

Background

Ohio partnered with Abbott and eMed to bring rapid, reliable testing into the home where the result is delivered in minutes. The Ohio Department of Health has secured the purchase of at least 2 million tests that can be self-administered outside of a clinical setting. It is the Governor's goal to make these tests available and accessible in every Ohio county.

The 15-minute [BinaxNOW COVID-19 Ag Card Home Test](#) has received [FDA Emergency Use Authorization](#) for at-home testing in collaboration with a telehealth session. Abbott has selected eMed, a digital health solution, as its telehealth partner. This service for COVID-19 testing prescribes and allows the test to be done rapidly at home with virtual instruction and consultation. A trained telehealth professional guides those being tested through the at-home self-test via video call using the BinaxNOW COVID-19 Ag Card Home Test and Abbott's complementary NAVICA mobile app to enable the testing process and display BinaxNOW COVID-19 test results.

The BinaxNOW COVID-19 Ag Card is a rapid antigen test and both the Food & Drug Administration and the Centers for Disease Control and Prevention have provided guidance on the use of antigen tests, and the interpretation of results. For example, the CDC provides the following guidance:

Healthcare providers should consider pretest probability when using antigen tests as screening tests, and confirmatory testing may be required for clinical management and public health decision-making. See each test's instructions for use at FDA's [In Vitro Diagnostics EUAs](#), and see FDA's [Recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19](#). Also see CMS' [Enforcement discretion for the use of SARS-CoV-2 point-of-care testing on asymptomatic individuals](#).

When testing a person who is asymptomatic and has not had known exposure to a person with COVID-19 within the last 14 days, indicating that the pretest probability is low, the healthcare provider generally can interpret a negative antigen test to indicate that the person is not infected with SARS-CoV-2. If the prevalence of SARS-CoV-2 infection is not low in the community, clinical judgement should consider whether this negative antigen test result should be followed by a confirmatory NAAT. See the antigen testing algorithm when pretest probability is low, Figure 4, which is excerpted directly from the full [antigen testing algorithm in Figure 1](#).

Note that there are two versions of the BinaxNOW Ag Card test – the at-home test described in this policy and a traditional version designed for use in clinical settings. The at-home test is self-administered (with telemedicine support to ensure proper administration), so it is best deployed for decentralized uses. The traditional version of Binax requires a provider order, CLIA waiver and centralized administration (and reporting), so it is best used in congregate settings and other environments where administration would be centralized. General information on BinaxNOW tests – including a demonstration – can be found on www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html

Procedures

See **Figure 1** below for a visual representation of these procedures

Dispensing/Distribution:

- Each distribution site – public or private – should have at least one administrator designated to be responsible for distribution.
 - The distribution site should provide to the state (TestingRequests@odh.ohio.gov) the following information:
 - Site Name
 - Site Address
 - Site Hours (if open to the public)
 - Administrator Name(s)
 - Administrator email address(es)
 - Public distribution points will have their addresses published on a public-facing website; private locations will not be published.
- A distribution site should require an individual to show a NAVICA ID for each person receiving a test (including children – see directions on adding Manage Profiles below under “Using the Test Kits”).

Storing Test Kits:

- Test kits should be stored between 35.6 and 86.0 degrees Fahrenheit.
- Expiration dates must be observed and kits removed from stored inventory when appropriate.

Required Reporting:

- Each distribution site needs to have one or more representatives designated as administrators to record required information, distribute tests, and report to the state the number of tests distributed at that site.

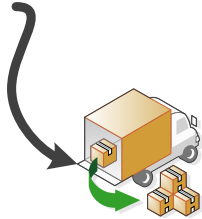
Using the Test Kits:

- BinaxNOW AG Card Home Test product information can be found on Abbott’s information page (www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html). It is a self-administered at-home test (with assistance from an eMed certified guide (ohio.emed.com)), so it is best deployed in non-clinical settings.
- Prior to receiving a test kit, an individual should download the NAVICA app on a mobile device and create an account.
 - **If the individual plans to test children or other dependent family members, they should create Managed Profiles from the “Account and Settings” portion of the app.**
- An individual should present a NAVICA ID (located within the NAVICA app) for each person receiving a test, including any dependents who have Managed Profiles.
- Individuals being tested should be given a BinaxNOW Ag Home Test and told to go to ohio.emed.com and select “Start Testing” to initiate the testing process.
 - Next, the user clicks the “Login With NAVICA” button and uses their NAVICA account credentials created above to proceed.

- There will be a series of questions to prepare for the visit with the eMed proctor. Once the user answers these questions and clicks “Continue,” the testing session with the eMed proctor will begin.
- After completing the test, the eMed proctor will report results to the Ohio Department of Health, and the user can utilize the NAVICA app to demonstrate their test results using the NAVICA Pass.
 - Go to www.abbott.com/corpnewsroom/diagnostics-testing/abbotts-new-NAVICA-app-what-you-need-to-know.html for information on how to get and use the NAVICA app.
- Helpful Hints for Test Takers:
 - The eMed proctor is not a healthcare provider but is qualified to administer the test and read the results.
 - Ensure that you have plenty of space in front of you to use the test kit. The test card must lay flat on a hard surface.
 - The eMed proctor will have you adjust your webcam at various times during the testing. The proctor will need to view the test kit on the surface in front of you at certain times and will need to view you (the patient) at other times. For the test to be validated, follow all of the proctor’s instructions. For example, the proctor must be able to view the test card during the 15 minutes the test runs or it will be invalidated.
 - You will need to scan the QR code on the test card with your webcam at two separate times. Make sure you hold the QR code up to the webcam when instructed. Keep the QR code in the center of the camera and hold it as still as possible.

Figure 1: At-Home Testing Distribution and Testing Process

Main library determines how many tests its network needs and sends the request/resupply order to TestingRequests@odh.ohio.gov.



Tests are shipped to main library for distribution to branches.

Each library distributing tests will be included on a list of sites where the public can pick up a test.



An individual who needs a test downloads the NAVICA app from the App Store or Google Play and creates a NAVICA account; and finds their closest pickup location.



Library staff check to see that the individual has a NAVICA pass and provides a test. At the time a test is distributed, staff will track the distribution of the test.



Negative results are stored within the NAVICA app and for a limited time, displays a "pass" that can be shown to an employer, school, etc,



eMed assists with administration of the test, reports the results to public health officials and provides information to individuals that test positive for COVID-19.



The individual goes to ohio.emed.com to begin a telehealth session with an eMed proctor.

Distributing and Using a BinaxNOW Home Test - Libraries