airbill from the list, use the mouse to direct the mouse arrow to the correct choice and left click. Alternatively, use the up and down keyboard keys to move up and down the list and left click when the correct choice is enclosed in the box. When the correct airbill is selected, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. Continue to edit the information associated with this airbill. To exit the window without recording or saving the information, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

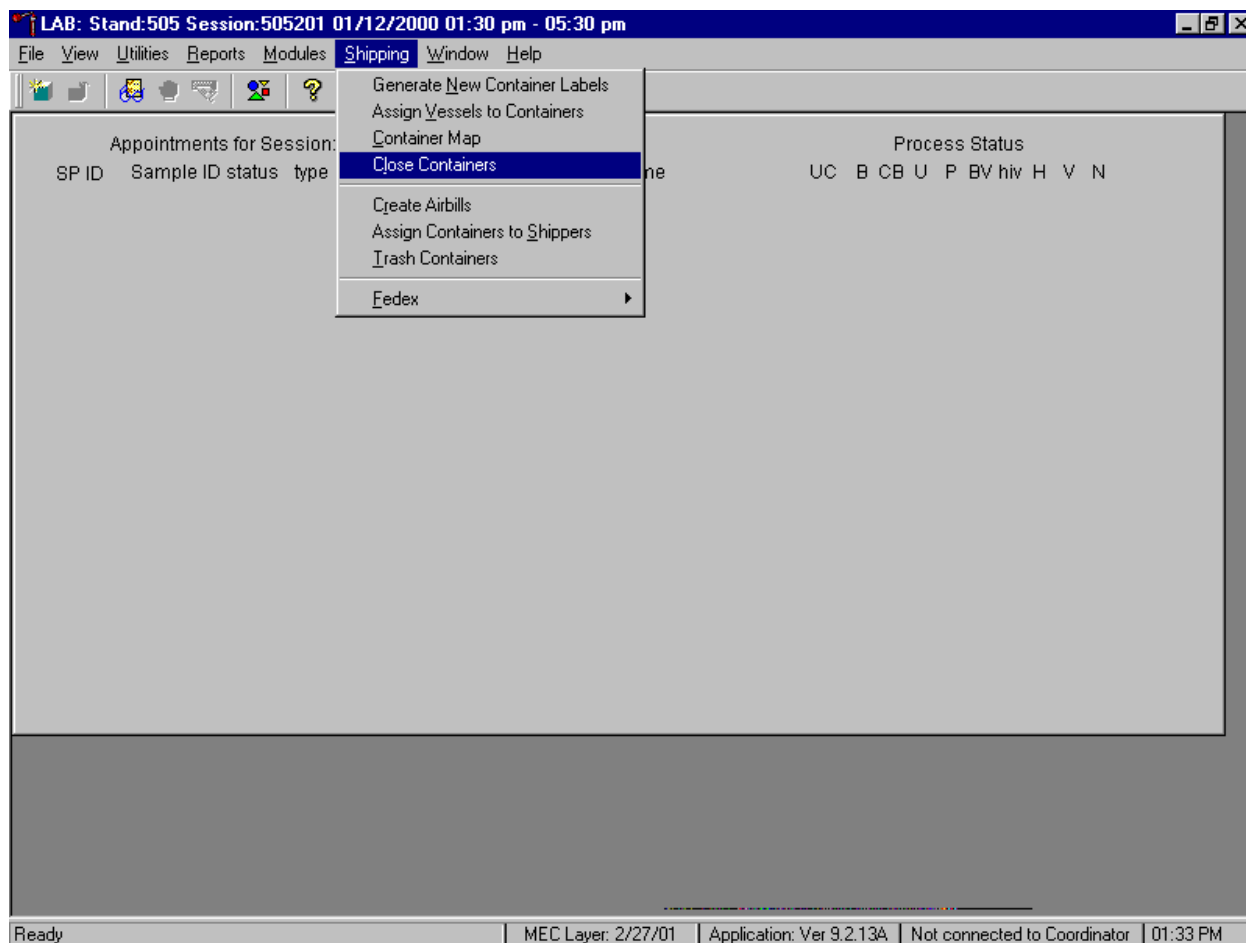
Edit the shipping date by using the mouse to direct the mouse arrow to the ellipsis button on the right side of the Shipment Date text box, left click, and enter the new date. Correct the Ship to Lab ID information. To display the list of contract laboratories and to select one laboratory, use the mouse to direct the mouse arrow to the drop down list on the right side of the Ship To Lab ID box, left click, drag

the arrow to the correct laboratory, and left click. To complete this process of associating a specific laboratory with this airbill number and date, use the mouse to direct the mouse arrow to the **Save** button and left click, or type [Shift] [S/s]. To continue creating additional airbills, and to save the current airbill, use the mouse to direct the mouse arrow to the **Add** button and left click, or type [Shift] [A/a]. To record or save the information and exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the module without recording or saving the information, use the mouse to direct the mouse arrow to the **Cancel** button, and left click.

9.10 Close Containers

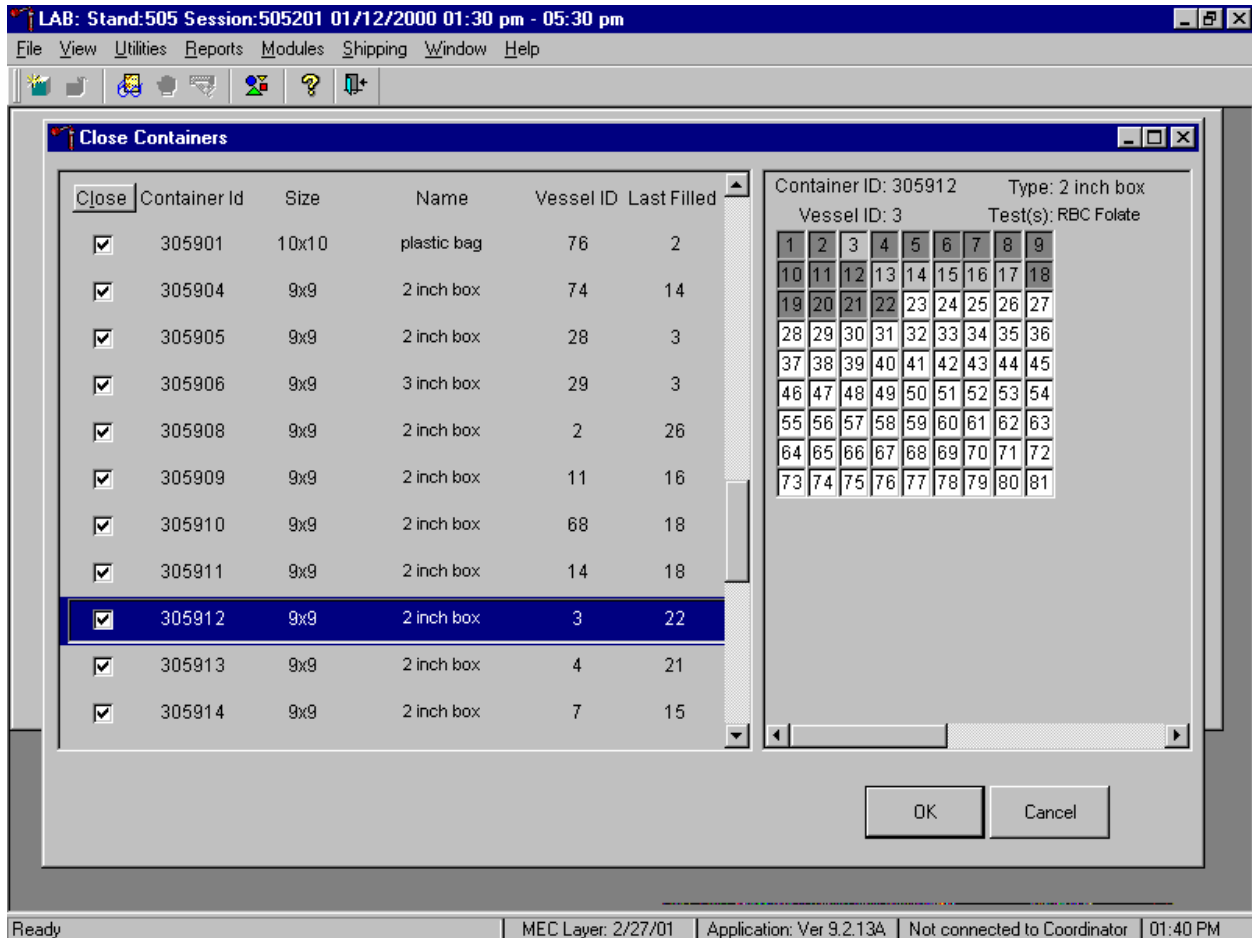
After a container is full, it is automatically closed. All open containers must be manually closed before shipping.

Access the Close Containers module.



To open the Close Container module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Close Containers} and left click, or type [Alt] [S/s], [L/l].

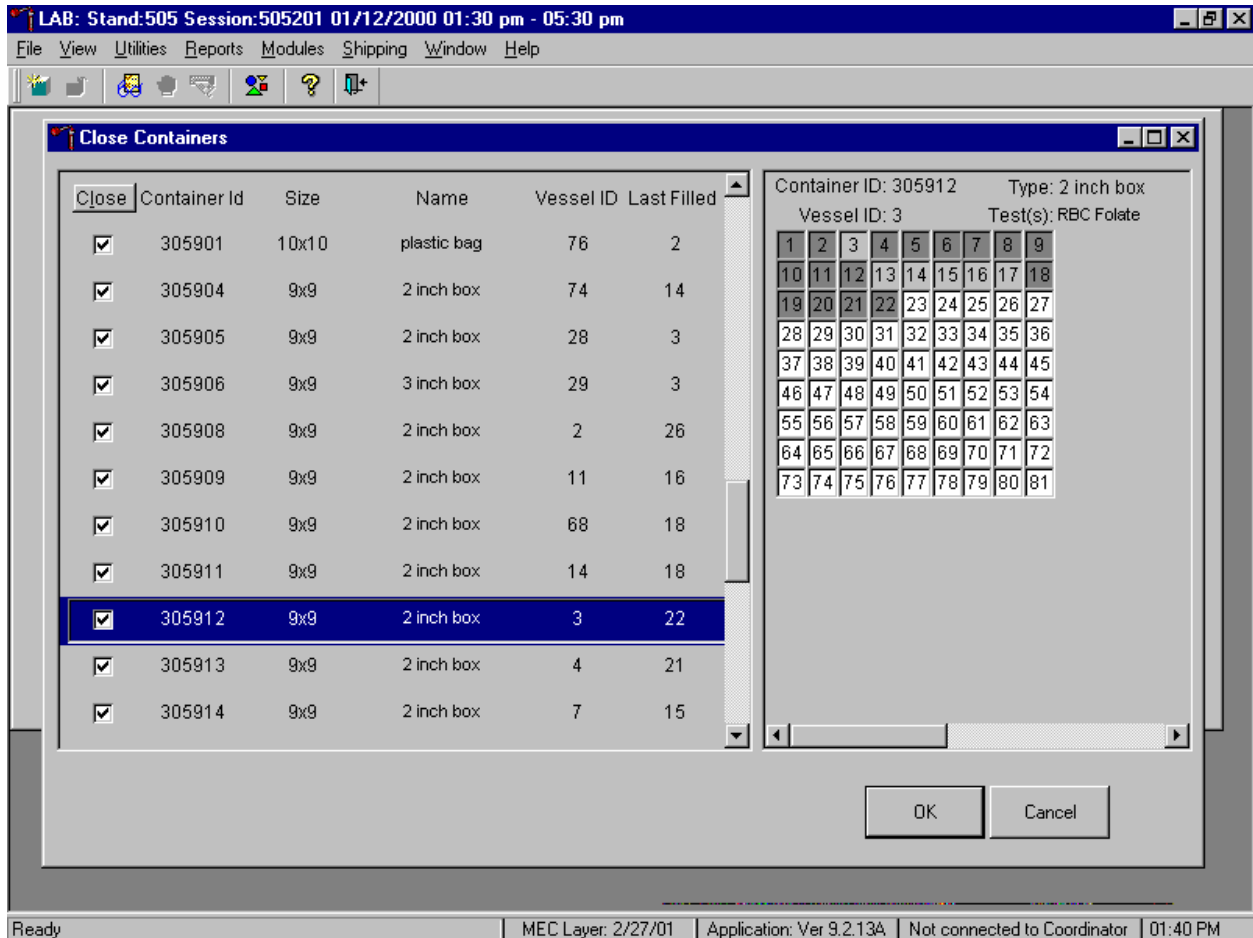
Individually close open containers or collectively close all open containers.



The left side of the Close Container screen includes a check box for each open container, the container ID, size, name, vessel ID, and number of the last slot filled. The container line in the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. To move up and down the list, use the up and down keyboard arrows or use the mouse to direct the mouse arrow to any individual line. Use the vertical scroll bar to view all containers.

To mark individual containers, use the mouse to direct the mouse arrow to individual Close button check boxes, and left click.

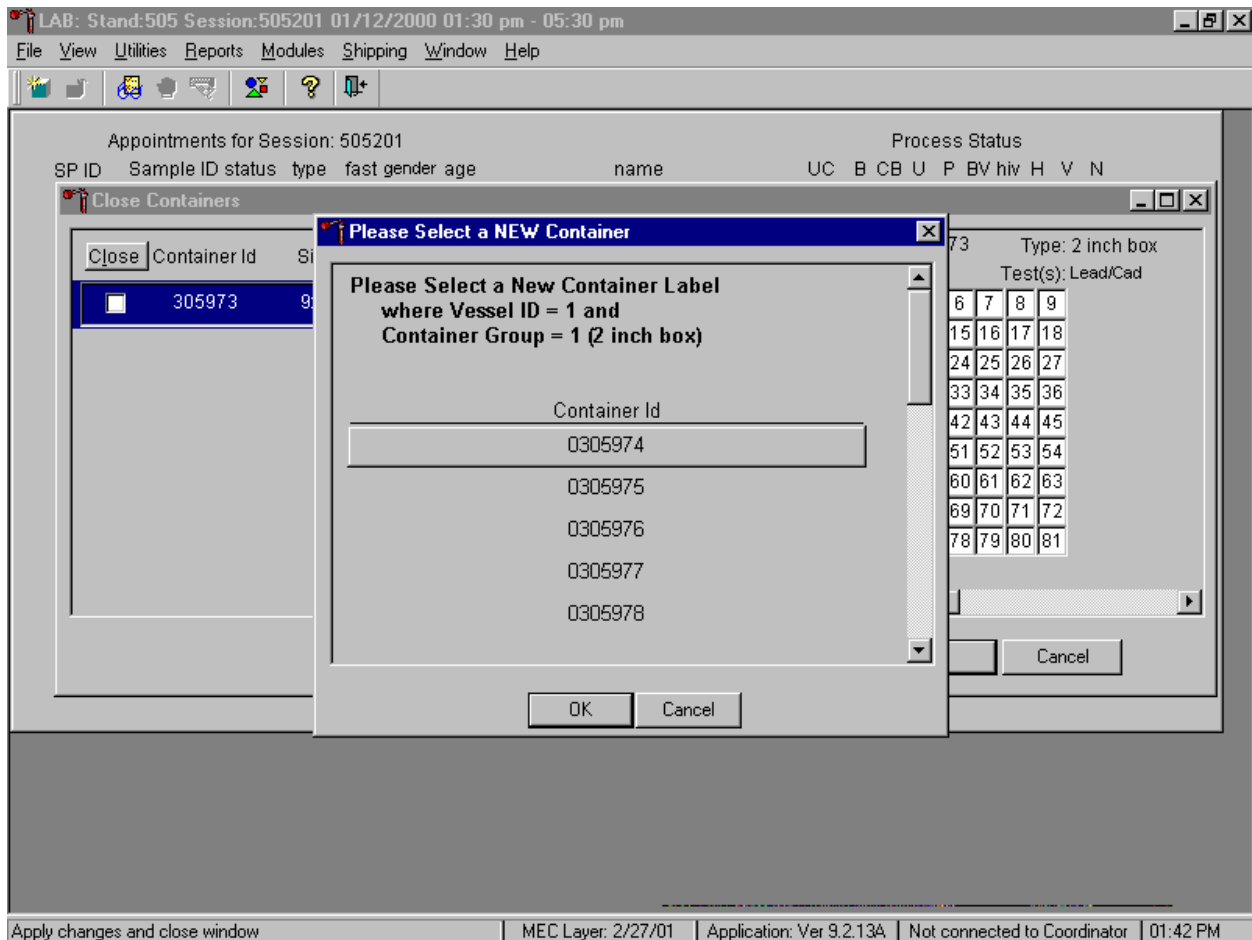
Collectively close all containers.



To close all open containers, use the mouse to direct the mouse arrow to the **C**lose button, and left click. To remove the check marks, use the mouse to direct the mouse arrow to the **C**lose button, and left click a second time.

Verify the contents of each closed box by visually matching the contents of the box to the map. To record these actions, use the mouse to direct the mouse arrow to the **O**K button and left click, or select [Enter]. To exit the Close Containers module without recording these actions, use the mouse to direct the mouse arrow to the **C**ancel button, and left click.

As each container's check box is individually marked, the opportunity to open a new container to replace the closed container is presented.



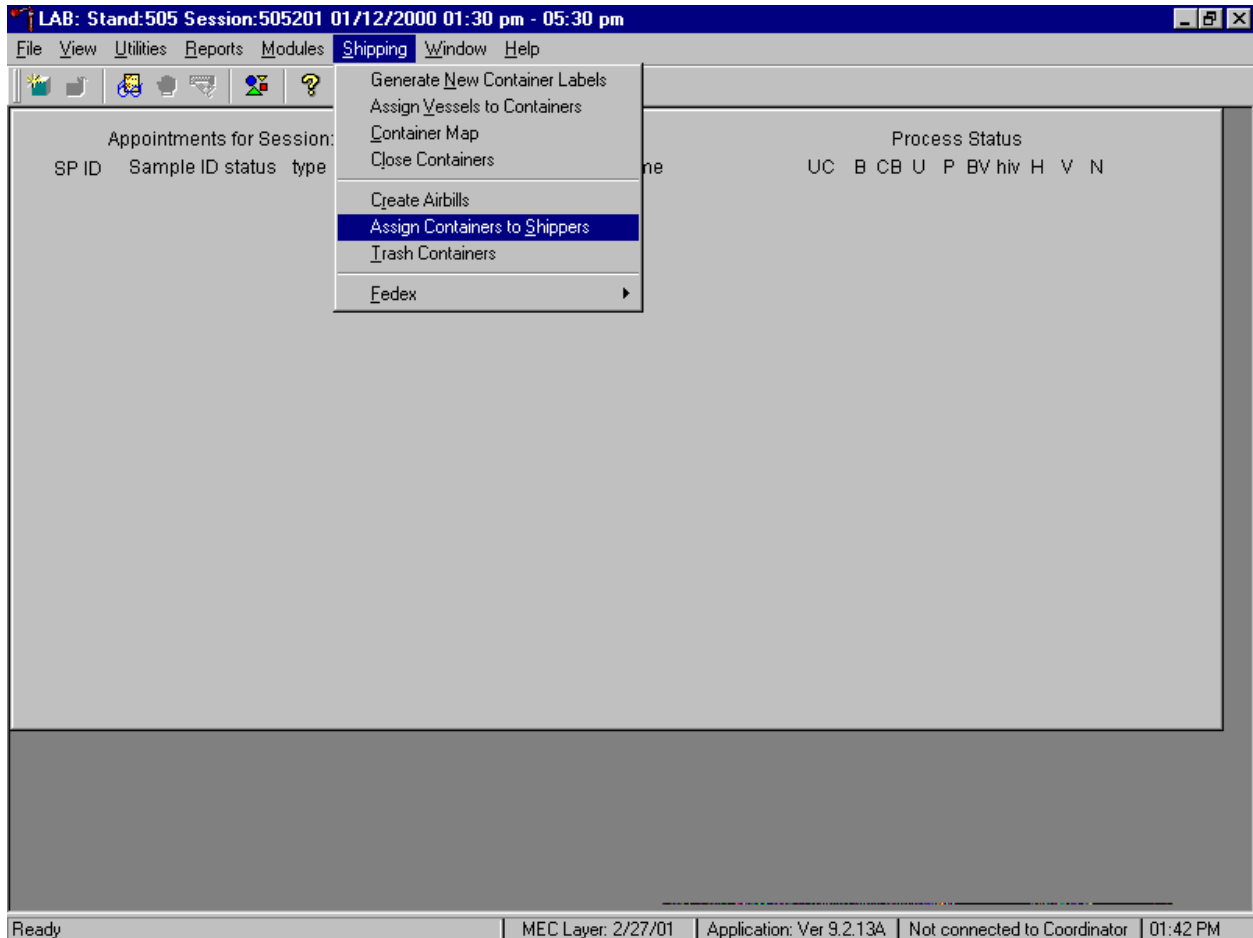
Do not individually mark containers in this manner on a routine basis. When a container is individually marked, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. To exit the window without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button, and left click.

9.11 Assign Containers to Shippers

Assign closed containers to or associate closed containers with a specific airbill. Use the Auto-Assign feature to automatically assign all closed containers associated with a specific laboratory to that laboratory's airbill. Manually verify and correct the assignment of Coulston Foundation's refrigerated

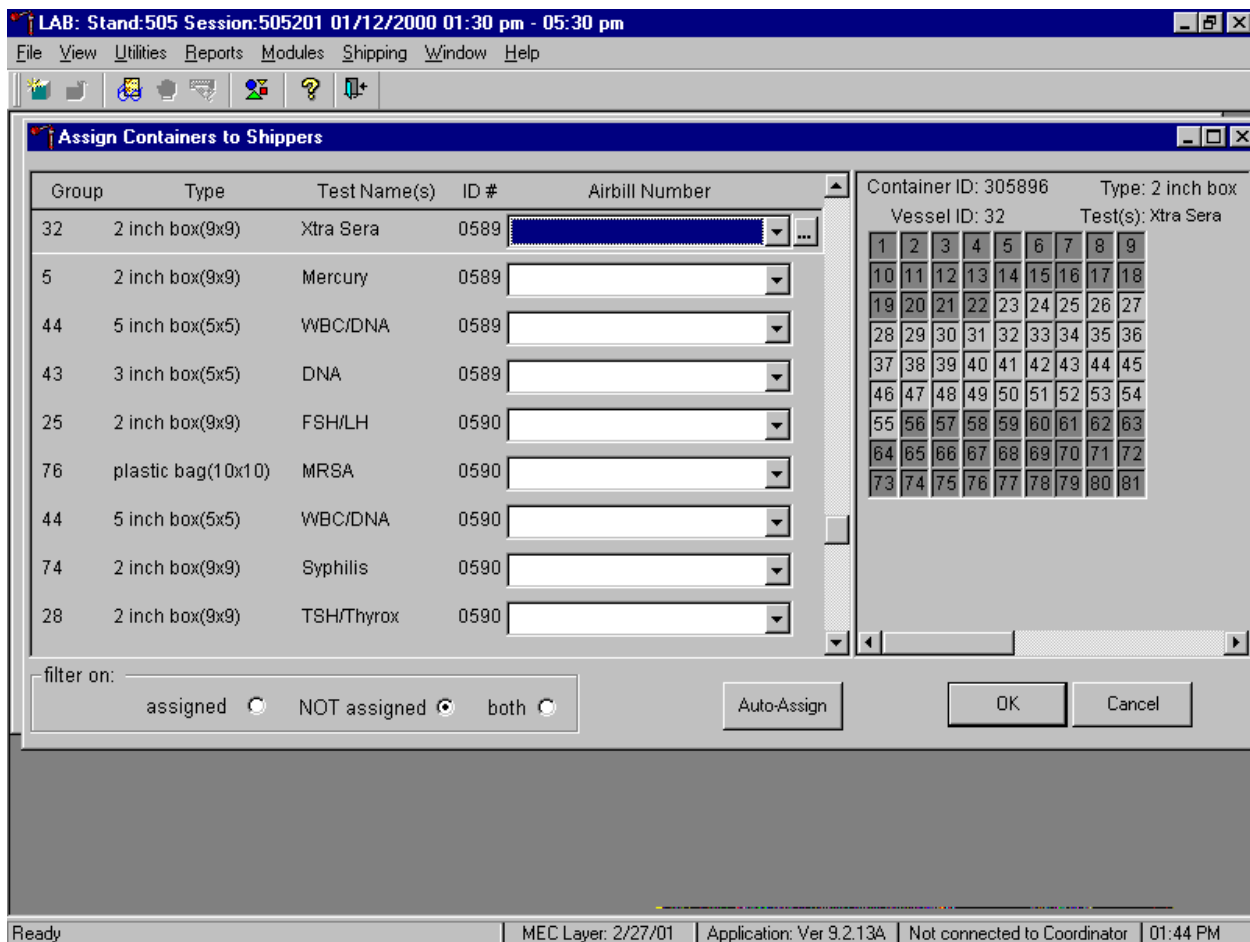
vessel 18 (Biochem) and frozen vessels 25 (FSH/LH) and 28 (TSH/Thyrox). Manually verify and correct the assignment of the University of Missouri's refrigerated vessel 4 (Glycohem) and frozen vessels 9 (Glucose) and 23 (Insul/Cpep). Manually verify and correct the assignment of the CDC/AIDS Division's refrigerated vessel 53 (urine HIV) and frozen vessel 22 (serum HIV). Verify and correct the assignment of all vessels to CASPIR, since there are multiple airbills.

Access the Assign Containers to Shipper module.



To access the Assign Containers to Shippers module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Assign Vessels to Containers} module and left click, or type [Alt] [S/s], [S/s].

