Nebraska Department of Health and Human Services

# HEALTH ALERT NETWORK Update

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

TO: Healthcare Providers, Infection Control, Hospitals, Labs, and Public Health

FROM: Gary Anthone, MD
Director of Public Health and Chief Medical Officer
PHONE: 402-471-8566

RE: Antigen Testing, Reinfections, Sequencing, & Antibody Test Reporting
DATE: February 25, 2021

SARS-CoV-2 antigen testing has become a prominent testing modality throughout the state, enabling more timely isolation of patients with COVID-19 in some instances. Providers must be vigilant, however, to watch for potential false-positive and false-negative results, which might require confirmatory testing on a molecular platform such as real-time polymerase chain reaction (RT-PCR). Test Nebraska, which performs RT-PCR testing, has 60 sites available to individuals seeking state-sponsored RT-PCR testing. Test Nebraska turnaround times for results have remained at a median of one day for more than 10 weeks. Additionally, since SARS-CoV-2 is mutating and multiple variants of concern that appear more contagious have been identified globally and in the United States, a program for detection of these variants in Nebraska has been initiated. Whole genome sequencing is the only method available to identify the variants. DHHS is requesting help in obtaining specimens from select patients for sequencing, which is conducted at the Nebraska Public Health Laboratory (NPHL). Finally, this guidance provides updated information for reporting antibody test results.

**Reinfection investigation guidance**

- Reinfection with SARS-CoV-2 remains rare, but surveillance and identification of reinfections remains a critical need while more is learned about risk, duration of immunity, and durability of naturally acquired immunity in the context of multiple circulating variants of concern.
- CDC currently identifies candidates for reinfection investigations as symptomatic patients with a positive molecular test collected more than 45 days after the first episode of infection, OR any patient (disregarding symptom status) with a positive molecular test collected more than 90 days after the first episode of infection. To confirm a reinfection, paired respiratory specimens must be available (one from the first episode of infection and one from the second episode of infection) and must be successfully sequenced. More information on considerations for reinfection can be found with CDC (https://www.cdc.gov/coronavirus/2019-ncov/php/reinfection.html#procedures).
- Given the scarcity of confirmed reinfections, other respiratory pathogens such as the influenza virus should be considered in a patient with respiratory symptoms who had previously been diagnosed and recovered from COVID-19. When

assessing whether such patients might have a second episode of COVID-19, we ask that providers 1) consider RT-PCR testing for SARS-CoV-2 and 2) consider ordering a respiratory pathogen panel (RPP) if available, to identify alternative etiologies as well. Since higher viral loads are more common earlier in the disease course, the earlier a specimen is collected, the more likely the laboratory will be successful in sequencing to identify reinfections.

- Please notify your local health department of suspected reinfections (www.dhhs.ne.gov/lhd).

**Variants of concern and sequencing capabilities in Nebraska**

- RNA viruses like SARS-CoV-2 mutate frequently. On occasion, a mutation results in a phenotypic change that affects the way the virus interacts with its host. Groups of mutations have now resulted in new lineages of SARS-CoV-2 that have become dominant in regions globally and are now circulating in the United States. While it is yet to be definitively determined whether these new "variants of concern" produce more clinically severe disease, they do appear to be more contagious. Some mutations identified in new variants appear to reduce neutralization by vaccine-induced antibodies, although real-world implications are unclear. Whole genome sequencing is required to identify the new variants. Early identification might allow for thorough case investigations and contact tracing efforts for mitigation and could allow healthcare facilities time to prepare for potential surges.
- NPHL, in collaboration with CDC, participates in a national program involving all states for population-based genomic surveillance. CDC began sequencing 10 specimens from Nebraska every other week in December, and since February 1st has increased sequencing to 17 specimens from our state every other week.
- DHHS and NPHL have now secured federal funding to support in-state sequencing of up to 100 SARS-CoV-2 positive specimens per week. Currently, NPHL is sequencing ALL positive specimens with sufficient viral nucleic acid that are detected in or sent to the laboratory.
- To expand prospective genomic surveillance in our state, DHHS and NPHL are requesting more positive specimens that meet criteria for sequencing. Nursing facilities, clinics, hospitals, and local health departments are requested to consider obtaining specimens and sending them to NPHL for the following scenarios:
    - **Potential reinfections, even if the specimen from the first episode of COVID-19 infection is not available**
    - **Potential vaccine failures (i.e., COVID-19 infection 14 days or more after a completed series of vaccination)**
    - **Patient presenting from areas or clusters experiencing rapid transmission, elevated attack rates, or elevated percent positivity**
    - **Increased severity of COVID-19 infection (e.g., younger patients in the ICU)**
    - **Confirmatory testing of presumptive positive or presumptive negative results from SARS-CoV-2 antigen tests**

