The University of Iowa | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa Third Quarter 2021

In This Issue...

In previous issues of the CLIA Corner, we discussed the necessity for all non-waived laboratories to have a comprehensive Quality Assessment (QA) policy that includes all four CLIA quality systems: general laboratory, pre-analytic, analytic, and post-analytic. The last CLIA Corner focused specifically on the analytic system. Since the analytic quality system encompasses the majority of the regulations, we thought it best to divide it between two editions of the CLIA Corner. In this issue, we'll conclude our look at Quality Assessment - Analytic system, and provide an example QA form. The laboratory must ensure its QA Policy includes multiple components used to meet the CLIA quality requirements and that they are appropriate for the specialties and subspecialties of testing performed by the laboratory.

Four QA Systems:

General Pre-Analytic **Analytic** Post– Analytic

The Analytic quality system is directly related to patient testing and pertains to all specialties and subspecialties. Below, sections of the Analytic system are reviewed and include QA probes on which to focus.

Quality Control

- For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.
- The general regulation is that the laboratory must perform two levels of external quality control each day of patient testing. ***However, the laboratory must be in compliance with all quality control regulations found in Subpart K, including quality control requirements for specialties and subspecialties like bacteriology, hematology, immunohematology, etc.***
- For certain test systems, the laboratory may choose to perform less frequent quality control. In these cases, an Individualized Quality Control Plan (IQCP) must be established. Refer to the 2014 1st Quarter issue of the CLIA Corner for an introduction to IQCP and the 2014 3rd Quarter, 2014 4th Quarter, and 2015 1st Quarter issues for an overview of each of the essential parts of an IQCP.

QA Probes:

- Has the laboratory established written policies and procedures for the ongoing monitoring of their Quality Control program?
- In the event of a QC failure, has the laboratory evaluated all patient test results since the last acceptable QC?
- What statistics does the laboratory have to demonstrate the number of assays and the period of time in which the laboratory repetitively tested control materials to verify or establish control limits?
- How does the laboratory evaluate QC results to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytic system?
- If more than one test system is in use for a test procedure, does the laboratory evaluate the QC data for both test systems in the establishment of control limits?

Comparison of Test Results:

- If the laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must perform comparisons between the methodologies or instruments twice annually.
- The laboratory must have a system to identify and assess patient test results that appear inconsistent with patient age, sex, diagnosis, distribution of patient test results, and relationship with other test parameters.

QA Probes:

- Does the laboratory perform the same test using different methodologies or instruments? Example, electrolytes being performed on a large analyzer and a point of care analyzer. If so, are comparisons performed twice annually?
- Has the laboratory established delta checks within the Laboratory Information System to help prevent the likelihood of sample-switching errors?
- Does the laboratory have procedures to assess and evaluate patient test results for inconsistencies?

Corrective Action:

- Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.
- The laboratory must document all corrective actions taken.

QA Probes:

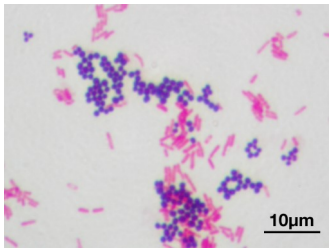
- When equipment malfunctions or a test method problem exists, how does the laboratory identify and solve the problem?
- When QC fails to fall within the defined limits of acceptability, how does the laboratory identify the reason for the failure and correct the problem before resuming patient testing?
- Does the laboratory document corrective action if the storage temperature for the test system's reagents falls outside the acceptable limits?

Test Records:

- The laboratory must maintain an information or record system that includes the positive identification of the specimen; date and time of specimen receipt; condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and the records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

QA Probes:

- How does the laboratory document all steps taken during patient testing, who performed the test, and date of testing? Example: for microbiology, does the laboratory document who set up the initial culture, who performed the gram stain, and who reported the final identification?
- Does the laboratory retain all testing records according to CLIA retention requirements? If the records are stored directly on the analyzer, can they be retrieved for a minimum of 2 years?



Interpretive Criteria for Enterobacteriaceae and Staphylococcus spp.:

Zone Diameter (mm)	Interpretation	MIC (mcg/mL)
≥ 18	Susceptible (S)	≤ 8
15 to 17	Intermediate (I)	-
≤ 14	Resistant (R)	≥ 32

An effective QA program is the key to ensuring accurate and reliable test results.

An example of an Analytic System QA audit tool can be found on the following pages. This example has been created by the Iowa CLIA State Agency as an aid in the laboratory QA process and is not an official form created by the Centers for Medicare & Medicaid Services.

Quality Assessment Audit: Analytical System

Policy/ Procedure/ Audit Tool Review	Yes	No	NA
Have all procedures and procedural updates been approve, signed and dated by the laboratory director? **Document corrective action if needed:**			
Test systems/Equipment/Instruments/Reagents/Materials/Supplies	**Yes**	**No**	**NA**
Are water quality, temperature, and humidity value records and within the acceptable ranges? Are reagents, solutions, media, control materials, calibration materials, and other supplies labeled and within expiration date? **Document corrective action if needed:**			
Establishment and Verification of Performance Specifications	**Yes**	**No**	**NA**
Has the laboratory introduced any new test kits or test systems since the last audit? If yes, has the laboratory established or verified the performance specifications? Has the laboratory director approved, signed and dated the performance specification records? **Document corrective action if needed:**			
Maintenance and Function Checks	**Yes**	**No**	**NA**
Is the laboratory performing and documenting maintenance and function checks according to the manufacturer's instructions for each test system? Has the laboratory established the frequency for performing maintenance and functions checks not defined by the manufacturer (e.g. centrifuge speed and timer checks, pipette calibration, etc.)? If the laboratory failed to document daily, weekly, monthly, and quarterly maintenance has corrective action been documented? **Document corrective action if needed:**			
Calibration and Calibration Verification	**Yes**	**No**	**NA**
For each test system does the laboratory perform calibrations according to the manufacturer's instructions? Has the laboratory performed calibration verification every six months? Date next calibration verification due: _____ **Document corrective action if needed:**			

Quality Control	Yes	No	NA
Does the laboratory have a policy for defining the criteria for acceptable QC, including the statistics it uses to verify or establish QC limits? Have QC results been reviewed and is QC within the acceptable range? If no, has corrective action been documented and patient results reviewed since the last QC was acceptable? Are the Individualized Quality Control Plans up to date? Is the QC frequency consistent between the test system procedure and Individualized Quality Control Plan? **Document corrective action if needed:**			

Comparison of Test Results	Yes	No	NA
Does the laboratory perform the same test using different methodology or instruments? If yes, have comparisons been performed twice annually? Date when comparisons are due: _____ Does the laboratory have a system in place to help prevent the likelihood of sample-switching errors? Do laboratory testing personal document errors/corrected results according to laboratory policy? **Document corrective action if needed:**			

Corrective Action	Yes	No	NA
When there are equipment malfunctions or test method problems, does the laboratory identify and documents corrective action? **Document corrective action if needed:**			

Test Records	Yes	No	NA
Does the laboratory have a system to document who performed each step of testing and the date of testing? Does the laboratory retain all testing records according to CLIA retention requirements? If records are stored on an analyzer, can they be retrieved for a minimum of 2 years*? *Ensure all laboratory records meet CLIA retention requirements. **Document corrective action if needed:**			

If you would like to be added to the CLIA Corner newsletter, email us at:

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