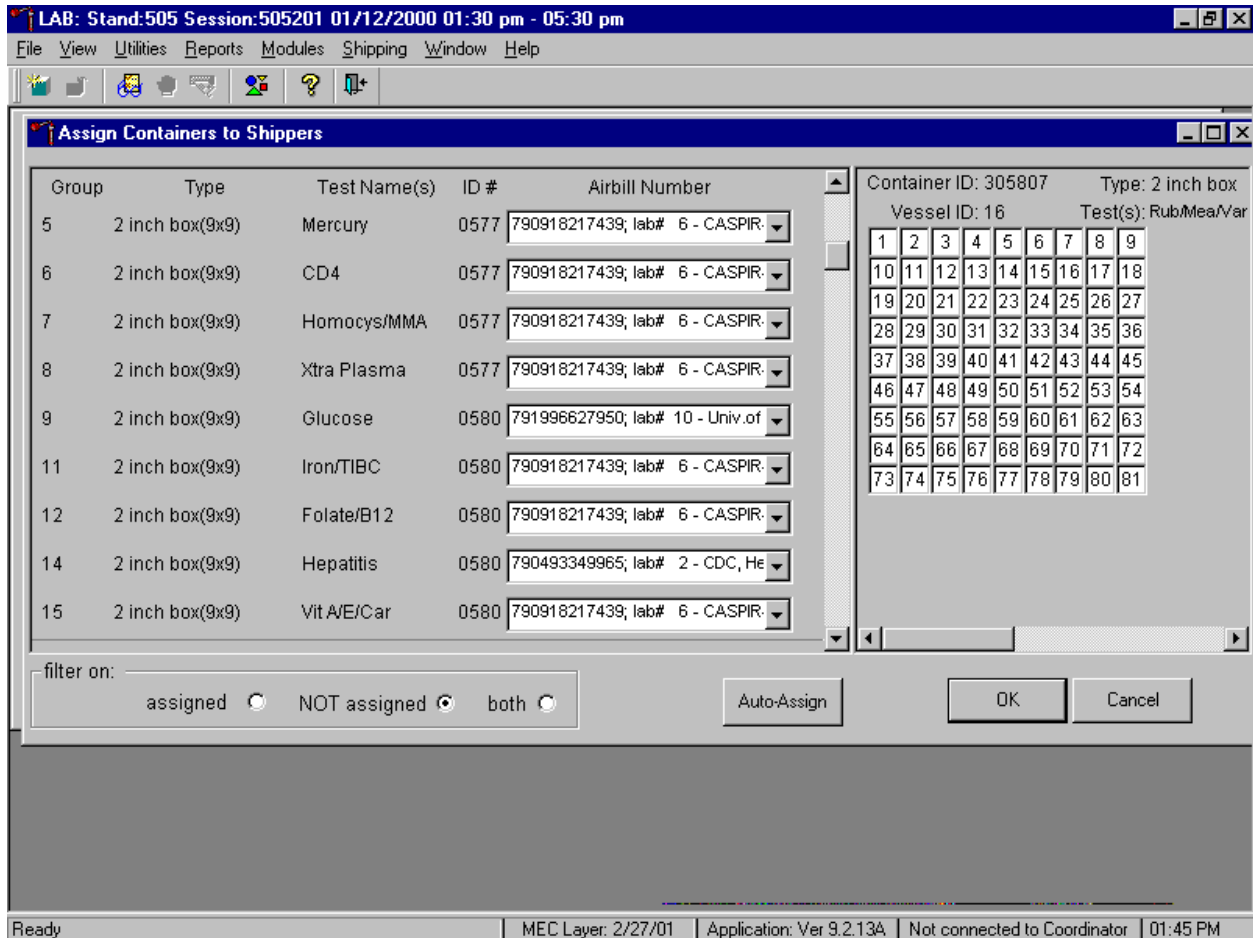
The Assign Containers to Shippers window displays.



This left side of the screen includes columns for a group designation (which represents one laboratory), Type of container, Test Name(s), Container ID number, and an Airbill Number. The Airbill Number text box includes a drop down list. The container line within the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. The bottom of the window contains three "filter on" radio buttons: "assigned", "NOT assigned", and "both," and an Auto-Assign button.

To auto assign all containers to their corresponding airbill,

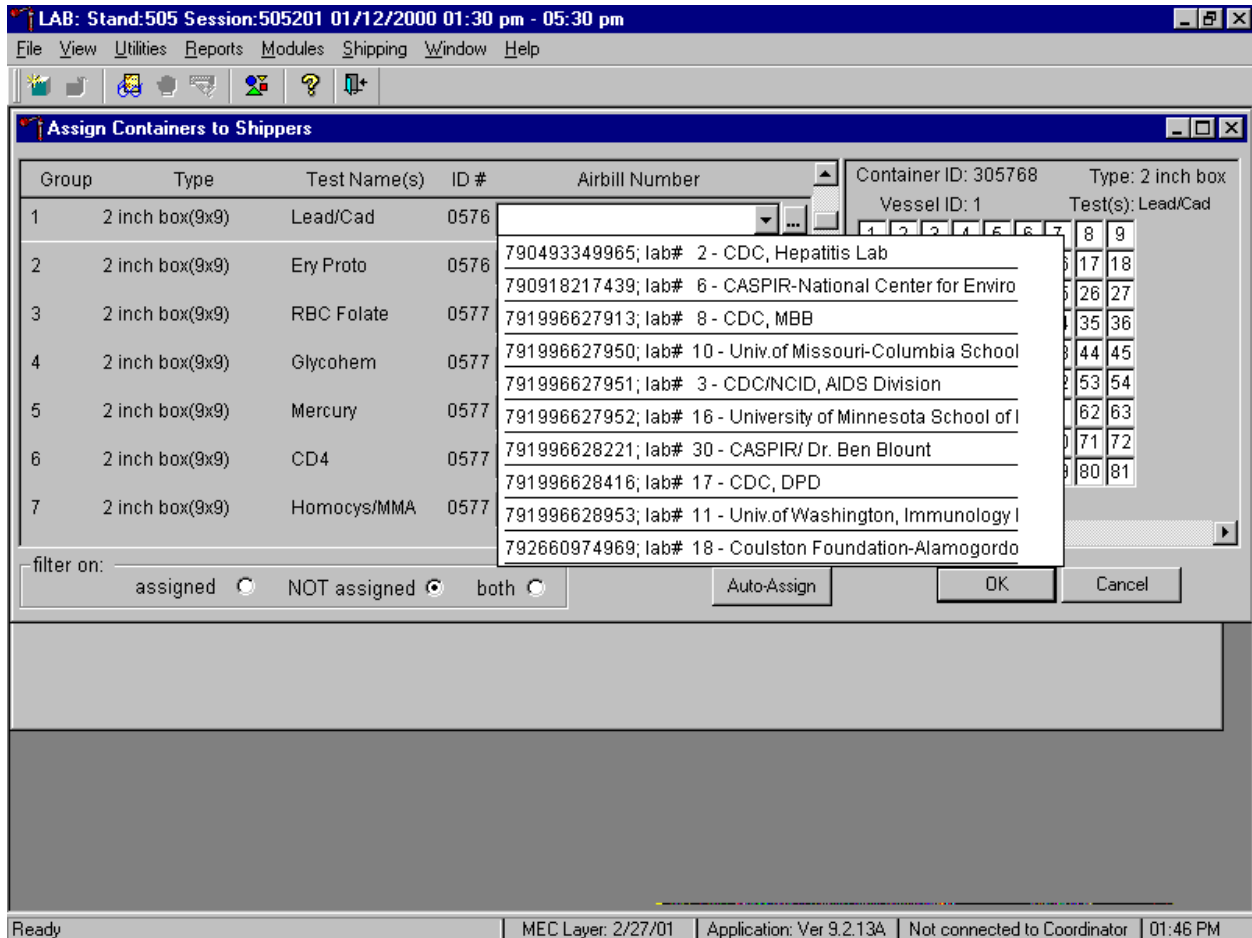
- Set the filter on: to NOT assigned.
- Use the mouse to direct the mouse arrow to the **Auto-Assign** button and left click.



- Containers are automatically assigned to the correct airbill associated with the correct laboratory with a few exceptions. Those exceptions are the assignment of containers to the airbills for Coulston Foundation, University of Missouri, CDC/NCID AIDS Division, and CASPIR.

To assign individual containers to the a shipper,

- Set the filter on: to NOT assigned.
- Use the mouse to direct the mouse arrow to the drop down list of the Airbill Number text box and left click to display the list of airbills.



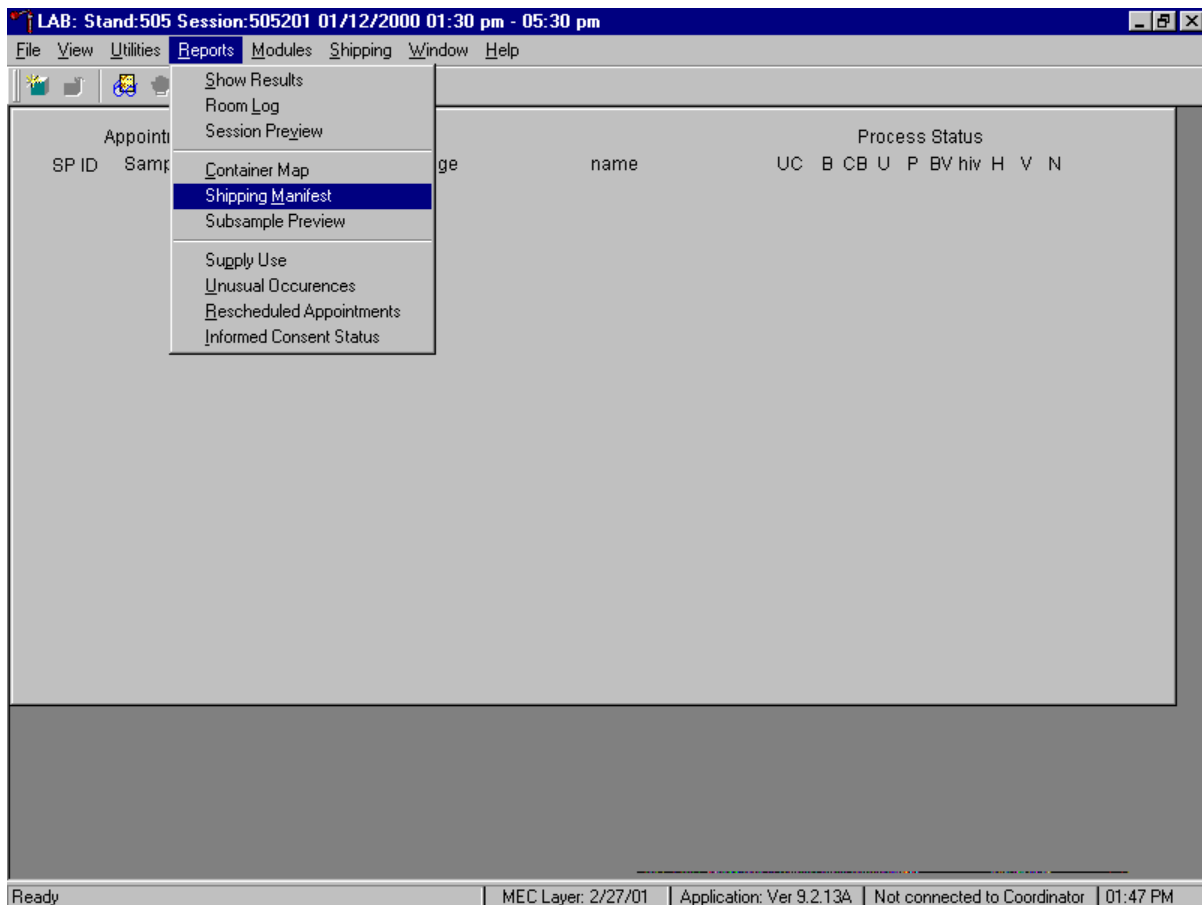
- To select or identify a specific airbill, use the up and down keyboard arrows to move up and down the list, use the mouse to direct the mouse arrow to the correct airbill, and left click.
- To view all choices, use the vertical scroll bar.

If necessary, verify the contents of each closed box by matching the contents of the box to the map. To record the assignment of containers to shippers, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. This step is required to save the information. To exit the Assign Containers to Shippers module without recording any assignments, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

9.12 Create Shipping Manifests

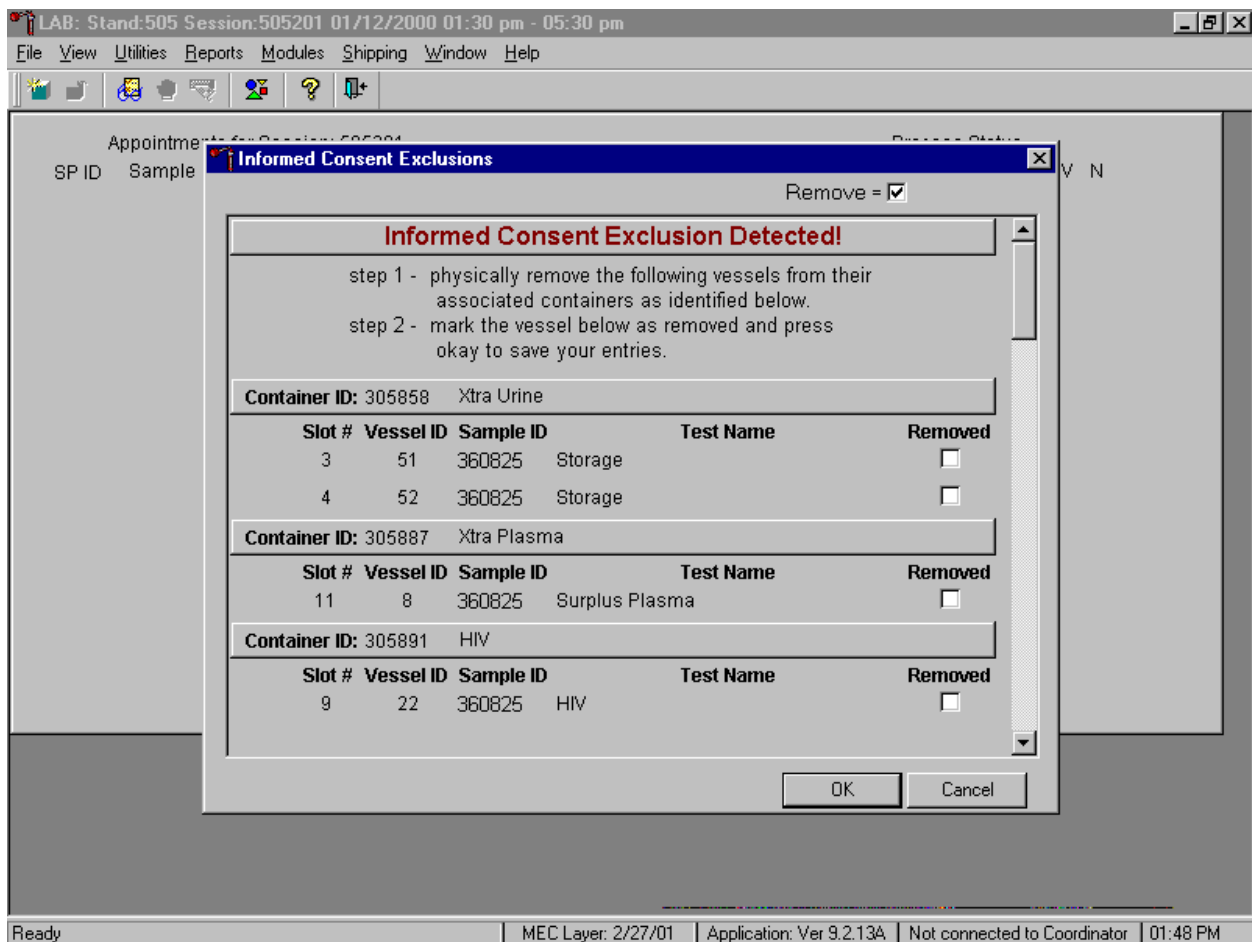
Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed below to prepare the paper manifest and to send the electronic file.

Access the Shipping Manifest module.



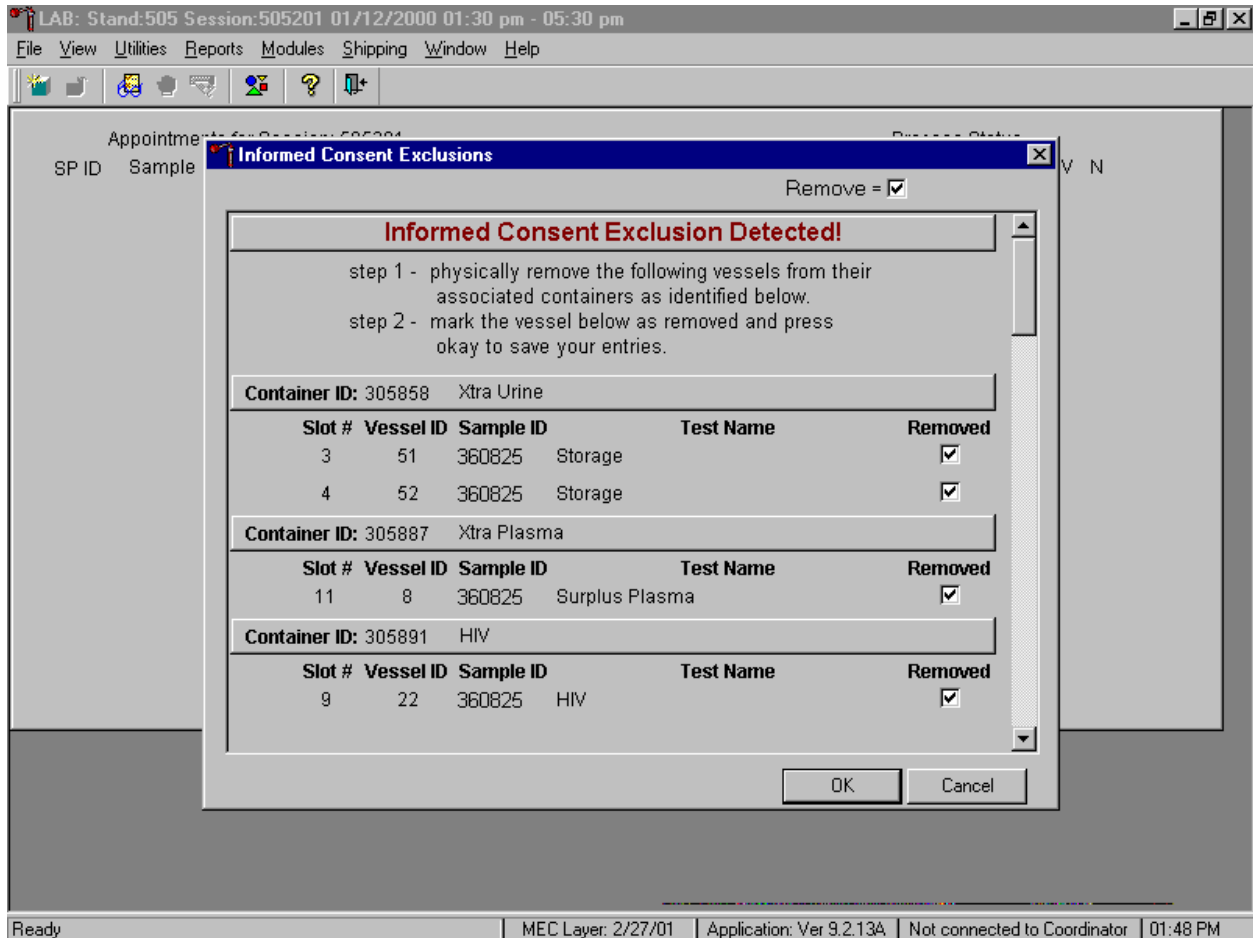
To access the Shipping Manifest module, use the mouse to direct the mouse arrow to {Reports}, left click, drag the mouse arrow to {Shipping Manifest} and left click, or type [Alt] [R/r], [M/m].

If a SP initially signed or agreed to their BV, PSA, STD, and/or future research consent form and subsequently refused, and the associated vessels have already been processed, the Informed Consent Exclusions window displays.



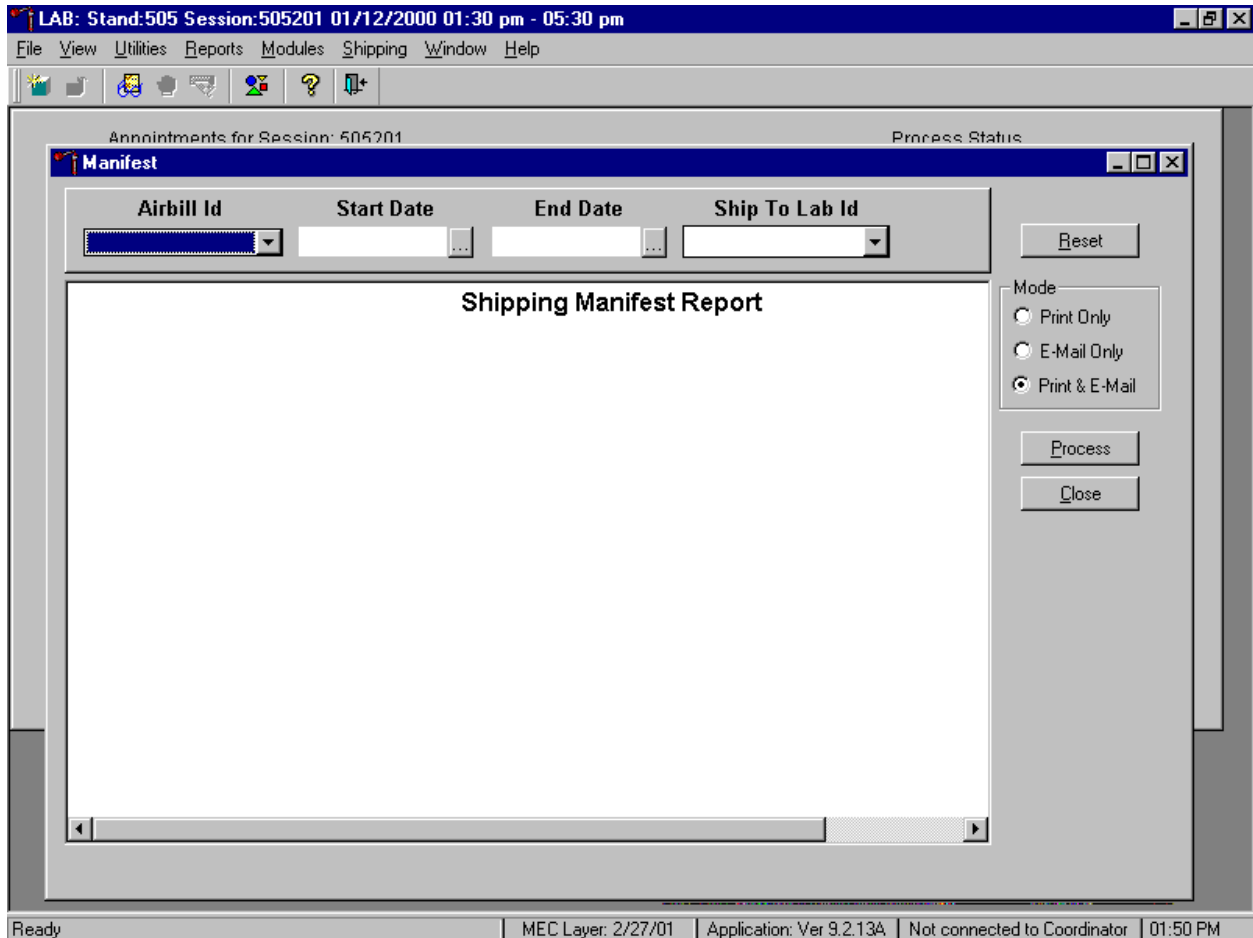
These vessels must be removed from the container and destroyed before the container is shipped. Follow the exact instructions contained in the window.

Affirm the actions taken to resolve these exclusions.



After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To remove the window and exit without saving the actions to the database, use the mouse to direct the mouse arrow to **Cancel** button, and left click.

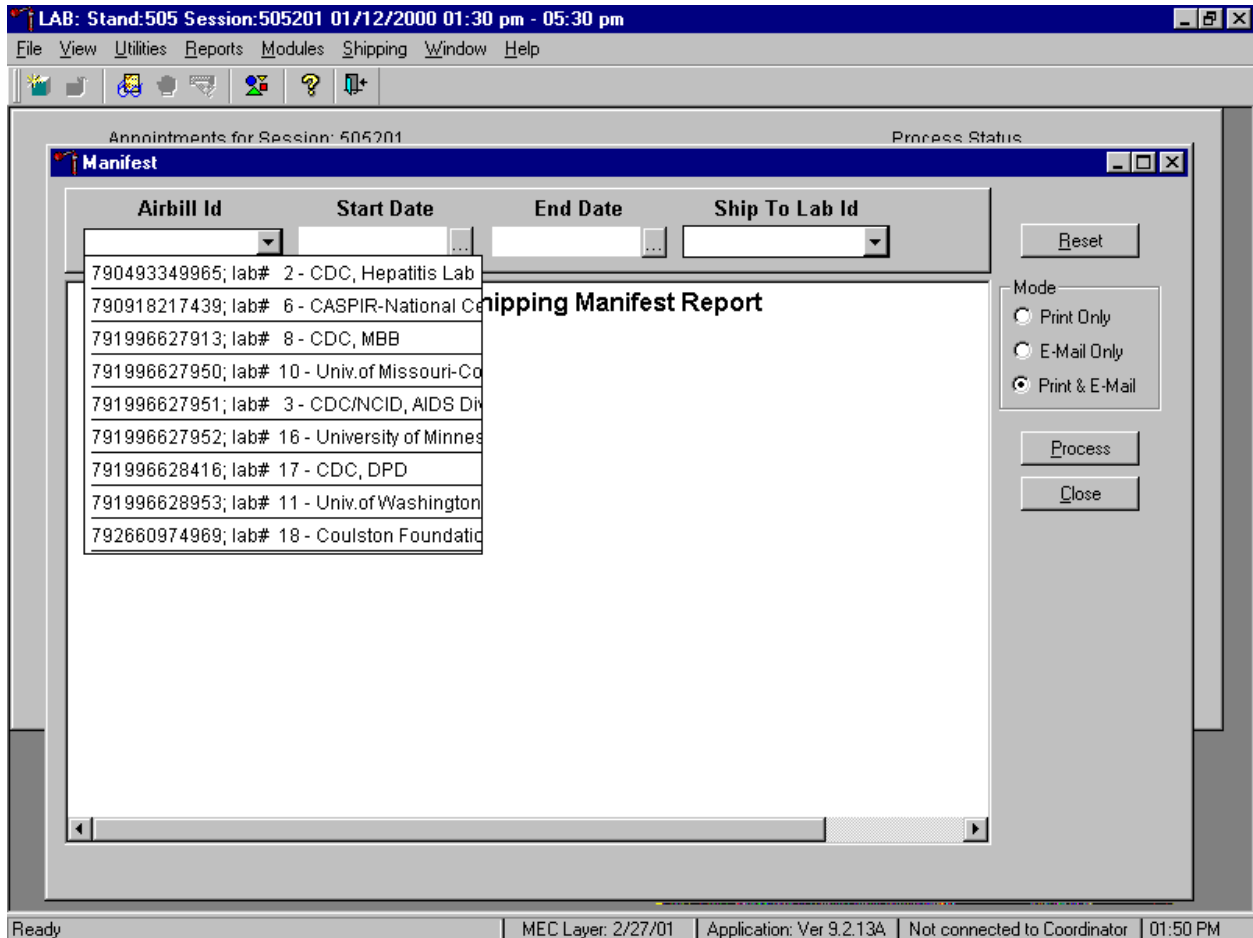
A blank manifest window displays.



The Shipping Manifest Report contains the Shipment ID or airbill number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Container IDs associated with the shipment ID, container Size, container Type, Test(s) associated with the container, and a list by Slot ID of the Sample/Vessel ID, Astro ID, and Date Collected.

