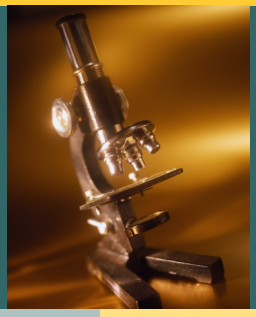
Summer 2015



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

Microbiology Changes

On Oct. 31, 2014, Centers for Medicare and Medicaid Services (CMS) released Survey and Certification (S&C) Letter 15-07 announcing the removal of references to Clinical Laboratory Standards Institute (CLSI) and CLSI documents. An education and transition period will be in effect until the Clinical Laboratory Improvement Amendments (CLIA) interpretive guidelines are revised.

This affects the media quality control (QC) requirements found in the CLIA regulations at 493.1256(e)(4). References to CLSI allowed exceptions to the media QC requirements for certain categories of commercially prepared media. With the change, laboratories will need 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. Reference to CLSI allowed for streamlined QC. With the change, laboratories will need to perform QC on each day of patient testing or implement an IQCP to validate reduced QC frequency.

Currently, laboratories have three options for media and susceptibility QC compliance for CLIA:

- Follow CLIA QC regulations for end-user media QC and perform QC for susceptibility testing each day of patient testing.
- Follow alternate QC requirements based on CLSI standards.
- Implement IQCP.

At the end of the education and transition period, laboratories will need to follow all applicable CLIA regulations or implement IQCP.

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.

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: My laboratory performs waived testing. Do we need to follow the manufacturer's recommendations?

A: CMS requires laboratories performing waived testing to follow manufacturer's instructions. If the manufacturer uses terms such as "always," "must," "require," "shall," "test," "perform," or "do," the instructions are regulatory and the laboratory must comply. CMS was considering a change for waived testing requiring laboratories to also comply with manufacturer's recommendations (terms such as "recommend," "suggest," "may," or "should"). Upon further review, it was determined there was no legal basis for this. Laboratories performing waived testing are encouraged to follow the manufacturer's recommendations as "good laboratory practice," but it is not mandatory.

Q: I understand that CMS regulations now allow the laboratory to provide patients access to their laboratory reports. If a patient requests their reports from the laboratory, may the lab direct the patient to the medical records department?

A: The laboratory must have a system in place to handle requests from patients for their lab reports. The lab may direct the patient to medical records if the lab has established this as their policy for patient access to laboratory reports.

Q: My facility uses a waived blood glucose meter with manufacturer's instructions including a limitation on use for "critically ill" patients. If we would like to use the glucose meter for these patients, what are our options?

A: This would be considered "off-label" use and the testing automatically defaults to high complexity. The facility must obtain the proper CLIA certificate (certificate of compliance or accreditation). All non-waived requirements must be followed, including quality control, proficiency testing, quality assessment, etc. In addition, the facility must establish performance specifications for the instrument and the high complexity laboratory personnel requirements must be met.

Q: Do laboratories need to develop an Individualized Quality Control Plan (IQCP) to continue performing Quality Control (QC) with each new lot/shipment of catalase reagent or weekly for Gram stains?

A: No, the CLIA regulations for those areas have not changed.

- 493.1256(e) - check each batch, lot number and shipment of reagents, disks, stains, antisera (except those referenced in 493.1261(a)(3)), and identification systems when opened for positive and negative reactivity.
- 493.1261(a)(2) - check for positive and negative reactivity using control organisms each week of use for Gram stains.

Laboratories who follow the regulations (CLIA default QC requirements), do not need to develop an IQCP. Laboratories who wish to decrease the frequency stated in the regulations, need to develop an IQCP.

Waived Glucose Testing

For all waived testing, the laboratory must follow the manufacturer's instructions. Pay particular attention to the intended use and limitations. Some manufacturers have not evaluated the use of their instruments under certain medical conditions or for certain populations, such as critically ill patients. If the laboratory uses the test system outside of FDA approved or cleared use, it is considered "off-label" use.

"Off-label" use is a modification of the test system. The test system automatically defaults to high complexity testing. CLIA does not prohibit the "off-label" use of test systems, but the laboratory must meet the additional requirements for high complexity testing. The laboratory must obtain the proper CLIA certificate, either a certificate of compliance or accreditation. Performance specifications must be established for accuracy, precision, sensitivity, specificity, reportable range and reference range. The laboratory personnel must be qualified for high complexity testing. For all non-waived testing, CLIA requirements must be followed, including quality control, proficiency testing, quality assessment, etc.

On Nov. 21, 2014, Centers for Medicare and Medicaid Services (CMS) issued Survey and Certification (S&C) Letter 15-11 providing information on the "off-label" or modified use of waived blood glucose monitoring systems. CMS withdrew S&C 15-11 on March 13, 2015 and reissued it in draft form in order to obtain more feedback regarding the use of waived blood glucose meters and to promote added education regarding the current CLIA requirements.

The CLIA requirements for waived testing have not been changed. Laboratories must follow the manufacturer's instructions in order to preserve the waived status of the test system.

If you wish to provide feedback, please email comments to LabExcellence@cms.hhs.gov.

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; Centers for Medicare and Medicaid Service Survey and Certification Letters 13-54, 14-11, 15-07, 15-11 (draft); CMS CLIA website at www.cms.hhs.gov/clia.

Around the Corner - IQCP

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.

CMS is also sponsoring a webinar for the laboratory community on July 15th to introduce participants to the workbook "Developing an IQCP, a Step-by-Step Guide." Please check the CMS website at www.cms.hhs.gov/clia for registration information. Registered participants will be eligible for continuing education credit.

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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