



CLIA BITS

SUMMER 2021

New CLIA Regulations

Centers for Medicare & Medicaid Services (CMS) has modified the CLIA regulations in response to the current COVID-19 public health emergency.

D1002 — During the Public Health Emergency, each laboratory that performs a test intended to detect SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

D3000 — Each laboratory that performs non-waived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS (Department of Health and Human Services) approves a procedure that provides equivalent quality testing as specified in Appendix C of State Operations Manual.

- a. Reporting of SARS-CoV-2 test results. During the Public Health Emergency, each laboratory that performs a test intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This reporting requirement is for waived and non-waived laboratories.

Laboratories must follow the manufacturer's instructions for quality control (QC) performance. For non-waived tests, the laboratory may choose to implement an individualized quality control plan (IQCP) if the manufacturer's QC requirements are less stringent than CLIA QC requirements.

Laboratories must use the specimen type and collection method listed by the manufacturer. If the laboratory uses a different specimen type or collection method, the test has been modified and becomes a high complexity test.

Laboratories must ensure the testing personnel are qualified to perform the testing as authorized. Waived testing personnel have no qualification requirements under CLIA.

Most of the manufacturer's instructions state the laboratory must have a process for reporting results. The laboratory should have a written policy and procedure regarding the reporting of COVID-19 test results. Both positive and negative test results need to be reported.

Testing of Asymptomatic Individuals

Centers for Medicare & Medicaid Services (CMS) is temporarily exercising enforcement discretion under CLIA for the duration of the COVID-19 public health emergency for the use of authorized SARS-CoV-2 molecular and antigen point of care tests on asymptomatic individuals outside of the test's authorization. This means CMS will not cite laboratories using authorized SARS-CoV-2 molecular and antigen point of care tests on asymptomatic individuals. CMS will not require non-waived laboratories to establish performance specifications for use of these tests on asymptomatic individuals. For more information refer to the document found at <https://www.cms.gov/files/document/clia-sars-cov-2-point-care-test-enforcement-discretion.pdf>

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CLIA Certificate Expiration Dates

All active laboratories' expiration dates for CLIA Certificates of Compliance or Certificates of Registration with expiration dates before 09/30/2021 have been extended to 09/30/2021.

FDA Approved Test System

A Federal Drug and Administration (FDA) cleared or approved test system means the test system has gone through a prescribed process with the FDA upon submission by the manufacturer. After the test system is cleared or approved, the FDA has the responsibility to categorize the test as waived, moderate complexity, or high complexity. 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>

Emergency Use Authorization for COVID-19 Testing

During a public health emergency, the United States Food and Drug Administration (FDA) may issue emergency use authorization (EUA) for certain tests applicable to the declared emergency. Since there may not be time for manufacturers to receive FDA approval and categorization of their emergency related tests, EUA gives manufacturers an avenue to rapidly deploy their emergency assays. The EUA is only in effect during the declared emergency. Tests receiving EUA are not categorized by the FDA, but they are authorized for use in certain testing settings: waived, moderate complexity, and/or high complexity.

Tests that have been issued an EUA are subject to all the CLIA requirements. If the test is authorized for use in a waived setting, the laboratory must follow the manufacturer's instructions. If the test is authorized for use in moderate or high complexity laboratories, all the CLIA regulations are applicable. The laboratory must ensure waived and non-waived SARS-CoV-2 test results are reported appropriately per the new CLIA requirements at D1002 and D3000.

After the public health emergency is terminated, any EUAs issued will no longer be in effect. In the meantime, some tests may have received official FDA approval and categorization. Laboratories must ensure they have the appropriate CLIA certificate to perform the tests as approved and categorized by the FDA. There is no guarantee a test with EUA for use in waived settings will receive waived categorization when FDA approved. If EUA tests are not FDA approved after the termination of the public health emergency, they may only be used in a high complexity laboratory after all performance specifications have been verified or established.

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.

Most Commonly Cited Deficiencies

A breakdown of the most common deficiencies cited in the North Dakota Clinical Laboratory Improvement Amendments (CLIA) program from Mar.1, 2019, through Feb. 28, 2021 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).

D2016 — Successful participation in proficiency testing. Each laboratory performing testing for non-waived, regulated analytes must successfully participate in an approved proficiency testing program.

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

D6089 — 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 systems before reporting patient results. This includes accuracy, precision, reportable range, and verification the normal values are appropriate.

Calibration and Calibration Verification Revisited

The CLIA regulations do not require calibration every six months unless required by the manufacturer. Calibration verification at least every six months is required (see CLIA regulations at §493.1255). The following are exemptions from the CLIA requirements for calibration verification every six months:

- When the manufacturer does not provide instructions for calibration and the laboratory calibrates at least every six months using low, mid, and high values of calibration material
- If the laboratory performs calibration at least every six months using low, mid, and high values of calibration material
- For automated cell counters, if the laboratory tests two levels of quality control each day of testing and the results are acceptable
- For automated chemistry analyzers, if the laboratory tests three levels of quality control more than once each day of testing and the results are acceptable
- If the instrument is factory or manufacturer calibrated
- Tests considered non-quantitative (for example: Protimes which are measured in units of time)

The laboratory must ensure analytes are calibrated or have calibrations verified at least every six months unless the analytes qualify for an exemption listed above. Make sure your laboratory has a system to track calibration and/or calibration verification.

Questions and Answers (Q & A)

Centers for Medicare and Medicaid Services (CMS) provide 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. Readers are welcome to submit questions to clialab@nd.gov.

Q: Should severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing be performed under a biosafety hood?

A: Refer to the Centers for Disease Control and Prevention (CDC) website under "Biosafety" at <https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Testing-Strategies-for-SARS-CoV-2>

Q: May the laboratory implement an Individualized Quality Control Plan (IQCP) for SARS-CoV-2 tests with EUA.

A: Yes, IQCP is an option for moderate and high complexity tests with an EUA when manufacturers' quality control requirements are less stringent than CLIA's requirements.

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) QSO-21-10-CLIA; 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 Disease Control and Prevention website at <https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Testing-Strategies-for-SARS-CoV-2>.

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*CLIA Bits is published by:
Division of Health Facilities
North Dakota Department of Health
1720 Burlington Dr
Bismarck, N.D. 58504-7736
Phone: 701.328.2352
Fax: 701.328.1890
<https://www.health.nd.gov/regulation-licensure/health-facilities/clia-laboratories>*

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