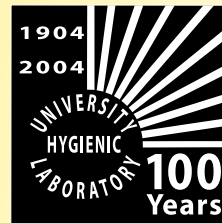


# CLIA Corner

The University of Iowa Hygienic Laboratory

Third Quarter 2008



Iowa CLIA Surveyors: Nancy Grobe, BS, MT(ASCP) & Kristine Rotzoll, BS, MT(ASCP)

*In This Issue...*

## **Top Ten Deficiencies Cited by the Iowa CLIA Surveyors**

Now is the time for your laboratory to review its procedures and processes to ensure compliance with the CLIA regulations listed. This is Iowa's current Top 10 list, and is based on deficiencies cited since January 2004 (the rankings and the standards are subject to change over time). To view the conditions, standards and Interpretative Guidelines in their entirety, go to [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia), click on link "Interpretative Guidelines."

### **IOWA CLIA TOP 10 CITED DEFICIENCIES**

#### **#10 - D5891 §493.1299 Standard: Postanalytic systems quality assessment.**

The laboratory must establish and follow written policies and procedures for an ongoing quality assessment (QA) plan to monitor and assess the requirements of **Postanalytic System**, as well as the corrective action process when problems or potential problems are identified. QA of Postanalytic System includes assessing practices/issues related to test reports.

#### **#9 - D3031 §493.1105 Standard: Retention requirements.**

The laboratory must retain quality control and patient test records (including instrument printouts) for at least two years. The records include instrument charts, graphs, printouts, transcribed data, manufacturers' assay information sheets (package inserts) for control and calibrations materials, temperatures (equipment, environment and storage), and instrument maintenance and function checks.

#### **#8 - D5431 §493.1254 Standard: Maintenance and function checks.**

The laboratory must perform and document functions checks as defined by the manufacturer. The function checks must be within the manufacturer's established limits before patient testing is conducted. Function checks refer to those activities performed to evaluate critical operating characteristics (e.g. background counts, electrical levels, optical alignment), including functions checks of laboratory information systems (LIS), if applicable.

#### **#7 - D5435 §493.1254 Standard: Maintenance and function checks.**

The laboratory is required to define the function check protocol for equipment and test systems when the manufacturer does not have set criteria. Then the laboratory must perform and document those functions checks per its protocol. The function checks must be within the laboratory's established limits before patient testing is conducted. Function checks refer to those activities performed to evaluate critical operating characteristics (e.g. centrifuges, cell washers, incubators, timers), including functions checks of laboratory information systems (LIS), if applicable.

#### **#6 - D5787 §493.1283 Standard: Test records.**

The laboratory must maintain an information or record system that includes the following:

- Positive identification of the specimen;
- Date and time of specimen receipt into the laboratory;

- Condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and
- Records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

#### **#5 – D2016 §493.803 Condition: Successful participation.**

Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by the Centers of Medicare and Medicaid Services (CMS) for all regulated analytes, tests specialties and subspecialties. Unsuccessful participation is defined as receiving unsatisfactory performance score for two consecutive, or two out of three testing events. An unsatisfactory performance score is any score below 80 percent with the exception of ABO and Rh typing and compatibility testing where unsatisfactory performance is any score below 100 percent.

#### **#4 – 5217 §493.1283 Standard: Evaluation of proficiency testing performance.**

For those tests not listed subpart I (not regulated), the laboratory must verify the accuracy of the test or procedure at least twice annually. The laboratory may meet this regulation by enrolling in a proficiency testing program, but it is not required as long as the process used verifies the accuracy. Refer to the CLIA Federal Regulations part 493, Subpart I, Proficiency Testing Programs for Nonwaived Testing, for the list of regulated tests (link found at [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)).

#### **#3 – D5429 §493.1283 Standard: Maintenance and function checks.**

The laboratory must perform and document maintenance as defined by the manufacturer. This means the laboratory complies with the maintenance recommended in package inserts and/or instrument operator manuals for each piece of equipment/instrument it uses, including incubators, centrifuges, safety cabinets, autoclaves, microscopes and laboratory information systems.

