



OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

LEADING AMERICA TO HEALTHIER LIVES



ABBOTT BINAXNOW™ WEBINAR FOR HOME HEALTH AND HOSPICE ORGANIZATIONS

SEPTEMBER 25, 2020



NOTICE

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

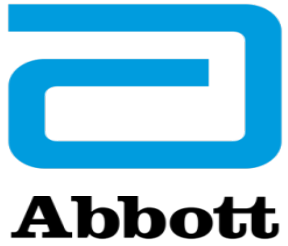
1:05 PM - 1:10 PM

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

Intended Use

Resources for Questions

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

BinaxNOW™ COVID-19 Ag

Emergency Use Authorization

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.

BinaxNOW™ COVID-19 Ag

Emergency Use Authorization Responsibility

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

HHS WEBINAR

BinaxNOW™ COVID-19 Ag Card Technical Overview

BinaxNOW™ COVID-19 Ag Card

Product Overview

Test Summary	Rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2
Testing Environment	Point of Care settings with a CLIA Certificate of Waiver, Compliance or Accreditation
Specimen Type	Direct nasal swab
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:

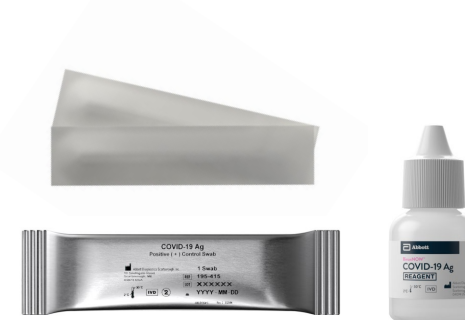
- Clock, timer or stopwatch

Optional Materials:

- Plastic Transport Tube

Storage & Stability:

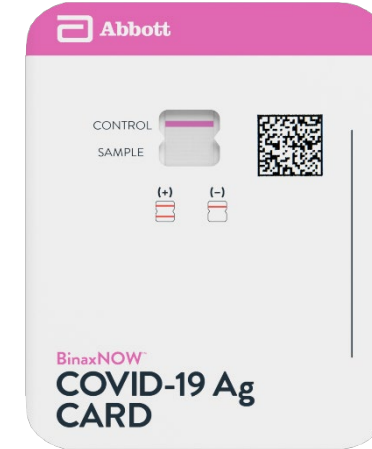
- Store kit at 2-30°C
- Ensure all test components are at room temperature before use
- Stable until the expiration date marked on the outer packaging



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.

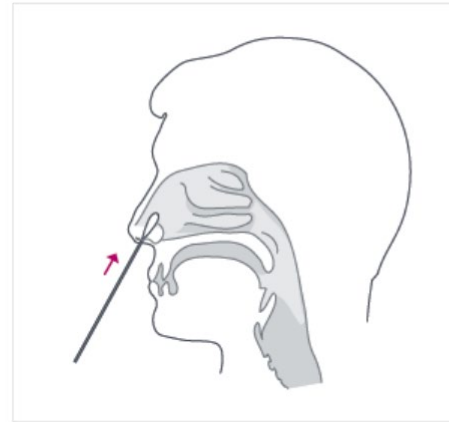


Note: If correct results are not obtained, contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday before testing patient specimens

