

COVID-19 Antigen Testing Guidance

Note: This information updates previous information published by the North Dakota Department of Health regarding antigen testing including use in long term care facilities or other congregate settings. This guidance applies to all providers or facilities considering the use of or conducting COVID-19 antigen testing.

Recently the Food and Drug Administration approved under an emergency use agreement, several antigen tests that detect proteins specific to the SARS-CoV-2 virus.

The North Dakota Department of Health offers the following guidance for providers and facilities opting to use antigen testing to supplement their other testing:

- These tests are authorized for use at the point of care (i.e., in-patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation).
- Develop a plan for testing based on science and current recommendations. Take time to understand the strengths and limitations of any testing program you choose to implement.
- Read and follow the instructions that came with the instrument or test kit, entirely and carefully.
- Since North Dakota has laboratory testing personnel licensure, please contact the North Dakota Board of Clinical Laboratory Practice to determine who is eligible to perform COVID-19 testing in your facility (701-530-0199 or www.ndclinlab.com).
- Long term care should be familiar with the [CMS guidance](#) and requirements for testing.
- Read the [guidance](#) from the Centers for Disease Control and Prevention (CDC) regarding antigen testing for COVID-19.
- Read the following [information](#) from the FDA regarding [antigen testing](#):
 - [Quidel](#)
 - [BD](#)
 - [LumiraDx](#)
 - [BinaxNOW](#)

- Information regarding discordant test results can be found at the Center for Health Policy Evaluation in Long Term Care [website](#). Additional guidance for Long term care on how to evaluate potential false positives and how to respond to individuals with discordant test results can be found on the [CDC website](#).
- The best utilization of this test is testing people who have symptoms consistent with a COVID-19 infection or for testing during institutional outbreaks.
- Specimen collection should occur within the first five to seven days after the onset of symptoms.
- Positive test results in symptomatic residents or staff should be treated as positive. Appropriate infection control measures should be implemented to protect other residents and staff.
- Any positive results from testing in response to a facility outbreak should be treated as positive and appropriate infection control measures should be implemented to protect other patients, residents and staff.
- Any positive test outside of the parameters outlined in the previous two bullets should be followed with a confirmatory PCR test, collected within 48 hours.
- Long term care facilities should consider testing visitors prior to allowing visitation. Testing should not be a substitute for symptom and exposure screening and facilities should be prepared handle visitors safely if they test positive.
 - Asymptomatic visitors testing positive should be advised to go home and self-isolate. They should follow-up with their health care provider.
- Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Specimen collection for PCR confirmation need to be collected within 48 hours of the original specimen and in the absence of any known exposures.
- **Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.** Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- If the health care worker, patient or resident is tested due to symptom onset or COVID suspicion, infection prevention protocol should be followed until verified by the molecular assay, if confirmation is indicated.
- Facilities opting to use antigen testing for serial testing during a facility outbreak should follow CDC's guidance and testing [algorithm](#).
- Facilities who choose to use antigen testing will be responsible for purchasing reagents and supplies to continue testing after the initial supply, if received, from the federal government is consumed.

- **Positive test results need to be immediately reported to the Division of Disease Control by calling 1-800-472-2180 or by submitting an online report at this [website](#). Both positive and negative tests need to be reported as required by the [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#).**
- Electronic reporting through the submission of HL7 messaging is preferred, if possible.
- You can call Disease Control, at the phone number listed above, to discuss other options for reporting, such as submission of a CSV file.
- CMS requires all COVID-19 test results to be reported to the Secretary of Health and Human Services in a standardized format and at a frequency specified by CMS. Additional guidance can be found at: <https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf>

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HAN Info Service Does not require immediate action; provides general public health information

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