Jackson Heart Study Exam 4

Manual 9

Specimen Collection and Processing

Version 2

Revised 05-24-2022

Table of Contents

1. Purpose…… …. 1
   A. Test/Assays……. 1
   B. Restrictions……. 1
   C. General Preparations…… 2
   D. OSHA Guidelines …… 2
2. Staff Certification Requirements ……... 3
3. Participant Preparation …… 3
4. Preparation for Specimen Collection ……. 3
   A. In the early morning……. 3
   B. At participant arrival …… 3
5. Draw tube #5…… 4
6. Urine Collection ……. 5
   A. Preparation of Participants for Urine Collection ……. 5
   B. Instructions for Participants …… 5
7. Blood Collection Procedure…… 6
8. Guidelines for Difficulties ……. 8
9. When Participants Feels or Looks Faint Following Blood Collection……. 9
10. Centrifuge Operation …… 9
11. Aliquoting ……. 10
12. Description of Aliquot Flow Chart…… 11
13. Cryovial Instructions……. 11
   A. EDTA Plasma from Tubes 2 and 4 …… 11
   B. Packed Red Blood Cells……. 11
   C. Serum from Tubes 1 and 3……. 11
   D. EDTA Plasma from Tube 6…… 12
   E. Urine Aliquots…… 12
14. Processing Completion……. 12
15. Special Circumstances……..…. 13
16. Shipping…… 13
   A. General…… 13
   B. Frozen Samples…… 14
   C. Frozen Sample Shipping Procedure……. 14
   D. Refrigerated Samples…… 15
   E. Refrigerated Sample Shipping Procedures…… 16
17. Quality Control…… 17
18. Training…… 21
19. Appendices…… 22
   Appendix 1 Supply & Vendor List…… 22
   Appendix 2 Urine/Phlebotomy Form (BIO form) ……. 23
   Appendix 3 Processing Form…… 24
   Appendix 4 Frozen Shipping Form……... 25
   Appendix 5 Refrigerated Shipping Form……. 26
   Appendix 6 Label Sample Set……... 27
   Appendix 7 Aliquoting Flow Chart……... 28
   Appendix 8 Freezer Box Diagram……. 29
   Appendix 9 Temperature Log…… 31
   Appendix 10 Supervisor Checklist…… 32
   Appendix 11 Certification Exam…… 38

1. PURPOSE

The Jackson Heart Study (JHS) is a longitudinal community based epidemiological study of the incidence and progression of heart disease in African Americans in the greater Jackson, Mississippi area. The Central Blood Analysis Laboratory (LCBR) will have responsibilities for blood collection and handling protocols as well as training and QC monitoring. The laboratory will also be responsible for performing the following assays and reporting results.

A. Tests / Assays

Jackson Heart Study

- Lipid panel (cholesterol, triglycerides, HDL, LDL, cholesterol to HDL ratio)
- Serum Glucose, Creatinine (Fasting)
- Potassium
- Cystatin C, C Reactive Protein
- Urinary Albumin, Urinary Creatinine, Albumin Creatinine Ratio
- Hemoglobin A1c

The blood samples collected and processed by Clinical Center technicians are the foundation for all these tests. The most important step – and potentially the most variable – is the collection and processing of the blood samples. If the blood sample itself is not correctly drawn and processed, the laboratory results may not be precise or may not be valid. Consistency in this step is vital to the study.

JHS ancillary studies may involve the collection of additional blood samples specific to their research aims (see table below). For details regarding collection and processing of the samples specific for these ancillary studies refer to the individual ancillary study protocols within the JHS Manual of Operations.

PI	Title (ancillary study)	Participants	Blood/Urine collection
Johnson	Rapid and comprehensive platelet reactivity phenotyping on small blood volumes in the Jackson Heart Study – addressing the unknowns of platelet reactivity in a large, diverse population sample	All consenting Exam 4	3 x 4.5 ml Citrate 1 x 2 ml EDTA

B. Restrictions

- The Informed consent form, which has been approved by the local IRB, must be obtained from the participant before drawing blood and collecting urine. This procedure is followed to ensure that the participant understands the purpose of having

blood drawn, and the possibility of venipuncture complications. The consent informs study participants that although there may be some minor discomfort, their blood will be drawn by trained technicians. It also states that clinically relevant test results will be sent to their physicians and they may be contacted if clinically important tests are abnormal if they so desire.

- Fasting clearly influences test parameters such as glucose and the lipid panel. Participants should have fasted for at least 12 hours prior to having their blood drawn and notified that they should drink only water so they will stay hydrated. However, blood will be collected on all participants regardless of fasting status.

C. General Preparation

Since the study depends on the voluntary participation of participants, every effort must be made to make the entire procedure as easy and painless as possible for them. The technicians must remain calm and project an attitude of competence even when faced with the most nervous or inquiring participant. The best way to achieve this is for the technicians to be thoroughly knowledgeable about all aspects of the procedures.

D. OSHA Guidelines

In accordance with the OSHA regulations on blood borne pathogens, the LCBR recommends the following laboratory safety protocol for the field center laboratories:

- Use of non-permeable lab coats, nitrile or latex gloves, and face shields 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.

- Wash hands thoroughly after removing gloves.

- Remove gloves before touching telephones, charts, computers, monitors, doorknobs, refrigerator handles, food, pens, and pencils.

- Use 0.5% sodium hypochlorite (household bleach diluted 1:10) to clean up any spills of blood, plasma, or serum.

- Follow ‘Universal Precautions’ when handling any blood products.

- Immediately place contaminated needles and sharps in a puncture-resistant, leak-proof container.

- Never recap or break needles.

- Offer Hepatitis B vaccine to all unvaccinated technicians handling/working with blood, blood products, or equipment contaminated with blood. Documentation of

vaccination, or technician's declining to be vaccinated, should be kept on file at the Clinical Center.

2. STAFF CERTIFICATION REQUIREMENTS

A certified JHS technician at the Clinic performs blood drawing and blood and urine processing. Technicians complete a training course taught by certified laboratory staff. Each technician must complete the training and pass both written and practical exams before becoming JHS-certified. Re-certification takes place annually and is authorized by supervisory personnel.

3. PARTICIPANT PREPARATION

Give the participant enough time to feel comfortable about the blood collection. In many cases, the most memorable part of the experience for participants will be the contact with the technicians who draw the blood and their general attitude and competence. Any participant who is concerned about the volume of blood should be reassured that the total amount of blood drawn is only about 4 ounces although it may look like more. They may also mention that 450ml of blood is collected during routine blood donations.

If the participant is nervous or excited, the technician briefly describes the procedure, e.g. "I am going to be drawing bout 4 ounces of blood. This blood will be used in tests for lipids (or fats) and cholesterol and some other specialized tests. We hope to be able to use the results of these tests to determine some of the causes of heart disease."

4. PREPARATION FOR SPECIMEN COLLECTION

A. In the early morning, prior to drawing blood from the participants.

- Check expiration dates on the blood draw tubes.
- Perform and record quality control (QC) check on centrifuge temperature (4^{o}C $^{+}$/- 2^{o}C)
- Perform and record QC check on refrigerator temperature (4^{o}C $^{+}$/- 2^{o}C)
- Perform and record QC check on freezer temperature (-70^{o}C $^{+}$/-10^{o}C)
- Perform and record QC check on room temperature

B. At participant arrival:

- Obtain ice and fill containers for ice bath from designated area.
- Place the LABID label on the Urine/ Phlebotomy Form. Make sure the JHS ID number on the phlebotomy form is correct.

- Ensure that the LABID's on forms and all urine/blood collection and processing tubes match.

- Enter the participant's JHS ID Number on the Urine/Phlebotomy Form when the participant arrives for the visit. At the completion of specimen collection and processing, the data will be entered into REDCAP and the original will be kept on file.

- Prior to venipuncture, two trays are prepared for each participant. One tray holds the Core draw vacutainer tubes used in blood collection, and also the pooling tubes.

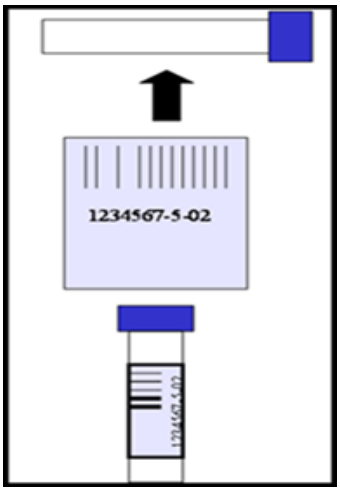
    - Two 10 mL Serum red top tubes
    - Three 10 mL EDTA lavender top tubes
    - One 4 mL EDTA lavender top tube
    - Two 10 mL tubes for pooling serum and plasma
    - Two 10 mL cryovials for Packed RBCs remaining after EDTA pooling
    - One clear transfer tube for plasma pooling of 4 mL EDTA tube

- The other tray is the aliquot rack that can hold up to 96 various plastic cryovials for the final serum, plasma and urine aliquots that are sent to the Central Laboratory.

    - 4 – 0.5 ml cryovials with purple tops
    - 8 – 1.5 ml cryovials with purple tops
    - 4 – 0.5 ml cryovials with red tops
    - 6 – 1.5 ml cryovials with red tops
    - 8 – 2.0 ml cryovials with yellow tops

Note: It is best to use one rack per participant.

5. Draw tube **#5**, Packed RBC tubes, and Cryovials should be prelabeled with the labels placed horizontally according to the picture below and placed in the aliquot rack.



6. URINE COLLECTION

A random spot urine will be collected on all JHS participants. The urine will be aliquoted and stored as part of the sample repository in Vermont and will be measured for urinary creatinine and micro albumin as samples are received.

Keep urine samples correctly labeled throughout the collection and processing stages. Pre-label collection container and cryovials prior to the participant's visit and cross-check the labels with each participant's ID number prior to specimen collection.

A. Preparation of Participants for Urine Collection

- Urine should be collected before venipuncture, preferably as early in the visit as possible. However, do not collect samples after acute fluid load (>24 oz) or after participant exertion. Participants having difficulty producing a urine specimen may be offered a glass of water, and a second (and third) urine specimen may be collected later in the visit to bring the volume up to the required amount.

- It is suggested that participants use the Covidien Sterile Midstream Urine Collection Systems for urine collection. Instructions are included in the package.

- Do not collect urine from females who are menstruating. Collect a sample at a later visit, if possible.

B. Instructions for Participants

- The participant's privacy should be assured.

- Give the supplies to the participant and explain the collection procedure for the (Covidien Sterile Midstream Urine Collection)

- Instruct the participant to wash his/her hands before and after voiding.

- Remove the cap from the collection container. If possible, start urinating into the toilet, and then void into the urine cup until at least half full. If unable to do so, a nun's cap can be provided to facilitate ease of collection. Carefully pour the urine into the collection cup and seal so that it is tight and leak proof.

- Females will then insert the urine cup into the metal door on the restroom wall. Men will bring their urine container to the JHS staff member.

The JHS staff member will record if urine is collected, the approximate volume on the Urine/Phlebotomy Form, and place it in the refrigerator to be processed later if unable to do so after collection.

7. BLOOD COLLECTION PROCEDURE

The following steps are the procedure for blood drawing. It is understood that Universal Precautions will be employed during specimen collection.

a) Gather the necessary supplies, arrange draw tubes in order of collection in a tube rack, and place it on the tabletop along with the ice bath, so that they are both within easy reach. **Ensure draw tube labels coincide with labels on Urine/Phlebotomy Form and Processing Form for the participant.** Assemble butterfly apparatus and vacutainer holders, gauze pads, and alcohol prep pads prior to tourniquet application.

b) The order in which the tubes are collected is important. Fill necessary blood vacutainers in the order described below.

- Tube 1 - 10 ml Serum red top
- Tube 2 - 10 ml EDTA purple top
- Tube 3 - 10 ml Serum red top
- Tube 4 - 10 ml EDTA purple top
- Tube 5 - 10 ml EDTA purple top
- Tube 6 - 4 ml EDTA purple top

c) Make positive participant identification and confirm that you have the correct JID labels along with the participant's chart. Access the Phlebotomy form and complete the top portion of form with the participant. Make sure to introduce yourself before you explain the planned procedure.

Note: If the participant consents to Biorepository, collect all six draw tubes. If the participant does not consent to Biorepository, **only collect draw tubes 1, 5 & 6 (Short Draw)** and document **"No Biorepository"** in the comment section of the Urine/Phlebotomy Form.

d) Position the participant's arm in a comfortable position and apply the tourniquet to identify the best available vein. Cleanse venipuncture site by wiping with an alcohol prep pad in a circular motion from center to periphery. Allow the area to dry.

