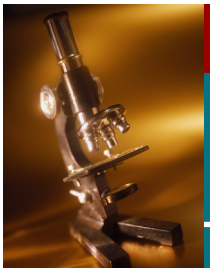

HEALTH FACILITIES UNIT

CLIA BITS

NORTH Dakota Be Legendary.
Health & Human Services

SPRING 2025

Most Commonly Cited Deficiencies

A breakdown of the most common deficiencies cited in the North Dakota Clinical Laboratory Improvements Amendment (CLIA) program from March 1, 2023, through February 29, 2024, is as follows:

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

D2028— Bacteriology/**D2096** Routine Chemistry/**D2107** Endocrinology. Failure to achieve a satisfactory score for two consecutive events or two of three consecutive events results in unsuccessful proficiency testing performance.

D6000/D6076— The laboratory director (moderate/high complexity testing) must meet the qualification requirements and provide overall management and direction.

D6029/D6102— The laboratory director (moderate/high complexity testing) must ensure new testing personnel are trained and competent before performing patient testing. The training must be documented.

D6021/D6094— The laboratory director (moderate/high complexity testing) must ensure the lab establishes and follows quality assessment policies and procedures to assure quality and identify failures.

D5217— For tests not listed under Subpart I (not regulated), the laboratory must verify the accuracy of the test biannually.

D2009— Statements attesting proficiency samples that were tested in the same manner as patient samples must be signed by the laboratory director and the person performing the testing. The laboratory director may delegate signing to a technical consultant for moderate complexity testing or a technical supervisor for high complexity testing.

D6014/D6087— The laboratory director (moderate/high complexity testing) is responsible for ensuring laboratory personnel are performing the test methods as required for accurate and reliable results.

D5413— Reagents and supplies must be stored at proper conditions and be labeled properly.

D5439— The laboratory must perform and document calibration verification following the manufacturer's instructions, using criteria verified by the laboratory at least once every six months and whenever the following occurs: a complete change of reagents for a procedure is introduced, after major preventive maintenance or replacement of critical parts, control materials reflect an unusual trend, shift or are outside acceptable limits, or the laboratory's schedule for verifying the reportable range requires more frequent calibration verification. See CLIA regulations at 493.1255(b) for exceptions to this requirement.

D6046/D6120— The technical consultant (moderate complexity testing)/technical supervisor (high complexity testing) must evaluate the competency of all non-waived testing personnel and assure staff maintains their competency to perform testing and reporting results promptly and accurately. This includes evaluation of all non-waived testing personnel and all non-waived testing platforms annually.

Inside this issue:

Proficiency Testing Analytes Updated

Effective July 11, 2024, the Clinical Laboratory Improvements Amendment (CLIA) program updated the analytes listed under Subpart I (regulated analytes). The implementation date will be January 1, 2025. Regulated analytes, including the new analytes listed, must be enrolled in an approved proficiency testing program including five samples per event three times a year. The changes were made based on the following criteria: current availability of proficiency samples; volume of patient testing nationally; impact on patient/public health; and cost and feasibility of implementation.

The following analytes were added:

- General Immunology: Hepatitis B surface antibody (Anti-HBs), Hepatitis C Virus antibody (HCV), high sensitivity C-Reactive Protein (CRP);
- Routine Chemistry: B-type Natriuretic Peptide (BNP), Pro BNP, Cancer Antigen 125 (CA125), Carbon dioxide, Carcinoembryonic Antigen (CEA), Low Density Lipoprotein (LDL) Cholesterol (direct measurement), Ferritin, Gamma-glutamyl Transferase (GGT), Hemoglobin (Hgb) A1c, Phosphorus, total Prostate-specific Antigen (PSA), Total Iron-binding Capacity (TIBC) (direct measurement), Troponin I, Troponin T;
- Endocrinology: Estradiol, serum Folate, Follicle-stimulating Hormone (FSH), Luteinizing hormone (LH) Progesterone, Prolactin, Parathyroid Hormone (PTH), Testosterone, Vitamin B12; and
- Toxicology: serum Acetaminophen, Salicylate, Vancomycin.

