OPERATING PROCEDURE
BinaxNOW™ COVID-19 Ag Card

PURPOSE

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 anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

The BinaxNOW™ COVID-19 Ag Card does not differentiate between SARS-CoV and SARS-CoV2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARSCoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARSCoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States.

BinaxNOW™ COVID-19 Ag Card is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasal swabs, without viral transport media. The BinaxNOW™ COVID-19 Ag Card kit contains all components required to carry out an assay for SARS-CoV-2.

The BinaxNOW™ COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

SCOPE

This document is to be used by trained staff as a Procedure Manual for performing the BinaxNOW™ COVID-19 Ag test for patient testing. This procedure is also used in accordance with the CDPH's health order requiring acute care hospitals in California to perform COVID-19 visitor screening. Visitors who are not fully vaccinated may be tested and, if negative, may be provided a 72-hour visiting pass. BinaxNOW™ COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization. Refer to the BinaxNOW™ COVID-19 Ag Card package insert and Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas for further details.

TESTING PERSONNEL

Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

REAGENTS & MATERIALS

A. Materials Provided

Test Cards (40): A cardboard, book-shaped hinged test card containing the test strip; cat#195-000

Extraction Reagent (1): Bottle containing 7.5 mL of extraction reagent

Nasal Swabs (40): Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card test; cat# 195-080

Positive Control Swab (1): Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab; cat# 195-080 (10 positive swabs)

Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained

Product Insert (1)

Procedure Card (1)

B. Materials Required but not Provided

Clock, timer or stopwatch

C. Materials Available as an Optional Accessory

Swab Transport Tube Accessory Pack

STORAGE AND STABILITY

Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use.
2. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens
5. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
7. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
8. Proper sample collection, storage and transport are essential for correct results.
9. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not use kit past its expiration date.
11. Do not mix components from different kit lots.
12. Do not reuse the used test card.
13. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
14. Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
15. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
16. Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
17. 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.
18. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly.
19. False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
20. Swabs in the kit are approved for use with BinaxNOW™ COVID-19 Ag Card. Do not use other swabs.

21. The Extraction Reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
22. Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.

QUALITY CONTROL

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

A. Procedural Controls:
    a. The pink-to-purple line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
    b. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

B. External Positive and Negative Controls:

The use of external positive and negative controls 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 and lot received and once for each untrained operator.

If the correct control results are not obtained, do not perform patient tests or report patient results. See below for corrective actions to further take.

Frequency of External QC Testing:

- When a new shipment and lots of kits is received
- When a new untrained operator performs testing

Corrective Actions When Controls Are Unacceptable:

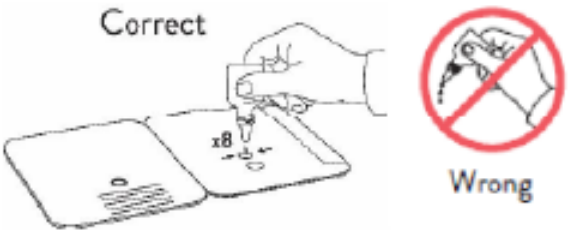
If the expected control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support (1-800-257-9525 or ts.scr@abbott.com) during normal business hours before testing patient specimens. Document any issues on the BinaxNOW™ Covid-19 Ag External Quality Control Log.

Quality Control Swab Test Procedure:

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

1. Label the cards appropriately (e.g., Neg, Pos) on the front of the card. The inside of the card may optionally be labeled as well (see designated lines and avoid writing on the

test strip). Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add **8 DROPS** to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



2. Follow Steps 3 – 5 of the Test Procedure for Patient Specimens.
3. Record the results and lot information on the BinaxNOW™ Covid-19 Ag External Quality Control Log.