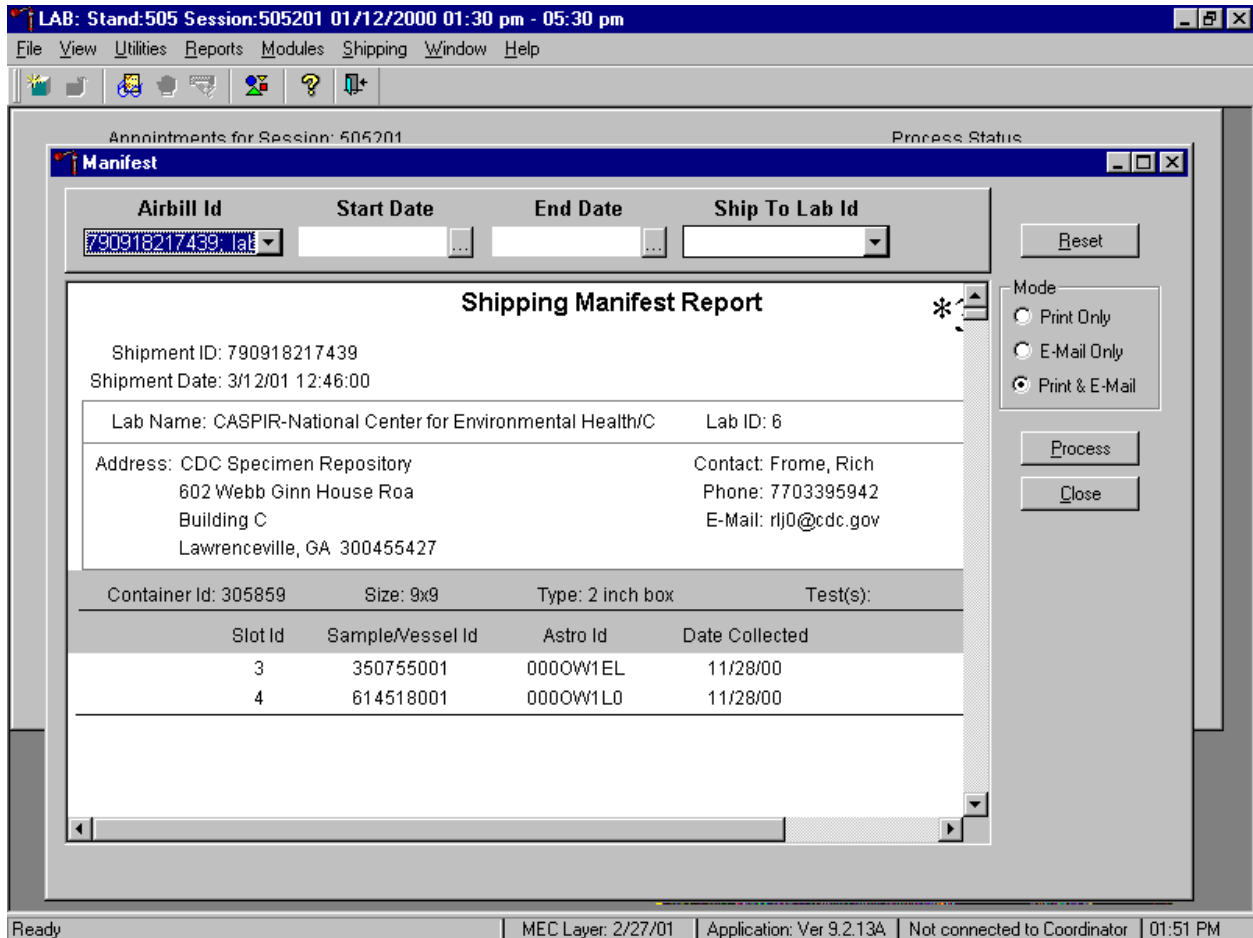
Set the Mode to "Print Only" to print the manifest(s), "E-mail Only" to send an electronic manifest to the analysis laboratory, or to "Print & E-mail" to print all manifests and send an electronic file to each laboratory. Select "Print & E-mail" as the default. Use "Print Only" and "E-mail Only" when necessary. To print the manifest and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [Shift] [C/c]. Use the **Reset** button to clear the requirements and begin again.

Select one manifest at a time by using the Airbill ID filter.



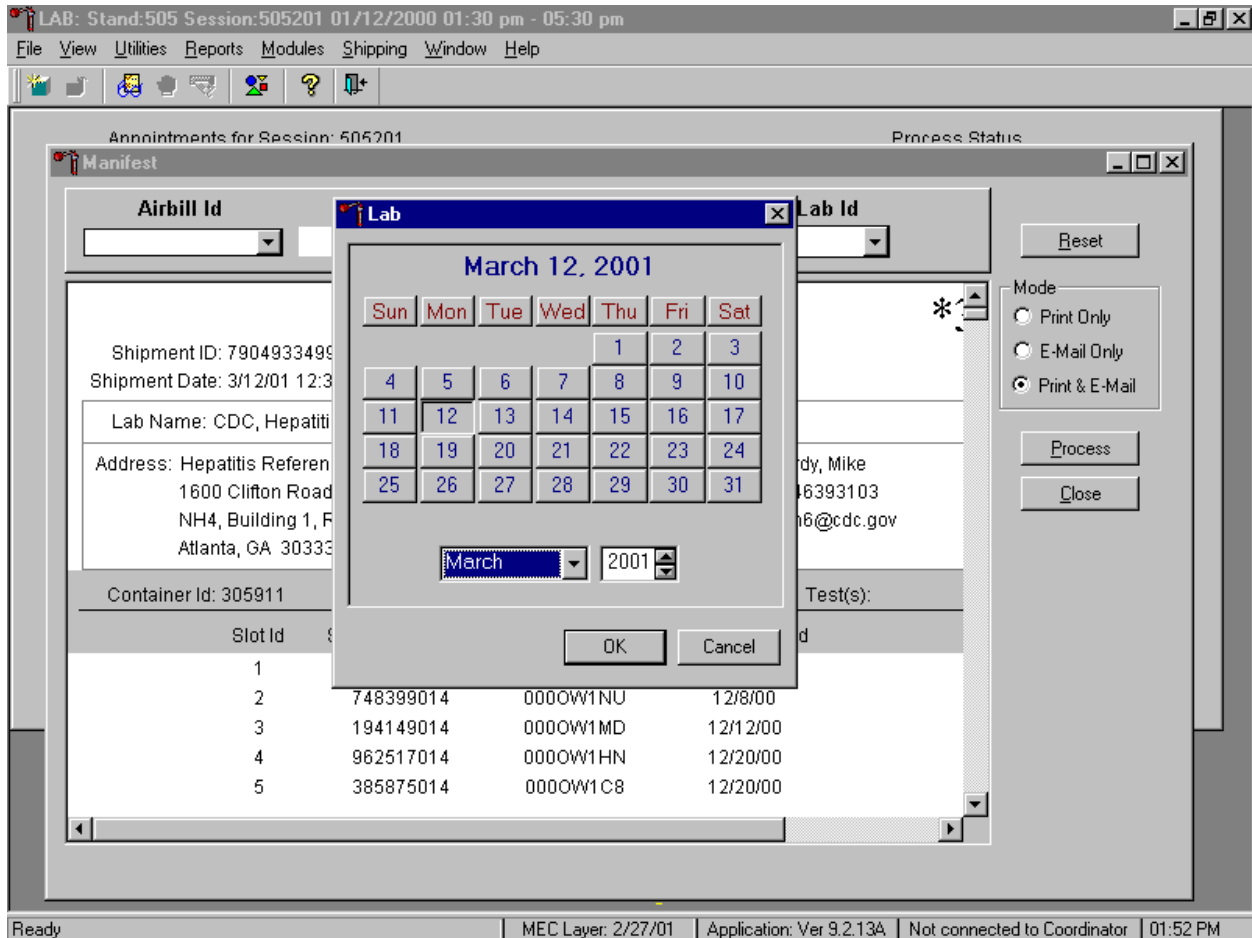
To print and/or email one manifest at a time, use the mouse to direct the mouse arrow to the drop down list on the right side of the Airbill ID text box, left click to display all existing airbills, drag the arrow to the appropriate airbill number, and left click.

The Shipping Manifest Report associated with that airbill displays.



To print the manifest and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [Shift] [C/c]. Use the **Reset** button to clear the requirements and begin again.

Select one or more manifests by using the Start Date and End Date filters.



To print and/or email one or more manifests at a time, use the calendar function on the Start and End Date filters. To access the calendar on either filter, use the mouse to direct the mouse arrow to the ellipsis button and left click. Alternatively, use the keyboard and press [Shift] then [C/c] to display the calendar. To select or specify a date, use the mouse to direct the mouse arrow to the month drop down list, drag the arrow to the correct month (use the vertical scroll bar if necessary), and left click. Select the correct day by using the mouse to direct the mouse arrow to the correct day on the displayed month and left click. Correct the year by using the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer the day, month, and year into the date space and to exit the calendar window, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter]. To exit the calendar window without entering or transferring a date into the date space, use the mouse to direct the mouse arrow to **Cancel** button, and left click.

The airbills generated between those start and end dates are included in the Shipping Manifest.

LAB: Stand:505 Session:505201 01/12/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505201 Process Status

SP ID Sample ID status type fast gender age name UC B CB U P BV hiv H V N

Manifest

Airbill Id Start Date End Date Ship To Lab Id

3/12/01 3/13/01

Reset

Mode

Print Only

E-Mail Only

Print & E-Mail

Process

Close

Shipping Manifest Report

Shipment ID: 790493349965
 Shipment Date: 3/12/01 12:37:00

Lab Name: CDC, Hepatitis Lab Lab ID: 2

Address: Hepatitis Reference Laboratory
 1600 Clifton Road
 NH4, Building 1, Room 138
 Atlanta, GA 30333

Contact: Purdy, Mike
 Phone: 4046393103
 E-Mail: lqm6@cdc.gov

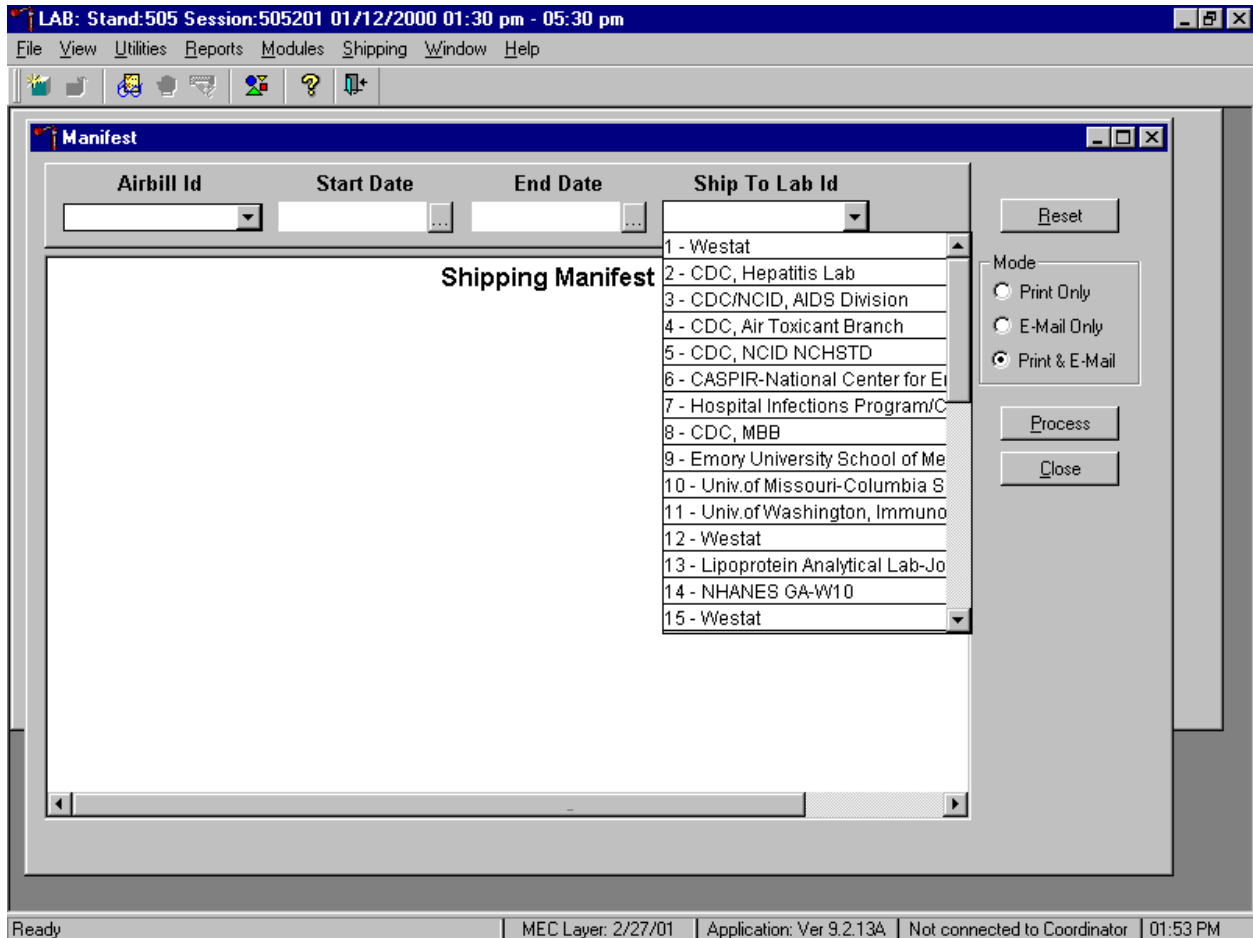
Container Id: 305911 Size: 9x9 Type: 2 inch box Test(s):

Slot Id	Sample/Vessel Id	Astro Id	Date Collected
1	275077014	000OW1JW	12/8/00
2	748399014	000OW1NU	12/8/00
3	194149014	000OW1MD	12/12/00
4	962517014	000OW1HN	12/20/00
5	385875014	000OW1C8	12/20/00

Apply changes and close window | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 01:53 PM

All shipments associated with airbills generated on or between those days are included in this manifest.

Select one manifest at a time by using the Ship To Lab ID filter.



To print and/or email manifest(s) to one lab at a time, use the mouse to direct the mouse arrow to the drop down list on the right side of the Ship To Lab ID text box and left click to display all existing laboratories, drag the arrow to the appropriate laboratory, and left click.

Print the manifest and send the electronic files.

LAB: Stand:505 Session:505201 01/12/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

Manifest

Airbill Id Start Date End Date Ship To Lab Id

2 - CDC, Hepatitis

Reset

Mode

Print Only

E-Mail Only

Print & E-Mail

Process

Close

Shipping Manifest Report

Shipment ID: 790493349965
Shipment Date: 3/12/01 12:37:00

Lab Name: CDC, Hepatitis Lab Lab ID: 2

Address: Hepatitis Reference Laboratory
1600 Clifton Road
NH4, Building 1, Room 138
Atlanta, GA 30333

Contact: Purdy, Mike
Phone: 4046393103
E-Mail: lqm6@cdc.gov

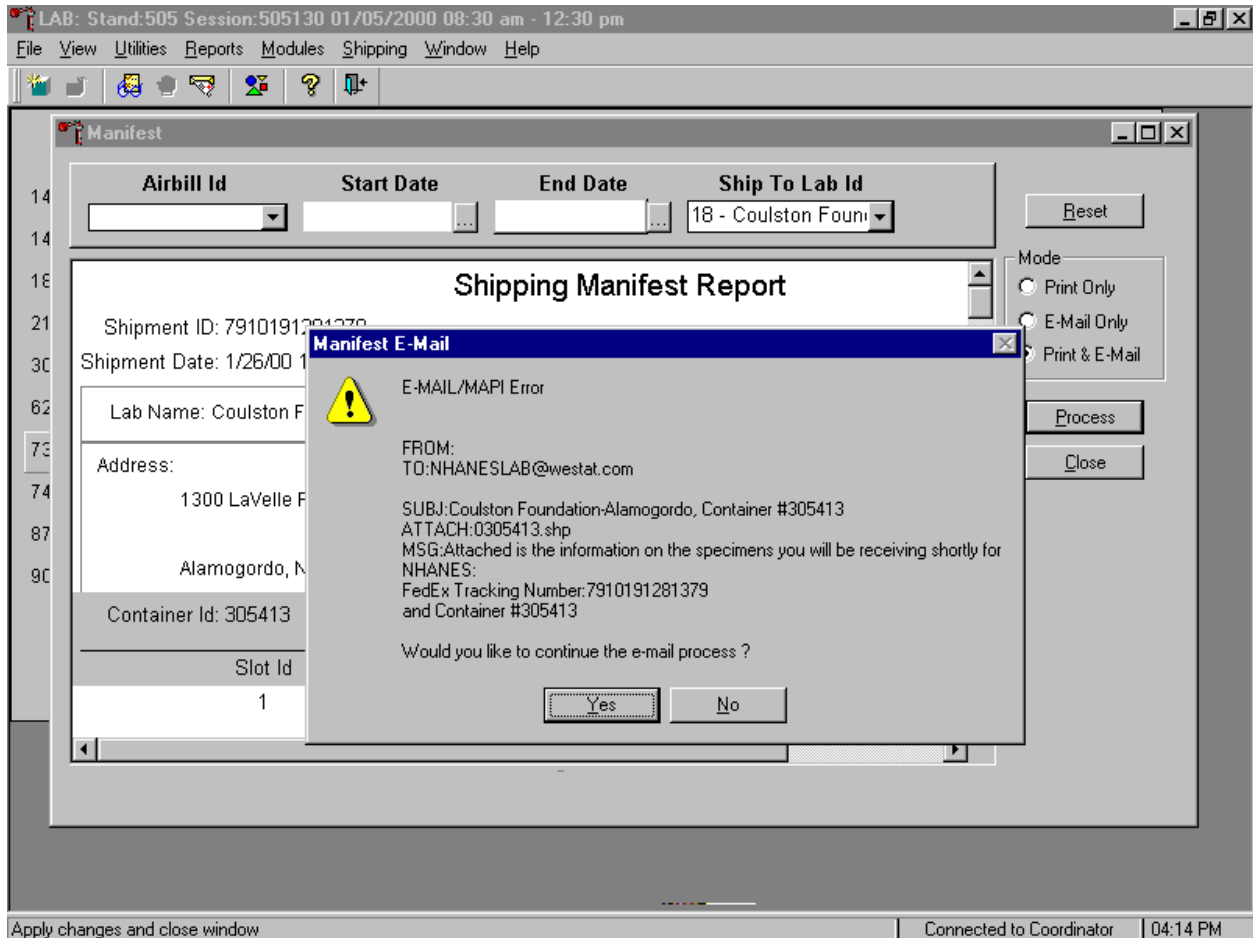
Container Id: 305911 Size: 9x9 Type: 2 inch box Test(s):

Slot Id	Sample/Vessel Id	Astro Id	Date Collected
1	275077014	000OW1JW	12/8/00
2	748399014	000OW1NU	12/8/00
3	194149014	000OW1MD	12/12/00
4	962517014	000OW1HN	12/20/00
5	385875014	000OW1C8	12/20/00

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 01:53 PM

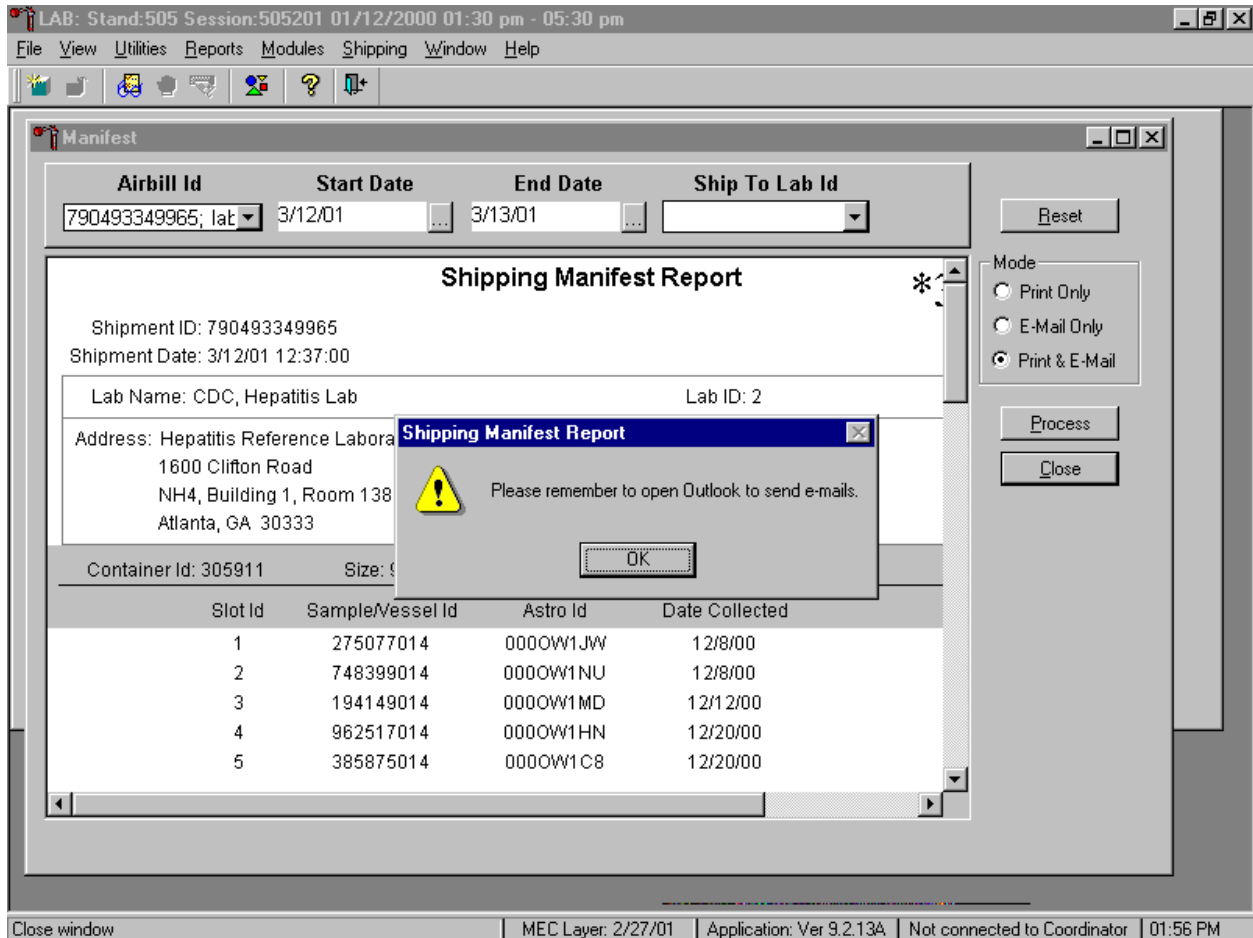
To print the manifests and send the email file, use the mouse to direct the mouse arrow to the **Process** button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [Shift] [C/c]. Use the **Reset** button to clear the requirements and begin again.

If the modem is not operating, a Manifest E-mail warning message text box displays.



Report this message to the data manager. Review the information in the warning text box. To continue to process the hard copy manifests, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y/y] or select [Enter]. To quit the manifest process, use the mouse to direct the mouse arrow to the **No** button and left click, or type [N/n].

After the **Close** button is selected, a Shipping Manifest Report message text box displays.



It is essential to open the Outlook email program to send the electronic files each time a manifest is created and a package is sent. It is the shipping technologist's responsibility to open the Outlook program immediately after shipping containers. Opening Outlook sends an email to each laboratory that receives a shipment. The email contains critical information and the contract laboratories rely on the electronic file contained in the email to prepare in advance for the shipment. Laboratories also use the airbill number in the email to track the shipment with FedEx. The data manager can explain the procedure to access and open Outlook. Do not transmit or send the electronic files more than once.

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

9.13 Packing Procedure for the Shippers

Most of the shipments require dry ice to keep the specimens frozen during shipment. Some shipments require reusable refrigerant packs to keep specimens cold but not frozen. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.) It is the chief medical technologist's responsibility to arrange for delivery of dry ice pellets or blocks for shipping specimens. Use sliced blocks whenever possible since these sublimate less than pellets. Well in advance of a scheduled shipment, the shipping technologist estimates how much dry ice to order for the shipment and informs the MEC manager. Store the dry ice in extra shipping containers. When handling dry ice, wear cryo gloves to avoid burning hands. Also, wear an eye shield when filling bags with ice chips or breaking blocks into chunks. Use the scale to ensure that each shipper has the required amount of dry ice. Exhibit 9-3 contains a list of all contract laboratory addresses.

