The University of Iowa | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa Second 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. We discussed the general laboratory system in the 2020 3rd Quarter issue and the pre-analytic system in the 2020 4th Quarter issue. In this issue, we'll begin to look at the analytic system. 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.

Procedure Manual: The laboratory must have a written procedure manual for all tests, assays, and examinations performed by the laboratory. It must be available to and followed by all laboratory personnel. Refer to the 2018 4th Quarter CLIA Corner for more details about procedure manual requirements.

QA Probes:

→ Format

- Paper based manuals must include the most current version of all procedures.
- Electronic based manuals must be available to all staff in all areas of the laboratory.
- The laboratory must have a plan in place for how it will handle power outages and system downtimes when electronic procedure manuals may not be available.

Test systems, equipment, instruments, reagents, materials, and supplies:

- ☑ Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system.
- ☑ The laboratory must define criteria for conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Criteria must be consistent with manufacturer instructions, if provided. As applicable, the laboratory must monitor and document: water quality; temperature; humidity; and protection of equipment and instruments from fluctuations and interruptions in electrical currents.
- ☑ Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled with the following: identity and when significant, titer, strength and concentration; storage requirements; preparation and expiration dates; and other pertinent information required for proper use.

- ☑ Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have expired, have deteriorated, or are of substandard quality.
- ☑ Components of reagent kits of different lot numbers must not be interchanged, unless otherwise specified by the manufacturer.

QA Probes:

→ Manufacturer instructions

- Laboratories must follow all manufacturer requirements and are highly encouraged to follow all manufacturer suggestions/recommendations so long as they do not conflict with regulatory requirements.
- The most current manufacturer package inserts must be available and followed.

→ Reagent and specimen storage

- Monitor/document temperatures at the same time(s) each day and when fluctuations are least likely to occur to ensure accurate readings and a higher likelihood of finding system failures prior to adverse outcomes.
- Ensure the laboratory documents corrective action for temperatures exceeding the laboratory's acceptability criteria for manual and electronic temperature monitoring systems.
- The laboratory must be able to provide daily temperature records when using an electronic temperature monitoring system.
- Conduct periodic expiration date audits for all reagents and other materials.
- Record open dates on all reagents, solutions, culture media, control and calibration materials, etc.
- When storage conditions or opening new materials results in a new expiration date (e.g., test cartridges moved from refrigerated to room temperature storage or control vial stability only 14 days once opened), the laboratory must record the new expiration date(s).

Establishment and verification of performance specifications:

☑ Prior to reporting patient test results, each laboratory that introduces an ***unmodified***, FDA-cleared or approved test system must demonstrate for each test system that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

- Accuracy
- Precision
- Reportable range
- Reference intervals

☑ Prior to reporting patient test results, each laboratory that ***modifies*** an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval, or uses a test system in which performance specifications are not provided by the manufacturer must establish for each test system the following performance characteristics, as applicable:

- Accuracy
- Precision
- Analytical sensitivity
- Analytical specificity, including interfering substances
- Reportable range
- Reference intervals
- Any other performance characteristic required for test performance

For a more comprehensive look at requirements for implementing new test systems, refer to the 2019 3rd Quarter and 2019 4th Quarter issues of the CLIA Corner.

QA Probes:

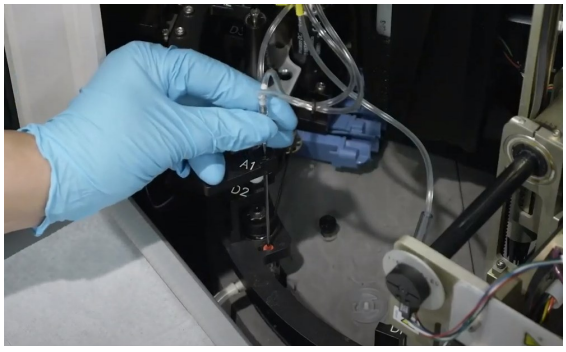
→ The laboratory/laboratory director must determine the number of samples to be used and the acceptability criteria for all performance specification data.

→ Calculations must be verified also, if applicable.

→ Performance specification records must be reviewed and evaluated prior to patient testing.

Maintenance and function checks:

☑ For ***unmodified*** manufacturer's equipment, instruments, or test systems, the laboratory must perform and document:



- Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
- Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

Maintenance and function checks, continued:

☑ For equipment, instruments, or test systems ***developed in-house***, commercially available and ***modified*** by the laboratory, or maintenance and function check protocols are ***not provided*** by the manufacturer, the laboratory must:

- Establish, perform, and document a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
- Define, perform, and document a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and result reporting. Function checks must be within the laboratory's established limits before patient testing is conducted.

QA Probes:

→ The laboratory must document required maintenance activities even if the instrument will not let the user proceed without performing the activity; if it's not documented, it didn't happen.

→ Manufacturers do not always provide maintenance/function check logs. It is the laboratory's responsibility to review manuals and document maintenance/ function checks as required.

→ Ensure the laboratory is following its own policies for maintenance/function check frequencies.

Calibration and calibration verification procedures:

☑ For each applicable test system, the laboratory must perform and document ***calibration*** procedures following the manufacturer's instructions, using calibration materials specified or provided, and with at least the frequency recommended by the manufacturer. If the manufacturer does not specify calibration frequency, the laboratory must establish its own schedule.

☑ For each applicable test system, the laboratory must perform and document ***calibration verification*** procedures at least every six months or according to the manufacturer's requirements. The laboratory must follow the manufacturer's instructions or criteria verified or established by the laboratory, including at least a minimal (or zero value), mid-point, and maximum value material to verify the laboratory's reportable range. Refer to the 2016 4th Quarter issue for more information about calibration verification requirements.

QA Probes:

→ Ensure the laboratory has a system to track calibration and calibration verification needs for test systems that do not provide alerts.

→ Ensure corrective action is performed and documented for all failed calibration and calibration verification activities.

CONTACT US

If you would like to be added to our mailing list, email us at:
Kristine-Rotzoll@uiowa.edu Or **Melinda-Bochmann@uiowa.edu**