



INTRODUCING

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

TAKING COVID-19 TESTING TO A NEW LEVEL

Designed to Restore Confidence in Daily Life

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

This first-of-its-kind app, available at no charge, allows people who test negative to get an encrypted temporary digital NAVICA Pass, similar to an airline boarding pass. NAVICA-enabled organizations will be able to verify an individual's negative COVID-19 test result by scanning the individual's digital NAVICA Pass to facilitate entry into facilities, along with hand-washing, social distancing, enhanced cleaning and mask-wearing.



Your Role in the NAVICA Process

As a NAVICA-enabled test site, you will use the NAVICA Administrator app to communicate encrypted BinaxNOW COVID-19 Ag Card test results to participants and allow them to obtain a digital NAVICA Pass with a negative test result. To conduct testing at your site, a CLIA-waived license is required per the FDA Emergency Use Authorization for BinaxNOW COVID-19 Ag Card.



As a **BinaxNOW™ COVID-19 Ag Card testing site**, you play an important role in helping people move about with greater confidence.

THE NAVICA™-BinaxNOW TESTING PROCESS IS SIMPLE:

- 1 Scan the participant's NAVICA ID on their mobile device and verify photo ID match.
- 2 Scan the unique QR code on the BinaxNOW COVID-19 Ag Card to create a secure link between the participant and the test card.
- 3 Perform the BinaxNOW COVID-19 Ag Card test, following the package insert instructions.
- 4 Rescan the QR code on the test card to confirm the link and chain of custody between the BinaxNOW COVID-19 Ag Card test and the participant.
- 5 Visually interpret the test result on the card and submit the positive or negative result accordingly via the NAVICA app.

The participant will be notified of their result submission through the NAVICA app. A negative result submission will generate an encrypted digital NAVICA Pass as a QR code on the individual's mobile device. If the participant tests positive, they will receive a NAVICA message to follow CDC Guidelines on quarantine and consult their healthcare provider.

Abbott believes the NAVICA app and BinaxNOW COVID-19 Ag Card test will help us recover a bit more freedom, confidence and normalcy in our everyday lives.



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.

TEST PROCEDURE**

- 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

KIT CONTENTS

- 40 Test Cards
- 40 Nasal Swabs
- Positive Control Swab
- Reagent Bottle
- Package Insert
- Procedure Card
- 40 Patient COVID-19 Fact Sheets
- Healthcare Provider COVID-19 Fact Sheet



ORDER INFORMATION

PRODUCT NAME	PRODUCT CODE
BinaxNOW™ COVID-19 Ag CARD 40 CT	195-000
BinaxNOW™ COVID-19 Ag CARD CONTROL KIT (10 POSITIVE)	195-080



NAVICA APP AVAILABLE FOR DOWNLOAD ON THE APP STORE® AND GOOGLE PLAY™
[NAVICA.ABBOTT](https://www.navica.abbott)

FOR MORE INFORMATION, CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE OR VISIT [BINAXNOW.NAVICA.ABBOTT](https://www.binaxnow.navica.abbott)

* Before testing patients, federal regulations require testing sites to have a CLIA certificate issued by CMS. Sites performing only waived tests must obtain a Certificate of Waiver by applying for this certification for each location performing testing.

**Refer to the product package insert for full instructions.

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The BinaxNOW™ COVID-19 Ag Card EUA has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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