

Winter 2018



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 Clinical Laboratory Improvement Amendments (CLIA) program from Oct. 1, 2016, through Sept. 30, 2017 is as follows:

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

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.

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.

D6054/6128 — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating the competency of all testing personnel at least annually.

IQCP Reminders

We have reached the second anniversary of the official start of Individualized Quality Control Plan (IQCP). Here are some reminders:

- IQCP is voluntary. The laboratory may perform CLIA default quality control and, therefore, would not need to develop an IQCP.
- The Risk Assessment must include the following areas: specimen, test system, reagent, environment, and testing personnel.
- The Quality Control Plan must at least include the number, type and frequency of testing control materials, as well as criteria for acceptability.
- Quality Assessment for the IQCP must be established and monitor the ongoing effectiveness of the IQCP. Quality assessment must include the following: specimen, test system, reagent, environment, and testing personnel. The laboratory's quality assessment monitoring must be spelled out in the IQCP.
- The data used to develop the IQCP must be retained for the life of the IQCP plus two years. Most IQCPs were developed using 2015 laboratory data. Now that 2017 has ended, make sure the lab has a plan to retain all the data used to support the IQCP.

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.

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Notification Requirements

As of Feb. 4, 2017, CLIA has a new process for changing lab directors in accredited labs. The CLIA state agencies will no longer be processing the lab director changes for accredited labs. Accredited labs must notify their accrediting agencies who will make the lab director change in the CLIA system. Please make sure to notify the accrediting agency of the lab director change. As a courtesy, the accrediting agency may have the laboratory notify the CLIA state agency (a new CLIA application form is not necessary).

In summary, as of Feb. 4, 2017, the accrediting agencies will make changes in the CLIA system for certificates of accreditation for directors and will continue to make specialty changes. The accrediting agency will be responsible for ensuring the new director possesses the appropriate qualifications.

Accredited labs must notify the CLIA state agency and submit a new CLIA application form for the following changes:

- Certificate type (e.g. accredited to waived).

- Change of ownership (contact our office for other required information to submit).

Provider Performed Microscopy (PPM) labs must notify the CLIA state agency and submit a new CLIA application form for the following change:

- Lab director (with evidence of qualifications)

Accredited, compliance, PPM or waived labs must notify the CLIA state agency in writing for the following changes (CLIA application form not required):

- Name
- Physical location
- Mailing address
- Telephone and/or fax numbers
- Multiple sites - addition or deletion
- Waived lab director changes
- Voluntary termination of CLIA certificate

Initial applications will be processed by the CLIA state agencies. The state agencies will require evidence of qualifications for new lab directors to be submitted with initial applications for certificates of accreditation, compliance, and PPM.

Modified Test Systems

If the laboratory changes the manufacturer's instructions, the test system is considered modified. The changes could affect the performance specifications for sensitivity, specificity, accuracy or precision. A change in the intended use of a test system is also considered a modification. Examples of test system modifications include:

- Change in specimen handling instructions;
- Change in incubation times or temperatures;
- Change in dilution of specimen or reagent;
- Change or elimination of a procedural step;
- Using a different sample matrix;
- Using a screening test for diagnostic purposes; and
- Using qualitative results to report quantitative results.



A modified test system is considered uncategorized for CLIA and defaults to high complexity test categorization. This applies to moderate complexity and waived test methods.



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. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q: Laboratories that receive urine specimens for drug testing often perform a preliminary test on the specimen to determine whether the sample was adulterated. Does urine adulteration testing fall under CLIA?

A: In general, urine adulteration testing is not considered to be subject to CLIA if the results are used to accept or reject the specimen. CLIA does not apply if the only information reported is pass/fail. However, if actual result values are reported, then the testing becomes subject to CLIA, even though the original purpose of the testing was to detect urine adulteration.

Q: How many waived laboratories can a laboratory director be affiliated with?

A: CLIA does not restrict the number of waived laboratories a laboratory director is affiliated with. It is the laboratory director's decision on how many waived labs to direct. The laboratory director is responsible for ensuring quality patient results for all their laboratories.

Q: Our laboratory has a protocol to centrifuge bloody urine samples and retest the urine dipstick (waived method) using the supernatant. Would this be considered a test modification?



A: The laboratory must follow the manufacturer's instructions for use of the dipstick test. The manufacturer's instructions must clearly state that the urine specimen can be centrifuged and retested. If they do not, this would be considered a modification to the test system. The waived dipstick test would default to a high complexity test.

Q: Our laboratory implemented an Individualized Quality Control Plan (IQCP) for several non-waived tests. If we already monitor specimen acceptability and performance of testing personnel competency evaluations as part of our quality assessment (QA) program, do we need to list these in the QA section of our IQCPs?

A: Yes, the IQCP should specifically list the QA areas that will be assessed to monitor the effectiveness of the IQCP.



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, Center for Clinical Standards and Quality/Survey & Certification Group, Admin Info: 16-17-CLIA.



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