

## LAB SPECIMEN PROCESSING

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## **1. Background and Rationale**

The Health ABC study involves the collection of approximately 17 mL of blood from participants. The blood is collected in two types of tubes for specialized processing of different blood components. After processing, the specimens will be aliquoted into cryovials to be sent to LCBR for immediate analysis or to McKesson BioServices to store for later analyses.

## **2. Equipment and Supplies**

A complete supply list with ordering information can be found in Appendix 1. Necessary supplies include:

- Centrifuges capable of spinning at 30,000 g-minutes
- -20° Freezer space is required
- Refrigerator space
- Dry Ice
- Blue ice or gel packs
- Pipets and tips: 0.5 and 1.0 mL volumes
- Lab coat and gloves
- Biohazardous waste disposal container
- Balance tubes for the centrifuge
- Lab mat
- 10% bleach solution
- Freezer boxes with 9 x 9 cell grid (supplied by McKesson)
- Rubber bands

### **2.1 Sample ID Labels**

You will be supplied with sheets of sample ID barcode labels to use for labeling forms, draw tubes, and cryovials. A sample sheet of barcode labels can be found in Appendix 2. All labels on each sheet have the same 6-digit sample ID number (the first digit identifies the clinic: Memphis = 1, Pittsburgh = 2).

Each cryovial label also has a 2-digit extension (01 to 13) that serves as a unique identifier for each cryovial within a sample ID. The labels for cryovials have bar codes to help McKesson and LCBR track the repository. To make it easy to differentiate cryovials that are to be sent to LCBR, their labels include the text “To LCBR”. See Appendix 2 for proper orientation of the barcode label.

Beneath the human-readable ID number, cryovial labels also have 1-3 lines of text. The first line consists of a letter, a word, and a number. This line of text is intended to increase accuracy in labeling and filling the cryovials. The letter refers to the color of the cryovial cap (R= red, W= white, etc., complete code can be found at the bottom of the Laboratory Processing form). The word corresponds to the type of sample to be stored in the cryovial (e.g. “EDTA” for EDTA-treated plasma). **The number refers to the cryovial volume (1.5 mL or 0.5 mL), not the volume aliquoted.**

There are also 4 labels containing the ID number with no extension. Two are to be used for pre-labeling the 2 draw tubes, with 2 extras for backup vacutainers. These labels have no barcode, and they have 1-4 lines of text indicating which specimen container they are intended for, including the stopper color and volume, if applicable.

There are 2 barcoded labels with the ID number, one with the words “Phlebotomy Form,” which is placed on the Phlebotomy Form (see Blood Collection chapter), and the other with the words “Laboratory Processing Form,” which is placed on the Laboratory Processing Form (Appendix 3). *This process of matching the participant-specific Health ABC Enrollment ID# (**already on the form brought to the lab by the participant**) to the sample-specific ID barcode is crucial to being able to use the data collected from laboratory tests.*

Finally, there are 5 barcoded labels with the same ID number and the words “BDID Form.” These labels may or may not be used, depending on whether there is extra sample left after processing the participant’s blood. Use of these labels is detailed under “Making Blind Duplicate Aliquots” below.

### **3. Safety Issues and Exclusions**

#### **3.1 Precautions for Handling Blood Specimens**

In accordance with the OSHA regulations on blood borne pathogens (see copy on file in laboratory), the LCBR recommends the following laboratory safety protocol for the field center laboratories:

- Non-permeable lab coats, latex gloves, and face shields should be used when handling any blood in any situation where splashes, spray, spatter, or droplets of blood may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- 'Universal Precautions' should be followed when handling any blood products.
- Contaminated needles and sharps shall be immediately placed in a puncture-resistant, leakproof container. Never recap or break needles.
- Hepatitis B vaccine should be offered to all unvaccinated technicians handling blood and documentation of vaccination or technician's declining to be vaccinated should be kept.

### **4. Participant and Exam Room Preparation**

#### **4.1 Preparation for Processing**

All items on the Sample Processing Checklist (Appendix 4) should be on hand before beginning processing.

Aliquot racks will be set up to correspond to each blood collection tube rack. Rack setup is completed the previous day. All tubes and vials are labeled with sample ID bar codes (see Label Orientation diagram in Appendix 2) and arranged in appropriate working order. After labeling draw tubes and cryovials, there will be 9 labels left: 2 "Backup Vacutainer" labels, 1 "Phlebotomy Form," 1 "Laboratory Processing Form" label, 5 "BDID Form" labels. These can be separated into 2 mini-sheets: The "Backup Vacutainer," "Phlebotomy Form" and "Laboratory Processing Form" labels should be clipped to the corresponding blood collection tray. "BDID Form" labels should be clipped to the corresponding aliquot rack.

There should also be a blind duplicate aliquot rack ready at all times. This aliquot rack is set up exactly like the other aliquot racks, except that cryovials #01 and #06 are omitted. To label the blind duplicate cryovials, *use a set of labels designated for blind duplicate samples (see Section 7, Quality Assurance, below)*. The “Laboratory Processing Form” labels (*not the “BDID Form” labels*) from the same sheet should be affixed to a Laboratory Processing form pre-labeled with a dummy participant ID and Acrostic (See Section 7, below). The “BDID Form” labels should be used to label the upper right corner of the Blind Duplicate Identification Form. The same dummy Health ABC ID #s and acrostics used in Year 1 should be used for the identifiers on the Year 4 dummy Phlebotomy and Laboratory Processing Forms. The dummy Laboratory Processing form and Blind Duplicate Identification Form should be clipped to the aliquot rack until all aliquots are filled.

## **5. Detailed Procedures**

### **5.1 Processing**

#### **5.1.1 General**

Tube #1 should be mixed and immediately placed on ice. The other tube (serum tube #2) should be held at room temperature for up to 90 minutes. Personal protective equipment (non-permeable lab coats, double-gloves with at least one latex pair, splatter shields) **MUST BE** worn for processing.

It is possible that not all tubes will be collected due to problems with phlebotomy. During processing, work in the order specified and make as many aliquots as possible while meeting the volume requirement of each cryovial. On the Laboratory Processing form, fill the bubble next to each cryovial that is filled, whether partially or totally. If the sample is hemolyzed, fill the bubble marked H. To determine whether a sample is hemolyzed, compare its color to the chart provided by LCBR. If the tube is only partially filled, fill the bubble marked P. If the tube is both hemolyzed and partially filled, fill the bubble marked B. If the tube is not filled at all, only fill the last bubble (marked not filled).

#### **5.1.2 Description of Blood Collection Tubes**

Each draw tube is color coded to aid in handling.

Tube #1 is a 7 ml lavender stoppered tube containing 15% liquid EDTA as the anticoagulant. After drawing, the tube should be mixed and immediately placed on

ice. 1 mL of whole blood will be collected and stored. This 1 mL will be sent to LCBR for analysis of HgA1c. The cryovial cap is coded white. The remaining blood in the draw tube will be spun. Cryovial caps are coded white. The plasma will be used for archival purposes.

Tube #2 is a 10 ml siliconized red stoppered tube used to collect serum. This tube contains no anticoagulant so that the blood clots to form serum. After drawing, the blood is allowed to clot at room temperature for 40-45 minutes (Maximum = 90 minutes). Cryovial caps are coded red. The serum is used for analysis of fasting glucose, cholesterol, and archiving.

### 5.1.3 Immediate Processing

Upon reaching the blood processing station, remove the blood drawing rack and ice bath containing tubes from the blood collection tray. The rack should contain tube #2. The ice bath should contain tube #1.

Tube #2 must remain at room temperature for a minimum of 40 minutes. Allowing the tubes to stand longer may increase the yield of serum. The maximum allowable time before centrifugation is 90 minutes. Note the time that serum processing started in the space provided on the Laboratory Processing form.

Tube #2 can be held at room temperature for up to 2 hours. These tubes should not be placed on ice. Note the time that cell processing started in the space provided on the Laboratory Processing form. Use standard 12-hour time, and include am/pm.

### 5.1.4 Aliquots per Sample Type:

The following is a summary of the processing. Detailed instructions follow (volume indicates sample size, not cryovial size).

**Whole Blood:** 1 mL of whole blood is collected from tube #1 before spinning. This sample is aliquoted into one 1.5 mL cryovial.  
The total number of aliquots is 1 (Color code = white)

**Plasma:** The plasma from tube #1 is aliquoted into four 0.5 mL cryovials for archival.  
The total number of aliquots is 4 (Color code = white)

**Serum:** The serum from tube #2 is aliquoted into eight 0.5 mL cryovials (One cryovial is sent to LCBR for fasting glucose and a cholesterol test. The remaining aliquots are designated for archival.)  
The total number of aliquots is: 8 (Color code = red)  
8 x 0.5 mL

The total number of aliquots per participant is 13. A detailed listing of aliquots can be found on the Laboratory Processing form

### 5.1.5 Making Whole Blood Aliquots

Collect 1 mL of whole blood from Tube #1 before spinning this tube down for plasma. Place the 1 mL of whole blood into a 1.5 mL cryovial with a white cap (cryovial # 01). Immediately place cryovial #01 in the sample box in the refrigerator. **Do not freeze the whole blood cryovial.**

Aliquots: 1 x 1.0 mL whole blood use 1.5 mL cryovial LCBR

- Follow the outline on the Laboratory Processing form for aliquoting the whole blood samples. Fill the bubble next to the cryovial that is filled, whether partially or totally. If the tube is only partially filled, also fill the bubble marked P. If the tube is not filled at all, fill the bubble in the last column (not filled).

