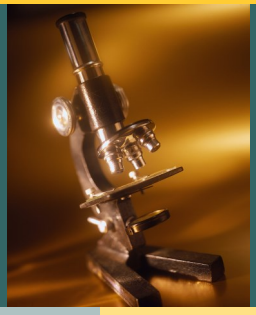
Fall 2015



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

Most Commonly Cited Deficiencies

The following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2014, through Sept. 30, 2015.

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

D5391 — Preanalytic Systems Quality Assessment. The laboratory must develop and implement policies and procedures to monitor, assess, and correct problems in the preanalytic systems.

D5217 — Evaluation of Proficiency Testing Performance. At least twice annually the laboratory must verify the accuracy of non-regulated analytes.

D6054/D6128 — Technical Consultant/Technical Supervisor Responsibilities. The technical consultant/technical supervisor is responsible for evaluating and documenting the performance of moderate/high complexity testing personnel at least annually.

D5451 — Control Procedures. Test procedures with graded results must have a negative control material and a graded control material performed each day of patient testing.

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

D6029 — Laboratory Director Responsibilities. Ensure that all testing personnel are appropriately trained before testing patient specimens.

D5413 — 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.

D5805 — Test Report. The test report must include the name and address of the laboratory location where the test was performed.

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.

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: What must be included in an Individualized Quality Control Plan (IQCP)?
A: IQCP consists of three parts; Risk Assessment, Quality Control Plan and Quality Assessment. For more details check the CMS CLIA website at www.cms.hhs.gov/clia.

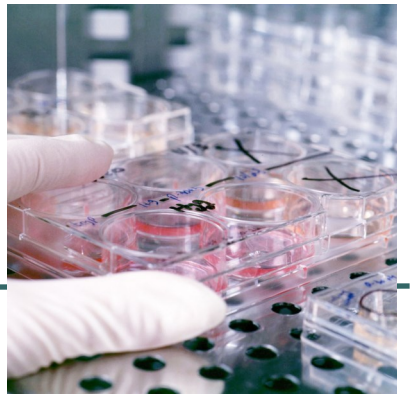
Q: Will the development of an IQCP reduce the frequency of quality control (QC) performance?
A: The development of an IQCP helps laboratories establish an effective QC protocol that is unique to their lab, taking into account their risks associated with patients, environment, specimens, testing personnel, test systems and reagents While not necessarily reducing the frequency of QC performance, the IQCP will help the lab establish the "right" QC protocol for their laboratory.

Q: Are all tests eligible for IQCP?
A: All CLIA specialties are eligible for IQCP, except pathology.

Q: When will the education and transition period for IQCP end?
A: It will end Jan. 1, 2016. After Jan. 1, 2016, laboratories must perform CLIA default QC or have implemented an IQCP.

Q: If the laboratory chooses to perform CLIA default QC for a test, do they need to develop an IQCP for that test?
A: No, IQCP is not necessary if CLIA default QC will be performed. Note: Equivalent Quality Control (EQC) will not be acceptable after Jan. 1, 2016.

Q: How many samples does the laboratory need to run for IQCP?
A: The CLIA regulations are not prescriptive about the amount of data used to develop an IQCP. The laboratory should use in-house data produced in their own environment by their own personnel. The laboratory should include historical data when developing an IQCP. It is up to the laboratory director to determine the amount of data to be included in the IQCP.



Microbiology Quality Control Changes

On May 29, 2015, The Centers for Medicare and Medicaid Services (CMS) released the revised Clinical Laboratory Improvement Amendments (CLIA) interpretive guidelines. The references to Clinical Laboratory Standards Institute (CLSI) and CLSI documents have been removed. This affects the media quality control (QC) requirements found in the CLIA regulations at 493.1256(e)(4). Laboratories are now required to perform end-user QC for all media or implement an Individualized Quality Control Plan (IQCP) to validate reduced QC frequency. The CLIA regulations for susceptibility testing requirements at 493.1261(b) are also affected with this change. Laboratories must now perform QC on each day of patient testing or implement an IQCP to validate reduced QC frequency. Please note the removal of CLSI references from the CLIA regulations only affects media and susceptibility QC found at 493.1256(e)(4) and 493.1261(b). All other microbiology CLIA QC requirements remain the same and do not need an IQCP if the laboratory follows the CLIA requirements.

Proficiency Testing Enrollment

Proficiency testing is used as a barometer to indicate the laboratory's ability to produce accurate and reliable patient results. Laboratories must enroll in a Centers for Medicare & Medicaid Services (CMS) approved proficiency program for all non-waived, regulated analytes (those listed in Subpart I of the CLIA regulations). A list of approved proficiency programs and the CLIA regulations may be found on the CMS CLIA website at www.cms.hhs.gov/clia.

Laboratories with multiple sites operating under the same CLIA certificate must enroll each analyte in a proficiency testing program. Laboratories with multiple sites do not enroll in proficiency testing for each site; rather, they enroll per analyte. The laboratory must not split samples within an event to be performed at different sites. Each event may be alternated between the different sites. When a laboratory has multiple sites performing the same tests, the laboratory must have a system to compare results twice a year.

Laboratories may perform testing of an analyte using different methodologies or instruments. Only one proficiency testing enrollment is required per analyte. The laboratory should test the proficiency testing samples with the primary method at the time of the proficiency testing event. The laboratory must not split samples within an event to be performed with different testing methods. The other methods must be compared with the primary testing method twice a year to evaluate and define the relationship between the different methods or instruments.

Keep in mind, if a laboratory has unsuccessful proficiency testing performance and sanctions are imposed, this action affects the testing of that particular analyte, subspecialty or specialty in all sites operating under the same CLIA certificate and for all methods or instruments used to perform the testing.

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories; CLIA Western Division Meeting May 2015; IQCP National Surveyor training Nov. 2013; FAQs for ICP by CMS, revised April 2015; Centers for Medicare and Medicaid Service Survey and Certification Letters 13-54 and15-07; CMS CLIA website at www.cms.hhs.gov/clia.

IQCP is Approaching

Reminder: The end of the education and transition period for Individualized Quality Control Plan (IQCP) is Jan. 1, 2016. Laboratories must perform CLIA default quality control or implement IQCP by the end of the education and transition period. For more information on IQCP, please visit the Centers for Medicare & Medicaid Services (CMS) website at www.cms.hhs.gov/clia. The Centers for Disease Control and Prevention and CMS have partnered to develop a tool laboratories may use as a guide for implementing IQCP. The workbook titled "Developing an IQCP, a Step-by-Step Guide" is available on the CMS website at www.cms.hhs.gov/clia.

Laboratories may contact manufacturers for guidance on IQCP. Many manufacturers have also developed tools to aid in the development of an IQCP.

The laboratory must use supporting data to develop their IQCP. The data will be reviewed along with the IQCP. Be sure your data is readily retrievable. The data must be retained for the life of the IQCP plus two years after discontinuance. Do you have a plan for retention of your IQCP data?

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