



Nebraska Department of Health and Human Services
HEALTH ALERT NETWORK
Update



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

FROM: Thomas J. Safranek, M.D. Gary Anthonie, MD
State Epidemiologist Director of Public Health and Chief Medical Officer
PHONE: 402-471-2937 PHONE: 402-471-8566

RE: Updated Testing Guidance for COVID-19
DATE: September 8, 2020

Six months into the COVID pandemic, laboratory testing for the virus continues to occupy center stage. Testing options have proliferated, creating opportunities for better control of the outbreak, and enhanced patient care. This Health Advisory is intended to provide background and context for providers who order and interpret these tests.

Public Health Reporting of COVID-19 Tests:

All COVID-19 tests (including rapid testing, point of care, in-state and national commercial laboratories) should be reported (**positive, negative, and inconclusive results**) to **Nebraska DHHS as required by 173 NAC 1. Reporting is required by healthcare providers including physicians, hospitals, physician assistants, advanced practice registered nurses, laboratories, or facilities.**

To avoid critical delays from paper/fax reporting ALL reporting entities can report electronically in one of 2 methods: automated electronic laboratory reporting via an HL7 interface OR via an electronic upload of a CSV or Excel file. For more information please visit <http://dhhs.ne.gov/Pages/Electronic-Lab-Reporting.aspx>. For any other questions regarding laboratory reporting please call 402-471-2937 or email dhhs.epi@nebraska.gov.

Testing Options:

Tests which detect COVID-19 nucleic acid (nucleic acid amplification tests [NAAT]):

- The FDA has granted Emergency Use Authorization to a growing number of NAATs (<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), many of which have attractive features.
- Options include specimen collection other than nasopharyngeal swabs (e.g., anterior nares and saliva), forgoing the challenges surrounding NP swab collection such as shortages of swabs, transport media, personnel to collect the specimen and the need for personal protective equipment (PPE).

- Some NAAT can be performed at point-of-care (POC) with short turn-around times (TAT).
- These tests detect viral nucleic acid beyond the period of contagiousness or infectivity, such that a negative NAAT is no longer required to terminate isolation of a person diagnosed with COVID-19 (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>).
- The original NAAT test originated out of the CDC and continues to be performed at the Nebraska Public Health Laboratory. The NAATs performed at complex labs are considered the gold standard with the best sensitivity and specificity for detecting the nucleic acid of COVID-19. These remain the most common test in use in Nebraska and are the tests performed by “high complexity” reference laboratories such as LabCorp, Quest, Regional Pathology Laboratory at UNMC, CHI-Creighton, Physician’s Laboratory and TestNebraska.
- Turn-around-time remains a challenge for the NAATs performed at the moderate-high complexity labs: TAT for the week ending August 30 were 3.7/3 (Mean/median) days (see table below).
- Some point-of-care NAAT tests (e.g., Abbott IDNow) have reduced sensitivity but the “false negatives” may include many individuals whose nucleic acid level/viral load is in the lower range, rendering them less or non-contagious. The reduced sensitivity may be outweighed by a short TAT that facilitates rapid isolation of contagious individuals and identification of contacts who can be quarantined in a timely way. Clinicians interpreting such test results need to consider the clinical and epidemiologic context, and consider a NAAT test at a reference laboratory when such factors suggest COVID infection is a strong possibility despite the negative POC test.
- Recently Yale University developed a NAAT protocol for specimen collection and processing with notable advantages. The SalivaDetect process uses saliva as a specimen source, avoids the need for transport media, tolerates ambient temperature for up to 48 hours, extracts/exposes viral RNA with a reagent that is commonly available. The resultant specimen can be assayed with generic reagents on a range of diagnostic platforms (<https://www.fda.gov/media/141192/download>), all with significant cost savings. Despite these advantages, no Nebraska laboratories have indicated plans to adopt these methods.
- Clinicians need to integrate clinical judgment and epidemiologic risk factors into their assessment of all these test results. False negatives and false positives are real phenomena and require clinical discernment. The NEJM recently published an excellent article addressing this issue: False Negative Tests for SARS-CoV-2 Infection — Challenges and Implications (<https://www.nejm.org/doi/full/10.1056/NEJMp2015897>)

Tests which detect COVID-19 Antigen:

- The FDA has issued 4 EUAs for antigen detection tests. This is established technology applied to COVID-19 detection. The FDA cites company data for sensitivity and specificity, but independent verification is pending. The cited values reflect very high specificity and sensitivity above 90%.
- The published materials for these tests on the FDA’s EUA website advise their use in symptomatic patients within seven days of symptom onset.
- The point-of-care tests can be performed on anterior nares swabs in laboratories certified under CLIA that meet the requirements to perform high, moderate, **or waived complexity** tests, which greatly broadens access to COVID-19 testing.