Proficiency Testing Changes

The Clinical Laboratory Improvements Amendment (CLIA) program has made the following changes to proficiency testing to be implemented January 1, 2025:

- Acceptable Performance Criteria for proficiency testing has been changed for most analytes from standard deviations to percentage-based criteria. Analytes with lower concentrations will be graded on percentages or fixed acceptance limits (see CMS QSO-22-21-CLIA).
- Microbiology requirements and changes:
  - ◊ Types of services were removed. Categories of testing with broader categories of organisms were added instead.
  - ◊ Miscellaneous microbiology requirements:
    - ♦ Labs must report proficiency results to the highest level reported for patients.
    - ♦ The percentage of mixed cultures for bacteriology, mycobacteriology, and mycology will decrease from 50% to 25% of the samples.
- Bacteriology requirements and changes:
  - ◊ Bacterial morphology will be required for gram stains if reported for patients.
  - ◊ Bacterial toxin detection will be required if reported for patients.
  - ◊ New criteria for direct bacterial antigen detection grading will be implemented.
  - ◊ Categories of proficiency testing include detection of presence or absence of bacteria with or without identification.
  - ◊ Antimicrobial susceptibility testing will include at least two samples per event.
  - ◊ Annually, the proficiency program will include aerobic and anaerobic bacteria, if appropriate, for gram-negative bacilli, gram-positive bacilli, gram-negative cocci, and gram-positive cocci.
- Mycobacteriology requirements and changes:
  - ◊ Categories of proficiency testing include acid fast stain and detection of presence or absence of mycobacteria with or without identification.
  - ◊ Annually, the proficiency program will include Mycobacterium tuberculosis complex and Mycobacterium other than tuberculosis.

- Mycology requirements and changes:
  - ◊ Categories of proficiency testing include direct fungal antigen detection and detection of presence or absence of fungi and aerobic actinomycetes with or without identification.
  - ◊ Annually, the proficiency program will include yeast or yeast-like organisms; molds including dematiaceous fungi, dermatophytes, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.
- Parasitology requirements and changes:
  - ◊ Categories of proficiency testing include direct parasite antigen detection and detection of presence or absence of parasites with or without identification.
  - ◊ Annually, the proficiency program will include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses.
- Virology requirements and changes:
  - ◊ Categories of proficiency testing include viral antigen detection and detection/identification of viruses.
  - ◊ Annually, the proficiency program will include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses.
- Hematology/coagulation changes:
  - ◊ Prothrombin Times—labs will be graded on results reported in seconds and International Normalized Ratio (INR) (same as patients).
  - ◊ Differentials—labs must enroll in automated differential counts and manual differentials if both methods are used by the lab.
  - ◊ Blood cell identification satisfactory (acceptable) score will change from 90% to 80%.
- Toxicology change:
  - ◊ Proficiency testing program must provide samples that cover the full range that could occur in patient samples.
- Immunohematology change:
  - ◊ Unexpected antibody detection satisfactory (acceptable) score will change from 80% to 100%.
- CLIA has made changes to the approval/reapproval process of proficiency company.

CLIA Fee Changes

The Department for Health and Human Services (HHS) implemented a process to sustain funding for the Clinical Laboratory Improvements Amendment (CLIA) program. Effective January 27, 2024, CLIA fees were increased by 18% across the board. In addition, certificate of waiver fees increased by $25.00 to help offset program obligations to the Federal Drug Administration for its role in categorizing tests. Every two years, CLIA fees will be increased based on a two-part calculation of the Consumer Price Index-Urban inflation adjustment. If applicable, there will be additional across the board increases.

Additionally, the following previously authorized activities will now be assessed fees:

- Providing a replacement CLIA certificate with no changes.
- Issuing a revised CLIA certificate due to information changes.
- Adding a specialty and determining compliance with testing in additional specialties outside of the Certificate of Compliance (CoC) survey cycle.
- Performing follow-up surveys or revisits to determine the correction of deficient practices found in either a CoC survey or Certificate of Accreditation (CoA) validation or complaint survey.
- Performing a substantiated complaint survey.
- Conducting desk reviews of unsuccessful proficiency testing performance to ensure successful laboratory proficiency testing.

