1. Purpose/Principle: This document serves to define the scope of laboratory testing, delegation of duties, General test management, QC/QA program oversite for Bioreach Laboratories. Applicable site and demographics are as follows:
   1. BIOREACH LABORATORIES Draper, UT CLIA # 46Dxxxxxxx
      1. 12162 Business Park Dr Ste 114, Draper, UT 84020
   2. BIOREACH LABORATORIES supports the Clinical Laboratory needs for individual and patient laboratory testing. The scope of Bioreach Laboratories involves performing clinical laboratory testing for patient in the greater U.S. Scope of testing includes chemistry, immunoassay, hematology, coagulation, and urinalysis testing. All testing is CLIA Moderately Complex and CLIA required regulations are in place and adhered to. Any tests ordered beyond the scope or complexity are reflexed to the appropriate reference laboratory.
   3. Delegation of duties:
      1. Laboratory Director, Ammon Bayles, PhD, HCLD(ABB)
         1. Ensures that all CLIA designated Laboratory Director duties are performed.
         2. Signs all PT scorecards.
         3. Delegates Certain Lab Director duties to qualified laboratory staff.
         4. Ensures TC/CC/Testing staff duties are complete.
      2. Clinical Consultant, Ammon Bayles, PhD, HCLD(ABB)
         1. Ensures that all CLIA designated Clinical Consultant duties are performed.
         2. Responds to clinical or patient related laboratory testing issues.
         3. Responsible for any Lab Director delegated duties.
      3. Technical Consultant, Laurence Schuermann, MT(ASCP)
         1. Ensures that all CLIA designated Technical Consultant duties are performed.
         2. Involved with Technical issues regarding patient testing.
         3. Responsible for any Lab Director delegated duties:
            1. Ensures Quality Assurance policy requirements are performed.
            2. May sign Lab Director attestation statements.
            3. Test implementation
            4. Policy creation
            5. CLIA program surveillance
            6. General technical troubleshooting issues.
      4. Testing Staff
         1. Ensures testing is performed in accordance with CLIA regulations.
         2. Ensures Quality Control/ Quality Assurance policies are adhered to.
         3. Responsible for any Lab Director delegated duties including:
            1. Adherence to Bioreach policies and procedures.
            2. If qualified, signage of Lab Director Lab Attestation statements.
            3. Routine specimen testing.
            4. Completion of proficiency testing
            5. Monitoring of equipment
            6. Reporting of any problems to appropriate laboratory/Human Resource staff.
   4. Specimen Collection/Processing/Transport:
      1. All Laboratory personnel will follow the Bioreach specimen collection, processing and transportation policy.
      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 makes 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.
      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 supervisor immediately.
   5. Test Report: Test report completeness (name and address of testing laboratory, patient identifier, test performed and its results), usefulness (information regarding specimen condition and disposition of unsuitable specimens, normal ranges) and any important comments regarding the need for additional testing or follow up are included on report.
   6. Timeliness of Reporting: The laboratory monitors and evaluates the timeliness of reporting based on priorities such as routine and batched work by making lab reports available to physicians and clinical staff as reports are completed.
   7. Accuracy and reliability of Test Reporting System: The laboratory participates in proficiency testing semiannually to assure test accuracy. The laboratory director reviews or delegates reviews annually and evaluates each laboratory staff’s ability to perform specified testing protocols to assure testing reliability.
   8. Test Records:
      1. The laboratory is responsible for patient test records for completeness (i.e., patient identifier, date and time of specimen receipt, disposition of specimens, records and dates of all specimens testing to include the identity of persons performing tests).
      2. Test Records are help for the CLIA required two-year minimum period. These include:
         1. Test orders
         2. Test Requisitions
         3. Quality Control/Quality Assurance records (QC, Temp charts, Maintenance checks, equipment checks)
         4. Test results from analyzers (either paper or digital).
         5. Patient reports (either paper or digital).
      3. Any analyzer implementation records are kept for the life of the analyzer plus two years.
   9. TESTING METHODS
      1. The laboratory monitors the completeness, accuracy, and adherence to established protocols. The lab director or designee monitors all techniques paying attention to the adherence to protocols. Issues are reported to Laboratory supervisory staff.
