DELTA COUNTY MEMORIAL HOSPITAL LABORATORY

Title: Bianx NOW COVID -19 Antigen Card		
Section: POC/Chemistry	**Approved by: Intermountain Pathologists**	
Written by: Brandi Moore	**Adopted: 12/16/2020**	**Revised:**
Replaces Procedure Adopted:N/A		

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 nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use 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. The BinaxNOW COVID-19 Ag Card does not differentiate between SARS- CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal 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 positive results to the appropriate public health authorities.

Symptomatic patients should be tested no more then five days from symptom onset. Negative results should be considered presumptive and should be followed up with an alternate PCR test method for confirmation. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

PRINCIPLE

The BinaxNOX 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.

SPECIMEN

Nasal 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 swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. 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 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, it is highly recommended the nasal swab is placed 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.

REAGENTS and MATERIALS

Material Provided

-Test Cards-40
-Extraction Reagent
-Nasal Swabs
-Positive Control Swab
-Negative Control Swab
-Package insert
-Procedure Card

Materials needed but not included

-Timer
-PPE
-Swab transport

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.

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.

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.

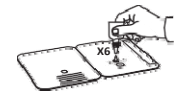
B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

External Positive and Negative Controls:
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.
If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

PROCEDURE
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.

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.

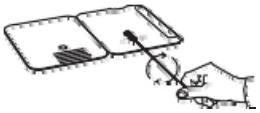
Correct



Wrong

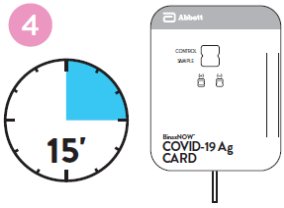
Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.

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.

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: 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.

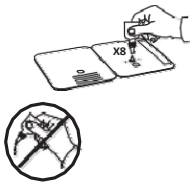


Procedure for BinaxNOW™ Swab Controls

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

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.

Correct



Wrong

Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

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. Invalid tests should be repeated.

<u>RESULT REPORTING</u>

<u>Clinics/ER</u>-

-Place patient sticker on the ABBOTT BinaxNOW COVID-19 Test information form.

-Place a Test ID # sticker on the ABBOTT BinaxNOW COVID-19 Test information form.

-Place a Check Mark for Acceptable/Unacceptable QC on the ABBOTT BinaxNOW COVID-19 Test information form.

-Write the kit lot number on the ABBOTT BinaxNOW COVID-19 Test information form.

-Circle the patients test result on the ABBOTT BinaxNOW COVID-19 Test information form.
-Place all patient ABBOTT BinaxNOW COVID-19 Test information forms in appropriate binder.
-Report results to provider.

NOTE AND 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 tested 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.
•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, from patients with symptom onset beyond five days, 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.

1. For *in vitro* diagnostic use.
2. This test has not been FDA cleared or approved; this test 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 test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

5.This test 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.
6. Laboratories within the United States and its territories are required to report all positive 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 specimens in viral transport media for specimen storage.
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, 1/2 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.**

REFERENCES

[1]CAP All Common Checklist 09172019 COM.40350
[2]Clinical Evaluation of the Investigational ID NOW™ COVID-19 Assay. Protocol Number: 2012601. Original (Version 1): 16 June 2020 Version 2: 01 July 2020
[3]CLSI EP12-A2:2008 User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition. Jan 2008 Vol 28 (3). ISBN 1-56238-654-9 ISSN 0273-3099
[4]BinaxNOW™ COVID-19 Ag Card Part Number # 195.000 Test Kit Laboratory Procedure

Pathologist Signature: Date:

Reviewed By: Date:

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