COVID-19 Ohio Department of Health

Abbott BinaxNOW Traditional Tests Guidance Document

Background

The following document provides an overview of Abbott BinaxNow COVID-19 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.

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.

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.

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.

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 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 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 U.S. Food & Drug Administration's (FDA) "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. The Centers for Disease Control and Prevention's (CDC) What Your Test Results Mean is a helpful resource.

Data Collection & Reporting

Persons in charge of any laboratory conducting COVID-19 testing under a CLIA waiver shall electronically report all positive results within 24 hours of the test result. Information about reporting results can be found at the Ohio Department of Health COVID-19 Reporting page.

Abbott NAVICA Mobile Application

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. 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.

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