

LAB SPECIMEN PROCESSING

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1. Background and Rationale

The Health ABC study involves the collection of approximately 42 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 15) 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, C= clear, B=Blue, 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 (4.0, 2.0, 1.5 mL or 0.5 mL), not the volume aliquoted.**

There are also 7 labels containing the ID number with no extension. Four are to be used for pre-labeling the 5 draw tubes, with 2 extras for backup vacutainers. Of these labels, only the Draw Tube #1 label has a barcode. They all have 1-3 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 3 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 7 labels left: 2 "Backup Vacutainer" labels, 1 "Phlebotomy Form," 1 "Laboratory Processing Form" label, 3 "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, #05, #06, #14, and #15 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" label (*not* a "BDID Form" label) 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). A "BDID Form" label 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 6 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

Tubes #1, 2, and 5 should be mixed and immediately placed on ice. The other tubes (serum tubes #3&4) 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 4-mL lavender stoppered tube containing 15% liquid EDTA as the anticoagulant. After drawing, the tube should be mixed and immediately placed on ice. This tube will not be processed; it will be kept refrigerated (not frozen) and sent to LCBR for analysis of HgA1c.

Tube #2 is a 10-mL lavender stoppered tube containing 15% liquid EDTA as the anticoagulant. After drawing, the tube should be mixed and immediately placed on ice. Immediately after the blood draw is complete, this tube will be spun. The plasma supernatant will be aliquoted into cryovials with white caps. The plasma will be used for measurement of lipids and for archival purposes. After the plasma is aliquoted, the buffy coat will be removed from on top of the layer of red cells. The buffy coat is stored in a cryovial with a clear cap.

Tubes #3&4 are 10-mL siliconized red stoppered tubes used to collect serum. These tubes contain no anticoagulant so that the blood clots to form serum. After drawing, the tubes should not be mixed. 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 and for archiving.

Tube #5 is a special 8 mL cell separation (CPT) tube with a blue/black stopper. This tube will be processed immediately to obtain clean buffy coat for the RNA*later* substudy. This tube uses citrate as the anticoagulant, so the plasma from these tubes is aliquoted into a blue-capped cryovial.

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 tubes #3&4. The ice bath should contain tubes #1, 2, and 5.

Tubes #3&4 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.

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: The 5-mL draw tube #1 is not processed. It should be stored in the refrigerator immediately after removal from the ice bath.

EDTA Plasma: Immediately after the draw, this tube is spun. The plasma from tube #2 is aliquoted into one 4.0-mL, two 1.5-mL, and one 0.5-mL cryovial. (The 4.0-mL cryovial is sent to LCBR for assays. The remaining aliquots are designated for archival.)
The total number of aliquots is 4 (Color code = white)
3 x 1.0 mL sample volume
1 x 0.5 mL sample volume

Buffy coat: The buffy coat is removed from tube #2 and placed into one 1.5-mL cryovial (Color code = clear)
1 cryovial, volume varies

Serum: The serum from tubes #3&4 are mixed and aliquoted into one 4.0-mL and seven 1.5-mL cryovials. (The 4.0-mL cryovial is sent to LCBR for assays. The remaining aliquots are designated for archival.)
The total number of aliquots is 8 (Color code = red)
7 x 1.0 mL sample volume
1 x 0.5 mL sample volume

Citrated Plasma: Immediately after the draw, this tube is spun. The citrated plasma from tube #5 is aliquoted into a single 4.0-mL cryovial, which is sent to McKesson. The total number of aliquots is 1 (Color code = blue)
1 cryovial, volume varies

Buffy coat: The buffy coat is removed from tube #5 and placed into one 2.0-mL cryovial prefilled with *RNAlater* (Color code = clear). After storing this cryovial in the 4°C refrigerator for at least 12 hours, the tube is frozen and sent to McKesson.
1 cryovial, volume varies

The total number of aliquots per participant is 15. A detailed listing of aliquots can be found on the Laboratory Processing form (Appendix 3).

5.1.5 Whole Blood

This year the whole blood for hemoglobin A1C analysis will be collected in a separate 4-mL EDTA tube. This tube will not be processed beyond the initial mixing immediately after drawing. As soon as the samples are brought to the lab, the entire draw tube should be placed in the refrigerator. **Do not freeze.**

5.1.6 Centrifugation of CPT Tubes

Tube #5 (CPT-tube) should be centrifuged as soon as possible. Until centrifugation, tube #5 should be stored upright **on ice**.

When ready to begin cell separation, the CPT tubes should be centrifuged for at least 20 minutes at 1500-1800 RCF (relative centrifugal force) in a horizontal (swing-out head), refrigerated centrifuge. To calculate the RCF of your centrifuge, please use the calculator at:

<http://www.bd.com/vacutainer/products/molecular/citrate/procedure.asp>. Input the rotor radius and 1500-1800 RCF to see what speed to run the centrifuge at. **The RCF should not exceed 2000, beyond which tube breakage may occur.**

Note that these tubes are taller than other sample collection tubes, and a different rotor may be necessary. When centrifugation is complete, several layers will be evident. On top will be a clear plasma layer, under which will be a cloudy cell layer (buffy coat). Below these layers there is a gradient gel layer that acts as a barrier to prevent contamination by red cells, which are at the very bottom of the tube.

While the tubes are spinning, aliquot 1 mL of RNAlater™ solution into cryovial #15.

5.1.7 Making Citrate Plasma Aliquots

Once centrifuged, the maximum time allowed before aliquoting the citrated plasma in the CPT tube (#5) is 15 min. 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 (#5) on ice until aliquoting can occur.

