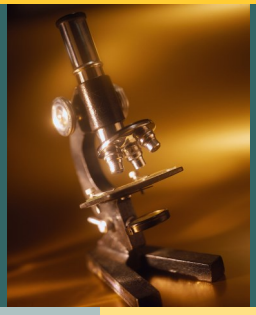
Fall 2016



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

Most Commonly Cited Deficiencies

A breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2015, through Sept. 30, 2016 is as follows:

D2016 — Successful Participation in Proficiency Testing. Each laboratory performing non-waived testing must successfully participate in an approved proficiency testing program.

D6046/D6120 — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating the competency of all testing personnel and assuring the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

D5421 — Establishment and Verification of Performance. Verification of performance specifications. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate it can obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, and reportable range before reporting patient test results. The laboratory must also verify the manufacturer's reference intervals are appropriate for the laboratory's patient population.

D5439 — Calibration and Calibration Verification. The laboratory must perform and document calibration verification procedures at least once every six months. For exceptions, see the CLIA regulations at 493.1255(b).

D5471 — Control Procedures. Check each batch, lot number, or shipment of media, reagents, disks, antisera and identification systems when opened for positive and negative reactivity.

D5481 — Control Procedures. Laboratory must document all control procedures performed.

D6102 — Laboratory Director Responsibilities. The laboratory director must ensure that prior to testing patients' specimens, all personnel receive the appropriate training and have demonstrated they can perform all testing operations reliably to provide and report accurate results.

Inside this issue:

If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at bweidner@nd.gov.

Multiple-Site Exceptions

Each location performing laboratory testing must have its own CLIA certificate unless it meets one of the following exceptions:

- Laboratories not at a fixed location (temporary testing site) may test under the CLIA certificate and address of the designated primary site or home base.
- Not-for-profit or Federal, State or local government laboratories that engage in limited (not more than a combination of fifteen moderately complex or waived tests per certificate) public health testing may operate under one CLIA certificate.
- Laboratories within a hospital that are located at contiguous building on the same campus and under common direction. The laboratory sites must be within the same physical location or street address.

What is a temporary testing site? Mobile units, health screening fairs or other temporary testing locations are considered temporary testing sites.

A mobile laboratory is a movable, self-contained laboratory with its own personnel, equipment and records. The equipment must be installed and remain permanently within the unit. The laboratory testing must be performed within the vehicle. A vehicle used to transport laboratory equipment from a home base to another location where the equipment is removed from the vehicle and taken into another location is not considered a mobile unit.

In order to qualify as a temporary testing site, the personnel, equipment, supplies, reagents, records and files must not be stored at the testing site permanently. The primary site or home base is where the staff is based and where equipment, supplies and records are stored. The primary site or home base maintains the CLIA certificate. Temporary testing sites may be located in different states as long as state and local laws do not prohibit this.

How does the temporary testing site exception apply to home health agencies (HHAs)? The parent branch may be designated as the home base for CLIA certification and the patients' homes would be considered the temporary testing sites. Multiple branches of an HHA may test under the parent branch's CLIA certificate, if they operate under the parent's provider number. HHA subunits have their own provider numbers, so they must have their own CLIA certificate.

Remember any action taken against a CLIA certificate affects all sites operating under the primary site or home base. The laboratory director named on the CLIA certificate of the primary site or home base is responsible for quality testing performed at all the sites.

The second and third multi-site exceptions will be included in future editions of CLIA Bits.

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories; Centers for Medicare & Medicaid Services Survey & Certification Letter 12-09

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