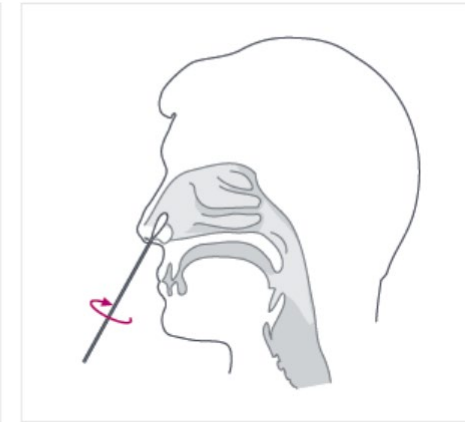
Nasal Swab Sample Collection

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



1 To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible.



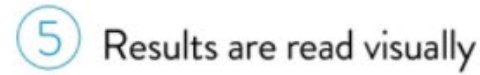
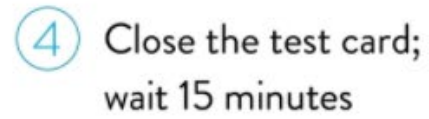
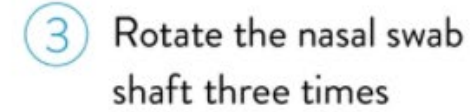
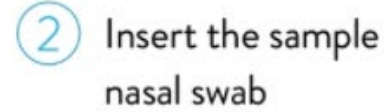
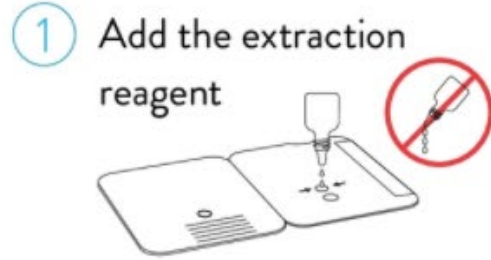
2 Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall and then slowly remove from the nostril.

3 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

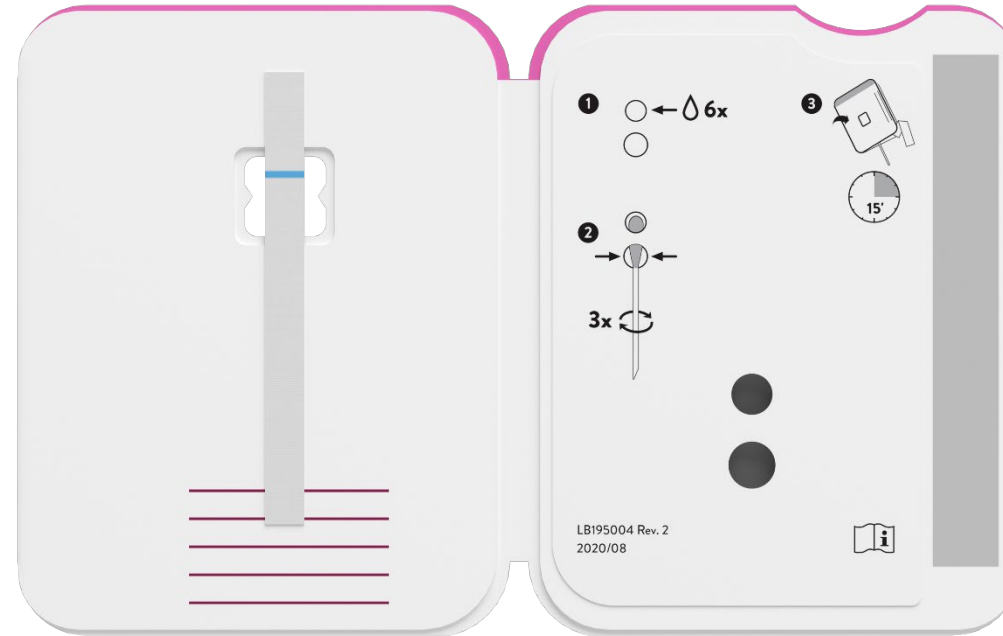


BinaxNOW™ COVID-19 Ag Card

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

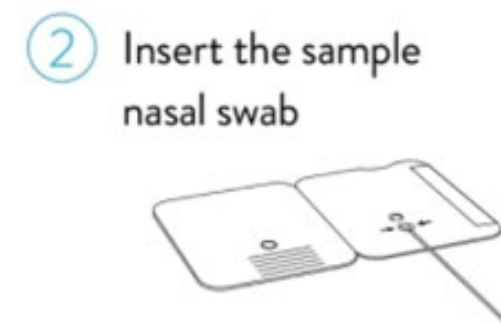
***If the blue line is not present at the Control Line prior to running the test, do not use and discard the test card.

