**SUBJECT: Quality Control, General**

1. **Scope:**
   1. This policy applies to all analytical testing in the laboratory.
2. **Policy:**
   1. Quality control procedures will be followed to monitor and evaluate the quality of analytical testing and to assure accuracy and reliability of patient results and reports. This is a general policy, referring to the test instructions or instrument protocol / operator’s manual for the specific procedure.
3. **Procedure:**
   1. At least two levels of control are run at least each day of testing.
   2. Over time, rotate QC testing among all operators who perform the test.
   3. Control samples are run in the same manner as patient samples.
   4. Parallel testing is performed on each new lot of quality control material prior to use and concurrently with established control material. Statistical parameters are established by running at least 20 samples of each level of unassayed quality control product.
   5. Patient results are not released when quality control results fall outside of acceptable limits. Patient results since the last acceptable QC run are verified.
   6. Analytical run is defined as a time period or number of measurements for which the accuracy and precision of the system is expected to be stable. Generally, this will be the manufacturer's recommended run length for the analytical system, not to exceed 24 hours.
   7. May use control procedures equivalent to traditional external QC, such as internal checks or built-in QC, electronic QC or control strips, etc, to meet QC requirements.
   8. Calibrators, used as QC, must be of a different lot and concentration than that used to calibrate the analyzer.
   9. For quantitative procedures, include two levels of control (different concentrations).
   10. For qualitative procedures, include a negative and positive control.
       * 1. Positive and Negative QC/results may **NOT** be documented as “+” or “-“.
   11. For tests that contain graded or tittered results; include a negative control and a control with a graded or tittered reactivity.
   12. For tests that contain an extraction phase; include two controls, one that is capable of detecting errors in the extraction phase.
   13. May use appropriate values from the package inserts of a commercially assayed QC only until lab specific values have been established or if the test is used so infrequently that calculations of valid statistics are not possible Follow manufacturer’s QC instructions if they meet or exceed the above requirements.
   14. Run controls before resuming patient testing, when there is a complete change of reagents, major preventative maintenance is performed, or any critical part is replaced that may influence test performance
   15. For quantitative tests, quality control data is plotted, and statistical indices are calculated to permit the laboratory to assess continued accuracy and precision of the method.
   16. **Facilities**
       1. Necessary space, ventilation, and utilities are available to conduct all phases of testing.
       2. Safety precautions are established, posted, and observed to protect employees from physical hazards and biohazardous materials.
   17. **Equipment, material and supplies**
       1. Instruments, equipment, reagents, materials, and supplies are appropriate and sufficient for the testing performed.
       2. Reagents are stored according to manufacturers’ instructions.
       3. Distilled water used in laboratory procedures is provided by the RO water tanks in the chemistry department.
          1. Acceptable water quality is 10 mega ohms or above (see Chem policy)
       4. Major laboratory analyzers are supplied with UPS and all equipment are attached to emergency generator power during power outages.
       5. Reagents are labeled with identity, strength of concentration, storage requirements, preparation and expiration dates, and other pertinent information. (See policy LAB 1.05)
          1. Reagents are **not** used beyond the expiration date.
       6. Components of reagent kits of different lot numbers are not interchanged unless specified by the manufacturer.
   18. **Procedure Manuals**
       1. Procedure are re-approved, signed and dated when the Medical Director changes.
       2. Procedure changes are approved, signed and dated by the Medical Director, prior to the changes taking affect.
       3. Dates of discontinuance are documented.
       4. Copies of outdated procedures are maintained for 2 – 10 years.
       5. Procedure manuals are available in all sections of the laboratory that describe the processes for testing and reporting patient results.
   19. **Performance Specifications**
       1. Manufacturers' performance specifications are verified and documented on all new methods, as applicable. Performance specification verification is kept for the life of the equipment, plus 2 years.
       2. Manufacturers' reference ranges are verified and, when possible, reference ranges are established using the local patient population.
   20. **Equipment maintenance and function checks**
       1. Maintenance and function checks are performed according to manufacturers' instructions and documented.
       2. Calibration and calibration verification procedures are performed and documented according to manufacturers' instructions. (Policy LAB 1.26)
