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 sends tests to nursing homes and assisted living facilities with a current CLIA Certificate of Waiver to support SARS-CoV-2 testing. Assisted living facilities must have a CLIA certificate of waiver with the appropriate type of laboratory designation of 04 – Assisted Living Facility, as listed on Form CMS-116. Nursing homes must also be Federally-certified by CMS as a Medicare Skilled Nursing Facility (SNF) and/or Medicaid Nursing Facility (NF).

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.

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.

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 permitted include schools, churches, or parking lots (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.

Training

Test site training will be provided by Abbott through online tools and reinforced with optional, reoccurring webinars. 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.

Allocation Strategy

Distribution of tests are prioritized based on Centers for Disease Control and Prevention (CDC) epidemiological hotspot data. Facilities in counties with a high degree of positivity will be prioritized to receive shipments. Hotspot data will be reevaluated on a biweekly basis to determine prioritizations and allocations for a two-week period. Nursing homes and assisted living facilities in areas with greater than 10% positivity (red counties) and 5-10% positivity (yellow counties) will be prioritized to receive tests.

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

Nursing homes and assisted living facilities below 5% positivity (green counties) will not receive tests through the federal distribution.

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

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 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

Authorized BinaxNOW COVID-19 Ag Card diagnostic antigen tests began shipping the week of September 14, 2020 and will continue through the end of December 2020. Supplies will be sent directly to each facility and will arrive in a single shipment directly from the manufacturer. Tests will be shipped weekly to facilities that meet the criteria described in the "Allocation Strategy" 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.

- Tracking storage condition for shipping/transport: 2-8°C with a Sensitech GPS device for security and temperature monitoring

Part Number	**195000**
Description	BINAX COVID-19ANTIGEN CARD KIT
# Tests per kit	40
# Kits per shipper	16
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.
Temperature Requirements	Ambient (2-30°C)