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

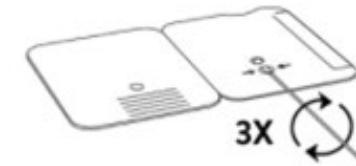
Step 3: Rotate (twirl) swab shaft 3 times
CLOCKWISE (to the right). Do not remove swab

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*

③ Rotate the nasal swab shaft three times



④ Close the test card; wait 15 minutes

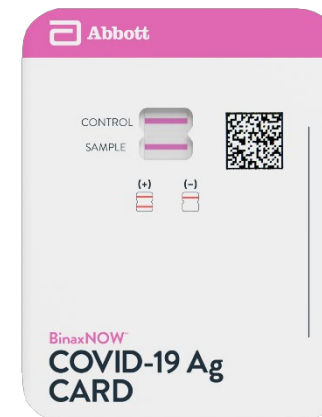


Result Interpretation

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

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NAVICA™ App

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

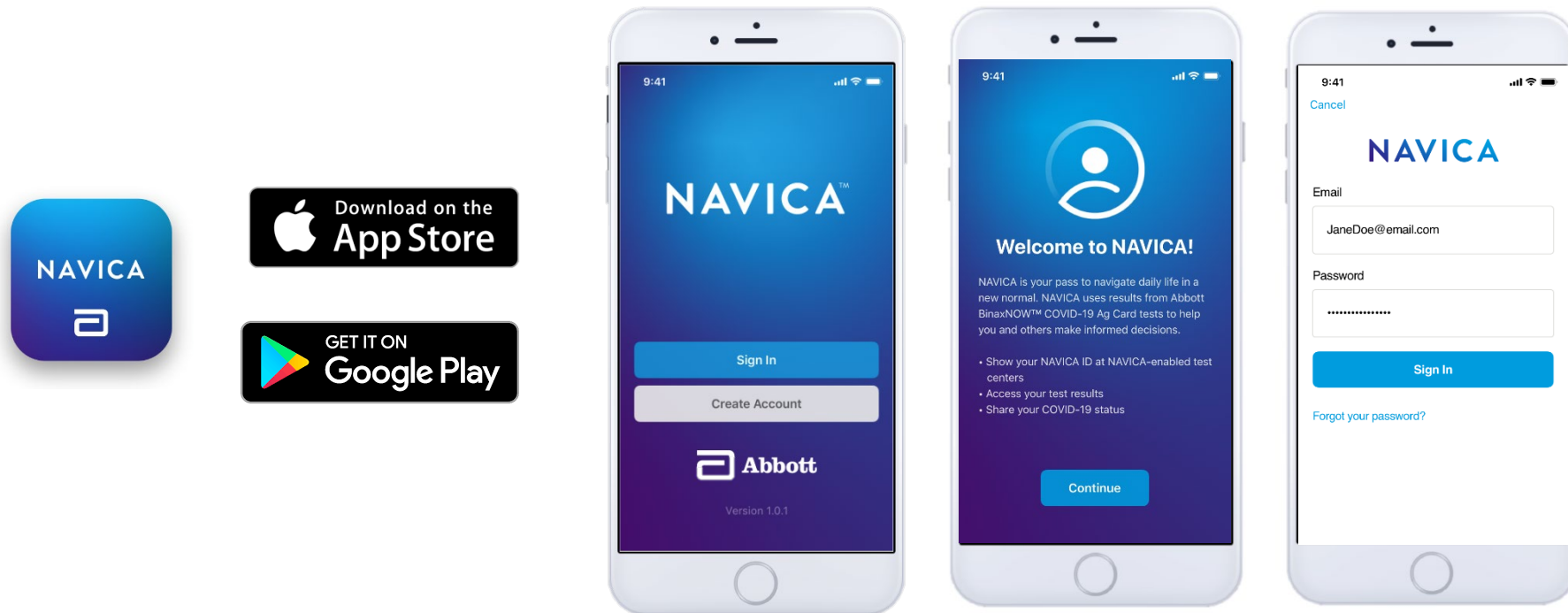
Security

- Cloud based, scalable infrastructure with independent ongoing security assessments to maintain the security of the platform
- Data is fully encrypted at all times.



