October 8, 2020 (Update from September 1, 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 provide additional guidance for serial use in congregate settings, interpretation of results, and 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. The Centers for Disease Control and Prevention (CDC) released guidance for rapid antigen testing for SARS-CoV-2 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, false negative antigen test results are possible and 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).

The current FDA authorized antigen tests are intended for use in symptomatic individuals within the first 5 to 7 days of symptom onset. However, antigen tests are also being used off-label for testing individuals who are asymptomatic and may have or not have known contact or specific exposure to SARS-CoV-2. There are limited data on antigen test performance in asymptomatic individuals; however, there have been anecdotal reports of positive antigen test results in asymptomatic individuals followed by negative PCR test results (presumed false positives).

Given the transmission of SARS-CoV-2 from asymptomatic and pre-symptomatic nursing home residents and healthcare personnel 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

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Amendments (CLIA) certificate of waiver when using antigen tests in asymptomatic individuals and in persons who are within the first 5 to 7 days after symptom onset.

Example populations or circumstances in which antigen testing could be considered:
- Symptomatic individuals in whom COVID-19 is suspected, particularly within 5 to 7 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.
  - As part of an outbreak response, serial testing should be performed (antigen or PCR) every 3 to 7 days, for all residents and healthcare personnel until no new cases are identified in a 14-day period.
  - Serial testing for all healthcare personnel (antigen or PCR) is required in skilled nursing facilities and may be considered in other congregate settings.

Evaluating Antigen Testing Results
Results from antigen tests should be interpreted with consideration of pre-test probability of infection, including the patient’s recent exposures and presence/absence of clinical signs and symptoms consistent with COVID-19.

<table>
<thead>
<tr>
<th>Antigen Test Result</th>
<th>Symptomatic (first 7 days) or Close Contact/Known Exposure#</th>
<th>Asymptomatic and No Close Contact</th>
</tr>
</thead>
</table>
| Positive            | • COVID-19 case  
                      • Prompt isolation  
                      • [Steps for People After COVID-19 Testing (Spanish)]  
                      • An individual who is a close contact/known exposure and tests negative must still complete a 14-day quarantine. | • Presumptive COVID-19 case  
                      • Prompt isolation  
                      • Confirm positive result with a PCR test in a CLIA certified laboratory* |
| Negative            | • Presumptive negative  
                      • If symptomatic, confirm negative antigen result with a PCR test in a CLIA certified laboratory*  
                      • An individual who is a close contact/known exposure and tests negative must still complete a 14-day quarantine. | • Negative  
                      • No additional case follow-up necessary  
                      • Reinforce prevention measures: Wear, Wait, Wash |

#Close contact/known exposure is defined as within 6 feet of someone known to have COVID-19 for 15 minutes or longer.

*A positive antigen result in an asymptomatic, unexposed individual should be immediately followed by a PCR test in a CLIA certified laboratory to verify the positive result. This follow-up specimen should be collected within 24 hours of the original test, if possible; and no more than 48 hours after the antigen test. Specimens collected greater than 48 hours after the initial test may lead to discordant results. If the confirmatory PCR is negative on an appropriate specimen collected in the proper timeframe and the individual has remained asymptomatic, the antigen test would be considered a false positive and the individual not counted as a COVID-19 case.

*While multiple specimen types may be acceptable, if possible, confirmatory tests should be performed using specimens with evidence of the most sensitivity, such as nasopharyngeal or mid-turbinate swabs.
Clinical management of patients with a positive antigen test should be the same as for patients with a positive PCR test, beginning with prompt isolation. Further public health actions including case investigation and contact tracing should be taken in coordination with the local health department. 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 and now appear on the State’s [COVID-19 dashboard](https://covid19.ncdhhs.gov/about-covid-19/testing). The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests – including the NC Administrative Code Emergency Rule and the associated guidance – are available on the DHHS health care guidance page.

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.

NC DHHS has developed an electronic survey to collect data on daily COVID-19 testing volumes from laboratories not currently reporting all results through Electronic Laboratory Reporting (ELR) or COVID-19 Lab Data Automation (CLDA). The survey, called “Electronic COVID-19 Aggregate Test Reporting” (eCATR) is used to collect aggregate testing volumes from laboratories and/or point of care (POC) facilities each day, including weekends, by 8:00 AM. For questions or comments about reporting, please email NCDHHS_LabsCommunications@dhhs.nc.gov.

**Please note:** This survey does not replace the requirement to submit positive COVID-19 test results to the Division of Public Health or Local Health Department, as required by the NC Administrative Code Emergency Rule.

**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](https://covid19.ncdhhs.gov/about-covid-19/testing).
- Additional information and resources for providers and the public are available at [https://covid19.ncdhhs.gov](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/](https://nccare360.org/).