### 5.1.6 Centrifugation of EDTA Plasma Samples

After 1 mL is collected for the whole blood sample, Tube #1 is restoppered and centrifuged at 4° C for 10 minutes at 3000 G. (A total of 30,000 g-minutes).

While these tubes are spinning:

- Restock the blood collection tray with tube rack and blood collection tubes, ice, and forms for the next participant.
- Recheck labels on the aliquot racks to ensure that they match the sample ID# on the draw tubes.
- Perform any necessary clean up.

### 5.1.7 Making EDTA Plasma Aliquots

Once centrifuged, the maximum time allowed before aliquoting the EDTA plasma tube (#1) is 15 minutes. If aliquoting is not immediate (within 15 minutes from removal of tubes from the centrifuge), please note the delay on the comment section of Laboratory Processing Form. Keep the collection tube (#1) on ice until aliquoting can occur.

Aliquots:                    4 x 0.5 mL plasma                    use 0.5 mL cryovial                    McKesson

- Allow the centrifuge(s) to come to a complete stop. Remove tube from the 4° C centrifuge, being careful not to shake the tubes, and put them on ice.
- Follow the outline on the Laboratory Processing form for aliquoting the plasma samples. Fill the bubble next to each cryovial that is filled, whether partially or totally. If the tube is only partially filled, also fill the bubble marked P. If the tube is not filled at all, fill the bubble in the last column (not filled).
- Pipet the plasma with the *proper volume pipet*. Do not use the cryovial to estimate volume.
- Recap aliquots after each sample tube has been pipetted.
- If a sample is hemolyzed, fill the bubble marked H. To determine whether a sample is hemolyzed, compare its color to the chart provided by LCBR. If the tube is both hemolyzed and partially filled, fill the bubble marked B.

**Extra plasma can be used for blind duplicates (see below). When you are finished, the original blood collection tubes should be discarded in a biohazard, puncture-proof sharps container.**

### 5.1.8 Centrifugation of Serum Samples

Tube #2 should be left at room temperature for at least 40-45 minutes (maximum 90 minutes) after it is drawn. It should be displaying a clot by this time. It is centrifuged at 4° C for 10 minutes at 3000 G.

### 5.1.9 Making Serum Aliquots

Allow the centrifuge to come to a complete stop. Carefully remove the tubes from the centrifuge, being careful not to shake the tubes, and place them on ice.

Serum (Tube #2) Color coded Red

Aliquots:	1 x 0.5 mL serum	use 0.5 mL cryovial	LCBR
	7 x 0.5 mL serum	use 0.5 mL cryovial	McKesson

- Follow the outline on the Laboratory Processing form for aliquoting the serum samples. Fill the bubble next to each cryovial that is filled, whether partially or totally. If the tube is only partially filled, also fill the bubble marked P.
- Pipet the serum with the *proper volume pipet*. Do not use the cryovial to estimate volume.
- Recap aliquots after each sample tube has been pipetted.
- If a sample is hemolyzed, fill the bubble marked H. To determine whether a sample is hemolyzed, compare its color to the chart provided by LCBR. If the tube is both hemolyzed and partially filled, fill the bubble marked B. If the tube is not filled at all, fill the bubble in the last column (not filled).

**Extra serum can be used for blind duplicates (see below). When you are finished, the original blood collection tubes should be discarded in a biohazard, puncture-proof sharps container.**

**5.1.10 Making Blind Duplicates (if applicable)**

*Be sure you have read Section 7, Quality Assurance, below and that you understand how the blind duplicate scheme works. Ask your supervisor if you have any questions.*

Each time sufficient sample exists to fill an extra cryovial, an empty cryovial of the correct type will be selected from the blind duplicate aliquot rack and filled with the appropriate quantity of sample (0.5 mL). The filled cryovial will be placed in the **participant’s aliquot rack**, which is in the ice bath.

*Before doing anything else*, a “BDID Form” label must be removed from the **participant’s** label sheet and affixed to the Blind Duplicate Identification Form in the spot corresponding to the aliquot number that was filled. You must also write the **participant’s** sample ID number next to the aliquot number in your Blind Duplicate ID log book. This book is simply a notebook with each page devoted to a separate blind duplicate ID number (see Appendix 5 for example).

For example (see figure on page 10), suppose there is sufficient extra plasma from sample ID #123456 to make a 0.5 mL aliquot. Cryovial 04 from the blind duplicate set ID #432890 has not yet been filled. You will pick up the pre-labeled cryovial 04 (#432890-04), put 0.5 mL of EDTA plasma into it, and place it in the **participant's** aliquot rack (on ice). You will then remove a "BDID Form" label from the **participant's** ID label sheet (#123456) and place it in the spot marked aliquot 04 on the Blind Duplicate Identification Form. You will then write the **participant's** ID #123456 next to aliquot 04 in the log book on the page devoted to blind duplicate set #432890.



### 5.1.11 Freezing

Upon completion of the processing steps, plasma and serum aliquots must be frozen at -70° or on dry ice within a maximum of 30 minutes. **Do not freeze the whole blood cryovial.** Remove that cryovial from the rack immediately after filling and place it in a separate box you will be keeping in your refrigerator (4°C).

After aliquoting is complete, the rack containing the remaining cryovials is removed from the ice bath and placed upright in the freezer at -70° C for at least half an hour (preferably until the end of the day). Make sure the aliquots are not wet when placed in the freezer. If a freezer is not immediately available, place the rack of samples on dry ice.

### 5.1.12 Return Visit Aliquots

Occasionally, participants return to the clinic just to have a blood draw. There are separate forms that must be filled out for return visits: the Return Visit Phlebotomy Form and the Return Visit Lab Processing Form (see Appendix 12). Use a new set of sample ID bar code labels. Place the Phlebotomy Form label in the Bar Code Label space on the Return Visit Phlebotomy Form. Place the Laboratory Processing Form label in the Bar Code Label space on the Return Visit Laboratory Processing Form. Use the rest of the labels in the same way as for the regular clinic visit. Be sure to fill out both forms with the header information including the Health ABC Enrollment ID #, Acrostic, Date Form Completed, and Staff ID #.

If the participant returned only because they were not fasting at the clinic visit, they should have had a complete draw during the clinic visit. You will therefore only have to draw a small amount of blood for a fasting serum sample. Do not draw tube #1. For tube #2, substitute a 3- or 5-mL siliconized red-stoppered tube (the 3-ml pediatric tubes may require a different adapter for the centrifuge). You will get more serum than you need for the fasting serum sample, but you should not fill more cryovials for storage. Fill cryovial 06 only. You may also fill one blind duplicate cryovial 06, if needed. The rest of the serum should be discarded.

Only if the participant did not have blood drawn at all during the clinic visit, use the draw tube labels for Draw Tube 1 and 2 and the cryovial labels for cryovials 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, and 13 as usual. If the participant had an incomplete draw, then draw the tube needed to complete the set of cryovials. For

example, if the participant had an EDTA tube drawn at their clinic visit, but a serum sample could not be obtained, draw the regular 10 mL tube #2 and fill cryovials 06-13.

### 5.1.13 Completed forms

The completed Phlebotomy and Laboratory Processing forms can be set aside in a daily work folder. These forms are copied (one copy of the Phlebotomy Form and two of the Laboratory Processing Form), and then the originals are scanned into the data system and filed at each Field Center. The copies are enclosed with each shipment of samples to the LCBR and to McKesson Bioservices. Note: McKesson only needs a copy of the Laboratory Processing form; the Phlebotomy form is not needed in their sample shipment. Be sure the participant's Health ABC Enrollment ID# and acrostic, the sample ID, and the staff ID are legible on the copies (e.g., not cut off by the copier).

Completed Blind Duplicate Identification forms should also be scanned into the data system. Once a week, make copies of the current Blind Duplicate ID log page(s), the associated dummy Laboratory Processing Forms, and any Blind Duplicate Identification forms completed during the week, and *fax them to Emily Kenyon at the Coordinating Center*. This serves as a backup in case of catastrophic loss of these forms, which would render the blind duplicates unidentifiable and therefore useless.

## 5.2 End of the Day Procedures

- Frozen cryovials in racks are packaged into freezer boxes by numeric order of cryovials per participant. Do not leave spaces in the boxes when the total number of cryovials is less than expected. Samples from one participant may overlap into two boxes. (See freezer box diagrams in Appendix 6)
- Filled blind duplicate cryovials should be temporarily stored in a separate freezer box until the full set has been completed. When all cryovials in the blind duplicate set have been completed, place them in the next available freezer box for McKesson.
- Cryovials (#01 and 06) sent to LCBR in Vermont are each separated out into separate boxes. *Note that the labels on these cryovials include the words "To LCBR" to make them easy to identify.* These boxes should be numbered consecutively (1, 2, 3, etc.) and should also be labeled with the name of the site (Appendix 6).
- Re-stock blood collection trays with supplies.
- Label the next day's draw tubes and cryovials.