NAVICA

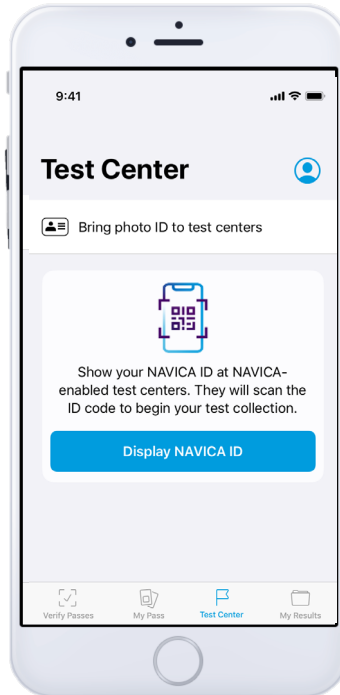
Downloading and sign-up is quick, simple, and secure



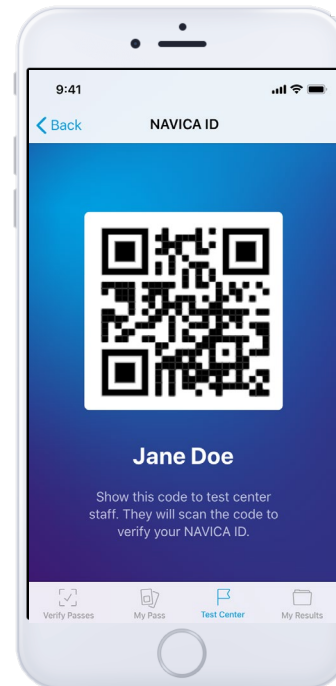


NAVICA

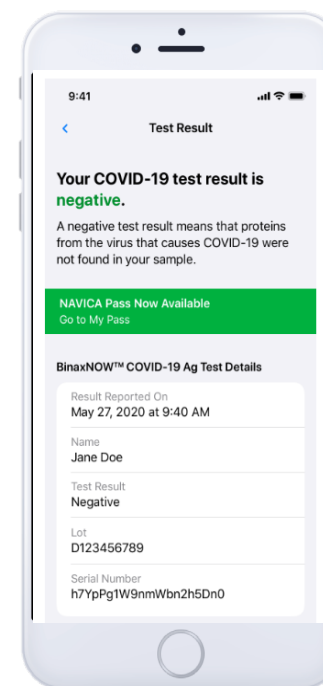
NAVICA™ App for Test Participants BinaxNOW™ COVID-19 Test Results Quickly and Securely Shared



