Abbott BinaxNOW Ag Home Tests Guidance Document (K-12 Schools)

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 Ohio schools. The state will allocate the tests through Ohio's Educational Service Centers (ESCs), and each district will make the decision about whether and how to use these tests, as well as how they will be distributed.

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.
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> 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 school district 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 district 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 school district 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.
- When dispensing a test, school personnel should remind the individual that a NAVICA account is required for taking the test. Adults – staff or parents – should be encouraged to download the NAVICA app on a mobile device and create an account prior to receiving a test if possible (for students, 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:

- The number of tests distributed each week must be reported 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 the number of tests at the district or building-level. Whichever reporting method is selected, the district must ensure that a distribution is only reported once.

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 initiating a testing session, an individual should download the NAVICA app on a mobile device and create an account.
    - **If the test is being used on a child, a parent should create an account and then create a Managed Profile (from the "Account and Settings" portion of the app) for each child being tested.**
- 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.
    - The BinaxNOW test is authorized for individuals age four and older, but a child under 15 must have an adult perform the swabbing.
    - 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.

Figure 1: At-Home Testing Distribution and Testing Process