

Abbott BinaxNOW Ag Home Tests Guidance Document

Background

Ohio has partnered with Abbott and eMed to bring rapid, reliable testing into the home where the result is delivered in minutes.

The 15-minute [BinaxNOW COVID-19 Ag Card Home Test](#) is available under U.S. Food and Drug Administration (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 to use the BinaxNOW COVID-19 Ag Card Home test via a video call. The telehealth professional will help the user complete the test and obtain BinaxNow COVID-19 test results while on the call.

There are three versions of the BinaxNOW Ag Card test – the at-home test described in this policy, an over-the-counter (OTC) self-administered test, and a traditional version designed for use in clinical settings. The at-home test is self-administered (with telehealth support to ensure proper administration), so it is best deployed for decentralized uses. The OTC test does not require clinical support or CLIA laboratory certification, but is intended to be used for personal decision-making. The traditional version of BinaxNOW 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 about BinaxNOW tests – including a demonstration – can be found on www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html.

The BinaxNOW COVID-19 Ag Card is a rapid antigen test, and both the FDA and the Centers for Disease Control and Prevention (CDC) have provided guidance on the use of antigen tests, and the interpretation of results. More information: [CDC Testing Guidance for the General Public](#).

Procedures

Distribution/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 weekly through an online portal.
- The testing partner must ensure that each distribution is only reported once. Partners are not required by the state to report any information about the individuals' receiving tests.
- Reporting site: <https://coronavirus.ohio.gov/contact-us/binaxnow-reporting-form/>

Information required:

- Name and email address of individual reporting
- Number of tests distributed (this is the total number of tests handed out)

- Note that the state is not requiring sites to report test results as part of this process.
- For Schools: Every district office and school building is available for selection in the reporting portal, and a district may choose to report at the district or building-level. Districts must select their reporting method, but also ensure that a distribution is only reported once.

Expiration Dates:

- Expiration dates must be observed, and tests removed from distribution inventory when appropriate.
- The FDA has made available on its website an [expiration date lookup tool](#) for all home test/OTC COVID-19 tests that have received an emergency use authorization (EUA). Details:
 - Scroll down to view the complete list of products.
 - Sites can select their specific test and within the “Expiration Date” column, click on **“Expiration Date: See link for list of updated expiration dates”**
 - Sites can then locate their lot #(s) on the list provided and find their expiration date

Using the Tests:

- The BinaxNOW test is authorized for individuals ages 4 and older, but a child under 15 must have an adult perform the swabbing.
- **The telehealth session is required for using the BinaxNOW tests** and can be completed using either a computer with webcam or a mobile device.
- DO NOT OPEN the packaging until instructed.
- Initiate the testing session by going to ohio.emed.com and select “Start Testing.” Follow the prompts.
- Users will need to create an eMed account to proceed.
 - eMed accounts online can only be used for individuals 18 years or older.
 - If you are assisting a minor with testing, additional instructions are below:
 - A NAVICA account and a managed profile must also be created. This can be done by using the NAVICA app or through the online portal at www.mynavica.abbott. Instructions can be found [here](#) for how to get and use the NAVICA app.
 - **A parent should create a NAVICA account and then create a Managed Profile for each child being tested in the Managed Profiles section on the portal or under the “Account and Settings” portion of the app.**
 - Individuals should then go back to ohio.emed.com and sign-in with their eMed account to initiate the testing process or begin testing in the NAVICA app.
 - 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. 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.

- After completing the test, the eMed proctor will report results to the Ohio Department of Health, and the user will receive their results via email. Results, including a NAVICA Pass, will also be available in the NAVICA smartphone app if an account was created.