ABBOTT BINAXNOW™ WEBINAR FOR HOME HEALTH AND HOSPICE ORGANIZATIONS

SEPTEMBER 25, 2020
This webinar is intended for home health and hospice organizations that may receive Abbott BinaxNOW™ tests from the U.S. Department of Health and Human Services.

It is not intended for members of the media.
Agenda for today

Welcome
12:00 PM - 12:05 PM

Bill Dombi, President, National Association for Home Care and Hospice
Dr. Tammy Beckham, Lead for Testing and Diagnostics Working Group at HHS

Abbott BinaxNOW™ Overview
12:05 PM - 1:05 PM

Ashley Cilfone, Director of Training and Development at Abbott
Amanda Simpson, Director of Field Technical Operations at Abbott
David Kowalski, Director of Global Marketing - Rapid Diagnostics

Update from the CDC
1:05 PM - 1:10 PM

Dr. Joseph Miller, Testing and Diagnostics Working Group

Q&A Session
1:10 PM - 1:30 PM

All panelists
ABBOTT RAPID DIAGNOSTICS

BinaxNOW™ COVID-19 Ag Card & NAVICA™ App

HHS Webinar
Agenda

• Introduce Testing Solution
  – BinaxNOW™ COVID-19 Ag Card Test Overview
  – BinaxNOW™ COVID-19 Ag Card Test Technical Overview
  – NAVICA™ App

• Training Toolkit & Technical Resources
HHS WEBINAR

BinaxNOW™ COVID-19 Ag Card Test Overview
BinaxNOW™ COVID-19 AG CARD

A Breakthrough Antigen Test

SIMPLIFYING THE TEST PROCESS

• Cost-effective, high performing test designed for decentralized testing
• Simple test procedure
  – Direct Nasal swab
  – Onboard extraction allows the swab to be directly inserted into the test card
  – Visually read results in 15 minutes (no instrument required)
• Emergency Use Authorization (EUA) supports testing in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation*

PERFORMANCE

Sensitivity (PPA) **97.1%**
Specificity (NPA) **98.5%**

Direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.
Intended Use

Key Points

• The BinaxNOW™ COVID-19 Ag Card is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

• Antigen is generally detectable in nasal swabs during the acute phase of infection.

• Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay if necessary, for patient management, may be performed.
Resources for Intended Use Questions:

• For FDA recommendations for Health Care Providers who are ordering tests outside of their authorization (e.g. antigen tests for asymptomatic individuals) – see FDA’s FAQ on Testing for SARS-CoV-2

• Refer to the PREP Act Coverage for COVID-19 Screening at Congregate Facilities document - for Guidance from the Department of Health and Human Services

• Direct any additional questions regarding BinaxNOW Ag Card Intended Use to the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday or email ts.scr@abbott.com
The BinaxNOW COVID-19 Ag Card is only for use under the Food and Drug Administration’s Emergency Use Authorization

What is Emergency Use Authorization (EUA)?

- FDA emergency access mechanism
- Health & Human Services declare when circumstances exist to justify use of diagnostics under EUA for the diagnosis of COVID-19
- It is not full FDA clearance or approval and is temporary, until the declaration is terminated or revoked.
Test Site Obligations:

- Notify relevant public health authorities on intent to run test
- Report all results to healthcare providers and include the Healthcare Provider Fact Sheet. Healthcare providers to include Patient Fact Sheet with results
- Utilize product as outlined in the BinaxNOW COVID-19 Ag Card Instructions for Use
- Ensure all operators are trained to perform and interpret the test
- Per Product Insert: Collect performance data and report any significant deviations from the product performance characteristics via email to FDA/HHS and to Abbott Technical Support
- Retain all records associated with EUA until otherwise directed by FDA
- Have process in place for reporting test result to Healthcare Providers & relevant public health authorities
COVID-19 CARES Act Reporting Requirements

Reporting requirements apply to COVID-19 testing sites performing diagnostic or screening testing, including:

- Laboratories that perform clinical diagnostic or screening testing under a Clinical Laboratory Improvement Amendments (CLIA) certificate
- Non-laboratory COVID-19 diagnostic or screening testing locations
- Other facilities or locations offering COVID-19 point-of-care diagnostic or screening tests, or in-home diagnostic or screening tests

Reach out to state agencies for specific guidance on implementation for reporting
BinaxNOW™ COVID-19 Ag Card Technical Overview
### BinaxNOW™ COVID-19 Ag Card

