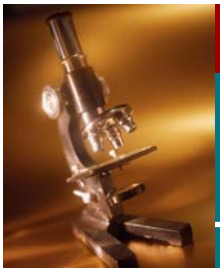

DIVISION OF HEALTH FACILITIES

CLIA BITS

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Spring 2020

Most Commonly Cited Deficiencies

A breakdown of the most common deficiencies cited in the North Dakota Clinical Laboratory Improvement Amendments (CLIA) program from Jan. 1, 2019, through Jan. 31, 2019 is as follows:

D2000 — Condition: Enrollment and testing of samples. Each laboratory must enroll in an approved proficiency testing (PT) program for each of its specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.

D2013 — Laboratories must not send proficiency testing samples to another laboratory for analysis. Any laboratory that receives a proficiency testing sample from another laboratory must notify Centers for Medicare & Medicaid Services (CMS).

D5805 — The test report must include the date the test results were generated as a final report and must include the address of the testing location.

D6076 — Condition: Laboratory Director of High Complexity Testing. The laboratory must have a laboratory director who provides overall management and direction of the laboratory.

D6078 — The high complexity laboratory director must ensure proficiency samples are tested as required.

D5421 — The laboratory must verify performance specifications of unmodified, FDA approved test system before reporting patient results. This includes accuracy, precision, reportable range, and verification the normal values are appropriate.

Corrected Test Reports

The laboratory must promptly notify the individual who ordered the test and the individual using the test results when errors in test reporting are detected. The laboratory must document the time when the error was identified and when the individuals were notified of the error. Errors may include: incorrect patient identification, test results, normal ranges, or other significant information. A corrected report must be promptly issued to the individual who ordered the test and the individual using the test results. The corrected report must be clearly labeled as a corrected report and include the corrected results. The laboratory must have a system for maintaining the original and corrected results.

Laboratory Panic Values

The laboratory must establish values considered panic, alert, or critical values or results that could indicate an imminently life-threatening condition. This must be included in the procedure manual, along with the mechanism to report the panic values. The laboratory must document the date, time, test results, and the person to whom the panic results were reported. This may be documented on the patient test report or in other laboratory records, such as a panic value log.

Coronavirus Laboratory Testing

For more information on Coronavirus testing please check updates at the Federal Drug Administration (FDA) website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2.

Inside this issue:

Questions and Answers (Q & A)

The Q & A section is a regular feature of the CLIA Bits newsletter. Questions originate from Centers for Medicare & Medicaid Services (CMS) specialized trainings for CLIA surveyors, CMS Quality, Safety & Oversight Group (QSO) memos, and laboratories. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Please note: accredited laboratories should check with their accrediting agencies as their requirements may differ.

Q: May a laboratory use a test system that has not been approved by the FDA or does not have an Emergency Use Authorization (EUA)?

A: Yes, but according to CLIA, these tests are considered high complexity. The laboratory must follow all the CLIA requirements for testing, including verification of performance specifications. If the manufacturer has established performance specifications, the laboratory must verify the performance. If the manufacturer has not established performance specifications, the laboratory must establish the performance specifications themselves. In addition, the laboratory must follow the personnel requirements for high complexity testing.

Q: What COVID-19 test systems have received an Emergency Use Authorization (EUA)?

A: All in vitro diagnostic tests that have received an Emergency Use Authorization (EUA) for COVID-19 testing can be found on the FDA's website at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

Q: May a laboratory perform COVID-19 testing in their parking lots or other areas outside of the laboratory?

A: As long as the facility has the appropriate CLIA certificate and follows applicable CLIA regulations, state regulations and guidelines, the laboratory may perform testing in the parking lot or any other designated overflow location in its facility. The lab director must approve of the outside testing as they are ultimately responsible for all operations of the laboratory.

Q: Does the laboratory need to verify performance specifications for qualitative (positive/negative) test systems?

A: Yes, the requirements for verification of performance specifications applies to qualitative test systems.

"What you do makes a difference, and you have to decide what kind of difference you want to make."
~ Jane Goodall

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories; Center for Clinical Standards and Quality/Survey & Certification Group QSO-20-21-CLIA.

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

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
www.ndhealth.gov/HF

Mylynn Tufte, MBA, MSIM, BSN, State Health Officer
Tim Wiedrich, Section Chief, Health Resources & Response Section
Bruce Pritschet, Director, Health Facilities
Bridget Weidner, Program Manager
Shelly Heilman, CLIA Surveyor
Rocksanne Peterson, Newsletter Design