Exhibit 9-3. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
California Dept of Health Services Attn: Cynthia Cossen 850 Marina Bay Parkway Richmond, CA 94804 510-307-2803	Rub/Mea/Var	Frozen	Cynthia Cossen 510-307-2803 ccossen@dhs.ca.gov
CASPIR 602 Webb Ginn House Road Building C Lawrenceville, GA 30045-5427 770-339-5942	Lead/Cad Ery Proto RBC Folate Mercury CD4 Homocys/MMA Xtra Plasma Iron/TIBC Ferritin Fol/B12 Vit A/E/Car Cotinine Selenium Vitamin D Env Serum Xtra Sera DNA Urn Iodine Urn Merc Heavy Metal Xtra Urine	Frozen	Richard Frome 770-339-5917 Elaine Gunter, MT (ASCP) 770-488-7938 Ewg1@cdc.gov

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
University of Missouri Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	Glycohem	Refrigerated	Hsiao-Mei Wiedmeyer 573-882-2705 wiedmeyerh@missouri.edu
University of Missouri Attn: Hsiao-Mei Wiedmeyer Department of Child Health One Hospital Drive Room M770 Columbia, MO 65212 573-882-2705	Glucose Insul/Cpep	Frozen	Hsiao-Mei Wiedmeyer 573-882-2705 wiedmeyerh@missouri.edu
University of Washington Attn: Phyllis Daum Immunology 1959 NE. Pacific Avenue Room NW 176 Seattle, WA 98195 206-548-6149	Fibrin CRP/Hpylori Bn Alk Phos NTX PSA	Frozen	Phyllis Daum 206-548-6149 daum@mail.labmed.washington.edu
CDC/NCID Hepatitis Ref Lab Attn: Mike Purdy Code NH4 1600 Clifton Road Building 1, Room 1389 Atlanta, GA 30333 404-639-2331	Hepatitis	Frozen	Mike Purdy 404-639-2331 (lab) mpurdy@cdc.gov
Coulston Foundation Attn: Love Julian 1300 LaVelle Road Alamogordo, NM 88310 505-434-1725	Biochem	Refrigerated	Love Julian 505-434-1725 ext 41 clinpath@zianet.com
CDC/Div of Parasitic Diseases Attn: Dr. Patrick Lammie 4770 Buford Highway. Atlanta, GA 30341 770-488-4054	Crypto	Frozen	Dr. Patrick Lammie 770-488-4054 jip8@cdc.gov

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
Lipoprotein Analytical Lab/JHU Attn: Donna Virgil 600 North Wolfe Street Blaylock 1379 Baltimore, MD 21287 410-614-1145	Lipids	Frozen	Donna Virgil 410-614-1145 klovejoy@welchlink.welch.jhu.edu
CDC/NCID AIDS Division Attn: Faye Cowert 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	HIV	Frozen	Faye Cowert 404-639-3174 mfcl@cdc.gov
CDC/NCID AIDS Division Attn: Faye Cowert 1600 Clifton Road NE Building 1, Room 2367 Atlanta, GA 30333 404-639-3174	HIV Urine	Refrigerated	Faye Cowert 404-639-3174 mfcl@cdc.gov
Emory University Dept of Pediatrics Attn: Dr. Francis Lee 46 Armstrong Street SE Room 219 Atlanta, GA 30303 404-616-4997	HSV	Frozen	Dr. Francis Lee Fax: 404-616-0129 Phone:404-616-6229 Francis Lee@emory.edu
CDC DASTLR/NCID Bldg 1, Room 3318 1600 Clifton Road, NE Atlanta, GA 30333 404-639-3224 404-639-3450	Syphilis	Frozen	Victoria Pope, PhD Vkp1@cdc.gov 404-639-3224 Martha Fears MBF1@cdc.gov 404-639-3450
Coulston Foundation Attn: Love Julian 1300 LaVelle Road Alamogordo, NM 88310 505-434-1725	FSH/LH TSH/Thyrox	Frozen	Love Julian 505-434-1725 ext 41
CDC/Hospital Infections Program Attn: Dr. Matthew Arduino 1600 Clifton Road, NE MS C01 Atlanta, GA 30333 404-639-2318	Latex	Frozen	Dr. Matthew J. Arduino 404-639-2318 mja4@cdc.gov Phyllis Miller 404-639-3475

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CASPIR/Dr. Wayman Turner Attn:Dr. Wayman Turner 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-7974	Persis Pest	Frozen	Dr. Wayman Turner 770-488-7974 pcm5@cdc.gov
CASPIR/Dr. Charles Dodson Attn: Dr. Charles Dodson 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-788-4504	Phytoestro	Frozen	Dr. Charles Dodson 770-788-4504 wcd1@cdc.gov
CDC/Molecular Biology Branch Attn: Linda Wohr 4770 Buford Highway Building 32, Room 1505 MS F24 Atlanta, GA 30341-3724 770-488-4313	WBC/DNA	Room temperature	Linda Wohr 770-488-4313 FAX: 770-488-4005 lsw@cdc.gov
University of Minnesota Attn: Susan Kupcho Department of Pediatrics 515 Delaware St. S.E. Room 13-219 - MOOS Tower Minneapolis, MN 55455 612-624-6153	Alb/Creat	Frozen	Susan Kupcho 612-624-6153 kupch001@aroon.tc.umn.edu
CDC/NCID/NCHSTD Attn: Jason Dover 1600 Clifton Road, NE MS D13 Atlanta, GA 30333 404-639-2870	Chlam/GC	Frozen	Jason Dover 404-639-2870 jwp6@cdc.gov
CDC/Dr. Dana Barr Attn: Dr Dana Barr 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341-3724 770-488-4598	Prior Pest Organophos Urn Phytoes	Frozen	Dr Dana Barr 770-488-4598

Exhibit 9-3. Contract laboratory addresses (continued)

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) telephone number and email address
CASPIR/Dr. James Grainger 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-4815	PAH	Frozen	Dr. James Grainger 770-488-4815 jag2@cdc.gov
CDC/Dr. John Brock Attn: Dr. John Brock 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341-3724	Phthalates	Frozen	Dr. John Brock Jbw6@cdc.gov jar2@cdc.gov
Research Triangle Institute Attn: Dr. Edo Pellizzari 3040 Cornwallis Road Dryfus Bldg Research Triangle Park, NC 27709-2194 919-541-6000	Methylmerc	Room Temperature	Dr. Edo Pellizzari 919-541-6000 edp@rti.org
University of Cincinnati Attn: Sandy Rhoda Dept of Env Services 3223 Eden Avenue Cincinnati, OH 45267-0056 513-558-1705	F Lead Dust W Lead Dust	Room Temperature	Sandy Rhoda 513-558-1705

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. The federal regulations include:

- A watertight primary receptacle e.g., sealed cryovial, sealed Vacutainer®, and sealed Falcon tubes
- A watertight secondary packaging e.g., a sealed plastic storage bag
- Ensuring that there is sufficient absorbent material between the primary receptacle and the secondary receptacle to absorb the entire contents of all primary receptacles
- If multiple glass primary receptacles are placed in a secondary packaging, they must be wrapped individually to ensure that contact between them is prevented
- Use of a sturdy outside packaging constructed of corrugated fiberboard

9.13.1 Pack Boxed Specimens

Store the blood and urine vessels, and ACD tubes in the 2, 3, and 5-inch storage boxes. Separate the boxed specimens with cardboard grids or foam inserts. Secure the top of the box to the bottom with a rubber band. Place the box in a plastic bag, add one absorbent paper, and seal the bag.

9.13.2 Pack Medium Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.
- Place a layer 3-inches thick or at least 15 pounds of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 15 pounds.
- Place the Styrofoam lid on top of the Styrofoam bottom
- Place a plastic envelope containing the appropriate shipping manifest and return address label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 35 pounds.
- Record the weight of the dry ice (30 pounds for a medium shipper) on the FedEx Class 9 label.

9.13.3 Pack Small Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.

- Place a layer 3-inches thick or at least 10 pounds of chipped dry ice or dry ice slabs in the bottom or up the sides of a small Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 10 pounds.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return address label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 25 pounds.
- Record the weight of the dry ice (20 pounds for a medium shipper) on the FedEx Class 9 label.

9.13.4 Pack Medium or Small Shipping Container for Refrigerated Shipment

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper.
- Place the sealed boxes on top of the refrigerant pack.
- Pack the sides with crumbled newsprint.
- Place two or three additional refrigerant packs on top of the containers.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid.

- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

9.13.5 Pack a Medium or Small Shipper for Ambient Temperature Shipment

Ship the ACD tubes at ambient temperature.

- Pack the bottom of the Styrofoam shipper with crumbled newsprint.
- Place the sealed boxes on top of the newsprint.
- Pack the sides with crumbled newsprint.
- Place more crumpled newsprint on top so that the shipper is filled to 1/4" below the rim.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the envelope (10 pounds) on the appropriate FedEx label.

9.14 Label Shippers

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand.

All shippers must contain a FedEx bar coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing dry ice with a "Keep Frozen" label and a FedEx Class 9—Miscellaneous Dangerous Goods label.
- Label shippers containing refrigerant packs with a "Refrigerate" label.
- Label shippers containing whole blood, serum, plasma, or urine with a "Biohazard" label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

Exhibit 9-4. Container protocol

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
1	Lead/Cad	WB	2 mL	9 x 9 two inch box	Freezer #2
2	Ery Proto	WB	2 mL	9 x 9 two inch box	Freezer #2
3	RBC Folate	WB	2 mL	9 x 9 two inch box	Freezer #2
4	Glycohem	WB	2-mL	9 x 9 two inch box	Refrigerator # 1
5	Mercury	WB	2 mL	9 x 9 two inch box	Freezer #2
6	CD4	WB	2 mL	9 x 9 two inch box	Freezer #2
7	Homocys/MMA	Plasma	2 mL	9 x 9 two inch box	Freezer #2
8	Xtra Plasma	Plasma	2 mL	9 x 9 two inch box	Freezer #2
9	Glucose	Plasma	2 mL	9 x 9 two inch box	Freezer #2
10	Fibrin	Plasma	2 mL	9 x 9 two inch box	Freezer #2
11	Iron/TIBC	Serum	2 mL	9 x 9 two inch box	Freezer #2
68	Ferritin	Serum	2-mL	9 x 9 two inch box	Freezer #2
12	Fol/B12	Serum	2 mL	9 x 9 two inch box	Freezer #2
13	CRP/Hpylori	Serum	2 mL	9 x 9 two inch box	Freezer #2
14	Hepatitis	Serum	2 mL	9 x 9 two inch box	Freezer #2
15	Vit A/E/Car	Serum	2 mL	9 x 9 two inch box	Freezer #2
16	Rub/Mea/Var	Serum	2-mL	9 x 9 two inch box	Freezer #2
17	Cotinine	Serum	2 mL	9 x 9 two inch box	Freezer #2
18	Biochem	Serum	2 mL	9 x 9 two inch box	Refrigerator # 1
19	Bn Alk Phos	Serum	2 mL	9 x 9 two inch box	Freezer #2
20	Crypto	Serum	2 mL	9 x 9 two inch box	Freezer #3
21	Lipids	Serum	2 mL	9 x 9 two inch box	Freezer #3
22	HIV	Serum	2 mL	9 x 9 two inch box	Freezer #3
23	Insul/Cpep	Serum	2 mL	9 x 9 two inch box	Freezer #3
24	HSV	Serum	2 mL	9 x 9 two inch box	Freezer #3
74	Syphilis	Serum	2-mL	9 x 9 two inch box	Freezer #3
75	PSA	Serum	2-mL	9 x 9 two inch box	Freezer #3
25	FSH/LH	Serum	2 mL	9 x 9 two inch box	Freezer #3
26	Selenium	Serum	2 mL	9 x 9 two inch box	Freezer #3
27	Latex	Serum	2 mL	9 x 9 two inch box	Freezer #3
28	TSH/Thyrox	Serum	2 mL	9 x 9 two inch box	Freezer #3
70	Vitamin D	Serum	2-mL	9 x 9 two inch box	Freezer #3
29	Persis Pest	Serum	5 mL	9 x 9 three inch box	Freezer #3
64	Phytoestro	Serum	5-mL	9 x 9 three inch box	Freezer #3
32-42	Xtra Sera	Serum	2 mL	9 x 9 two inch box	Freezer #3
43	DNA	Clot	14 mL tube	5 x 5 three inch box	Freezer #3
44 & 71	WBC/DNA	WB	8 mL ACD	5 x 5 five inch box (foam insert)	Workstation #1
45	Alb/Creat	Urine	5 mL	9 x 9 three inch box	Freezer #1
46	Chlam/GC	Urine	5 mL	9 x 9 three inch box	Freezer #1
47	NTX	Urine	2 mL	9 x 9 two inch box	Freezer #1
69	Urn Iodine	Urine	5 mL	9 x 9 three inch box	Freezer #1
48	Prior Pest	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
49	Organophos	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
62	Urn Merc	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
50	Heavy Metal	Urine	14 mL tube	5 x 5 three inch box	Freezer #1
65	Urn Phytoes	Urine	5 mL	9 x 9 three inch box	Freezer #1
66	PAH	Urine	5 mL	9 x 9 three inch box	Freezer #1
67	Phthalates	Urine	5 mL	9 x 9 three inch box	Freezer #1

Exhibit 9-4. Container protocol (continued)

Vessel ID	Test ID/Name	Sample Type	Vessel Type	Vessel Storage	Storage Unit
51 & 52	Xtra Urine	Urine	5 mL	9 x 9 three inch box	Freezer #1
53	HIV Urine	Urine	5 mL	9 x 9 three inch box	Refrigerator #1
54	VOC Blood	WB	7 mL Gray top	1 x 5 foam mailer	Refrigerator #2
55	VOC Blood	WB	7 mL Gray top	1 x 5 foam mailer	Refrigerator #2
56	VOC Water	Water	10 mL glass vial	1 x 3 foam mailer	Refrigerator #2
57	VOC Badge	Badge	Badge	12 x 12 plastic bag	Refrigerator #2
59	Methylmerc	Hair	Plastic bag	12 x 12 plastic bag	Workstation 2
60-61	Lead Dust	Dust	50-mL tube	4 x 4 five inch box	Workstation 2
72	Vaginosis	Vaginal swab	Glass slide	1 x 25 slide box	Workstation 2
73	T <i>vaginalis</i>	Vaginal swab	Swab	12 x 12 plastic bag	Workstation 2
76	MRSA	Nasal swab	Culturette	12 x 12 plastic bag	Workstation 2

Number of Boxes Per Week

Number	Box type	Number	Box type
34	9 x 9 two inch box	2	1 x 5 foam mailer
10	9 x 9 three inch box	1	1 x 3 foam mailer
5	5 x 5 three inch box	4	12 x 12 plastic bag
1	5 x 5 five inch box (foam insert)	1	4 x 4 five inch box
1	1 x 25 blue slide box		

Exhibit 9-5. FedEx Weekly Shipping List

Laboratory/Destination	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
California Dept of Health Services	16	Rub/Mea/Var	Frozen	25	20	10
CASPIR	1	Lead/Cad	Frozen	35	25	12
	2	Ery Proto				
	3	RBC Folate				
	5	Mercury				
	6	CD4				
	7	Homocys/MMA				
	8	Xtra Plasma				
	11	Iron/TIBC				
	68	Ferritin				
	12	Fol/B12				
	15	Vit A/E/Car				
	17	Cotinine				
	26	Selenium				
	70	Vitamin D				
	32-42	Xtra Sera				
	43	DNA				
	69	Urn Iodine				
	62	Urn Merc				
	50	Heavy Metal				
	51-52	Xtra Urine				
CASPIR/Dr Charles Dodson	64	Phytoestro	Frozen	25	20	10
CASPIR/Dr. James Grainger	66	PAH	Frozen	25	20	10
CASPIR/Dr. Wayman Turner	29	Persis Pest	Frozen	35	25	12
CDC, Air Toxicant Branch	54	VOC Blood	Refrigerated	10		
	55	VOC Blood				
	56	VOC Water				
CDC DASTLR/NCID	74	Syphilis	Frozen	25	20	10
CDC, DPD	20	Crypto	Frozen	25	20	10
CDC, Hepatitis Lab	14	Hepatitis	Frozen	25	20	10
CDC, MBB	44	WBC/DNA	Room	10		
	71		Temperature			
CDC, NCID NCHSTD	46	Chlam/GC	Frozen	25	20	10
CDC/Dr. Dana Barr	48	Prior Pest	Frozen	35	25	12
	49	Organophos				
	65	Urn Phytoestro				
CDC/Dr. John Brock	67	Phthalates	Frozen	25	20	10
CDC/NCID AIDS Division	22	HIV	Frozen	25	20	10
CDC/NCID AIDS Division	53	HIV Urine	Refrigerated	10		
CDC/Sigrid K. McAllister	76	MRSA	Refrigerated	10		
Coulston Foundation-Alamogordo	18	Biochem	Refrigerated	10		
Coulston Foundation-Alamogordo	25	FSH/LH	Frozen	25	20	10
	28	TSH/Thyrox				

Exhibit 9-5. FedEx Weekly Shipping List (continued)

Laboratory/Destination	Vessel ID	Vessels/Assays	Conditions	Total Weight	Dry Ice Pounds	Dry Ice Kg
Hospital Infections Program/CDC	27	Latex	Frozen	25	20	10
Lipoprotein Analytical Lab Johns Hopkins	21	Lipids	Frozen	25	20	10
Mcgee Womens Hospital	72 73	Vaginosis <i>T vaginalis</i>	Refrigerated	10		
Research Triangle Institute	59	Methylmerc	Room Temperature	1		
RWJMS/UMDNJ	57	VOC Badge	Refrigerated	10		
Univ of Missouri Columbia School of Medicine	4	Glycohem	Refrigerated	10		
Univ of Missouri Columbia School of Medicine	9 23	Glucose Insul/Cpep	Frozen	25	20	10
University of Washington Immunology Division	10 13 19 47 75	Fibrin CRP/Hpylori Bn Alk Phos NTX PSA	Frozen	35	25	12
University of Cincinnati	60 61	F Lead Dust W Lead Dust	Room Temperature	5		
University of Minnesota School of Medicine	45	Alb/Creat	Frozen	25	20	10

Shaded = Verify correct assignment of container to FedEx airbill

10. QUALITY CONTROL AND QUALITY ASSURANCE - POLICIES AND PROCEDURES

National Health and Nutritional Examination Survey 1999-2004
National Center for Health Statistics
Centers for Disease Control and Prevention
Public Health Service
Department of Health and Human Services

Current revision: 4/1/01

Approval: _____ Date: _____
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Approval: _____ Date: _____
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Technical Supervisor, Westat

Abbreviations

NCHS - National Center for Health Statistics
CDC - Centers for Disease Control and Prevention
NHANES - National Health and Nutrition Examination Survey
MEC - mobile examination center
LPM - NHANES Laboratory Procedures Manual
U.S. - United States
CBC - complete blood count
IRB - institutional review board
QC - quality control
QA - quality assurance
IQAP- Interlaboratory Quality Assurance Program
PT - proficiency testing
CLIA - Clinical Laboratory Improvement Amendments of 1988
HCFA - Health Care Finance Administration
ISIS - Integrated Survey and Information System
PC - personal computer
LAN - local area network

This policies and procedure quality control and quality assurance chapter is an adjunct to the Westat Policies Manual.

10.1 Safety

10.1.1 Introduction

NCHS and Westat maintain an ongoing Health and Safety Committee that acts in cooperation with the CDC Office of Health and Safety to assure safe working conditions for technologists in the NHANES MEC. Safety precautions for all methods are documented in the Biosafety chapter in the *NHANES Laboratory Procedures Manual, 2001*. This manual is readily available to all laboratory staff. In addition to annual safety training, the NCHS Biomedical Engineer performs safety inspections at the beginning of each location. The technical supervisor assures that the primary laboratory analyst reads and is familiar with safety precautions.

10.2 Specimen Submission and Handling

10.2.1 Introduction

The goal of specimen submission and handling is to optimize the accurate and reliable measurement of analytes of interest. Each analytical procedure used in NHANES is documented in the *NHANES Laboratory Procedures Manual (LPM)*. Each method in the LPM specifies the procedure to be used for preparation of the sample person, specimen collection, labeling, processing, and preservation, and conditions for specimen transport that are appropriate for that method. The methods may refer to the NHANES blood collection protocol, or urine collection protocol, noting any special requirements specific to the particular method. These protocols are a starting point. This is due to the special contamination requirements needed for collection of specimens analyzed for metals.

10.2.2 Identification of Specimens

Personal identifiers (e.g., names) are not included on test specimens. NHANES uses a random internal specimen ID number to identify and track individual samples. The Integrated Survey and

Information System (ISIS) system at Westat and NCHS maintains information that links the specimen ID number to the sample person's name.

10.2.3 Questions on Specimen Submission and Handling

The Chief Medical Technologist addresses questions concerning specimen collection including handling and testing.

10.3 Test Requisition

10.3.1 Introduction

Under a congressional mandate since 1960, the National Center for Health Statistics (NCHS) has collected data on the health of the people of the United States through interviews and extensive physical examinations. As in previous NHANES programs, the survey's primary purpose is to produce descriptive statistics that can be used to measure and monitor the health and nutritional status of the civilian, noninstitutional U.S. population. Data collection for the entire survey of about 40,000 sample persons, of whom about 75 percent are expected to be examined, began in April 1999 and continues for about 6 years at about 90 locations (stands). NHANES performs a complete blood count on sample persons 1 year and older. A record of the test result report is maintained for a period of 7 years by Westat, the primary NHANES contractor, and by NCHS for an indefinite period.

10.3.2 Laboratory Tests

"Panic" or abnormally high CBC results are reported to the sample person. The report includes laboratory tests that will be performed. The NCHS Medical Officer or MEC physician involved in the measurement may also confer with the sample person to obtain any other pertinent information, which might facilitate the laboratory measurement process.

10.3.3 Human Subjects Review

The NCHS IRB as defined by the CDC institutional review board (IRB) criteria shall perform all laboratory analyses conducted on human specimens, which 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 sample person specimens and to report accurate test results. The laboratory test record system is distinguished from the test report that is provided to the sample person.

10.4.2 Components of Test Records

Test records include:

1. Person performing the test (may be identified by initials)
2. Printed or electronically stored output from instrumentation which the technical supervisor judges as necessary to document the analytical result
3. Date of specimen analysis
4. Date and time specimen was collected into the laboratory
5. Condition of specimens that did not meet criteria for acceptable specimens (e.g., hemolyzed or insufficient quantity for test)

Test records are maintained for at minimum of 7 years. Records may be bound in laboratory notebooks, in loose-leaf form, or stored electronically.

10.5 Test Report

10.5.1 Introduction

The laboratory report is provided promptly to the sample person. This occurs as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the sample person results since it identifies samples only by a specimen ID number. Westat and NCHS maintain the link between the specimen ID number and the identity of the sample person.

10.5.2 Review, Approval, and Release of Test Results

Upon completion of laboratory testing, results are reviewed by laboratory staff responsible for review of the quality control results to assure the measurement process was in-control for each of the sample person's analyses.

For NHANES surveys, the initial evaluation of QC results is accomplished electronically by comparing the QC results to QC limits stored in a relational database. The laboratory staff performing the CBC reviews these QC performance results and assures that only acceptable SP data is reported.

Review and approval of the results by the MEC physician are documented. Review by the MEC physician includes an evaluation of the consistency of sample person results with information that may be available on the sample person (e.g., age, sex). All SP's samples are run in duplicate, whenever possible. If inconsistent results are noted, and an adequate sample is available, the test is repeated a third time. If inconsistent results are again noted, the sample is run a fourth time. If the amount of sample is inadequate for repeat, then the sample person is informed verbally and in writing of the inconsistent result.

The paper hard copy of the results with the NCHS Medical Officer's signature is filed by Westat and kept with the test record for 7 years. The NCHS Medical Officer signs all laboratory reports before release.

Laboratory reports are released only to the authorized sample person. Each method includes a description of actions taken such as when results are markedly elevated or are "panic values." The sample person is contacted immediately by the MEC physician with such results.

In addition to the written laboratory report, the data may be transmitted electronically in a suitable format; for example, a SAS data set or an ASCII file by email to the Westat home office and to NCHS.

10.5.3 List of Methods and Method Details

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

10.5.4 Format of the Test Report

The test report includes:

- The name and address of NCHS
- The test result
- Units of measurement
- Reference range for each analyte, if available
- The condition of specimens not meeting the laboratory's criteria for acceptability
- Signature of the NHANES Medical Officer

The laboratory report consists of:

- 1st page: a cover letter
- 2nd page: an analysis summary table

A corrected laboratory report has the same format except the words "corrected laboratory results" replaces the words "laboratory results" in the letter and title of the pages. In addition, in the text of the cover letter, the date of the previous laboratory report is noted.

10.5.5 Format for Laboratory Report Cover Letter

An example of the Laboratory Report cover letter (report of findings) is available upon request.

10.5.6 Format for Listing of Laboratory Results

An example of the laboratory results is available upon request.

10.6 Quality Control

10.6.1 Introduction

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

Quality control in laboratory medicine is the study of those errors that are the responsibility of the laboratory, and the procedures used to recognize and minimize them. An alternate term, "quality assurance," represents the techniques available to ensure with a specified degree of confidence that the result reported by the laboratory is correct. Both "precision control," (the agreement between replicate measurements), and "accuracy control" (the agreement between the mean estimate of a quantity and its true value), are evaluated to establish this degree of confidence.

A quality control program also monitors laboratory performance to detect excessive random or systematic error. Factors contributing to random error are those that affect the reproducibility of the measurement. These include instability of the instrumentation, variations in the temperature, and variations in reagents and calibrators, handling techniques such as pipetting, mixing, and timing, and operators. Terms used to describe random error include precision, imprecision, reproducibility, and repeatability. Systematic error describes the error that is consistently low or high. Factors that contribute to systematic error are independent of the analyte concentration. Examples of these factors include interfering substances, or incorrect assignment of the amount of substance in the calibrator.

A good quality control program includes both internal (intralaboratory) and external (interlaboratory) surveillance and monitors the following five parameters:

- **Clerical Error:** This includes properly documented acknowledgment of transmittal and receipt of specimens (for example, "logging in"), proper labeling of all specimens, correct assignment of laboratory values to the proper SP ID number, and maintenance of proper records for all specimens for future reference.
- **Techniques:** This includes continued assurance that all personnel performing an assay understand the principles underlying a particular assay and are cognizant of the proper technique for that assay; that all personnel use the same technique for a particular assay; that there is ready access to a current technique manual; and that periodic review is undertaken to ensure use of the most current and reliable techniques.
- **Reagents and Materials:** This includes confirmation of commercial standards and controls before they reach the bench; proper labeling of reagents, particularly those prepared in the laboratory; insuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; proper calibration of equipment, such as pipettes; and proper washing of glassware.
- **Bench Performance:** This includes the use of controls and standards for each assay performed, a technique based on sound statistical principles, which allows the technologist performing the assay to detect error outside of previously determined limits before reporting data, and documentation of daily bench performance for detection of less obvious error (particularly those which tend to accumulate over time, so-called "drift"), and established procedures to be followed wherever error is found to exceed previously determined limits.
- **Instrumentation:** This includes periodic preventive maintenance of all instruments in use in the laboratory and documentation that each instrument is maintaining a previously determined level of each performance at each check.

In this context, quality control (QC) procedures monitor and evaluate the quality of the analytical testing process of each method to assure the accuracy and reliability of test results. Thus, QC procedures referenced here refer to the analytical phase of testing and not to the pre-analytic or post-analytic phases. Quality assurance (QA) addresses all three phases of measurement: pre-analytic, analytic, and post-analytic. QC is therefore viewed here as one part of the overall QA process.

10.6.2 Method Specific QC Procedures

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

10.6.3 QC Definitions

Internal ("Bench") Quality Control

For purposes of this document, internal quality control (QC) is the evaluation of analytical performance that includes QC bench samples for which the analyst knows the expected measurement result. Internal commercial quality control materials contain predetermined amounts of analyte in the matrix, qualify under Clinical Laboratory Improvement Amendments (CLIA) as "calibration materials," and may be used as a "calibration verification" as defined by CLIA.

- **External ("Blind") Quality Control** – For purposes of this document, external quality control is the evaluation of analytical performance that includes QC samples for which the analyst does *not* know the expected measurement result. The analyst is "blind" to the expected measurement result. Examples include proficiency testing samples.
- **Interlaboratory Quality Assurance Program (IQAP)** – For purposes of this document NHANES participates in Beckman Coulter's® IQAP program. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance.
- **Proficiency testing** – For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).
- **Analytical run (sometimes referred to just as a run)** – An analytical run is a set of samples analyzed in a time within which the measurement system is considered to have stable accuracy and precision. The time for a run may not exceed 24 hours. An analytical run usually consists of both quality control specimens and sample person specimens.
- **Calibration** – Defined by CLIA as "the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure."
- **Calibration material** – Defined by CLIA as "a solution which has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference or definitive test method." Many standards are therefore calibration materials.
- **Calibration verification** – Defined by CLIA as "the assaying of calibration materials in the same manner as sample person samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for sample person test results."
- **QC Requirements of each Analytical Run** – Analysis of sample person samples is organized into analytical runs. The minimum QC requirement for an analytical run,

which is analyzing sample person specimens, is that the run includes four internal ("bench") QC specimens.

10.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC

A Beckman Coulter® technical representative performs instrument setup, verification, and performs and verifies QC checks according to their procedure at the beginning of each stand. Medical technologists perform instrument calibration.

Most laboratory quality control programs include running internal ("bench") QC with each analytical run to assure each analytical run is in control. The X_b analysis is a QC method monitoring instrument performance. In addition, the laboratory participates in proficiency testing programs administered by an outside scientific group to be sure on a periodic basis that accuracy and precision are within acceptable limits. The IQAP compares NHANES 5C cell control results to other laboratories. These QC systems are used within NHANES. The linearity of the instrument is evaluated at least once a year.

In addition to these systems, NHANES uses calibration materials at the beginning of each stand to standardize the three Beckman Coulter® MAXM instruments and to provide additional objective evaluation of the quality of specimen analysis. S-CAL is a calibration material as defined by CLIA (i.e., "a solution, which has a known amount of analyte, weighed in or has a value determined by repetitive testing using a reference or definitive test method") that is useful for monitoring method performance.

10.6.5 Internal ("bench") QC

The goal of internal QC is to provide a rapid feedback to the analyst on the performance of the measurement process to be sure analytical results and factors affecting analytical results are within acceptable limits. At least three internal QC specimens (5C® Cell control) are included in each analytical run. The QC material used as internal QC specimen has levels of the analyte, which are useful for monitoring method performance.