**Product Overview**

<table>
<thead>
<tr>
<th><strong>Test Summary</strong></th>
<th>Rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing Environment</strong></td>
<td>Point of Care settings with a CLIA Certificate of Waiver, Compliance or Accreditation</td>
</tr>
<tr>
<td><strong>Specimen Type</strong></td>
<td>Direct nasal swab</td>
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</table>
| **Time to Result** | Results visually read at 15 minutes  
*Results should not be read after 30 minutes* |
| **Reagent & Materials** | 40 test cards, extraction reagent, QC & patient collection swabs, Product Insert, Procedure Card & Fact Sheets  
Store kit at 2-30°C |
| **Waste Disposal** | All components should be discarded as Biohazard Waste |
| **PPE for Specimen Collection and Handling** | Refer to CDC Guidelines for collecting, handling and testing clinical specimens (link in Product Insert) |
Reagent and Materials

Materials Provided:
- 40 Test Cards
- Extraction Reagent
- Patient Collection Nasal Swabs
- Positive Control Swab
- Blank Nasal Swab for Negative Control
- Product Insert
- Procedure Card
- Healthcare Provider & Patient COVID-19 Fact Sheets

Materials Required but not Provided:
- Clock, timer or stopwatch

Optional Materials:
- Plastic Transport Tube

Storage & Stability:
- Store kit at 2-30°C
- Ensure all test components are at room temperature before use
- Stable until the expiration date marked on the outer packaging
Internal Quality Control

Internal Procedural Controls:

• BinaxNOW™ COVID-19 Ag Card has built-in procedural controls

• In an untested card there will be a blue line at the Control Line position

• In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working

Note: If the blue line is not present at the Control Line position prior to running the test, do not use and discard
When is Quality Control Required?

External Positive & Negative Controls:

• Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working properly and that the test is correctly performed

• BinaxNOW™ COVID-19 Ag Card kits contain a positive control swab and sterile swabs that can be used as a negative control

Required Frequency:

• New shipments received

• Untrained operators

• Conforming with local, state, and/or federal regulations, accrediting groups, or lab’s standard QC procedures.

Note: If correct results are not obtained, contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday before testing patient specimens.
Nasal Swab Sample Collection

Test specimens immediately after collection for optimal performance

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
  - At the level of the nasal turbinates
  - Less than one inch into nostril
- Rotate the swab 5 times or more against the nasal wall
- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril

Only the swab provided in the kit is to be used for nasal swab collection.
BinaxNOW™ COVID-19 Ag Card
Test Procedure Overview

1. Add the extraction reagent
2. Insert the sample nasal swab
3. Rotate the nasal swab shaft three times
4. Close the test card; wait 15 minutes
5. Results are read visually
BinaxNOW™ COVID-19 Ag Card
Card Overview

Exterior View

Interior View
BinaxNOW™ COVID-19 Ag Card
Procedure for Patient & QC Tests

*Ensure all test components are at room temperature before use

**Open test card just prior to use, lay it flat and perform assay as follows

***If the blue line is not present at the Control Line prior to running the test, do not use and discard the test card.

**Step 1:** Hold extraction reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add:
- **6 DROPS** to the top hole if performing a patient test
- **8 DROPS** to the top hole if performing positive and negative control tests

**DO NOT** touch the card with the dropper tip while dispensing

**Step 2:** Insert patient or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**
BinaxNOW™ COVID-19 Ag Card
Procedure for Patient & QC Tests

**Step 3:** Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab

*Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card*

**Step 4:** Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read results in the window **15 minutes** after closing the card

*Note: In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes*
Result Interpretation

**Negative:** 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.

**Positive:** A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple line is positive.
**Result Interpretation**

**Invalid:** If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.

**Disposal**

- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements
Additional Resources

Ordering Information
• 195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)
• 195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit (10 positive swabs)
• 190-010: Optional COVID-19 Swab Transport Tube Accessory Pack (24 tubes)

Technical Support Line:
• US +1 800 257 9525, 8am-8pm EST M-F
• ts.scr@abbott.com
Introducing NAVICA.
An end-to-end, secure, accessible COVID-19 Testing Solution

A digital COVID-19 application designed to create a personalized and seamless testing experience that is available to all
NAVICA™ Has a Familiar Experience to Apps We Use Everyday

**Simplicity**
- Based on familiar consumer experiences
- Low learning required to setup and use without help
- Designed to scale rapidly

**Availability**
- Available on App Store and Google Play Store

**Security**
- Cloud based, scalable infrastructure with independent ongoing security assessments to maintain the security of the platform
- Data is fully encrypted at all times.
Downloading and sign-up is quick, simple, and secure
NAVICA™ App for Test Participants
BinaxNOW™ COVID-19 Test Results Quickly and Securely Shared

