Winter 2019

CLIA BITS

DIVISION OF HEALTH FACILITIES

NORTH Dakota | Health

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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, 2017, through Sept. 30, 2018 is as follows:

D2009 — Testing of Proficiency Testing Samples. The individual testing proficiency samples and the laboratory director (or designee) must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

D5217— Evaluation of Proficiency Testing Performance. At least twice annually, the laboratory must verify the accuracy of any test or procedure not included in subpart I (not regulated).

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.

Evaluation of Proficiency Testing Results

The laboratory director must ensure proficiency testing (PT) results are reviewed by the appropriate staff to evaluate the laboratory's performance and determine if corrective action is necessary. Unacceptable or unsatisfactory results need to be investigated and corrective action performed. Acceptable or satisfactory results less than 100% should be investigated and corrective actions performed, if necessary. Left ignored, these scores may lead to unacceptable or unsatisfactory scores in future events.

The PT program may assign a score that does not reflect laboratory test performance. If there are less than ten participants for an analyte or the needed agreement is not obtained, an artificial score will be assigned. If the laboratory does not test a proficiency specimen or the submission deadline is missed, the PT program will assign a zero score. In these situations, the laboratory must verify the accuracy of the results not reflecting true laboratory performance.

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Inside this issue:

Proficiency Testing Reminders

Test proficiency samples in the same manner as patient specimens with the primary method used for patient testing.

Test and report proficiency samples to the degree the testing is performed in-house. Do not send proficiency samples to another laboratory for confirmatory testing even if that is what is done for patient samples.

If more than one instrument or method is used for the same test, the laboratory may alternate testing events with the different instruments/methods if both are routinely used for patient testing.

Test proficiency samples with the regular patient workload by personnel who routinely test patient samples using the laboratory's routine methods.

The individual testing proficiency samples and the laboratory director must attest to the routine integration of samples into patient workload using the laboratory's routine methods. The laboratory director may designate a qualified technical supervisor or technical consultant to sign the attestation statements. Keep in mind the technical supervisor qualifications for immunohematology.

Test proficiency samples the same number of times routinely used for patient samples.

Do not engage in inter-laboratory communication regarding the proficiency testing samples until after the submission deadline.

Multi-laboratory systems must not communicate regarding the proficiency testing samples until after the submission deadline.

Do not send proficiency samples or portions to another laboratory for testing.

Rotate proficiency testing among testing personnel. Each individual should test all five samples for that event (unless the laboratory routinely uses more than one individual to perform patient testing).

Document the handling, preparation, processing, examination, and each step in the testing and reporting of proficiency samples (including reconstitution, thawing, warming, mixing, dilution calculations, unit conversions, etc.).

Maintain the proficiency testing results, report forms, instrument printouts, and attestation statements for two years.

Questions and Answers (Q&A)

Q: The lab has two identical blood gas analyzers used alternately for patient testing. Must the lab enroll in proficiency testing for each instrument?

A: No, proficiency testing enrollment is based on analyte, so only one enrollment is needed. The lab may alternate testing events with the different instruments. Keep in mind if laboratories use different methods or instruments for the same analyte, the laboratory must have a system that twice annually compares the results from the different methods or instruments. The laboratory must have written criteria for acceptable differences in test values.

Q: May the laboratory repeat testing on proficiency testing samples before submitting their results to the proficiency testing program?

A: The laboratory must treat proficiency samples the same as patient samples. If the laboratory would repeat patient testing for the same results, the proficiency sample may be repeated. Documenting the reason for the repeat testing is suggested (for example: elevated white blood cell count).

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

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