> **Note**: Do not leave tightened tourniquet on for no longer than 2 minutes. It may be removed and reapplied after vein selection. If the participant has a skin problem or excess arm hair, place the tourniquet over the shirt sleeve.

e) After the tourniquet is applied, start the timer. The total time the tourniquet is applied is recorded on the Phlebotomy Form. (It is best to release the tourniquet as soon as possible after flow has been established.) It may be loosened or removed, however, doing this may result in cessation of blood flow, especially in sick and/or elderly participants. This may also result in the need for a second venipuncture. Therefore, this is a "judgment call" based upon the phlebotomist's experience and skill. If tourniquet is reapplied, be sure to record all tourniquet times on the Urine/Phlebotomy Form.

f) Grasp the participant's arm firmly, using your thumb to draw the skin taut to anchor the vein and keep it from rolling. The thumb should be 1 to 2 inches below the venipuncture site. With the needle bevel upward, enter the vein in a smooth continuous motion at a 15 degree angle. Take note of the time needle is inserted as this is considered the start of venipuncture and is documented on the Urine/Phlebotomy Form.

g) Note the blood flow into the first collection tube. If blood is flowing freely, the butterfly needle can be taped to the participant's arm for the duration of the draw. If the blood is isn't coming or the flow has stopped, try repositioning the needle without causing discomfort to the participant. If the flow is very slow, especially with the EDTA tube, gently invert the tube to mix the additive during the duration of the draw.

h) Fill each vacutainer as completely as possible until the vacuum is exhausted and blood flow cease. Immediately after collecting each tube, mix by gently inverting at least 5 times. Place the serum (red top) tubes in the collection rack, and the EDTA (purple top) tubes in the ice bath until processed.

i) If a vacutainer tube fills only partially (<½ full), remove the tube and attach another of the same type without removing the needle from the vein. Depending on how the participant feels, either perform a re-draw or document a refusal. If a tube is not completely filled, clearly document on the Urine/Phlebotomy Form.

j) When the blood draw is complete and the final tube is collected, release the tourniquet and remove the tube from the vacutainer holder. When removing the needle, place a clean gauze pad or cotton ball over the venipuncture site without putting pressure on the needle. Remove the needle quickly and immediately apply pressure to the site with the gauze pad.

Have the participant hold the gauze pad firmly for one to two minutes to prevent formation of a hematoma. Apply a bandage and instruct the patient to leave it on for at least 15 minutes.

Discard needle and tubing in the appropriate puncture-proof sharps container. Note time needle is removed as this is considered the end of venipuncture and is recorded on the Urine/Phlebotomy Form.

k) Take the blood collected to the processing area. Place all EDTA tubes on the rocker to mix for 30 seconds. They can be stored on ice, preferably < 15 minutes (maximum < 30 minutes) until able to centrifuge. **EDTA Tube 5 DOES NOT GET CENTRIFUGED and should be placed in the refrigerator after mixing.** Document the centrifuge start time on top of the processing form for EDTA.

> **Note:** If unable to fill Tube #5, place 2 ml of well mixed whole blood from tube #2 into a 2.0 ml cryovial and attach an "extra" ID label and save at refrigerated temperature for the glycated hemoglobin analysis and ship with the other Tube #5 samples. Record in comment section of the Urine/Phlebotomy Form.

l) Leave the serum tubes upright in the rack to incubate at room temperature for a minimum of 60 minutes but no longer than 90 minutes to allow blood to clot completely. Centrifuge, documenting the start time on the processing form for serum.

m) While the collection tubes are centrifuging/incubating, the urine sample can be removed from the refrigerator and aliquoted into the proper cryovials. Document urine processing start time on processing form.

n) For any ancillary study, please refer to their study specific protocol for number and type of tubes to be collected. Also, check the requirements for temperature and mixing as this can have a significant impact on the quality of the blood sample for the study's research aims.

o) Clean and disinfect the phlebotomy area, and check that the Urine/Phlebotomy Form is completed. Fill in the processing form after each sample (EDTA, Serum, Urine) have been aliquot into the appropriate cryovial and frozen.

8. GUIDELINES FOR DIFFICULTIES

Do not under any circumstances force the participant to have blood drawn. It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible.

A. *Handling participants who are extremely apprehensive about having blood drawn*

- Have the participant relax in the blood drawing chair just so the phlebotomist can check the participant's veins without actually drawing blood. It is sometimes best to let the participant go on with another part of the visit and return later for the blood draw. (Note: the participant should not be given a snack until the decision on the blood draw has been reached). If the participant refuses, note this on the phlebotomy form.

B. *Procedures for Difficult Draw*

- If there is a sucking sound, turn needle slightly or lift the holder to move the bevel edge away from the wall of the vein. If no blood appears, move needle slightly in attempt to enter the vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm or in the back of the hand.

- Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a Velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.

- Reassure the participant that the inability to obtain a clean venipuncture is not any sign of a medical problem on their part. It is permitted to use a heating pad to facilitate a better blood draw, however the phlebotomist would have to wait 10-15 minutes after the heating pad is removed, before performing the venipuncture.
- If venipuncture is unsuccessful, note on the Urine/Phlebotomy Form.

C. ***Other Possible Problems – Draw Tube Does Not Fill***

- Try another draw tube of the same type. All volume serum tubes are acceptable. Because of the additives, **ONLY** EDTA tubes half-filled to completely full are acceptable. Partially filled tubes can possibly yield a reduced number of aliquots. Note any partially filled draw tubes on Urine/Phlebotomy Form.

9. WHEN A PARTICIPANT FEELS OR LOOKS FAINT FOLLOWING THE BLOOD COLLECTION

A. If necessary, have participant sit with his/her head between knees or with head laid on the back of the chair. Prop their feet up on a stool and place a cool cloth on back of neck or on forehead.

B. Make sure that participant is not diabetic which may have caused a drop in their blood sugar.

C. Provide the participant with a leak proof biohazard bag if he/she feels nauseous.

D. If the participant faints, crush an ampoule of ammonia and wave it beneath the participant's nose for a few seconds taking care not to allow the ammonia to come into contact with the skin.

E. Have the participant remain seated until he/she feels better and until their color returns.

F. If the participant continues to feel ill, contact a medical staff member to take a blood pressure and pulse reading. Get advice on further steps to take next if necessary.

10. CENTRIFUGE OPERATION

A. Set the power switch to on and let the centrifuge pre-cool to 4 degree Celsius ensuring shields are attached to centrifuge cups during this time. Maintain the temperature of 4 degrees Celsius by keeping the centrifuge door closed and locked until ready for loading.

B. To balance, the opposite loads must not only be equal in mass, but also have the same center of gravity. Opposing containers must be alike in shape, thickness, and distribution of glass or plastic. An unbalanced load produces vibration and can damage the unit. Push the run button to begin the cycle.

C. The centrifuge will stop automatically at the pre-selected time and the stop indicator will light up. Remove the samples one at a time and carefully place them in the ice water bath for processing.

11. ALIQUOTING

Ensure the LABID labels on the filled draw tubes match the LABID labels on the cryovials just before processing. Aliquoting involves removing the serum or plasma in small amounts (e.g., 0.5 ml) by pipette and placing it into the appropriate labeled and pre-determined volume cryovials. Color-coded caps are used as part of sample identification. The aliquoting process must be done while the draw tubes and cryovials are on wet ice (unless otherwise noted).

A. Manual pipettes may be used if the volume is low or other difficulties are encountered. The appropriate procedure is to insert the tip as far into the vacutainer as possible, tilting the vacutainer slightly and moving the pipette down as the pipette tip is filled.

B. Whenever pipetting from a draw tube, always use a new pipette for each draw tube and always use a new pipette tip for each pooling tube.

C. Pool like tubes from the same participant (i.e., pool the two 10 ml EDTA tubes from the same participant, and pool the two 10 ml serum tubes from the same participant) before aliquoting. After pooling, gently mix the pooled sample at least 4-5 times.

D. If any draw tubes are accidentally mixed during pipetting so that plasma or serum is contaminated with red cells, the tubes may be re-centrifuged at the same speed and duration as the original spin.

E. Aliquot the cryovials in ascending numerical order adhering specified tube volume. Any partially filled cryovials, as a result of insufficient sample volume within a sample type, should be marked with a **"P"** on the cryovial label (preferred) or the cap. Also, document **"partial"** in the comment field next to that cryovial number on the Processing Form. Leave any empty cryovials uncapped with sample set.

F. Freeze each sample set in an upright position within 10 minutes after aliquoting. **See Appendix 8 – Freezer Diagram Box for cryovial placement**

12. DESCRIPTION OF ALIQUOT FLOW CHART

Collection Tube	Sample Type	Number of Aliquot vials	Color Code	Volume per Aliquot Vial
2 x 10 ml EDTA draw tubes (#2 & #4)	Plasma (pooled)	4 (Cryovials #01-04)	Purple	0.5 ml plasma in 0.5 ml cryovials
		6 (Cryovials #05-10)	Purple	1.0 ml plasma in 1.5 ml cryovials
	pRBC	2 (Cryovials #11&12)	White or Clear	~4 ml pRBC in 10 ml tube
2 x 10 ml Serum draw tubes (#1 & #3)	Serum (pooled)	4 (Cryovials #13-16)	Red	0.5 ml serum in 0.5 ml cryovial
		6 (Cryovials #17-22)	Red	1.0 ml serum in 1.5 ml cryovials
1 x 4 ml EDTA draw tube (#6)	Plasma	2 (Cryovials #23&24)	Purple	1.0 ml plasma in 1.5 ml cryovials
Urine	Urine	8 (Cryovials #25-32)	Yellow	1.5 ml Urine in 2.0 ml cryovial

13. CRYOVIAL INSTRUCTIONS

A. <u>EDTA plasma from tubes 2 and 4</u>

- Keep draw tubes, pooling tube, and cryovials on wet ice during processing. After centrifuging, pool plasma from the two 10 ml EDTA tubes in a 10 ml pooling tube. The draw tubes with the remaining packed cells are saved for further aliquoting (see below cryovials 11-12). Gently invert pooling tube several times to mix plasma. Aliquot by the volumes specified in the table above and cap. Double check the specified sample volume is being aliquoted into the correctly labeled cryovial. After aliquoting is complete, discard the empty pooling tube in the biohazard waste container.

B. <u>Packed Red Blood Cells</u>

- For EDTA blood draw tubes #2 and #4, transfer remaining packed cells in each tube into one 10ml transfer tube (#11 &12) using a transfer pipet. Discard the empty draw tubes in the biohazard waste container.

C. Serum from tubes 1 and 3

- Keep draw tubes, pooling tube, and cryovials cool on wet ice during processing. After centrifuging, pool serum from the two 10 ml serum tubes in a 10 ml pooling tube. The draw tubes are discarded into a biohazard container. Gently invert pooling tube several times to mix serum. Aliquot by the volumes specified in the table above and cap. Double check the specified sample volume is being aliquoted into the correctly labeled cryovial.

D. EDTA plasma from tube 6

- Keep draw tube and cryovials on wet ice during processing. After centrifuging, remove plasma carefully from this smaller 4 mL EDTA tube into a small clear. The draw tube with the remaining cells can be discarded into an appropriate biohazard waste container. Gently invert the pooling tube several times to mix plasma. Aliquot by the volume specified in the table above and cap. Discard empty transfer tube in biohazard waste container.

E. Urine aliquots

- Keep urine refrigerated or on ice until processing. Keep cryovials on wet ice during processing. Gently swirl urine immediately prior to aliquoting to ensure sample is thoroughly mixed. Aliquot by volume specified in the table above and cap. Do **NOT** overfill the cryovials. There must be space for urine expansion when frozen. Double-check urine aliquots have the correct participant ID labels and caps are securely tightened. Discard any extra urine by flushing in the toilet.

Note: For a Short Draw (participants not consenting to Biorepository), following the cryovial specific instructions, aliquot the following:

- From draw tube 1 2 - 1.0ml labeled cryovials (red caps)
- From draw tube 6 1 - 1.0ml labeled cryovial (purple cap)
- From urine 2 - 1.5ml labeled cryovials (yellow cap)

***Refrigerated tube 5 after 30 seconds rocking**

On the Processing Form, select which cryovials were done and document **"No Biorepository"** in the comment section at bottom of form. **DO NOT** discard empty cryovials. Leave them uncapped with sample.

14. Processing Completion

A. Complete the Processing form by selecting the box of all filled cryovials. Note any partials. Check processing start times are recorded. Data will be will be entered into Redcap and the Processing Form kept in a temporary file ready for easy access at the time of packaging the

frozen shipment. Copies of the Processing Forms are enclosed with each shipment of samples shipped to the LCBR. Upon receipt at LCBR, forms and samples are examined for monitoring and quality control purposes.

