

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 weekly to the state (TestingRequests@odh.ohio.gov) 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.

Why is the state providing these tests?

The State has secured the purchase of at least 2 million tests that can be self-administered outside of a clinical setting. The new Abbott BinaxNOW Home Test can be provided to individuals for at-home use, and is packaged with a telehealth session to oversee test administration, including prescription writing and result reporting. The state's objective is to make rapid testing much more broadly accessible throughout the state.

How reliable are these tests?

The lab-based PCR tests remain the gold standard in terms of sensitivity of the tests. But the rapid antigen tests have the ability – with their scale, quick results, and lower cost – to be powerful tools in slowing the spread of COVID, by focusing on the period of time that an individual is most infectious and greater risk of spreading the disease. The BinaxNOW tests have proven extremely effective and easy to use.

Antigen tests are generally less sensitive than PCR-based methods, and their clinical performance depends on the circumstances in which they are used. The fact that antigen tests generally have lower sensitivity but consistently high specificity means there is some risk of false negatives with antigen tests, but generally not false positives when the test is administered according to the instructions. More recently, there has been more study of the use of antigen tests as screening tests for asymptomatic populations, including [this recent one from the CDC](#). Note that its conclusion, while recognizing the limitations of antigen tests, is that “Antigen tests can be an important tool in an overall community testing strategy to reduce transmission.” Here is [another recent study](#) evaluating the use of antigen tests in asymptomatic populations.

How does a user get the test?

A user should start by downloading the NAVICA app onto a mobile device and create an account for themselves and, if they want to test any children or other dependents, create managed profiles from the “Account and Settings” portion of the app. An Ohioan can find sites that have tests available at ohio.emed.com, and can use their NAVICA ID to obtain the test from the distribution site they select. Before going to a distribution site, a user should call ahead to confirm hours and make sure the site has tests available for pickup.

How does a user get a test for a child or other dependent who doesn't have their own email address to create a NAVICA account?

In the NAVICA app, once a user has created their account, they can create Managed Profiles for children and other dependents who might not have a separate email address or are otherwise unable to create a separate NAVICA app. Go to the “Account and Settings” portion of the app to create a Managed Profile. The app will display separate NAVICA IDs (used for obtaining a test from a distribution site) and NAVICA passes (used to show test results) for each profile on an account. When a user initiates a test through ohio.emed.com, they will be asked which person on the account is being tested, and the results will be reported for the appropriate user.

What if someone who wants to use the test doesn't have an internet connection or equipment to complete the telehealth session?

The BinaxNOW Home tests are intended to make decentralized, at-home use more accessible. But if a person (or group of people) lacks access to all the necessary resources, a distribution site may create workarounds – e.g., centralized locations with computers and internet available to perform the telehealth. In addition, while the NAVICA app is the primary way to receive individual results from the test, specific requests can be made for an email or other mechanism of delivering a result to an individual who doesn't have a smartphone. A person can call eMed customer support at (844) 943-0061 to have the test results sent outside of the NAVICA app.

What should an individual do if their telehealth session is interrupted before completion?

If a telehealth session is interrupted, the individual should immediately return to ohio.emed.com and select the option to begin a test and explain to a proctor that the prior session was interrupted. If the proctor determines that the session is unable to proceed, contact eMed support at (844) 943-0753 for assistance.

How are results reported?

eMed is responsible for reporting results. For the individual being tested, results are returned through the NAVICA app, and the NAVICA pass can be used to demonstrate a test result to an employer, school, or other party. For public health reporting, eMed sends results through the electronic lab reporting system.

Can we skip the telehealth portion of the test and just have the distribution site also perform the test?

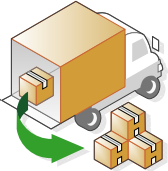
No, the Home test's [Emergency Use Authorization](#) from the FDA specifically states, "The BinaxNOW COVID-19 Ag Card Home Test is to be performed only with the supervision of a telehealth proctor." Bypassing the telehealth portion of the test would also mean there would not be a prescription for the test to be administered, as the prescription specifically includes this aspect of the test. However, there are more appropriate, rapid antigen tests that can be administered at a distribution site that has a CLIA certification or waiver, can provide an order for the test, trained medical staff to administer and a mechanism for reporting the results of the test to the Ohio Department of Health. If appropriate, please contact the state testing team at TestingRequests@odh.ohio.gov to discuss these alternative options.

What if the results of my test or my pass are not available within the NAVICA app?

Call eMed Customer Support at (844) 943-0061.

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.



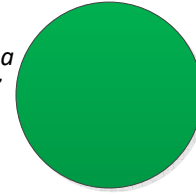
An individual who needs a test downloads the NAVICA app from the App Store or Google Play and creates a NAVICA account; and finds their closest pickup location.



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.

Distributing and Using a BinaxNOW Home Test - Libraries

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.

