Name of Policy: Quality Control
Policy Number: 3364-107-302
Department: Pathology-Laboratory
Approving Officer: Chief Operating Officer-UTMC
Responsible Agent: Director, Clinical Pathology
                     Administrative Director, Lab
Scope: Pathology-Laboratory

Effective Date: 1/4/2023
Initial Effective Date: 6/1/2001

(A) Policy Statement

The laboratory has defined a program for quality control that encompasses all analytes and tests performed.

(B) Purpose of Policy

To define general QC goals to monitor analytical performances in the Clinical Laboratory. To provide a global guideline for QC protocol for the routine clinical laboratory.

(C) Procedure

The following are general guidelines. Specific policies and/or procedures may exist for each department and each test, including establishment or verification of acceptable range for quality control values.

1. Test two QC control levels daily for any analyte with high and low levels available in the control material.

2. Handle controls the same as patients; repeat the analysis if there is a risk of carry-over from a preceding abnormal sample.

3. Plot/enter all control data points (all runs; all shifts) noting any that do not meet run acceptance criteria.

4. Document the cause for any out-of-control situation and the disposition of patient samples.

5. The QC values are used to ascertain whether or not a given “run” of patient values can be considered valid for reporting. Criteria used for evaluation are as follows: (QC values referred to are those charted on the Levy-Jennings chart).
   A. Both QC values within $2 \pm S.D.$ of mean; accept the run.
   B. Either QC value outside $2 \pm S.D.$ limits: conditionally accept the run unless-
      i. This the second such occurrence for the QC serum.
      ii. The other control is barely within the same 2 S.D. limit.
   C. Either QC value beyond $\pm 3$ S.D. of mean, or both QC values beyond $\pm 2$ S.D. mean.
      i. Hold patient results
      ii. Consult supervisor
      iii. Determine cause of aberrant results.
      iv. Fill out Action Log report
   D. Be aware of “trends” in the QC values, i.e., repeated values (6 or more) on the same side of the mean. These may indicate deteriorating reagents or standards.
   E. If run is rejected:
      i. Do not report patient results.
      ii. Review procedure and analytic system for identifiable errors.
      iii. Reconstitute fresh control(s) and run both prior controls) and fresh control(s) with patient specimens from the run.
iv. If fresh control(s) is/are now within limits, report patient results from the repeated run. Enter/Plot and note out of range value and explain on quality control chart or alternate document.

v. If fresh control(s) and repeat control(s) remain unacceptable, notify supervisor or director to determine cause of aberrant results.

F. Discard any control vials which yield erroneous results for any analyte.

G. One QC value out of range:
   i. Analyze fresh QC material and a few patients. (IF fresh QC is within limits and patient values repeat same as in run-in question, accept the patient results from questionable run).

H. Both QC values out of range:
   i. Check for obvious instrument malfunction. Temperature, concentration factor, clots in tubing, pipette settings, etc.

6. Designated technologists will routinely document and review all QC records.