- Many Nebraska long-term care facilities are receiving COVID-19 antigen detection equipment and supplies (BD Veritor or Sofia SARS Antigen FIA), and should be operational by the end of September. On-going supply of test kits remains an open question. Training will be forthcoming in the near future.
- Beginning this month, Abbott is marketing a large supply of antigen detection kits (BinaxNOW COVID-19 Ag Card) which is expected to have a major impact on the availability and frequency of testing.
- CDC has issued guidance regarding the ordering/interpreting of COVID-19 antigen tests: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Additional Details for Local and National labs:

- Some national labs utilize priority levels for sequencing the order in which labs are processed. Further details can be found at the laboratory's website or by contacting them directly, particularly for up-to-date lab-specific turnaround times. It is important when referring patients to public testing options such as those through local/chain pharmacies, clinics, or Test Nebraska to be aware of the most recent turnaround times.
- There are several options for local and national reference laboratories (in-state: Nebraska Medicine, CHI Core Laboratory, Nebraska Methodist Medical Center, Physicians Laboratory, or Bryan Medical Center); national reference labs: LabCorp, Mayo Clinic, Quest, etc). Local and national laboratories can experience the bottlenecks listed above with delayed results.
- Physicians should consider if a lab test is warranted or whether clinical diagnosis of COVID-19 infection suffices. Patients with a clear source of exposure (e.g., household member of a known lab-confirmed case) and a clinical presentation consistent with COVID-19 may not warrant a lab test.
- Clinics and facilities who lack an established relationship with a commercial laboratory should set up a commercial account to arrange electronic ordering and courier services.

TestNebraska:

- TestNebraska is expanding lab capacity from 3,600 tests to 7,000 tests per day. More appointments and locations have been added as testing continues to scale up.
- All persons living in Nebraska including those experiencing symptoms and those with an exposure to COVID-19 are invited to complete an assessment and to schedule a COVID-19 test. Nebraskans can complete an assessment at [TestNebraska.com](https://www.testnebraska.com) or [Testnebraska/es](https://www.testnebraska.com/es) for Spanish.
- Upon completion of the assessment applicants receive an email from TestNebraska directing them to select a specimen collection site, date and time. A confirmation email will include a QR code, which must be brought to the collection site.
- A **TestNebraska hotline** is available to provide individuals completing an assessment with answers to general questions at (402) 207-9377.

Nebraska Public Health Laboratory (NPHL):

- NPHL will not be testing on weekends or holidays at this time. If testing is needed during these days, please consider another lab option. Please have specimens to the lab by 11 am Friday for results before the weekend.

- NPHL COVID-19 testing at public health expense remains available. The laboratory's capacity is approximately 450 tests/day and is running five days/week. As throughout the country, capacity may be limited by availability of reagents and supplies.
- Patients tested at NPHL are required to meet the priority requirements below:
 - In-patients:** Any symptomatic hospitalized patient suspected of COVID-19.
 - Out-patients:** Persons with a clinical or rule-out diagnosis of COVID-19 in groups as follows:
 - Healthcare workers who are symptomatic or have a high-risk exposure
 - Patients of Federally Qualified Health Centers (FQHC) or tribal health centers only by prior arrangement with local or state public health. NOTE: To minimize burden on NPHL, FQHCs are encouraged to consult with local or state public health to establish alternate arrangements besides NPHL for testing at public health expense. Contact phone number for State: (402) 471-2937.
 - NPHL can also be utilized to define an outbreak situation as determined by the LHD or DHHS. Use of NPHL is not intended for large scale testing and should be used for the symptomatic individual and their close contacts only.
- **Specimen Ordering Requirements (NPHL ONLY):** Use NUIirt (NPHL's Internet-based, electronic lab information system) to complete an order. To access NUIirt click here (<https://nulirt.nebraskamed.com>) using your existing NUIirt 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 NUIirt system. For issues related to NUIirt access, contact the NUIirt 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):** See **Collecting and Handling COVID-19 Laboratory Specimens**, <http://www.nphl.org/>. One nasopharyngeal swab should be placed in a single tube of transport medium provided by NPHL. To order specimen collection kits please complete this survey: <https://redcap.link/yiro9omf>

Number of Nebraska Residents Tested^a for COVID-19 by Performing Laboratory -- 8/24-8/30/2020

| Laboratory Name | No. tested/day | Total tested | Positive | | TAT ^b (days) |
|-------------------------------|----------------|--------------|----------|--------|-----------------------------|
| | (mean) | (n) | (n) | (%) | mean, median (range) |
| TestNebraska | 1801.1 | 12608 | 870 | 6.90% | 4.02, 4 (0-17) |
| NPHL | 56.0 | 392 | 68 | 17.35% | 1.92, 1 (1-63) |
| Nebraska Medicine | 259.7 | 1818 | 199 | 10.95% | 1.21, 1 (0-6) |
| CHI/Creighton | 116.7 | 817 | 125 | 15.30% | 2.28, 2 (1-5) |
| LabCorp | 282.3 | 1976 | 184 | 9.31% | 2.59, 2 (1-12) |
| Quest | 73.1 | 512 | 76 | 14.84% | 3.50, 3 (2-24) |
| P-Lab | 165.6 | 1159 | 132 | 11.39% | 1.76, 2 (1-5) |
| All Laboratories ^c | 3247.3 | 22731 | 2213 | 9.74% | 3.87, 3 (0-99) ^d |



MEMO

To: Laboratories and Facilities Performing COVID-19 Testing

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

Date: September 4, 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 or to diagnose a possible case of COVID-19 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 RT-PCR, antibody, and rapid antigen diagnostic test results (positive and negative) to the Division of Public Health. 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](#)).

Sincerely,

A handwritten signature in blue ink that reads "Gary Anthon, M.D.".

Gary Anthon, M.D.

CMO/Director

Division of Public Health DHHS