B. Cryovials #01-10, 13-32 from three participants are placed into one 2" freezer box with 10x10 box grid. Place cryovials 11-12 into 5x5x3" freezer box with 7x7 grid. Store these boxes in a -80°C freezer till shipping to LCBR. (Refer to Appendix, Freezer Box Diagrams for shipping frozen samples to LCBR.)

C. Label and arrange cryovials in aliquot racks along with processing form for the next day's blood/urine processing.

D. Wipe down all work areas with 10% bleach solution or approved biohazard disinfectant.

15. Special Circumstances

A. EDTA and Serum cannot be processed within time limits of collection

If unable to centrifuge filled draw tubes within specified time limits following collection, process them as soon as possible. Document the time of collection and centrifugation on the Processing Form. Keep the EDTA tubes upright and on wet ice, and serum tubes upright at room temperature until centrifugation.

B. Serum, plasma or urine cryovials cannot be frozen within 10 minutes of aliquoting

If cryovials cannot be frozen at -80°C or colder within 10 minutes of aliquoting, do it as soon as possible. They may be temporarily (< 2 hours) placed on dry ice (preferred but be sure to keep the cryovials in an upright position) or stored at -20°C until transfer to -80°C or colder is possible. If cryovials are not frozen at -80 within 10 minutes of being aliquoted, record storage conditions, storage temperature, and length of time at that temperature on the Processing Form.

16. SHIPPING

A. General

In JHS Visit 4, frozen JHS samples will be shipped to the LCBR every other week on Wednesdays to LCBR. The refrigerated 10 ml EDTA Tube #5 and 2.0 ml cryovial will be shipped to the LCBR biweekly on Mondays and Wednesdays. Both sample types will be shipped by Federal Express to:

University of Vermont
Attn: Elaine Cornell, JHS
Laboratory for Clinical Biochemistry Research

360 South Park Drive
Colchester, VT 05446
(802) 656-8963

B. Frozen Samples

1. Packaging Frozen Samples Checklist

- Frozen samples (plasma, serum and urine) – Cryovials# 01-10 and 13-32 in labeled 2" freezer boxes, and cryovials 11-12 (PRBCs) packed in labeled 3" freezer boxes.
- Styrofoam shipping containers with outer cardboard sleeve.
- Rubber bands for freezer boxes.
- Zip top plastic bags for freezer boxes.
- Absorbent material in sufficient quantity to absorb the entire liquid contents of the package.
- Packaging tape.
- Dry ice (~10-15 lbs. per shipping container)
- Shipping Labels (FedEx address labels)
- Category B labels (UN3373 BIOLOGICAL SUBSTANCE CATEGORY B)
- Dry Ice Labels (Dry Ice UN1845 class 9 – Miscellaneous Dangerous Goods Label)
- Copies of completed Processing Forms
- Completed Shipping Forms (**See Appendix 4 – Frozen Shipping Form)**

C. Frozen Sample Shipping Procedure

This shipping protocol follows procedures mandated by the International Air Transport Association's Dangerous Goods Regulations – Packaging Instructions 650 and 954.
For <u>frozen</u> shipments to the University of Vermont:

1. Line Styrofoam shipper(s) with absorbent material (i.e., absorbent pads).
2. Place approximately ½ the dry ice (~7-10 lbs.) on the bottom of the shipping container.

3. Collect the freezer boxes containing samples to be shipped. Check the participant ID numbers against the Processing Forms and Shipping Forms for that shipment before placing bagged boxes in shipper on top of dry ice.

    - For the 2" size freezer boxes, place an absorbent strip inside the freezer box on top of the cryovials. Replace the freezer box lid and secure closed with a rubber band. Place each freezer box in a leak-proof zip top plastic bag, ensuring the bag is properly zipped closed, then carefully place these bagged boxes in the shipping container. The rubber band helps prevent freezer boxes from opening and spilling contents; the zip top bag serves as an additional form of containment, and the absorbent material is essential in the event of a thaw and spill.

4. Add remaining dry ice followed by layer of absorbent material then Styrofoam shipper lid.

5. Place copies of Processing Forms for all the samples included in the shipment along with a copy of the corresponding Shipping Form(s) in a zip top bag, then place the zip top bag **on top** of the Styrofoam lid before securely taping the outer cardboard sleeve closed.

6. Affix shipping labels below to the shipping container:

    - A UN3373 Biological Substance Category B label
    - Dry ice label (with dry ice weight in kg)
    - A completed FedEx Air bill for FedEx ***Priority Overnight***
    - The shipper and recipient's name, address, and phone number

7. Make certain to ship FedEx **priority overnight.**

8. E-mail notification of the shipment, including the FedEx air bill number(s) and number of participant sample sets shipped, the day samples are packaged to: Elaine.Cornell@uvm.edu and jessica.lanzer@med.uvm.edu

D. Refrigerated Samples

1. Packaging Refrigerated Samples Checklist

- Refrigerated Samples – EDTA tube #5/2.0 ml cryovial
- Absorbent draw tubes sleeves
- Styrofoam shipping containers with outer cardboard sleeve.
- Rubber bands for fiberboard boxes.
- Zip top plastic bags for fiberboard boxes.

- Absorbent material in sufficient quantity to absorb the entire liquid contents of the package.
- Packaging tape.
- Ice Packs (Fisher Cat# 03-600-179)
- Refrigerate label
- Shipping Labels (FedEx address labels)
- Category B labels (UN3373 BIOLOGICAL SUBSTANCE CATEGORY B)
- Completed Shipping Forms (**See Appendix 5 – Refrigerated Shipping Form)**

E. Refrigerated Sample Shipping Procedure

This shipping protocol follows procedures mandated by the International Air Transport Association's Dangerous Goods Regulations – Packaging Instructions 650. For refrigerated shipments to the University of Vermont:

1. Line Styrofoam shipper(s) with absorbent material (i.e., absorbent pads).
2. Place 2 FROZEN ice packs on the bottom of the mailer. Place packing material on top of the ice packs. This can be more absorbent material, several small pieces of cardboard, etc. This prevents direct contact of the ice packs with the refrigerated samples.
3. Collect the EDTA blood draw Tube #5/2.0 ml cryovial samples to be shipped and check the participant ID numbers against the Shipping Forms for that shipment.
    - Insert each blood draw tube in an individual slot in the adsorbent blood draw sleeves. Place inside a laboratory biohazard bag and put bag in a freezer box. If there are 12 or less tubes, use a 5 x 5 x 2 inch freezer box. If there are more than 12 tubes use a 5 x 5 x 3 inch box or multiple 5x5x2 inch boxes. Put lid in place and secure with a rubber band. Place each fiberboard box in a leak-proof zip top plastic bag with absorbent pad. The rubber band helps prevent freezer boxes from opening and spilling contents; the zip top bag serves as an additional form of containment, and the absorbent material is essential in the event of a spill and helps to insulate the tubes from the frozen cold packs.
4. Place the bagged boxes in the shipping container followed by another layer of absorbent material.
5. Add 2 more FROZEN ice packs on top of this last layer of absorbent material in the shipping container then the Styrofoam lid.

6. Place a copy of the corresponding Shipping Form(s) for all the samples included in this shipment in a zip top bag, then place the zip top bag **on top** of the Styrofoam lid before securely taping the outer cardboard sleeve closed.

7. Affix shipping labels below to the shipping container:

    - A UN3373 Biological Substance Category B label
    - A completed FedEx Air bill for FedEx ***Priority Overnight***
    - The shipper and recipient's name, address, and phone number
    - Refrigerate label

8. E-mail notification of the shipment, including the FedEx air bill number(s) and number of participant sample sets shipped, the day samples are packaged to: Elaine.Cornell@uvm.edu and jessica.lanzer@med.uvm.edu

17. QUALITY CONTROL

A. Venipuncture and Equipment Records

In the Clinic there are two different aspects of quality control.

- One is the daily or monthly record of the performance of the refrigeration equipment and centrifuge. This is most easily kept as a check sheet with the daily or monthly records, as described below. For the equipment, daily records should be kept on all refrigerators and freezers. The temperature of the refrigerated centrifuge must be recorded daily. In addition, the actual speed of the centrifuge needs to be checked and recorded annually with a tachometer. A sample Quality Control Checklist is enclosed in this manual. The local blood processing certifier will fill out this sheet monthly, certifying that daily checks have been performed properly and describing any problems in this area. The Monthly Quality Control Checklists should be kept in a permanent file in the Clinic.

- The other aspect of quality control is the Urine/Phlebotomy Form that is part of each participant's records. It shows the number of attempts it takes to achieve a successful venipuncture and the staff ID number of the technician who performs the venipuncture. This record provides needed documentation that the blood was drawn in a standardized manner and that the equipment was functioning properly. This quality control documentation is the best evidence that all specimens in the Clinic are being drawn and processed identically. Differences in the way the samples are collected or processed could potentially create a significant difference in assay results, which could seriously compromise the laboratory test data. It is very important that the quality control records of the procedures and the equipment be properly maintained.

B. Reporting of Results

The Central Laboratory has the responsibility for reporting results to the Clinic. All test results are transmitted via FTP and received by the staff RN (Registered Nurse). This transmission occurs once per week. In addition, any alert result will be included in a separate transmit file via FTP. The following table summarizes the reference ranges and JHS alert ranges for routinely performed tests:

Table K.1 JHS Exam 4 Threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care

Measurement	Threshold Values / Trigger conditions	Reported to participant as:			Script for Report
Seated blood pressure	SBP <120 and DBP <80	Normal			Your blood pressure was normal. Please recheck it in one year. If you are being treated for high blood pressure, your physician may have given you a schedule for your next check-up. Please follow that schedule.
	SBP 120-129 and DBP <80	Normal			Your blood pressure was somewhat elevated, according to recent guidelines. Please recheck it in 3-6 months. If you are being treated for high blood pressure, your physician may have given you a schedule for your next check-up. Please follow that schedule.
	SBP 130-139 or DBP 80-89		Abnormal		Your blood pressure was high, according to recent guidelines. You should have your blood pressure checked within two months by a physician. If you are being treated for high blood pressure please see your physician.
	SBP 140-179 or DBP 90-119		Abnormal		Your blood pressure was quite high. You should have your blood pressure checked within a month by a physician. If you are being treated for high blood pressure, please see your physician.
	SBP 180-199 or DBP 110-119			Alert Arrange for medical evaluation within 48 hrs	Your blood pressure was very high. At the time of your ARIC visit we indicated that you should see a medical professional within 48 hours to determine whether treatment should be started or changed. If you have not done so already, please see your physician without delay.
	SBP >= 200 or DBP >=120			Alert. Stop the exam & arrange for same-day eval.	Your reading was very high. At the time of your ARIC visit we indicated that you should see a medical professional within hours to determine whether treatment should be started or changed. If you have not done so already, please see your physician without delay.

Table K.1 JHS Exam 4 Threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care

Measurement	Threshold Values / Trigger conditions	Reported to participant as:			Script for Report
Weight	Value	Can use 'Normal' cover letter			N/A
Body mass index (BMI)	N/A	Can use 'Normal' cover letter			The body mass index (BMI) is an estimate of your body fat, based on your height and weight. In adults, the BMI provides information on health and potential health risks. A BMI of less than 18.5 is Underweight; 18.5 to 24.9 is Healthy; 25.0 to 29.9 is Overweight; 30.0 or more indicates Obesity
Waist circumference	N/A	Can use 'Normal' cover letter			The waist girth is a marker of fat deposited in the abdomen. Excess abdominal fat contributes to risk of disease.
Total cholesterol	Value	Can use 'Normal' cover letter			Total cholesterol levels less than 200 mg/dL are optimal
LDL-cholesterol (calculated)	Value	Can use 'Normal' cover letter			LDL-cholesterol values less than 100 mg/dL are optimal, 100-129 mg/dL are near or above optimal, 130-159 mg/dL are borderline high, 160-189 mg/dL are high. 190 mg/dL and above are very high.
HDL-cholesterol	Value	Can use 'Normal' cover letter			HDL-cholesterol values below 40 mg/dL are sub-optimal
Triglycerides	Female: <220 mg/dl Male: < 250 mg/dl	Normal			Your serum triglyceride is in the normal range.
	Female: 220-999 mg/dl Male: 250-999 mg/dl		Abnormal		Your serum triglyceride is high. You should check with your physician about this.
	>=1000 mg/dl			Alert	Your serum triglyceride is very high. You should check with your physician about this as soon as possible.