Laboratories will be assessed fees to cover the administrative program costs of these activities. Fees for these activities had previously been authorized but not collected. The fee for providing a replacement CLIA certificate is $75.00. The fee for issuing a revised CLIA certificate due to changes is $95.00 for certificates of waiver and accreditation and $150.00 for certificates of compliance, registration, and provider performed microscopy. The fees for the other four activities will vary based on the resources and time necessary to perform the tasks. Laboratories will be notified and receive a fee coupon when payment is necessary. Additionally, CLIA will revoke the laboratory's certificate for failure to pay the assessed fees. Although these fees are effective January 27, 2024, assessment and collection may not begin until the new data system is online.

For more information, refer to the Federal Register at https://www.federalregister.gov/ (Search term: CMS-3326-F). See 42 C.F.R. 493 subpart F, General Administration (§§ 493.638-39, 493.643, 493.645, 493.649, 493.655, and 493.680).

Verification of CLIA Certification

Laboratories who would like to verify their Clinical Laboratory Improvements Amendment (CLIA) certification may use the Centers for Medicare & Medicaid Services (CMS) Quality, Certification & Oversight Reports (QCOR) website: https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp

- Click on "CLIA Laboratory Lookup" under "Tool" at the top of the listing on the left side
- Enter your CLIA number in the specified box (second from top) or search using other criteria
- Click on "search" button
- Click on the facility name for an expanded report that can be printed

No fees are assessed by CLIA for using this process for CLIA certification verification.

Public Health Emergency Expired

On May 11, 2023, the Public Health Emergency expired.

Tests With Emergency Use Authorization After The Public Health Emergency Expires

The U.S. Food & Drug Administration's (FDA's) website, under frequently asked questions for SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) testing, explains what will happen to tests with emergency use authorization (EUA) after the public health emergency expires. The FDA does not plan to take any action that would leave the public without needed tests. The FDA is allowed to issue EUAs under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The use of EUAs is not dependent on the public health emergency declaration, but rather on the EUA declaration under section 564. SARS-CoV-2 EUAs will continue until the HHS (Health & Human Services) Secretary terminates them. Many in vitro diagnostic tests with previous EUA declarations, such as Ebola, remain in effect to this day.

The FDA issued draft guidance on December 23, 2021, describing the process manufacturers are recommended to take to obtain full authorization of their tests. The guidance proposes at least a 180-day transition period for the process. When a test receives full authorization, it is subject to CLIA categorization (waived, moderate complexity, or high complexity).

Read the FDA's full explanation of this topic at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2?utm_medium=email&utm_source=govdelivery.

To find a SARS-CoV-2 test system with EUA, search the FDA database at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. Be sure to check the authorized settings for use of the test.

To identify the complexity of a test system, search the FDA's CLIA test categorization database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

Questions and Answers (Q & A)

Centers for Medicare and Medicaid Services (CMS) provides specialized Clinical Laboratory Improvements Amendment (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. Readers are welcome to submit questions to clialab@nd.gov.

Q: My laboratory performs SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) antigen and molecular testing. What does CLIA require to be reported?

A: CMS had authority to require reporting of SARS-CoV-2 test results until the end of the public health emergency (PHE), so the CLIA reporting requirement ended with PHE expiration on May 11, 2023. Some states and local public health units may still require reporting. Long term care facilities must still report results to the Health Safety Network (HSN).

Q: My laboratory performs a waived B-type Natriuretic Peptide (BNP) test. With the addition of analytes listed under Subpart I (regulated analytes), will we be required to enroll in proficiency testing for our waived BNP test?

A: No, CLIA does not require proficiency testing for waived analytes. If a laboratory uses a non-waived BNP test, they will be required to enroll in proficiency testing (including five samples per event three times a year) effective January 1, 2025.

Q: Does CLIA require laboratory directors to make on-site visits?

A: Yes, the revised CLIA regulations at 493.1407(c) and 493.1445(c) require the laboratory director be on-site at least once every six months, with at least four months between the minimum two on-site visits. The visits must be documented with a listing of the activities performed by the laboratory director. These visits cannot be delegated.

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 and Medicaid Services (CMS) CLIA website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories;
Centers for Medicare and Medicaid Services (CMS) QS0-22-21-CLIA, 07/11/22; Admin Info-23-07-CLIA, 05/03/23; QSO-23-15-CLIA, 05/11/23; QSO-24-03-CLIA, 12/28/23;
U.S. Food & Drug Administration's website at https://www.fda.gov;
ASPEN Central Office Tag Summary Report;
CLIA Final Rule found in the Federal Register at https://www.federalregister.gov/

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