Aliquots: 1 x 3.5-4 mL plasma use 4.0 mL cryovial McKesson

- Allow the centrifuge(s) to come to a complete stop. Remove tube from the centrifuge, being careful not to shake the tubes, and put them on ice.
- Using a transfer pipet, transfer the supernatant from each tube into the respective cryovials. Be very careful not to disturb the cell layer. It is fine if some plasma is left on top of the cell layer. Put all of the plasma obtained into one 4.0 mL cryovial
- Fill in the bubble next to cryovial #14 on the Laboratory Processing Addendum and indicate whether the cryovial is filled partially or totally. If the tube is not

filled at all, fill the bubble in the last column (“Not filled”). If the tube is only partially filled (e.g., less than 3 mL), also fill the bubble marked P. 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 (only one P, H, or B bubble should be filled for each cryovial, if applicable).

5.1.8. Making Buffy Coat Aliquot for RNA Preservation

Tube #5 remains on ice as long as it is not further processed after the centrifugation. The buffy coat aliquot is obtained from tube #5 after the plasma is removed. Use a Pasteur pipette to completely suction off the white cell layer and transfer it into one clear-coded 2-mL cryovial prefilled with 1 mL of RNAlater™ solution. It is okay to include some plasma in this cryovial. The main focus should be to obtain a large enough volume of white cells. The volume of buffy coat will vary (approximately 200-400 µL).

Close the labeled cryovial and invert it twice to ensure a homogenous cell suspension. Store the vial overnight (for at least 12 hours) at 4°C in the refrigerator. Record the time at which you place the cryovial in the refrigerator on the Laboratory Processing Addendum (Appendix 5). If samples are processed on Fridays, they may be stored in the refrigerator until the following Monday.

After at least 12 hours of storage in the refrigerator, take the cryovial out of the refrigerator and store it in the -70°C freezer. Record the date and time at which you place the cryovial in the freezer on the Laboratory Processing Addendum. Be very careful to double check that the barcode on the tube matches the barcode number written on the Laboratory Processing Addendum.

5.1.9 Centrifugation of EDTA Plasma Samples

Tube #2 is centrifuged at 4° C for 10 minutes at 3000 G. (A total of 30,000 g-minutes). Be sure to balance the centrifuge either with another plasma tube from another participant or with a balance tube filled with an equal volume of water.

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.

5.1.10 Making EDTA Plasma Aliquots

Once centrifuged, the maximum time allowed before aliquoting the EDTA plasma tube (#2) 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 (#2) on ice until aliquoting can occur.

| | | | |
|-----------|-------------------|---------------------|----------|
| Aliquots: | 1 x 1.0 mL plasma | use 4.0-mL cryovial | LCBR |
| | 2 x 1.0 mL plasma | use 1.5-mL cryovial | McKesson |
| | 1 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 in the bubble next to each cryovial that is filled, whether the cryovial is filled partially or totally. If the tube is not filled at all, fill the bubble in the last column ("Not filled"). If the tube is only partially filled, also fill the bubble marked P. 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 (only one P, H, or B bubble should be filled for each cryovial, if applicable).
- 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.

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.

5.1.11 Centrifugation of Serum Samples

Tubes #3&4 should be left at room temperature for at least 40-45 minutes (maximum 90 minutes; longer duration gives higher serum yield) after they are drawn. They should be displaying a clot by this time. They are centrifuged at 4° C for 10 minutes at 3000 G.

5.1.12 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 (Tubes #3&4) Color coded Red

| | | | |
|-----------|------------------|---------------------|----------|
| Aliquots: | 1 x 0.5 mL serum | use 4.0-mL cryovial | LCBR |
| | 7 x 1.0 mL serum | use 1.5-mL cryovial | McKesson |

- Pool the serum supernatant from both tubes before aliquoting.

- Follow the outline on the Laboratory Processing form for aliquoting the serum samples. Fill in 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 a sample is hemolyzed, fill in 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 (only one P, H, or B bubble should be filled for each cryovial, if applicable). If the tube is not filled at all, fill the bubble in the last column (“Not filled”).
- 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.

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.