- Arrange draw tubes and aliquots in their proper racks.
- Wipe down all work areas with 10% Clorox solution.

### 5.3 Summary of Processing Time Limitations

From end of venipuncture to start of processing:

1.	EDTA 7 ml	15 minutes
2.	Serum 10 mL	90 minutes

Once centrifuged, maximum time before aliquoting: 15 minutes. After aliquoting samples, freeze within 30 minutes.

### 5.4 Shipping the Blood Samples

#### 5.4.1 General

Frozen blood samples are shipped **weekly** to both McKesson Bioservices and LCBR by Federal Express overnight delivery. The schedule will be as follows:

Monday	Memphis
Tuesday	Pittsburgh

This allows the laboratory and repository to stagger the arrival of samples on Tuesdays and Wednesdays for easier processing. When Monday is a holiday, the Monday shipment may be shipped on Tuesday.

Shipments to McKesson are charged to your local Federal Express account number. All shipments to LCBR are charged to the University of Vermont (recipient) Federal Express account.

This shipping protocol follows the procedures mandated by the International Air Transport Association's Dangerous Goods Regulations-Packaging Instructions 650 and 904. All items from the shipping checklist (Appendix 7) should be kept in stock at all times.

Whole blood samples (cryovial 01) must be shipped separately twice weekly by Federal Express overnight delivery to LCBR. This must be done on Monday and Wednesday to allow LCBR to process the tubes within 7 days of collection. Again, when Monday is a holiday, that shipment may be delayed until Tuesday.

### 5.4.2 Methods for shipping frozen samples

The frozen samples to be shipped are those from the previous week. There will be two separate shipments made: one to McKesson Bioservices and one to the University of Vermont.

Make complete copies (all pages) of corresponding Phlebotomy and Laboratory Processing forms for the LCBR shipment. Copies of the Laboratory Processing forms only are made for the McKesson shipment.

Samples should be prepared for shipping as follows:

- Wrap each freezer box in paper towels to absorb possible leakage. Put a rubber band around the towel-wrapped box or bag.
- Put the individual freezer boxes containing the samples into a leakproof zip-lock plastic bag. Seal the zip-lock bags.
- Line the styrofoam mailer with absorbent material (e.g., paper towels).
- Place approximately one third of the dry ice on the bottom of the mailer.
- Carefully place the freezer boxes into the styrofoam mailer. Place no more than a total of 4 L of sample into the styrofoam shipping container. Use two or more styrofoam mailers for the McKesson shipment when necessary. (In this case, label the mailers “1 of 2” and “2 of 2”).
- Place the remaining dry ice (approximately 7 - 14 lbs total) on top and around the samples to fill the styrofoam container.
- Seal the top of the styrofoam container with tape.
- Enclose the styrofoam container in the outer cardboard sleeve.
- Place the copies of the Phlebotomy and Laboratory Processing forms (LCBR) or Laboratory Processing form (McKesson) on top of the styrofoam container before closing up the outer sleeve with tape.

Fill out the FedEx Airbill as follows (Appendix 8):

- Type in your FedEx account number (for both McKesson and LCBR shipments)
- Type the date of the shipment
- Type the name of the person sending the shipment under Section one, where it says ‘From’
- Type in your address and telephone number in Section one.
- Type the recipient’s name, address, and telephone number in Section two. *The telephone number is mandatory.*
- Type an ‘X’ in the Bill Sender box for the McKesson shipment

- Type an 'X' in the Bill Recipient box for the LCBR shipment. Fill in the University of Vermont account number (1531-6949-7) and internal reference number (5-26713) below the account number
- Type an 'X' in Priority Overnight under Section 4a
- Type an 'X' in the Other Packaging box in Section 5
- Type an 'X' in the Deliver Weekday box (Box 2).
- Place an 'X' in the "Dry Ice" box in Section five (Box 6). Enter the weight of the dry ice in kilograms as specified and the number of boxes shipped.
- In section 6, place an 'X' in the 'Yes (Shipper's declaration not required)' box

Affix the completed airbill to the front side of the package in the plastic pouch (see Appendix 9).

The following additional labels are to be attached to each shipping box. (A diagram showing the placement of these labels on the shipping container is shown in Appendix 9):

- Return Address Label: placed on top in upper left corner.
- Consignee Address Label: placed on top in bottom right corner.
- Black and White Class 9 Label: placed on top in upper right hand corner.  
(UN1845, see Appendix 9)
- Diagnostic Specimen Label: placed on top under the return address label.
- Keep Frozen Label (optional): placed on any side

It is necessary to weigh the entire shipping container. The weight of the dry ice in kilograms is written on the Black and White Class 9 Label (Appendix 9) in the space provided and filled in on the FedEx airbill.

The LCBR mailing address at the University of Vermont is:

Elaine Cornell  
University of Vermont-Pathology  
55 A South Park Drive  
Colchester, VT 05446  
(802) 656-8963

The McKesson Bioservices mailing address is:

Patrick Hobson-Garcia  
McKesson BioServices  
685 Lofstrand Lane  
Rockville, MD 20850  
(301) 340-1620

FAX the following information to McKesson Bioservices at (301) 340-3275 when a shipment is sent:

Date of shipment  
Expected arrival date  
Number of styrofoam mailers shipped  
FedEx airbill number

#### 5.4.3 Methods for shipping whole blood samples

The refrigerated samples to be shipped on Monday are those from that day and the previous Thursday and Friday. The samples to be shipped on Wednesday are those from that day and Tuesday. These samples are already packaged in pre-labeled boxes stored in the refrigerator.

- Fill out the LCBR Shipping Form for Whole Blood (Cryovial #1) (Appendix 10), listing the sample barcode, participant's HABCID, the date of the Year 4 clinic visit for each sample in the box. The easiest way to do this is by copying this information from the stack of xeroxed Phlebotomy and Laboratory Processing forms in your daily work folder (see section 5.1.13), making sure you don't include any cryovials that have already been shipped. Once the Shipping Form is completed, double check against the vials in the box to be shipped, to ensure that all vials in the box are listed on the form and all vials listed on the form are in the box.
- Fax a copy of the LCBR Shipping Form for Whole Blood to Elaine Cornell (Fax # 802-656-8965).
- Wrap the box containing the samples in paper towels to absorb possible leakage. Put a rubber band around the box.
- Place the box into a leakproof zip-lock plastic bag and seal.
- Line the styrofoam mailer with absorbent material (e.g., paper towels)
- Place one or two ice packs or frozen gel packs **not dry ice** into the bottom of the mailer. Add a layer of newspaper.
- Carefully place the sample box into the styrofoam mailer on top of the newspaper, then cover with another layer of newspaper. Place another one or two

ice packs on top and around it. **Do not let the ice pack come into direct contact with the sample box.**

- It may be helpful to pack any remaining empty space with newspaper to prevent the package from shifting during shipment.
- Keep a copy of the shipping form to fax to LCBR with the FedEx tracking number. Enclose one copy with the styrofoam mailer.
- Seal the top of the styrofoam container with tape.
- Enclose the styrofoam container in the outer cardboard sleeve.
- Place the LCBR Shipping Form for Whole Blood (Cryovial #1) on top of the styrofoam container before closing up the outer sleeve with tape. Do not enclose copies of the Phlebotomy and Laboratory Processing forms with this shipment, as they will be included in the shipment of frozen samples for the same participants.
- Seal the outer sleeve with tape.
- Be sure to use appropriate styrofoam mailers that LCBR provides.
- Fill out the FedEx Airbill as above, except that the “Dry Ice” box should not be checked in section 5.
- Fax the LCBR Shipping Form for Whole Blood to LCBR at 802-656-8965.

The LCBR mailing address at the University of Vermont is:

Elaine Cornell  
University of Vermont-Pathology  
55 A South Park Drive  
Colchester, VT 05446  
(802) 656-8963

## **6. Procedures for Performing the Measurements at Home**

This procedure is the same for home visits as for clinic visits. The samples will be returned to the lab as soon as possible after the home visit, preferably within 2 hours. Be sure to check the "time blood draw completed" field on the Phlebotomy form and begin processing within the time limits described in Section 5.3. This may not be possible if there was a delay in getting the samples back to the lab. It is therefore doubly important to record the time processing was started on the Lab Processing form.

## 7. Quality Assurance

### 7.1 Blind duplicate aliquots

#### 7.1.1 Rationale:

In order to monitor reproducibility of the assays being carried out by LCBR, it is necessary for them to assay 5% of the samples twice, *without knowing which samples are duplicates*. This year, this applies only to assays that will be run later from archived samples.

In order for this process to work, the duplicate blood must appear to be blood from another participant. A further complication is that almost the full yield of serum collected from each participant will be aliquoted for immediate assay or storage. The process of producing these blind duplicates is therefore difficult to explain, but easy to carry out once the process is understood.

