

CLIA Corner

State Hygienic Laboratory at the University of Iowa

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In This Issue we continue with...

Top Ten List of the most common CLIA deficiencies cited nationally in 2012—numbers five (#5) through one (#1)

NOTE:

The CLIA regulations and interpretative guidelines are located at www.cms.gov/CLIA. Click on the link for *Interpretative Guidelines for Laboratories* or *CLIA Regulations and Federal Register Documents*. The Clinical Laboratory Improvement Amendments (CLIA) can also be found in the Code of Federal Regulations (CFR), Title 42-Public Health, Part 493-CLIA Laboratory Requirements.

#5

D5439 §493.1255(b) Standard: Calibration and Calibration Verification Procedures.

(b) Perform and document calibration verification procedures—

- (1) Following manufacturer's calibration verification procedures;**
- (2) Using the criteria verified or established by the laboratory under §493.1253(b)(3)—**
 - (i) Including the number, type and concentration of the materials, as well as, as acceptable limits for calibration verification; and**
 - (ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and**
- (3) At least once every 6 months and whenever any of the following occur:**
 - (i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.**
 - (ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.**
 - (iii) Control materials reflect an unusual trend or shift, or are outside the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.**
 - (iv) The laboratory's established schedule for verifying the reportable range for patient results requires more frequent calibration verification.**

This standard is cited when the laboratory is not performing calibration verification for a particular test system that requires calibration verification at least every six (6) months. Non-waived test systems using a reagent cartridge with built-in calibration (e.g. i-STAT, Siemens DCA Advantage, Biosite Triage) are subject to calibration verification.

If the test system's calibration procedure uses three (3) or more levels of calibration materials that include a low,

mid and high value at least every six months, the calibration verification requirement is met. Performing routine control procedures does not satisfy the calibration verification requirements.

Calibration materials, proficiency testing samples with known results or control materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured values obtained, versus the actual concentration of the materials. The actual measurement(s) taken, reactions and/or observation must be documented.

EXCEPTIONS

- For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and tests two (2) levels of control materials each day of testing provided the control results meet the laboratory's criteria for acceptability.
- Arterial blood gas testing devices/instruments are not subject to calibration verification.

#4

D5403 §493.1251 Standard: Procedure Manual.

(b) The procedure manual must include the following when applicable to the test procedure:

- (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.**
- (2) Microscopic examination, including the detection of inadequately prepared slides.**
- (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.**
- (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.**
- (5) Calibration and calibration verification procedures.**
- (6) The reportable range for test results for the test system as established or verified in 493.1253.**
- (7) Control procedures.**
- (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.**
- (9) Limitations in the test methodology, including interfering substances.**
- (10) Reference intervals (normal values).**
- (11) Imminently life-threatening test results, or panic, or alert values.**
- (12) Pertinent literature references.**
- (13) The laboratory's system for entering results in the patient record and reporting patient results, including, when appropriate, the protocol for reporting imminent life-threatening results, or panic, or alert values.**
- (14) Description of the course of action to take if a test system becomes inoperable.**

This standard is cited when the laboratory's procedure (or procedures):

- Omits one of the criteria listed above;
- Does not contain or match the actual practices and processes used by the laboratory;
- Does not meet the CLIA regulations for the test system (e.g. corrective action when control results are unacceptable for antimicrobial susceptibility testing, refer to §493.12); and
- Does not follow manufacturer's requirements and recommendations.

#3

D5411 §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) 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 as determined under §493.1253.

This deficiency is cited when the laboratory does not perform testing according to the manufacturer's guidelines or fails to select a test method that meets the performance specifications as described in its procedure resulting in test results that may be inaccurate or unreliable.

“Following manufacturer's instructions” means that the laboratory complies with the recommendations, suggestions and requirements in package inserts and/or operator manuals. These include, but are not limited to:

- Handling reagents, materials and supplies;
- Adhering to conditions of storage and testing; and
- Performing equipment maintenance and function checks.

