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

Distribution to Nursing Homes and Assisted Living Facilities

Overview

As part of an historic initiative led by the U.S. Department of Health and Human Services (HHS) and the Department of and Defense (DOD), the Administration awarded a contract for $760 million to Abbott for delivery of 150 million rapid, Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 diagnostic tests to expand strategic, evidence-based testing in the United States.

The Federal Government continues to prioritize vulnerable populations and has procured tests to send to nursing homes and assisted living facilities with a current CLIA Certificate of Waiver (see CLIA Guidance below).

FDA-Authorized Intended 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.

Testing 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. This test is authorized for use at the Point of Care (POC), i.e., inpatient care settings operating under a CLIA Certificate of Waiver, Certificate for Provider-performed Microscopy procedures, Certificate of Compliance, or Certificate of Accreditation. More information is available in the Instructions for Use.

Testing Locations

This memo addresses the Clinical Laboratory Improvement Amendments of 1988 (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. Examples of off-site locations we will permit are a school, a church, or parking lot (with approval of the local and state authorities). 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: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency.

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 off site facilities without a CLIA Certificate of

Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the FDA FAQ.

Shipping Schedule

Authorized BinaxNOW COVID-19 Ag Card diagnostic antigen tests begin shipping the week of September 14, 2020 and will continue through December 20, 2020. Supplies will be sent directly to each facility, and will arrive in a single shipment directly from the manufacturer.

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	**BINAX COVID-19 ANTIGEN CARD KIT**	**BINAX COVID-19 ANTIGEN CONTROL KIT**
# 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
Temperature requirements		
DC to end customer	Ambient (2-30C)	Ambient (2-30C)

Allocation Strategy

Distribution of tests are prioritized based on Centers for Disease Control and Prevention (CDC) epidemiological hotspot data. Facilities with a high incidence of cases will be prioritized to receive the first waves of shipments. Hotspot data will be reevaluated on a monthly basis to determine prioritizations. Nursing homes and assisted living facilities 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.

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^{TM} 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

Training

Abbott will contact public health officials at the state level and territories to provide guidance regarding training and review implementation resources. 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 distribution to nursing homes and assisted living facilities have occurred.