

FREQUENTLY ASKED QUESTIONS ON BINAXNOW™ COVID-19 AG CARD AND NAVICA™

FOR TESTING ADMINISTRATORS

BINAXNOW™ COVID-19 PRODUCT AND AVAILABILITY QUESTIONS

HOW AND WHEN IS THE BINAXNOW COVID-19 PRODUCT GOING TO BE SHIPPED TO MY LOCATION?

HHS is allocating a supply of product through each state's Governor's office.

WE NEED ADDITIONAL TESTS, WHO DO I CONTACT?

HHS is allocating a supply of product through each state's Governor's office. Information on product supply and availability will be forthcoming.

WHAT KIND OF TEST IS THE BINAXNOW COVID-19 TEST AND IS IT ACCURATE?

Abbott's BinaxNOW COVID-19 Ag Card is a rapid antigen test for detection of COVID-19. It is a reliable, highly portable tool for detecting active coronavirus infections. BinaxNOW uses proven Abbott lateral flow technology, used in a number of our rapid tests including strep, flu and legionella – as well as HIV and malaria. The visually read test is about the size of a credit card and requires no equipment and provides results in 15 minutes.

In data submitted to the FDA from a clinical study conducted by Abbott with several leading U.S. research universities, the BinaxNOW COVID-19 Ag Card demonstrated sensitivity of 97.1% (positive percent agreement) and specificity of 98.5% (negative percent agreement) in direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset.

WHAT PPE DO I NEED TO WEAR/USE TO PERFORM A TEST?

Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19. Visit the CDC website for PPE guidance or contact your local Department of Public Health. All components of this kit should be discarded as biohazard waste according to Federal, State and local regulatory requirements.

DO WE NEED A CLIA LICENSE? HOW DO WE GET ONE?

Yes. The BinaxNOW COVID-19 Ag Card has been authorized by the FDA under an Emergency Use Authorization for use at the Point of Care, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. If you do not have a CLIA certificate, we have an informational sheet that will provide guidance on how to apply for a CLIA certificate. [Click here](#) to download the informational sheet.

HOW DO I GET MY SITE UP AND RUNNING WITH THE BINAX COVID-19 AG CARD TESTING?

This website contains BinaxNOW COVID-19 Ag Card training materials for your reference. If you are reviewing this FAQ document and not online, here is the link to the website. [Click here](#)

WHAT IS THE GUIDANCE FOR QUALITY CONTROL (QC) TESTING FOR BINAXNOW COVID-19 AG CARD?

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working 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 Swab. These swabs will monitor the entire assay.

Test these swabs **once with each new shipment** received and **once for each untrained operator**. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures. Refer to the product insert, found in each test kit, for complete instructions on how to perform Quality Control testing.

If you have numerous operators to train you may need additional Quality Control swabs. Below are examples to help guide you:

- **For each shipment: 1 set of QC swabs (positive and negative) is run to validate the shipment, and 1 operator can be trained for every test kit received in that shipment.**
 - 5 kits received: 5 operators can be trained (1 QC of shipment – can use one of the untrained operator's passing results, 5 operators can be trained)
 - If there are any new operators that fail the quality control training tests, they must repeat the tests to obtain passing results. Additional quality control swabs may be needed if this occurs. Please see ordering info further below.
- **If there are more operators than test kits:**
 - 2 kits received with 4 operators to be trained (1 QC of shipment – can use one of the untrained operator's passing results, 2 operators can be trained). Will need to request 1 BinaxNOW COVID-19 Ag Card Control Kit from HHS.
 - Please note: 1 control kit can train up to 10 operators

If you have more operators than test kits, below is the ordering information for additional control swabs:

Description	Order Number
BinaxNOW COVID-19 Ag Card Control Kit (10 Positive Swabs)	195-080

WHAT IS NAVICA?

The NAVICA app is your pass to navigating daily life in a new normal. NAVICA displays results from the 15-minute Abbott BinaxNOW COVID-19 Ag Card, a rapid antigen test, to help you and others make informed decisions.

If person's test results are negative, the NAVICA app will display a temporary digital NAVICA Pass. Organizations will be able to view and verify a person's digital NAVICA Pass on their mobile device to facilitate entry into facilities, along with handwashing, social distancing, enhanced cleaning and mask-wearing.

More information on the role of the NAVICA app in your testing program will be forthcoming. To learn more about NAVICA in general [Click here](#).

WHO CAN I CONTACT FROM ABBOTT FOR QUESTIONS ON THE BINAXNOW COVID-19 PRODUCT

For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact Abbott Technical Services at 1-800-257-9525 between 8 a.m. – 8 p.m. EST Monday-Friday or by emailing ts.scr@abbott.com.