CF Carrier Testing: SPECIMEN TYPE, COLLECTION, TRANSPORT, STORAGE AND PROCESSING

Specimen Collection

Blood sample should be collected in sterile collection tubes with EDTA anticoagulant (purple top). Collect at least 3 ml using standard venipuncture techniques. It is important that collection is done only after proper genetic consent has been obtained by the ordering physician and all necessary patient information is provided in Cerner.

Insure proper specimen barcode label(s) are on collected specimen.

Transport of Specimen

Collected specimen will be transported in regulation containers at room temperature by courier to the Central Accessioning service of the Clinical Laboratory on the 2nd floor of the hospital within 1-2 hours after collection. Samples are then routed to the Molecular Pathology Laboratory located at the 4th floor of the BSB, Room 4-128.

Sample Accessioning, Storage and Processing at the Molecular Pathology Laboratory

It is essential that each sample be received and identified, verified, and processed correctly.

- 1. Patient and specimen information, including name, age, clinical information, physician's name and date of collection are to be verified. Follow LIS Accessioning instructions on separate binder.
- 2. Evaluate specimen according to criteria enumerated below.
- 3. If specimen is acceptable, it is then placed in a box in the refrigerator that is strictly for incoming specimens in Room 4-125 (Sample Preparation Room).
- 4. Notify the Supervisor or the Director immediately if there is any confusion or if an error is suspected.
- 5. Store blood samples in designated box at 4°C until processed.
- 6. Using the three-rack system, take 350 uL of the sample to be processed for DNA extraction, the rest is saved as back-up until the report is issued. **NO ALIQUOT IS EVER RETURNED TO THE ORIGINAL CONTAINER!!!**
- 7. Blood may be kept at 4°C for re-extraction for a period of 6 weeks.
- 8. Turn around time for most nucleic acid-based tests is 2-3 weeks.
- 9. Retention of records and materials/specimen will be according to LAB Policies (LAB-35).

Evaluation of Specimen

To avoid contamination, specimen receiving and processing will be done in Room BSB 4-128 _. The criteria in

rejecting specimen and action to be taken that are enumerated under the General Lab-11 Policy will be implemented. The following criteria are specific to Molecular Pathology Laboratory specimen:

Acceptance Criteria

- 1. Specimen collected after proper written consent with appropriate LIS barcode label.
- 2. Blood must be at least 3 mL in an EDTA tube (purple top) and placed in a leak-proof transport bag.
- 3. Non-hemolyzed blood.

Rejection Criteria

- 1. Lack of written consent for testing
- 2. Unlabeled and/or mislabeled tubes of blood
- 3. Blood in anticoagulant other than EDTA
- 4. Empty collection tube or Insufficient quantity
- 5. Clotted blood
- 6. Hemolyzed blood
- 7. Blood-soiled tube or evidence of leakage
- 8. Duplicate samples
- 9. Contaminated blood
- 10. Outdated specimen (>48 hours after venipuncture)

If a sample is rejected, the laboratory notifies the physician/location and request repeat collection with corrective action depending on the reason for rejection.