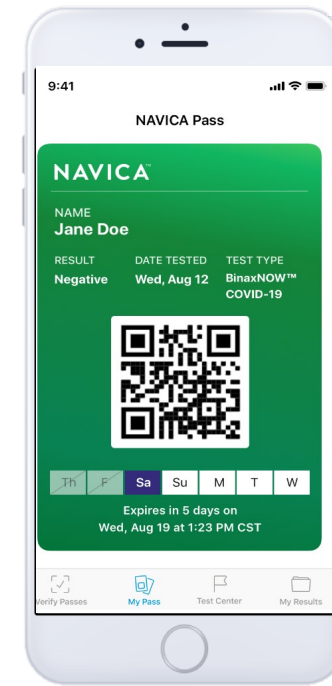
Find Testing Sites



**Use NAVICA ID
To Get Tested**



**Receive Test Results
Electronically**



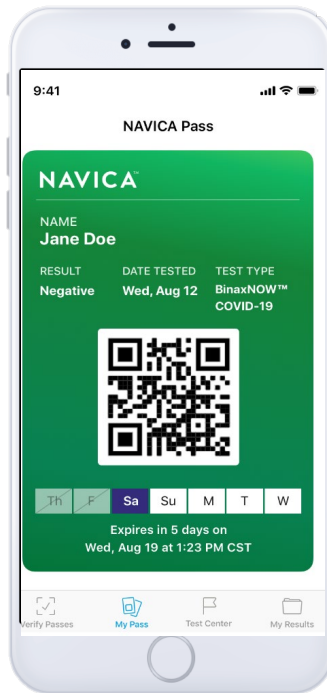
**Use NAVICA Pass
To Show Status**



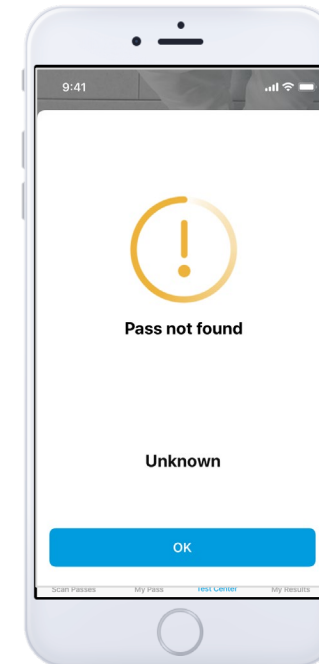
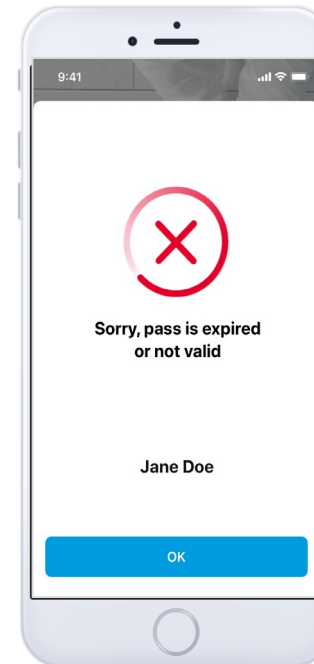
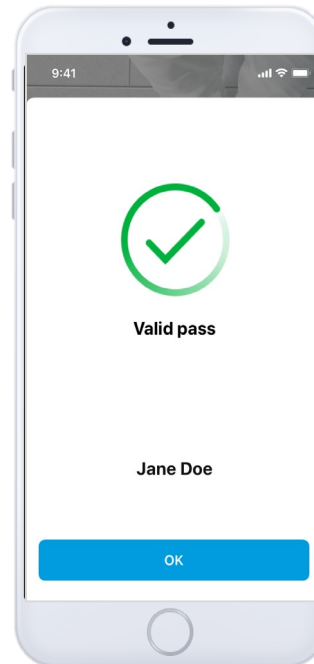
NAVICA

NAVICA™ Verifier

Verification of an Authentic and Secure NAVICA Pass



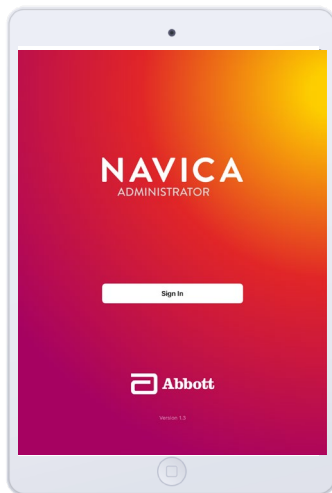
NAVICA Pass



Status Can Be Confirmed Using NAVICA Verifier Available in NAVICA Application

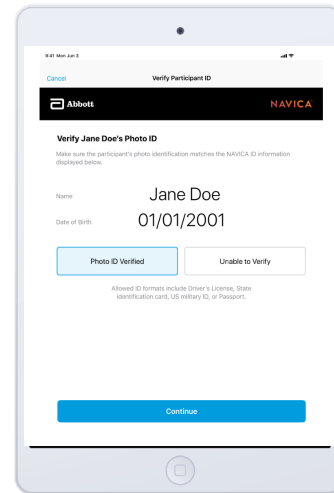


NAVICA Administrator guides the test operator through the process of capturing the test result*