SPECIMEN REQUIREMENTS

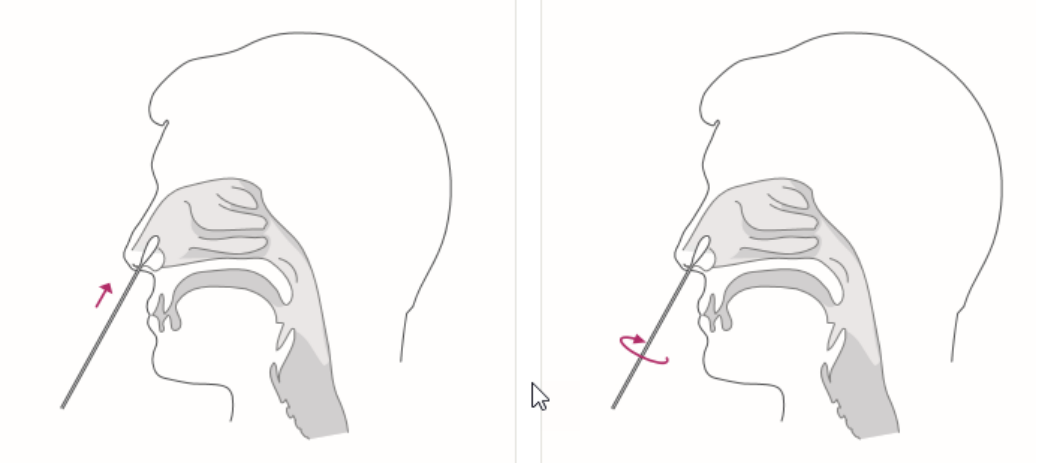
Specimen Collection and Handling:

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Anterior Nasal (Nares) Swab

Only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the entire absorbent tip of the swab (usually ½ to ¾ of an inch (1 to 1.5 cm) into the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 15 seconds, then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.



Specimen Transport and Storage

Do not return the nasal swab to the original paper packaging.
For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, place the nasal swab in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. **If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.**

Unacceptable Specimens:

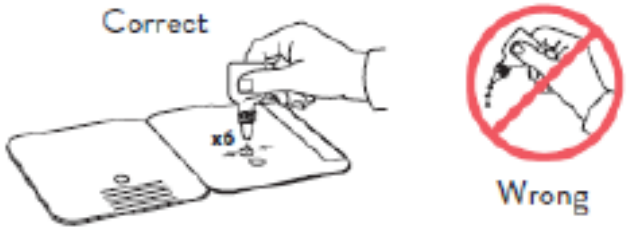
- Specimens collected with swabs other than those in the test kit
- Specimens that are damaged or compromised
- More than an hour delay from the time of collection to the time of testing
- When specimen storage conditions are not met
- Unlabeled or mislabeled specimens

PROCEDURE

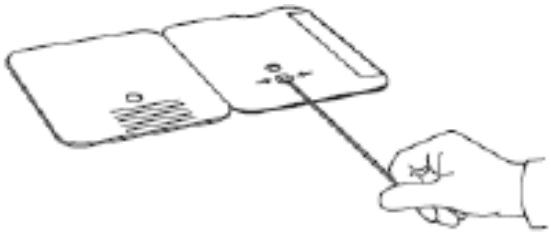
PATIENT TESTING
Open the test card just prior to use, lay it flat, and perform assay as follows. The test card must be flat when performing testing, do not perform testing with the test card in any other position.

1. Label the card(s) with the appropriate patient identifiers (e.g., patient name and MRN) on the front of the card. The inside of the card may optionally be labeled as well (see designated lines and avoid writing on the test strip).
2. Hold Extraction Reagent bottle **vertically**. Hovering 1/2 inch above the TOP HOLE, slowly add **6 DROPS** to the TOP HOLE of the swab well. DO NOT touch the card with

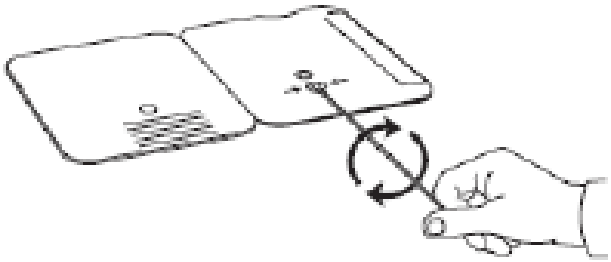
the dropper tip while dispensing. NOTE: Step 2 must be performed within 3 minutes of adding the extract.



