

CLIA Corner

State Hygienic Laboratory at The University of Iowa

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In This Issue...

- **Top Ten List of the most common CLIA deficiencies cited nationally in 2012**—Numbers ten through six (Next quarter's CLIA Corner will continue with numbers five through one.)

NOTE: The CLIA regulations and interpretative guidelines are located at www.cms.gov/CLIA. Click on the link for *Interpretative Guidelines for Laboratories*.

#10

D5401 §493.1251 Standard: Procedure Manual

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

Procedures may be organized in the form of paper manuals or be stored electronically. The laboratory will have to ensure the manuals are accessible to all laboratory personnel, including staff only performing specimen collection. Manufacturers' operating manuals and package inserts may be used provided they include all of the applicable procedure requirements found in D5403 §493.1251.

#9

D2016 §493.803 Condition: Successful participation

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

1. There is immediate jeopardy to patient health and safety;
2. The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance;
3. The laboratory has a poor compliance history.

This condition level deficiency is related to repeated unsatisfactory proficiency testing (PT) scores. Unsatisfactory PT scores result from the laboratory's failure to attain minimum satisfactory scores for an analyte, test, subspecialty or specialty for a PT testing event. In most cases, receiving less than 80 percent is considered unsatisfactory, with the exception for the analytes: ABO grouping, Rho typing and compatibility testing. For these analytes, anything less than 100% is considered an unsatisfactory score. Unsuccessful participation in proficiency testing means any of the following:

1. Unsatisfactory performance for the same analyte in two consecutive, or two out of three testing events. *(Example: for the analyte potassium the laboratory receives a score of 60% for 2012 testing event 3 and 40% for 2013 testing event 1);*
2. Repeated unsatisfactory overall testing event scores for two consecutive, or two out of three testing events for the same specialty or subspecialty. *(Example: the laboratory receives an overall score of 40% for specialty of hematology for 2012 testing event 2 and 2013 testing event 1);*
3. An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology or syphilis serology) for the same subspecialty for two consecutive, or two out of three testing events. *(Example: for the subspecialty bacteriology the laboratory receives a score of 60% for 2012 testing event 3 and 2013 testing event 1);*
4. Failure of a laboratory performing gynecology cytology to meet the standard at §493.855.

#8

D6021 §493.1407 Standard: Laboratory director responsibilities - QA

(e) The laboratory director must ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided.

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. CLIA has four quality systems: general laboratory, pre-analytic, analytic, and post-analytic. It is the laboratory director's responsibility to ensure that the laboratory has an acceptable quality assessment (QA) program that monitors each of these systems, and that the laboratory is following the established QA program.

Many times this deficiency is cited when either the laboratory does not have a QA plan or when the laboratory is not following the established plan. There are specific QA regulations related to each of the four quality systems. For example, the surveyor finds deficiencies related only to pre-analytic testing during the survey process. Based upon review of the laboratory's QA program and whether or not it is effective, the surveyor may cite the regulation specific to pre-analytic QA as well as this standard.

#7

D5417 §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

The laboratory CANNOT use expired reagents, solutions, culture media, calibration material and other supplies even if quality controls are performed with the expired materials and are within the acceptable range. The surveyor will also be checking for contamination, drying or other signs of deterioration of laboratory materials during the survey process.

There is an exception for rare reagents; an example would include rare antisera (anti-Jk^b or anti-Le^b) for blood bank testing. In order to use rare reagents beyond their expiration date, the laboratory must document that adequate controls are used and the reactivity and specificity of the reagents.

#6

D5805 §493.1291 Standard: Test report

(c) The test report must indicate the following:

(c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number;

(c)(2) The name and address of the laboratory location where the test was performed;

(c)(3) The test report date;

(c)(4) The test performed;

(c)(5) Specimen source, when appropriate;

(c)(6) The test result and, if applicable, the units of measurement or interpretation, or both.

With the emergence of electronic health records (EHR) we have observed that in many instances all of the required information may be in the EHR system, but the information does not appear on the test report when generated and/or printed. A helpful hint would be to print test reports from different locations throughout your facility (i.e., patient room, laboratory, satellite clinic, etc.) and make sure that the above information is included on all test reports.

If your laboratory has multiple sites, there must be a system in place to identify which tests were performed at each site. For example, a hospital laboratory and the hospital's family practice clinic qualify for the multiple site exceptions under the CLIA regulations and both sites perform complete blood cell counts (CBC) under the same CLIA number. The test report must specify which site performed the CBC test.

Also when portions of a test are performed at different laboratories or sites, the test report must indicate the name and location of the laboratory performing each portion of the test. Example one: Laboratory A uses a BacTec system to process blood cultures and reports the negative cultures, but sends out all positives to Laboratory B for identification and antimicrobial susceptibility testing. Example two: Laboratory A performs frozen sections on-site, but the remainder of the histopathology testing is referred to Laboratory B for processing and interpretation. For both of these examples the test report must specify the name and address of Laboratory A for the in-house testing and the name and address of Laboratory B for the reference testing.

Conclusion:

Now that you've been educated on five of CLIA's ten most commonly cited deficiencies, you can prepare your laboratory for its next survey/inspection. Watch for the next issue of the CLIA Corner for the remaining top five cited CLIA deficiencies!

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>.)