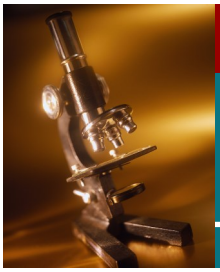

DIVISION OF HEALTH FACILITIES

CLIA BITS

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SUMMER 2022

COVID-19 Reporting Update

Previously, laboratories were required to report all SAR-CoV-2 (severe respiratory syndrome coronavirus 2) test results (positive, negative, and inconclusive). Per the Centers for Medicare & Medicaid Services (CMS) QSO-21-10-CLIA, revised on 04/15/22, the SAR-CoV-2 reporting requirements have been changed a follows:

- Certificate of waiver (CoW) and provider performed microscopy (PPM) laboratories must report positive SARS-CoV-2 test results for antigen and molecular/NAAT (nucleic acid amplification test) tests. Negative and inconclusive results do not need to be reported. All SARS-CoV-2 tests performed in these laboratories must be classified as waived or have emergency use authorization (EUA) for use in waived settings.
- Certificate of compliance, accreditation, and registration laboratories must report positive SARS-CoV-2 test results for antigen tests which are classified as waived, moderate complexity, or high complexity or have an EUA for use in waived, moderate complexity, or high complexity settings. Negative and inconclusive results do not need to be reported.
- Certificate of compliance, accreditation, and registration laboratories must report positive SARS-CoV-2 test results for molecular/NAAT tests which are classified as waived or have an EUA for used in waived settings. Negative and inconclusive results do not need to be reported.
- Certificate of compliance, accreditation, and registration laboratories must report positive, negative, and inconclusive SARS-CoV-2 test results for molecular/NAAT tests which are classified as moderate or high complexity or have an EUA for use in moderate or high settings.
- For all laboratories, neither positive nor negative serology (antibody) test results need to be reported.

Competency Evaluations

For non-waived testing, new testing personnel must have a competency evaluation performed at six–months and then again at one year. After the first year, competency evaluations must be performed annually. All non-waived testing platforms must be included in each evaluation. If test methods or instrumentation changes, an individual's competency must be evaluated before patient test results are reported. Competency evaluations must include:

- Direct observation of test performance
- Monitoring recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
- Direct observation of maintenance and function check performance
- Assessment of test performance through testing previously analyzed specimens, internal blind samples, or proficiency testing sample; and
- Assessment of problem-solving skills

Be sure to evaluate all non-waived personnel, including weekend, PRN (as needed), temporary, and contracted staff.

Inside this issue:

Most Commonly Cited Deficiencies

A breakdown of the most common deficiencies cited in the North Dakota Clinical Laboratory Improvement Amendments (CLIA) program from Jan.1, 2021 through Dec. 31, 2021 is as follows:

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

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

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

D5421 — The laboratory must verify performance specifications of unmodified, FDA (U.S Food & Drug Administration) approved test systems before reporting patient results. This includes accuracy, precision, reportable range, and verification the normal values are appropriate.

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 or 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.

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 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 Dec. 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 setting 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) 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: If a laboratory performs SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) antigen testing, what results need to be reported?

A: For certificate of waiver, provider performed microscopy, compliance, accreditation, and registration laboratories, only positive antigen test results need to be reported. This applies to waived, moderate complexity, or high complexity tests.

Q: If a laboratory performs SARS-CoV-2 molecular/nucleic acid amplification testing, what results need to be reported?

A: For certificate of waiver, provider performed microscopy, compliance, accreditation, and registration laboratories, only positive test results need to be reported for molecular/nucleic acid amplification tests that are waived. For certificate of compliance, accreditation, and registration laboratories positive, negative, and inconclusive test results need to be reported for molecular/nucleic acid amplification tests that are moderate complexity or high complexity.

Q: If a certificate of waiver laboratory performs SARS-CoV-2 antigen testing using a method that has not been FDA (U.S. Food & Drug Administration) approved or does not have emergency use authorization, what results need to be reported?

A: Tests that have not been FDA approved or do not have emergency use authorization automatically default to high complexity. With a certificate of waiver, the laboratory cannot use a test without FDA approval or emergency use authorization. The laboratory must immediately discontinue use of this test or change their CLIA certificate type.

Q: The FDA has approved the first COVID-19 (SARS-CoV-2) diagnostic testing using breath samples (see the FDA website *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-diagnostic-test-using-breath-samples?utm_medium=email&utm_source=govdelivery*). What type of CLIA certificate is needed to perform this test?

A: Tests using breath samples are not CLIA applicable, therefore, no CLIA certificate is required for this type of test.

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, revised 04/15/22; Centers for Medicare and Medicaid Services (CMS) CLIA website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories; U.S. Food & Drug Administration's website at https://www.fda.gov .

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