**Changes in Grey**

1. **Policy:**

* For each test system, Bioreach Laboratory shall have control procedures that monitor the accuracy and precision of the complete analytical process.
* The laboratory must establish the number, type and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory, as specified in CLIA 88 Sec. 493.1253(b)(3).
* Failure of Quality Control material should be investigated, corrected and documented.
* Results cannot be released on any patient until the appropriate QC for that day has been verified as complete and within acceptable range.
* No Individualized Quality Control Programs (IQCP) are present at Bioreach Laboratories.

1. **PROCEDURE:**
2. Specific testing procedure should include which type of control media used and QC schedule.
   1. For Attellcia Analyzers: 2 levels of Bio-Rad QC material for each day of testing.
   2. For Advia Analyzers: 3 levels of Siemens QC material for each day of testing.
   3. For Sysmex/Siemens Coagulation analyzers: 2 levels of Siemens QC for each 8 hours of testing.
   4. For Beckman DXU Iris: 2 levels of Beckman Coulter QC for Dipstick testing for each day of testing.
3. For any systematic errors in Quality Control ran at the same time as patient testing, evaluation of patient specimens ran since the last acceptable Quality Control should occur and be documented.
   1. This pertains to QC ran/repeated during daily workshift and does not pertain to normal QC schedule, such as QC ran after a major instrument maintenance/troubleshooting issue.
4. QC results are reviewed at time of testing to detect immediate errors that may occur due to:
   1. Instrument or procedural failures
   2. Adverse environmental conditions
   3. variance in operator performance
5. Out of control issues should be investigated and documented before testing results are released.
   1. All values falling outside of 2 SD are to be investigated and determined if the level can be accepted. Additional Westgard rules determining shifts or trends must be considered before accepting the one time, one level out of control value. If no additional issues are noted, results can be released, and the out of control can be deemed a random error.
   2. If 2 levels of control fall outside 2SD on the same day, this indicates a systematic error and should be investigated.
   3. If 2 consecutive QC values on the same QC level fall outside of 2SD, this indicates a systematic error and should be investigated.
   4. **All values falling outside of 3 SD indicate a systematic error and should be investigated before results are released.**
   5. Other issues such as shifts greater than 1SD and wide range variances (two consecutive levels showing a spread of greater than 4 SD) should be investigated as well.
6. Quality Assurance review of QC values is to be performed monthly.
7. Monthly QC review is to be performed and documented by the Lab Director, Technical Consultant, Lab Supervisor, or qualified testing personnel.
8. Out of Control issues:
   1. Determine level of control and test in question.
   2. Apply specific test related rule to QC.
      1. Assayed control limits are set by the manufacturer.
      2. Adjustments to QC ranges or mean are to be documented.
   3. Inspect QC material for stability issues, expiration dates, and defects.
   4. Repeat testing of opened QC material or new vial of QC material.
9. Repeated QC failures:
   1. Determine if Calibration is required.
   2. Re-Calibrate if necessary.
   3. Investigate further, communicate issue with Supervisory Staff, Lab Director or qualified co-worker, when necessary. Document any analyzer repairs or protocol changes.
   4. BioRad Peer Data or Analyzer specific Peer data is to be used to adjust QC limits.
   5. Calls to specific customer support representatives, or technical support may be necessary if in-house investigations do not correct out of control issue. Ensure that documentation of service is provided by technical support (Call ticket number, emailed report)