Table K.1 JHS Exam 4 Threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care

Measurement	Threshold Values / Trigger conditions	Reported to participant as:			Script for Report
Glycosylated hemoglobin	HbA1c	Can use 'Normal' cover letter			Normal A1c values are less than 5.7% for someone who does not have diabetes. A result between 5.7 and 6.4% can indicate prediabetes (a high risk of developing diabetes). A result of 6.5% or higher may indicate diabetes. You should check with your physician about this. If you have previously been diagnosed with diabetes, please follow your physician's guidelines.
Fasting glucose	Fasting glucose <100 mg/dl	Normal			Your fasting blood glucose is in the normal range.
Fasting glucose	Fasting glucose 100 – 125 mg/dl		Abnormal		Your fasting blood glucose is somewhat high. You may have a condition called pre-diabetes and should check with your physician about this at your next appointment. If you know that you have diabetes, please follow your physician's instructions.
	Fasting glucose 126 – 399 mg/dl		Abnormal		Your fasting blood glucose is high. You should check with your physician about this.
	Fasting glucose >=400 mg/dl			Alert	Your fasting blood glucose is very high. You should check with your physician about this as soon as possible.
Creatinine	Serum Creatinine <1.5 mg/dL	Normal			Your serum creatinine is in the normal range.
	Serum Creatinine 1.5 – 5 mg/dL		Abnormal		Your serum creatinine is high. You should check with your physician about this.
	Serum Creatinine > 5 mg/dL			Alert	Your serum creatinine is very high. You should check with your physician about this as soon as possible.
Albumin Creatinine Ratio	ACR<= 300 ug/mg creatinine	Normal			Normal ACR values are less than 30 ug/mg creatinine. A result between 30 and 300 ug/mg creatinine indicates moderately increased albuminuria.
	ACR >300 ug/mg creatinine		Abnormal		Your albumin creatinine ratio is greater than 300 ug/mg creatinine. This result indicates severely increased albuminuria. You should check with your physician about this.

Table K.1 JHS Exam 4 Threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care

Measurement	Threshold Values / Trigger conditions	Reported to participant as:			Script for Report
Serum potassium		Normal			Your serum potassium is in the normal range.
	K<3 mEq/L			Alert	Your serum potassium is low (<3 mEq/L) you should check with your physician about this as soon as possible.
	K>6 mEq/L w/ no more than mild hemolysis			Alert	Your serum potassium is high (>6 mEq/L) you should check with your physician about this as soon as possible.

18. TRAINING

A. Technician Training and Evaluation

The technician must study the JHS Specimen Collection and Processing Manual and the JHS training PowerPoint. The next step in training is to watch the procedure being performed from start to finish. Upon successful completion of the written exam, the technicians are ready to perform the procedure under the close supervision of a certified technician. They become certified when the supervising certified technician approves them using the supervisor check list. Once certified, a technician must draw and process at least once per month while be supervised to maintain certification (scan and send certification checklists to LCBR). Once certified, you can then assist in certifying other technicians.

APPENDIX 1 SUPPLY/VENDOR LIST

Use	Supplier	Catalogue #	Description	Unit
General Lab	Fisher	14-809-122	Draw tube racks 16 mm tube	pack of 8
General Lab	Fisher	14-809-116	Draw tube racks 13 mm tube	pack of 8
General Lab	Fisher	19-048-133	Nitrile Exam Gloves	Pack of 200
General Lab	Fisher	14-206-38	Versi-Dry Small Bench Mat	Case of 350
General Lab	Fisher	06-666C	Kimwipes	Pack of 140
General Lab	Fisher	06-670-36	BloodBloc™ Biohazard Wipes	Pack of 200
General Lab	Fisher	NC9724348	Bleach	Case of 6, 1 gallon jugs
General Lab	Fisher	23-100-145	Sani-Cloth™ Bleach Wipes	Pack of 75 wipes
General Lab	Fisher	18-880B	Biohazard Waste Container (37 liter)	1 container
General Lab	Fisher	03-411-701	Biohazard Waste Bags	Pack of 200
General Lab	Fisher	06-662-46	Timers	1
Collection	Fisher	22-045172	Midstream specimen collection kit	case of 100
Collection	Fisher	02-664-1	Blood collection set with 21G Butterfly (BD #367281)	Pack of 50
Collection	Fisher	22-289-953	BD Vacutainer™ Tube Holder (BD #364815)	Pack of 250
Collection	Fisher	22-363-750	Alcohol Swabs	Pack of 200
Collection	Fisher	22-415-504	Sterile Gauze Sponges	Case of 3000
Collection	Fisher	19-156-103	Nonlatex Disposable Tourniquet	Pack of 100
Collection	Fisher	19-027761	Surgical Tape	Pack of 12 rolls
Collection	Fisher	23-666-044	Adhesive Bandages	Pack of 1200
Collection	Fisher	22-899-244	Cohesive Bandages	Pack of 36 rolls
Collection	Fisher	19-090-680	Ammonia Inhalant Wipes	Case of 300
Collection	Fisher	22-555-249	Phlebotomy Cart	1
Collection	Fisher	14-827-122	Sharps Container 5 qt	Case of 30
Collection	Fisher	02-685-112	10 mL Serum tube (BD 367820)	Pack of 100
Collection	Fisher	02-657-32	10 mL EDTA Tube (BD 366643)	Pack of 100
Collection	Fisher	02-687-107	4 ml EDTA Tube (BD 367862)	Pack of 100
Processing	Fisher	02681333	0.5 mL Microcentrifuge Tubes	pack of 500
Processing	Fisher	02681338	1.5 mL Microcentrifuge Tubes	pack of 500
Processing	Fisher	02681343	2 mL Microcentrifuge Tubes	pack of 500
Processing	Fisher	nc9261180	10 mL Transfer Tubes	case of 1000
Processing	Fisher	02681361	Red Screw Caps	pack of 500
Processing	Fisher	02681366	Purple Screw Caps	pack of 500
Processing	Fisher	02681360	Yellow Screw Caps	pack of 500
Processing	Fisher	s29413	Cryovial Racks	1
Processing	Fisher	0553859A	15 mL centrifuge tubes (for pooling serum/EDTA)	case of 500
Processing	Fisher	13-711-42	Transfer pipettes	Pack of 500
Processing	Fisher	14-386-320	100-1000 ul Pipette	1
Processing	Fisher	21-377-840	Pipette Tips	Case of 960
Storage	Fisher	11-394-307	Cryo-Gloves with Elbow Length	1 pair
Storage	Fisher	1167824A	5x5x2" Fiberboard Boxes	pack of 12
Storage	Fisher	11-678-24b	5x5x3" Fiberboard Boxes	pack of 12
Storage	Fisher	13-989-218	7 x 7 grids	pack of 12
Storage	Fisher	1167824c	10 x 10	pack of 12
Shipping	Fisher	22-130-321	Insulated Shipper (15x 13 x 12)	Case of 4
		22130320	Insulated shipper (18 x 16 x 14)	Case of 2
Shipping	Fisher	NC9193000	Absorbent strips	Case of 250
Shipping	Fisher	22-130-043	Absorbent Tube Sleeves	Pack of 300
Shipping	Fisher	22-130-065	Dry Ice Shipping Label	Pack og 500
Shipping	Fisher	22-130-067	UN3373 Biological Substance Category B Labels	Pack of 500
Shipping	Fisher	19-240-218	Specimen Storage Bag	Pack of 250
			ice packs	
			smaller shipper for HbA1c tubes	

Jackson Heart Study

Visit 4

Urine/Phlebotomy

Participant ID #: J

Date: Month / Day / Year

Phlebotomist ID

Lab ID: *Place label here*

PARTICIPANT QUESTIONS

		Yes	No	Don't Know
1	Do you bleed or bruise easily?	O	O	O
2	Have you ever been told you have a disorder relating to blood clotting or coagulation?	O	O	O
3	Have you ever experienced fainting spells while having blood drawn?	O	O	O
4	When was the last time you ate or drank anything other than water?			

: AM/PM

Month Day Year

PROCEDURE

5 Was urine sample collected?

O YES → Urine Cup Filled? Yes O No O — Approx. vol. (mls) — Time of Collection : AM/PM

O NO → Why was urine sample not taken?
- O Participant unable to void
- O Refused
- O Other:

6 Time at start of venipuncture: : AM/PM

7 Was any blood drawn?
- O Yes
- O No, refused
- O No, hard to stick → *If NO, end of form*
- O No, other:

8 Elapsed time until tourniquet released: seconds *(120-seconds optimum)*

9 Time at end of venipuncture: : AM/PM

10 Quality of venipuncture: O Traumatic O Clean

Mark all that apply
- O Vein collapsed
- O Hematoma
- O Excessive duration of draw
- O Multiple sticks
- O Vein hard to get
- O Leakage at venipuncture site

***NOTE:** If ppt DID NOT consent to store samples but consented to assays, collect tube #1, 5 and 6 only. Write "No Biorepository" in comment section.*

11 Blood Volume per tube:

		Filled Yes	Filled No	Filled Partial	If Partial *(specify volume)*: *min ½ full*
1.	Serum 10 mL	O	O	O	
2.	EDTA 10 mL	O	O	O	
3.	Serum 10 mL	O	O	O	
4.	EDTA 10 mL	O	O	O	
5.	EDTA 10 mL *(for whole blood)*	O	O	O	
6.	EDTA 4mL	O	O	O	
7.	Consent for ASN0209?	O	O →	*If NO, end of form*	
8.	Citrate 4.5mL	O	O	O	
9.	Citrate 4.5mL	O	O	O	
10.	Citrate 4.5mL	O	O	O	
11.	EDTA 2mL *(for local CBC Diff)*	O	O	O	

Comments: _____

APPENDIX 3 **PROCESSING FORM**

Jackson Heart Study

Visit 4

Processing Form

Lab ID #:

Place label here

Processor ID: _____

Processing Start Time: _____:_____ EDTA
Processing Start Time: _____:_____ Serum
Processing Start Time: _____:_____ Urine

Cryo #	Type	Color	Sample Vol (ml)	✓ if Done	Comment	No biorepository consent.
1	EDTA	P	0.5			
2	EDTA	P	0.5			
3	EDTA	P	0.5			
4	EDTA	P	0.5			
5	EDTA	P	1.0			
6	EDTA	P	1.0			
7	EDTA	P	1.0			
8	EDTA	P	1.0			
9	EDTA	P	1.0			
10	EDTA	P	1.0			
11	pRBC	W	4.0			
12	pRBC	W	4.0			
13	Serum	R	0.5			
14	Serum	R	0.5			
15	Serum	R	0.5			
16	Serum	R	0.5			
17	Serum	R	1.0			
18	Serum	R	1.0			
19	Serum	R	1.0			
20	Serum	R	1.0			
21	Serum	R	1.0			
22	Serum	R	1.0			
23	EDTA	P	*1.0*		*ASN1078*	
24	EDTA	P	*1.0*		*ASN1078*	
25	Urine	Y	1.5			
26	Urine	Y	1.5			
27	Urine	Y	1.5			
28	Urine	Y	1.5			
29	Urine	Y	1.5			
30	Urine	Y	1.5			
31	Urine	Y	1.5			
32	Urine	Y	1.5			

COLOR: R=red, P=purple, W=white, Y=yellow. ***COMMENT:*** P for partial volume, H for hemolysis

Comments: _____

LCBR Rec'd Date: _____ Frozen: Y / N

Visit 4 Frozen Specimen

SHIPPING FORM

Include in shipment AND email:
Elaine.Cornell@uvm.edu and
Jessica.Lanzer@med.uvm.edu

Date of shipment: _____ Prepared by:_____

FedEx Air Bill#: _____

LABID#	VISIT Date	BOX #

APPENDIX 5 **REFRIGERATED SHIPPING FORM**

Visit 4
Refrigerated Whole Blood Specimen
SHIPPING FORM
Include in shipment AND email:
Elaine.Cornell@uvm.edu and
Jessica.Lanzer@med.uvm.edu

