1. **Principle:** Pre-Analytical systems are the most important part of the Clinical Laboratory Testing process. Issues with specimen collection can affect lab results. It is important for all Bioreach staff to ensure proper specimen collection and processing of samples in the laboratory.
2. **Phlebotomy: Specimen Collection/Processing/Transport Policy overview.**
   * 1. All Laboratory personnel or phlebotomy staff will follow the Bioreach specimen collection, processing, and transportation policies.
     2. All instructions (written and those given verbally) for patient collected specimens will be reviewed as needed, and revised, if necessary, to assure that they are:
        1. Clearly stated and easily understood by the patient.
        2. Contain all relevant information provided in “Patient Preparation”.
        3. Provide instructions on the proper collection, handling, storage, and transport to the laboratory to maintain optimum integrity of the specimen from the time of collection to the time of receipt in the laboratory.
     3. Any employee using inappropriate collection techniques is advised in the proper collection methods by immediate evaluation of instructions and to make proper adjustments.
     4. Labeling: All procedures require a requisition or order form with at minimum the patient’s name, date of birth on both the requisition and the specimen container.
        1. **Labels should be placed on tubes to ensure a clear window to specimen** to ensure complete filling of tube and allow testing staff to visualize any specimen issues such as clots or hemolyzed specimens.
     5. **Criteria for Rejection of a Specimen**: The laboratory establishes criteria for rejection of a test specimen. Improperly labeled containers, improper containers and improper methods of collection will be rejected. If a question of specimen integrity exists, report the problem to the laboratory testing staff or management immediately.
3. **Phlebotomy procedure**: **Only venipuncture procedures are an approved method of blood collection at Bioreach Laboratories. No finger sticks or draws on individuals less than 16 years old are approved.** 
   1. Patient Preparation: Patients should be aware of the blood collection process and be willing to provide a sample.
      1. Patients should be relaxed and sitting down.
      2. Patients are to be asked their fasting status. If a patient is fasting, then this should be noted on the tube or in the Bioreach LIS ordering details.
         1. Fasting Status is listed on the patients Order detail in the StratusDx lab order/requisition.
   2. Ensure order or test requisition is accurate. Ensure all patient information is correct and complete. Name, Date of Birth, address, test requested. Complete any missing information at the time of draw.
   3. Select tube or tubes appropriate for required specimen.
   4. Assemble needle in holder. Be sure the needle is firmly seated to ensure the needle does not unthread during use.
   5. Place the tube into the holder. Note: Do not puncture the stopper.
   6. Select site for venipuncture.
   7. Apply a tourniquet. Tourniquets should only be tight around the arm for 60 seconds maximum.
   8. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
   9. Place the patient's arm in a downward position.
   10. Remove the needle shield.
   11. Perform venipuncture with the arm in a perpendicular or downward angle.
   12. Push tube onto needle, puncturing stopper diaphragm.
   13. REMOVE TOURNIQUET within one minute of placement on arm.
   14. Practice Universal Precautions to minimize exposure hazard.
   15. If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:
       1. Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
       2. Confirm the correct position of needle cannula in vein.
       3. Remove tube and place a new tube on the needle holder.
       4. If the second tube does not draw, remove needle, apply gauze on the venipuncture site and discard the needle and used tubes.
       5. Repeat procedure.
   16. When the first tube has filled to its stated volume and blood flow ceases, remove it from the holder.
   17. Place succeeding tubes in the holder, puncturing the diaphragm to begin flow.
   18. Recommended Order of Draw:
       1. NaCitrate/Blue Top
       2. Serum Separator/SST/Gold Top/Red/Yellow Top
       3. EDTA/Purple Top
   19. While each successive tube is filling, Invert filled tubes 8-10 times.
   20. As soon as blood stops flowing in the last tube, remove tube from holder, remove needle from vein, apply pressure to puncture site with dry sterile cotton swab or gauze until bleeding stops.
   21. Apply bandage.
   22. After venipuncture, ensure tubes have all been inverted 8-10 times.
   23. Dispose of needle and holder in a sharp container.
   24. Specimens are then labeled with the patient still present.
   25. Ensure venipuncture site is bandaged and that the patient is ok before leaving the patient.
4. **Transportation of specimens to lab**: Samples collected outside the lab will be safely transported or shipped to lab.
   1. Transportation of specimens is directed by the phlebotomist to ensure specimens arrive in a timely manner.
      1. Room temperature specimens must arrive within 2 hours of collection time.
      2. Delays in transport will necessitate centrifugation of Serum tubes and placement of Serum tubes and ETDA plasma tubes in a refrigerated cooler pack.
      3. Excessive delays in transport may result in certain tests not being performed.
   2. **Shipping of specimens to lab:**
      1. All shipping of specimens is to be done using the “Exempt Human Specimens” designation. No shipping of select agents or presumptive select agents is to be performed.
      2. Shipping container must contain a three layers of contaminants:
         1. Sealed Primary specimen bag containing absorbent material for spillage.
         2. Cooler pack box.
         3. Shipping packaging bag or box.
      3. Specimens are to be shipped overnight.
   3. Receipt of shipped specimens into lab: All shipped specimens must have internal temperature monitored at time of receipt into lab.
5. **Processing of specimen:**
   1. Samples are processed using mobile centrifuges or delivered directly to the lab for processing.
   2. Samples are received into the Lab using the StratusDx LIS. Any sample issues are to be noted at time of receipt.
   3. Samples should be completely clotted, with a recommended minimal clot time of 30 minutes.
   4. Centrifugation of specimens: SST and Blue top tubes should be centrifuged for 10 minutes at 2500 rpms which is preset into the 6 slot preprogrammed centrifuges.
      1. See Validation study for NaCitrate Platelet poor plasma determination.
   5. Samples are then delivered to the specific lab department and testing is initiated.
6. **Specimen rejection:**
   1. Any rejected specimen or specimen issue resulting in a test not performed must be documented in the “Test No Performed Log” on the Bioreach Share drive.
      1. Upper management is to be notified and documented on log.
   2. Unlabeled specimens are to be rejected by lab staff and recollection initiated.
   3. Unspun SST tubes not received in the lab within 2 hours should be recollected or Glucose not reported.
   4. EDTA tubes should be refrigerated at 2 -8 Deg C within 7 hours of collection.
   5. **CBC specimens** are viable for 48 hours refrigerated.
   6. **NaCitrate tubes** are to be processed and testing performed within 24 hours of collection time at room temperature.
   7. **Chemistry/Immunoassay** specimen requirements are to be ensured for Serum samples. See Bioreach Specimen Stability log for complete details.
      1. All Serum samples are to be spun down within 2 hours of collection.
      2. All samples are to be placed in a 2-8 Deg C cooler for delivery to lab.
         1. **PTH:** Must be performed within 8 hours of collection (room temp or refrigerated) or promptly frozen upon receipt into lab (30-day Frozen stability).
         2. **SHBG:** 4 hours room temperature stability: refrigerate after centrifugation.
         3. **DHEA:** 4 hours room temperature stability: refrigerate after centrifugation.
         4. **Homocysteine**: Must be refrigerated immediately after centrifugation.
         5. **Insulin:** 8 hours room temperature and 24 hour refrigerated stability.
         6. **C-peptide**: 8 hours room temperature and 24 hour refrigerated stability.
         7. All other serum analytes have a minimum of 8-hour room temperature stability.
   8. **Analyzer downtime**: Any serum sample unable to be tested should be frozen. Any CBC or Coagulation test unable to be tested in the required time, should be recollected.