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)

A variety of testing modalities for SARS-CoV-2 continue to emerge. Throughout the pandemic, molecular and antigen testing have been widely used for diagnostic purposes. The tests have typically been performed in a clinical laboratory or healthcare provider's office/facility. However, at-home test options are increasing, which will permit an individual to perform a test for SARS-CoV-2 within their home and obtain a result in about 15 minutes. At-home testing technologies and understanding of best use cases are evolving; therefore, guidance will change. This initial document is modelled after the DHHS Antigen Testing Guidance. The Centers for Disease Control and Prevention (CDC)also provides general information on at-home testing for the public.

## 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 over 40 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 one is currently 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

Healthcare providers may consider recommending, and prescribing when required, at-home test devices for symptomatic individuals who have limited access to other testing options such as those found on the DHHS Find My Testing Place tool. At-home test devices that require prescription will also require delivery of the device to the individual's home.

To avoid potential delays in diagnosis, physicians should consider preemptively prescribing 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, but could require a symptomatic individual to leave their home should alternate device procurement options be unavailable.

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.

Pharmacies are likely to be a primary source of at-home test devices. Pharmacies should: (a) develop a communication and distribution plan to minimize the risk that patients seeking an at-home test could transmit the virus to others in the pharmacy; and (b) counsel patients seeking an at-home test on proper use, interpretation, results reporting, and disposal.

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. 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.

## Evaluating At-Home Testing Device Results

General evaluation guidance is provided below. 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.

| At-Home Test Result | Symptomatic or Close Contact/Known Exposure[#] | Asymptomatic and No Close Contact |
|---|---|---|
| Positive | • COVID-19 case<br>• Prompt isolation<br>• Follow Steps for People After COVID-19 Testing (Spanish)<br>• Notify close contacts | • Presumptive COVID-19 case<br>• Prompt isolation<br>• Follow Steps for People After COVID-19 Testing (Spanish)<br>• Notify close contacts<br>• Consider confirming positive result with a PCR test in a CLIA certified laboratory[+]* |
| Negative | • Presumptive negative<br>• If symptomatic, confirm negative result with a PCR test in a CLIA certified laboratory[+]<br>• An individual who is a close contact/ known exposure and tests negative **must still complete quarantine** | • Negative<br>• No additional case follow-up necessary<br>• Reinforce prevention measures: Wear, Wait, Wash |
| Invalid/Error | • Repeat the at-home test using a new device<br>• If symptomatic or close contact, consider a PCR test in a CLIA certified laboratory[+] | |

[#]Close contact/known exposure is defined as within 6 feet of someone known to have COVID-19 for 15 minutes or longer within a 24-hour period.

*Providers should consider confirming a positive at-home test device result in an asymptomatic, unexposed individual using a PCR test in a CLIA certified laboratory. This follow-up specimen should be collected within 24 hours of the at-home test, if possible; and no more than 48 hours after the at-home test.

[+]Individuals may access confirmatory testing through a healthcare provider or though the DHHS Find My Testing Place.

**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 reported to public health. 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 arrange a confirmatory PCR or visit the DHHS Find My Testing Place tool to identify a testing location in NC.

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 NCDHHS_LabsCommunications@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/.