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July 31, 2020 (Update from July 16, 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 (2 pages)

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 2 antigen tests for SARS-CoV-2.

Antigen tests are generally less sensitive than PCR-based methods. Due to the lower sensitivity, antigen testing is best when there is a high pre-test probability of SARS-CoV-2 infection. **Populations or circumstances in which antigen testing should be considered include:**

- Symptomatic individuals in whom COVID-19 is suspected at a time and place of known high prevalence of COVID-19.
- Symptomatic and asymptomatic individuals in correctional facilities, long-term care facilities or other high risk, congregate settings where active cases have been confirmed as part of an active outbreak investigation.

Settings where antigen tests could be deployed include:

- Strike teams to provide targeted testing in emergency or outbreak situations
- High risk congregate settings as part of outbreak response
- Triage for individuals with respiratory symptoms in an Emergency Department or similar setting
- Primary care or urgent care for symptomatic patients
- Community based testing sites for symptomatic individuals in populations with known high prevalence rates

Antigen tests are less useful where pre-test probability is lower. **Populations or circumstances in which antigen testing are not appropriate include:**

- Asymptomatic individuals not in high risk settings

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

- Asymptomatic screening of individuals or populations
- Screening of health care workers, emergency responders and other essential personnel
- Population-based surveillance studies.

Positive antigen tests should be considered an indication of likely SARS-CoV-2 infection. Clinical management of patients with a positive antigen test should be the same as a molecular PCR test. 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 results with an antigen test 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.

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. The most current information on reporting requirements and methods of reporting for COVID-19 diagnostic tests is available at:

- https://files.nc.gov/covid/documents/guidance/healthcare/SHD-Temporary-Order-Reporting-Requirements.pdf_and
- <https://files.nc.gov/covid/documents/guidance/healthcare/SHD-Order-Guidance-SL-2020-4-Sec.4.10.a.pdf>

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, despite this difference in national case definition and public reporting requirements, clinical management, and public health follow up should be followed for both confirmed and probable 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.
- 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/>.