5.1.13 Making Blind Duplicates (if applicable)

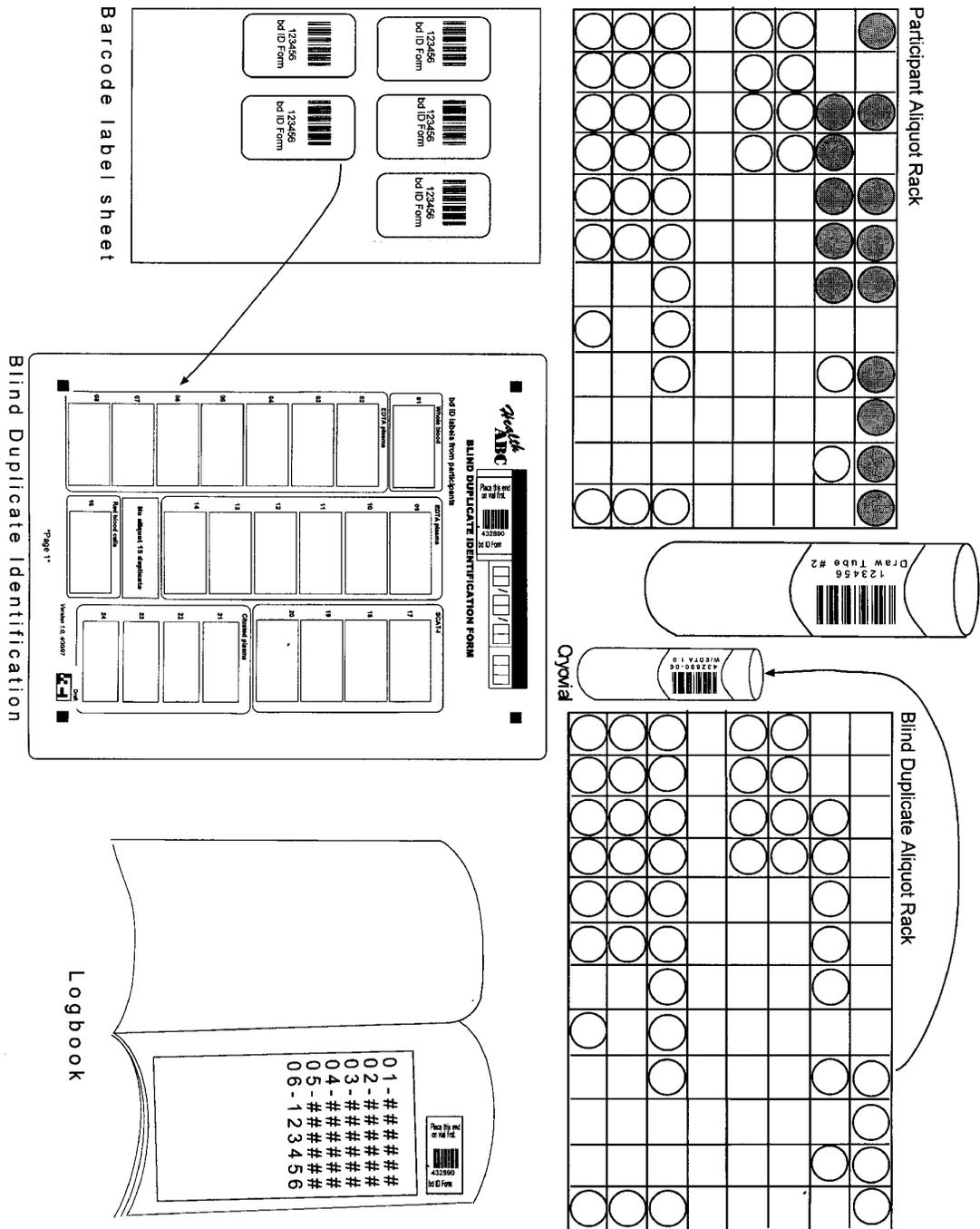
Be sure you have read Section 7, Quality Assurance, below and that you understand how the blind duplicate scheme works. Ask your supervisor if you have any questions.

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 (1.0 mL or 0.5 mL). The filled cryovial will be placed in the **participant’s aliquot rack**, which is in the ice bath (see Figure 1 on page 11).

*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 6 for example).*

For example, 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.

Figure 1



5.1.14 Freezing

Upon completion of the processing steps, citrated plasma, EDTA 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 tube. The buffy coat + RNA later will not be frozen until it has been refrigerated for at least 12 hours).**

After aliquoting is complete, the rack containing the 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.

5.1.15 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, the Return Visit Lab Processing Form (see Appendix 13), and (if applicable), the Laboratory Processing Addendum. 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 all 3 forms with the header information including the Health ABC Enrollment ID #, Acrostic, Date Form Completed, and Staff ID #. Even if the first draw was totally unsuccessful, do not re-use the phlebotomy and laboratory processing forms in the clinic visit workbook.

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 tubes #1, 2, 4, or 5. For tube #3, 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 and 07 only. 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 Tubes 1-5 and the cryovial labels for cryovials 01 through 15 as usual. If the participant had an incomplete draw, then draw the tube(s) needed to complete the set of cryovials. For example, if the participant had both EDTA tubes drawn at their clinic visit, but a serum sample and CPT tube could not be obtained, draw the regular 10-mL tube #3&4 and the CPT tube and fill cryovials 06-15.

5.1.16 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 in the participants' charts. 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 7).
- Cryovials #01 and #06, which do not have color-coded caps and are being sent to LCBR for immediate analysis, should be stored in separate boxes (i.e., cryovials #01 in one box and #06 in another) to help keep the samples sorted. Note that these samples require a larger freezer box with a 7x7 grid (supplied by LCBR).
- Cryovials #14 and 15 should also be stored in a separate box, which should be included in the weekly McKesson shipment (see Appendix 7).
- Cryovials #07 are earmarked for later assays of insulin and cytokines. These cryovials should be grouped together for easier retrieval in the future. Therefore, cryovials #07 should also be stored in a separate box, which should be included in the weekly McKesson shipment (see Appendix 7).
- 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 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 7).
- 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 10 mL | 15 minutes |
| 2. | Serum 2 x 10 mL | 90 minutes |
| 3. | CPT 8 mL | 15 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 8) should be kept in stock at all times.

Whole blood samples (draw tube #1) 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 9):

- 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 10).

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 10):

- 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 10)
- 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 10) 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
208 South Park Drive, Suite 2
Colchester, VT 05446
(802) 656-8963

The McKesson Bioservices mailing address is:

Sandra Ke
McKesson BioServices
625 Lofstrand Lane
Rockville, MD 20850
(301) 340-1620

FAX the following information to McKesson Bioservices at (301) 838-9753 or LCBR at 802-656-8965, as applicable, 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.