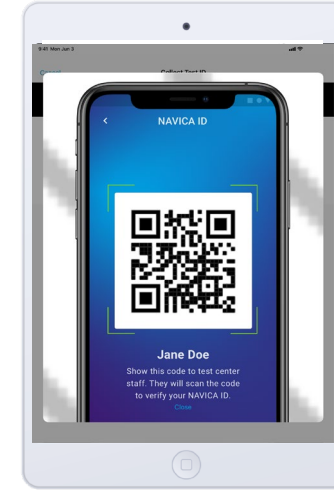
Ease of Use

- Intuitive Design
- Simple Log in Process
- Focus on Patient/Participant



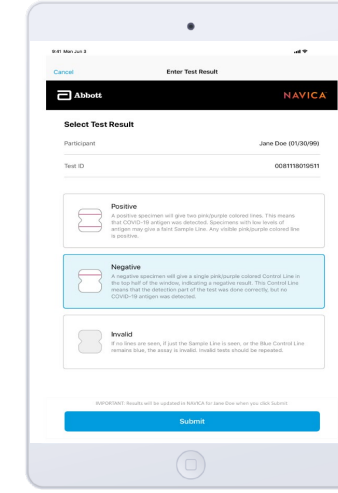
Workflow Confirmations

- 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

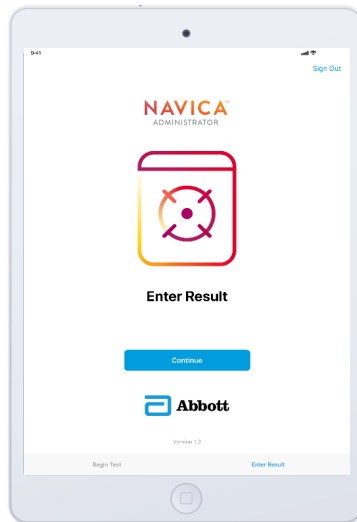
- NAVICA ID and test card connection confirmed by rescanning test card
- Results visually interpreted and then securely communicated to NAVICA test participant

*NAVICA Administrator app is designed be used with a tablet

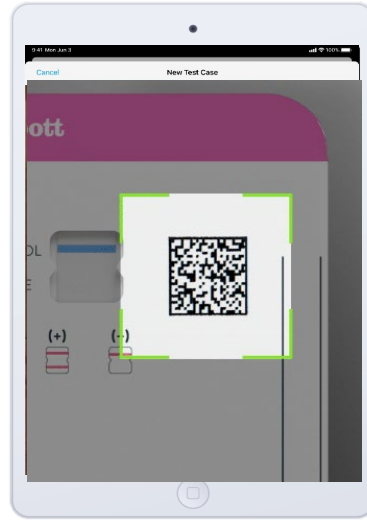


NAVICA™ Administrator

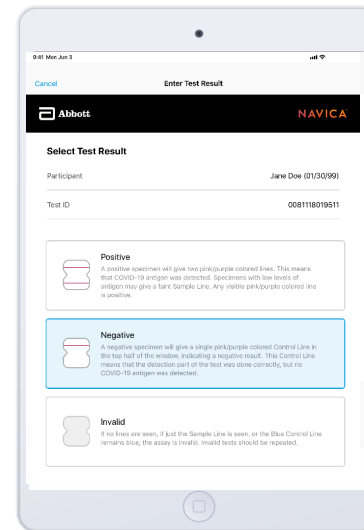
Verify Test is Authentic, Unused, and Will be Matched to the Participant



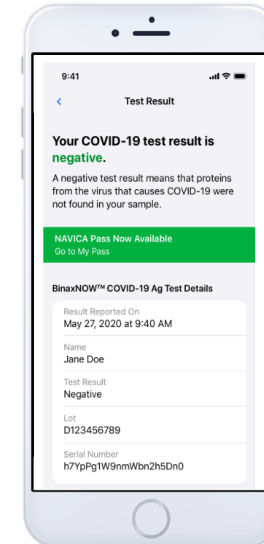
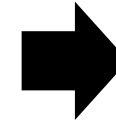
Intuitive workflow for reporting results digitally



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

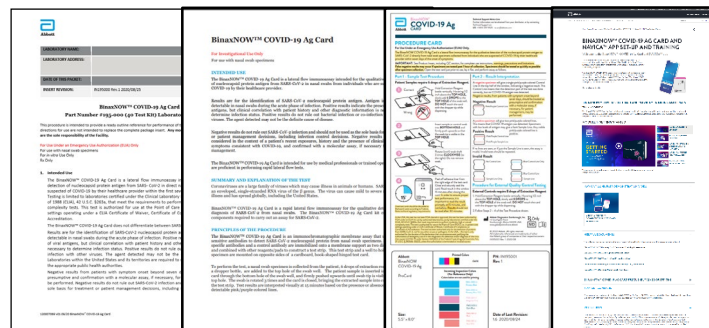
MODULE 1: GETTING STARTED



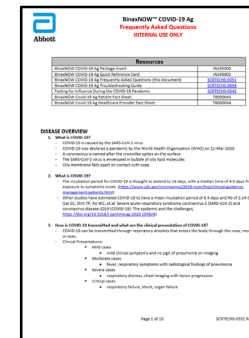
Detailed Training Videos



PowerPoint Training



Support Tools




FAQs and Technical Service Contacts

Training Toolkit Navigation

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.



