



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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September 1, 2020 (Update from July 31, 2020)

To: All North Carolina Clinicians and Laboratories
From: Zack Moore, MD, MPH, State Epidemiologist
Scott Shone, PhD, HCLD (ABB), Public Health Laboratory Director
Re: Antigen Testing (3 pages)

Updated to include new information about use of antigen tests in nursing homes and additional guidance for reporting of antigen test results.

A variety of testing modalities for SARS-CoV-2 are emerging. Molecular testing has been widely used for diagnostic purposes since the pandemic began. However, the need for rapid results, supply chain challenges, and molecular testing capacity issues necessitate diversifying testing modalities.

Antigen tests are designed for rapid diagnosis of active infection by detecting viral proteins on the surface of SARS-CoV-2 virus (the virus that causes COVID-19) in nasal swabs or similar clinical specimens. This test works similarly to a rapid flu test. The results take about 15 minutes. Several commercial manufacturers are developing SARS-CoV-2 antigen tests. As of today, the US Food and Drug Administration (FDA) has authorized four antigen tests for SARS-CoV-2. The Centers for Disease Control and Prevention (CDC) recently released [guidance](#) and specific [considerations for use of SARS-CoV-2 antigen testing in nursing homes](#).

Use of Antigen Tests

Antigen tests are generally less sensitive than PCR-based methods and their clinical performance depends on the circumstances in which they are used. Due to the lower sensitivity, antigen testing is best when there is a high pre-test probability of SARS-CoV-2 infection (e.g., high prevalence of infection in the community, clinical context and symptoms of the recipient of the test).

There are limited data on antigen test performance in asymptomatic persons. However, given the transmission of SARS-CoV-2 from asymptomatic and pre-symptomatic nursing home residents and healthcare personnel (HCP) with SARS-CoV-2 infection, CDC has provided considerations for the use of antigen tests in asymptomatic persons during this public health emergency. Facilities should be aware of the [FDA EUA](#) for antigen [tests](#) and potential implications for the [Clinical Laboratory Improvement Amendments \(CLIA\)](#) certificate of waiver when using antigen tests in asymptomatic individuals and in persons >5 days from symptom onset.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

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Example populations or circumstances in which antigen testing could be considered:

- Symptomatic individuals in whom COVID-19 is suspected, particularly within 5-7 days of symptom onset. Note that two of the four [antigen tests with FDA EUA](#) are approved for use within 5 days, one within 7 days, and one within 12 days of symptom onset.
- Symptomatic and asymptomatic individuals in congregate settings, like nursing homes or similar settings, where less frequent, highly sensitive tests are not available or subject to prolonged turnaround times and in accordance with [federal guidance](#).

Evaluating Antigen Testing Results

Positive antigen tests should be considered an indication of likely SARS-CoV-2 infection, especially when pretest probability is high. Clinical management of patients with a positive antigen test should be the same as for patients with a positive molecular PCR test beginning with prompt isolation. In cases of a positive antigen test with low pretest probability, persons who receive a positive antigen test should isolate until they can be confirmed by RT-PCR. Clinicians should review [Steps for People After COVID-19 Testing \(Spanish\)](#) with patients who have antigen testing performed and immediately report to the state or local health departments per existing guidance for COVID-19 diagnostic test. Further public health actions including isolation and contact tracing will be taken in coordination with the local health department.

Negative antigen test 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, and confirmed with an FDA authorized molecular assay, if necessary, for patient management. Specific [considerations for interpreting antigen results in nursing homes](#) have been posted by CDC.

Reporting Antigen Test Results

All positive and negative antigen results must be reported as part of required reporting of COVID-19 diagnostic tests. The requirements and methods of reporting for antigen tests are the same as for molecular PCR tests.

Laboratories are required to report electronically, either via Electronic Lab Reporting (ELR) or in accordance with the laboratory data automation process outlined in the [guidance for reporting results](#).

The most current information on reporting requirements and methods of reporting for COVID-19 diagnostic tests is available in this [State Health Director Order](#) and [associated guidance](#).

Physicians and other healthcare providers are required to report all positive and negative test results that will not be reported by a laboratory in accordance with this guidance within 24 hours of receiving the test result to the local health director in the [county or district where the patient resides](#). The State is developing an online survey wherein providers can report the aggregate number of positive and negative nucleic acid COVID-19 diagnostic tests and the aggregate number of positive and negative antigen COVID-19 diagnostic tests per day to the Division of Public Health.

Physicians are required to report accompanying data for all positive tests by telephone or secure fax to the local health director in the [county or district where the patient resides](#), even if the result is reported by a laboratory in accordance with this guidance.

Based on current national case definitions of COVID-19, patients with a positive antigen test who do not have a positive molecular (PCR) test are defined as probable cases. Patients with a positive molecular PCR test are defined as confirmed. Public reporting of cases will reflect this difference in case definition. However, reporting requirements and public health follow up should be followed for both confirmed and probably cases as described above.

Additional Information for Healthcare Providers

- The most current information on testing and testing resources is available at <https://covid19.ncdhhs.gov/about-covid-19/testing>.
- The most current recommendations regarding infection prevention, therapeutic options and other topics are available at <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>.
- Additional information and resources for providers and the public are available at <https://covid19.ncdhhs.gov>.
- Providers needing consultation can call the epidemiologist on call at 919-733-3419. Questions about how to report can be submitted to NCDHHS_LabsCommunications@dhhs.nc.gov with subject "Antigen Guidance"
- Members of the public should call 2-1-1 or 888-892-1162 or text COVIDNC to 898211.
- Providers and patients can utilize NCCARE360 to identify and connect to medical and non-medical health related resources <https://nccare360.org/>.