- The samples should be placed in a 3" tall box with a 9 x 9 grid. If the stoppers get in the way of each other, you may skip a space.
- 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 bagged samples 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.
- Fill out the LCBR Shipping Form for Whole Blood (Draw tube #1) (Appendix 11), listing the sample barcode, participant's HABCID, the date of the Year 6 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 5.1.15), making sure you don't include any cryovials that have already been shipped. Once the Shipping Form is completed, double check against the tubes in the box to be shipped, to ensure that all tubes in the box are listed on the form and all tubes listed on the form are in the box. In addition the tubes should be in the same order in the shipping box as they are on the form.
- 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 (Draw tube #1) on top of the styrofoam container before closing up the outer sleeve with tape. Do not enclose copies of the Plebotomy 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. Include the FedEx tracking number, so the samples can be tracked down promptly if they fail to arrive on time.

The LCBR mailing address at the University of Vermont is:

Elaine Cornell
University of Vermont-Pathology
208 South Park Drive, Suite 2
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 placed on ice (except for serum) and returned to the lab as soon as possible after the home visit, preferably within 1 hour. 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, it is necessary for the lab 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 since the lab has already demonstrated the accuracy of all the assays being run immediately.

In order for this process to work, the duplicate blood must appear to be blood from another participant. A further complication is that most 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 or plasma 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, 05, 06, or 14-15. 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 12), *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 or printed directly from the Health ABC website. 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.

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 Laboratory Processing form.

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
- Certification by the Department of Transportation or other organization for packaging and shipment of biological specimens (information on training courses can be found at <http://hazmat.dot.gov/training.htm#classes> or <http://www.fedex.com/us/services/options/seminars.html>)

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

- Remove buffy coat cryovials that have been stored for at least 12 hours at 4° C from the refrigerator and place them in a separate freezer box in the freezer for shipment to McKesson

Processing CPT tubes

- Time checked to ensure that tube #5 is processed within 15 minutes of completion of phlebotomy
- Tube #5 centrifuged for 20 min at 1500-1800 RCF
- 1 mL of RNA*later* added to cryovial #15 while tube is spinning
- Plasma correctly aliquoted into a 4.0-mL cryovial
- Buffy coat correctly aliquoted into a 2.0-mL cryovial
- Cryovial inverted twice to mix
- Time buffy coat cryovial is put into the refrigerator recorded on the Laboratory Processing Addendum
- Buffy coat cryovial stored in the refrigerator (4°C) for at least 12 hours.
- After at least 12 hours, buffy coat cryovial moved to freezer
- Time buffy coat cryovial moved to freezer recorded on the Laboratory Processing Addendum

Processing EDTA whole blood and plasma

- Time checked to ensure that tube #2 is processed within 15 minutes of completion of phlebotomy
- Tube #2 centrifuged at 4° C for 10 min at 3000 G
- Plasma correctly aliquoted
- No cells contaminating aliquots (except buffy coat aliquot)
- Buffy coat correctly aliquoted

Processing serum tubes

- Time checked to ensure that tubes #3&4 has stood at room temperature for at least 40 minutes, maximum 90 minutes
- Tubes 3&4 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

- 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

- Shipment person certified by DOT
- 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 for shipment to LCBR
- Aliquots 02-05, and 08-13 placed in freezer boxes for McKesson
- Aliquots 07 placed in a separate freezer box for McKesson
- Aliquots 13&14 placed in a separate freezer box for McKesson

Shipment procedures -- dry ice

- Shipment person certified by DOT
- 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 Supplies

| |
|--|
| VENDORS: VWR: 800-932-5000 www.vwrsp.com Fisher Scientific: 800-766-7000 www.fishersci.com Polyfoam Packers: 800-323-7442 www.polyfoam.com 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 |
|--|

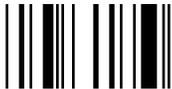
Note: Prices are from the catalogs. Educational discounts should apply.

| cryovials / caps/ racks | # per participant | sample type | vendor: catalog # | \$ price/pk |
|--|--------------------------|----------------------|--------------------------------------|----------------------|
| 0.5 mL cryovial with skirt w/o cap non-sterile | 2 | serum, plasma | VWR: 20170-209 | 28.10/ 500 |
| 1.5 mL cryovial with skirt w/o cap | 9 | serum, plasma, buffy | VWR: 20170-213 | 28.10/ 500 |
| 2.0 mL cryovial with skirt w/o cap | 1 | CPT buffy | VWR: 20170-205 | 28.10/ 500 |
| 4.0 mL cryovial with screw cap | 2 | LCBR | Provided by LCBR | NA |
| colored screw cap: red | 7 | serum | VWR: 20170-247 | 50.24/ 500 |
| colored screw cap: white | 3 | plasma | VWR: 20170-274 | 50.21/ 500 |
| colored screw cap: blue | 4 | citrate | VWR: 20170-251 | 50.24/ 500 |
| clear screw cap | 1 | buffy | VWR: 20170-241 | 49.95/500 |
| cryovial rack | 1 | all | VWR: 30128-346 Fisher: 07-200-618 | 60.00/ 5 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 | 2 | serum | VWR:VT6430 / BD: 6430 Fisher: 02-685-A | 25.94/ 100 28.81/ 100 |
| 4 mL EDTA vacutainer / 13 x 75 size | 1 | whole blood | VWR: BD:367861 Fisher: 02-683-99C | 24.59/ 100 |
| 10-mL EDTA vacutainer/16 x100 size | 1 | plasma | VWR: VT5457 Fisher: 02-683-84 | 25.94/100 31.64/100 |
| CPT tubes | 1 | Buffy, citrate | Supplied by Bernd Meibohm | NA |
| vacutainer blood collection set 21G 3/4" | 1 | | VWR: VT7251 Fisher: 02-664-1 | 60.50/ 50 |
| vacutainer needle holders | 1 | NA | BD: 4893 Fisher 02-665-10 | |
| Transfer pipets (3.2 mL is fine) | 1 | | Fisher: 13-711-7 | \$293.51/5000 \$35.65/500 |