3. Verify that the patient label on the swab matches that on the test card. If they match, insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.

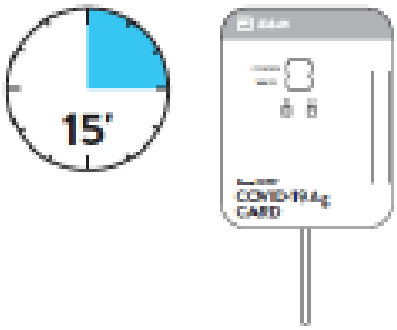


4. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



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

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

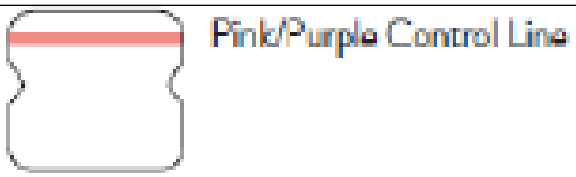
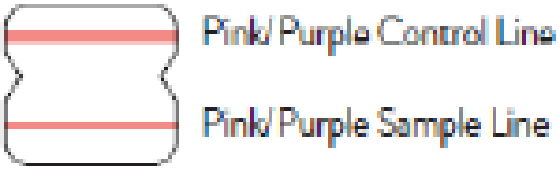


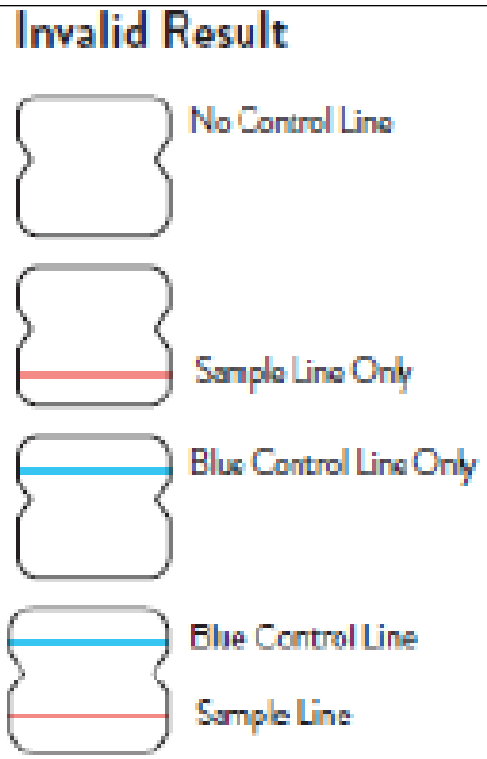
Note: False negative results can occur if test results are read before 15 minutes.

Note: When reading test results, tilt the card to reduce glare on the result window if necessary. **Individuals with color-impaired vision may not be able to adequately interpret test results.**

RESULT INTERPRETATION

Note: In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present 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. **If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.**

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 colored line is positive.	

Invalid If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. **Do not report invalid tests results.** When possible, obtain a new collection and repeat the test using a new test card. If not possible or if an invalid result is obtained upon repeat testing, then cancel the BinaxNOW COVID-19 Ag test order and recollect and send to the Clinical Laboratory for testing (e.g., PCR method).	

EXPECTED VALUE

Negative

REPORTING

Enter the result and procedural control result in the patient's medical record or manual result form. All valid results must be reported to the appropriate public health authorities.

LIMITATIONS

- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the BinaxNOW™ COVID-19 Ag Card was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
- False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).
- False negative results may occur if specimen swabs are not twirled within the test card.

- False negative results may occur if swabs are stored in their paper sheath after Specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- False negative results are more likely after eight days or more of symptoms.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- The presence of mupirocin may interfere with the BinaxNOW™ COVID-19 Ag test and may cause false negative results.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

PERFORMANCE CHARACTERISTICS

Refer to the package insert for assay performance information.

REFERENCES

- BinaxNOW™ COVID-19 Ag Card Package Insert (IN195000), Rev. 2 2020/12.

DISTRIBUTION

A. POCT Master Procedure Binder

B. POCT website: www.sfgh-poct.org