The 5C® Cell Control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. The 5C® cell control consists of

human blood so repeated measurements to monitor daily performance of the instrument system is possible. 5C® Cell Controls Tri-Pack contains 3 levels, normal, abnormal I, and abnormal II. When used with Beckman Coulter's® blood diluent, Isoton III, they serve as a check on the accuracy of dilution, WBC counts, RBC counts, platelet counts, hemoglobin determinations, and differential counts.

Run all three levels at the beginning of each session to monitor the precision of the instrument following procedures described in Chapter 7, Section 7.9.

Standard Levy-Jennings QC charts are maintained for this internal QC specimen. A separate QC chart is to be maintained for each QC material used for this internal QC specimen. Standard criteria for run rejection based on statistical probabilities are used to declare a run either in-control or out-of-control. No results for a given analyte are reported from an analytical run that has been declared out-of-control for that analyte as assessed by internal ("bench") QC. Rejection criteria are described in each method procedure in the LPM. Quality control results and remedial actions for out-of-control conditions are documented in a QC logbook.

In addition, a latex control (Latron®) is used to monitor the volume, conductivity, and light scatter (VCS) of the diff mode only. This control is run at the beginning of each day.

The Latron® control is a ready-to-use suspension of latex particles used to monitor differential parameters on the Beckman Coulter® MAXM. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter. Use the Latron® control immediately following the Latron® primer.

10.6.6 Interlaboratory Quality Assurance Program (IQAP)

All MAXM instruments participate in Beckman Coulter's® Interlaboratory Quality Assurance Program (IQAP.) The Beckman Coulter® Data Management System saves results of 5C® cell controls in files. Technologists transfer the files to a disk and then send the disk to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure on the last day of each month, at the end of each stand, or when a control lot expires using procedures described in Chapter 7, Section IX.

10.6.7 Proficiency Testing

Participation in the College of American Pathologist (CAP) proficiency-testing program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

The laboratory will satisfactorily participate in the HCFA-approved PT program for each method used to analyze human samples. Performance in the PT program, along with documentation of remedial action taken for unacceptable performance, is documented in a QC logbook that is available for review.

CAP samples are sent three times a year for hematology. Each shipment includes five 2.5-mL whole blood specimens. Duplicate Beckman Coulter® CBC determinations are performed on each whole blood sample using procedures described in Chapter 7, Section XI. PT samples are handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS.

CAP samples are sent three times a year for qualitative serum hCG. Each shipment includes five lyophilized sera specimens. PT samples are handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS at the following address:

Brenda Lewis, MPH
National Center for Health Statistics
Room 900
6525 Belcrest Road
Hyattsville, MD 20782

10.6.8 Calibration Verification

Calibration verification is defined by CLIA as "the assaying of calibration materials in the same manner as sample person specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for sample person test results." Thus, calibration verification assures that the accuracy of the measurement process across the reportable range is maintained over time. For methods approved by FDA, calibration verification is performed according to the manufacturer's specification and at the frequency recommended by the manufacturer.

Note that the calibration materials must bracket the reportable range; i.e., results should not be reported as a numerical value unless they are within the reportable range. If a result is higher than the upper end of the reportable range and the method permits sample dilution, the sample may be diluted to bring it within the reportable range. If dilution has been necessary, the reported value will exceed the upper end of the reportable range. Each analytical procedure specifies acceptable limits for results of analyses of the calibration materials based on the method precision of these materials.

The reliability of analytical values obtained when using a procedure often depends on the quality of the standards and the calibration procedure. The College of American Pathologists (CAP) suggests that automated instruments be calibrated using multiple analytical whole blood specimens or a certified, stabilized whole-blood type preparation. The International Committee for Standardization of Hematology (ICSH) by its definition requires that a calibrator "be based on or traceable to a reference preparation or material."

Beckman Coulter® provides the S-CAL® calibrator to meet these requirements. The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the WBC, RBC, Hgb, MCV, Plt, and MPV parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration. Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give an Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

S-CAL® is used to calibrate the Beckman Coulter® MAXM at the beginning of each stand (once every 6-8 weeks), after replacing any component dealing with dilution preparation, if the Beckman Coulter® representative suggests it, controls demonstrate unusual trends or are outside limits, or when the temperature varies by more than 10°F (5.5°C) from the room temperature during the last calibration.

Instructions for the performance of calibration procedures using S-CAL® calibration are in Section VII of Chapter 7.

10.6.9 X_B Analysis

X_B analysis is a QC method that monitors instrument performance by tracking the MCV, MCH, and MCHC parameters of SP's samples. These indices are very stable and show little variance between patient samples. This method displays the moving average of SP's samples and compares it to established target values. Target values are MCV = 88.5 (fL), MCH = 29.5 (pg), and MCHC = 33.5 (g/dL or g/100 mL). Review and print the X_B current batch at the beginning on each session when printing the 5C Cell control results. Review, print, file, and delete the Batch Means at the beginning of each week when performing the weekly laboratory QC and at the end of each stand. Evaluate the percentage difference from the target limit to determine whether the batch is in or out of control. Refer to the troubleshooting section of the Beckman Coulter® manual if the batch is out of control.

10.6.10 Linearity

The linearity controls verify the reportable range of Beckman Coulter® hematology systems. Linearity is performed at installation, at least yearly, and whenever experiencing an altitude change of 1 mile or more between locations using either Beckman Coulter® Lin-C™ or CAP LN9 survey material.

Beckman Coulter® Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent. Controls contain one each of Ultra Low Range, Low Range, Mid Range, and High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt. Beckman Coulter® Lin-C™.

CAP Hematology Calibration Verification/Linearity Survey (LN9) materials are shipped twice per year and consist of 18 3.0-mL liquid specimens. The medical technologist follows all CAP instructions in preparing and running the materials before performing the test. They fill out the CAP result form, make a copy for the logbook, send results to CAP, and send the copy back to the home office at the end of the stand.

10.6.11 Quality Control Records

Records of all quality control results are maintained for at least 7 years. A QC logbook is maintained which documents quality control results, out-of-control conditions, and remedial actions taken to correct out-of-control conditions. The QC logbook also includes copies of results for Proficiency Testing.

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

10.7.1 Introduction

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the method. The documentation of individual analytical procedures included in the *Laboratory Procedures Manual* (LPM) specifies acceptable equipment, reagents, materials, and supplies. If special requirements concerning water quality, temperature, humidity, electrical power, or other conditions are required for acceptable method performance, then these are described for each procedure in the LPM. Special procedures to monitor these requirements are also included in the documentation of the individual procedure. A lack of requirements in the documentation of the analytical procedure means that the expected day-to-day variation in any of these parameters is acceptable for proper method performance.

Documentation of problems with conditions required (e.g., water quality) for acceptable method performance is maintained in the logbook of the primary instrument used in the analysis. This documentation includes remedial action.

10.7.2 Labeling of Reagents, Solutions, Supplies

Reagents, solutions, and other supplies are labeled to indicate the identity of contents, the concentration (if significant), the recommended storage requirements, the preparation and expiration date, and any other pertinent information required for proper use. Reagent, solutions, and other supplies are not used when they have exceeded their expiration date.

If a method uses a manufacturer's kit, components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

Beckman Coulter® reagents are monitored and documented in the Beckman Coulter® Data Management System and are additionally located on the daily instrument startup result sheet. A copy of all startup results is filed in the quality control notebook. Document any unusual occurrence or repair of the Beckman Coulter® MAXM on the Unusual Occurrence Log.

Maintain logs for reagents other than the Beckman Coulter® reagents. Document reagent use by entering the reagent's name, date made, date put into use, expiration date, and tech ID on the Supply Use Control Log. Send these logs back to the home office at the end of each stand.

10.7.3 Facilities

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

10.8 Analytical Procedure Manual

10.8.1 Introduction

All procedures performed in the laboratory on human specimens are documented in the *Laboratory Procedures Manual* (LPM). A copy of the LPM is maintained at the Westat home office and NCHS. The individual procedure is also available at or nearby the bench site where the procedure is performed.

10.8.2 Contents of the Analytical Procedure Documentation

Each analytical procedure includes, when applicable:

- Requirements for specimen collection and processing including criteria for specimen rejection
- Step-by-step performance of the procedure including test calculations and interpretation of results
- Preparation of reagents, calibrators, controls, solutions, and other materials used in testing

- Calibration and calibration verification procedures
- The reportable range for sample person test results
- Quality control procedures
- Remedial action to be taken when calibration or control results are outside acceptable limits
- Limitation in methods, including interfering substances
- Reference range (normal values)
- Life-threatening or "panic values"
- Pertinent literature references
- Specimen storage criteria
- Protocol for reporting panic values
- Course of action if test system becomes inoperable
- Safety considerations for performing the method

10.8.3 Approval and Record Maintenance

Each procedure is reviewed, approved, signed, and dated by the Clinical Consultant and Technical Supervisor and Laboratory Director of NHANES. Procedures are reapproved, signed, and dated if the Director changes. Each change in a procedure is approved, signed, and dated by the current Director. The procedure includes the dates of initial use and discontinuance, if discontinued. The procedure documentation is maintained for 7 years after discontinuance of the method.

10.8.4 Method Performance Specifications

Method performance specifications for each analytical method is established or verified:

- Accuracy - accuracy of each analytical method will be determined by analysis of calibrators, X_B analysis and yearly linearity checks as described in the section of the LPM on quality control.
- Precision - precision of each analytical method is determined by analysis of QC reference materials as described in the section of this manual on quality control.

- Analytical specificity - analytical specificity is determined for each method including effects of potential interfering substances. This may be verified by testing the effect of potential interfering substances in method development, by analyzing reference materials, by comparing results on split samples with a method considered more definitive, and/or by analyzing a sample of persons ($n > 20$) and examining the measurement output searching for interference. The appropriate procedures for verifying analytical specificity will vary by analytical method. Substances, which interfere with the analysis in the reportable range, are listed in the method procedure.
- Reportable range of test results - the reportable range of test results is described in the documentation of the analytical procedure.
- Reference range (normal range) - if available, the reference range of test results is described in the documentation of the analytical procedure and on the test report.
- Other pertinent performance specifications - other performance specifications that are required for adequate method performance are specified in the documentation of the analytical procedure.

10.9 Equipment Maintenance and Function Checks

10.9.1 Introduction

Laboratory equipment is checked regularly to assure acceptable performance. Maintenance (including preventive maintenance) and function checks are documented in ISIS. The frequency of maintenance and function checks follows manufacturer's recommendations, when available. Manufacturer's recommendations are included in the manuals that are located in notebooks in the laboratory.

Each analytical procedure outlines the equipment maintenance and function checks for proper method performance and acceptable results from the checks. These checks must be made at the interval specified in the documentation of the procedure. Failure of a function check is documented in the Unusual Occurrence Log.

10.9.2 Temperature Monitoring

Temperature recordings are required for storage and preservation of reagents and sample material (analytical specimens), as well as quality control and reference materials.

Beckman Coulter® and Vacutainer have recommended the following storage conditions for reagents and tubes. Quality control temperature ranges have been established based on these recommendations.

Reagent	Manufacturer's recommended storage conditions	Established range
Coulter® reagents Isoton Coulter Clenz Scatter Pack Lyse-S III	2-25°C (36-77°F)	17-25°C (63-77°F)
S-Cal at room temperature	16-32°C (60-90°F)	17-25°C (63 to 77°F)
S-Cal at refrigerated temperature	2-8°C (35-46°F)	2-8°C (36 to 46°F)
Latron	2-30°C (36-86°F)	17-25°C (63 to 77°F)
5C Cell Control	2-8°C (36-46°F)	2-8°C (36 to 46°F)
Vacutainers	Not greater than 77°F	17-25°C (63 to 77°F)

The following ranges have been established for monitoring instrument quality control.

Instrument	Manufacturer's instrument range or limit	Established range
Beckman Centrifuge (Refrigerated)	-5 to +25°C (23-77°F)	2-8°C (36 to 46°F)
Beckman Centrifuge (Room temperature)	-5 to +25°C (23-77°F)	17-25°C (63 to 77°F)
Jewett Freezer	-8.9°C (16°F) Limit	-18 to -23°C (0 to -10°F)
Jewett Refrigerator	2-5°C	2-8°C (36 to 46°F)
LFBS	0.450	0.350 to 0.550
Phlebotomy Refrigerator	None	2-8°C (36 to 46°F)

Two thermometers monitor ambient temperature in the laboratory and one thermometer monitors ambient temperature in the phlebotomy room. The allowable temperature range for these rooms is 17-25°C (63 to 77°F).

The acceptable temperature range for refrigerators used for storage of CLIA-regulated specimens and reagents is 2-8°C and is checked and recorded daily. If temperatures are recorded automatically on a continuous monitoring system graph, the individual's initials are captured.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. All freezers are monitored automatically by built-in visual systems (with

thermographic or digital reading). The range of allowable temperature is –18 to -23°C. If this range is exceeded, the technologist contacts the MEC manager.

A separate automated continuous Sensaphone 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 designed staff. The MEC managers and data managers 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 or a compressor malfunction or failure. 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 MEC manager.

10.10 Calibration and Calibration Verification

10.10.1 Introduction

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

10.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites

At least once every 6 to 8 weeks, each of the three instruments is calibrated with S-Cal.

10.11 Remedial Actions

10.11.1 Introduction

Remedial actions are taken and documented when:

- Test systems perform outside acceptable performance specifications. Remedial action is documented in the appropriate QC manual.
- Results of control materials and calibration materials fail to meet quality control criteria. Remedial action is noted in the appropriate QC logbook.
- The laboratory cannot report sample person test results within its established period. If the reporting of data will exceed the agreed upon time frame, the MEC and final Report of Findings indicate that test results are not available.
- Errors in the reported SP test results are detected. When errors are detected in the reporting of sample person results, the MEC physician notifies the sample person by phone, followed by the issuance of a corrected report within a time period suitable to the sample person, but not to exceed 1 week. The corrected report clearly shows the corrected results in the title. Exact duplicates of the original as well as the corrected report are maintained for 7 years.

10.12 Integrated Survey Information System (ISIS)

10.12.1 Introduction

One of the purposes of the ISIS is to store sample person results for retrieval in a period acceptable for the intended use of the data. Sample person test results are stored in a database. The ISIS consists of the PC databases used for storing sample person results. This form for the ISIS facilitates the interfacing of varied and complex instrumentation used in many of the analytical procedures. The MEC LAN hardware serves as the hardware for the ISIS. The identification of the sample person result will be by specimen ID number and the result is accessible by this number.

The minimum amount of data stored for each analytical result is the specimen ID number, the analyte name, and the measured result. If the specimen ID does not provide sufficient information to relate the measured result to the QC data for the run, then the run number and run date must also be stored. The specimen ID, run date, and run number should be sufficient information to relate the measured result to the quality control information for that run. Access to the ISIS database is password protected so that only the persons authorized by Westat and NCHS may access the data.

10.12.2 Integrated Survey and Information System Data Down Times

Each laboratory method is able to run and temporarily store results even if the MEC LAN is inoperable.

10.12.3 Maintenance of LAN Hardware

After failure of a LAN component, ISIS should be able to be repaired or replaced within a day by a functioning component. LAN hardware is almost totally readily available. PC components and the infrequent problems with this hardware are readily correctable in this period. Westat participates in the standard service contract arranged for NHANES for service of failing or failed computer equipment.

10.12.4 Backup Schedule of Integrated Survey and Information System Data

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

10.13 Communications and Complaints

10.13.1 Introduction

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

Similarly, complaints of laboratory performance are carefully considered. Usually, these complaints are fixed with minor adjustment or explanation. Each member of the laboratory staff is responsive to complaints that have merit and relate to her/his responsibilities. Nontrivial complaints are

reported to supervisors who will decide appropriate actions, including investigation and remedial action. The technical supervisor maintains documentation of nontrivial complaints concerning laboratory performance that are reported to her or him.

10.14 Quality Promotion

10.14.1 Introduction

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

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

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

10.15 Quality Assurance Program

10.15.1 Introduction

The goal of the NHANES Quality Assurance Program (QAP) is to monitor and evaluate the overall quality of the testing process including pre-analytic, analytic, and post-analytic phases.

The initial database and reporting system design included the following requirements:

- All data are released in a timely manner relative to its intended use. All CBC results are provided to the SP in a preliminary Report of Findings when the SP checks out of the MEC. If the results are not available by the time the SP checks out of the MEC, they are reviewed by the MEC physician as soon as they are available and the SP is notified by phone of any abnormal results. A hard copy of the CBC results 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 enough blood drawn to test." In the case where no results were transmitted, the preliminary or final Report of Findings states, "Not Done."

- The preliminary and final Report of Findings are ISIS generated and are based on results in the database; they are not predefined reports stored in the system. The format for the English and Spanish preliminary and final Report of Findings is tested annually to determine if the generic format is legible.
- The preliminary and final Report of Findings format includes reference ranges, units of measure, or notation for inadequate specimen. Sample preliminary and final English and Spanish Report of Findings are printed and the format is tested annually.
- NCHS is responsible for sending the final Report of Findings to each survey participant. Mailing labels are printed, the mailing label is matched to the final Report of Findings, and the final Report of Findings is inserted into the envelope. NCHS monitors communications from SPs who report that they have received the incorrect Report of Findings.
- All results are generated based on results stored in the database. The ISIS system prohibits the MEC technologist from changing data in the database after the SP has checked out of the MEC or if the MEC Report of Findings has been printed. All subsequent copies of results should match the original results. If any result is ever changed in the database, a back-end editing request system form is submitted, tracked, and maintained by ISIS.
- A comprehensive security system guards against unauthorized access. A complete description of this system is maintained by and is available through NCHS.

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

10.15.2 Quality Audit: Sample Person Test Management

The quality audit for sample person test management is conducted at least yearly and consists of:

- A survey of the laboratory staff, and of the analytical procedures used in NHANES. The survey includes requests for information on:
 - Any changes which need to be made in sample person preparation, specimen collection, labeling, preservation, and transportation
 - Any changes which need to be made in completeness and relevance of sample person information obtained at the time the specimen is acquired, and the use

and appropriateness of specimen rejection criteria based on their experience and interactions with persons requesting the tests

- Laboratory-reporting errors encountered since the last survey
- Whether the performance of the Integrated Survey and Information System (ISIS) is adequate for their measurement systems
- Nontrivial complaints from outside the laboratory about performance of the lab

The technical supervisor and laboratory director assess the results of the audit and in consultation with Beckman Coulter® implement corrective actions that are warranted.

10.15.3 Quality Audit: Quality Control

Quality control addresses the analytic phase of measurement. The purpose of the internal ("bench") quality audit is to assure that the QC analyses were performed and appropriate actions were taken when out-of-control conditions occurred. The quality audit of quality control shall be conducted at least yearly by technical supervisor and laboratory director and shall consist of:

- A review of a random 10 percent sample of 5C Cell and Latron control results. The review evaluates whether appropriate corrective action was performed and documented for out-of-control conditions.
- An analysis of the proficiency testing results. The analysis and review will assess PT performance and if unsatisfactory, whether the deficiencies have been adequately addressed. The technical supervisor and laboratory director compare results to determine the correlation coefficient. This correlation must be greater than 0.95 or the laboratory director may give written approval that the methods are sufficiently similar for the intended use of the data.
- The review of documents that demonstrate that at least once every 6 to 8 weeks S-Cal calibrator was run on three instruments.

The technical supervisor and laboratory director assess the results of the audit and in consultation with Beckman Coulter® implement corrective actions that are warranted.

10.15.4 Quality Audit: Personnel

Well-trained and competent personnel are essential components of good laboratory performance. The quality audit of personnel is conducted at least yearly by the technical supervisor and laboratory director and shall consist of:

- A review of the 5C Cell and Latron control ("bench") results or IQAP QC results for 10 percent of the total control runs covering a period of not less than one year. The internal ("bench") QC reflects the performance of persons performing the method. If out-of-control conditions occur with a frequency more than twice the expected statistical probability (e.g., 95% control limits would normally be exceeded by 5% of the analytical runs), the technical supervisor and laboratory director will assess whether the unacceptable performance is due to the performance of the person in question or other factors (e.g., failing equipment). If the personnel performance is the cause, the technical supervisor and laboratory director determine and implement appropriate remedial action (e.g., training).
- A review of all remedial action since the last audit to assess the effectiveness of the action. Acceptable performance of the method by the person involved for 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 first year performing a new method). The evaluation criteria are described in the Personnel Training and Evaluation section of the Laboratory Procedures Manual (Chapter 10, Section 10.16).

The Technical Supervisor maintains documentation of the results of the audit.

10.15.5 Quality Assurance Review with Staff

The technical supervisor and laboratory director prepare a report of the results of quality audits within 3 weeks of the completion of the audit. The technical supervisor and laboratory director review pertinent information with appropriate staff to assure effective remedial actions are taken. The technical supervisor and laboratory director also notify staff members who have been involved in the audit if performance was acceptable and no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

10.16 Personnel Training and Evaluation

The technical supervisor assures that persons performing laboratory tests receive appropriate training. The performance of persons performing laboratory tests is evaluated every 6 months for the first year testing is performed and annually thereafter. The evaluation shall consist of:

- Direct observation of test performance including sample person preparation (if applicable), specimen handling, specimen processing, and testing

- Direct observation of the recording and reporting of test results
- Review of QC results, IQAP, PT, Xb analysis, and linearity results and preventive maintenance records
- Direct observation of performance of instrument maintenance and function checks
- Assessment of testing performance using blind QC materials
- Assessment of problem-solving skills

The technical supervisor maintains documentation of the evaluations for at least 7 years. If remedial action is warranted, the technical supervisor shall discuss the results of a personnel evaluation with the person evaluated and implement appropriate action (e.g., training).

11. OPERATIONAL ISSUES

11.1 Start of Stand Activities

The Westat warehouse manager sends supplies for all stands and schedules shipments so that they arrive on set-up day and ships supplies requiring refrigeration so that they arrive the day before set up. Store laboratory supplies in the laboratory cabinets or in MEC trailer compartments.

The advance arrangement staff may assist in completing some set-up activities. On set-up day the phlebotomist, medical technologists, and home examiners work together to complete all activities. These activities include assisting in unpacking the warehouse pallets and boxes, sorting the laboratory supplies by storage location, inventorying all existing and new supplies, organizing and storing all inventoried supplies in MEC cabinets or trailer compartments, and setting up each work area by stocking the area with appropriate supplies. Medical technologists and phlebotomists perform maintenance on all instruments and equipment, and test equipment functions. Notify the MEC manager if additional supplies are required. Document all instrument and equipment malfunctions in the Unusual Occurrence Log.

Mark and store miscellaneous hardware in a safe location in the laboratory until the end of stand. Hardware includes wood blocks with Velcro, refrigerator and freezer bottle caps, temperature-recording pen protectors, restraining straps, wood boards, and carpeted counter supports and straps for the Beckman Coulter® MAXM instrument and printer.

Phlebotomy Room

- Phlebotomist
 - Inventory consumables and non-consumables.
 - Check the sink for hot and cold running water and proper drainage.
 - Remove the wood door and drawer blocks from the refrigerator and store for reuse at the end of the stand.
 - Turn on the refrigerator.
 - Verify refrigerator's operation.
 - Check the function of the telephone intercom.
 - Clean the refrigerator.

- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Record all lot numbers and expiration dates in the Supply Use Control Log.
- Check the computer operations.

Laboratory

- Medical Technologists and Home Examiners
 - Inventory consumables and non-consumables.
 - Check the sink and eyewash for cold running water and proper draining.
 - Check telephone operation.
 - Check the wall thermometers for damage.
 - Remove the wood door blocks from the refrigerators and freezers and store.
 - Replace the freezer and refrigerator temperature probe solid bottle caps with the caps with holes and save solid caps for reuse at the end of the stand.
 - Place the temperature probes back into the bottles.
 - Turn on or plug in the refrigerators and freezers.
 - Verify freezers and refrigerator operation.
 - Reconnect the batteries inside the temperature recording units.
 - Change temperature-recording charts, check pen ink and save the black pen protector for use at the end of the stand.
 - Check light, blowers, and magnehelic pressure gauge reading in the LFBSC.
 - Release the Beckman Coulter restraining straps, remove the wood board, detach the bolted carpeted counter supports and store the straps, wood board and counter supports until the end of the stand.
 - Remove the restraining strap on the Beckman Coulter® printer and store the straps until the end of the stand.
 - Contact Beckman Coulter® at 1-800-526-7694 to schedule instrument verification by a service technician. Provide the current address and instrument system ID.
 - Perform all Beckman Coulter® beginning of stand operations as described in Chapter 7, Section VIII.F. This includes installing and priming all new

reagents, performing a start-up procedure, and reviewing and verifying the system set up.

- Calibrate the Beckman Coulter® MAXM. Complete the calibration before performing routine CBCs on SPs.
 - Refrigerate the serum and urine pregnancy controls, and Beckman Coulter® Latron and 5C Cell controls as soon as they arrive.
 - Clean all work surfaces and storage areas.
 - Stock and organize supplies.
 - Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC.
 - Perform centrifuge maintenance.
 - Open all new containers using the laboratory application and label the containers.
 - 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.
 - Verify that the biomedical engineer entered the centrifuge readings.
 - Call FedEx to check availability (1-800-463-3339).
- NCHS Biomedical Engineer
- Determine the rpm of the centrifuges using a strobe or tachometer and performing a timer check.
 - Verify that both centrifuges are operating at 4-8°C. Fill two 15-mL red top Vacutainer® tubes with water, load and balance the aerosolve buckets, run the centrifuge at 4-8°C for 10 minutes, and immediately place the dial thermometer into the water. Record the results on a piece of paper and tape the paper to the workstation 2 terminal. Enter the results in the Laboratory QC module.

11.2 End of Stand Activities

For security reasons, lock all needles in the cabinet each day after examinations are complete. Turn off the centrifuges. Sign off from all computer terminals.

At the end of a stand, shut down all equipment and inventory all supplies. On teardown day the phlebotomist, medical technologists, and home examiners (if available) work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Lock all cabinets and drawers or secure with Velcro straps. Safely discard all biohazardous waste.

Packing Phlebotomy Room

- Phlebotomist
 - Inventory all consumables and non-consumables.
 - Turn off and clean the refrigerator in phlebotomy.
 - Place wood blocks with Velcro strips on the refrigerator door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
 - Pack the juice and crackers in labeled plastic boxes and store them in the MEC.
 - Pack and ship (to the warehouse) all unopened VOC canisters.
 - Remove all loose supplies (clock, telephone handset, etc.) and equipment from the counter tops; pack loose supplies in boxes and label "Phlebotomy Room." If possible, place the boxes in the cupboards above the counter, under the bench, or in the corners on the floor in phlebotomy. If these areas are full, place the boxes in the designated compartments under the trailers. Do not store Vacutainer® tubes in these trailer compartments.
 - Lock the wall arm boards.
 - Bolt the room door in the open position.
 - Close all cabinets and lock them or secure with Velcro strips.
 - Place a dowel through the drawer handles or secure with a stretch cord.

- Lock all needles in the cupboards or in compartments under the MEC.
- Lay the phlebotomy cart on its side on the floor.