| Storage/ Shipping Supplies | # suggested | sample type | vendor: catalog # | \$ price/pk |
|---|--------------|-------------|---|------------------------|
| freezer boxes (from McKesson)(2") | NA | all | VWR: 55705-424 Krackeler: 114-5144-F12 | 24.00/ 12 24.03/ 12 |
| box dividers (9X9) | NA | all | VWR: 55701-762 Krackeler: 114-5144-F29 | 16.00/ 12 16.19/ 12 |
| Boxes for 4mL tube shipment | NA | LCBR | Supplied by LCBR | NA |
| Leakproof ziplock bags (12 x 12") for freezer boxes | 10 per week | | VWR: 11217-128 | 101.51/ 250 |
| Leakproof ziplock bags (6 x 6") for whole blood tubes | 6-8 per week | | Fisher: 01-800-01 | 107.73/1000 |
| 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 Krackeler | 21.40/ 24 26.00/ 24 |

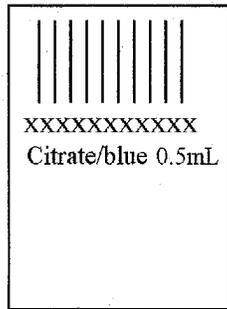
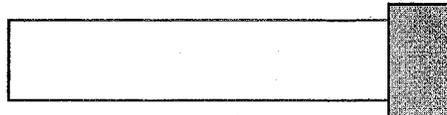
**APPENDIX 2
Sample Label Sheet (Bar Codes)**

| | | |
|--|--|--|
| <p>Place this end On vial first</p>  <p>##### Draw Tube 1 Purple top 4 mL</p> | <p>##### Draw Tube 2 Purple top 10 mL</p> | <p>##### Draw Tube 3 Red top 10 mL</p> |
| <p>##### Draw Tube 4 Red top 10 mL</p> | <p>##### Draw Tube 5 Blue/black top 8 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/EDTA 4.0 To LCBR</p> | <p>Place this end on vial first</p>  <p>#####-02 W/EDTA 1.5</p> | <p>Place this end on vial first</p>  <p>#####-03 W/EDTA 1.5</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 C/Buffy 1.5</p> | <p>Place this end on vial first</p>  <p>#####-06 R/Serum 4.0 To LCBR</p> |
| <p>Place this end on vial first</p>  <p>#####-07 R/Serum 1.5</p> | <p>Place this end on vial first</p>  <p>#####-08 R/Serum 1.5</p> | <p>Place this end on vial first</p>  <p>#####-09 R/Serum 1.5</p> |
| <p>Place this end on vial first</p>  <p>#####-10 R/Serum 1.5</p> | <p>Place this end on vial first</p>  <p>#####-11 R/Serum 1.5</p> | <p>Place this end on vial first</p>  <p>#####-12 R/Serum 1.5</p> |
| <p>Place this end on vial first</p>  <p>#####-13 R/Serum 1.5</p> | <p>Place this end on vial first</p>  <p>#####-14 B/Citrate 4.0</p> | <p>Place this end on vial first</p>  <p>#####-15 C/Buffy 2.0 Buffy coat + RNA-later</p> |
|  <p>##### BDID Form</p> |  <p>##### BDID Form</p> |  <p>##### BDID Form</p> |

HEALTH ABC STUDY

Label Orientation on Cryovial



**APPENDIX 3
Laboratory Processing Form**

| | | | | | | |
|--|----------------------|----------------------|--|-------|-----|------------|
| | HABC Enrollment ID # | Acrostic | Date Scan Completed | | | Staff ID # |
| | <input type="text"/> | <input type="text"/> | <input type="text"/> / <input type="text"/> / <input type="text"/> | Month | Day | Year |

LABORATORY PROCESSING

Bar Code Label

Time at start of processing: : am
 pm

| Collection Tubes | Cryo # | Vol. | Type | To | Fill in Bubble | Problems | Not Filled |
|------------------|--------|------|-------|----|-----------------------|---|-----------------------|
| #2 EDTA plasma | 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"/> |
| | 02 | 1.0 | W/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 03 | 1.0 | W/1.5 | 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"/> |
| #2 buffy | 05 | var | C/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| #3,4 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 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 08 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 09 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 10 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 11 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 12 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 13 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |

C=Clear; L=LCBR; M=McKesson; H=Hemolyzed; P=Partial; B=Both; R=red; W=white
 LCBR Use only: Received Date: _____ Time: _____
 Frozen Yes No

APPENDIX 4
Sample Processing Checklist

- Blind duplicate aliquot rack
- Crushed ice in ice bucket or plastic tub
- Pipets: 0.5 and 1.0 mL volumes and pipet tips
- Transfer pipets
- 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
- Freezer boxes with 7 x 7 grid
- Rubber bands

**APPENDIX 5
Year 6 Laboratory Processing Addendum**

| | | | | | | |
|---|---|---|---|-------|-----|------------|
|  | 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"/> | Month | Day | Year |

YEAR 6 LABORATORY PROCESSING ADDENDUM

1 Draw Tube # 5 (CPT)

Barcode

Time at start of processing: : am
 pm

| Collection Tubes | Cryo # | Vol. | Type | To | Fill in Bubble | Problems | Not Filled |
|-------------------|--------|------|-------|----|-----------------------|---|-----------------------|
| Citrated plasma | 14 | var | B/4.0 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| Buffy + RNA-later | 15 | var | C/2.0 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |

2 Time buffy coat aliquoted into cryovial #05 containing RNA-later and placed in 4°C refrigerator:

: am pm
 Hours Minutes

3 Date sample placed in -70°C freezer (should be at least 12 hours after being placed in cryovial #05 containing RNA-later):