The screenshot shows the Abbott website's training page for the BinaxNOW COVID-19 AG CARD and NAVICA™ APP. The page is titled "BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING" and includes a welcome message, a description of the resources, and a list of training materials. A large arrow points from the "Step 1" section to the "BINAXNOW COVID-19 AG CARD OVERVIEW" video thumbnail.

BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING

Welcome to the BinaxNOW™ COVID-19 Ag Card and NAVICA™ app.

The resources below are designed to provide the training necessary to successfully test patients using the BinaxNOW COVID-19 Ag Card. These materials are available for your reference as you prepare to implement your site's testing program.

The BinaxNOW COVID-19 Ag Card is a rapid antigen test for detecting active infections of COVID-19. The complementing NAVICA app is a mobile app intended to be used with BinaxNOW COVID-19 Ag Card. The BinaxNOW™ COVID-19 Ag Card and NAVICA app are cleared by the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

Only available in the US.

BINAXNOW™ COVID-19 AG CARD AND NAVICA™ TRAINING MATERIALS

OVERVIEW & TRAINING VIDEOS

The BinaxNOW™ COVID-19 Ag Card training video provides a detailed step-by-step guide to the test process. The training video, divided into modules, should be completed in its entirety before performing tests on individuals. The modules are designed to be completed in the order shown below.

BINAXNOW COVID-19 AG CARD OVERVIEW

Watch the demonstration videos.

- NAVICA™ CONSUMER DEMONSTRATION VIDEO
- HELPFUL DOCUMENTS
- BINAXNOW™ COVID-19 AG CARD FREQUENTLY ASKED QUESTIONS
- SUPPORT CONTACTS
- REFERENCES

NAVICA™ MOBILE APP AND BINAXNOW™ COVID-19 AG CARD

The first-of-its-kind NAVICA™ app helps people navigate daily life in a new context. NAVICA displays results from the 15-minute BinaxNOW™ COVID-19 Ag Card, a rapid antigen test, to help individuals make informed decisions.


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



The screenshot shows the Abbott website's training page for the BinaxNOW COVID-19 Ag Card and NAVICA app. The page is titled "BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING". It includes a welcome message, a description of the resources, and a list of training materials. A large arrow points from the text on the left to the "BINAXNOW COVID-19 AG CARD OVERVIEW" section. This section features a video player with the title "BinaxNOW™ COVID-19 Ag CARD OVERVIEW" and a list of modules: "MODULE 1: GETTING STARTED", "MODULE 2: QUALITY CONTROL", "MODULE 3: SPECIMEN COLLECTION AND HANDLING", and "MODULE 4: PATIENT INDIVIDUAL TEST". Below the video player, there are links to "NAVICA™ CONSUMER DEMONSTRATION VIDEO", "HELPFUL DOCUMENTS", "BINAXNOW™ COVID-19 AG CARD FREQUENTLY ASKED QUESTIONS", "SUPPORT CONTACTS", and "REFERENCES". At the bottom, there is a section for "NAVICA™ MOBILE APP AND BINAXNOW™ COVID-19 Ag CARD" with a description of the app's functionality.

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

The screenshot shows the Abbott website's training page for the BinaxNOW COVID-19 Ag Card and NAVICA app. The page is titled "BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING". It includes a welcome message, a description of the resources, and a section for training materials. The training materials section includes an overview and training videos, a list of modules (Module 1: Getting Started, Module 2: Quality Control, Module 3: Specimen Collection and Handling, Module 4: Patient Individual Test), and a list of support documents and contacts. The page also features a video player for the NAVICA™ Consumer Demonstration Video and a section for helpful documents, frequently asked questions, support contacts, and references.

BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING

Welcome to the BinaxNOW™ COVID-19 Ag Card and NAVICA™ app.

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Only available in the U.S.