      2. The laboratory monitors and makes changes in its procedure manual as needed to include times when manufacturers make modifications to procedures; method changes are directed by supervisor. These changes are conveyed to the testing personnel with appropriate training to perform tasks.
      3. Correlation of analytes on multiple analyzers at same site or CLIA ID:
         1. Only pertains to paired analyzers at the same location performing the same testing routinely.
         2. 10 to 20 samples are to be ran on each analyzer.
         3. Data is plotted and Slope and regression limits must be between 0.90 and 1.10
   10. QUALITY CONTROL: The laboratory monitors adherence to specified quality control and calibrations procedures as stated in the BIOREACH LABORATORIES Quality Control/Quality Assurance Policy.
       1. Quality Control Data Analysis: Supervisor/designee monitors the documentation of quality control values and their interpretation monthly and the laboratory director/designee reviews.
   11. Corrective Action: The designated supervisors at BIOREACH LABORATORIES evaluate and document the measures taken to correct testing procedures when they do not perform as expected by the lab director or designee.
       1. As Clinical QA, QC, Proficiency testing or competency assessment issues arise the laboratory director will work with designated staff to ensure corrective actions are timely and complete.
   12. Corrected Reports: All Clinical Laboratory Corrected reports must include:
       1. Notation of “Corrected/Amended Report in Result.
       2. Reference to previously resulted values.
   13. Proficiency testing: Bioreach Laboratory will ensure:
       1. Participation in an Approved Program.
       2. The laboratory monitors its participation in all necessary proficiency testing programs. The laboratory is enrolled in an approved program for all testing in the lab.
       3. Laboratory ensures that CLIA non-regulated tests are monitored semi-annually for accuracy via the appropriate proficiency testing program.
       4. Any unsatisfactory or unsuccessful Proficiency testing performance is to be investigated by Lab Director or designee.
       5. The laboratory assures that all proficiency-testing specimens are tested in the same manner as patient specimens.
       6. The laboratory director/designee reviews proficiency testing reports when received for closeness to target values by documenting review. The lab director is informed when values are outside expected limits.
       7. The laboratory director/designee reviews proficiency testing reports for unacceptable results and documents necessary corrective actions taken.
   14. Personnel Competency:
       1. The laboratory provides and assures adequate training to the testing personnel to the extent necessary to consistently provide reliable test results.
       2. Competency assessment are to adhere to CLIA standards for non-waived (6 items) and waived testing (2 of 4 items).
       3. Competency Assessments are performed at orientation (review only), After completion of training (semi-annual) and annually.
   15. Communication: Proper communication with routine or urgent matters is of the utmost importance in the laboratory.
       1. Any issues requiring immediate assistance are to be addressed to the direct supervisor.
       2. The laboratory participates in a monthly staff meeting to discuss issues of patient care and quality assurance.
       3. The laboratory director communicates with the lab staff routinely and as needed. The laboratory director reviews lab performance weekly with the designated supervisory staff.
       4. Laboratory staff will ensure that the daily shift change handoffs are completed.
   16. Complaint Investigation. The laboratory monitors and documents all complaints received from staff, referring providers or patients regarding problems that occur as a breakdown in Quality Assurance, testing issue or with proper delivery of reports. Incident Reports are to be created for all patient/regulatory complaints and kept on file.
   17. Corrective Action: The Laboratory Supervisor/designee reviews incident reports in order to identify the problem and to take the necessary corrective action to assure that future problems will be eliminated. All corrective action plans must be documented and reviewed as needed during monthly QA/QC checks.
   18. Annual Quality Assurance review is to be completed by Lab Director or designee and will include:
       1. Overview of monthly QC/QA assessments.
       2. Annual result review audit (random or targeted).
       3. Annual CLIA regulatory assessment
       4. New test implementation plans
       5. Staffing assessment.