The University of Iowa | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University o f Iowa — Fourth Quarter 2019

In This Issue...

Verification Checklist for New Unmodified FDA-Cleared or Approved Non-Waived Test Systems

In the last edition of the CLIA Corner, the requirements for implementing a new test system were discussed. Planning for and implementing a new test system requires organization, preparation, hard work, and patience. It can be a daunting task for even the most experienced laboratorians. Wouldn't it be great to have a checklist to help guide you though the process? Here you go!

NOTE: This checklist has been created by the Iowa CLIA State Agency as an aid in test system implementation and is not an official form or checklist endorsed by the Centers for Medicare and Medicaid Services (CMS). Laboratories are not required to utilize it, and are free to modify the checklist as needed.

Contact Us

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"What are the performance specifications again?"

"How many samples do I need?"

"Where do I even begin?!?"

New Test/ System Verification (Non-waived, unmodified FDA-cleared or approved)

Analyzer/ Test System/Analyte _____

Date of Initial Use _____

Materials

___ Correlation specimens obtained

Obtained from: _____

Number of specimens used: _____

___ QC ordered ___ Verification material ordered ___ Calibration material ordered

Acceptance Criteria (Must be established for each performance specification and approved by the Laboratory Director (or designee), prior to verification)

___ Established

___ Approved by Laboratory Director

Performance Specifications

___ **Accuracy**: verified with **(choose only method(s) used):**

___ QC with known values ___ Proficiency testing material

___ Calibrators ___ Previously tested patient specimens

___ Split samples run on previously verified method

___ **Precision** (assess day-to-day, run-to-run, and within run variation and operator variance); verified with **(choose only method(s) used)**:

___ Repeat testing of known patient samples (same samples at different times, over different days)

___ Repeat testing of QC material in duplicate and over time

___ Repeat testing of calibration materials over time

___ **Reportable Range** Manufacturer stated range: _____ Verified range: _____

Verified with **(choose only method(s) used)**:

___ Linearity kit ___ Calibration materials

___ QC materials ___ Known samples of abnormal high and low values

___ Programmed into the analyzer

___ Procedure includes how lab will report results greater/ less than verified range

___ **Reference Intervals** (normal values); which of the following will be used?

___ Manufacturer's suggested range ___ Published range from textbook or journal

___ Established by laboratory with patient samples

___ Programmed into instrument

LIS and Test Reporting System

Yes / No Does test/analyte include calculation by the LIS/Analyzer/or both?

___ Calculation verified

___ Interpretations and/ or comments

Yes / No Does test/analyte include panic/critical value?

___ Panic low flags correctly ___ Panic high flags correctly

Test result values verified in LIS and/or instrument, including but not limited to:

___ Test value consistent from instrument to LIS

___ Units of measure ___ Reference Range

___ Abnormal low flags correctly ___ Abnormal high flags correctly

___ Linearity values ___ Delta checks

___ Maximum and minimum values

Procedure Manual (may use operator's manual and/ or package inserts; lab must add anything missing from the following list)

All of the following criteria must be included:

___ Requirements for patient preparation

___ Specimen collection, labeling, storage, preservation, transportation, processing, and referral

___ Specimen acceptability and rejection

___ Microscopic examination, including the detection of inadequately prepared slides

___ Step-by-step performance, including test calculations and interpretation of results

___ Preparation of slides, solutions, calibrators, controls, reagents, stains, etc.

___ Calibration and calibration verification procedures and corrective action to take when they fail

___ Reportable range

___ Control procedures and corrective action to take when they fail

___ Limitations in test methodology, including interfering substances

___ Reference intervals (normal values)

___ Imminently life-threatening test results, or panic/ alert values

___ Pertinent literature references

___ System for entering results in the patient record and reporting patient results

___ Protocol for reporting imminently life threatening results or panic/ alert values

___ Course of action to take if the test system becomes inoperable

___ Procedure approved, signed and dated by Laboratory Director prior to patient testing

___ Training documented for each testing personnel

___ Enrolled in proficiency testing (required for regulated analytes, optional for unregulated analytes) or twice annual verification plan (unregulated analytes only)

___ Documentation review and Laboratory Director approval completed

___ Notified CLIA State Agency or Accreditation Organization of test menu change

Navigating the Checklist

The checklist is specific for non-waived, unmodified FDA-cleared or approved test systems and does not include all requirements for a modified FDA–cleared or approved system or a laboratory developed test.

