


<b>Name of Policy:</b> <b>Quality Control</b> <b>Policy Number:</b> 3364-107-302 <b>Approving Officer:</b> Medical Director, Clinical Pathology <b>Responsible Agent:</b> Director, Clinical Pathology Administrative Director, Lab <b>Scope:</b> Pathology Laboratory University of Toledo Medical Center		 <b>Effective date:</b> 01/04/2025 <b>Original effective date:</b> 06/01/2001	
Key words: Quality Control (QC) program, analytes & tests, QC goals, QC requirements, documentation review.			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

The laboratory has defined a program for quality control (QC) 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 of 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. The 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 is 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 the 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 control(s) 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.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology</p> <p>1/10/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Joshua Otiso, Administrative Director, Lab</i></p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"><li>• <i>Q-02</i></li></ul> <p>Initial effective date: 06/01/2001</p> <p>Review/Revision Date: 01/04/2025</p> <p>Next review date: 01/04/2027</p>
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