BinaxNOW™ COVID-19 Ag 2 CARD

For Use Under an Emergency Use Authorization (EUA) Only

For use with anterior nasal (nares) swab specimens

For *in vitro* Diagnostic Use Only

INTENDED USE

The BinaxNOW COVID-19 Ag 2 Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with symptoms of COVID-19 within the first seven days of symptom onset. This test is also authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. 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 2 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 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 SARS-CoV-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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

The BinaxNOW COVID-19 Ag 2 Card is authorized for non-prescription use by medical

professionals or trained operators who are proficient in performing rapid lateral flow tests. BinaxNOW COVID-19 Ag 2 Card is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-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 2 Card is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The BinaxNOW COVID-19 Ag 2 Card kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES OF THE PROCEDURE

The BinaxNOW COVID-19 Ag 2 Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior 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.

To perform the test, an anterior nasal swab specimen is collected from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

REAGENTS AND MATERIALS

Materials Provided

Test Cards (40): A cardboard, book-shaped hinged test card containing the test strip

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

Nasal Swabs (40): Sterile swabs for use with BinaxNOW COVID-19 Ag 2 Card test

Positive Control Swab (1): Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab

Negative Control Swab (1): The use of a sterile patient swab ensures appropriate negative results are obtained

Product Insert (1)

Procedure Card (1)

Materials Required but not Provided

Clock, timer or stopwatch

Materials Available as an Optional Accessory

Swab Transport Tube Accessory Pack

PRECAUTIONS

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 authorized laboratories; 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. This product 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.
3. This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens
4. The emergency use of 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.
5. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
6. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
7. Proper sample collection, storage and transport are essential for correct results.
8. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
9. Do not use kit past its expiration date.
10. Do not mix components from different kit lots.
11. Do not reuse the used test card.
12. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
13. Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
14. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
15. 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.
16. 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.
17. 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.
18. False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
19. Swabs in the kit are approved for use with BinaxNOW COVID-19 Ag 2 Card. **Do not use other swabs.**
20. 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.
21. Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.

STORAGE AND STABILITY

Store kit at 2-30°C. The BinaxNOW COVID-19 Ag 2 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 2 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 2 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.

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

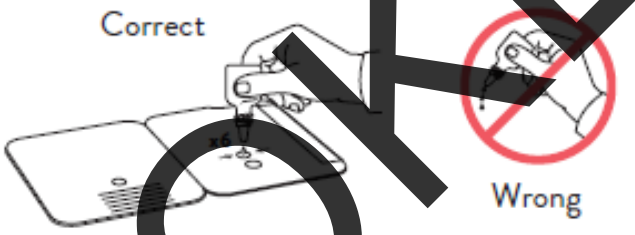
Do not return the nasal swab to the original paper packaging.

For best performance, direct anterior 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.

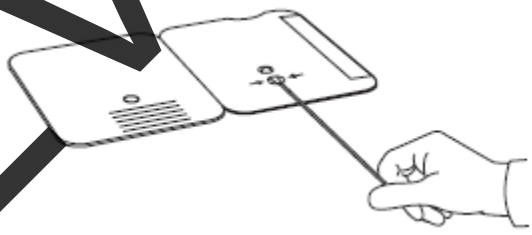
TEST PROCEDURE
Procedure for Patient Specimens

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.**

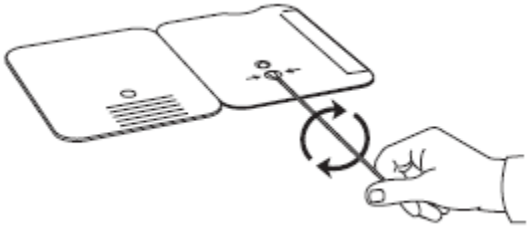
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



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

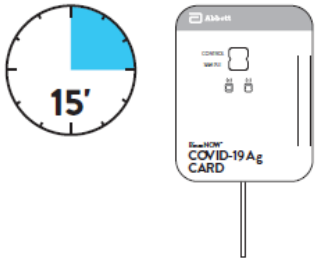


3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.



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

4. 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.