Here are two examples where a surveyor would cite this as a deficiency:

Example #1: When the laboratory switches to a new lot of coagulation reagent, and it does not perform one or more the following in order to verify the performance specifications:

- o Establish a normal patient prothrombin time mean.
- o Verify that the new normal patient mean and International Sensitivity Index (ISI) values are programmed into the analyzer or the laboratory information system [whichever calculates the International Normalized Ratio (INR)].
- o Perform comparison studies with patient results in the therapeutic range and abnormal patients with the old and new lot of reagents to verify consistency of results.
- o Compare and verify the INR calculation from the coagulation analyzer or laboratory information system (LIS) by a manual calculation check.
- o Verify that the centrifuge speed and time used to process coagulation specimens produces platelet poor plasma.

Example #2: The laboratory performs urine sediment examination/microscopy. The centrifuge used to process the urine has one set speed and the revolutions per minute (rpms) are too fast, therefore causing the fragile elements to disintegrate.

#2

D5791 §493.1289 Standard: Analytic Systems Quality Assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas of the facility of which it is a part.

QA of the Analytic System includes assessing:

- Test procedures;
- Accurate and reliable test systems, equipment, instruments, reagents, materials and supplies;
- Specimen and reagent storage conditions;
- Equipment/instrument/test system maintenance and function checks;
- Establishment and verification of method performance specifications;
- Calibration and calibration verification;
- Control procedures;
- Comparison of test results;
- Corrective actions; and
- Test records.

This deficiency is cited when the laboratory is not reviewing, assessing and monitoring one or more of the sections of the Analytic System to ensure continuous improvement and quality testing, or its assessment(s) fails to discover an error or identify a potential problem and take corrective action(s) to correct the situation. This corrective action process involves identification and resolution of the problem, and development of policies that will prevent recurrence. The corrective action must be documented and communicated to the laboratory personnel and other staff, clients, etc., as appropriate.

Example #1: If the surveyor identifies quality control failures or omissions that the laboratory has not assessed and taken corrective action for, then the laboratory's system for monitoring and evaluating quality control may not be adequate.

Example #2: The laboratory fails to maintain the identity of the patient specimen throughout the testing process

#1

D5217 §493.1236 Standard: Evaluation of proficiency testing performance.

(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included subpart I.

Subpart I, Proficiency Testing Programs for Nonwaived Testing, (refer to Code of Federal Regulations, 42, CFR, Part 493) includes those specialties, subspecialties and analytes that are considered regulated tests. For those tests not listed in subpart I (not regulated), the laboratory must verify the accuracy of the test or procedure twice annually.

The deficiency is cited when the laboratory fails to verify the accuracy of a non-regulated test twice per year. Common non-regulated tests that laboratories fail to verify include, but are not limited to, vaginal wet mount examination, potassium hydroxide (KOH) preparation and post-vasectomy semen analysis.

- The laboratory can meet this standard by enrolling in a CLIA-approved proficiency testing program or using an alternate method. Alternate methods include, but are not limited to the following:
- Split sample with another laboratory (DO NOT use proficiency testing samples);
- Internal split-sample (e.g. retest a patient specimen by a different method or retest using the same method by a different testing personnel);
- Audit-sample (i.e. aliquots of patient specimen are stored, then retested and results compared);
- Analysis of calibrator or control materials (Note: The laboratory must use a different lot number of the material from that used to calibrate or control the method.);
- Reevaluation of morphologic analyses (i.e. review of glass slides by the supervisor or another testing personnel, and review of "unknown" glass slide sets); or
- Direct observation of technique-dependent tests (e.g., sweat test, bleeding time).

CONCLUSION:

Now that you have the information about the top five cited CLIA deficiencies, you can review your laboratory's procedures and processes and prepare the laboratory for its next survey/inspection.

For more specific information about proficiency testing, quality assessment and procedures you can review our archived CLIA Corners (<http://www.shl.uiowa.edu/labcert/cli/cliacorner.xml>).

