Guidance Document

BinaxNOW Testing (Higher Education)

Traditional Version

The federal government, via the U.S. Department of Health and Human Services, has distributed Abbott BinaxNOW™ COVID-19 tests to expand strategic, evidence-based testing in the United States. As the pandemic continues to evolve, the state wants to emphasize the importance of continued testing as part of the overall strategy to keep campuses open and safe, the State of Ohio will use a portion of its allocation of these rapid antigen tests to support Ohio's higher education institutions in their campus community surveillance efforts.

The following document provides an overview of these tests, operational needs to deploy, and data and reporting requirements. These materials should be used in conjunction with available guidance from the manufacturer, as well as other state and federal guidelines and requirements.

NOTE: Abbott Laboratories has established a training and support website for the deployment of BinaxNOW tests: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html. This site will be your primary source of information and support. The information below is intended to supplement the Abbott support site, and support contacts are listed later in this resource to assist directly with implementation.

1. Abbott BinaxNOW COVID-19 Tests

The BinaxNOW™ COVID-19 test is a lateral flow test that detects the presence of protein antigens from SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

These tests are authorized for point-of-care delivery, meaning that the test can be processed at the site of care without requiring a laboratory for test processing and results are indicated on the BinaxNOW Ag card within 15 minutes of administration.

Abbott's BinaxNOW can be linked with NAVICA, a mobile testing app designed to provide results to the patient. The application does not report results to the state and local health departments and is not required for using BinaxNOW.

2. Intended Usage at Colleges and Universities

The Ohio Departments of Health (ODH) and Higher Education (ODHE), in close consultation with institutions for higher education (IHE) and local public health officials, recommend that any IHE with on-campus student housing should develop a screening testing program focused on testing asymptomatic individuals. Specifically, Ohio's Responsible Restart Guidelines for Higher Education include guidance that campuses "screen through testing at least 3% of their at-risk population, including regularly testing a

sample population of asymptomatic students. This should be done in partnership with their local health department."

3. Operational Needs for BinaxNOW Testing

Sites of administration

The BinaxNOW test is authorized for point-of-care use in settings operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certification of Compliance, or Certificate of Accreditation.

The application to apply for a CLIA certification or waiver can be found here and additional support can be provided by contacting Abbott support, the Ohio Department of Health, or by contacting Ohio's testing team at TestingRequests@odh.ohio.gov. Once a testing site has identified a laboratory director and provided all required information on the application, a CLIA number will be assigned and the site can begin testing for COVID-19.

Testing environment

In order to effectively administer BinaxNOW tests, sites must ensure the proper resources and structures are in place. This includes understanding personnel, testing, and reporting requirements. Sites administering tests must also ensure that they are following the latest guidelines for maintaining physical distance, wearing face coverings, monitoring the daily health of patients/employees (e.g., temperature checks), and ensuring a clean and disinfected environment.

Testing equipment

Test kits include test cards (40), one bottle of extraction reagents (1), nasal swabs (40), positive control swab (1), negative control swab (1), product insert (1), and product card (1). Testing kits will not provide a clock or stopwatch to monitor the time waiting for results, materials available as an optional accessory, or swab transport tube accessory packs.

Test kits should be stored at a temperature between 35.6 and 86 degrees Fahrenheit. The tests are viable until the expiration date marked on the outer packaging and should only be used with swabs provided in testing kits. All test components should be at room temperature before use.

For additional precautions on testing equipment (e.g., do not mix components from test kits, do not reuse test cards), and for instructions on testing, please see the Abbott support page.

Quality control

Prior to beginning testing, positive and negative control swabs should be used to ensure test reagents are working and tests are performing correctly. ***Quality control should be run once for each new shipment received, and once for each untrained operator.*** A quality control instruction video is available on the Abbott support portal.

Test administrators

BinaxNOW tests must be administered by medical professionals (e.g., physicians, nurses, pharmacists) or trained operators proficient in performing rapid lateral flow tests. Each test administrator should be properly trained in administering BinaxNOW COVID-19 tests and interpreting results. Abbott has provided modules

and video instruction to aid in training testing administrators. Additional guidance on the administration of the tests, including recommended PPE usage, is available on the Abbott support site and through the CDC.

Patient registration and data collection

Additional personnel will likely be needed to conduct patient intake and record relevant data, including a .csv file provided by the State to collect relevant information about the patient and test. This information will need to be linked to the broader reporting system on a daily basis. (See Section 5 on Data Collection and Reporting). Please note that data collection on testing is required by the state.

Patient education

It is important to provide patients with information about both the BinaxNOW test, and about the implications of their results.

