

## Abbott BinaxNOW Ag Home Tests Q&A (K-12 Schools)

### *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.

As one primary use of these new tests, the State is partnering with Educational Service Centers (ESCs) to make the tests available in Ohio schools, including public and private schools. Each district will make the decision about whether and how to use these tests, as well as how they will be distributed.

### *What kind of test is being made available to schools?*

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.

### *Is the state requiring us to use the tests for anything specific?*

Each school district or private school system will decide if and how the tests are to be used. School leaders should consider the fact that COVID-19 vaccines have been made available to teachers and staff, as well as the state guidance around quarantine of in-classroom exposures to positive cases. That said, the at-home tests would be appropriate for testing symptomatic students, teachers, and staff. In addition, school leadership might decide to use the tests for regular asymptomatic screening, including for individuals participating in extracurricular activities. The tests could also be used for testing individuals in quarantine for release after seven days, pursuant to [CDC guidance](#). Schools are encouraged to consult with their local health districts (LHDs) about appropriate testing strategies.

In addition, the Centers for Disease Control and Prevention (CDC) [have invested \\$10 billion](#) from the American Rescue Plan for screening testing in K-12 schools. CDC provided [guidance to states](#) for how to implement this initiative. While testing remains voluntary for schools, and the specific elements of the testing strategy are to be determined by the school, the CDC is strongly emphasizing aggressive weekly screening testing as a mitigation strategy in schools. More information about the screening strategy advocated by the CDC can be found in their [guidance to states](#).

### *How should BinaxNOW Home tests be utilized in schools?*

Broadly speaking, there are two ways to utilize these specific tests for students and/or staff members:

1. Home Administration – have the student/staff person pick up the test from a distribution point inside or outside of the school (e.g., school nurse's office, District offices, Local Health Districts, etc.), and then take the test home for self-administration utilizing the eMed telehealth service. Under this scenario, the school personnel would presumably desire to see the test results through the NAVICA app, but would not participate in administration of the tests.
2. In-School Telehealth – a school could dedicate a computer that can be used by the individual for the eMed telehealth session under the supervision of school personnel. The school would need to navigate issues around parental consent and access to the student's profile in NAVICA, but if it could resolve those issues, the BinaxNOW Home test could be used in this manner.

Some schools have asked about eliminating the telehealth session and instead, utilizing school personnel to conduct the test. The BinaxNOW Home test is not the appropriate test for this scenario. 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 the school, by school personnel. If a school 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, the State may be able to provide the appropriate tests. Please contact the state testing team at [TestingRequests@odh.ohio.gov](mailto:TestingRequests@odh.ohio.gov) to discuss these alternative options.

### ***Should tests be used for individuals who have been vaccinated?***

Schools should follow [CDC guidance](#) regarding vaccinated individuals. As of March 8, 2021, the following guidance was in place for non-healthcare settings:

Although the risk that fully vaccinated people could become infected with COVID-19 is low, any fully vaccinated person who experiences [symptoms consistent with COVID-19](#) should [isolate themselves from others](#), be clinically evaluated for COVID-19, and tested for SARS-CoV-2 if indicated. The symptomatic fully vaccinated person should inform their healthcare provider of their vaccination status at the time of presentation to care.

Fully vaccinated people with no COVID-like symptoms do not need to [quarantine](#) or be tested following an exposure to someone with suspected or confirmed COVID-19, as their risk of infection is low.

Fully vaccinated people who do not quarantine should still monitor for [symptoms of COVID-19](#) for 14 days following an exposure. If they experience symptoms, they should isolate themselves from others, be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated, and inform their health care provider of their vaccination status at the time of presentation to care.

### ***How does a school get access to these tests?***

The state will allocate the tests through Ohio's Educational Service Centers (ESCs). Each district (including private schools) that wants to access the tests should work with its ESC to request an initial allocation, and to request additional tests if necessary. The district will also work with the ESC to designate one or more individuals to keep track of the number of tests distributed and to report that information to the state on a weekly basis.

### ***What equipment/software does an individual need to perform the test?***

- Windows or Mac/Apple laptop with a webcam (or a desktop computer with an adjustable/ moveable webcam), microphone, and speaker;
- An Apple phone/tablet or an Android phone/tablet, with the NAVICA app from Abbott downloaded;
- An email address; and
- An internet connection
- Note that at this time, a testing session can be completed end-to-end using a computer with webcam, a cell phone or other mobile device, or a combination of the two.
  - a. A testing session should be initiated by going to [ohio.emed.com](http://ohio.emed.com) and selecting "Start Testing."
  - b. A NAVICA account can be created and results can be received and reviewed through the NAVICA app or by visiting [www.mynavica.abbott](http://www.mynavica.abbott).

### ***How does a student or staff demonstrate a negative test result?***

A test result will be reported to the NAVICA app, and will display the name of the person who took the test, the date the test was taken, and the test result. An individual who does not have access to a smart phone may also obtain a record of their test by logging into their NAVICA account at [www.mynavica.abbott](http://www.mynavica.abbott). Each school can decide how it wants to receive the results, but options include displaying the result directly from the NAVICA app, displaying a screenshot of the NAVICA pass, or providing an email from eMed with the test result.

### ***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 parent or guardian initiate a test for a student who can't create their own NAVICA account?***

In the NAVICA app or at [www.mynavica.abbott](http://www.mynavica.abbott), once a parent 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 account. In the 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](http://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 school may create workarounds – e.g., centralized locations with computers and internet available to perform the telehealth.

***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](http://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 their NAVICA account, either in the app or at [www.mynavica.abbott](http://www.mynavica.abbott), 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 school 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](mailto:TestingRequests@odh.ohio.gov) to discuss these alternative options.

***Can we use these tests to avoid quarantine requirements?***

These tests are a tool for identifying individuals who are infected and are most likely to transmit the virus. They do not change policy. On January 5, 2021, Governor DeWine issued [guidance on K-12 school quarantines](#), which is not changed by this offer for testing.

***If a student, teacher or staff member is required to quarantine pursuant to state or local guidance, may a test be used to end the quarantine period early?***

Pursuant to [CDC guidance](#), quarantine can end after day seven if a diagnostic specimen tests negative and if no symptoms were reported during daily monitoring. The specimen may be collected and tested within 48 hours before the time of planned quarantine discontinuation (e.g., in anticipation of testing delays), but quarantine cannot be discontinued earlier than after day seven.

***Can we provide a symptomatic student or staff multiple tests so that family members can also be tested?***

Yes.

***What information is a school required to report to the state about people who are given tests?***

Each school participating in the state testing initiative must report certain information to the state weekly through an online portal (<https://coronavirus.ohio.gov/wps/portal/gov/covid-19/contact-us/binaxnow-reporting-form/>). 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. Whichever reporting method is selected, the district must ensure that a distribution is only reported once. The following information is required to be reported:

- 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 schools to report test results as part of this process. Some of the information is required to be reported to the CDC as part of the federal K-12 testing initiative. It is extremely important that all participating schools report by the close of business each Monday.

***What do we do if tests are unused at the end of the school year?***

An ESC that has extra test kits at the end of the year is asked to contact the state testing team at [TestingRequests@odh.ohio.gov](mailto:TestingRequests@odh.ohio.gov) to make arrangements to return them to the state. School districts that have extra tests should notify the state testing team and make arrangements to deliver any leftover tests to a local public library or local health department that is serving as a pickup site for tests.

***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.