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December 10, 2020 (Update from October 8, 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 use in decisions regarding duration of quarantine, broader use in coordinated screening programs, 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 few days of symptom onset. There are increasing data to help guide the use of antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19. See [FDA's Recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19](#). Also see information from the Centers for Medicare & Medicaid Services (CMS) on [Enforcement discretion for the use of SARS-CoV-2 point-of-care testing on asymptomatic individuals](#).

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.
- Close contacts to a COVID-19-positive individual in whom the local health department has determined that quarantine can be ended on day 7 after receiving a negative test result in accordance with [CDC guidance](#). This test must occur on day 5 or later.
- Asymptomatic individuals in other settings (including [educational settings](#)) as part of a coordinated screening program.

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.

Antigen Test Result	Symptomatic (first 7 days) or Close Contact/Known Exposure [#]	Asymptomatic and No Close Contact
Positive	<ul style="list-style-type: none"> • COVID-19 case • Prompt isolation • Steps for People After COVID-19 Testing (Spanish) 	<ul style="list-style-type: none"> • Presumptive COVID-19 case • Prompt isolation • Confirm positive result with a PCR test in a CLIA certified laboratory⁺*
Negative	<ul style="list-style-type: none"> • 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⁺⁺ 	<ul style="list-style-type: none"> • 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.

** *If approved by the local health department, quarantine can end after Day 7 in accordance with [CDC guidance](#) if a diagnostic specimen tests negative by antigen or molecular test and if no symptoms were reported during daily monitoring. The specimen may be collected and tested within 48 hours before the time of planned quarantine discontinuation (e.g., in anticipation of testing delays), but quarantine cannot be discontinued earlier than after Day 7.*

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](#). 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](#).

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/>.