

Abbott BinaxNOW™ COVID-19 Ag Card Point of Care SARS-CoV-2 Diagnostic Test

Overview

As part of a historic initiative led by the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD), on August 27 the Trump Administration awarded a contract for \$760 million to Abbott for delivery of 150 million rapid, Abbott BinaxNOW™ COVID-19 Ag Cards, a point of care (POC) SARS-CoV-2 diagnostic test, to expand strategic, evidence-based testing in the United States.

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. This U.S. Food and Drug Administration (FDA)- authorized diagnostic test does not require any instrumentation to test the samples and instead determines a COVID-19 negative or positive result using a test card. This test has been authorized only for the detection of the nucleocapsid protein antigen from SARS-CoV-2, not for any other viruses or pathogens. BinaxNOW™ COVID-19 Ag Card FDA Emergency Use Authorization (EUA) can be found [here](#).

The Federal Government is distributing tests to nursing homes, assisted living facilities, home health and hospice agencies, Historically Black Colleges and Universities (HBCUs), and the Indian Health Service. The federal government will also distribute approximately 100 million tests to states and territories through the end of December 2020.

FDA-Authorized Use

The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. This test is authorized by FDA to be run in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests and is also authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. However, the FDA has clarified that POC antigen tests may be appropriate for use in asymptomatic patients in certain situations. Specifically, the FDA issued a [statement](#) on screening testing on August 24, 2020 (updated September 2, 2020) that clearly states that if healthcare providers are using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals, and highly sensitive tests are not feasible, or if turnaround times are prolonged, healthcare providers may consider the use of a less sensitive POC test, even if they are not specifically authorized for this indication (commonly referred to as “off label use”). For congregate care settings – like nursing homes or similar settings – repeated use of rapid POC testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times. Further, the FDA clarified that when testing in these circumstances, it is not necessary to perform confirmatory high-sensitivity molecular tests for individuals with negative antigen test or other POC test results if they are obtained during routine screening or surveillance.

CLIA Guidance

Use of this authorized test is limited to laboratories certified under the CLIA, 42 U.S.C. § 263a,

that meet the requirements to perform moderate, high or waived complexity tests and POC settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. However, this memo addresses the CLIA implications of the use of SARS-CoV-2 POC antigen tests on individuals without known or suspected COVID-19 infection. During this public health emergency, CMS is exercising its enforcement discretion and will permit a laboratory to extend its existing CLIA Certificate to operate a COVID-19 temporary testing site in an off-site overflow location, which may include schools, churches, or parking lots. The temporary site would only be permitted to perform tests consistent with the existing certificate and would be under the direction of the primary site's existing laboratory director. For more information on testing at a temporary location, please see CMS' CLIA guidance for the COVID-19 emergency: [CLIA Laboratory Guidance During COVID-19 Public Health Emergency](#).

In addition, [CMS will temporarily exercise enforcement discretion](#) for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the [FDA FAQ](#).

Public Readiness and Emergency Preparedness Act (PREP Act)

On August 31, 2020 the Assistant Secretary for Health, issued guidance that extends coverage under the PREP Act to licensed health care practitioners prescribing or administering point-of-care tests using anterior nares specimen collection or self-collection for screening in congregate facilities across the nation. Facilities that were specifically identified were nursing homes, assisted living, long-term care facilities and other facilities where people congregate to receive care or education, or to work. This PREP Act coverage also preempts any state and local law that prohibits or effectively prohibits licensed health care practitioners from administering FDA-authorized COVID-19 test to symptomatic and asymptomatic individuals in congregate facilities as set forth in the guidance

Allocation Strategies

States

States and territories will receive approximately 100 million tests through December 2020, distributed in proportion to their population. Governors will determine the best use of tests for their states; suggested deployment includes use cases for which a low cost, rapid, easily administered test is uniquely able to fill state needs, such as opening of K-through-12 schools through testing of teachers, staff, and students, protecting first responders, supporting critical infrastructure, enhancing higher education programs, testing during outbreaks, supplementing assisted living facilities and nursing homes, and other priorities the governors deem fit.

