

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES



To: Laboratories, facilities, and health care providers performing COVID-19 testing.

From: Gary Anthone, M.D., Chief Medical Officer

Date: 4/28/2022

RE: Changes in Reporting Negative COVID-19 Results - Effective 4/28/2022

The following is intended to notify entities performing COVID-19 testing of updated guidance regarding the reporting of <u>negative</u> COVID-19 results to the State of Nebraska.

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "[e]very laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). The statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. This updated guidance outlines requirements for data submission to HHS as authorized under this law.

In an effort to receive these data in the most efficient and effective manner, and to reduce the administrative burden to Nebraska's healthcare colleagues Nebraska is moving to align with the COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 March 8, 2022 advisory put out by US HHS regarding the reporting of Negative COVID-19 test results: <u>https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/hhs-laboratory-reporting-guidance-508.pdf</u>

Effective 4/28/2022: Reporting of NEGATIVE COVID-19 results for testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings becomes OPTIONAL. Continued requirement to report all Positive Results.

Please refer to the table below for additional details. Questions can be addressed to <u>dhhs.epi@nebraska.gov</u>

The Nebraska Department of Health and Human Services (DHHS) is committed to the health and safety of all people in Nebraska. Pursuant to 173 NAC 1 all healthcare providers and laboratories must electronically report to DHHS all positive laboratory test results for COVID-19. DHHS uses the electronically submitted data for the purpose of disease surveillance. The Electronic Laboratory Reporting (ELR) process does not replace or relieve requirements for laboratories and facilities to report results back to the requesting providers.

COVID-19 test results must be reported within 24 hours of result availability using electronic exchange via an HL7 interface, an Excel file or a CSV file to avoid the critical delays experienced with manual reporting.

Gary J. Anthone, MD Chief Medical Officer Director, Division of Public Health

Gay arthur mo

Helping People Live Better Lives

Department of Health and Human Services

Reporting Requirements by Entity and Type of Testing			
Type of Testing	Is Reporting Required Under this Guidance?		Examples
	Positive Results	Negative & Inconclusive Results	
NAAT-testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests	Required	Required	Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests See <u>https://www.cdc.gov/coronavirus/2019-</u> <u>ncov/lab/naats.html</u> for more information
All other testing (except antibody)	Required	Optional	Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, longterm care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites) Non-NAAT (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high- complexity tests
Antibody testing	Optional	Optional	Tests used to determine previous infection with SARS-CoV-2 in any setting

Refer to this link for specific information on HL7 electronic data exchange:

https://dhhs.ne.gov/Pages/ELR-Useful-Documents.aspx

Refer to the documents listed under 'Lab Data Reporting via HL7 Interface' and 'Reportable Diseases' for detailed information. Facilities may be required to submit results using Excel or CSV files until the interface has been completed to avoid any lapse in reporting test results.

Refer to this link for specific information on Excel or CSV electronic reporting – available to reporting entities unable to create an HL7 interface:

https://dhhs.ne.gov/Pages/ELR-Useful-Documents.aspx

Refer to the 'Implementation Guide – Submission of Laboratory Tests Results to DHHS Using CSV or Excel Data Format' document for detailed information.