#### 7.1.2 Blind duplicate sample IDs:

Before the sample ID labels sheets are sent to the clinics, the coordinating center will identify a random sample of 5% of the IDs. These sample IDs, *indistinguishable from regular sample IDs*, will become blind duplicate sample IDs. The labels for sample collection should be removed from these sheets so they cannot be confused with participant sample labels.

To create a “blind duplicate participant” the blood processing staff will need to aliquot into extra cryovials any extra serum left after completing the set of cryovials for any particular participant. The cryovials to be used for this process will be set up in an aliquot rack exactly like those for a participant except that there will be no cryovial 01 or 06. This blind duplicate aliquot rack must be kept handy during the processing of all participant samples.

A sheet of blind duplicate sample ID labels will be used to label the cryovials in the blind duplicate aliquot rack exactly as is done for regular cryovials. A “BDID Form” label from the sheet of **blind duplicate sample ID labels** will be placed in the appropriate box at the top of the “Blind Duplicate Identification Form” (see Appendix 11), *and this form must be kept with the corresponding aliquot rack until all the cryovials are filled*. Since each aliquot labeled with the blind duplicate ID number may be filled with sample from a different participant, it is vital that the **participants’**

**sample IDs** be associated with the correct aliquots in the data system. Therefore, a “BDID Form” label from the **participant’s** label sheet will be placed in the bubble corresponding to the aliquot filled with that participant’s sample.

### 7.1.3 Paperwork:

*In addition, a dummy Laboratory Processing form must be made for each blind duplicate ID number used (no dummy Phlebotomy form is needed this year because no blind duplicate samples are being sent directly to LCBR). It is not necessary to waste an entire clinic visit workbook to get this form. The Laboratory Processing form should be photocopied from a blank workbook. The dummy Laboratory Processing forms should be filled out with the same dummy Health ABC Enrollment ID#s and Acrostics used for the first visit. The Coordinating Center has provided a list of Health ABC Enrollment ID#s and Acrostics used in Year 1; if you need another copy, contact Emily Kenyon.*

Keep the dummy form with the blind duplicate aliquot rack until all cryovials are filled. McKesson and the Coordinating Center need only the Laboratory Processing form. **Once copies of the Laboratory Processing forms are sent to the Coordinating Center and McKesson, selected fields from the original Laboratory Processing form need to be entered into the data system.** Only the Health ABC Enrollment ID#, acrostic, date that the form was completed, staff ID #, the bar code, and the visit year will need to be entered. A separate screen has been created for the entry of this form (for data entry purposes, the form is called the “Laboratory Processing for Blind Duplicate Form”). These few fields will have to be keyboard entered (including the bar code number), not scanned.

A central file should be created for all of the Laboratory Processing Forms for the blind duplicates. Once the Laboratory Processing Form has been entered into the data system, it should be filed in this central file.

Completed Blind Duplicate Identification Forms should be scanned into the data system. Note that this is *in addition* to the weekly faxing of current forms to the Coordinating Center. Once the Blind Duplicate Identification form has been scanned it should be filed with its associated dummy Phlebotomy and Laboratory Processing forms.

### 7.1.4 Keeping the blind duplicates “in sync” with the normal samples:

Blind duplicate cryovials should be filled in the same order as regular cryovials. Do not make partial blood aliquots for blind duplicates. If there is not enough sample

left to fill a blind duplicate aliquot to the intended level, discard the remaining sample.

Note that you should be completing a blind duplicate set for approximately every 20 participants. You should not get far ahead or fall far behind. If you fill up a blind duplicate set quickly, wait until the next blind duplicate ID is in the series of regular IDs that you are currently using on participants. If you fall behind, adjustments will have to be made.

If your blind duplicates are falling behind, the first thing to do is examine your pipetting technique. Variations in pipetting, especially the depth to which the pipet is dipped in the sample, can have large effects on sample loss during aliquoting. If this is not the problem and you find that you are unable to fill up blind duplicate sets as planned, notify your supervisor and they should contact the Health ABC Coordinating Unit. This should be done as soon as the problem is detected, as alternative plans will have to be made.

## **7.2 Training Requirements**

Clinical experience with processing of blood samples is strongly recommended. Additional training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe processing by experienced examiner)
- Discuss problems and questions with local expert or QC officer

## **7.3 Certification Requirements**

- Complete training requirements
- Explain blind duplicate aliquoting scheme
- Recite shipping schedule for applicable field center
- Process samples from volunteer or participant while being observed by QC officer using QC checklist

## **7.4 Quality Assurance Checklist**

### Preparation

- Aliquot racks correctly set up
- Blind duplicate rack correctly set up

- Cryovials correctly labeled
- Hepatitis B vaccination given or offered to all personnel handling blood

#### Processing EDTA whole blood, plasma and urine

- Time checked to ensure that tube 3 is processed within 15 minutes of completion of phlebotomy
- Whole blood correctly aliquoted
- Tube #1 centrifuged at 4° C for 10 min at 3000 G
- Plasma correctly aliquoted

#### Processing serum tubes

- Time checked to ensure that tube# 2 has stood at room temperature for at least 40 minutes, maximum 90 minutes
- Tube 2 centrifuged for 10 minutes at 3000 G.
- Centrifuge correctly balanced with water tube(s)
- Serum correctly aliquoted

#### Blind duplicates

- Extra sample stored as blind duplicates, if available
- All remaining sample discarded in hazardous waste container

#### Freezing

- Remaining aliquots checked to ensure they are not wet
- Rack placed upright in -20° C freezer or samples placed on dry ice

#### Whole Blood Sample

- Sample placed immediately in refrigerator after filling.

#### Shipment procedure – whole blood

- Boxes correctly wrapped, etc.
- Styrofoam mailers correctly packed – absorbent material, ice pack or frozen gel pack not dry ice, newspaper, sample, more newspaper, more ice packs, top sealed with tape.

## End of day procedure

- Phlebotomy and Laboratory Processing forms placed in daily work folder
- Frozen aliquots removed from rack and placed in appropriate freezer boxes
- Freezer boxes correctly labeled
- Aliquots 01 and 06 stored in separate boxes, each for shipment to LCBR
- Aliquots 02-05, and 07-13 placed in freezer boxes for McKesson

## Shipment procedures -- dry ice

- Freezer boxes correctly wrapped -- absorbent material, rubber band, and zip-lock bag
- Styrofoam mailers correctly packed -- absorbent material, dry ice, top sealed with tape
- Styrofoam mailer sealed in cardboard sleeve
- FedEx airbill correctly filled out
- Labels correctly affixed

## APPENDIX 1 Health ABC Cryovials and Processing

<b>VENDORS:</b>
VWR: 800-932-5000 <a href="http://www.vwrsp.com">www.vwrsp.com</a>
Fisher Scientific: 800-766-7000 <a href="http://www.fishersci.com">www.fishersci.com</a>
Polyfoam Packers: 800-323-7442 <a href="http://www.polyfoam.com">www.polyfoam.com</a>
Krackler Scientific: 800-334-7725 (NY)
Krackler Scientific: 800-221-6921 (NC)
BD- Vacutainer: 888-237-2762
BD: Becton Dickson brand, available through VWR, Baxter, and Fisher

Note: Prices are from the catalogs. Educational discounts should apply.

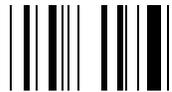
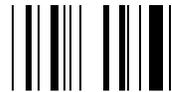
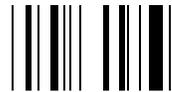
cryovials / caps/ racks	# per participant	sample type	vendor: catalog #	\$ price/pk
0.5 mL with skirt w/o cap non-sterile	12	serum, plasma	VWR: 20170-209	28.10/ 500
1.5 mL with skirt w/ clear cap	1	whole blood	VWR: 20170-213	28.10/ 500
colored screw cap: red	8	serum	Fisher: 02-681-361	68.77/ 500
colored screw cap: white	5	WB, plasma	VWR: 20170-274	50.21/ 500
cryovial rack	1	all	VWR: 30128-346	60.00/ 5
			Fisher: 07-200-618	37.15/ 2
cover for cryovial rack	1 optional	all	VWR: 30128-350	39.00/ 5

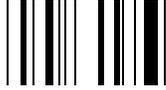
Blood collection supplies	# per participant	sample type	vendor: catalog #	\$ price/pk
10 mL vacutainer/ 16 x 100 size	1	serum	VWR:VT6430 / BD: 6430	25.94/ 100
			Fisher: 02-685-A	28.81/ 100
7 mL EDTA vacutainer / 13 x 75 size	1	plasma	VWR:VT6454/BD:366454	28.81/ 100
			Fisher: 02-685-2A	31.64/ 100
vacutainer blood collection set 21G 3/4"	1		VWR: VT7251	60.50/ 50
			Fisher: 02-664-1	78.25/ 50
vacutainer needle holders	1	NA	BD: 4893	
			Fisher: 02-665-110	182.00/ 10
transfer pipets (3.2 mL is fine)	~4	all	Fisher: 13-711-7	33.80/ 500

