



Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2010, through Sept. 30, 2011.

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

D5407 — Procedure Manual. Procedures and changes in procedures must be approved, signed and dated by the current laboratory director before use.

D2010 — Testing of Proficiency Samples. The laboratory must test samples the same number of times that it routinely tests patient samples.

D5401 — Procedure Manual. A written procedure manual for all tests performed by the laboratory must be available to and followed by laboratory personnel.

D5417 — Test Systems, Equipment, Instruments, Reagents, Materials and Supplies. Reagents, solutions, culture media, control materials and other supplies must not be used when they have exceeded their expiration date, have deteriorated or are of substandard quality.

D5421 — Establishment and Verification of Performance. Each laboratory that introduces a test method must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: accuracy, precision and reportable range of test results. The laboratory also must verify over time that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

D5439 — Calibration Verification. Calibration verification must be performed at least once every six months. See CLIA regulations at 493.1255(b) for more details.

D5439 — Control Procedures. For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

Inside this issue:

Most Commonly Cited Deficiencies	1
The Laboratory Director's Role in the Laboratory	2
Reagent Quality Control	2



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.

The Laboratory Director's Role in the Laboratory

The laboratory director ultimately is responsible for the overall operation and administration of the laboratory. The laboratory director may delegate duties to other qualified personnel, but he or she remains responsible for ensuring the duties are properly performed. The laboratory director does not need to be on-site, but must be accessible by telephone or electronically to provide consultation to the laboratory. The laboratory director must specify in writing the responsibilities and duties of laboratory personnel. If the laboratory director has delegated duties to others, this must also be in writing.



The laboratory director must ensure:

- The laboratory provides quality services.
- The physical plant and environment are appropriate and safe.
- Test methods provide quality results, are verified and are performed properly.
- The laboratory is enrolled in proficiency testing, tests samples as required, submits results timely, reviews results and performs corrective action if necessary.
- The laboratory has effective quality control and quality assessment programs.

- The laboratory identifies failures in quality and takes remedial action when necessary.
- Patient results are reported only if the test system is functioning properly.
- The test reports include pertinent information and consultation is available to the laboratory's clients.
- The laboratory employs a sufficient number of qualified personnel.
- The testing personnel have adequate education and experience and appropriate training.
- A general supervisor provides on-site supervision of testing personnel for high complexity testing.
- The laboratory personnel are competent.
- An approved procedure manual is available.

The laboratory director may not delegate the duty of approving, signing and dating of policies and procedures. Each laboratory director may direct no more than five non-waived CLIA certified laboratories. CLIA does not limit the number of laboratories an individual may serve as technical consultant/supervisor or clinical consultant. For more details regarding laboratory director's responsibilities, see the CLIA regulations at 493.1445 for high complexity testing and 493.1407 for moderate complexity testing.

Reagent Quality Control

Does your laboratory check potassium hydroxide (KOH) reagent for quality? According to the CLIA regulations at 493.1256(e), the laboratory must check each batch, lot number and shipment of reagents when prepared or opened. The results must be documented.

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services and State Operations Manual, Chapter 6 - Special Procedures for Laboratories



*CLIA Bits is published by:
Division of Health Facilities
North Dakota Department of Health
600 E. Boulevard Ave., Dept. 301
Bismarck, N.D. 58505-0200
Phone: 701.328.2352
Fax: 701.328.1890
Web: www.ndhealth.gov*

*Terry Dwelle, M.D., M.P.H.T.M., State Health Officer
Darleen Bartz, Ph.D, Chief, Health Resources Section
Bruce Pritschet, Director, Health Facilities
Bridget Weidner, Program Manager
Shelly Heilman, CLIA Surveyor
Rocksanne Peterson, Newsletter Design*