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HEALTH ALERT NETWORK | HEALTH ADVISORY | March 28, 2022

Update to COVID-19 laboratory reporting requirements to public health: effective April 4, 2022

This health update provides updated reporting requirements of COVID-19 test results from the Department of Health and Human Services (HHS) and the North Dakota Department of Health (NDDoH). The changes replace the blanket requirement to report all SARS-CoV-2 tests results with new requirements based on the type of test and the entity performing the test. This change reduces the reporting burden for clinical laboratories, point of care testing sites, and public health.

Under the updated guidelines, the following results should continue to be reported to the NDDoH:

- **ALL positive** SARS-Cov-2 test results (excluding home tests and antibody tests)
- **Positive, negative, and indeterminate** SARS-Cov-2 results from **Nucleic Acid Amplification Tests (NAAT)** conducted in a facility certified under CLIA (Clinical Laboratory Improvement Amendments) to perform moderate- or high-complexity tests

Negative and indeterminate rapid antigen and other non-NAAT test results will no longer require reporting to the NDDoH. Reporting of antibody test results to the NDDoH has also been discontinued. This means that many facilities conducting testing under a CLIA certificate of waiver will only need to report positive SARS-Cov-2 test results to the NDDoH. This includes rapid and antigen testing conducted at schools, correctional facilities, employee testing programs, long-term care facilities, rapid testing at pharmacies, medical provider offices, and community testing sites. The table below summarizes reporting requirements to the NDDoH.

NDDoH Reporting Requirements by Entity and Type of Test			
	Positive Results	**Negative** and **Inconclusive** Results	Additional Details
NAAT tests conducted in a facility certified under CLIA to perform moderate- to high-complexity tests	**YES**	**YES**	• Laboratory-based Nucleic Acid Amplification Test (NAAT) tests, including RT-PCR, TMA, LAMP, and SDA tests • See www.cdc.gov/coronavirus/2019-ncov/lab/naats.html for more information
All other tests (except antibody)	**YES**	NO	• Tests conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening tests at schools, correctional facilities, employee testing

			programs, long-term care facilities, and point-of-care tests performed in pharmacies, medical provider offices, and drive-through and pop-up test sites) • Non-NAAT (e.g., high throughput antigen) tests conducted in a facility certified under CLIA to perform moderate or high-complexity tests
Antibody tests	NO	NO	• Tests used to determine previous infection with SARS-CoV-2 in any setting

Centers for Medicare and Medicaid Service (CMS) regulated long-term care facilities should continue to follow CMS SARS-Cov-2 reporting requirements. CMS reporting requirements have not been updated to align with the new reporting guidance outlined here at the time this HAN was issued. Until that happens, please follow CMS requirements.

The updated reporting guidelines do not prohibit entities such as local public health, long-term care, schools, corrections, and other entities from entering non-positive test results in NDDoH-supported software or other programs (e.g., TestReg) that is used to report results to clients or manage result data. The full HHS guidance is available at www.cdc.gov/coronavirus/2019-ncov/downloads/lab/HHS-Laboratory-Reporting-Guidance-508.pdf. For question regarding this guidance, call Disease Control at 701-328-2378 or email questions to disease@nd.gov.

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