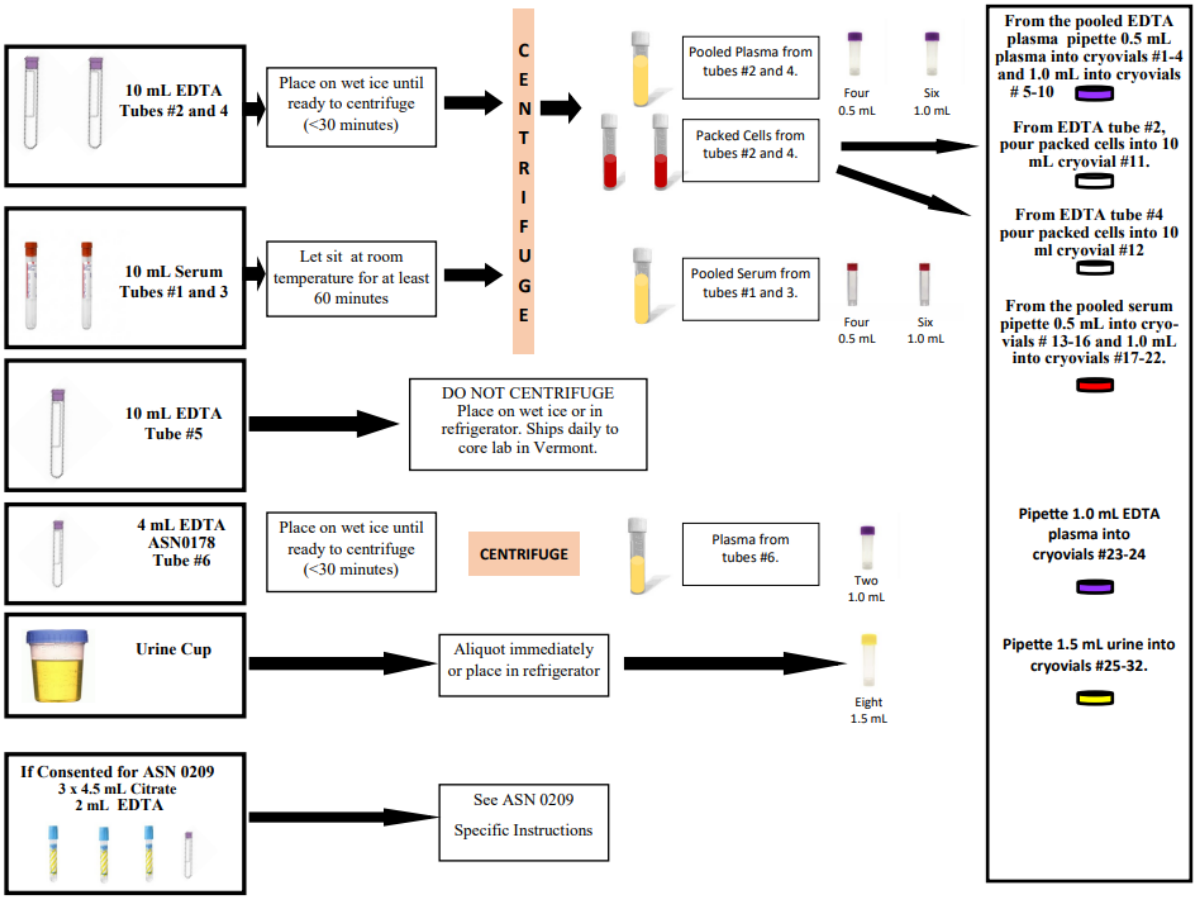
Date of shipment: _____ Prepared by: _____

FedEx Air Bill#: _____

LABID#	VISIT Date	BOX #

APPENDIX 6 LABEL SAMPLE SET

APPENDIX 7 ALIQUOTING FLOW CHART



APPENDIX 8 **FREEZER BOX DIAGRAMS**

EDTA (Purple), SERUM (Red), URINE (Yellow)

PT1 Cryo 1 0.5 ml	PT1 Cryo 13 0.5 ml	PT1 Cryo 23 1.0 ml	PT2 Cryo 1 0.5 ml	PT2 Cryo 13 0.5 ml	PT2 Cryo 23 1.0 ml	PT3 Cryo 1 0.5 ml	PT3 Cryo 13 0.5 ml	PT3 Cryo 23 1.0 ml	
PT1 Cryo 2 0.5 ml	PT1 Cryo 14 0.5 ml	PT1 Cryo 24 1.0 ml	PT2 Cryo 2 0.5 ml	PT2 Cryo 14 0.5 ml	PT2 Cryo 24 1.0 ml	PT3 Cryo 2 0.5 ml	PT3 Cryo 14 0.5 ml	PT3 Cryo 24 1.0 ml	
PT1 Cryo 3 0.5 ml	PT1 Cryo 15 0.5 ml	PT1 Cryo 25 1.5 ml	PT2 Cryo 3 0.5 ml	PT2 Cryo 15 0.5 ml	PT2 Cryo 25 1.5 ml	PT3 Cryo 3 0.5 ml	PT3 Cryo 15 0.5 ml	PT3 Cryo 25 1.5 ml	
PT1 Cryo 4 0.5 ml	PT1 Cryo 16 0.5 ml	PT1 Cryo 26 1.5 ml	PT2 Cryo 4 0.5 ml	PT2 Cryo 16 0.5 ml	PT2 Cryo 26 1.5 ml	PT3 Cryo 4 0.5 ml	PT3 Cryo 16 0.5 ml	PT3 Cryo 26 1.5 ml	
PT1 Cryo 5 1 ml	PT1 Cryo 17 1 ml	PT1 Cryo 27 1.5 ml	PT2 Cryo 5 1 ml	PT2 Cryo 17 1 ml	PT2 Cryo 27 1.5 ml	PT3 Cryo 5 1 ml	PT3 Cryo 17 1 ml	PT3 Cryo 27 1.5 ml	
PT1 Cryo 6 1 ml	PT1 Cryo 18 1 ml	PT1 Cryo 28 1.5 ml	PT2 Cryo 6 1 ml	PT2 Cryo 18 1 ml	PT2 Cryo 28 1.5 ml	PT3 Cryo 6 1 ml	PT3 Cryo 18 1 ml	PT3 Cryo 28 1.5 ml	
PT1 Cryo 7 1 ml	PT1 Cryo 19 1 ml	PT1 Cryo 29 1.5 ml	PT2 Cryo 7 1 ml	PT2 Cryo 19 1 ml	PT2 Cryo 29 1.5 ml	PT3 Cryo 7 1 ml	PT3 Cryo 19 1 ml	PT3 Cryo 29 1.5 ml	
PT1 Cryo 8 1 ml	PT1 Cryo 20 1 ml	PT1 Cryo 30 1.5 ml	PT2 Cryo 8 1 ml	PT2 Cryo 20 1 ml	PT2 Cryo 30 1.5 ml	PT3 Cryo 8 1 ml	PT3 Cryo 20 1 ml	PT3 Cryo 30 1.5 ml	
PT1 Cryo 9 1 ml	PT1 Cryo 21 1 ml	PT1 Cryo 31 1.5 ml	PT2 Cryo 9 1 ml	PT2 Cryo 21 1 ml	PT2 Cryo 31 1.5 ml	PT3 Cryo 9 1 ml	PT3 Cryo 21 1 ml	PT3 Cryo 31 1.5 ml	
PT1 Cryo 10 1 ml	PT1 Cryo 22 1 ml	PT1 Cryo 32 1.5 ml	PT2 Cryo 10 1 ml	PT2 Cryo 22 1 ml	PT2 Cryo 32 1.5 ml	PT3 Cryo 10 1 ml	PT3 Cryo 22 1 ml	PT3 Cryo 32 1.5 ml	

APPENDIX 8 **FREEZER BOX DIAGRAMS**

PRBC ALIQUOTS

Pt 1 Cryo 11 pRBC	Pt 4 Cryo 11 pRBC	Pt 7 Cryo 11 pRBC	Pt 10 Cryo 11 pRBC	Pt 13 Cryo 11 pRBC	Pt 16 Cryo 11 pRBC	Pt 19 Cryo 11 pRBC
Pt 1 Cryo 12 pRBC	Pt 4 Cryo 12 pRBC	Pt 7 Cryo 12 pRBC	Pt 10 Cryo 12 pRBC	Pt 13 Cryo 12 pRBC	Pt 16 Cryo 12 pRBC	Pt 19 Cryo 12 pRBC
Pt 2 Cryo 11 pRBC	Pt 5 Cryo 11 pRBC	Pt 8 Cryo 11 pRBC	Pt 11 Cryo 11 pRBC	Pt 14 Cryo 11 pRBC	Pt 17 Cryo 11 pRBC	Pt 20 Cryo 11 pRBC
Pt 2 Cryo 12 pRBC	Pt 5 Cryo 12 pRBC	Pt 8 Cryo 12 pRBC	Pt 11 Cryo 12 pRBC	Pt 14 Cryo 12 pRBC	Pt 17 Cryo 12 pRBC	Pt 20 Cryo 12 pRBC
Pt 3 Cryo 11 pRBC	Pt 6 Cryo 11 pRBC	Pt 9 Cryo 11 pRBC	Pt 12 Cryo 11 pRBC	Pt 15 Cryo 11 pRBC	Pt 18 Cryo 11 pRBC	Pt 21 Cryo 11 pRBC
Pt 3 Cryo 12 pRBC	Pt 6 Cryo 12 pRBC	Pt 9 Cryo 12 pRBC	Pt 12 Cryo 12 pRBC	Pt 15 Cryo 12 pRBC	Pt 18 Cryo 12 pRBC	Pt 21 Cryo 12 pRBC

Temperature Log

MONTH _____ YEAR _____

REFRIGERATOR **Acceptable Range**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

FREEZER **Acceptable Range**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

ROOM **Acceptable Range**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

CENTRIFUGE **Acceptable Range**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Tech Initials

Comments : _____

_____

_____

_____

_____

_____

Supervisor _____ Date _____

APPENDIX 10 **SUPERVISOR CHECKLISTS**

JHS Exam 4 Phlebotomy - Supervisor Checklist

DATE: ☐ ☐ ☐ **Technician Name/ID:** _____
mo **day** **year**

Supervisor: _____

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Phlebotomy area properly prepared and stocked with supplies (tube rocker, ice bucket, extra draw tubes & labels, etc.).
2. ☐ Blood draw tubes in correct order and correctly labeled.
3. ☐ Checked Phlebotomy Form has correct participant ID.
4. ☐ Questions on Phlebotomy Form asked and answers recorded.

Venipuncture:

5. ☐ Non-permeable lab coat, gloves, and face shields used.
6. ☐ Correct preparation of venipuncture site.
7. ☐ Venipuncture smoothly executed.
8. ☐ Tubes filled in correct draw tube priority order.
9. ☐ Any replacement tubes correctly labeled.
10. ☐ Tourniquet released within 2 minutes; time noted on Phlebotomy form.
11. ☐ Proper appropriate care of venipuncture site after needle is removed.
12. ☐ Needle & tubing appropriately disposed.

Handling of filled draw tubes:

14. ☐ The correct tubes inverted and placed on the rocker for the time limits specified in the protocols.
15. ☐ Filled tubes placed in the correct racks - on ice or at room temperature – ASAP per protocol.
16. ☐ EDTA, serum tubes < ½ full discarded.

P/P Form:

17. ☐ Correct sample ID labels on both pages of Phlebotomy/Processing form.
18. ☐ Venipuncture starts and end times legibly recorded on the Phlebotomy form.
19. ☐ Elapsed tourniquet time noted on form.
20. ☐ Form completely filled out, and any comments recorded in the Comments section.

Urine:

22. ☐ Urine collection container correctly labeled and urine section on Phlebotomy Form completed.

Comments: _____

JHS Exam 4 Laboratory Processing - Supervisor Checklist

DATE: ☐ ☐ ☐ **Technician Name/ID:** _____

mo **day** **year**

Supervisor: _____

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Aliquot racks organized and cryovials checked that they are correctly labeled
2. ☐ Non-permeable lab coats, gloves, and face shields (if desired) used.

Stage 1:

3. ☐ Time checked to ensure tubes are processed within the correct time limits post venipuncture per protocol.
4. ☐ Equipment is checked to ensure all tubes requiring centrifuging are centrifuged at the correct temperature and speed.
5. ☐ EDTA plasma from 10 mL tubes pooled before aliquoting into correctly labeled and color-coded cryovials.
6. ☐ New pipet tip used for each sample type and aliquots kept on ice during aliquoting.
7. ☐ Packed red blood cells from each tube transferred to correctly labeled freezing tube.
8. ☐ Filled cryovials checked off on the Processing Form and frozen upright @ -80 ^{o}C within 10 minutes

Stage 2:

12. ☐ Time monitored to ensure serum tubes remain at room temperature for > 40 minutes and < 90 minutes.
13. ☐ Serum from 10 mL tubes pooled before aliquoting into correctly labeled and color-coded cryovials.

Processing Completion:

15. ☐ Urine is kept refrigerated until aliquoting into correctly labeled tubes (#25-32)
16. ☐ Processing area and equipment is cleaned with appropriate disinfectant.
17. ☐ Processing Form completely filled out, including recording all blood and urine aliquots obtained and if any are less than the required volume. Any comments noted in comment section.