Each patient should receive the FDA's "Fact Sheet for Patients," providing information about COVID-19 protocol and the BinaxNOW test.

In addition, patients should be provided with information on actions to take based on the results of their test, and specifically what to expect if they receive a positive test result (e.g., contact tracing). Patient materials can be found here including FAQs and what to do for individuals that test positive.

4. Implications of 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.

5. Data Collection & Reporting

Reporting requirements

All sites performing COVID testing on Ohio residents must meet the public health reporting requirements for COVID-19. There are two current Ohio requirements (1) daily aggregate count reporting of total tests performed, by result type, and (2) individual case/line level reporting with patient information.

Note that no personal health information is made available to the public under these reporting requirements.

Aggregate count reporting

Aggregate testing reports are used to track testing volume, capacity, and key metrics like percent positivity which are presented daily at coronavirus.ohio.gov and reported to the CDC and FEMA.
For aggregate count reporting, each testing site will need to register with ODH in order to be able to use data reporting tools. Once registered, the site must report all COVID-19 results daily by 11 am ET at coronavirus.ohio.gov/labreport. This includes the breakdown of positives, indeterminates, and negative test results.

Case/line level reporting

To be compliant with Health & Human Services (HHS) requirements (as of 8/1/2020), sites administering tests must also report all individual case results (e.g., positive, negative, indeterminate, invalid) to ODH within 24 hours of completion of the test being performed, using an approved electronic submission method (i.e. HL7, CSV format). ODH requires that you set up an electronic laboratory reporting (ELR) data feed to reduce the burden on the laboratory/facility, and allow LHDs and ODH to receive your data daily, securely, and most efficiently. This involves setting up a secure connection with ODH and working on a HL7 or CSV formatted file to send COVID-19 results electronically.

Three submission methods will be available to securely send a file to ODH, including secure file transfer protocol (SFTP), authenticated web portal file upload, and Simple Report Data Hub (US Digital Service). SFTP should be utilized by laboratories with adequate IT support to set up this type of connection and for laboratories that will automate their file transfer. The authenticated web portal file upload option should be utilized by non-traditional laboratories and other laboratories that will manually upload files. This option allows multiple users to upload files through a secure account. For non-traditional laboratories struggling with the creation of CSV files and/or who do not have access to a lab information system or true electronic medical record system, you may inquire about enrolling as a facility with the Simple Report Data Hub through the US Digital Service of CDC.

While you are in the process of onboarding, you should report all positive test results to the local health department (LHD) where the patient resides within 24 hours of case identification (i.e. time the test results are available). This is generally completed by faxing the confidential case report form or the Human Infection with 2019 Novel Coronavirus Case Report Form to the LHD. To identify the LHD where the patient resides, you may use the LHD address tool. If the patient resides out of state, you must report those results to the appropriate state health department where that person resides. You should maintain a copy of all negative test results and report the backlog of tests performed since October 20, 2020 using your electronic submission method once approved for production.

Please note that appropriate data collection and reporting is required by the State of Ohio.

6. Abbott NAVICA Mobile Application

The NAVICA Mobile APP is a free smartphone application from Abbott designed to provide results to the patient. It allows the BinaxNOW test to be linked to the patient through a QR code. For more information, refer to the NAVICA Mobile APP on the Abbott website. Currently, the NAVICA Mobile App is available only in English. The BinaxNOW test can be done without using the NAVICA mobile application

7. Additional Key Resources:

Support Contacts:

- Abbott Laboratories: Shawn Fisher, Shawn.Fisher@abbott.com
- Ohio Testing Team: TestingRequests@odh.ohio.gov
- Ohio Department of Higher Education: Charles See, CSee@highered.ohio.gov

About Antigen Testing and BinaxNOW:

CDC COVID-19 Testing Page
CDC COVID-19 Guidance for Antigen Testing
BinaxNOW Instructions
About NAVICA Mobile Application
BinaxNOW Fact Sheet for Patients
BinaxNOW Fact Sheet for Providers

Testing site certification:

CMS CLIA Laboratory Guidance
CLIA Application

Training:

BinaxNOW training videos, modules and FAQs
BinaxNOW COVID-19 Ag Card and NAVICA App Set-Up and Training

ODH Data reporting:

Ohio Department of Health Laboratory Testing Report
Testing site registration

For more information on COVID-19, please visit coronavirus.ohio.gov

For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).

Your mental health is just as important as your physical health. If you or a loved one are experiencing anxiety related to the coronavirus pandemic, help is available 24 hours a day, seven days a week. Call the COVID-19 CareLine at 1-800-720-9616.