- **Returning travelers from out of state who have tested positive for SARS-CoV-2**

**Instructions to order testing at NPHL for SARS-CoV-2 sequencing**

- Use NUlirt (NPHL's Internet-based, electronic lab information system) to complete an order for **NCOVFL – COVID-19 and Influenza A/B multiplex RT-PCR assay**. The specimen will be first tested using the multiplex RT-PCR assay to ensure the positive specimen has sufficient viral nucleic acid for sequencing. To access NUlirt click here (https://nulirt.nebraskamed.com) using your existing NUlirt account. If you are a new user, follow the link to register and create a new account. Please complete all of the requested data fields included with the Ask On Entry (AOE) questions. A properly completed requisition is required for order processing. For orders created electronically, submitters should print a completed batch list to accompany the specimen by clicking within the NUlirt system. For issues related to NUlirt access, contact the NUlirt support group via email nulirtsupport@nebraskamed.com or contact client service representatives at 402-559-2440; or toll free: 1-866-290-1406.
- Specimen Collection Requirements (NPHL only): One nasopharyngeal swab should be placed in a single tube of transport medium provided by NPHL. See Collecting and Handling COVID-19 Laboratory Specimens, http://www.nphl.org/. To order specimen collection kits please complete this survey: https://redcap.link/yiro9omf
- Facilities that order SARS-CoV-2 testing for sequencing will receive results for the NCOVFL multiplex RT-PCR assay. Results for sequencing will be shared with DHHS. For the immediate future, when a variant of concern is detected an epidemiologist will be in contact with the facility as part of a case investigation.

**Antibody reporting clarification – laboratories without an ELR connection should not report antibody test results**

- In accordance with Public Law 116-136, § 18115(a) and the declaration attached, all laboratories and testing sites must report SARS-CoV-2 molecular (e.g., RT-PCR) and antigen diagnostic test results (positive and negative) to the Division of Public Health.
- Laboratories reporting via automated electronic laboratory reporting (ELR) must also report antibody tests used to diagnose possible or suspect cases of COVID-19. Laboratories without an ELR connection should not report antibody test results.
- For help with electronic laboratory reporting (ELR), please follow instructions at http://dhhs.ne.gov/Pages/ELR-Useful-Documents.aspx.

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

# MEMO

To: Laboratories and Facilities Performing COVID-19 Testing

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

Date: December 12, 2020

RE: Public Health Reporting Requirements for COVID-19 Testing

As specified in 173 NAC 1-004.04A, https://www.nebraska.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-173/Chapter-01.pdf, the Chief Medical Officer (CMO) of the Division of Public Health may require reporting, or a change in method or frequency of reporting, of newly recognized or emerging diseases. As SARS-CoV-2, the virus that causes COVID-19, causes serious morbidity or mortality, reporting is necessary to monitor, prevent, and control this newly recognized disease. According to 173 NAC 1-004.04, the CMO may also specify a specific mechanism for such reporting, including persons and entities required to report. Further, Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every 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).

In response to this federal law and under the authority of 173 NAC 1-004.04, as CMO of the Division of Public Health, I hereby declare all tests intended to detect SARS-CoV-2 as reportable in Nebraska to include the results of each such tests whether positive or negative. *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* outlines the requirements for data submission as authorized under federal law. In accordance with Public Law 116-136, § 18115(a) and this declaration, all laboratories and COVID testing sites must report molecular (e.g., RT-PCR) and antigen diagnostic test results (positive and negative) to the Division of Public Health. Laboratories reporting via automated electronic laboratory reporting (ELR) must also report antibody tests used to diagnose possible or suspect cases of COVID-19. For help with electronic laboratory reporting (ELR), please follow instructions at http://dhhs.ne.gov/Pages/ELR-Useful-Documents.aspx. Laboratories without an ELR connection should not report antibody test results. All three test types should be clearly identified as PCR, antigen or serology/antibody. Reports should include complete patient demographic information and correct LOINC codes (LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests).

Gary Anthone, MD

Gary J. Anthone
Chief Medical Office- Dept. of Public Health -State of Nebraska
Dept. of Health and Human Services