Packing the Laboratory

- Medical Technologist and/or Home Examiners
 - Inventory consumables and non-consumables.
 - Perform the Beckman Coulter® end of stand procedures as described in Chapter 7.
 - Review, print, and clear the error file.
 - Download the IQAP files.
 - Print DMS database.
 - Print Latron and 5C Cell control cum statistics (files) and graphs.
 - Print X_B means and graph.
 - Perform daily shut down.
 - Bleach the apertures and flow cell.
 - Bleach, rinse, and drain reagent lines.
 - Turn off the power.
 - Rinse exterior of the BSV.
 - Wash exterior of the instrument.
 - Dispose of all opened reagents. Save the empty Isoton® III container for a waste container at the next stand.
 - Check the expiration dates on the Beckman Coulter® Latron, Beckman Coulter® 5C Cell control, pregnancy test kit, and pregnancy controls. If unopened and they will not expire before the beginning of the next stand, pack them in a shipper with refrigerant packs, print a label using FedEx Ship, and ship back to the warehouse.
 - Unplug the refrigerators and freezers.
 - Clean refrigerators and freezers.
 - Replace the freezer and refrigerator temperature probe bottle caps (with holes) with the bottle caps without holes and save the caps with holes for reuse at the start of the next stand.

- Place wood blocks with Velcro strips on each refrigerator and freezer door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
- Remove the temperature recording charts and send to the home office. Store the pen arm in the “Change chart” (#3) position. Replace the black pen tip protectors.
- Disconnect the batteries inside the temperature recording units.
- Unplug the LFBSC.
- Close and lock centrifuge lids and turn off centrifuges.
- Pack all tube rockers securely in boxes or in drawers.
- Remove all small supplies from the counters and LFBSC and pack in boxes or cabinets.
- Close all cupboards and secure with Velcro strips.
- Remove the fire extinguisher from the wall and lay inside the laboratory sink.
- Clean all counters, the LFBSC, and equipment with 1:100 bleach solution.
- Place chairs upside down or lay them down on the floor.
- Attach Beckman Coulter’s bolted carpeted supports to the counter. Secure the Beckman Coulter® by laying the wood board across the top of the instrument and tightening the straps. Place foam blocks behind the instrument. Place a strap around the bottom front of the instrument. (Do not apply too much pressure.)
- Secure the Beckman Coulter® printer by strapping it to the printer shelf.

Sending Laboratory Files and Supplies

At the end of each stand, use FedEx Ship to create a label to send the following hard copy documentation to the technical supervisor at the home office:

- Temperature recording charts
- Beckman Coulter® Start Up printouts
- Beckman Coulter® Latron and 5C Cell Control printouts
- Calibration printouts
- Linearity printouts

- X_b means and graphs printouts
- Latex CBC/Diff cumulative statistic and graph printouts
- Error file printout
- Proficiency testing copies (hematology and serum hCG)
- Unusual Occurrence Log(s)
- Supply Use Control Log(s)
- Lead dust transmittals
- Dry ice receipts (at the discretion of the MEC manager)
- Biohazard receipts (at the discretion of the MEC manager)

At the end of each stand use FedEx Ship to create a label to send the following supplies to the warehouse supervisor:

- Unopened VOC canisters
- Unopened pregnancy test kits
- Unopened pregnancy urine controls – refrigerated
- Pregnancy serum controls - refrigerated
- Unopened Coulter® 5C Cell and Latron controls – refrigerated

Pack supplies using procedures described in Chapter 9.

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.

- Verify the correct counting
- Enter only one name in the “Counted By” field. This is the person responsible for taking and verifying the inventory count.
- Do not write any notes, comments, etc. on the count sheet. Only write one name in the “Counted By” field and place a number in the “Count” box. Do not redefine or reiterate the Unit of Measure. Address questions to the MEC manager.

- Do not count partial units; record whole numbers only in the “Count” field.
- If the PAR for an item is more than one and the box or container is open, do not count that container.
- If the PAR for an item is only 1 unit and it is more than ½ empty place a 0 in the count unit.
- Lot #'s and expiration dates – all applicable active lot #'s and expiration dates are included on the count sheets. If there is a lot # and expiration date put a count (even if it is 0) in this field. Use items with older expiration dates first.

Start of Stand Counting Procedures

- Verify the End of Stand Count and the Ship to Stand amount to ensure that the component is now at or above PAR level. Address any concerns to the MEC manager.
- Restocking Supplies – Use items on hand in the rooms and items in the belly compartment first. Many items such as gloves, alcohol prep pads, electrodes, etc. deteriorate over time.

Consumables vs. Non-Consumables

Inventory items are broken out into two categories – consumable and non-consumable. Inventory both types of items at the end of each stand. The definition for a consumable item is anything that is typically consumed during an examination. Whereas some items may be used (consumed) in case of emergency, these are still considered non-consumables since they are not typically consumed during the course of an exam.

Shipping Excess Inventory Back to the Warehouse

When shipping excess inventory back to the warehouse, use the “Transfer Inventory to Warehouse Manifest” which is found on the IntraWeb. The MEC manager or data manager have the ability to access and print this form. This form looks similar to the “End of Stand Count Sheets.” Enter one name in the “Count By” field and indicate next to each item how many units are being shipped back to the warehouse. The warehouse manager enters this information into the system, which adjusts the stand inventory and usage information as well as increases the warehouse inventory counts.

Tracking of Expired and Broken Inventory

Complete a “Delete Expired/Broken Inventory Report” whenever inventory has expired and must be destroyed or has broken and is no longer usable. Locate this report on the IntraWeb, complete, and forward it to the warehouse manager so that he or she can remove the expired or broken inventory from the stand inventory.

DO NOT BORROW ANY SUPPLIES FROM ANY OTHER COMPONENTS – Usage is tracked by stand and inconsistencies and trends are tracked by tech. Everyone is accountable for his or her component counts.

REMEMBER – everyone is responsible for ensuring that there are enough supplies to perform an exam. Notify the MEC manager as soon as possible if additional supplies are required.

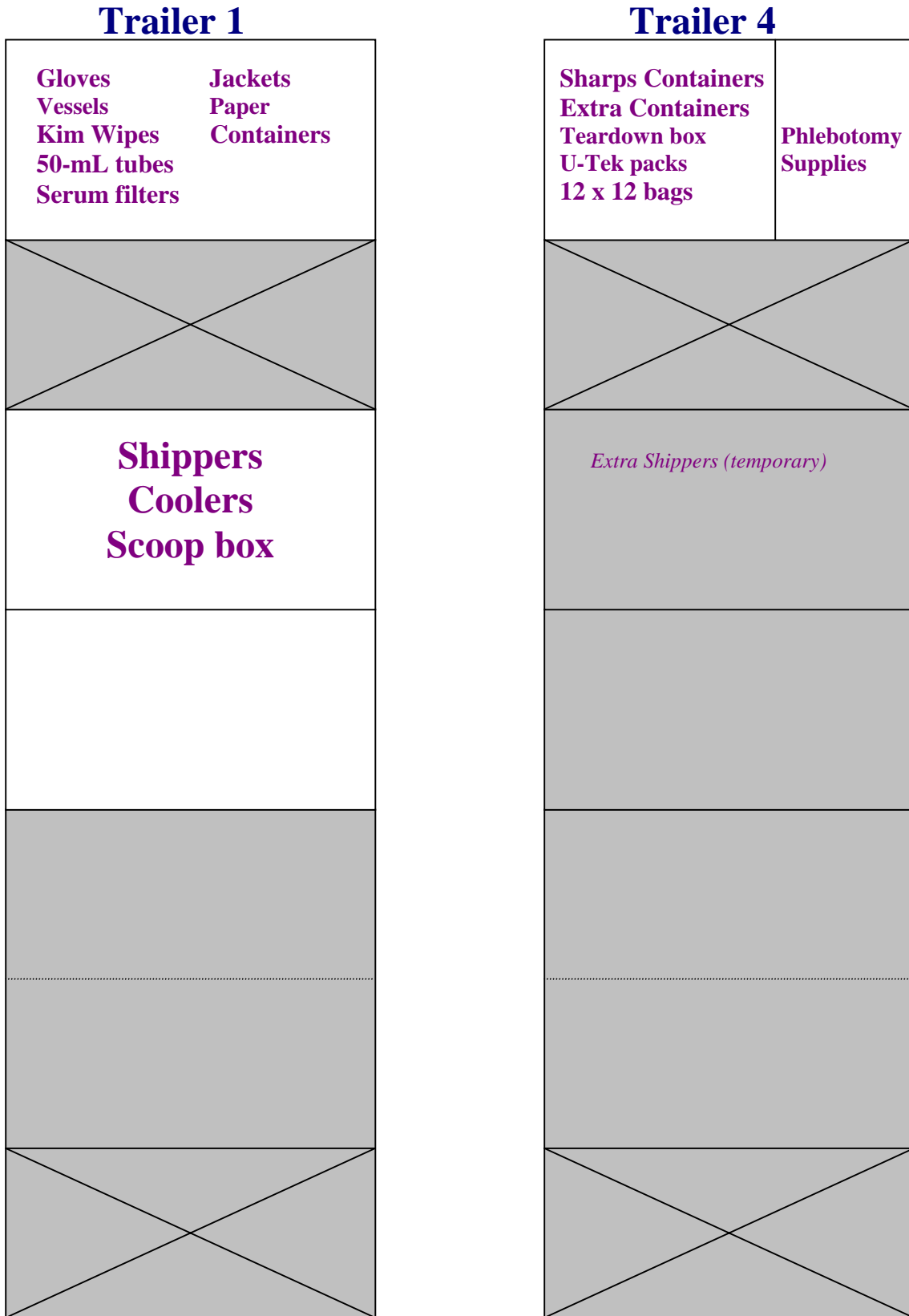
The equipment and supplies used as part of quality assurance/quality control are listed in Exhibit 11-1.

Exhibit 11-1. Equipment and supplies

Three Jewett freezers UCF5BH	Two Jewett refrigerators UC5B
Two Beckman Coulter GS 6R centrifuges	Five Jewett temperature monitoring units 8ER-1B
Two Thermolyne Vari-Mix M48700	Laminar flow biological safety cabinet
One Revco refrigerator (phlebotomy)	One Thermolyne Speci-Mix (phlebotomy)
Two solar wall thermometers (lab)	One solar wall thermometer (phlebotomy)
Temperature charts	Temperature chart pens
Thermometer (centrifuge calibration)	

Store supplies in the trailer compartments as indicated in the trailer maps (Figure 11-1).

Figure 11-1. MEC trailer compartment maps



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 301-330-7092.

11.4 Dry Run

After setting up the phlebotomy and laboratory rooms at each new stand, the staff conducts a “dry run” session using volunteers to verify data collection and specimen collection and processing procedures. One purpose of the dry run session is to help identify any problem areas, particularly with equipment, and to resolve the problems before the stand begins. Another purpose is to provide the contract laboratories with blind split samples for quality control determinations. Document the results of the dry run session in a manner identical to an actual session except enter results twice, first using the SP ID, and second using the Sample ID.

During the dry run session, prepare split samples for each volunteer. Send these split samples to contract laboratories for analysis with the first routine shipment. Collect the amount of blood specified in the Dry Run Venipuncture Protocol (see Exhibit 11-2). This amount is less than the blood required from a routine examinee. Collect 10-mL of urine and process as specified in Dry Run Urine Processing Protocol (see Exhibit 11-3). Process the blood as directed in the Dry Run Blood Processing Protocols (see Exhibits 11-4, 11-5, and 11-6).

11.4.1 Phlebotomy Protocol and Procedures

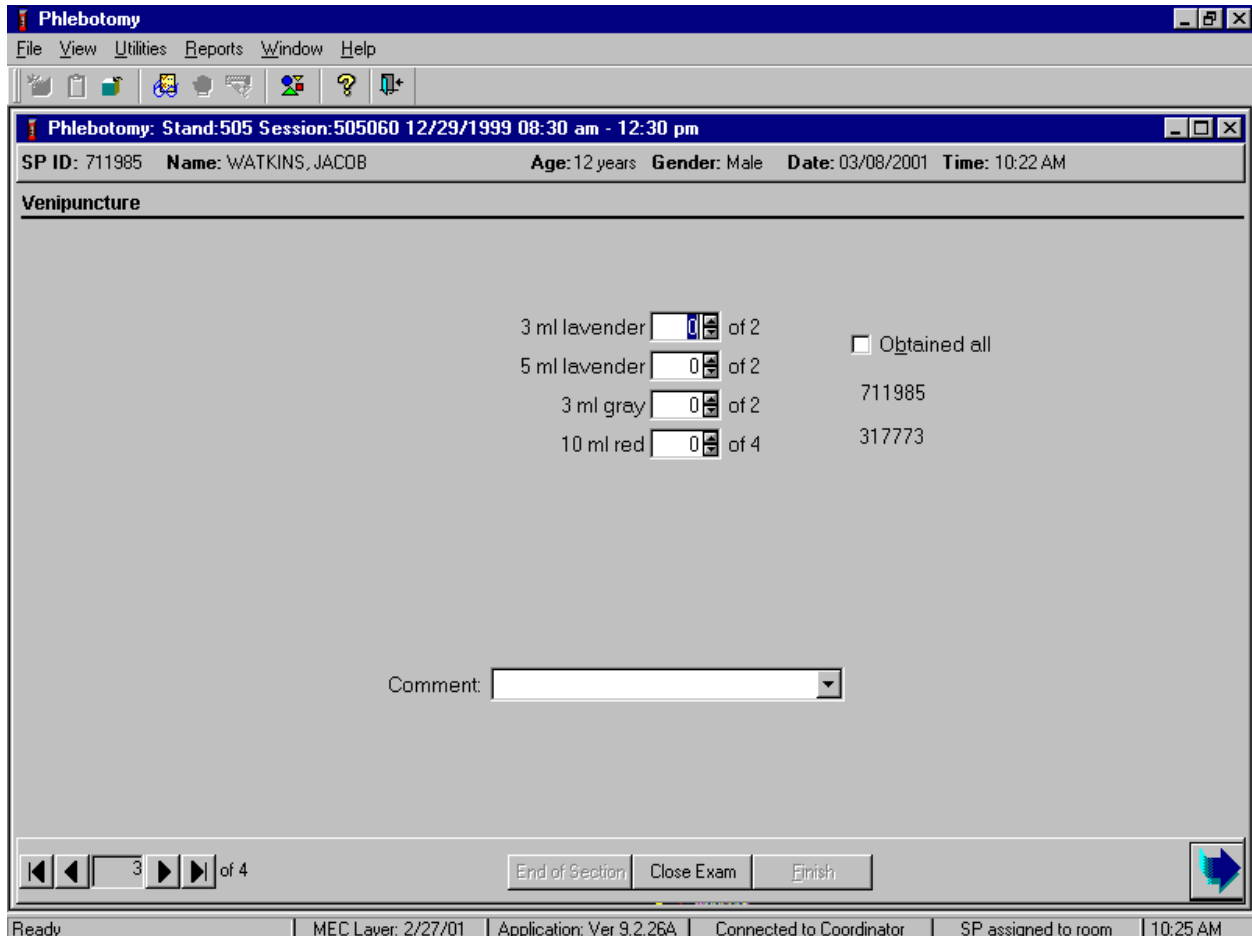
Exhibit 11-2. Dry run venipuncture protocol

Tube type (in priority order)	Number of tubes
3-mL EDTA	2
5-mL EDTA	2
3-mL Gray	2
3-mL Blue	2
10-mL Red	4

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

- Access the phlebotomy application; open the exam and wand the dry run volunteer into the component.
- Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 4.
- Perform the venipuncture using procedures described in Chapter 4.

The session and the volunteer's group designation determine the dry run venipuncture protocol. The correct venipuncture automatically displays. Note that there are two IDs and that both the SP ID and the Sample ID display.



Enter the venipuncture results using procedures described in Chapter 4. Enter any reasons for a tube not being drawn according to protocol, and any comments about the venipuncture. Refer to Chapter 4 for specific instructions.

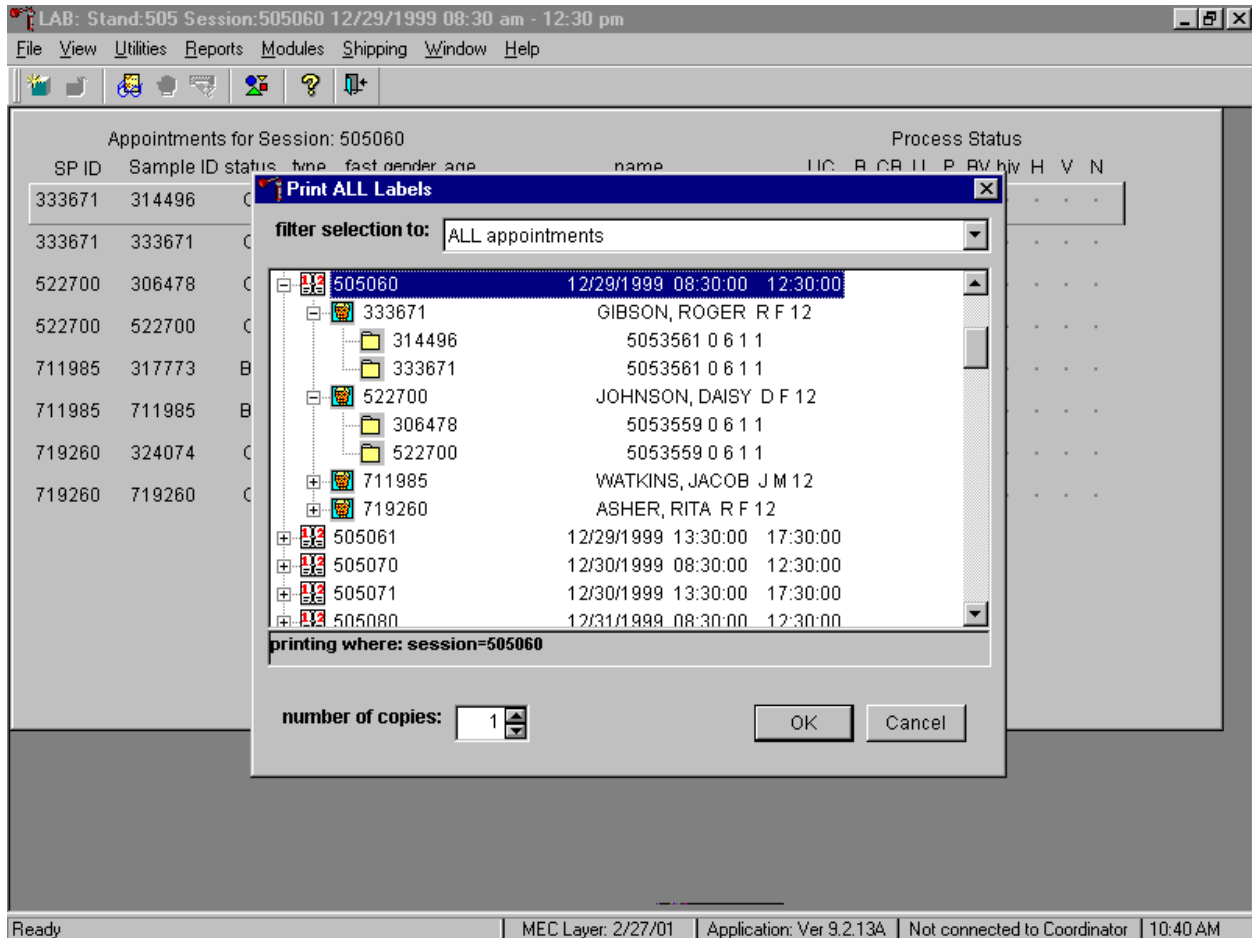
Label half of the tubes with the first SP ID and the other half with the sample ID. Label the Vacutainer® tubes for each volunteer as follows:

- Place the original SP ID number on one tube of the pair of 3-mL EDTA tubes and the second Sample ID number on the other tube of the pair. Follow the same procedure for the pair of 5-mL EDTA, 3-mL gray tubes, and 3-mL blue tubes. Place an original SP ID number on two of the four 15-mL red tubes and the second Sample ID number on the other two 15-mL red tubes. If only one tube is drawn, discard the tube. If less than four of the 15-mL red tubes are drawn successfully, label the first tube with the

original SP ID and the second one with the Sample ID. If an odd number of tubes are drawn, discard the odd tube.

11.4.2 Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window. Two distinct IDs are assigned to each volunteer, the original SP ID and a second unique Sample ID.



The Print All Labels pick list demonstrates that for each dry run volunteer, there are two entries, the original SP ID and the Sample ID. The last digit of both numbers is either even or odd. Volunteers with an original SP ID number ending in an odd digit are assigned to Urine or Blood Processing Protocol Group 1 and volunteers with an original SP ID number ending in an even digit are assigned to Urine or Blood Processing Protocol Group 2.

There are two sets of urine and blood vessel labels and one pregnancy label (if eligible) for each dry run volunteer. The correct vessel labels automatically print for the protocol. Print labels using

procedures described in Chapter 9. Place urine and pregnancy labels at workstation 2. 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 9.

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

Appointments for Session: 505060								Process Status									
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
333671	314496	SC	D	N	F	12	GIBSON, ROGER	.	○	●
333671	333671	SC	D	N	F	12	GIBSON, ROGER	●	○	○	.	○
522700	306478	CI	D	N	F	12	JOHNSON, DAISY	.	○	○	○
522700	522700	CI	D	N	F	12	JOHNSON, DAISY	○	○	○	○	○
711985	317773	SC	D	N	M	12	WATKINS, JACOB	.	○	○
711985	711985	SC	D	N	M	12	WATKINS, JACOB	.	○	○
719260	324074	CI	D	N	F	12	ASHER, RITA	.	○	○	○
719260	719260	CI	D	N	F	12	ASHER, RITA	○	○	○	○	○

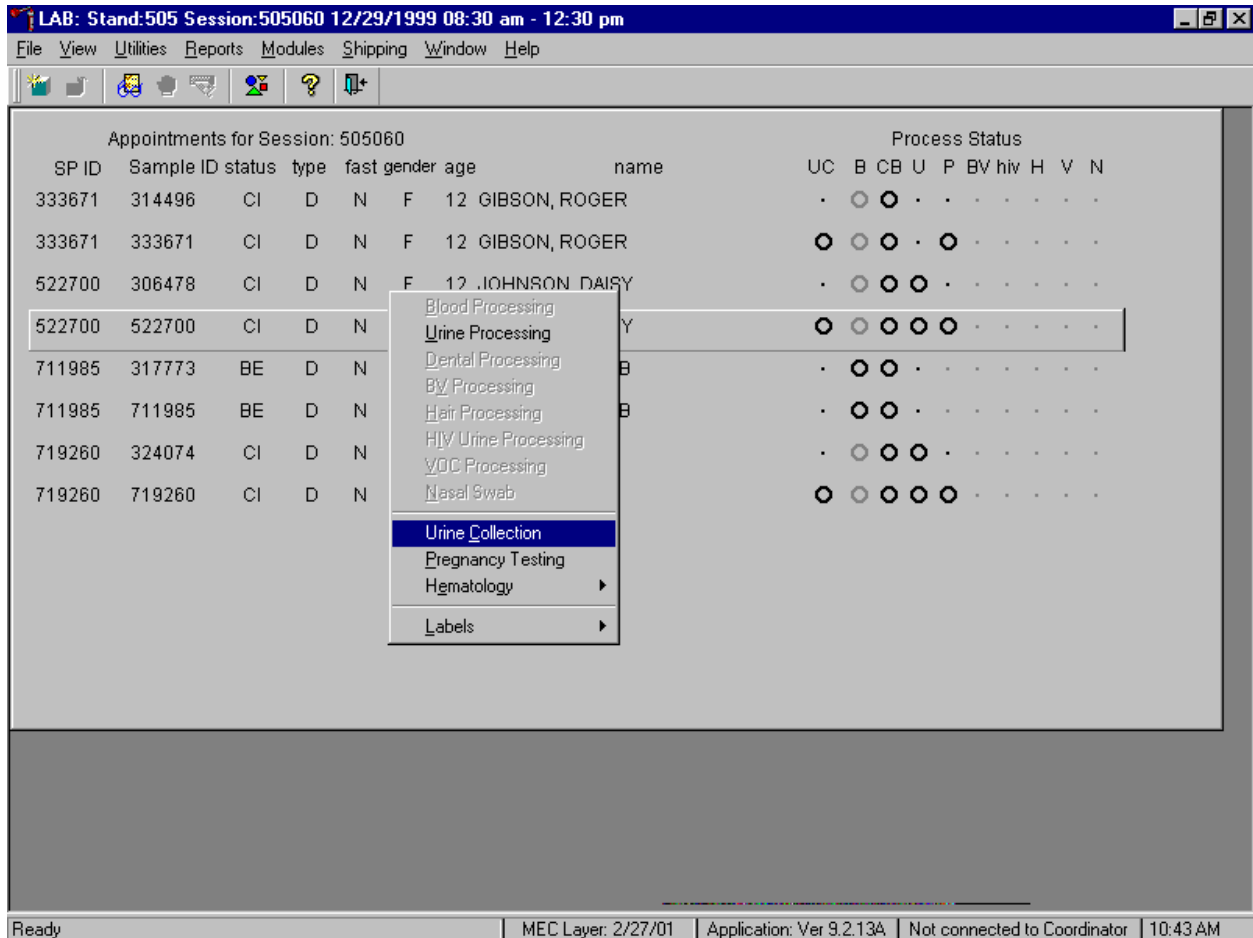
Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 10:17 AM

The heads-up display lists each dry run volunteer twice. Note the difference between the SP ID and the Sample ID and the types of tests for which the dry run volunteer is eligible. Dry run volunteers are only eligible for urine collection and processing, CBC, blood processing, and the pregnancy test. The urine and blood protocols constitute a limited subset of the primary SP's test protocol. Each test has the same age and gender restrictions as a primary SP. Dry run volunteers are never eligible for future research vessels (surplus serum, plasma, or urine), genetic vessels (44, 71 and 43), hair collection, MRSA - nasal swab, HIV serum or urine, CD4, urine mercury, or any subsamples,

including VOC. Notice that one urine collection and one pregnancy test are required for each dry run volunteer.