Nursing Homes

Tests are distributed based on the degree of community spread within the county where the nursing home is located and are intended to support screening of nursing home staff to meet CMS requirements. Long-term care facilities and nursing homes must have a CLIA Certificate of Waiver with facility type designation as a skilled nursing facility (SNF), and nursing homes must be certified under Medicare as an SNF and/or Medicaid as a nursing facility. Distribution is based on the degree of positivity within counties: nursing homes in areas with greater than 10% positivity (red counties) and those in areas with 5 to 10% positivity (yellow counties) are prioritized.

- Red counties: test allocation for testing **all staff** 2x/week.
- Yellow counties: test allocation for testing **all staff** 1x/week.

The federal distribution of BinaxNOW™ is intended to supplement the capabilities already provided to these facilities through the distribution of other point-of-care instruments, tests, and funding. Nursing homes should use their existing procurement processes to ensure adequate testing for residents based on current guidelines and/or requirements.

Assisted Living

Assisted living facilities with a CLIA Certificate of Waiver with the appropriate laboratory type, 04 - Assisted Living Facility, as listed on [Form CMS-116](#), receive BinaxNOW™ tests. As with nursing homes, distribution is based on the degree of positivity within counties: assisted living facilities in areas with greater than 10% positivity (red counties) and those in areas with 5 to 10% positivity (yellow counties) are prioritized.

- Red counties: test allocation for testing **all staff** 2x/week.
- Yellow counties: test allocation for testing **all staff** 1x/week.

The distribution of BinaxNOW™ tests to assisted living facilities is intended to supplement existing testing capabilities available to those facilities. Assisted living facilities should use their existing procurement processes to ensure adequate testing for residents based on current guidelines and/or requirements.

Home Health and Hospice Agencies

Tests are sent to the more than 300 home health and hospice agencies to then be distributed to test staff within their agencies. Test allocations are dependent on available inventory to facilitate agencies' capability to test staff who provide care to vulnerable or at-risk patients.

Historically Black Colleges and Universities (HBCUs)

Allotments of tests are based on the total number of faculty, staff, and students within the specific HBCU. Testing may be used for diagnosis in symptomatic individuals, contact tracing, baseline surveillance, or other needs as determined by the HBCU leadership. HHS has multiple lines of communication with HBCUs to support the development of individual strategies.

Indian Health Service (IHS)

IHS received 929,000 tests to distribute based on IHS identified priority settings. Examples include eligible health programs that care for K-12 schoolchildren who attend Bureau of Indian Education-funded schools, students at tribal colleges and universities, and elders in senior living arrangements. IHS may also provide tests to address particular testing needs by federal, tribal, and urban facilities that request them from the IHS National Service Supply Center. Allocations are determined by IHS.

Training

Abbott will contact public health officials at the state level and territories to provide guidance regarding training and review implementation resources. Each state has designated a single point of contact for Abbott to work with on training. Test site training will be provided through online tools and reinforced with optional, reoccurring webinars. Testing sites should work with state officials or Abbott on specific needs related to specialized training, including where distributions have occurred.

Training videos, modules, guidance documents, and FAQs for the BinaxNOW™ test can be accessed [here](#) on Abbott’s website. For questions regarding the BinaxNOW™ test, please call Abbott Technical Services at 1-800-257-9525 or email ts.scr@abbott.com. For shipment issues or questions, email ARDxUSGovernmentSupport@abbott.com.

Reporting Requirements

All diagnostic test results for COVID-19 must be reported to the appropriate federal, state, or local public health agencies.

All data for testing completed, for each individual tested, must be reported. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual’s residence. Testing sites must report all diagnostic test data in accordance with the [HHS Lab Data Reporting Guidance](#) for COVID-19 issued June 4, 2020 and were to meet these reporting requirements by August 1, 2020 including providing your facility name and CLIA number when reporting results. Please visit the [CDC website](#) for more information about data reporting requirements.