**Laboratory Specimen Processing  
Operations Manual Vol. VI**

<b>Storage/ Shipping Supplies</b>	<b># suggested</b>	<b>sample type</b>	<b>vendor: catalog #</b>	<b>\$ price/pk</b>
freezer boxes (from McKesson)(2")	NA	all	VWR: 55705-424	24.00/ 12
			Krackeler: 114-5144-F12	24.03/ 12
box dividers (9X9)	NA	all	VWR: 55701-762	16.00/ 12
			Krackeler: 114-5144-F29	16.19/ 12
Leakproof ziplock bags (12 x 12")	23 per week		VWR: 11217-128	101.51/ 250
Polyfoam Packer products(reusable):	4 for start			
styrofoam shipping containers: 346			Krackeler	112.90/ 8
styrofoam shipping containers: 430			Krackeler	84.70/ 4
ice packs: U-TEK reusable packs	12 oz		VWR: 15715-105	21.40/ 24
			Krackeler	26.00/ 24

**APPENDIX 2 Sample Label Sheet (Bar Codes)**  
**(page 1 of 3)**

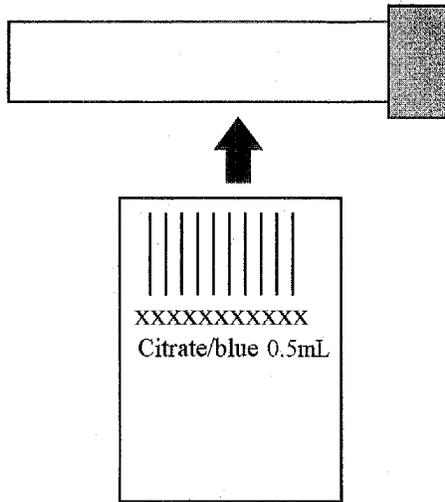
<p>##### Draw Tube 1 Purple top 7 mL</p>	<p>##### Draw Tube 2 Red top 10 mL</p>	<p>##### Backup Vacutainer</p>
<p>##### Backup Vacutainer</p>	<p>##### Phlebotomy Form</p>	<p>##### Laboratory Processing Form</p>
<p>Place this end on vial first</p>  <p>#####-01 W/1.5 whole blood To LCBR DO NOT FREEZE</p>	<p>Place this end on vial first</p>  <p>#####-02 W/EDTA 0.5</p>	<p>Place this end on vial first</p>  <p>#####-03 W/EDTA 0.5</p>

<p>Place this end on vial first</p>  <p>#####-04 W/EDTA 0.5</p>	<p>Place this end on vial first</p>  <p>#####-05 W/EDTA 0.5</p>	<p>Place this end on vial first</p>  <p>#####-06 R/Serum 0.5 To LCBR</p>
<p>Place this end on vial first</p>  <p>#####-07 R/Serum 0.5</p>	<p>Place this end on vial first</p>  <p>#####-08 R/Serum 0.5</p>	<p>Place this end on vial first</p>  <p>#####-09 R/Serum 0.5</p>
<p>Place this end on vial first</p>  <p>#####-10 R/Serum 0.5</p>	<p>Place this end on vial first</p>  <p>#####-11 R/Serum 0.5</p>	<p>Place this end on vial first</p>  <p>#####-12 R/Serum 0.5</p>
<p>Place this end on vial first</p>  <p>#####-13 R/Serum 0.5</p>	 <p>##### BDID Form</p>	 <p>##### BDID Form</p>



# HEALTH ABC STUDY

## Label Orientation on Cryovial



APPENDIX 3 Laboratory Processing Form

**Health ABC**

HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
H <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
		Month / Day / Year	

**LABORATORY PROCESSING**

Time at start of processing:  :   am  
 pm

Bar Code Label

Collection Tubes	Cryo #	Vol.	Type	To	Fill in Bubble	Problems	Not Filled
#1 whole blood	01	1.0	W/1.5	L	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
#1 EDTA plasma	02	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	03	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	04	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	05	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
#2 serum	06	0.5	R/0.5	L	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	07	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	08	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	09	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	10	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	11	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	12	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	13	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>

L=LCBR; M=McKesson; H=Hemolyzed; P=Partial; B=Both; R=red; W=white

LCBR Use only: Received Date: \_\_\_\_\_ Time: \_\_\_\_\_

Frozen?  Yes  No

Page Link #

◆Page 41◆ Y4CVW Version 1.0, 6/06/2000 pjm

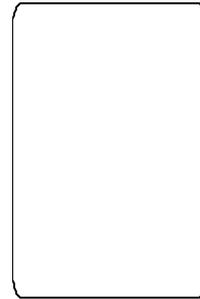


**APPENDIX 4 Sample Processing Checklist**

- Blind duplicate aliquot rack
- Crushed ice in ice bucket or plastic tub
- Pipets: 1.0 volumes and pipet tips
- Labeled cryovials in rack
- Lab coat and gloves
- Biohazardous waste disposal
- Refrigerated centrifuge capable of spinning at 30,000 g-minutes
- Room-temperature centrifuge
- Balance tubes for the centrifuge
- 10% bleach solution
- Styrofoam container for freezing cell cryovials
- Freezer boxes with 9 x 9 grid
- Rubber bands

**APPENDIX 5 Example of Blind Duplicate ID Log Page**

bd ID Form  
label from  
**blind duplicate**  
label set



	Sample ID Bar Code #
aliquot 2	
aliquot 3	
aliquot 4	
aliquot 5	
aliquot 7	
aliquot 8	
aliquot 9	
aliquot 10	
aliquot 11	
aliquot 12	
aliquot 13	

**APPENDIX 6 Freezer Box Diagrams**  
(page 1 of 3)

**Freezer Box Diagram for Shipping Plasma and Serum Samples  
to McKesson Bioservices**

Numbers = cryovial #

Complete sets of cryovials available for these four participants. 11 total blood sample cryovials per participant

start #1

Top

<b>Ppt #1</b> 02	03	04	05	07	08	09	10	11
12	13	<b>Ppt #2</b> 02	03	04	05	07	08	09
10	11	12	13	<b>Ppt #3</b> 02	03	04	05	07
08	09	10	11	12	13	<b>Ppt #4</b> 02	03	04
05	07	08	09	10	11	12	13	<b>Ppt #5</b> 02
03	04	05	07	08	09	10	11	12
13	<b>Ppt #6</b> 02	03	04	05	07	08	09	10
11	12	13	<b>Ppt #7</b> 02	03	04	05	07	08
09	10	11	12	13	<b>Ppt #8</b> 02	03	04	05

Bottom

End#81

Label outside of box: Health ABC Plasma/Serum Box #1 Date: \_\_\_ / \_\_\_ / \_\_\_

Continue to next box. . .

**APPENDIX 6  
Freezer Box Diagrams  
(page 2 of 3)**

**Freezer Box Diagram for Whole Blood to LCBR**

**Note: this box must be clearly labeled “Whole Blood -- do not freeze”**

Numbers = cryovial #

start #1

Top

<b>Ppt #1</b> 01	<b>Ppt #2</b> 01	<b>Ppt #3</b> 01	<b>Ppt #4</b> 01	<b>Ppt #5</b> 01	<b>Ppt #6</b> 01	<b>Ppt #7</b> 01	<b>Ppt #8</b> 01	<b>Ppt #9</b> 01
<b>Ppt #10</b> 01	<b>Ppt #11</b> 01	<b>Ppt #12</b> 01	<b>Ppt #13</b> 01	<b>Ppt #14</b> 01	<b>Ppt #15</b> 01	<b>Ppt #16</b> 01	<b>Ppt #17</b> 01	<b>Ppt #18</b> 01
<b>Ppt #19</b> 01	<b>Ppt #20</b> 01	<b>Ppt #21</b> 01	<b>Ppt #22</b> 01	<b>Ppt #23</b> 01	<b>Ppt #24</b> 01	<b>Ppt #25</b> 01	<b>Ppt #26</b> 01	<b>Ppt #27</b> 01
<b>Ppt #28</b> 01	<b>Ppt #29</b> 01	<b>Ppt #30</b> 01	<b>Ppt #31</b> 01	<b>Ppt #32</b> 01	<b>Ppt #33</b> 01	<b>Ppt #34</b> 01	<b>Ppt #35</b> 01	<b>Ppt #36</b> 01
<b>Ppt #37</b> 01	<b>Ppt #38</b> 01	<b>Ppt #39</b> 01	<b>Ppt #40</b> 01	<b>Ppt #41</b> 01	<b>Ppt #42</b> 01	<b>Ppt #43</b> 01	<b>Ppt #44</b> 01	<b>Ppt #45</b> 01
<b>Ppt #46</b> 01	<b>Ppt #47</b> 01	<b>Ppt #48</b> 01	<b>Ppt #49</b> 01	<b>Ppt #50</b> 01	<b>Ppt #51</b> 01	<b>Ppt #52</b> 01	<b>Ppt #53</b> 01	<b>Ppt #54</b> 01
<b>Ppt #55</b> 01	<b>Ppt #56</b> 01	<b>Ppt #57</b> 01	<b>Ppt #58</b> 01	<b>Ppt #59</b> 01	<b>Ppt #60</b> 01	<b>Ppt #61</b> 01	<b>Ppt #62</b> 01	<b>Ppt #63</b> 01
<b>Ppt #64</b> 01	<b>Ppt #65</b> 01	<b>Ppt #66</b> 01	<b>Ppt #67</b> 01	<b>Ppt #68</b> 01	<b>Ppt #69</b> 01	<b>Ppt #70</b> 01	<b>Ppt #71</b> 01	<b>Ppt #72</b> 01
<b>Ppt #73</b> 01	<b>Ppt #74</b> 01	<b>Ppt #75</b> 01	<b>Ppt #76</b> 01	<b>Ppt #77</b> 01	<b>Ppt #78</b> 01	<b>Ppt #79</b> 01	<b>Ppt #80</b> 01	<b>Ppt #81</b> 01