   21. **Review of Quality Control, patient results and equipment function**:
       1. Daily review is the responsibility of the tech. verifying results in that work area. Review is documented by initials attached to QC, patient results or instrument maintenance functions.
       2. The Technical Specialist or designee, of each work area is responsible for documented periodic reviews of all functions according to specific area protocol.
   22. **Corrective Actions**:
       1. Corrective action is performed and documented when problems or errors are identified and when any of the following occur:
          1. Equipment or methodologies perform outside established parameters.
          2. Patient test values are outside the lab’s reportable range for that test/method.
          3. The normal range for the test is determined to be inappropriate for the lab’s population.
          4. Controls &/or calibrations fail to meet the established acceptable criteria.
          5. Criteria for proper storage of reagents or supplies are not met.
       2. Recalibrate when quality control shows trends, shifts, or is out of limits, and other corrective action has not remedied the problem, where appropriate.
4. **Specialty and Subspecialty Procedures:**
   1. Written procedures for quality control are available in each specialty or subspecialty area procedure manual.
5. **Tests for which there are no calibrators or control materials available:**
   1. The laboratory must determine what processes or mechanisms can be used to detect errors that may occur in the complete testing process. Employ alternative mechanisms such as:
      1. testing in duplicate
      2. internal or external split samples
      3. comparison of results to other methodologies
      4. correlation of related test results
      5. other means to detect potential errors.
   2. Testing procedures should be performed in accordance with standard methodologies whose reliability is supported in literature references.
   3. Document all activities performed that are used as alternatives to traditional calibrators and controls.
6. **Individualized Quality Control Plan (IQCP):**
   1. A minimum of two levels of control material must be assayed each day of use except as allowable through the Individualized Quality Control Program (IQCP) regulations.
      1. If less frequent assay of controls is recommended by the manufacturer, an IQCP for testing and documentation must be followed.
      2. Tests performed in the following specialty/subspecialty areas are NOT eligible for use of an IQCP: Pathology / Cytology
      3. IQCP does NOT apply to Waived tests.
      4. IQC plans will be reviewed by the Lab Manager on an annual basis. The Quality Assessment for the IQCP plan will be reviewed by Medical Director, Lab Manager, Lead Techs for the year ending, to occur no later than 1st quarter of the new year. (2022 yearly data reviewed no later than March 2023 etc.)
         1. Plans will be reviewed when significant changes occur, such as use of different kits/reagent, Proficiency testing failure, etc.
      5. A complete IQCP consists of the following three parts:
         1. Risk assessment, Quality control plan and Quality assessment
   2. A **risk assessment** is established by each laboratory considering its own environment with its own testing personnel.
      1. The risk assessment may include test, method or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included but cannot be the only data source for the assessment.
      2. The risk assessment contains the following five components:
         1. Specimen, Environment, Reagent, Test system and Testing personnel
      3. The risk assessment encompasses the following three phases of the testing process:
         1. Pre-analytic, Analytic and Post-analytic
      4. The risk assessment identifies the sources of potential failures and errors for a testing process and evaluates the frequency and impact of those failures and sources of errors.
      5. The risk assessment includes the manufacturer’s instructions and / or other information needed to assess risk in all three phases of the testing process.
      6. The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers’ instructions.
   3. A **Quality Control Plan** (QCP) for devices at each location throughout a facility. Practices, procedures and resources that may be incorporated in your QCP includes, but not limited to:
      1. Electronic controls
      2. Internal controls
      3. Proficiency testing
      4. Calibration
      5. Maintenance
      6. Training & Competency assessment
      7. The QCP (or changes to the plan) must be signed & dated by the Medical Director before implementation.
   4. A **Quality Assessment** to monitor ongoing effectiveness, may include, but not limited to:
      1. QC review
      2. PT performance review
      3. Chart review
      4. Specimen rejection logs
      5. Turnaround time reports
      6. Complaint reports

**Policy reviewed:**

**Dr. Elsa Malcolm, MD**

**Laboratory Medical Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE\_\_\_\_\_\_\_\_\_**

**Thomas Geis, MT(ASCP) \_\_\_Thomas Geis\_DATE \_\_\_\_2-14-23\_\_\_\_\_**

**Laboratory Manager**