NAVICA™ Mobile APP

The NAVICA™ Mobile APP is a free smart phone application from Abbott designed to provide test results to the patient that can be used to demonstrate the individuals testing status. It allows the BinaxNOW™ test to be linked to the patient through a QR code. For more information, refer to the NAVICA™ Mobile APP and BinaxNOW™ COVID-19 Ag CARD landing page on the Abbott website. Currently the NAVICA™ Mobile APP is only available in English.

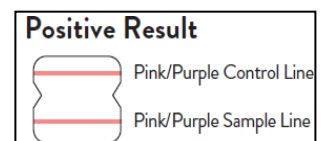
The BinaxNOW™ test can be done without using the NAVICA™ mobile application; however, the goal of the application is to provide the patient a way to safely record their test result for COVID-19 for future use, where applicable.

Reading Results

A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected. Negative results from patients with symptom onset beyond a seven-day period should be treated as presumptive, and confirmation with a molecular assay for patient management may be performed, if necessary.



A positive specimen will give two pink/purple colored lines one for the Control and one for the sample. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample

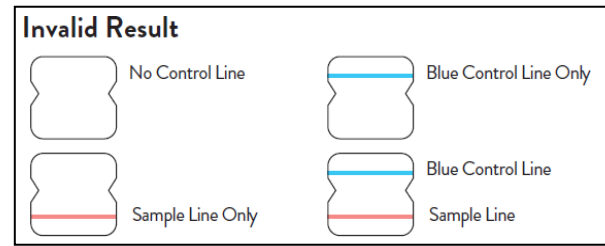


Line. If both pink/purple colored lines are visible the test is considered positive.

For indeterminate results, Tests are considered invalid if:

- No lines are present
- The Sample Line only is present
- Blue Control Line does not change to pink

Invalid tests should be repeated.



The BinaxNOW™ COVID-19 Ag Card test has demonstrated a 97.1% sensitivity rate and a 98.5% specificity rate, according to a recent clinical study.

Materials Provided Per Kit

- Test Cards (40): A cardboard, book-shaped hinged test card containing the test strip
- Extraction Reagent (1): Bottle containing 10 mL of extraction reagent
- Nasal Swabs (40): Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card test
- Positive Control Swab (1): Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
- Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained
- Product Insert (1)
- Procedure Card (1)

Materials Required but not Provided Per Kit

- Clock, timer or stopwatch

Materials Optional but not Provided Per Kit

- Swab Transport Tube Accessory Pack
- BinaxNOW™ COVID-19 AG Card Control Kit (10 positive swabs)

Shipping Schedule

BinaxNOW™ COVID-19 Ag Card diagnostic antigen tests began shipping the week of September 14, 2020 and will continue until all 150 million tests have been shipped. Supplies will be sent directly to each central distribution point or facility from the manufacturer.

Tests will be shipped weekly to assisted living facilities and nursing homes that meet the criteria described in the “Allocation Strategies” section above. Allocations will be updated bi-weekly, and facilities that meet the criteria will receive two consecutive weekly shipments of the same number of tests.

Shipping Specifications

Below are shipping specifications. Facilities must ensure that they are able to receive and store supplies per the manufacturer’s guidance.

- Pallet weight: 350.5 lbs.

- Pallet dimensions: length 48 in x width 40 in x height 47.24 in

Part Number	195000
Description	BINAX COVID-19 ANTIGEN CARD KIT
# Tests per kit	40
# Kits per shipper	16
# Shippers per pallet	10
# Kits per pallet	160
# Tests per pallet	6400
Kit Box Dimension US	10 x 7.52 x 5 inches
Kit Box Dimension Metric	25.4 x 19.100 x 12.7 cm
Shipper Dimension	20.875 x 20.625 x 16 inches
Weight per Kit	1.87 lbs.
Total Pallet Weight	350.5 lbs.
Pallet Height	47.24 in
Pallet Length	48.03 in
Pallet Width	40 in
# of Shippers per Layer	5
# of Layers per pallet	2
Temperature Requirements	Ambient (2-30°C)

- Trailer load: 26 pallets per full trailer load = 26 x 6,400 tests per pallet = 166,400 tests per full trailer load
- Tracking storage condition for shipping/transport: 2-8°C with a Sensitech GPS device for security and temperature monitoring