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 through 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.
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
- 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.*

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