

## **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 has already begun distributing tests to nursing homes, assisted living facilities, home health and hospice agencies, Historically Black Colleges and Universities (HBCUs), the Indian Health Service, and States recovering from natural disasters. The federal government will distribute approximately 100 million tests to states and territories through the end of December of 2020, in addition to continuing to support other priorities like nursing homes and assisted living centers.

### **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.

## **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, and will arrive in a single shipment directly from the manufacturer.

## **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, and other priorities the governors deem fit.

### ***Nursing Homes***

Distribution of tests are distributed based on the degree of community spread within the county where the home is located, and are intended to support screening of nursing home staff to meet CMS requirements. Current 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 5-10% positivity (yellow counties) will be prioritized.

- Red counties: test allocation for testing of all staff 2x/week.
- Yellow counties: test allocation for testing of 50% of staff 1x/week.

The distribution of BinaxNOW™ is in addition to the capabilities already provided to these facilities through the distribution of BD or Quidel point of care instruments, tests, and funding.

### ***Assisted Living Facilities***

All assisted living facilities with a CLIA Certificate of Waiver will receive BinaxNOW tests. Currently, there are approximately 5,000 assisted living facilities with such a Waiver. Similar to nursing homes, distribution is based on the degree of positivity within counties: assisted living in areas with greater than 10% positivity (red counties) and those in areas with 5-10% positivity (yellow counties) will be prioritized.

- Red counties: test allocation for testing of all staff 2x/week.
- Yellow counties: test allocation for testing of 50% of staff 1x/week.

### ***Home Health and Hospice Agencies***

Distribution of tests will be sent to the largest 100+ home health and hospice agencies to then be distributed to locations within their agencies. Tests allocations will allow agencies to test staff once a week. This allocation will cover staff that visit over 1.8M patients.

### ***Historically Black Colleges and Universities***

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 received 300,000 tests that will be potentially distributed to eligible health programs that care for K-12 schoolchildren who attend Bureau of Indian Education-funded schools, students at tribal colleges and universities, or elders in senior living arrangements and other special needs populations by federal, tribal, and urban facilities that request them from the IHS National Service Supply Center. Allocations will be 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 on specific needs related to specialized training or questions about the assay, including where distributions have occurred.

Training videos, modules, 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](mailto:ts.scr@abbott.com). For shipment issues or questions, email [ARDxUSGovernmentSupport@abbott.com](mailto:ARDxUSGovernmentSupport@abbott.com).

### **Reporting Requirements**

All states and labs must report the results of the COVID-19 tests that they conduct to the appropriate federal, state, or local public health agencies.

Laboratories must report data for all testing completed, for each individual tested. 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.

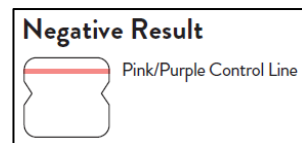
### ***NAVICA™ Mobile APP***

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.

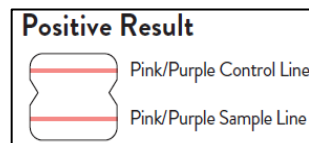
The BinaxNOW™ test can be done without using the NAVICA™ mobile application, however the goal of the application is to provide the patient a way to safely record their test result for COVID-19 for future use, where applicable. The application does not report results to the state and local public health departments and is only designed to report testing status to the patient.

## 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.



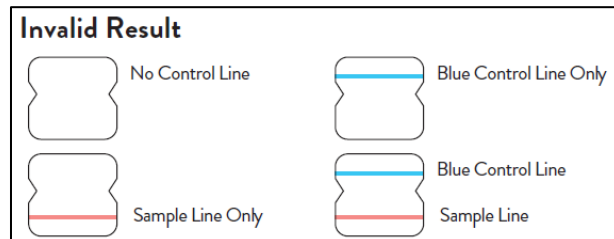
A positive specimen will give two pink/purple colored lines one for the Control and one for the sample. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. If both pink/purple colored lines are visible the test is considered positive.



For indeterminate results, 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.

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.

## 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

- Clock, timer or stopwatch
- Materials Available as an Optional Accessory
- Swab Transport Tube Accessory Pack

## 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
- 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: 2-8C with a Sensitech GPS device for security and temperature monitoring

Part Number	195000	195080
Description	<b>BINAX COVID-19 ANTIGEN CARD KIT</b>	<b>BINAX COVID-19 ANTIGEN CONTROL KIT</b>
# Tests per kit	40	10 Swabs
# Kits per shipper	16	90
# Shippers per pallet	10	14
# Kits per pallet	160	1260
# Tests per pallet	6400	N/A
Kit Box Dimension US	10 x 7.52 x 5 inches	8.5 x 6.25 x 3.25 inches
Kit Box Dimension Metric	25.4 x 19.100 x 12.7 cm	21.59 x 15.875 x 8.255 cm
Shipper Dimension	20.875 x 20.625 x 16 inches	26 x 19 x 13 inches
Weight per Kit	1.87 lbs.	0.4 lbs.
Total Pallet Weight	350.5 lbs.	504 lbs.
Pallet Height	47.24 in	59 in
Pallet Length	48.03 in	48 in
Pallet Width	40 in	40 in
# of Shippers per Layer	5	5
# of Layers per pallet	2	3
<b><u>Temperature requirements</u></b>		
DC to end customer	Ambient (2-30C)	Ambient (2-30C)