BINAXNOW™ COVID-19 AG CARD AND NAVICA™ TRAINING MATERIALS

OVERVIEW & TRAINING VIDEOS

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BINAXNOW COVID-19 AG CARD OVERVIEW

Watch the demonstration video.

NAVICA™ CONSUMER DEMONSTRATION VIDEO

HELPFUL DOCUMENTS

BINAXNOW™ COVID-19 AG CARD FREQUENTLY ASKED QUESTIONS

SUPPORT CONTACTS

REFERENCES

NAVICA™ MOBILE APP AND BINAXNOW™ COVID-19 AG CARD

The first of its kind NAVICA™ app helps people navigate daily life in a new normal. NAVICA displays results from the 15-minute BinaxNOW™ COVID-19 Ag Card, a rapid antigen test, to help individuals make informed decisions.

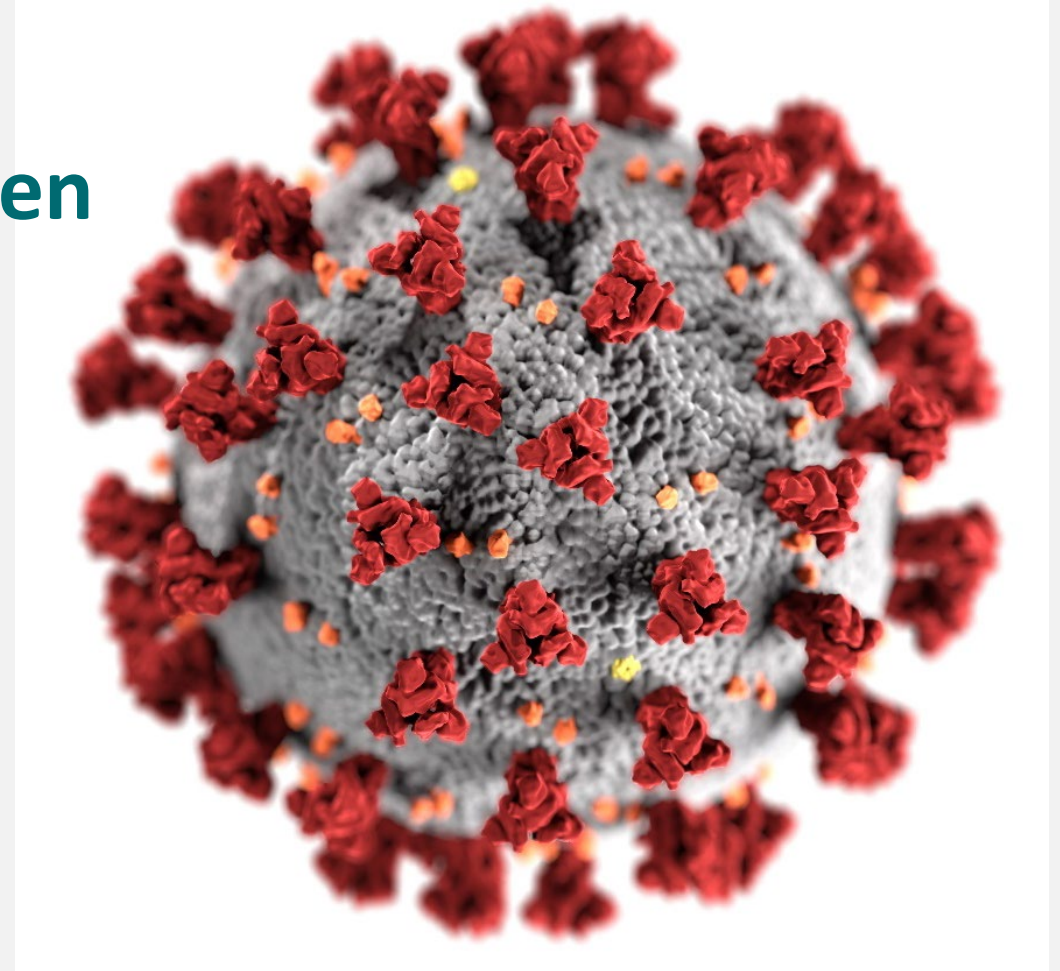
Technical Services

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.



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For additional
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Thank you!