Abbott BinaxNOW Ag Home Tests
Q&A (Higher Education)

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, it is the Governor's intention to make these tests available for free to institutions of higher education. Each institution 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 institution will decide how the tests are to be used. The at-home tests would be appropriate for testing symptomatic students, faculty, and staff. In addition, 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. Institutions are encouraged to consult with their local health districts (LHDs) about appropriate testing strategies.

How should BinaxNOW Home tests be utilized on campus?
Broadly speaking, there are two ways to utilize these specific tests for students and/or staff members:

1. Home Administration – have the student or faculty/staff pick up the test from a set distribution point, and then take the test home for self-administration utilizing the eMed telehealth service. Under this scenario, the institution's personnel would not participate in administration of the tests.
2. On-Site Telehealth – an institution could dedicate a computer that can be used by the individual for the eMed telehealth session under the supervision of the institution's 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 institutions have asked about eliminating the telehealth session and instead, utilizing their 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, the state is also making available to colleges and universities the traditional version of BinaxNOW, which can be administered at the school, by school personnel. If an institution 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, it can request these tests by contacting the state testing team at TestingRequests@odh.ohio.gov.

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.
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> 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.
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> 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.

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

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 result by calling eMed customer support at (844) 943-0061 to have the test results sent outside of the NAVICA app. Each institution 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 child who can't create their own NAVICA account?

In the NAVICA app, 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 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, an institution 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, the state is also making available to colleges and universities the traditional version of BinaxNOW, which can be administered at the school, by school personnel. If an institution 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, it can request these tests by contacting the state testing team at TestingRequests@odh.ohio.gov.

If a student, faculty 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.

What information is an institution required to report to the state about people who are given tests?
Each school is required 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. The institution does not need to provide a list of the individual(s) responsible for reporting – names will be collected at the time the report is submitted. The institution must ensure that each distribution is only reported once. Schools are not required by the state to report any information about the students or staff receiving 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.