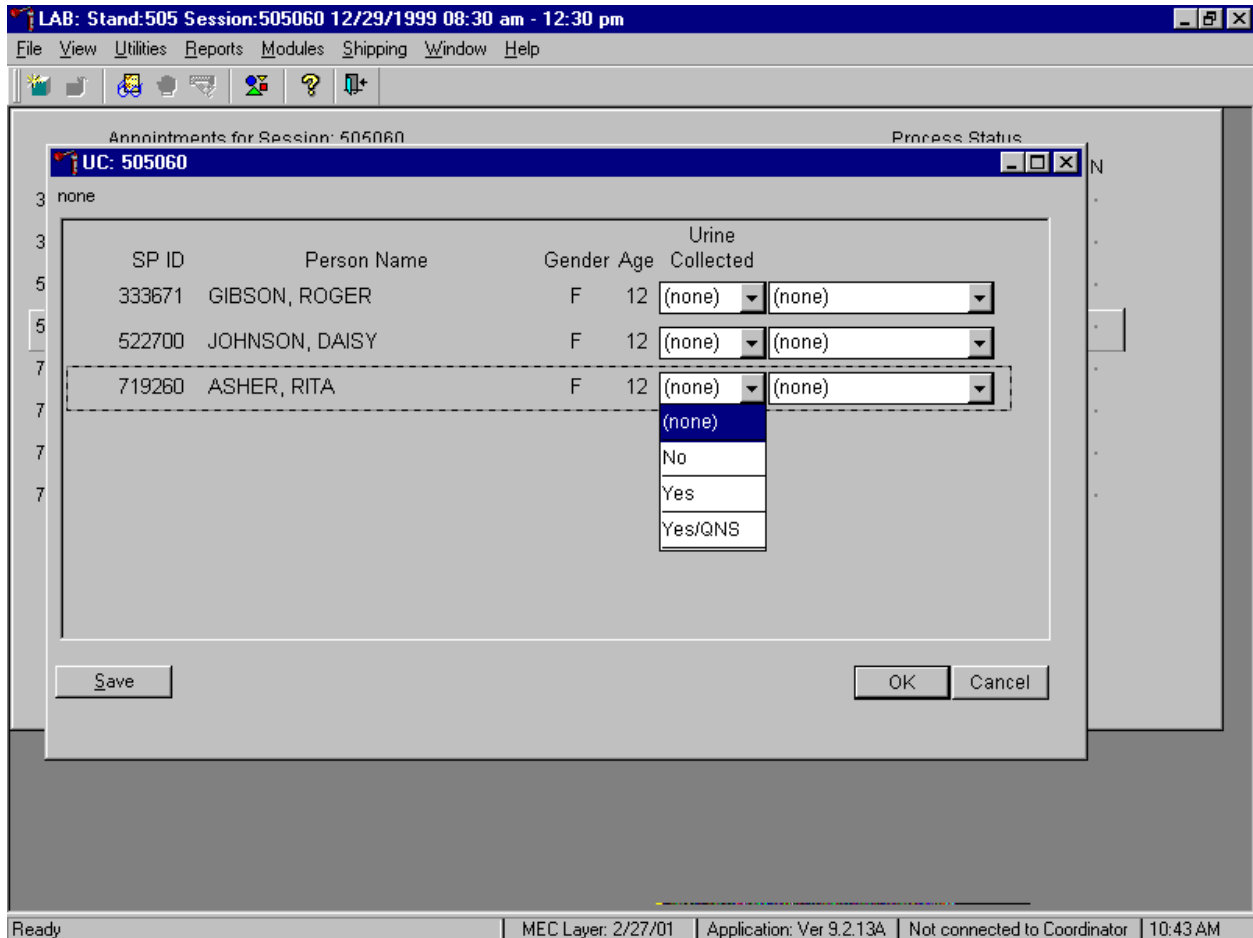
Collect approximately 10-mL urine from all dry run volunteers. The MEC coordinator instructs each volunteer to void at the same time that the volunteer changes clothes or ideally, within 45 minutes after arrival at the MEC. After collection, the coordinator or local assistant transports the initial specimen to the laboratory. Dry run volunteers assigned to protocol group 1 (SP ID ending in an odd digit) do not require any urine at this time, since they are not eligible for any tests. Discard urine if it is not required.

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 or type [C/c].

The urine collection window displays.



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

Evaluate the sufficiency of the quantity of urine received in the laboratory. Use the gradations on the urine collection cup to estimate the amount of urine received. Record the urine collection result for each volunteer by typing [Y/y] for “Yes,” [N/n] for “No” [Y/y] a second time for “Yes/QNS.” Alternatively to record the collection result, use the mouse to direct the mouse arrow to the drop down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result notifies the coordinator, who then asks the dry run volunteer to provide an additional urine specimen. Refrigerate all insufficient urine samples. If additional urine is obtained, pool the urine and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each dry run volunteer. Enter “No” in the result field for all volunteers who have not produced a urine sample. Record a result other than “(none)” for all records. Record a comment for all insufficient urine collections.

Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the **Save** button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the **X** in the upper right hand corner of the module and left click.

Use the urine processing labels printed in advance to label the SP’s urine vessels. The correct protocol is determined in advance by assigning dry run volunteers with an original SP ID number that ends in an odd digit to Protocol Group 1 and assigning dry run volunteers with an original SP ID number that ends in an even digit to Protocol Group 2. Protocol group 1 does not require any urine. 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 of vessels with the second set of labels (Sample ID).

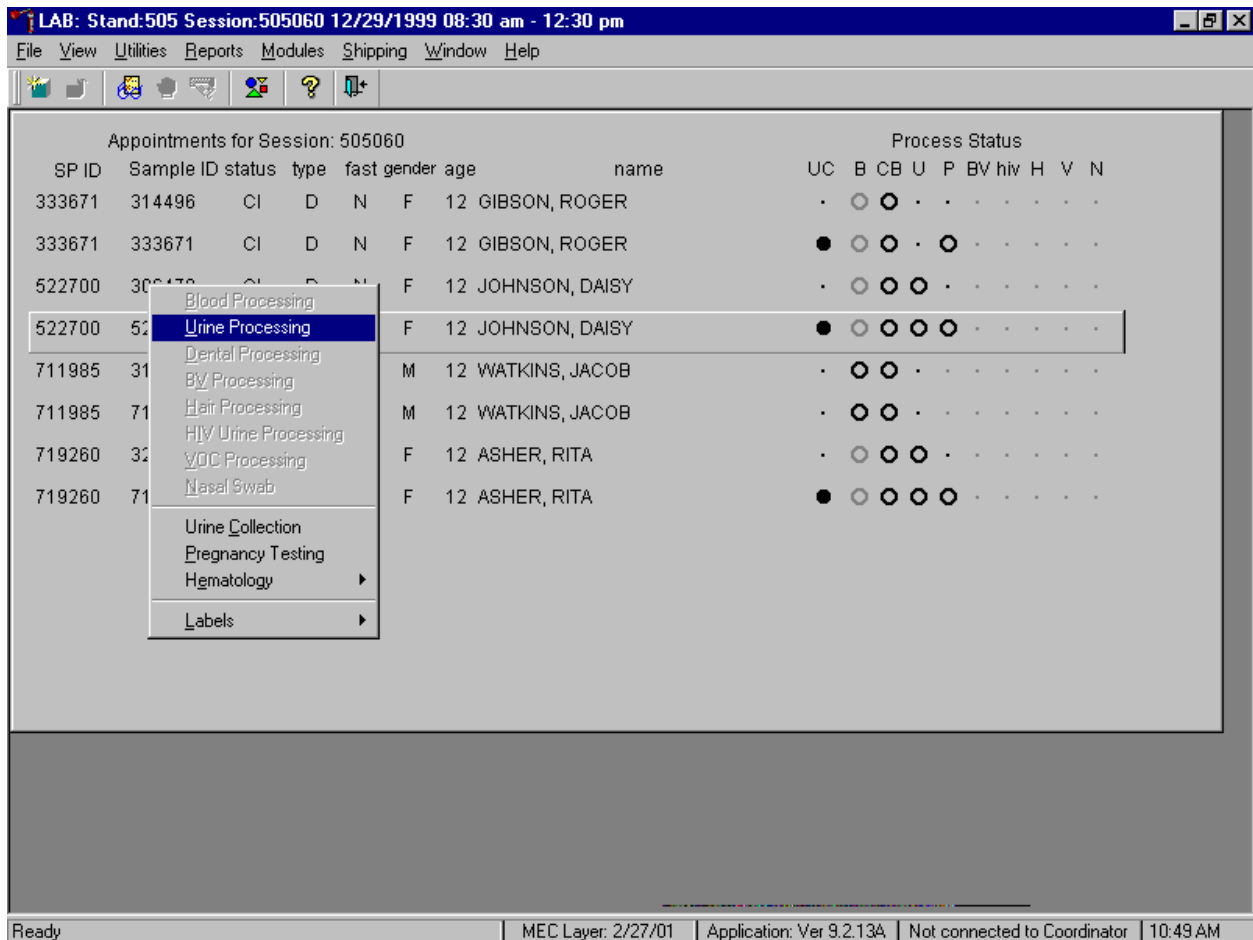
Exhibit 11-3. Dry run urine processing protocol

ID	Assay	Group 1-Odd	Group 2-Even	Sample size mL	Vessel
45	Alb/Creat		6	3	5-mL Cryovial
47	NTX		2	1	2-mL Cryovial

- Label one 5-mL cryovial for the first test - #45. Label one tube with the volunteer’s original SP ID number. Label the other tube with the volunteer’s second Sample ID number.
- Pour 3-mL urine into the vessels.
- Label one 2-mL cryovial for the second test - #47. Label one tube with the volunteer’s original SP ID number. Label the other tube with the volunteer’s second Sample ID number.
- Pour 1-mL urine into the vessels.

- Enter the results of urine processing for the original SP ID and again for the second Sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the urine processing results.



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

The volunteer's urine processing screen displays.

Appointments for Session: 505060

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
3336	UR: 522700																
3336	none																
5227																	
5227																	
7119																	
7119																	
7192																	
7192																	

Tech ID: 1226 Sample ID: 522700 Name: JOHNSON, DAISY Gender: F Age: 12
 SP ID: 522700 SubSample: 6 Fasting_Req: 4

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
45	Alb/Creat	3	U	5 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		
47	NTX	1	U	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input type="radio"/> No	(none)		

Save OK Cancel

Ready MEC Layer: 2/27/01 Application: Ver 9.2.13A Not connected to Coordinator 10:49 AM

To mark an individual urine vessel as collected or Filled – “Yes” use the mouse to direct the mouse arrow to the “Yes” radio button and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container. To mark an individual urine vessel as not collected or Filled – “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. As each vessel is marked as Filled – “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column. To collectively mark all vessels as Filled – “Yes,” use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [Shift] [F/f]. To mark all vessels as Filled – “No,” use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click, drag the mouse arrow to {Not Filled All} and left click or type [Shift] [F/f], [N/n]. Use the quality comment code to indicate if blood is present. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use

the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Access the Sample ID record on the heads-up display and record the processing results. Remember to process vessels in pairs and if the quantity of urine is insufficient to fill both vessels, do not record either vessel as filled.

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

The urine-processing technologist performs the pregnancy test on female dry run volunteers aged 8-59 years and documents the results following the procedures in Chapter 6.

11.4.3 Hematology

The technologist at workstation 2 runs two CBCs, in duplicate, for each dry run volunteer after the blood processing technologist processes whole blood from the 3-mL EDTA tubes according to the Whole Blood Processing Protocol (see Exhibit 11-4). Run the first CBC in duplicate on the first 3-mL EDTA tube with the original SP ID number on the tube. Evaluate results, and save the data using procedures described in Chapter 7.

Run the second CBC in duplicate on the second 3-mL EDTA tube using the second Sample ID number. Evaluate results, and save the data using procedures described in Chapter 7.

11.4.4 Blood Processing and Storage

Print blood-processing labels using procedures described in Chapter 9. There are two sets of labels for each dry run volunteer. Prepare two blood processing racks using the blood-processing template for age 12+.

Treat each set of venipuncture tubes and prelabeled blood processing racks as two independent and separate dry run volunteers. Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID, then process the second set of venipuncture tubes and blood processing vessels using the second Sample ID.

For each set of tubes, process the 3-mL EDTA top tube (with the original SP ID) for Lead/Cad, Ery Proto, RBC Folate, and Mercury using the same procedures described in Chapter 8. Process the first 5-mL EDTA top tube (with the original SP ID) for Glycohem using the same procedure described in Chapter 8. Reserve the remaining whole blood in the 5-mL EDTA tube for the plasma vessel 7.

Exhibit 11-4. Dry run processing protocol – whole blood

ID	Test name	Groups	Sample (mL)	Sample type	Collection type	Vessel type
1	Lead/Cad	Both	0.5	Whole Blood	3-mL EDTA	2-mL
2	Ery Proto	Odd	0.4	Whole Blood	3-mL EDTA	2-mL
3	RBC Folate	Odd	0.1	Whole Blood	3-mL EDTA	2-mL
4	Glycohem	Odd	0.4	Whole Blood	5-mL EDTA	2-mL
5	Mercury	Odd	1.0	Whole Blood	3-mL EDTA	2-mL

Follow the identical procedure for processing the second 3-mL and 5-mL EDTA tube with the second Sample ID.

Process the remaining whole blood in the 5-mL EDTA tube, the 3-mL gray and 3-mL blue top tubes for plasma as described in Chapter 8.

Exhibit 11-5. Dry run processing protocol - plasma

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
7	Homocys/MMA	Even	1.0	Plasma	5-mL EDTA	2-mL
9	Glucose	Both	0.5	Plasma	3-mL Gray	2-mL
10	Fibrin	Even	1.0	Plasma	3-mL Blue	2-mL

Follow the identical procedure for processing the second 5-mL EDTA tube, the 3-mL gray and 3-mL blue top tubes with the second Sample ID.

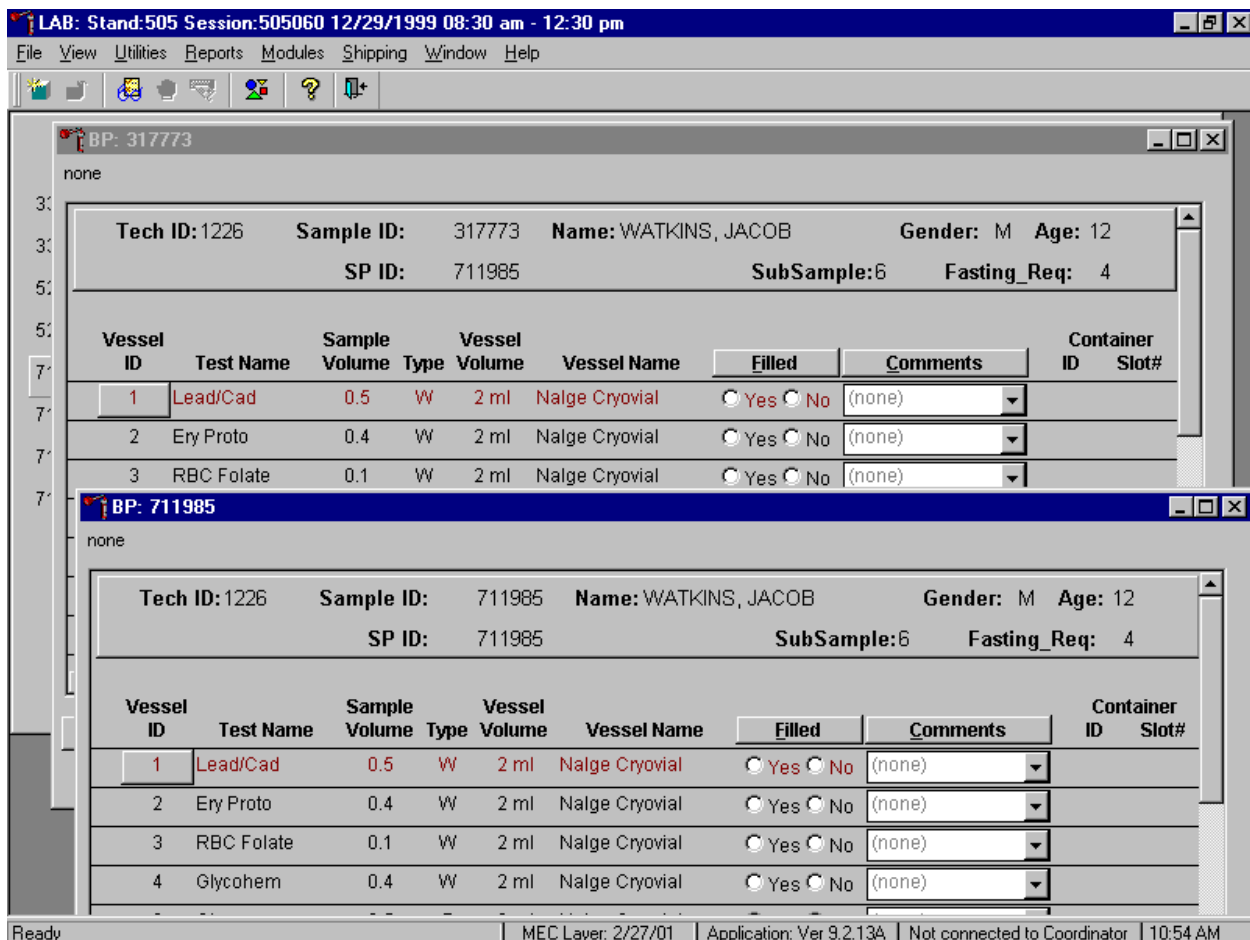
Process pooled serum for the dry run volunteers using the Dry run blood processing protocol-serum (Exhibit 11-6).

Exhibit 11-6. Dry run blood processing protocol - serum

ID	Test Name	Groups	Sample (mL)	Sample Type	Collection Type	Vessel Type
11	Iron/TIBC	Even	1.2	Serum	15-mL Red	2-mL
12	Fol/B12/Fer	Odd	1.3	Serum	15-mL Red	2-mL
13	CRP/Hpylori	Even	0.5	Serum	15-mL Red	2-mL
14	Hepatitis	Odd	1.5	Serum	15-mL Red	2-mL
15	Vit A/E/Car	Even	0.4	Serum	15-mL Red	2-mL
16	Rub/Mea/Var	Odd	0.4	Serum	15-mL Red	2-mL
17	Cotinine	Even	2.0	Serum	15-mL Red	2-mL
18	Biochem	Both	0.8	Serum	15-mL Red	2-mL
19	Bn Alk Phos	Odd	0.5	Serum	15-mL Red	2-mL
20	Crypto	Odd	0.5	Serum	15-mL Red	2-mL
21	Lipids	Both	2.0	Serum	15-mL Red	2-mL
23	Insul/Cpep	Even	1.0	Serum	15-mL Red	2-mL
25	FSH/LH	Odd	0.8	Serum	15-mL Red	2-mL
27	Latex	Even	0.5	Serum	15-mL Red	2-mL

- Fill each vessel as described in the blood processing protocol.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID. Continue to use the labeled vessels in the prepared rack.
- Process the second set of venipuncture tubes and blood processing vessels using the second Sample ID. Continue to use the labeled vessels in the prepared rack.
- Use the same techniques for spinning and separating the blood as described in Chapter 8.
- Check the vessel 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.



Enter results for those vessels where both vessels are filled for the whole blood, plasma, and serum protocol. Enter the results of blood processing using the correct Sample ID and SP ID numbers and procedures described in Chapter 8, Section 8.8. Store the blood vessels in a manner identical to blood vessels processed during a regular session.

11.4.5 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 9.

11.5 Centrifuges – Equipment Maintenance

Technologists are responsible for inspecting the centrifuges at the beginning of each stand, and inspecting and cleaning the centrifuges at the end of each stand and whenever necessary. Clean the interior of the chamber with a mild soap, as time permits. Rinse thoroughly and dry completely.

1. Inspect the rotor yolk and buckets:
 - Inspect for rough spots or pitting, white powder deposits or heavy discoloration. If any of these signs are evident, do not use the rotor. Use the second centrifuge and notify the NCHS engineer. Check the condition of the O-ring in the tie-down nut; replace it if it is worn or damaged.
2. Clean the rotor:
 - Use mild detergent, diluted 10 to 1 with water and a soft brush to clean the rotor yolk and tie-down nut. Thoroughly rinse the cleaned rotor and components with water and air-dry upside down. When the rotor is dry, lubricate the bucket sockets and pins by saturating a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk. Before reinstalling the rotor, lightly lubricate the drive hole of the rotor with Anti-Seize to prevent the rotor from sticking, as follows:
 - Apply the lubricant onto a swab.
 - Draw the coated swab through a paper towel to remove excess lubricant.
 - Lightly coat the inside of the drive hole with the lubricant remaining on the swab.
3. Clean the buckets:
 - Remove the O-ring.
 - Clean the bucket and O-ring with a mild detergent diluted 10 to 1 with water, then rinse thoroughly, and dry completely.
 - Coat the O-ring with a light film of silicone vacuum grease. Place the O-ring on the ledge inside the bucket.
 - Once a week and after every cleaning, lubricate contact areas between the buckets and the pins on the rotor. Saturate a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk.
4. Inspect and clean Aerosolve canisters:

- Inspect the O-ring for nicks, abrasions, or other damage. Coat the O-ring with a light film of silicone vacuum grease before installing. Place the O-ring in the groove.
- Inspect the canister and lid threads and bottom of canister for heavy crazing or cracks.
- Inspect the tube racks for heavy scratches or cracks and inspect the rubber cushions for damage or for imbedded glass from broken tubes.
- Clean the canisters, lids, and racks with a mild detergent, diluted 10 to 1 with water, and a soft brush. Thoroughly rinse the cleaned components with water and air-dry upside down. Coat the O-ring with a light film of silicone vacuum grease before reinstalling it into the groove.

The NCHS biomedical engineer certifies both centrifuges at the beginning of each stand. The NCHS engineer determines the rpm of the instruments using a strobe light or a tachometer. The engineer records multiple readings for each centrifuge. The Beckman GS-6R centrifuge should exceed 3,750 rpm to ensure adequate centrifugal force development. The engineer checks each centrifuge timer against a stopwatch and records the values in the Laboratory QC module – Start of Stand.

Document beginning and end of stand cleaning procedures in the Laboratory QC module.

11.6 Refrigerators and Freezers – Equipment Maintenance

Quality control procedures for the refrigerators and freezers include cleaning them at the beginning and end of the stand and whenever necessary, continuously monitoring their temperatures on a daily basis and recording the results in the Laboratory QC module. Additionally, monitor temperatures using the automated recording instrument procedure that follows. Before putting a new chart on the recording device, date the chart and record the assigned instrument number.

1. Monitor Temperatures:
 - Change the tempscribe chart weekly.
 - Save and send the used charts to the home office at the end of each stand.
 - Document these activities in the Laboratory QC module.
 - Change recording pens when necessary.
 - Document any necessary unscheduled maintenance in the Unusual Occurrence Log.

2. Cleaning:

Wear rubber gloves when cleaning. Use warm soapy water and avoid the use of abrasive cleansers. After cleaning the unit, disinfect the interior and exterior by cleaning with a 1:100 solution of bleach and water.

11.7 Use of the Temperature Recording Instrument

The Jewett Instrument is a microprocessor based, AC powered operated, temperature recording device, which automatically monitors the interior temperature of the refrigerator and freezers. The device continuously graphs this record on a circular paper chart so that 7 days of temperature data can be inspected easily. When this recorder functions under normal conditions and receives proper care it renders lasting accurate service.

The NHANES engineer is responsible for mounting, installing, and calibrating the recorder as specified in the manufacturer's Operating Manual. Monitor the results of the recorder at the beginning of each day, replace charts on a weekly basis, and replace batteries and pens, as needed.

To monitor the results of the recorder, look at the chart for each refrigerator and freezer at the beginning of each day, read the temperature indicated on the chart, and record it in the Laboratory QC module. Record the highest temperature shown on the chart since the last reading.

The allowable temperature range for the refrigerators is 2 to 8°C, (36 to 46°F) and the allowable temperature range for the freezers is -18 to 23°C (0 to -10°F). Note that if the temperature for a refrigerator or freezer exceeds the allowable temperature range, document this in the Unusual Occurrence Log, and inform the MEC manager immediately. Transfer contents of the refrigerator or freezer to a temperature controlled environment.

Maintenance of the Jewett Temperature Recorder involves chart installation on a weekly basis, replacement of the cartridge pen, and replacement of the batteries as needed (approximately once a year).

1. To install the new chart:
 - Press and hold the Change Chart push button switch for 1 second until the pen begins to move to the left of the chart.

- To remove the chart, unscrew the knob at the center of the chart.
- Position the new chart so that the correct time line coincides with the timeline groove on the chart plate, then replace the knob and screw tightly against the chart.
- Again, push the Change Chart push button switch for 1 second until the pen begins to move back onto the chart.
- Check to make sure the pen is marking on the paper. If not, lightly adjust the pen arm to establish contact with the paper.

The Jewett temperature recorder uses a standard cartridge pen that requires no filling. It consists of a self-contained ink reservoir with a porous plastic stylus that snaps around the outer edge of the pen. Use the two- (2) screws at the top of the pen arm to adjust the length to ensure that the pen tracks the timeline on the chart. Check the length after each pen replacement and adjust accordingly if required. If the stylus does not touch the chart, make adjustments by slightly bending the pen arm in the center. Do not use more pressure than is necessary to create a fine line. NOTE: As the ink supply runs out, the ink color becomes lighter. Replace the pen when this occurs.

If AC power fails, the LED changes to a flashing green to alert the user of the power failure. The 9-Volt battery allows the recorder to sense and record temperatures for a minimum of 12 hours.

Occasionally, a recorder may malfunction. Contact technical service at 800-879-7767. The manufacturer offers the following troubleshooting guide:

LED status	Chart rotation	Pen location	Battery status	AC power status	Cause	Repair
Green	OK	OK	OK	OK	Normal	None required
Flashing Green	OK	OK	Low	Off	AC failure or Low Battery	Check power source and transformer – Replace battery if necessary.
Green	OK	Inner hub	OK	OK	Probe Failure	Check Connection on board – Replace probe

11.8 Use of the Class II Type A Biological Safety Cabinet

The Class II Laminar Flow Biological Safety Cabinet (LFBSC), with proper technique, provides an effective partial containment system for safe manipulation of moderate and high-risk microorganisms. The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and the technologist. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

Installation, Certification, and Maintenance

The NCHS biomedical engineer arranges for a certified engineer to perform the required annual certification that includes replacement of HEPA filters as necessary.

The basic concept of the LFBSC is to take air through a blower system, pressurize a plenum, and force air through a filter. Built-in supply and exhaust blowers come with separate HEPA filters. The recirculating airflow pattern directs a portion of the HEPA filtered air straight down over the central work area driving the airborne contaminants into the surrounding grills, allowing a pollution free environment for particular specifications. If a filter is defective, the filtration system no longer filters and becomes a vacuum cleaner, taking in gross contamination and exploding it through the defective filter onto and around the critical work area. The filter of the LFBSC is a permanent part of the disposable plenum. A magnehelic gauge is calibrated in “inches of water gauge” pressure (w.g.). The gauge indicates when the supply HEPA filter is clogged. As the filter loads with particulate matter, the amount of pressure registered on the gauge will increase. The initial pressure reading is approximately 0.4 w.g. \pm 0.05 w.g. depending on the altitude from sea level. Check and record the reading on the gauge every day. **If the gauge registers an increase in pressure of more than 0.1 w.g., notify the NCHS engineer.** The NCHS

engineer will arrange to have the airflow pressure and the HEPA filter system checked. If the HEPA filter is no longer effective, the engineer or MEC manager discards the entire filter and plenum and substitutes a new replacement unit.

Clean the LFBSC at the beginning and end of each stand. Lift the front glass and wash both the interior and exterior glass. Remove all contents from the interior of the cabinet. Remove and wash the front grill. Lift the cover to the table and wash the base underneath. Put table cover and grill back into cabinet. Lock front glass into place. Document these activities in the Laboratory QC module. Take and record the pressure reading in the Laboratory QC module at the beginning of stand and at the start of each session.

Document all unscheduled maintenance for the LFBSC in the Unusual Occurrence Log.

