NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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To: All North Carolina Clinicians and Laboratories
From: Zack Moore, MD, MPH, State Epidemiologist
Scott Shone, PhD, HCLD (ABB), Public Health Laboratory Director
Re: At-Home COVID-19 Testing (4 pages)

As accessibility of over-the-counter home testing for SARS-CoV-2 continues to expand, these tests will play an increasing role in identification of infection and prevention of spread. This document is being updated to reflect new guidance for use of home test results in making treatment decisions as well as clarifications from the Centers for Medicare and Medicaid Services (CMS) regarding CLIA applicability.

Types of Home Tests

Two types of home testing options comprise the products authorized by FDA for the detection of SARS-CoV-2. These options are authorized for use in different locations, with different specimen types, and for different age groups.

- At-home collection devices permit an individual to collect a specimen at home and ship it to a CLIA-certified laboratory for analysis using a molecular test. Results for at-home collections are typically reported to the individual, the individual's healthcare provider, and public health authorities. Currently, the FDA has authorized at-home devices for the collection of nasal swabs or oral fluids. To see a current list of FDA authorized at-home collection devices, please visit the FDA's Emergency Use Authorization for Molecular Diagnostic Tests website and enter the search term "home collect" including quotes.

- At-home test devices permit an individual to test and obtain a result for a self-collected specimen at home. Currently, the FDA has authorized both molecular and antigen-based at-home devices that use nasal swab or anterior nares specimens. Some at-home tests require a prescription from a healthcare provider while others are authorized for over-the-counter use. In addition, some at-home test devices require a smartphone to perform the test or obtain results. To see a current list of FDA authorized at-home collection devices, please visit the FDA's Emergency Use Authorization for Molecular Diagnostic Tests and Antigen Diagnostic Tests websites and enter the search term "home test" including quotes. **This guidance focuses on at-home test devices.**

Considerations for Use of At-Home Test Devices

To avoid potential delays in diagnosis, healthcare providers should consider recommending, and prescribing when required, at-home tests for patients who are at increased risk for

infection or might have limited access to other testing options. At-home testing devices available over-the-counter will expedite rapid testing and diagnosis.

In addition to at-home testing for symptomatic individuals, there is a growing interest in the potential use of these devices for routine screening or serial testing of people with no symptoms or recognized exposure. Individuals considering using at-home test devices for asymptomatic screening or for post-exposure testing should select devices authorized by FDA for this purpose.

Results from at-home test devices may not be accepted for all purposes, such as documentation of a negative result before a medical procedure or air travel or to satisfy an employment requirement. Therefore, before recommending their use, the primary purpose of the at-home test device use should be considered. Regardless of the purpose of the at-home test device use, it is critical that individuals pay close attention to the test's required storage conditions (i.e., temperature) and expiration date.

At-Home Testing and CLIA Applicability

Generally, a test that has been cleared, approved, or authorized specifically for home use by the FDA is not regulated under CLIA when that test is self-administered in accordance with the FDA's authorization and authorized labeling. Additional information is available here.

If the test is either performed by someone other than the individual being tested (e.g., other staff, employee health personnel), or the results are interpreted and reported by someone other than the individual, then a CLIA certificate would be required. If the individual performs and interprets their own test and then shows their test result to someone else (e.g., employer) as proof of their result, CMS does not consider this to be interpretation or reporting and therefore CLIA certification is not required.

Over the counter home tests may also be used in CLIA-certified facilities that perform waived, moderate and high complexity testing; provided the tests have been authorized for use in those settings by the FDA. Tests issued Emergency Use Authorization (EUA) are not categorized, so they will not be found in the FDA's CLIA Database. However, the settings in which an EUA-authorized test may be used are described in the Letter of Authorization issued by the FDA. Tests authorized under EUA for use at the point of care (POC) are deemed to be CLIA waived tests while the EUA is in effect. The FDA's Tables of In Vitro Diagnostics EUAs provides regularly updated lists of tests granted EUA, including information about the authorized setting(s).

Evaluating At-Home Testing Device Results

CDC has posted detailed guidance for interpretation of antigen test results guidance for interpretation of antigen test results in community and long-term care settings. However, if an individual requires guidance on the interpretation of results from their at-home test device, they should be directed to carefully follow the device's instructions for use. Some at-home test devices may require use of a smartphone to assess results.

NOTE: Laboratory confirmation of positive at-home test results is NOT required or recommended before initiating treatment with antiviral medications or monoclonal antibodies when indicated (see NIH COVID-19 Treatment Guidelines for more information). Providers can accept patients' report of positive home tests. If confirmatory testing is performed, treatment should not be delayed while awaiting results. Patient information on monoclonal antibodies is available at https://covid19.ncdhhs.gov/treatmentadd.

Reporting At-Home Test Device Results

For at-home tests ordered by a healthcare provider, individuals who test positive should immediately report the result to that provider. Individuals with positive results should be instructed to isolate as described in the DHHS Steps for People After COVID-19 Testing (Spanish). While some at-home test device apps report results to public health, this is not the case for all tests or in all jurisdictions; therefore, healthcare providers remain responsible for reporting all results to public health. The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests – including the NC Administrative Code Rule and the associated guidance – are available on the DHHS health care guidance page. In addition, individuals should be directed to consider notifying any close contacts using available tools like SlowCOVIDNC (for users of the app whose results were reported to public health) or Tell Your Contacts.

If an individual notifies a healthcare provider about a positive result using a non-prescribed over the counter at-home test device, they should be instructed to isolate as described in the DHHS Steps for People After COVID-19 Testing (Spanish) and to notify close contacts. These results do not need to be routinely reported to public health, but providers should notify their local health department of positive results in residents or staff of congregate living facilities or other high priority settings. The individual should be instructed to contact the provider again if they have persistent or worsening symptoms or other concerns about their health or preventing the spread of COVID-19.

Individuals who are symptomatic but test negative on an at-home test device should also contact their healthcare provider to understand if they need a confirmatory PCR test and, if so, arrange a confirmatory PCR or visit the DHHS Find My Testing Place tool to identify a testing location in NC. A negative antigen test in a person with symptoms may not need confirmatory testing if the person has a low likelihood of SARS-CoV-2 infection (e.g., the person has had no known or suspected exposure to a person with COVID-19 within the last 14 days or is fully vaccinated or has had a SARS-CoV-2 infection in the last 3 months.)

If an individual with no symptoms or known close contact notifies a healthcare provider about a negative result on an at-home test device, no further action is necessary. The utilization of prevention measures should be reinforced - Wear, Wait, Wash.

Disposal

Individuals using at-home test devices should be instructed to dispose of the devices in accordance with the device's instructions for use. Some devices contain batteries that have

specific disposal instructions. Most at-home test devices can be disposed in regular trash but should be placed in a bag or other secondary container prior to disposal.

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 catr@dhhs.nc.gov with subject "At Home Testing Guidance"
  Providers and patients can utilize NCCARE360 to identify and connect to medical and non-medical health related resources https://nccare360.org/.