Comments: _____

_____

_____

Supervisor Signature _____

JHS Exam 4 Laboratory Refrigerated Shipping - Supervisor Checklist

DATE: ☐ ☐ ☐ **Technician Name/ID:** _____

mo **day** **year**

Supervisor: _____

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Shipping packs have been stored at -20ºC for at least 24 hours.
2. ☐ All packing materials are available and in good condition
3. ☐ Shipping list printed of samples to be shipped

Shipping:

4. ☐ Line Styrofoam shipper(s) with absorbent material (i.e. absorbent pads).
5. ☐ Place 2 FROZEN ice packs on the bottom of the mailer. Place packing material on top of the ice packs. This can be more absorbent material, several small pieces of cardboard, etc. This prevents direct contact of the frozen ice packs with the refrigerated samples.
6. ☐ Collect the EDTA blood draw Tube #5 samples to be shipped, and check the participant ID numbers against the Processing Forms and Shipping Forms for that shipment.
7. ☐ Place each blood draw tube in an individual slot in the adsorbent blood draw sleeves.
8. ☐ Lay the tubes (wrapped in the absorbent sleeves) on their side in a freezer box. If there are 12 or less tubes, use a 5 x 5 x 2 inch freezer box. If there are more than 12 tubes use a 5 x 5 x 3 inch box or multiple 5x5x2 inch boxes.
9. ☐ Put lid in place and secure with a rubber band.
10. ☐ Place each freezer box in a leak-proof zip top plastic bag with absorbent pad, then carefully place these bagged boxes in the shipping container. The rubber band helps prevent freezer boxes from opening and spilling contents; the zip top bag serves as an additional form of containment, and the absorbent material is essential in the event of a thaw and spill.
11. ☐ Place another layer of absorbent material on top of the bagged freezer boxes containing the samples.
12. ☐ Add 2 more FROZEN ice packs on top of this last layer of absorbent material in the shipping container.
13. ☐ Place the Processing Forms for all the samples included in the shipment, along with a copy of the corresponding Shipping Form(s), in a zip top bag, then place the zip top bag **on top** of the Styrofoam lid before securely taping the outer cardboard sleeve closed.

13. ☐ The outside of all packages must be marked with the following:
    - A UN3373 Biological Substance Category B label
    - A completed Fed-Ex Airbill for Fedex ***Priority Overnight***
    - The shipper and recipient's name, address, and phone number

14. ☐ E-mail notification of the shipment, including the FedEx airbill number(s) and number of participant sample sets shipped, the day samples are packaged to: Elaine.Cornell@uvm.edu and Jessica.lanzer@med.uvm.edu

15. ☐ All packages will be shipped to:

Elaine Cornell/ JHS
University of Vermont,
Laboratory for Clinical Biochemistry Research
360 South Park Drive,
Colchester, VT 05446
(802) 656-8963

Comments: _____

_____

_____

Supervisor Signature _____

JHS Exam 4 Laboratory Frozen Shipping - Supervisor Checklist

DATE: ☐ ☐ ☐ **Technician Name/ID:** ☐

mo **day** **year**

Supervisor: ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Ensure sufficient dry ice is available for shipping.
2. ☐ All packing materials are available and in good condition
3. ☐ Shipping list printed of samples to be shipped

Shipping:

3. ☐ Line Styrofoam shipper(s) with absorbent material (i.e. absorbent pads).
4. ☐ Place approximately ½ the dry ice (~7-10 lbs) on the bottom of the shipping container.
5. ☐ Place another layer of absorbent material on top of the dry ice – so it will be between the dry ice and the zip top plastic bag enclosing freezer boxes containing samples.
6. ☐ Collect the freezer boxes containing samples to be shipped, and check the participant ID numbers against the Processing Forms and Shipping Forms for that shipment.
7. ☐ For the 2" size freezer boxes, place an absorbent strip inside the freezer box on top of the cryovials. Replace the freezer box lid and secure closed with a rubber band. Place each freezer box in a leak-proof zip top plastic bag, ensuring the bag is properly zipped closed, then carefully place these bagged boxes in the shipping container. The rubber band helps prevent freezer boxes from opening and spilling contents; the zip top bag serves as an additional form of containment, and the absorbent material is essential in the event of a thaw and spill.
8. ☐ Place another layer of absorbent material on top of the bagged freezer boxes containing the samples.
12. ☐ Add remaining dry ice on top of this last layer of absorbent material in the shipping container.
13. ☐ Place the Processing Forms for all the samples included in the shipment, along with a copy of the corresponding Shipping Form(s), in a zip top bag, then place the zip top bag **on top** of the Styrofoam lid before securely taping the outer cardboard sleeve closed.
15. ☐ Affix shipping label(s) to the shipping container. Make certain to ship Fedex **priority overnight** [NOTE this is ***not*** first overnight] (Package samples as close to time of FedEx pick-up as possible to minimize the length of time on dry ice.)
16. ☐ E-mail notification of the shipment, including the FedEx airbill number(s) and number of participant sample sets shipped, the day samples are packaged to: Elaine.Cornell@uvm.edu and Jessica.lanzer@med.uvm.edu

Mailing Address:

Elaine Cornell/ JHS
University of Vermont,
Laboratory for Clinical Biochemistry Research
360 South Park Drive,
Colchester, VT 05446
(802) 656-8963

Comments: _____

_____

_____

Supervisor Signature _____

Appendix 11: Certification Exam

JHS Exam 4 - Field Center Technician Certification Exam

PHLEBOTOMY

Multiple choice questions. Circle the one BEST response.

1. Which tube is drawn first?
   - A. EDTA (10ml lavender top)
   - B. Serum (10ml red top)
   - C. EDTA (4.0ml lavender top)
   - D. Citrate (4.5ml blue top)

2. Which is the correct draw tube order?
   - A. Serum, EDTA, Citrate, Serum, EDTA
   - B. Serum, EDTA, Serum, EDTA, EDTA, 4 ml EDTA.
   - C. EDTA, EDTA, Serum, EDTA, Citrate, Citrate, EDTA.
   - D. Draw tube order is not important.

3. How much blood is drawn for the main JHS lab component?
   - A. 40 ml
   - B. 50 ml
   - C. 54 ml
   - D. 69.5 ml

4. How are 10 ml EDTA tubes handled after they are drawn?
   - A. Place on mixer for at least 30 seconds, then placed on ice.
   - B. Do not mix, place in rack on ice.
   - C. Gently invert, then place in rack at room temp.
   - D. Do not mix, place in rack at room temp.

5. Even though it is acceptable to collect the urine sample at any time during the visit, the preferred collection time is?
   - A. At the end of the visit.
   - B. As early in the visit as possible
   - C. After lunch
   - D. After phlebotomy

6. Which draw tubes require mixing then storing on ice immediately after filling?
   - A. EDTA & Serum
   - B. EDTA, Citrate, & Serum
   - C. EDTA only
   - D. Serum only

Continue with True/False questions on page 2 of Exam.

.

PHLEBOTOMY - TRUE OR FALSE QUESTIONS. Circle T if statement is TRUE. Circle F if statement is FALSE

T F Gloves should be worn by the phlebotomist when obtaining the blood sample.
T F Venipuncture procedure maybe performed before the JHS participant gives informed consent.
T F Ideally, the tourniquet should not be on longer than 2 minutes, however maybe reapplied if needed.
T F Venipuncture start and end times are important and are recorded on the Phlebotomy / Processing Form.
T F Needles should be disposed of in a biohazard sharps container.
T F The order the blood collection tubes are filled is not important.

T F The Phlebotomy Form lists the specific draw tubes to be collected on each participant.
T F Serum tubes are immediately placed on ice after collection.
T F The Phlebotomist does not need to check that the draw tubes are labeled with the correct participant ID.
T F In JHS phlebotomy, multiple sticks on the same participant are not classified as traumatic venipuncture.
T F EDTA tubes less than half full (<1/2) should be discarded.
T F A total of 31 ml collected urine is sufficient to create all the urine aliquots in the processing step.
T F Prior to the participant's arrival, the phlebotomy area should be tidy, stocked with all items needed, and the draw tube mixer checked that it is working.

JHS Exam 4 – Field Center Technician Certification Exam

PROCESSING

Multiple choice questions. Circle the one BEST response.

1. Which size and color-coded aliquots are prepared from the EDTA plasma?
   A. 8 x 1.5 ml cryovials with yellow caps
   B. 4 x 0.5 ml + 6 x 1.0 ml with red caps
   C. 4 x 0.5 ml + 6 x 1.0 ml with purple caps
   D. 8 x 1.0 ml cryovials with purple caps.

2. Which draw tube does not get processed and is shipped as whole blood?
   A. Tube #3: 10 ml Serum
   B. Tube #2: 10 ml EDTA
   C. Tube #5: 10 ml EDTA
   D. Tube #6: 4 ml EDTA

3. For which type of sample are the cryovials color coded red?
   A. Packed red blood cells.
   B. EDTA plasma.
   C. Urine
   D. Serum.

4. What is the volume aliquoted for each urine tube?
   A. 5.0 µL
   B. 0.5 ml
   C. 1.0 ml
   D. 1.5 ml

5. Which choice below best summarizes the storing and time requirements for the filled draw tubes before they are centrifuged?
   A. EDTA on ice < 30 mins; Serum on ice > 30mins, but < 90mins.
   B. EDTA on ice > 30 mins; Serum at room temperature < 90 mins.
   C. EDTA on ice < 30 mins; Serum at room temperature > 40 mins
   D. EDTA on ice < 30 mins; Serum at room temperature > 60 mins, but < 90 mins.

Continue with True/False questions on page 2 of Exam.

TRUE OR FALSE

Circle T if the statement is TRUE. Circle F if the statement is FALSE.

T F Personal protective equipment (lab coat, gloves, face shield/safety glasses, etc.) are to be worn when processing blood samples.

T F JHS cryovials are kept on wet ice during the aliquoting process and all aliquots are frozen immediately (< 10 minutes) after processing.

T F Color coding of the JHS aliquots is random and not important.

T F Eating and drinking is not permitted in the blood processing lab.

T F The serum from the two 10 ml serum tubes is not pooled before aliquoting.

T F After the plasma from the EDTA tubes 2 and 4 has been aliquoted, the draw tube with remaining RBC can be discarded.

T F Pipette tips do not need to be changed when aliquoting blood from different draw tube types so long as it is all blood from the same participant.

T F Urine needs to be stored on wet ice or refrigerated before aliquoting.

T F Filled 10 ml EDTA draw tube #5 is centrifuged before shipping.

T F Centrifugation of the JHS blood collection tubes in a non- refrigerated centrifuge, providing the G-force is adequate, is standard procedure.

T F Labels on all aliquots should be checked that they are the correct participant ID number and the correct cryovial number prior to aliquoting the sample.

T F Cryovial# 13 is the first serum aliquot.

T F Cryovials filled with less than the specified volume are to be recorded as partially filled ("P") on the Processing Form and marked with a "P" on the cryovial label.

T F EDTA 10 ml whole blood tubes are shipped daily to the central lab.

T F Completed JHS Phlebotomy and Processing Forms should be entered into REDCAP as soon as possible after completion of blood draw and processing.

BLOODBORNE PATHOGEN SAFETY PROCEDURES

UMMC Policy and Procedure Manual	H-CL-CGEN-CYTO-PR-00003
Subject: BLOODBORNE PATHOGEN SAFETY PROCEDURES	
Old Title: BLOODBORNE PATHOGEN SAFETY PROCEDURES	
Revised Date: 10/16/2020	**Effective Date:** 11/17/2018
Prepared By: Suzanne Hurley	**Approved By:** Timothy C. Allen **Reviewed By:** Cicily D. Thompson Sarika P. Jain

BLOODBORNE PATHOGEN SAFETY PROCEDURES

1. All containers of biological materials to be discarded are to be placed in red plastic biohazard bags and collected by UMMC Waste Management for disposal.

2. Used disposable pipettes are discarded in the red biohazard sharps containers and collected by a UMMC authorized entity for disposal.

3. Spent or contaminated media is placed in disposable plastic containers containing 10% bleach. When full (500 mls), discard in dirty sink with copious amounts of water.

4. Slides covered with cell suspensions are placed in red biohazard sharps containers and collected by UMMC authorized entity.

5. Only disposable instruments and pipets for tissue culture are used. After use, they are placed in red biohazard sharps containers and collected by a UMMC authorized entity.

6. All tissue culture procedures are done in a Biological Safely Cabinet.

7. The Biological Safety Cabinet blower (in blood room) is turned on for 20 minutes before use. The Biological Safety Cabinet in the amnio room will display a green light indicating the "ready" status of the cabinet. The cabinet is cleaned with 70% ETOH or VIREX at 1X strength before and after each use.

8. Accidental biological spills are flooded with 70% ETOH or VIREX at 1X strength and soaked up by paper toweling. These towels are discarded in a biohazard bag and collected by UMMC waste management.

