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. (Copies of the studies are attached.)

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 <u>Emergency Use Authorization</u> 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 <u>TestingRequests@odh.ohio.gov</u> 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.