11.9 Ambient Air Temperature

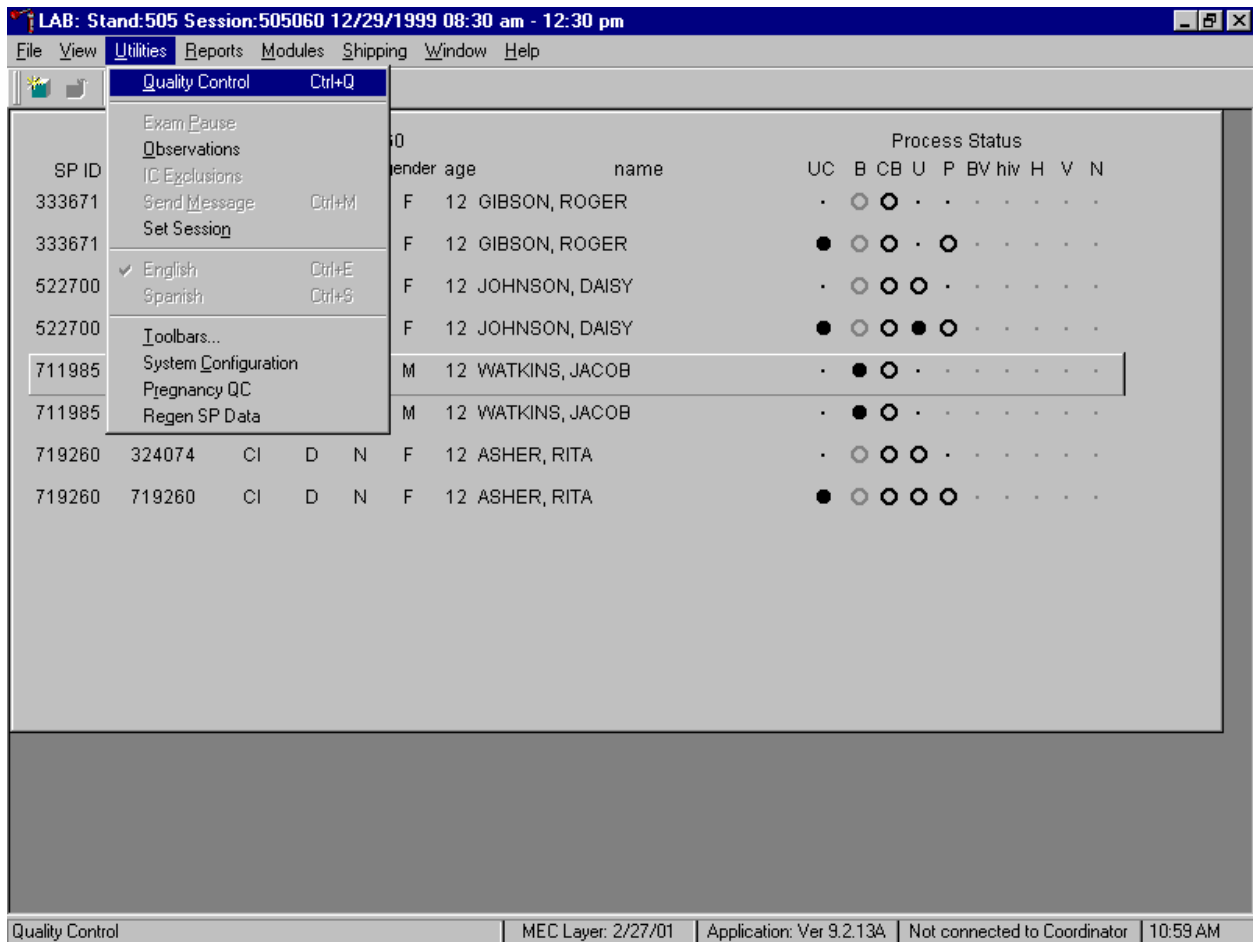
Two thermometers monitor ambient temperature in the laboratory. Quality control procedures for ambient air temperatures involve checking these thermometers for damage, monitoring the temperature each session, and documenting any unusual occurrences. Check the two wall thermometers for damage at the beginning of each stand. Notify the MEC manager of any damage.

The allowable ambient temperature range for the laboratory is 17 to 25°C (63 to 77°F).
NOTE: If the room temperature is out of allowable range since the last reading, document this in the Unusual Occurrence Log and inform the MEC manager immediately.

11.10 Laboratory Quality Control Module

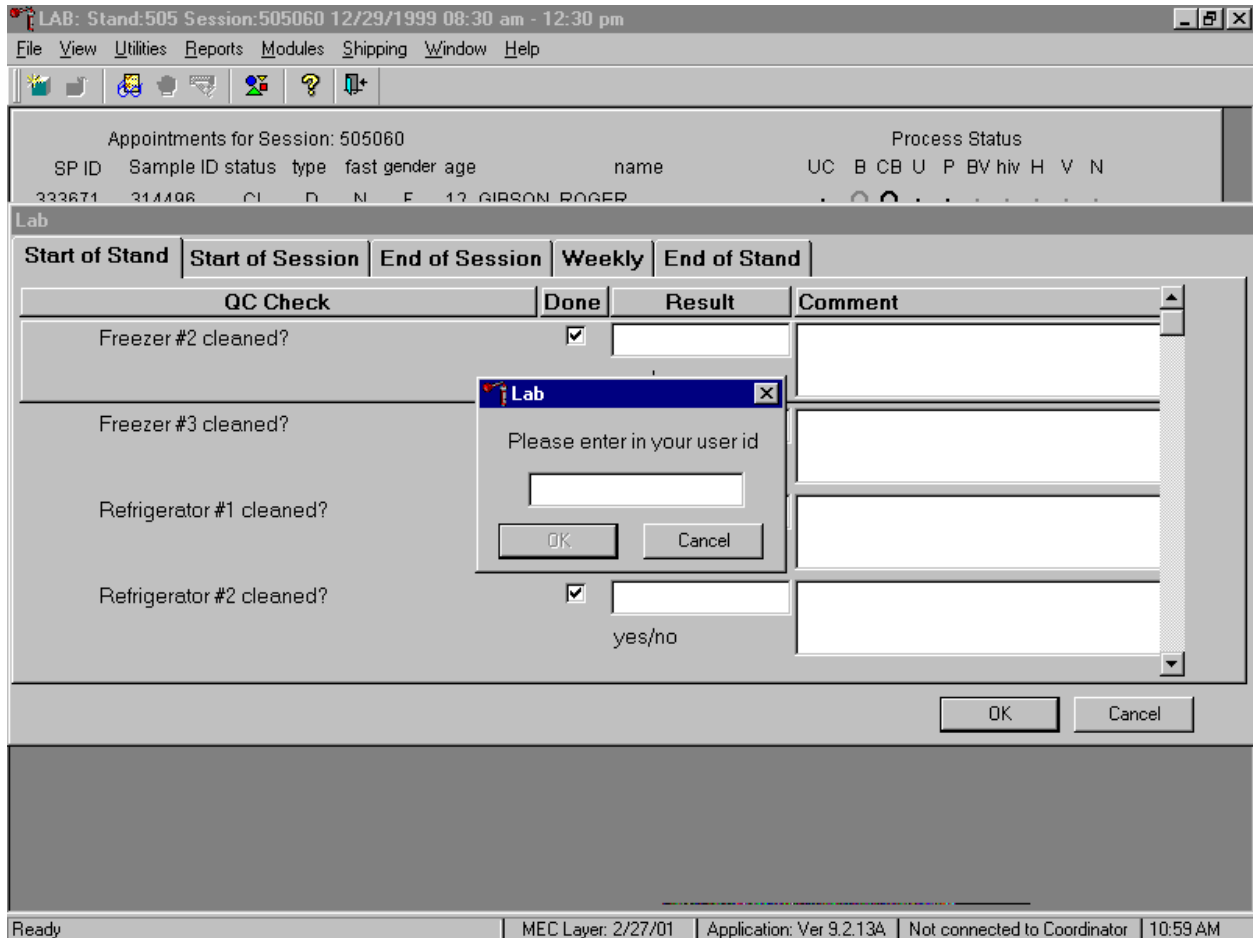
Document all instrument quality control activities in the Laboratory QC module.

Access the Laboratory QC module.



To access the QC module, use the mouse to direct the mouse arrow to {Utilities}, drag the arrow to {Quality Control} and left click or type [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Enter the required user ID.



Enter user ID as last name_first initial and [Enter] or type in the user ID and use the mouse to direct the mouse arrow to the **OK** button and left click. To exit without entering a user ID use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Enter quality control activities and readings.

LAB: Stand:505 Session:505060 12/29/1999 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505060 Process Status

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
333671	314496	CL	D	N	F	12	GIBSON, ROGER										

Lab

Start of Stand | **Start of Session** | End of Session | Weekly | End of Stand

QC Check	Done	Result	Comment
Freezer #1 temperature reading °C (-18 to -23)	<input type="checkbox"/>	<input type="text"/> degrees C	
Freezer #2 temperature reading °C (-18 to -23)	<input type="checkbox"/>	<input type="text"/> degrees C	
Freezer #3 temperature reading °C (-18 to -23)	<input type="checkbox"/>	<input type="text"/> degrees C	
Refrigerator #1 temperature reading °C (2 to 8)	<input type="checkbox"/>	<input type="text"/> degrees C	

OK Cancel

Cancel changes | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:03 AM

Select the correct activity (Start of Stand, Start of Session, End of Session, Weekly, or End of Stand) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. At each stand, perform and record weekly activities on the same weekday as set up.

Mark activities as done and enter the result.

LAB: Stand:505 Session:505060 12/29/1999 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505060

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
333671	314496	CL	D	N	F	12	GIBSON, ROGER										

Process Status

Lab

Start of Stand
 Start of Session
 End of Session
 Weekly
 End of Stand

QC Check	Done	Result	Comment
Freezer #3 temperature reading °C (-18 to -23)	<input checked="" type="checkbox"/>	-20 degrees C	
Freezer #2 temperature reading °C (-18 to -23)	<input checked="" type="checkbox"/>	-20 degrees C	
Freezer #1 temperature reading °C (-18 to -23)	<input checked="" type="checkbox"/>	-21 degrees C	
LFBSC pressure gauge reading (0.350 to 0.550 w.g.)	<input checked="" type="checkbox"/>	0.450 w.g.	

OK Cancel

Apply changes and close window | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:07 AM

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box.

Enter the response or reading in the Result text box.

LAB: Stand:505 Session:505060 12/29/1999 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505060

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N
333671	314496	CL	D	N	F	12	GIBSON, ROGER										

Process Status

Lab

Start of Stand Start of Session End of Session Weekly End of Stand

QC Check	Done	Result	Comment
Freezer #3 temperature reading °C	(-18 to -23) <input checked="" type="checkbox"/>	-20 degrees C	
Freezer #2 temperature reading °C	(-18 to -23) <input checked="" type="checkbox"/>	-20 degrees C	
Freezer #1 temperature reading °C	(-18 to -23) <input checked="" type="checkbox"/>	-15 degrees C	Notified MEC Manager.
LFBSC pressure gauge reading (0.350 to 0.550 w.g.)	(0.350 to 0.550 w.g.) <input checked="" type="checkbox"/>	0.450 w.g.	

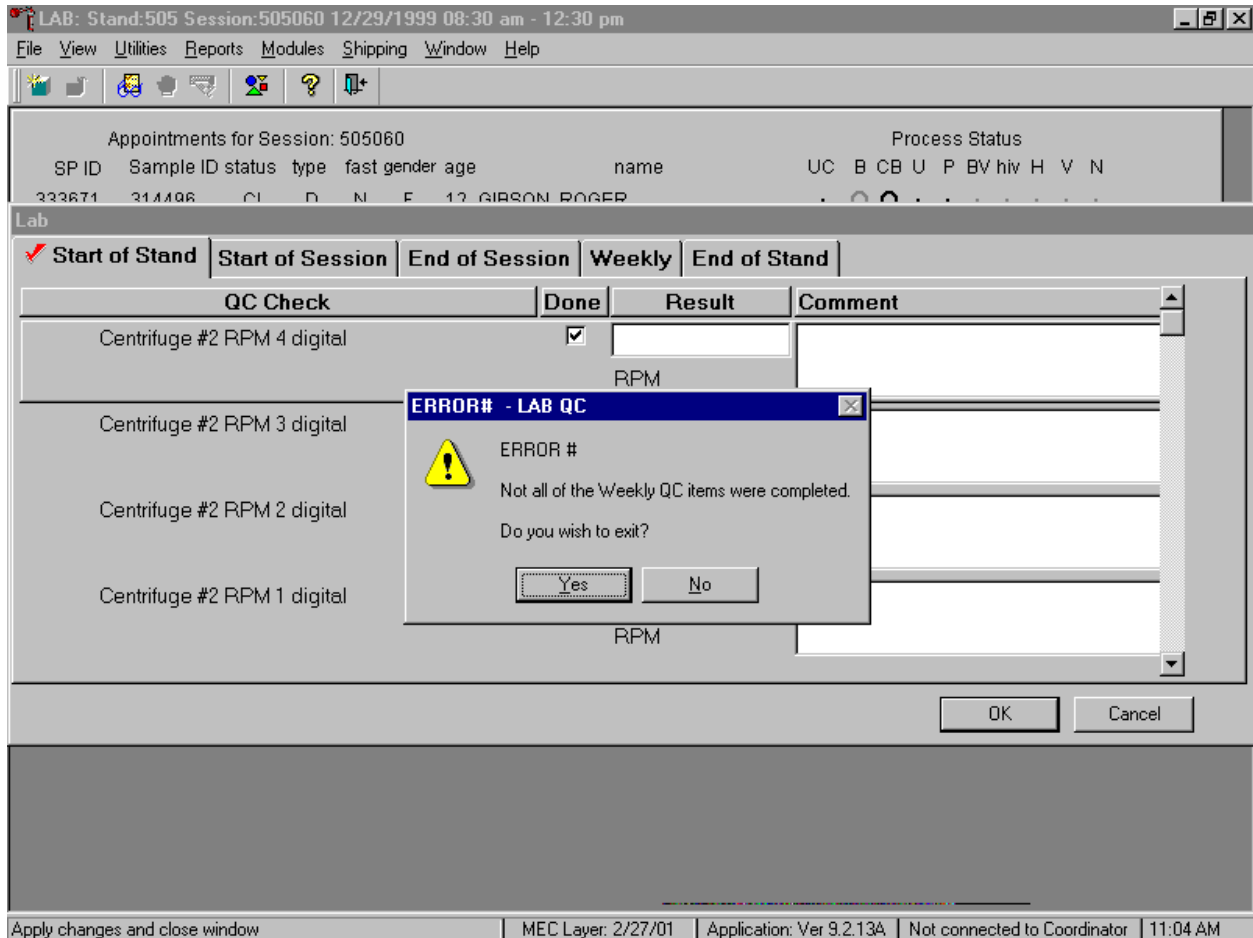
OK Cancel

Apply changes and close window | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 11:08 AM

Enter “Yes” or “No,” for text responses, whole numbers for rpm measurements, minutes and seconds for timer readings, three decimals for w.g., and whole negative and positive numbers for thermometer readings in the Result text box. Select [Tab] or [Enter] to move to the Comment text box. Type any actions associated with an unexpected result in the Comment text box. Select [Tab] to move to the next line.

To save the results to the database, use the mouse to direct the mouse arrow to the **OK** button and left click, or to exit the QC module without saving the results, use the mouse to direct the mouse arrow to the **Cancel** button and left click. Once results are saved to the database, they cannot be changed.

A warning message text box displays if required QC is incomplete.



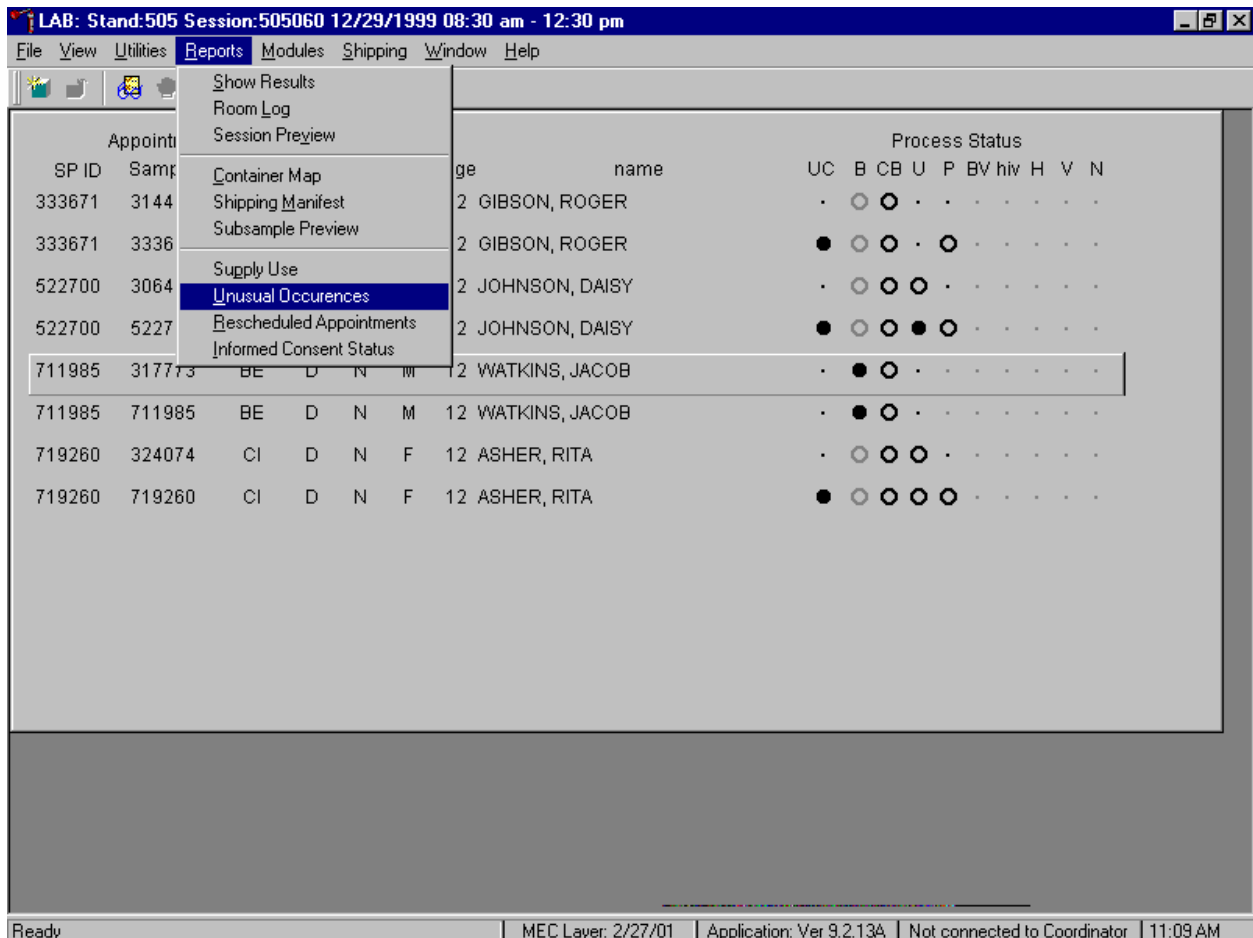
When attempting to access laboratory modules a warning message text box displays if required QC activities have not been performed or if some activities are incomplete. Respond to the message text box. To exit the QC module, use the mouse to direct the mouse arrow to the **Yes** button and left click, or type [Y/y] or select [Enter]. To remain in the QC module, use the mouse to direct the mouse arrow to the **No** button, and left click or type [N/n]. Continue to perform the required QC activities and record the results.

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.

11.11 Unusual Occurrence Log

Document any instrument malfunction using the Unusual Occurrence Log (see Exhibit 11-7). Record the date, Tech ID number, an explanation of the incident, and the steps to resolve the incident. Be sure to record the model and the serial number of the instrument. Access this document electronically or use a preprinted blank hard copy.

Access the Unusual Occurrence Log.



To access the Unusual Occurrence Log, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, drag the arrow to {Unusual Occurrence Log} and left click or type [Alt][R/r], [U/u].

Enter information into the appropriate line(s):

- Stand Number
- Beginning Stand Date
- Technologist Name and ID
- Date
- Time
- Comments or Issue
- Action Taken
- Resolution

Do not enter any text in the Reviewed by or Date reviewed lines.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

Exhibit 11-7. Unusual Occurrence Log

NHANES

Unusual Occurrence Log

Stand Number _____

Beginning Stand Date _____

Technologist Name and ID

Date

Time

Comments or Issue

Action Taken

Resolution

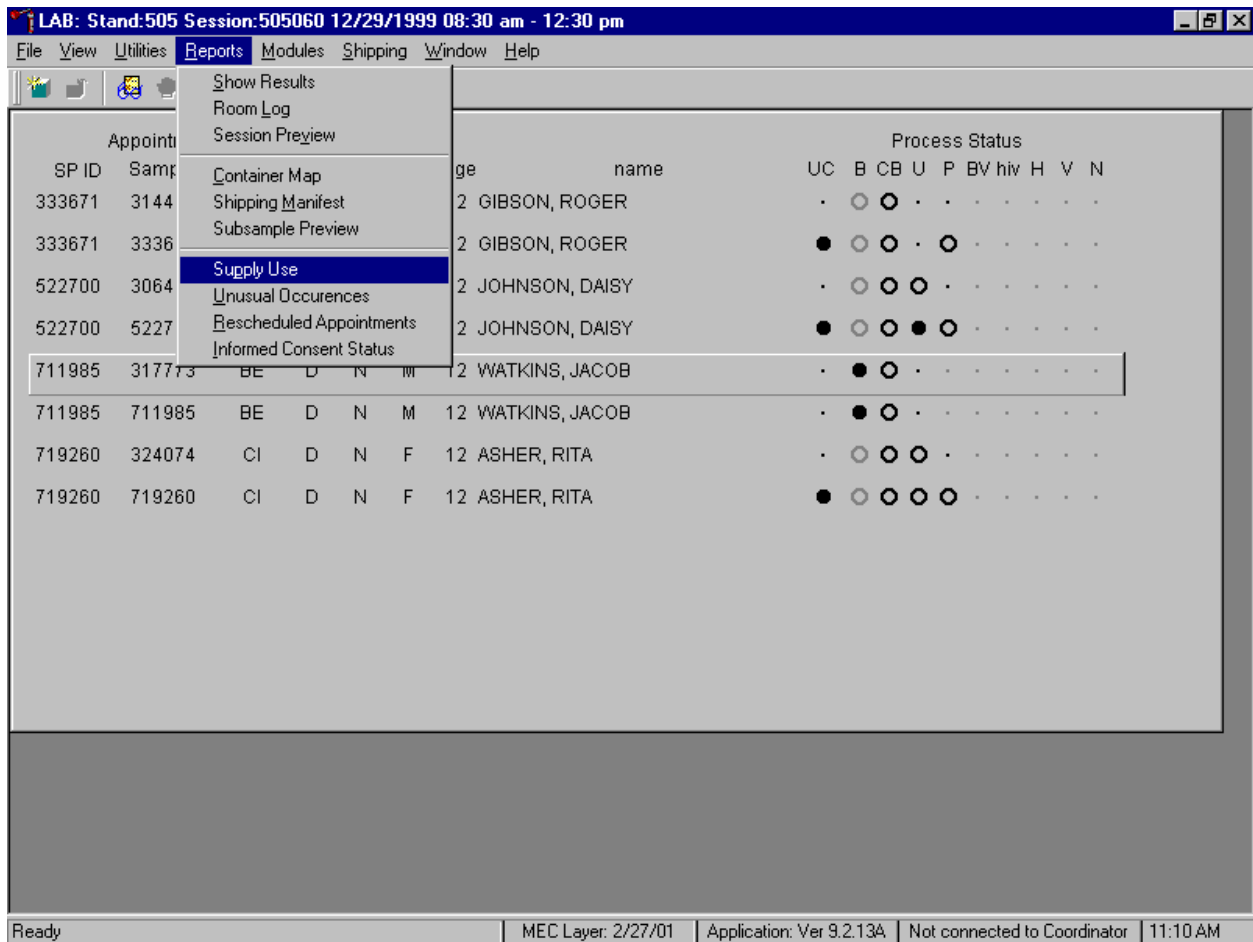
Reviewed by _____

Date reviewed _____

11.12 Supply Use Control Log

Document the lot number and expiration dates for all Vacutainer® tubes, needles, and reagents in the Supply Use Control Log. It is not necessary to record the pregnancy test kit and the serum and urine pregnancy control lot numbers and expiration dates since these are captured in the Pregnancy QC module. Access this document electronically or use a preprinted blank hard copy.

Access the Supply Use Control Log.



To access the Supply Use Control Log (see Exhibit 11-8), use the mouse to direct the mouse arrow to {Reports} in the top menu bar, drag the arrow to {Supply Use Control Log} and left click or type [Alt] [R/r], [S/s].

Enter information into the appropriate column(s):

- Reagent or Supply Name

- Beginning Stand Date
- Lot Number
- Date in Use
- Expiration Date
- Technologist ID

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

11.13 Eppendorf Pipette Care, Sterilization, Maintenance and Calibration

The MEC laboratory has four Eppendorf Research pro electronic pipettes: one 5-100 μ L, two 50-1000 μ L, and one 100-5000 μ L. The lab also uses 100 μ L and 1000 μ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- ✓ Do not clean the display or any of the labeling using acetone or aggressive solutions.
- ✓ Do not allow any liquid to enter the device.
- ✓ Authorized service personnel may carry out repairs only.
- ✓ Use original spare parts and accessories (battery, pipette tips) only.

Care

Wipe the outside of the pipette with a moist cloth. The use of water with a wetting agent is also permitted.

DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.

Rinse (with distilled water) and dry only the lower part of the pipette. The pipette may be wiped clean with 60% Isopropanol.

Disassemble the lower half of the Research pro if the pipette is very contaminated or if very aggressive chemicals are dispensed. Rinse the individual parts in distilled water and then dry the parts. Lightly lubricate the piston using silicone grease.

After opening the pipette, check the position of the piston and execute a motor reset. Trigger the motor reset by holding down the Reset key until **R** appears in the display.

Sterilization

Disassemble only the lower half of the pipette. The individual parts of the lower part must be disassembled as separate pieces. Please review the diagrams on page 27 of the Instruction Manual before attempting to disassemble any pipette.

To loosen the lower part of the pipette (for all pipettes except the 5,000 μ L):

4. Hold down the ejector and pull off the ejector sleeve. Force may be required.
5. Unscrew the lower part using the key. During disassembly, do not damage the piston!
6. Unscrew the piston. If necessary, first loosen the piston at the upper end using flat nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000 μ L pipette:

4. Hold down the ejector and pull off the ejector sleeve. Force may be required.
5. Unscrew the cylinder. The piston is held in place magnetically. During reassemble, do not damage the piston!
6. Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000 μ L piston as shown in the diagram on page 27 of the Instruction Manual. Check that the dispensing function of the pipette is working correctly.

Maintenance and Calibration

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced. Part B: "Ordering information/service parts," describes the process for replacing the seals in the lower part.

Brinkmann performs on-site calibration twice per year in April and October. Contact the Service Department at Brinkmann Instruments at 800-645-3050 Ext 404 to schedule the calibration.

A complete list of troubleshooting information is included on pages 28 and 29 of the Instruction Manual.