/ /

Month Day Year

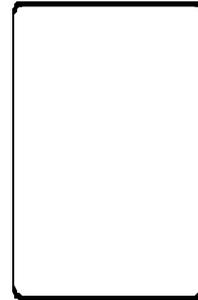
4 Time sample placed in -70°C freezer:

: am pm
 Hours Minutes



APPENDIX 6 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 7 | |
| aliquot 8 | |
| aliquot 9 | |
| aliquot 10 | |
| aliquot 11 | |
| aliquot 12 | |
| aliquot 13 | |

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

APPENDIX 7 Freezer Box Diagrams
(page 1 of 4)

**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

| | | | | | | | | |
|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|----|---------------------|
| Ppt #1 02 | 03 | 04 | 05 | 08 | 09 | 10 | 11 | 12 |
| Ppt #1 13 | Ppt #2 02 | 03 | 04 | 05 | 08 | 09 | 10 | 11 |
| Ppt #2 12 | 13 | Ppt #3 02 | 03 | 04 | 05 | 08 | 09 | 10 |
| Ppt #3 11 | 12 | 13 | Ppt #4 02 | 03 | 04 | 05 | 08 | 09 |
| Ppt #4 10 | 11 | 12 | 13 | Ppt #5 02 | 03 | 04 | 05 | 08 |
| Ppt #5 09 | 10 | 11 | 12 | 13 | Ppt #6 02 | 03 | 04 | 05 |
| Ppt #6 08 | 09 | 10 | 11 | 12 | 13 | Ppt #7 02 | 03 | 04 |
| Ppt #7 05 | 08 | 09 | 10 | 11 | 12 | 13 | 07 | Ppt #8 02 |
| Ppt #8 03 | 04 | 05 | 08 | 09 | 10 | 11 | 12 | 13 |

Bottom

End#81

Continue to next box. . .

APPENDIX 7
Freezer Box Diagrams
 (page 2 of 4)

Freezer Box Diagram for Shipping EDTA Plasma Samples to LCBR/Vermont

Numbers = cryovial #

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

Bottom

End#81

continue to
next box....

Label outside of box: Health ABC EDTA Plasma Box #1 Date: ____ / ____ / ____

TO LCBR

**APPENDIX 7
Freezer Box Diagrams
(page 3 of 4)**

Freezer Box Diagram for Shipping Serum Samples to LCBR/Vermont

Numbers = cryovial #

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

Bottom

End#81

continue to
next box....

Label outside of box: Health ABC Serum Box #1 Date: ____ / ____ / ____

TO LCBR

APPENDIX 7
Freezer Box Diagrams
 (page 4 of 4)

Freezer Box Diagram for Shipping Citrated Plasma and Buffy Coat with RNA_{later} to McKesson

Numbers = cryovial #

| | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--|
| start #1 | | Top | | | | | | | |
| Ppt # 1 14 | 15 | Ppt # 2 14 | 15 | Ppt # 3 14 | 15 | Ppt # 4 14 | 15 | Ppt # 5 14 | |
| Ppt # 5 15 | Ppt # 6 14 | 15 | Ppt # 7 14 | 15 | Ppt # 8 14 | 15 | Ppt # 9 14 | 15 | |
| Ppt # 10 14 | 15 | Ppt # 11 14 | 15 | Ppt # 12 14 | 15 | Ppt # 13 14 | 15 | Ppt # 14 14 | |
| Ppt # 14 15 | Ppt # 15 14 | 15 | Ppt # 16 14 | 15 | Ppt # 17 14 | 15 | Ppt # 18 14 | 15 | |
| Ppt # 19 14 | 15 | Ppt # 20 14 | 15 | Ppt # 21 14 | 15 | Ppt # 22 14 | 15 | Ppt # 23 14 | |
| Ppt # 23 15 | Ppt # 24 14 | 15 | Ppt # 25 14 | 15 | Ppt # 26 14 | 15 | Ppt # 27 14 | 15 | |
| Ppt # 28 14 | 15 | Ppt # 29 14 | 15 | Ppt # 30 14 | 15 | Ppt # 31 14 | 15 | Ppt # 32 14 | |
| Ppt # 32 15 | Ppt # 33 14 | 15 | Ppt # 34 14 | 15 | Ppt # 35 14 | 15 | Ppt # 36 14 | 15 | |
| Ppt # 37 14 | 15 | Ppt # 38 14 | 15 | Ppt # 39 14 | 15 | Ppt # 40 14 | 15 | Ppt # 41 14 | |

Bottom

End#81

continue to
next box....

Label outside of box: Health ABC RNA_{later} substudy Box #1 Date: ____ / ____ / ____

APPENDIX 8
Sample Shipping Checklist

- Styrofoam Mailing Container (2 different sizes) with outer cardboard sleeve
 - Polyfoam Packers # 430*
 - Polyfoam Packers # 346*
- Absorbent material
- 2" Freezer boxes with 9x9 grids
- 3" Freezer boxes with 9x9 grids (supplied by LCBR)
- 3" Freezer boxes with 7 x 7 grids (supplied by LCBR)
- 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
- Rubber bands for boxes

Shipping materials can be purchased from: (see 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, airbill pouches, and class 9 labels:

Local FedEx office

"Diagnostic Specimens" and "Keep Frozen" labels:

The sites can produce these labels.