9. Syringes and needles are placed in red biohazard sharps containers and collected by a UMMC authorized entity.

Injury and Accident Reporting Policy

UMMC Policy and Procedure Manual	H-CL-POC-POCT-PR-00059
Subject: Injury and Accident Reporting Policy	
Revised Date: 1/28/2021	**Effective Date:** 10/8/2018
Prepared By: Jennifer Casey	**Approved By:** John T. Lam **Reviewed By:** J. Nancy Prezas-Jones

INJURY AND ACCIDENT REPORTING PROCEDURE

PURPOSE:

To provide a uniform procedure for reporting injuries and accidents in the Laboratory.

EMPLOYEE INJURY REPORTING PROCEDURE:

All employee injuries are to be reported to the employee's immediate supervisor. The supervisor will resolve the problem and after informing the Laboratory Director will return an answer to the originator of the report of the incident.

PROCEDURE TO REPORT INJURIES:

Laboratory employees are to report any injuries to the supervisor or the section head by the electronic "Employee Injury "report. The report can be found accessing the UMMC intranet →Healthcare→Employee Injury Report. The report should include the following:

1. An explanation of the injury.
2. A list of the people involved.
3. The date and time the injury occurred.
4. The place where the injury occurred.
5. Supervisor's name

If an injury occurs, the employee notifies the supervisor and fills out an online "Employee Injury Report", and then goes to Employee Student Health where an evaluation is made and medical treatment is given if necessary. If the injury occurs after clinic hours, the employee should report to the Adult Emergency Room.

After review by Employee Student Health the report is forwarded to the employee's Technical Supervisor. The Supervisor will report the injury in writing to the Laboratory Director who will retain a copy in a central file. The Laboratory Director will decide further action by the laboratory staff.

ACCIDENT REPORTING PROCEDURE:

Occupational Safety and Health Manual, 02-2010; Hospital Administrative Policies Manual, HADM/A-3, 12-2007

1. All accidents must be reported to the immediate supervisor, either by the one who is injured or by another employee, and an online "Employee Injury Report" found under "Healthcare" must be filed in accordance with procedures outlined in the Hospital Administrative Policies Manual and the Handbook for Employees.

2. The injured employee should go the Employee Student Health during day time hours or the Adult Emergency Room (night and holidays) for treatment.

3. The Director of Human Resources and Safety Officer are responsible for coordinating all accidental injury report procedures. They make timely investigations and the reports of all serious accidents and those causing loss of work time.

4. The Safety Officer tabulates all accident reports and provides monthly summaries. The responsibility for investigating and reporting accidents rests with the department head and supervisor of the injured employee.

5. The human resources representative ensures that the department heads and safety committee members are instructed in investigation procedures.

6. Supervisors and/or department heads investigate all accidents involving their employees.

7. Accident reports must be completed within 24 hours or the accident and sent to Human Resources.

8. Serious accidents and fatalities must be reported to the Director of Human Resources immediately by telephone and by written report filed within 24 hours.

9. The investigation of an accident should be pursued in a manner that will most effectively control the hazard.

10. The investigation will not be completed until all causes contributing to the accident have been discovered and corrected.

The Medical Center tries to maintain safe working conditions for all employees to prevent accidents. Employees must cooperate by observing reasonable and normal safety precautions in their work. If someone should be injured on the job, the injury should be reported to the supervisor at once, either by the one who is injured or by another employee. Go to the employee health service (day) or the Adult Emergency Room (night) for treatment. When injured on the job, always fill out the online "Employee Injury Report". The injury report form can be found under "Healthcare" on the UMMC intranet.

All accidents resulting in fatalities or in the hospitalization of three (3) or more employees must be reported to risk management. Risk management must be informed of these types of accidents immediately. Risk management will report accidents of this nature to the Occupational Safety and Health Administration (OSHA) within 8 hours of the accident. In the event that risk management cannot be contacted, the lab must report the incident to OSHA within 8 hours.

ACCIDENTS RESULTING IN PROPERTY DAMAGE:

1. All accidents resulting in property damage must be reported to the immediate supervisor by the person responsible for or witnessing the damage, and a "Property Damage Report" must be completed and given to the supervisor.
2. The responsibility for investigating the accident rests with supervisor of the department in which the accident occurred.
3. The investigation of an accident should be pursued in a manner that will most effectively control the hazard.
4. The investigation will not be completed until all causes contributing to the accident have been discovered and corrected.
5. Accident reports must be completed within 24 hours.
6. The Safety Officer tabulates all accident reports and provides monthly summaries.
    -
    - The property damage report should include:
    - Date and Time Damage Occurred
    - Name of damaged property
    - Describe the damage to the property
    - Estimated replacement/repair cost
    - Owner of the Property: UMMC/Personal
    - Property control number, if applicable
    - Room number damage occurred
    - Person reporting damage/Telephone number
    - Witnesses
    - Provide name and telephone number

References:

Occupational Safety and Health Manual

Hospital Administrative Policies and Procedures Manual, University of Mississippi Medical Center

PERSONNEL AND LABORATORY SAFETY REQUIREMENTS

UMMC Policy and Procedure Manual	H-CL-SAFE-GEN-PR-00007
Subject: PERSONNEL AND LABORATORY SAFETY REQUIREMENTS	
Revised Date: 9/22/2021	**Effective Date:** 3/26/2018
Prepared By: Darlene M. Hamilton	**Approved By:** Timothy C. Allen **Reviewed By:** Vonda Clack Patrick Kyle

PERSONNEL AND LABORATORY SAFETY REQUIREMENTS

PURPOSE:

To instruct the personnel in the Anatomic Pathology and Clinical Laboratory Divisions of the Department of Pathology in the proper procedures to ensure laboratory safety.

PERSONNEL REQUIREMENTS:

1. Eating and drinking are prohibited in the technical work areas.
2. Smoking or vaping is prohibited on the facilities and adjacent grounds.
3. Food is not permitted in the technical refrigerators.
4. Application of cosmetics (including lip balm) in the technical work areas is prohibited.
5. Handling or placing of contact lenses in the technical work areas is prohibited.
6. Gloves should be worn for venipuncture and other vascular access procedures.
7. Gloves should be worn when processing patient specimens.
8. Mask and safety glasses should be worn if splashing or aerosolization is anticipated.
9. Clothing: See UMMC policies on Biological Safety

   See Professional Appearance Policy

   https://intranet.umc.edu/Health%20Care/files/UMMC-standards-guide_web_022515.pdf
10. Shoes: See UMMC policies on a) Biological Safety and b) Professional Appearance listed above.

11. Lab Coats: Should be removed when leaving the lab for lunch and breaks.

12. Hair: Shall be secured back and off the shoulders in such a manner as to prevent it from coming into contact with contaminated material or surfaces and also to prevent shedding of organisms into the work area. This is especially true in microbiology. It is also important to keep hair out of moving machinery such as centrifuges.

13. Men with beards: Must observe the precautions. Employees who wear mustaches, beards or sideburns should keep them trimmed appropriately and well groomed. Those who shave their facial hair should make every effort to maintain a clean shaven look. Employees whose jobs require exposure to potentially infectious patients, necessitating use of a respirator are prohibited from having facial hair that interferes with the seal.

14. Hand Washing: Hands should be washed frequently during the day, before leaving the laboratory, before and after contact with patients, after handling patient specimens even if gloves are worn, and before eating and smoking.

15. Pipetting by mouth is prohibited. There are pipetting aids for every task.

16. Use 10% Clorox or CaviCide as a disinfectant to clean work area at the end of

each shift and after each spill in the area. Solution must be in contact with blood for

30 seconds.

17. Employee identification tag must be visible and above the waist at all times.

18. Exits and Aisles:

a. Must not be obstructed in any way. No equipment, chairs, supplies, or trash is permitted in exit routes or egresses.

b. Laboratory exit doors must not be blocked, bolted, or obstructed in any way to block egress.

c. Wheel chair or stretcher patients should be placed so as not to obstruct aisles or routes of egress.

SPECIMEN TRANSPORT:

All specimens delivered via pneumatic tube system or hand delivered to the Clinical Laboratory or Anatomic Pathology Divisions of the Department of Pathology should be transported in a secondary container, e.g., (sealed plastic biohazard bag or other appropriate container) in case of accidents or leaks. Specimens sent via the pneumatic tube system in the Clinical Laboratory Division must be placed within a sealed plastic biohazard bag. The biohazard bag must be placed within a sealed zip-n-fold pouch. The sealed pouch is placed in a sealed carrier tube and delivered to the Clinical Laboratory Division of the Department of Pathology in accordance with OSHA guidelines.

GOOD HOUSEKEEPING:

1. Rags and/or flammable solvents will be disposed of in self-closing metal containers.

2. Do not hang clothing on or near radiators, steam pipes, heating instruments, or open flames.

3. Do not allow trash to accumulate in any area. Trash should be disposed of daily.

4. Festive decorations are a hazard and are not allowed unless approved by the Hospital Safety Committee.

GLASSWARE:

PERSONNEL AND LABORATORY SAFETY REQUIREMENTS

1. Do not use broken or chipped glassware. Discard in "BROKEN GLASS DISPOSAL" or SHARPS containers. Do not fill past the indicated "Fill Line" on disposal container. Call Housekeeping for removal of containers. Order new glassware as needed.

2. Do not leave pipettes or glass slides sticking out of bottles, flasks or beakers.

3. Do not attempt to remove stoppers on glass tubing by forcing. If they are stuck cut them off.

4. Decontaminate glass exposed to possible hepatitis- containing samples by soaking with 10% household bleach (1:10 dilution of undiluted bleach) for 15 minutes or discard glassware in SHARPS container.

5. Disposal of broken glass along with paper and trash is a hazard to the custodial staff and is not permitted.

6. HOT GLASS: Heated containers must be handled with protective gloves.

CENTRIFUGES:

1. Employees must not use their hand to stop centrifuge rotation. The centrifuge cover should remain closed until all rotation stops. Keep hair, beard, neckties, hair ribbons, or any other items out of the way.

2. Do not centrifuge uncapped tubes of specimens (blood, urine, sputum) or flammable liquids. Centrifugation creates a vacuum and volatilizes liquids. Contaminated items become aerosols; flammable liquids become bombs, etc. USE CAPS OR PARAFILM.

AUTOCLAVES:

1. Personnel should not operate autoclaves until they have been checked out on the proper operation of this equipment.

2. Eye goggles or a face shield must be worn when opening a hot autoclave.

3. Do not open until both temperature and pressures are back to normal.

4. Be sure intake steam valve is off before opening.

5. Use Protective gloves when putting items into or removing items from the autoclave. The sides and door may be hot in addition to the material being autoclaved.

NOTE: BEWARE OF STEAM WHICH CAN PERMEATE PROTECTIVE GLOVES.

Before autoclaving, loosen caps of any containers to allow equalization of pressures inside containers. This prevents explosion, boil-over, and implosions.

NEEDLES, SCALPELS OR SHARPS:

1. All needles must be disposed of in puncture-proof needle disposal containers (SHARP container). Do not fill past the fill line. Needle disposal containers are to be disposed of by each section. These containers are sent for incineration by a UMMC contracted company for biohazard waste disposal.

2. Needles and syringes should be discarded as a unit. Do not separate from each other.

3. Do not recap, purposeful bend, break, remove from disposable bin, or any other manual manipulations of needles.

4. Do not dispose of sharp or pointed materials in waste containers or autoclave bags.

5. A needle stick or any cut, no matter how small or apparently insignificant, must be reported immediately. The injured employee should complete the online Employee Injury report as soon as they are able, not an Occurrence Report. Only the injured employee can file the electronic Employee Injury report because it is based on that employee's personal information. A supervisor can assist the employee, but have that employee present to get the proper log on information. The electronic Employee Injury form is accessed by clicking on the UMMC Intranet.

LADDERS: Occupational Safety and Health Manual, 02-2010

All ladders will conform to the OSHA 1910 parts 25-30. Copies of these standards may be obtained by contacting the Environmental Health and Safety office at extension 4-1980. Ladders should be inspected prior to each usage. Care should be taken in moving ladders to ensure that trailing ends do not cause damage.

General safety rules for ladders:

1. Metal ladders should not be used in the vicinity of electrical circuits.

2. Periodically inspect wooden ladders. Wooden ladders shrink over time causing steps or back bar members to become loose. Hold the rods beneath the steps with pliers and tighten the nut at the end with a wrench to maintain strength and steadiness.

3. Wooden ladders or scaffold planks should not be painted as defects may be covered by paint. Use a good grade or spar varnish, or a mixture or linseed oil turpentine to preserve the wood.

4. Non-skid feet should be used on all straight and extension ladders.

5. Straight ladders form a triangle when placed against walls or objects for climbing. When properly placed, the Bottom side of the triangle should be about one fourth (1/4) as long as the vertical (i.e. if the ladder is leaning eight (8) feet high against a wall, the feet should be set two (2) feet from the wall). Ladders should never be placed against window sashes.

