DRAFT

The Early Detection Research Network (EDRN)

Standard Operating Procedure (SOP)

COLLECTION OF SERUM

PURPOSE: To ensure technically correct, consistent, and safe methods for drawing, processing, storing, and shipping serum specimens.

Gloves must be worn at all times when handling specimens. This includes during removal of the rubber stopper from the blood tubes, centrifugation, pipetting, disposal of contaminated tubes, and clean up of any spills. Tubes, needles, and pipets must be properly disposed of in biohazard containers, in accordance with institutional requirements.

Sample Collection Procedure

1. Seat the Subject for at least five minutes prior to blood collection.

2. Explain purpose of study; allow for any questions from the patient. Request that the patient sign an informed consent. IF THE PATIENT REFUSES TO PROVIDE INFORMED CONSENT, STOP AT THIS POINT. (Remember to get two copies of informed consent – one for research records, and one for the study participant. Informed Consent should NOT be placed in the medical record due to the risk to the participant from having genetic information in the record.)

3. Once informed consent is signed, complete the eligibility checklist.

4. All vacutainers and transfer vials are labeled using a unique barcode*. These vacutainers and bar-coded transfer vials are prepared by the serum bank facility and supplied as a component in the combined specimen collection packet.*

Contents of Blood Drawing Kit

Small, bar-coded plastic bag that contains:
__ Red top (serum) Vacutainer tubes (7-10 ml glass)
Barcode stickers for Vacutainer collection tubes
Vacutainer Adapter & needle
Thirty pre-labeled 0.25ml small plasma aliquot vials
Transfer pipets with 0.25 ml and 0.5 ml markings
One absorbent pad
8 1/2” by 11” paper with kit number and barcodes printed on it

5. Remove the blood collection tubes (“vacutainers”).

6. Enter the date and time of the draw on the specimen tracking form.

7. Put on gloves and prepare needle, vacutainer adaptor, and collection tubes to draw the blood.

8. Using a Vacutainer® adapter, and a 21 g needle (smaller tends to lyse the cells), draw the blood. (can use butterfly or straight needle or draw from IV site—key is needle gauge)

9. After collection, place the bar-coded labels on the appropriate vacutainer tubes. The filled red top tubes should sit at **room temperature for a minimum of 30 to a maximum of 60 minutes** to allow the clot to form, and then the tubes should be **refrigerated (4°C) for 12-26 hours.**

10. After **12-26 hours** at 4°C, all tubes should be centrifuged:
    - in a refrigerated centrifuge (4°C)
    - at a minimum force of 1300g
    - for 20 minutes

11. Use plastic, disposable pipettes provided in the kits to transfer the serum. From **red top** tubes, pipette 0.25 ml serum into the serum vials, filling the vials in sequential order. **2ml screw cap tubes (VWR 66008-284) and have been used.** Close the caps on the vials tightly. ***Be very careful not to pick up red blood cells when aliquotting. This can be done by keeping the pipet above the red blood cell layer and leaving a small amount of serum in the tube.***

12. Database. Scan all aliquots into the database

13. Carefully match ID labels on the collection tubes with ID labels on corresponding aliquot tubes from the same kit.

Storage

- Check that all aliquot tube caps are secure.
- Check that all labels are secure on the tubes.
- Place all aliquots upright in a specimen box or rack in a -80ºC freezer.

Shipping samples

The **frozen aliquots** can be shipped once a month (depending on the rate of collection) to the Receiving Laboratory (need to be discussed)

Shipping Instructions for Serum ALIQUOTS:

1. Place the serum aliquot vials in the cardboard storage boxes provided after scanning them into the database for shipping.
2. Put the filled cardboard boxes in a plastic ziplock bag along with an absorbent pad/material and seal.
3. Place bagged boxes (lid side up) in the bottom of the shipping box.

4. Fill the shipping box (around the storage boxes) with as much dry ice as possible to assure the contents stay frozen even if delivery is delayed. Pellitized dry ice works best for this.
5. Print the Blood Tracking form from the database, seal it in a plastic bag, and place on top of the dry ice before putting the insulated lid on box.
6. Seal the shipping box by taping the flaps of the insulated box at the main seam across the top. Do not tape the seams along the top edges (required by shipping regulations to allow for the release of carbon dioxide gas).
7. Place a black and white label that reads "Dry Ice _____kg" on top of each insulated shipping container. Complete the dry ice weight in the space "UN 1845, _____kg."
8. Place the required hazard sticker on the shipping container(included).
9. Complete the airbill and ship **overnight** (but NOT on a Friday) to the address listed
10. Please send a notification e-mail to ( ) state you are sending the samples and list the carrier and the carrier tracking number in the e-mail.

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