Materials

This section is meant to help determine materials needed for the overall verification process. Check all that apply.

Acceptance Criteria

This section is a reminder that acceptance criteria must be established for each performance specification. The criteria must be approved by the laboratory director, or their designee, prior to implementation.

Performance Specification

Each performance specification under this section must be verified for each test system/analyte implemented.

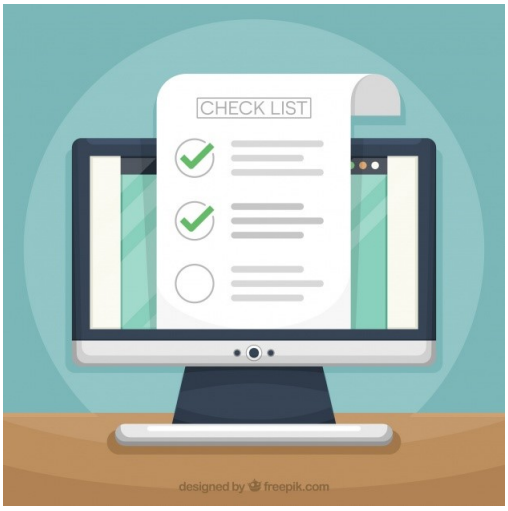
→ Accuracy– check each method used for verification. The laboratory must use at least one method, but may use more, as deemed necessary.

→ Precision- check each method used for verification. The laboratory must use at least one method, but may use more, as deemed necessary.

→ Reportable Range– check the manufacturer's package insert, instructions for use or operator's manual for the manufacturer's established range; write it in the space provided.

* Check each method used for verification. The laboratory must use at least one method, but may use more, as deemed necessary.
* In the "verified range" space provided, write the highest and lowest recovery values obtained by the laboratory.
* Ensure the verified range is programmed into the analyzer.
* Also ensure the test/analyte procedure includes how the laboratory will report results greater/less than the verified range.

→ Reference Intervals (normal values)- check which range is to be used by the laboratory. Ensure it is programmed into the analyzer.



Laboratory Information System (LIS) and Test Reporting System

* Indicate "yes" or "no" for whether or not the test/analyte includes a calculation. If it does, ensure the calculation is performed correctly by the LIS and/or analyzer.

* Verify interpretations and/or comments appear as necessary.

* Indicate "yes" or "no" for whether or not the test/analyte includes panic/critical values. If it does, ensure the panic high and panic low values flag at the correct thresholds in the LIS.

Other components to verify in the LIS

* Verify results flow correctly from the instrument into the LIS if they are interfaced.
* Ensure that the correct units of measure for each analyte appear in the LIS.
* Verify test result values entered into the LIS test meet all defined parameters, including but not limited to: system messages, warnings, and numeric boundaries such as; high, low critical, reference ranges, linearity, delta checks and maximum and minimum values.
* Verify that results flow correctly to patient electronic medical records (EMR) and patient portals, including units of measure and reference ranges, as applicable.

Procedure Manual

Check that each applicable criteria is included the test/analyte procedure. **ALL CRITERIA MUST BE ADDRESSED!** If using the operator's manual and/or package inserts, include (in a separate procedure) anything missing from the list. The laboratory director **MUST** approve all procedures prior to patient testing.

Training

Training must be performed and documented for each testing personnel. Remember to document training for new non-waived kit tests also.

Proficiency Testing and Accuracy Verification

All testing must be verified for accuracy. For regulated analytes, the laboratory must enroll in proficiency testing. For unregulated analytes, the laboratory must verify accuracy twice annually. This can be accomplished by enrolling in proficiency testing or by another method.

Review

The laboratory director (or designee) must review and evaluate performance specification records prior to performing patient testing.

Changes

All non-waived test menu changes must be submitted, in writing, to the CLIA State Agency or Accreditation Organization.

Implementing a new test system is both challenging and rewarding. When it is done thoroughly and correctly, you can be confident that your laboratory is reporting the most accurate and reliable patient test results.

Missed a previous edition of the CLIA Corner?

Find archived newsletters at the University of Iowa State Hygienic Laboratory's website:

http://www.shl.uiowa.edu/labcert/clia/cliacorner.xml