6. When using a straight ladder, it should be long enough to extend at least three (3) feet above the level to which the employee is climbing. Stepladders must not be used as straight ladders. They are not designed for this purpose.

7. If the bottom of a ladder is placed on an unsecured surface, secure the ladder in position by using hooks, ropes, spikes, cleats, or other anti-slip devices, or by stationing an employee at the base of the ladder to hold it in position.

8. Employees should never stand on the top step of a stepladder.

9. Only one person should be on a ladder at a time.

10. Do not carry tools or materials by hand while climbing ladders. Use a hand line to raise and lower tools and materials, or carry them in a tool belt. Hands must be kept free to grasp the ladder while climbing.

11. Always face a ladder when ascending or descending.

12. Clean muddy or slippery shoes before climbing.

13. Keep rungs clean and free from grease and oil.

14. If it is necessary to place a ladder near a door or where there is potential traffic, set up warning signs and any other precautionary measures needed to ensure that the ladder will not be struck by anyone or anything.

15. Follow the instructions posted on the side of the ladder.

LIFTING:

1. Use good posture when lifting. Make arms and legs work, not the back.

2. Get adequate mechanical or personal assistance when lifting or moving heavy objects or equipment.

REPORTING ACCIDENTS: Occupational Safety and Health Manual, 02-2010; Hospital Administrative Policies Manual, HADM/A-3, 12-2007

1. All accidents must be reported to the immediate supervisor and an online “Employee Injury Report” must be filed in accordance with procedures outlined in the Hospital Administrative Policies Manual and the Handbook for Employees.

2. The Director of Human Resources and Safety Officer are responsible for coordinating all accidental injury report procedures. They make timely investigations and the reports of all serious accidents and those causing loss of work time.

3. The Safety Officer tabulates all accident reports and provides monthly summaries. The responsibility for investigating and reporting accidents rests with the department head and supervisor of the injured employee.

4. The human resources representative ensures that the department heads and safety committee members are instructed in investigation procedures.

5. Supervisors and/or department heads investigate all accidents involving their employees.

6. Accident reports must be completed within 24 hours or the accident and sent to Human Resources.

7. Serious accidents and fatalities must be reported to the Director of Human Resources immediately by telephone and by written report filed within 24 hours.

8. The investigation of an accident should be pursued in a manner that will most effectively control the hazard.

9. The investigation will not be completed until all causes contributing to the accident have been discovered and corrected.

REPORTING UNSAFE CONDITIONS:

All individuals in the Anatomic Pathology and Clinical Laboratory Divisions of the Department of Pathology are to be held responsible for reporting unsafe conditions in the laboratory to his/her immediate supervisor.

DRESS CODE:

All Clinical Laboratory Hospital employees will wear a uniform designated for the lab; currently, this is navy blue scrubs and gray scrubs. All other Clinical Laboratory (non-clinical) employees should dress in professional attire as outlined in the Professional Appearance Policy HADM/P-14 at all times.

All Anatomic Pathology employees may wear scrubs (no specified color) or professional attire with a long white lab coat as outlined in the Professional Appearance Policy HADM/P-14 at all times.

Examples of attire which are not acceptable, include blue jeans, blue jean skirts, other denim attire, “sweat” clothing and open toed shoes.

TOBACCO-FREE POLICY:

It is the policy of the Medical Center to provide a tobacco-free workplace and environment, prohibiting smoking or the use of other tobacco products in these facilities or on its adjacent grounds. Employees are prohibited from using tobacco products on and in all of the Medical Center's designated sites, owned, and leased properties, buildings and university vehicles. Disregard for this policy may lead to progressive discipline up to and including termination. (Tobacco-Free Policy, Hospital Administrative Policies Manual, 10-12-06).

Those smokers who wish assistance with reducing or stopping their smoking may contact the ACT Center at 815-1180.

Those persons who do smoke may do so on their morning or afternoon breaks and during their lunch break; however, additional breaks to smoke are prohibited. For obvious reasons, taking an additional break to smoke would jeopardize work attendance.

OSHA REGULATIONS:

The UMHC Hospital, while not subject to OSHA fines, is compliant with OSHA regulations.

Link to Hospital Administrative Policies and Procedures Manual

https://intranet.umc.edu/Administration/Document%20Center%20-%20Administration%20Policies.html

Link to Occupational Safety and Health Manual

https://documents.umc.edu/policy/H-EH-GS-GEN-PR-00003/

Link to Online Injury Report

http://paws0/EmployeeInjury/secure/home.action

REFERENCES:

Hospital Administrative Policies and Procedures Manual, University of Mississippi Health Care.

Occupational Safety and Health Manual, University of Mississippi Health Care, February 2010.

Laboratory General Checklist, June 2020

Thermo Scientific Sorvall ST 8 / 8R Centrifuge

Maintenance and Care

Cleaning Intervals

For the sake of personal, environmental, and material protection, it is your duty to clean and if necessary disinfect the centrifuge on a regular basis.

Maintenance	Recommended Interval
Rotor Chamber (Bowl)	Daily or when polluted
Rotor	Daily or when polluted
Accessories	Daily or when polluted
Filter Mat (Capacitor)	Every six weeks or when polluted
Cabinet	Once per month
Ventilation Holes	Every six months

Basics

CAUTION
Not rated procedures or agents could deteriorate the materials of the centrifuge and lead to malfunction. ***Refrain from using any other cleaning or decontamination procedure than those recommended here, if you are not entirely sure that the intended procedure is safe for the equipment.*** ***Use only approved cleansers.*** ***If in doubt, contact Thermo Fisher Scientific***.

- Use warm water with a neutral detergent that is suitable for use with the materials. If in doubt contact the manufacturer of the cleaning agents.

- Never use caustic cleaning agents such as soap suds, phosphoric acid, bleaching solutions or scrubbing powder.

- Remove rotor and clean bowl with a small amount of cleaning agent, applied to a clean cloth.

- Use a soft brush without metal bristles to remove stubborn residue.

- Afterwards rinse with a small amount of distilled water and remove any excess with absorbent towels.

- Use only disinfectants with a pH of 6-8.

Rotor and Accessories Inspection

After thoroughly cleaning rotors, they should be inspected for damage, wear and corrosion.

Metal Parts

Ensure that the black protective coating is complete. It can be removed through wear and chemical attack and can lead to unseen corrosions. Any signs of corrosions, such as rust or white / metalic pitting, the rotor or accessories should be immediately removed from service. Particular attention should be taken with the bottom of buckets on swing out rotors and tube cavities on fixed angle rotors.

Plastic Parts

Check for signs plastic crazing, fading, bruising or cracking

CAUTION
Do not run any rotor or accessories with sign of damage. ***Ensure that the rotor, buckets and accessories are within the service life and number of cycles.*** ***It is recommend that you have rotors and accessories inspected yearly as part of your routine service to ensure safety.***

Cleaning

CAUTION
Before using any cleaning methods except those recommended by the manufacturer, users should check with the manufacturer of the cleaning agents that the proposed method will not damage the equipment.

Clean as follows:

1. Clean rotor, buckets and accessories outside of the centrifuge bowl.

2. Separate all rotors, buckets, lids, adapters and tubes to allow thorough cleaning.

3. Rinse rotor and all accessories with warm water and a neutral detergent that is suitable for use with the materials. If in doubt contact the manufacturer of the cleaning agents. Ensure grease on rotor trunnions (pivot point for swinging buckets) is cleaned away.

4. Use a soft brush without metal bristles to remove stubborn residue.

5. Rinse rotor and all accessories with distilled water.

6. Place the rotors on a plastic grate with their cavities pointing down, to allow to fully drain and dry.

7. Dry all of the rotors and accessories after cleaning with a cloth or in a warm air cabinet at a maximum temperature of 50 °C. If drying boxes are used, the temperature must never exceed 50 °C, since higher temperatures could damage the material and shorten the lifetime of the parts.

Once clean and dry, inspect the rotor and accessories.

After cleaning, treat the entire surface of aluminum parts including the cavities with corrosion protection oil (70009824).

Treat the bolt of the swing out rotor with bolt grease (75003786).

CAUTION
Drive and doo lock can be damaged by entering liquids. Do not allow liquids, especially organic solvents, to get on the drive shaft, the drive bearings or the centrifuge door locks. ***Organic solvents break down the grease in the motor bearing. The drive shaft could lock up.***

Cleaning the Filter Mat

It is recommended that you clean the filter mat (50141352) regularly every six weeks. Depending on the environmental conditions it may be necessary to clean it more often.

How to clean the filter mat:

1. Unscrew the ventilation grid placed on the right side of the centrifuge.

2. Remove the ventilation grid.

3. Remove the filter mat.

4. Clean the filter mat by tapping off the dust. The filter mat can be rinsed with water, if needed. Dry the filter mat before using it again.

NOTE: *Moisture can damage electronics and lead to additional damages at the centrifuge. Only use dry filter mats.*

5. Place the filter mat back on the capacitor.

6. Screw the ventilation grid onto the centrifuge

Disinfection

WARNING
Hazardous infection is possible when touching the contaminated rotor and centrifuge parts. Infectious material can get into the centrifuge when a tube breaks or as a result of spills. In case of contamination, make sure that others are not put at risk. Disinfect the affected parts immediately.

CAUTION
Equipment can be damaged by inappropriate disinfection methods or agents. Before using any cleaning or disinfection methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment. Observe the safety precautions and handling instructions for the cleaning agents used.

The rotor chamber and the rotor should be treated preferably with a neutral disinfectant.

Contact the Service Department of Thermo Fisher Scientific for questions regarding the use of other disinfectants. For details check ***"Basics" on page 33.***

Disinfect as follows:

1. Disinfect rotor, buckets and accessories outside of the centrifuge bowl.

2. Separate all rotors, buckets, lids, adapters and tubes to allow thorough disinfection.

3. Treat the rotor and accessories according to the instructions for the disinfectant. Adhere strictly to the given application times. Be sure the disinfectant can drain off the rotor.

4. Rinse the rotor and accessories thoroughly with water and then rub down.

5. Place the rotors on a plastic grate with their cavities pointing down, to allow to fully drain and dry

6. Dispose the disinfectant according to the applicable guidelines.

7. Clean the rotor after disinfecting as described in ***"Cleaning" on page 34***.

Decontamination

WARNING
Radiation is possible when touching the contaminated rotor and centrifuge parts. ***Radioactive material can get into the centrifuge when a tube breaks or as a result of spills.*** ***In case of contamination, make sure that others are not put at risk.*** ***Decontaminate the affected parts immediately.***

CAUTION
Equipment can be damaged by inappropriate decontamination methods or agents. ***Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.*** ***Observe the safety precautions and handling instructions for the cleaning agents used.***

For general radioactive decontamination use a solution of equal parts of 70% ethanol, 10% SDS (Sodium Dodecyl Sulfate) and water.

Decontaminate as follows:

1. Decontaminate rotor, buckets and accessories outside of the centrifuge bowl.

2. Separate all rotors, buckets, lids, adapters and tubes to allow thorough decontamination.

3. Treat the rotor and accessories according to the instructions for the decontamination solution. Adhere strictly to the given application times.

- Be sure the decontamination solution can drain off the rotor.

4. Rinse the rotor first with ethanol and then with deionized water.

- Adhere strictly to the given application times.
- Be sure the decontamination solution can drain off the rotor.

5. Rinse the rotor and accessories thoroughly with water.

6. Place the rotors on a plastic grate with their cavities pointing down, to allow to fully drain and dry.

7. Dispose of the decontamination solution according to the applicable guidelines.

8. Clean the rotor after disinfecting as described in ***"Cleaning" on page 34.***

WEEKLY EYEWASH FUNCTION CHECKS

Verify that eyewash station is clear and unobstructed. Visually inspect for cleanliness and functionality.

Year:_____	Week 1	Week 2	Week 3	Week 4	Week 5	Review
January						
February						
March						
April						
May						
June						
July						
August						
September						
October						
November						
December						

Wipe down station and re-install protective covers if applicable.

Plumbed eyewashes: Verify hands-free once activated; allow to run at least 3 minutes; ensure temperature is tepid. Check temperature quarterly and document below.

Self-contained eyewashes: Check to see if fluid needs to be changed or supplemented; check expiration date of fluid.

Initial and date upon completion of function checks. Report any deficiencies to Physical Facilities @ 4-1420 immediately.

QUARTERLY EYEWASH FUNCTION CHECKS – Acceptable Limit 60^{o} – 100^{o} F or 16^{o} – 38^{o} C

Quarter	Date	Temp	Sign	Comments
1st				
2nd				
3rd				
4th				