Find Testing Sites

Use NAVICA ID To Get Tested

Receive Test Results Electronically

Use NAVICA Pass To Show Status
NAVICA™ Verifier
Verification of an Authentic and Secure NAVICA Pass

Status Can Be Confirmed Using NAVICA Verifier Available in NAVICA Application
Ease of Use
• Intuitive Design
• Simple Log in Processon
• Focus on Patient/Participant

Workflow Confirmations
• App guides admin through process
• Verify NAVICA ID with Photo ID

Accurate and Secure.
• Connects NAVICA ID with BinaxNOW COVID-19 test card

Connected and Private
• NAVICA ID and test card connection confirmed by rescanning test card
• Results visually interpreted and then securely communicated to NAVICA test participant

*NAVICA Administrator app is designed be used with a tablet
NAVICA™ Administrator
Verify Test is Authentic, Unused, and Will be Matched to the Participant

Intuitive workflow for reporting results digitally
Scan the test to securely retrieve the right test record
Tap to report the results to the participant electronically
Automatically updates NAVICA participant
NAVICA APP AND BINAXNOW COVID-19 AG CARD

Training Toolkit
Online Toolkit: Virtual Set-Up and Training Guide

DESIGNED TO SUPPORT LARGE-SCALE IMPLEMENTATION THROUGH WEB-BASED TRAINING IN SELF-PACED TOOLKIT

- Detailed Training Videos
- PowerPoint Training
- Support Tools
- FAQs and Technical Service Contacts
Step 1:

BinaxNOW® COVID-19 Ag Card Demo Video

The BinaxNOW demo video provides an overview of the BinaxNOW test process. This video can be viewed prior to the more detailed training to see a brief demonstration of the testing process from start to finish.
Training Toolkit Navigation

Step 2:

**BinaxNOW® COVID-19 Ag Card Training Videos**

The BinaxNOW training video provides a detailed step by step guide to the BinaxNOW test process. The training video, divided into modules, should be completed in its entirety before performing tests on individuals.

- Module 1: Getting Started
- Module 2: Quality Control
- Module 3: Specimen Collection & Handling
- Module 4: Patient Test
- Module 5: NAVICA Admin App
- Module 6: NAVICA Participant App
Training Toolkit Navigation

Step 3:

Review Support Documents & Contacts

- NAVICA™ Demonstration Video
- BinaxNOW® COVID-19 Ag Card Training Document
- Product Insert
- Procedure Cards
- Clinical and Laboratory Standards Institute (CLSI) Documents
- Introduction to CLIA-Waived Testing
- Support Contacts: Technical Service Phone and Email
- FAQs
Technical Services

For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact the Abbott Technical Services Team

1-800-257-9525 between 8 a.m and 8 p.m. EST Monday-Friday
Email ts.scr@abbott.com.
Considerations for SARS-CoV-2 Antigen Testing

Joseph Miller, PhD, MBA
Testing and Diagnostic Work Group

For more information: www.cdc.gov/COVID19
COVID-19 Guidance

- **Antigen Testing**
  - [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)

- **Shared and Congregate Housing**
  - [COVID-19 Guidance for Shared or Congregate Housing](#)

- **Specimen Collection and Handling**
  - [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#)

- **Reporting**
  - [How to Report COVID-19 Laboratory Data](#)
Factors that can impact test results

- Quality of the specimen collection
  - Inadequate sampling or mishandling of the specimen prior to running the diagnostic test can impact detection

- Proper use of the testing platform
  - Personnel should be trained and proficient in sample handling and running the tests
  - Follow manufacture’s instructions for test incubation times
  - Use of positive and negative quality controls

- Clinical presentation at the time of the test (e.g., recent exposure or symptoms) and prevalence of COVID-19
Q&A

To ask a question of the panelists, please submit your question through the Zoom Q&A Chat Box.

For further questions, please contact Abbott at ts.scr@abbott.com.
Retail pharmacy contacts

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For additional questions to our presenters, please reach out directly:

- **Abbott BinaxNOW™ technical assistance**: ts.scr@abbott.com.
- **Abbott BinaxNOW™ shipment assistance**: ARDxUSGovernmentSupport@abbott.com.
- **CDC**: [https://www.cdc.gov/cdc-info/index.html](https://www.cdc.gov/cdc-info/index.html) (800)-232-4636
- **CMS**: COVID-19@cms.hhs.gov
Thank you!