Bottom

End#81  
continue to

Label outside of box: Health ABC Whole Blood Box #1 Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ next box....  
**Do not freeze**

**APPENDIX 6**  
**Freezer Box Diagrams**  
**(page 3 of 3)**

**Freezer Box Diagram for Shipping Serum Samples to LCBR/Vermont**

Numbers = cryovial #

start #1				Top				
<b>Ppt #1</b> 06	<b>Ppt #2</b> 06	<b>Ppt #3</b> 06	<b>Ppt #4</b> 06	<b>Ppt #5</b> 06	<b>Ppt #6</b> 06	<b>Ppt #7</b> 06	<b>Ppt #8</b> 06	<b>Ppt #9</b> 06
<b>Ppt #10</b> 06	<b>Ppt #11</b> 06	<b>Ppt #12</b> 06	<b>Ppt #13</b> 06	<b>Ppt #14</b> 06	<b>Ppt #15</b> 06	<b>Ppt #16</b> 06	<b>Ppt #17</b> 06	<b>Ppt #18</b> 06
<b>Ppt #19</b> 06	<b>Ppt #20</b> 06	<b>Ppt #21</b> 06	<b>Ppt #22</b> 06	<b>Ppt #23</b> 06	<b>Ppt #24</b> 06	<b>Ppt #25</b> 06	<b>Ppt #26</b> 06	<b>Ppt #27</b> 06
<b>Ppt #28</b> 06	<b>Ppt #29</b> 06	<b>Ppt #30</b> 06	<b>Ppt #31</b> 06	<b>Ppt #32</b> 06	<b>Ppt #33</b> 06	<b>Ppt #34</b> 06	<b>Ppt #35</b> 06	<b>Ppt #36</b> 06
<b>Ppt #37</b> 06	<b>Ppt #38</b> 06	<b>Ppt #39</b> 06	<b>Ppt #40</b> 06	<b>Ppt #41</b> 06	<b>Ppt #42</b> 06	<b>Ppt #43</b> 06	<b>Ppt #44</b> 06	<b>Ppt #45</b> 06
<b>Ppt #46</b> 06	<b>Ppt #47</b> 06	<b>Ppt #48</b> 06	<b>Ppt #49</b> 06	<b>Ppt #50</b> 06	<b>Ppt #51</b> 06	<b>Ppt #52</b> 06	<b>Ppt #53</b> 06	<b>Ppt #54</b> 06
<b>Ppt #55</b> 06	<b>Ppt #56</b> 06	<b>Ppt #57</b> 06	<b>Ppt #58</b> 06	<b>Ppt #59</b> 06	<b>Ppt #60</b> 06	<b>Ppt #61</b> 06	<b>Ppt #62</b> 06	<b>Ppt #63</b> 06
<b>Ppt #64</b> 06	<b>Ppt #65</b> 06	<b>Ppt #66</b> 06	<b>Ppt #67</b> 06	<b>Ppt #68</b> 06	<b>Ppt #69</b> 06	<b>Ppt #70</b> 06	<b>Ppt #71</b> 06	<b>Ppt #72</b> 06
<b>Ppt #73</b> 06	<b>Ppt #74</b> 06	<b>Ppt #75</b> 06	<b>Ppt #76</b> 06	<b>Ppt #77</b> 06	<b>Ppt #78</b> 06	<b>Ppt #79</b> 06	<b>Ppt #80</b> 06	<b>Ppt #81</b> 06

Bottom

End#81  
continue to  
next box...

Label outside of box: Health ABC Serum Box #1 Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
**TO LCBR**

**APPENDIX 7 Sample Shipping Checklist**

- Styrofoam Mailing Container (2 different sizes)
- with outer cardboard sleeve
- Polyfoam Packers # 430*
- Polyfoam Packers # 346*
- Absorbent material
- Freezer boxes with 9x9 grids (rubber bands around box)
- Leakproof Zip-lock bags
- Packaging tape
- Dry ice (approximately 20 lbs. per week)
- Ice packs for whole blood shipments
- FedEx Labels (provided by carrier)
- Copies of Completed Phlebotomy/Processing Forms

Shipping materials can be purchased from: (these materials are also included in Appendix 1)

**Insulated shipping boxes:**

Polyfoam Packers 1-800-323-7442

Catalog No. 346 - for shipping up to twelve 2" freezer boxes

Catalog No. 430 - for shipping up to five 2" freezer boxes

**Leakproof ziplock bags:**

VWR 1-800-234-5227

Cat. No. 11217-128 - Bitran 12" x 12" zip-lock bag

**Freezer storage boxes:**

VWR 1-800-234-5227

Cat. No. 5954 - 2" freezer boxes for 2 mL cryovials

Cat. No. 6212 - 81-cell dividers for freezer boxes

**Ice Packs:**

VWR 1-800-234-5227

Cat. No., 14715-105 U-TEK Reusable Refrigerant Packs

**FedEx airbills and airbill pouches:**

Local FedEx office

**Class 9 labels:**

Local FedEx office

“Diagnostic Specimens” and “Keep Frozen” labels:  
The sites can produce these labels.

APPENDIX 8 Federal Express Airbill for Dry Ice Shipment

**FedEx USA Airbill** Tracking Number **9260216991**

**1 From (please print)**  
 Date \_\_\_\_\_ Sender's FedEx Account Number \_\_\_\_\_  
 Sender's Name \_\_\_\_\_ Phone (\_\_\_\_) \_\_\_\_\_  
 Company \_\_\_\_\_ Dept./Floor/Suite/Room \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

**2 Your Internal Billing Reference Information**  
 (Optional) (First 24 characters will appear on invoice)

**3 To**  
 Recipient's Name **Patrick Hobson-Garcia** Phone: **301-340-1620**  
 Company **McKESSON BIOSERVICES**  
 Dept./Floor/Suite/Room \_\_\_\_\_  
 Address **685 LOFSTRAND LANE**  
 (No "HOLD" or FedEx location, print FedEx address here) (We Cannot Deliver to P.O. Boxes or P.O. Zip Codes)  
 City **ROCKVILLE** State **MD** Zip **20850**

**For HOLD at FedEx Location check here** (Not available at all locations)  
 Hold Weekday (Not available with FedEx First Overnight or FedEx Standard Overnight)  
 Hold Saturday (Not available at all locations)  
**For Saturday Delivery check here** (Extra Charge. Not available at all locations)  
 (Not available with FedEx First Overnight or FedEx Standard Overnight)

**Service Conditions, Declared Value, and Limit of Liability:** By using this Airbill, you agree to the service conditions in our current Service Guide or U.S. Government Service Guide. Both are available on request. See back of Sender's Copy of this airbill for information and additional terms. We will not be responsible for any claim in excess of \$100 per package unless the result of loss, damage, or delay, non-delivery, misdelivery, or misrouting, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. Your right to recover from us for any loss includes intrinsic value of the package, loss of sales, interest, profit, attorney's fees, costs, and other items of damage, whether direct, incidental, consequential or special, and is limited to the greater of \$100 or the declared value but cannot exceed actual documented loss. The maximum declared value for any FedEx Letter and FedEx Pak is \$500. Federal Express may, upon your request and with your authorization, refund all transportation charges paid. See the FedEx Service Guide for further details.

