



# CLIA BITS



North Dakota Department of Health  
Division of Health Facilities Winter 2008

## **CLIA Quality Systems Assessment (Part 3 of a continuing series) Analytic Systems – 493.1250-493.1289**

Analytic Systems is the third of four quality systems. Analytic Systems includes laboratory activities related to the actual testing of patient specimens. The components of analytic systems include the following: procedure manual, test systems, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification, control procedures, comparison of test results and test records.

A procedure manual must be available and followed. The current laboratory director must approve, sign and date all procedures. This duty may not be delegated. Operator's manuals and package inserts may be used as procedures, but they must address the specifics for each laboratory and they must be approved by the laboratory director.

The laboratory selects test systems, equipment, instruments, reagents, materials and supplies. Testing must be performed following the manufacturer's instructions. Conditions essential for proper operation of reliable tests systems must be monitored and documented. These conditions include water quality, temperature, humidity and fluctuations in electrical current. Reagents and supplies must be properly

**ASCLS-ND  
Spring Break in Oh-8  
April 23-25, 2008  
Radisson Inn, Bismarck**

The North Dakota Department of Health CLIA staff will be presenting "Let's Talk CLIA."

See [www.asclsnd.org](http://www.asclsnd.org) for more information and registration forms.

labeled with identity, storage requirements, and preparation and expiration dates. Reagents and supplies must not be used when they have exceeded their expiration date or are of substandard quality. Kit components of different lot numbers may not be interchanged unless specified by the manufacturer.

When a laboratory introduces an unmodified test system approved by the Federal Drug Administration (FDA), performance specifications must be verified. The laboratory must demonstrate it can obtain performance specifications comparable to

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those established by the manufacturer for accuracy, precision and reportable range. The laboratory must verify the reference range is appropriate for its patient population. If the laboratory modifies an FDA-approved test system, performance specifications must be established. The laboratory must establish accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference range. Laboratory modifications could include a change in incubation time or temperature, a change in dilution or using a different specimen type (urine instead of serum). Maintenance and function checks must be performed and documented as specified by the manufacturer. Function checks must be within the established limits before patient specimens are tested. If the manufacturer has no requirements and the laboratory determines maintenance or function checks are necessary to ensure accurate and reliable test results, the laboratory must establish its own protocol.

The laboratory must calibrate following the manufacturer's instructions. Calibration verification must include minimal, mid-point and maximum values. Calibration verification must be performed following the manufacturer's instructions; following the laboratory's policies; at least once every six months; when a complete change of reagents occurs; after major preventive maintenance or replacement of critical parts; and when control values shift, trend or are outside acceptable limits with no explainable cause. Calibration verification is not required if the laboratory performs calibration using three or more calibrators with a low, mid and high value at least every six months or if two levels of control are run each day of testing on an automatic cell counter.

The laboratory must have control procedures for each test system that monitor the accuracy and precision of the complete analytic process. The laboratory must establish the number, type and frequency of testing control materials or follow the manufacturer's specifications. The control procedures must detect immediate errors and monitor the accuracy and precision over time. Perform control procedures in the same manner as patient specimens. Rotate the testing of control materials among all personnel operating the test system. The laboratory must establish or verify acceptable limits for all control materials. Statistical parameters (mean and standard deviation) must be determined for each batch and lot number of control materials. Results of control materials must meet the laboratory and/or manufacturer's acceptable criteria before patient results are reported.

If the same test is performed using different methods or instruments or at multiple sites, the laboratory must evaluate test results between the different methods, instruments or testing sites at least twice a year. The laboratory must establish criteria for acceptable differences. Monitor and evaluate test results for inconsistencies with patient information and in relationship with other test parameters.

The laboratory must maintain test records that include positive identification of the specimen, date and time of specimen receipt, unacceptable specimens, records and dates of all testing and identity of personnel who performed the testing.

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## **Most Commonly Cited Deficiencies**

Analytic System areas to consider monitoring include:

- Availability of test procedures and approval by laboratory director.
- Manufacturer's instructions being followed.
- Recording of temperature and humidity.
- Proper labeling.
- Proper storage conditions.
- Expiration dates.
- Performance and documentation of maintenance and functions checks.
- Calibration performance.
- Calibration verification on required test systems.
- Control procedures performed as required.
- Corrective action performed as necessary and documented.
- Comparison of test results at least twice annually.
- Evaluation of inconsistent test results.
- Retention of instrument printouts.
- Positive identification of the specimen.
- Identification of the testing personnel.

Quality assessment is an ongoing process covering all functions of the laboratory. Analytic Systems encompasses a large part of laboratory activities. Make sure your laboratory is effectively monitoring Analytic Systems.

Sources: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CLIA Basic and Beyond Training Sept. 2006; National Laboratory Training Network Teleconference Jan. 19, 2006.

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2006, through Sept. 30, 2007.

**D5805 – Test Report.** The test report must include the patient's name and identification number, name and address of laboratory, report date, specimen source (when appropriate), test result, units of measurement or interpretation and unacceptable specimens.

**D5217 – Evaluation of Proficiency Testing Performance.** The laboratory must verify the accuracy of any nonregulated analyte at least twice a year.

**D5413 – Test Systems, Equipment, Instruments, Reagents.** The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens. These conditions must be monitored and documented.

**D5215 – Evaluation of Proficiency Testing Performance.** The laboratory must verify the accuracy of any assigned proficiency testing score that does not reflect laboratory test performance.

**D5417 – Test Systems, Equipment, Instruments, Reagents.** The laboratory must not use reagents and supplies when they have exceeded their expiration date or are of substandard quality.

Take a look at your laboratory to see if it is deficient in these areas. If so, take corrective action to fix the problem areas before your next survey.

## **Reminder to Review Package Inserts**

Due to a change in manufacturer, certain mono tests now indicate that children younger than 18 were not included in the clinical trials. This means these kits are not Federal Drug Administration approved for children younger than 18 and should not be used for testing this population.

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## **QUESTIONS AND ANSWERS (Q & A)**

The Centers for Medicare and Medicaid Services (CMS) provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. Readers are welcome to submit questions to [bweidner@nd.gov](mailto:bweidner@nd.gov) or [sheilman@nd.gov](mailto:sheilman@nd.gov)

### ***Q. Do CLIA proficiency testing requirements apply to waived testing?***

A. No. Waived testing is not subject to the proficiency testing requirements unless the manufacturer requires it.

### ***Q. What do laboratories do about proficiency testing if they don't perform certain tests during certain times of the year (e.g., influenza testing not offered in the summer months)?***

A. Special consideration may be given for non-participation. The laboratory must notify the proficiency testing company and their state agency in a timely fashion, and the laboratory must have participated in the previous two events.

### ***Q. If a reference laboratory report is scanned into the patient's chart, does the laboratory need to keep a hard copy?***

A. If the scan is an exact copy, the laboratory does not need to keep a hard copy.

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