☐ ADMINISTRATE POLICY & PROCEDURE (APP)	☐ INSTITUTIONAL POLICY & PROCEDURE (IPP) ☐ INTERDEPARTMENTAL ☐ INTERNAL	
TITLE		**POLICY NUMBER/V#**
Quality Control Policy		MMC – LAB – 06 (01)
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02/08/2025	**01/09/2025**	**01/08/2028**
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APPLIES TO	**RESPONSIBILITY**	
All laboratory staff	All laboratory staff	

1. Policy

1.1 Each laboratory section will develop and implement a quality control program that meets or exceeds (CBAHI) general and section specific checklist requirements. All implemented corrective actions must be documented. QC records must be retained for a minimum of two years. QC results must be reviewed as per the following schedule:

1.1.1. Daily- all QC results must be reviewed by the technologist with regular review by the area senior to determine if they meet the acceptability criteria.

1.1.2. Weekly - all QC results must be reviewed and documented by the area senior.

1.1.3. Monthly - the Section Head, Section Supervisor, and area seniors must collectively review and document all QC data.

1.1.4. External proficiency surveys will be reviewed, documented and corrective action taken when necessary, as soon as survey reports are available.

1.1.5. All quality control results must be reviewed and approved by the laboratory director.

2. Purpose

2.1 The purpose of quality control (QC) is to monitor the performance of an analytical system to ensure the reliability of the process or measurement performed on a patient sample. An effective QC program identifies areas for process improvement and ensures reliable results for both short-term and long-term medical decisions.

3. Definition

3.1 The College of American Pathologists endorses the following definitions of quality assurance, quality control, and quality improvement:

3.2 Quality assurance in pathology and laboratory medicine is the practice of assessing performance in all steps of the laboratory testing cycle including pre-analytic, analytic, and post-analytic phases to promote excellent outcomes in medical care.

3.3 Quality control is an integral component of quality assurance and is the aggregate of processes and techniques to detect, reduce, and correct deficiencies in an analytical process.

3.4 Quality improvement is the practice of continuously assessing and adjusting performance using statistically and scientifically accepted procedures.

4. Affected department

4.1. All laboratory sections

5. Procedures

5.1 Materials:

5.1.1 Commercially available solutions or lyophilized control material (may be assayed or unassayed) are most commonly used. Typically control materials should be very stable, tested for the presence of transmissible disease agents, easily prepared, and allows peer group comparisons. The laboratory must determine the acceptable ranges for each lot of control. A large, continuous supply of control material with the same lot number is beneficial as this reduces the necessity of frequent control range establishment.

5.1.2 Pooled frozen patient samples prepared and assayed in the laboratory. This is the least expensive way to prepare controls but there are several disadvantages including: requires specialized expertise and time, biohazard risk due to possible presence of transmissible disease agents, and the inability to compare results to other labs. If commercial products are unavailable, this is often the only way to verify the reliability of patient test results.

5.1.3 The analyte concentrations in the control solutions should reflect the values at which clinical medical decisions are made and not coincide with the calibration points. Some examples include:

5.1.3.1 Low control: within the normal range (negative).

5.1.3.2 High control: at a concentration where a medical decision may be made (positive).

5.2 Methods:

5.2.1 Determining acceptable range of unassayed control material.

5.2.2 At least 20 measurements should be collected over a 2- 4-week period. The mean, standard deviation and % coefficient of variation are calculated in the usual fashion. These values should be used for the Levey-Jennings plot and should not be changed without careful consideration of the reasons for such action. Any changes must be documented and pre-approved by the Supervisor and Section Head. Monthly statistics (mean, SD and CV) should be kept in the computer system and used to monitor changes and/or trends in QC values.

5.2.3 Determining acceptable range of assayed control material

5.3 Frequency of QC testing:

5.3.1 The frequency of QC analysis is outlined as follows:

5.3.1.1 At the minimum, at least once per day (ON EACH DAY OF USE) or with each analytical batch if the test is not run daily.

5.3.1.2 At least as often as specified by CAP or the manufacturer, whichever is most frequent.

5.3.1.3 If unsure, run more often rather than less often, until reliability is established and documented.

5.3.2 Interpretation of QC results:

All results for each control should be plotted versus time on a chart that has lines drawn for the mean, 1SD, 2SD and 3SD. Plotting can be accomplished manually or through the use of the Laboratory Information System (LIS) or a PC computer system. This type of display gives a visual indication of drifts or shifts that have occurred in QC results. Once recorded, a decision to accept or reject the result must be made. All QC data should be accepted and included on the QC plot unless an obvious assignable cause for the error is known i.e. no reagent added, mechanical failure. Indiscriminate rejection of QC data will mask problems, make troubleshooting difficult and lead to unreliable patient reporting.

5.3.3 The QC results for all controls must be within the +/- 2 SD of the mean to accept the run. When the QC results are out-of-control, the cause of the problem must be identified and appropriate corrective action implemented. Re-running the QC until the results are in-control is not an acceptable solution.

5.3.4 Each laboratory section must establish guidelines for dealing with patient samples when the QC results are out-of-control. Whatever method is selected must ensure that the reported patient results are valid and reliable. All decisions must be fully documented and approved by the Section Head or designee. Some strategies to be considered are:

5.3.5 Repeat or review, for clinical significance, every sample analyzed since the last successful QC with acceptance/rejection justification of results clearly documented.

5.3.6 Repeat the samples run during the 1-2 hours (for example) before the out-of-control QC.

5.3.7 Run a group of 5-6 samples on another analyzer, if available, and compare these results to the original results. If the means agree within a specified concentration, the results can be accepted.

5.4 The laboratory quality control system conforms to the manufacturer's instructions: The procedure described for determining the acceptable range of unassayed control material should be used whenever possible.

6. Responsibilities

6.1. All laboratory staff.

7. Reference

7.1 College of American Pathologists, Laboratory Accreditation Manual, October 2001 Edition College of American Pathologists, Inspection Checklists. 06/21/2001 Edition NCCLS Document C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions. February 1999.

7.2 CBAHI Standard Number: LB.70.

8. Attachments

8.1. Corrective action form for quality control deviation

9. APPROVALS & REVIEWS

APPROVALS & REVIEWS:			
Prepared By	**Title**	**Date**	**Signature**
Dr. Hafez ALsheikh Mohammed	**Head of Department**	**02-08-2025**	
Reviewed By			
Dr. Mostafa Mohammed Osman	**Quality Director**	**02-08-2025**	
Approved By			
Dr. Abdulmajeed Abdullah Saleh	**Medical Director**	**02-08-2025**	
Eng. Meshaal Hussein Alghamdi	**Executive Director**	**02-08-2025**	