**Questions?**  
 Call 1-800-Go-FedEx (1-800-463-3339)

*The World On Time*

**Sender's Copy**

**4 Service** Delivery commitment may be later in some areas.  
 FedEx Priority Overnight (Next business morning)  FedEx Standard Overnight (Next business afternoon)  FedEx 2Day\* (Second business day)  
 FedEx Govt. Overnight (Authorized user only)  FedEx 2Day Freight  
 FedEx Overnight Freight (For packages over 150 pounds. Call for delivery schedule.)  
 NEW FedEx First Overnight (Earliest next business morning delivery to select locations) \*FedEx Letter Rate not available. Minimum charge: One pound FedEx 2Day rate. (Higher rates apply)

**5 Packaging**  
 FedEx Letter\* (Declared value limit \$500)  FedEx Pak\*  FedEx Box  FedEx Tube  Other Packaging

**6 Special Handling**  
 Does this shipment contain dangerous goods?  Yes (Do not attach Shipper's Declaration)  Yes (Shipper's Declaration not req.)  
 Dry Ice (5, UN 1845 III) (Dangerous Goods Shipper's Declaration not required)  No 904 CA  Cargo Aircraft Only

**7 Payment**  
 Bill to:  Sender (Account no. in section 7 will be billed)  Recipient (Enter FedEx account no. or Credit Card no. below)  Third Party  Credit Card  Cash/Check

FedEx Account No. \_\_\_\_\_ Card No. \_\_\_\_\_ Exp. Date \_\_\_\_\_

Total Packages	Total Weight	Total Declared Value*	Total Charges*
		\$ 00	\$

\*When declaring a value higher than \$100 per package, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

**8 Release Signature**  
 Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.  
 FORM ID NO. **0200** **232**  
 Rev. Date 10/05 • PART #147382  
 ©1994-95 FedEx • PRINTED IN U.S.A.  
 CDRF 100

**FedEx USA Airbill** Tracking Number **9260217002**

**1 From (please print)**  
 Date \_\_\_\_\_ Sender's FedEx Account Number \_\_\_\_\_  
 Sender's Name \_\_\_\_\_ Phone (\_\_\_\_) \_\_\_\_\_  
 Company \_\_\_\_\_ Dept./Floor/Suite/Room \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

**2 Your Internal Billing Reference Information**  
 (Optional) (First 24 characters will appear on invoice)

**3 To (please print)**  
 Recipient's Name **ELAINE CORNELL** Phone: **(802) 656-8963**  
 Company **UNIVERSITY OF VERMONT - PATHOLOGY**  
 Dept./Floor/Suite/Room \_\_\_\_\_  
 Address **55A SOUTH PARK DR**  
 (No "HOLD" or FedEx location, print FedEx address here) (We Cannot Deliver to P.O. Boxes or P.O. Zip Codes)  
 City **COLCHESTER** State **VT** Zip **05446**

**For HOLD at FedEx Location check here** (Not available at all locations)  
 Hold Weekday (Not available with FedEx First Overnight or FedEx Standard Overnight)  
 Hold Saturday (Not available at all locations)  
**For Saturday Delivery check here** (Extra Charge. Not available at all locations)  
 (Not available with FedEx First Overnight or FedEx Standard Overnight)

**Service Conditions, Declared Value, and Limit of Liability:** By using this Airbill, you agree to the service conditions in our current Service Guide or U.S. Government Service Guide. Both are available on request. See back of Sender's Copy of this airbill for information and additional terms. We will not be responsible for any claim in excess of \$100 per package unless the result of loss, damage, or delay, non-delivery, misdelivery, or misrouting, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. Your right to recover from us for any loss includes intrinsic value of the package, loss of sales, interest, profit, attorney's fees, costs, and other items of damage, whether direct, incidental, consequential or special, and is limited to the greater of \$100 or the declared value but cannot exceed actual documented loss. The maximum declared value for any FedEx Letter and FedEx Pak is \$500. Federal Express may, upon your request and with your authorization, refund all transportation charges paid. See the FedEx Service Guide for further details.

**Questions?**  
 Call 1-800-Go-FedEx (1-800-463-3339)

*The World On Time*

**Sender's Copy**

**4 Service** Delivery commitment may be later in some areas.  
 FedEx Priority Overnight (Next business morning)  FedEx Standard Overnight (Next business afternoon)  FedEx 2Day\* (Second business day)  
 FedEx Govt. Overnight (Authorized user only)  FedEx 2Day Freight  
 FedEx Overnight Freight (For packages over 150 pounds. Call for delivery schedule.)  
 NEW FedEx First Overnight (Earliest next business morning delivery to select locations) \*FedEx Letter Rate not available. Minimum charge: One pound FedEx 2Day rate. (Higher rates apply)

**5 Packaging**  
 FedEx Letter\* (Declared value limit \$500)  FedEx Pak\*  FedEx Box  FedEx Tube  Other Packaging

**6 Special Handling**  
 Does this shipment contain dangerous goods?  Yes (Do not attach Shipper's Declaration)  Yes (Shipper's Declaration not required)  
 Dry Ice (5, UN 1845 III) (Dangerous Goods Shipper's Declaration not required)  No 904 CA  Cargo Aircraft Only

**7 Payment**  
 Bill to:  Sender (Account no. in section 7 will be billed)  Recipient (Enter FedEx account no. or Credit Card no. below)  Third Party  Credit Card  Cash/Check

FedEx Account No. **1531-6949-7** (5-26713) Card No. \_\_\_\_\_ Exp. Date \_\_\_\_\_

Total Packages	Total Weight	Total Declared Value*	Total Charges*
		\$ 00	\$

\*When declaring a value higher than \$100 per package, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

**8 Release Signature**  
 Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.  
 FORM ID NO. **0200** **232**  
 Rev. Date 10/05 • PART #147382  
 ©1994-95 FedEx • PRINTED IN U.S.A.  
 CDRF 100

**APPENDIX 9 Dry Ice Label and Labeling Diagram**  
(page 1 of 2)

Shipper's Declaration not Required.

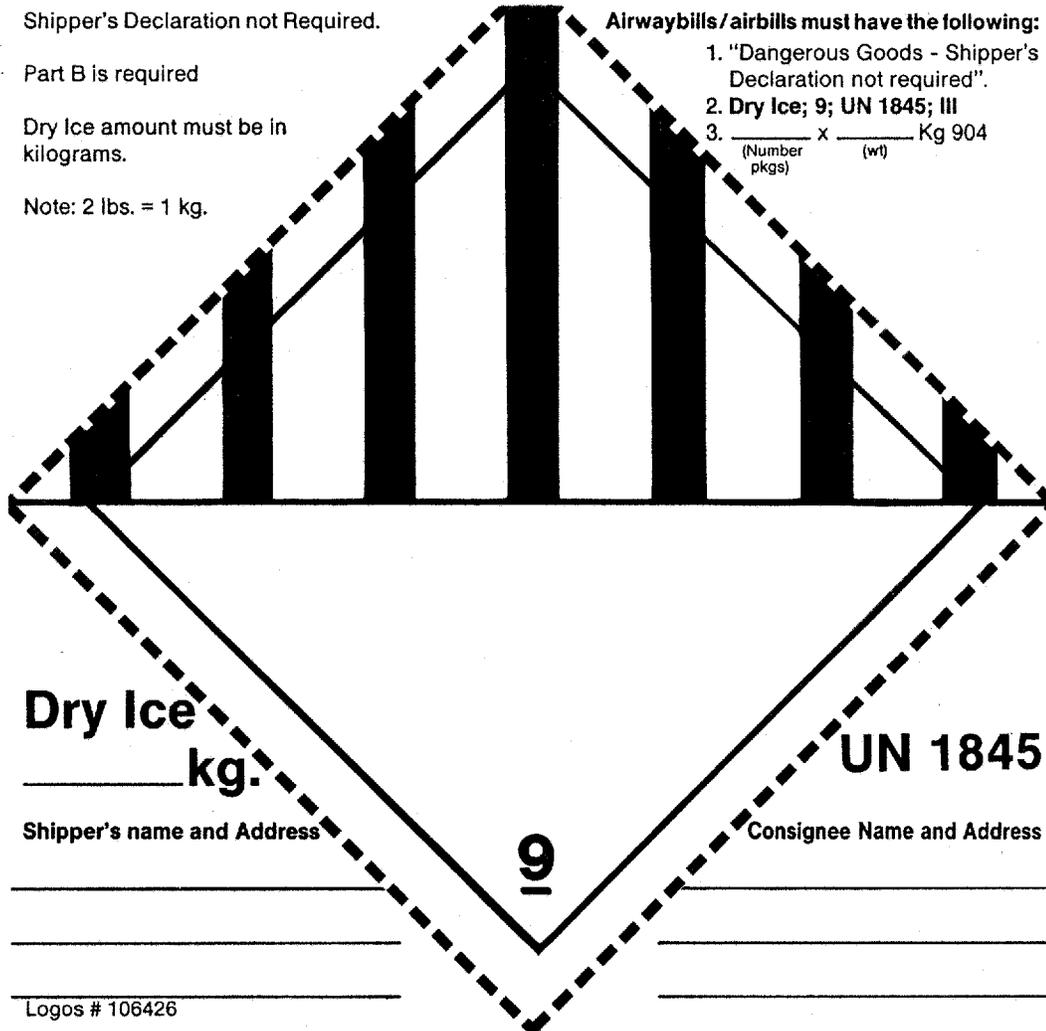
Part B is required

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills/airbills must have the following:

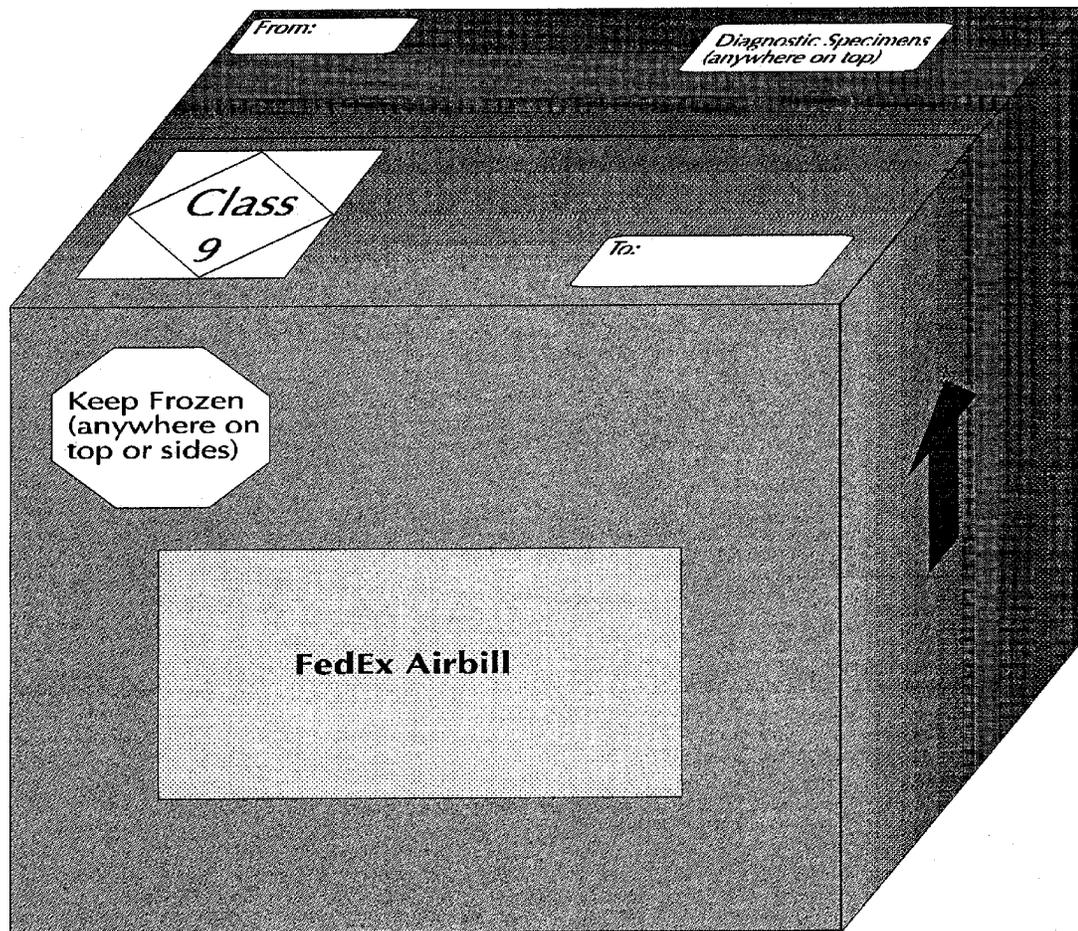
1. "Dangerous Goods - Shipper's Declaration not required".
2. Dry Ice; 9; UN 1845; III
3.  $\frac{\text{Number}}{\text{pkgs}}$  x  $\frac{\text{wt}}{\text{kg}}$  Kg 904



**'DIAGNOSTIC SPECIMENS'**  
**"PACKED IN COMPLIANCE WITH**  
**IATA PACKING INSTRUCTION 650"**

APPENDIX 9  
Dry Ice and Labeling Diagram  
(page 2 of 2)

# Outer Box Labeling



NOTE: Labels must not overlap

**APPENDIX 10 LCBR Shipping Form for Whole Blood (Cryovial #1)**



**LCBR SHIPPING FORM  
FOR WHOLE BLOOD (CRYOVIAL #01)**

Date of Shipment:   /   /     
Month Day Year

Field Center:  Memphis  
 Pittsburgh

Shipment prepared by: \_\_\_\_\_

Fed Ex Air Bill #: \_\_\_\_\_

Bar Code	HABC Enrollment ID #	Date of Year 4 Clinic Visit
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
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		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>
		____ / ____ / ____ <small>Month Day Year</small>

Y4 LCBR Shipping Form Version 1.1, 8/7/00 pjm

APPENDIX 11 Blind Duplicate ID Form



Date Form Completed	Staff ID#	Attach BDID label from Blind Duplicate Label Sheet
<input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	<input type="text"/>	

**YEAR 4 BLIND DUPLICATE  
IDENTIFICATION FORM**

Attach BDID labels from Participants' Label Sheets in appropriate spaces below.

No aliquot  
01  
duplicate

EDTA plasma

02

03

04

05

No aliquot  
06  
duplicate

Serum

07

08

09

Serum

10

11

12

13

10427



**APPENDIX 12 Return Visit Laboratory Forms  
(page 1 of 4)**

	HABC Enrollment ID #	Acrostic	Date Form Completed		Staff ID #
	H [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]	[ ] / [ ] / [ ] [ ] [ ] [ ]	Month	Day

**YEAR 4 RETURN VISIT PHLEBOTOMY**

Bar Code Label

1 Do you bleed or bruise easily?

Yes    No    Don't know    Refused

2 Have you ever experienced fainting spells while having blood drawn?

Yes    No    Don't know    Refused

3 Have you ever had a radical mastectomy? (Female Participants Only)

Yes    No    Don't know    Refused

Which side?

<input type="radio"/> Right	<input type="radio"/> Left	<input type="radio"/> Both
Draw blood on left side.	Draw blood on right side.	Do NOT draw blood. Go to Question #10 on page 3.

4 Have you ever had a graft or shunt for kidney dialysis?

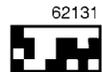
Yes    No    Don't know    Refused

Which side?

<input type="radio"/> Right	<input type="radio"/> Left	<input type="radio"/> Both
Draw blood on left side.	Draw blood on right side.	Do NOT draw blood. Go to Question #10 on page 3.

**Examiner Note:** If the participant is having a repeat blood draw only because they were not fasting during their Year 4 clinic visit, only draw a 3 to 5 ml serum tube. In Question #10.2, mark "Yes" when asked whether the serum tube was filled to capacity (even though the volume is less than 10 ml).

Page Link #



**APPENDIX 12  
Return Visit Laboratory Forms  
(page 2 of 4)**

**Health ABC** YEAR 4 RETURN VISIT PHLEBOTOMY

5 Time at start of venipuncture:

:       am     pm  
Hours    Minutes

6 Time blood draw completed:

:       am     pm  
Hours    Minutes

7 Total tourniquet time:  
*(Examiner Note: If tourniquet was reapplied, enter total time tourniquet was on.  
Note that 2 minutes is optimum.)*

minutes

Comments on phlebotomy:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

8 What is the date and time you last ate anything?

a. Date of last food:   /   /      
Month    Day    Year

b. Time of last food:   :       am     pm  
Hours    Minutes

c. How many hours have passed since the participant last ate any food?

hours (Question 6 minus Question 8b. Round to nearest hour.)



**APPENDIX 12  
Return Visit Laboratory Forms  
(page 3 of 4)**



YEAR 4 RETURN VISIT PHLEBOTOMY

9 Quality of venipuncture:

- Clean
- Traumatic

**Please describe. Mark all that apply:**

- Vein collapse
- Hematoma
- Vein hard to get
- Multiple sticks
- Excessive duration of draw
- Leakage at venipuncture site
- Other *(Please specify:)*  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

10 Was any blood drawn?

- Yes
- No

Please describe why not: \_\_\_\_\_  
 \_\_\_\_\_

Were tubes filled to specified capacity? If not, comment why.

Tube	Volume	Filled to Capacity?		Comment
		Yes	No	
1. EDTA	7 ml	<input type="radio"/>	<input checked="" type="radio"/>	_____
2. Serum *	10 ml	<input type="radio"/>	<input checked="" type="radio"/>	_____

**\*Examiner Note:** If the participant had a repeat blood draw only because they were not fasting during their Year 4 clinic visit, mark "Yes" to Question #10.2 when asked whether the serum tube was filled to capacity (even though the volume is less than 10 ml).

Page Link #

**APPENDIX 12  
Return Visit Laboratory Forms  
(page 4 of 4)**



HABC Enrollment ID # H	Acrostic	Date Form Completed	Staff ID #
		Month / Day / Year 2 0 0	

**YEAR 4 RETURN VISIT LABORATORY PROCESSING**

Time at start of processing:  :   am  
 pm

Bar Code Label

Collection Tubes	Cryo #	Vol.	Type	To	Fill in Bubble	Problems	Not Filled
#1 whole blood	01	1.0	W/1.5	L	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
#1 EDTA plasma	02	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	03	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	04	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	05	0.5	W/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
#2 serum	06*	0.5	R/0.5	L	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	07	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	08	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	09	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	10	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	11	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	12	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>
	13	0.5	R/0.5	M	<input type="radio"/>	<input type="radio"/> H <input type="radio"/> P <input type="radio"/> B	<input type="radio"/>

**\* Examiner Note: If the participant had a repeat blood draw only because they were not fasting during their Year 4 clinic visit, only fill cryovial #06.**

L=LCBR; M=McKesson; H=Hemolyzed; P=Partial; B=Both; R=red; W=white

LCBR Use only: Received Date: \_\_\_\_\_ Time: \_\_\_\_\_  
Frozen?  Yes  No

63016

Y4RVLP Version 1.0, 6/06/00 pj/m