#### **#2 – D5403 §493.1283 Standard: Procedure manual.**

The laboratory's procedure must include the following when applicable to the test procedure:

- Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral and criteria for specimen acceptability and rejection.
- Microscopic examination, including the detection of inadequately prepared slides.
- Step-by-step performance of the procedure, including test calculations and interpretation of results.
- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
- Calibration and calibration verification procedures.
- Reportable range for test results for the test system as established or verified.
- Control procedures, including type of control, identity (e.g. normal, abnormal, level I, II or patient), number and frequency of testing controls, established control limits, and criteria to determine acceptable control results.
- Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
- Limitations in the test methodology, including interfering substances.
- Reference intervals (normal values).
- Imminently life-threatening test results, or panic or critical values.
- Pertinent literature references.
- Laboratory's system for entering results in the patient record and reporting patient results, including, when appropriate, the protocol for reporting panic or critical test results.
- Description of the course of action to take if a test system becomes inoperable.

#### **#1 – D5805 §493.1283 Standard: Test report.**

The test report must indicate the following:

- For positive patient identification, either the patient’s name and identification number, or a unique patient identifier and identification number.
- Name and address of the laboratory location where the test was performed.
- Test report date.
- Test performed.
- Specimen source, when appropriate.
- Test result and, if applicable, the units of measurement or interpretation, or both.
- Any information regarding the condition and disposition of specimens that do not meet the laboratory’s criteria for acceptability.

<b>COMPARISON OF DEFICIENCIES CITED IN IOWA TO NATION*</b>		
<b>RANKING</b>	<b>IOWA</b>	<b>NATION</b>
<b>#1</b>	<b>D5805</b>	<b>D5413</b>
<b>#2</b>	<b>D5403</b>	<b>D5217</b>
<b>#3</b>	<b>D5429</b>	<b>D5791</b>
<b>#4</b>	<b>D5217</b>	<b>D5411</b>
<b>#5</b>	<b>D2016</b>	<b>D5403</b>
<b>#6</b>	<b>D5787</b>	<b>D5291</b>
<b>#7</b>	<b>D5435</b>	<b>D6021</b>
<b>#8</b>	<b>D5431</b>	<b>D5417</b>
<b>#9</b>	<b>D3031</b>	<b>D5805</b>
<b>#10</b>	<b>D5891</b>	<b>D6000</b>

**\*Nation Deficiencies NOT in Iowa’s Top 10**

**Nation #1 – D5413** §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, supplies.

**(Iowa citation ranking #11)**

The laboratory must define criteria for those conditions that are essential for proper storage of specimens and reagents, accurate and reliable test system operation, and test result reporting. These conditions must be monitored and documented.

**Nation #3 – D5791** §493.1289 Standard: Analytic systems quality assessment.

**(Iowa citation ranking #12)**

The laboratory must establish and follow written policies and procedures for an ongoing quality assessment (QA) plan to monitor and assess the requirements of **Analytic System**, as well as the corrective action process when problems or potential problems are identified. QA of Analytic System includes assessing practices/issues related to test procedure; accurate and reliable test systems, equipment, reagents and supplies; specimen and reagent storage, test system maintenance and function checks, establishment and verification of performance specifications; calibration and calibration verification; control procedures; comparison of test results; test records; and corrective action.

**Nation #4 – D5411** §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, supplies.

**(Iowa citation ranking #14)**

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.

**Nation #6 – D5291 §493.1239 Standard: General systems quality assessment.**

The laboratory must establish and follow written policies and procedures for an ongoing quality assessment (QA) plan to monitor and assess the requirements of **General System**, as well as the corrective action process when problems or potential problems are identified. QA of General System includes assessing practices/issues related to patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance.

**Nation #7 – D6021 §493.1407 Standard: Laboratory director responsibilities.  
(Iowa citation ranking #13)**

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

### **References**

State Operations Manual, *Appendix C- Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services*; Centers for Medicare and Medicaid Services (CMS); published January 12, 2004.

### **Contact Information:**

**If you want to be added to our e-mailing list, need a change of address, or have a question or topic suggestion for the CLIA Corner you can contact either Kristi Rotzoll at [krotzoll@uhl.uiowa.edu](mailto:krotzoll@uhl.uiowa.edu) or Nancy Grove at [ngrove@uhl.uiowa.edu](mailto:ngrove@uhl.uiowa.edu).**