APPENDIX 9
Federal Express Airbills for Dry Ice Shipment

FedEx USA Airbill Express
From: Sender's FedEx Account Number
To: Recipient's Name: Brad Toms, Company: McKESSON BIOSERVICES, Address: 685 LOFSTRAND LANE, City: ROCKVILLE, State: MD, ZIP: 20850

Sender's Copy
4a Express Package Service
4b Express Freight Service
5 Packaging
6 Special Handling
7 Payment
8 Release Signature

FedEx USA Airbill Express
From: Sender's FedEx Account Number
To: Recipient's Name: ELAINE CORNELL, Company: UNIVERSITY OF VERMONT-PATHOLOGY, Address: 208 SOUTH PARK DRIVE, SUITE 2, City: COLCHESTER, State: VT, ZIP: 05446

Sender's Copy
4a Express Package Service
4b Express Freight Service
5 Packaging
6 Special Handling
7 Payment
8 Release Signature

APPENDIX 10
Dry Ice Label and Labeling Diagram
(page 1 of 2)

Shipper's Declaration not Required.

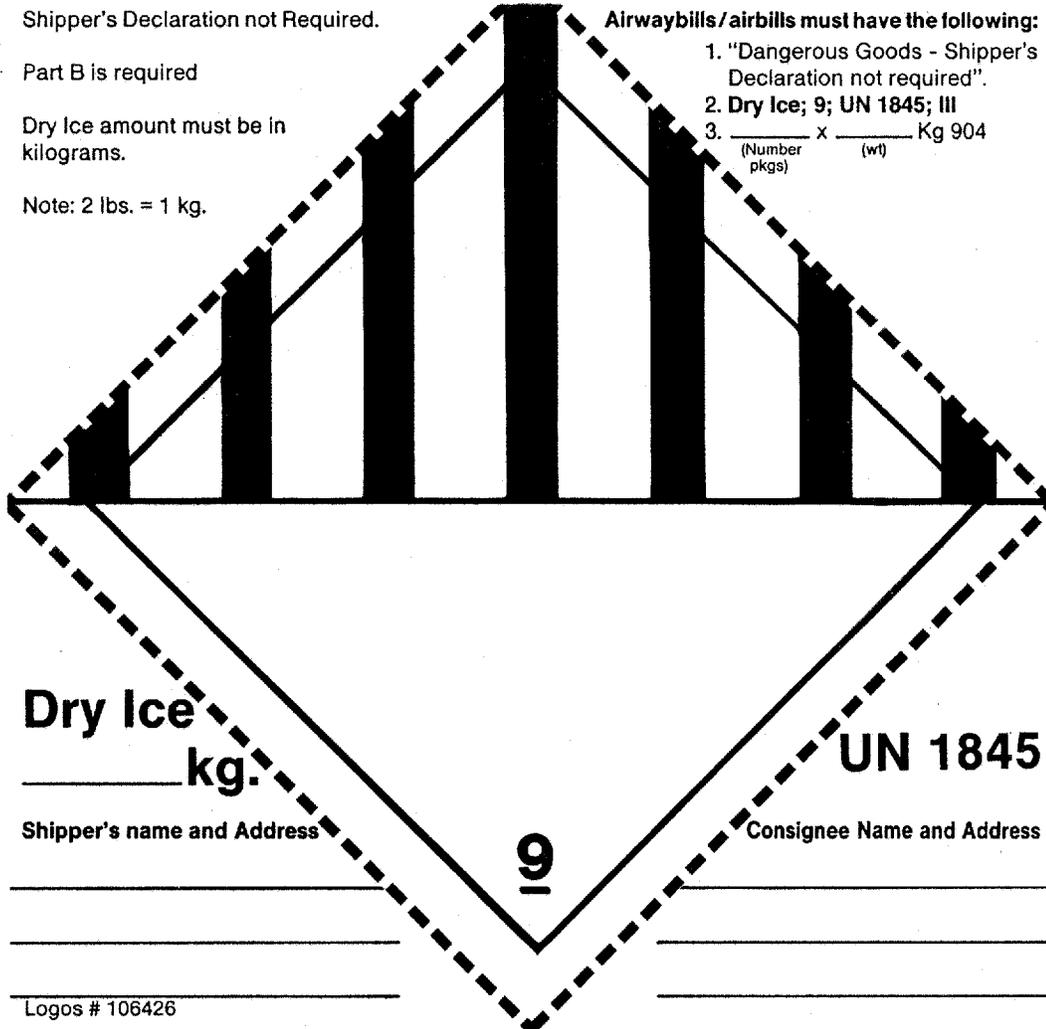
Part B is required

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills/airbills must have the following:

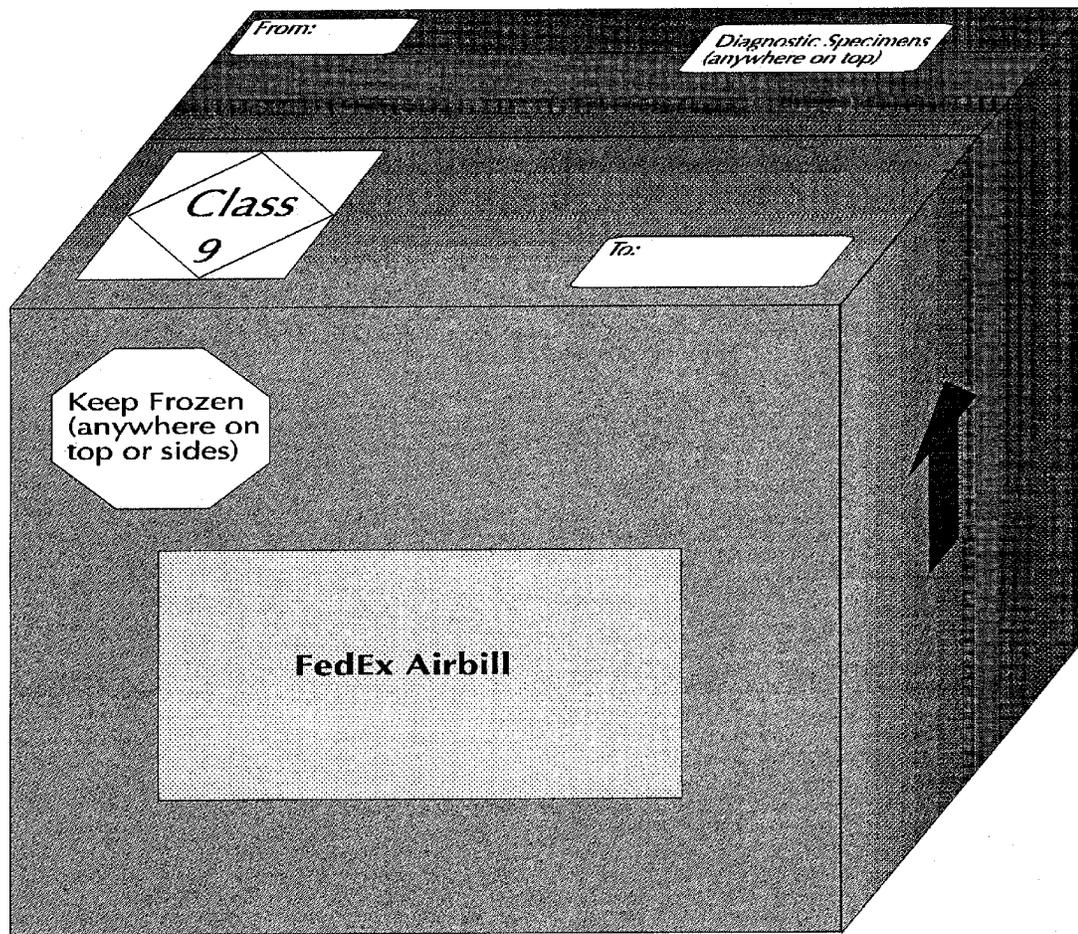
1. "Dangerous Goods - Shipper's Declaration not required".
2. **Dry Ice; 9; UN 1845; III**
3. $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg 904}$



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

APPENDIX 10
Dry Ice and Labeling Diagram
(page 2 of 2)

Outer Box Labeling



NOTE: Labels must not overlap

APPENDIX 11

LCBR Shipping Form for Whole Blood (Draw Tube #1)

Health ABC **LCBR SHIPPING FORM**
FOR WHOLE BLOOD (DRAW TUBE #1)

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 6 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> |
| | | ____ / ____ / ____ <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> |
| | | ____ / ____ / ____ <small>Month Day Year</small> |

APPENDIX 12
Blind Duplicate ID Form



No aliquot
01, 05, or 06
duplicate

| Date Form Completed | Staff ID# | Attach BDID label from Blind Duplicate Label Sheet |
|--|----------------------|---|
| <input type="text"/> / <input type="text"/> / 200 <input type="text"/> Month Day Year | <input type="text"/> | |

**YEAR 6 BLIND DUPLICATE
IDENTIFICATION FORM**

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

| |
|-------------|
| EDTA plasma |
| 02 |
| 03 |
| 04 |

| |
|-------|
| Serum |
| 07 |
| 08 |
| 09 |

| |
|-------|
| Serum |
| 10 |
| 11 |
| 12 |
| 13 |




YEAR 6 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 8a minus Question 8b. Round to nearest hour.)



Health ABC **YEAR 6 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 | 5 ml | <input type="radio"/> | <input type="radio"/> → | _____ |
| 2. EDTA | 10 ml | <input type="radio"/> | <input type="radio"/> → | _____ |
| 3. Serum* | 10 ml | <input type="radio"/> | <input type="radio"/> → | _____ |
| 4. Serum | 10 ml | <input type="radio"/> | <input type="radio"/> → | _____ |

**Examiner Note: If the participant had a repeat blood draw only because they were not fasting during their Year 6 clinic visit, mark "Yes" to Question #10.3 when asked whether the serum tube was filled to capacity (even though the volume is less than 10 ml).*



Health ABC

| | | | | | |
|----------------------|----------------------|--|----------------------|----------------------|----------------------|
| HABC Enrollment ID # | Acrostic | Date Scan Completed | | | Staff ID # |
| <input type="text"/> | <input type="text"/> | <input type="text"/> / <input type="text"/> / 2000 | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | Month | Day | Year | |

YEAR 6 RETURN VISIT LABORATORY PROCESSING

Bar Code Label

Time at start of processing: : am pm

| Collection Tubes | Cryo # | Vol. | Type | To | Fill in Bubble | Problems | Not Filled |
|------------------|--------|------|-------|----|-----------------------|---|-----------------------|
| #2 EDTA plasma | 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"/> |
| | 02 | 1.0 | W/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 03 | 1.0 | W/1.5 | 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"/> |
| #2 buffy | 05 | var | C/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| #3,4 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 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 08 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 09 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 10 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 11 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 12 | 1.0 | R/1.5 | M | <input type="radio"/> | <input type="radio"/> H <input type="radio"/> P <input type="radio"/> B | <input type="radio"/> |
| | 13 | 1.0 | R/1.5 | 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 6 clinic visit, only fill cryovial #06.**

L=LCBR; M=McKesson; H=Hemolyzed; P=Partial; B=Both; C=Clear; R=red; W=white
 LCBR Use only: Received Date: _____ Time: _____
 Frozen Yes No