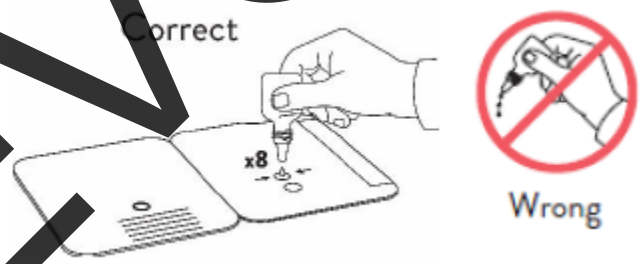
Note: *False negative results can occur if test results are read before 15 minutes.*

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.*

Procedure for BinaxNOW™ Swab Controls

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

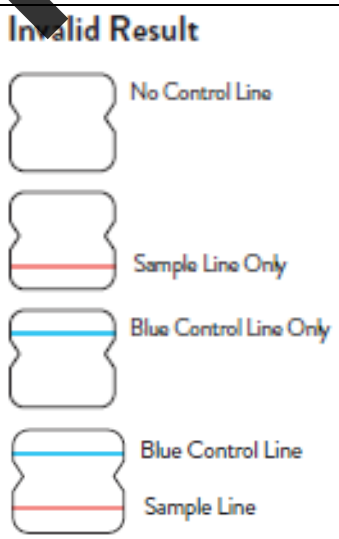
1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the **TOP HOLE,** slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



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

RESULT INTERPRETATION

Note: *In an untested BinaxNOW COVID-19 Ag 2 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. Note: If the patient does not have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) between tests.	
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.	

SERIAL TESTING RESULTS REPORTING

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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 2 Card was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Clinical performance of anterior nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection, or for serial screening when tested twice over three days with at least 24 hours between tests has not been determined, a study to support use will be completed.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- 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 2 Card 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between July, 2020 and October, 2020.The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS

The BinaxNOW COVID-19 Ag 2 Card 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/in-vitro-diagnostics-euas.

However, to assist clinical laboratories using the BinaxNOW COVID-19 Ag 2 Card, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the "BinaxNOW COVID-19 Ag 2 Card" Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. (via email: ts.scr@abbott.com, or via phone by contacting Abbott Diagnostics Scarborough, Inc. Technical Service at 1-800-257-9525) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Abbott Diagnostics Scarborough, Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, 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." as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

Clinical performance characteristics of BinaxNOW COVID-19 Ag 2 Card was evaluated in a multi-site prospective study in the U.S in which patients were sequentially enrolled and tested. A total of ten (10) investigational sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who are representative of the intended

users at CLIA waived testing sites. In this study testing was conducted by sixty-two (62) intended users. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19. Patients who presented within 7 days of symptom onset were included in the initial primary analysis. Two nasal swabs were collected from patients and tested using the BinaxNOW COVID-19 Ag 2 Card at all study sites. An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

At all sites, one nasal swab was tested directly in the BinaxNOW COVID-19 Ag 2 Card test according to product instructions and the other swab was eluted in viral transport media (VTM). Swabs were randomly assigned to testing with the BinaxNOW or RT-PCR testing and were tested by minimally trained operators who were blinded to the RT-PCR test result. All sites shipped the VTM sample to a central testing laboratory for RT-PCR.

External control testing, using BinaxNOW COVID-19 Ag 2 Card Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The performance of BinaxNOW COVID-19 Ag 2 Card was established with 460 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

BinaxNOW COVID-19 Ag 2 Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW COVID-19 Ag 2 Card	Comparator Method		
	Positive	Negative	Total
Positive	99	5	104
Negative	18	338	356
Total	117	343	460
Positive Agreement: 99/117	84.6% (95% CI: 76.8% - 90.6%)		
Negative Agreement: 338/343	98.5% (95% CI: 96.6% - 99.5%)		

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

Patient Demographics

Patient demographics (gender and age) are available for the 460 samples used in the analysis of patients with symptom onset within the previous seven (7) days. The table below shows the positive results broken down by age of the patient:

Age	Comparator Method		
	Total #	Positive	Prevalence
≤ 5 years	0	-	-
6 to 21 years	17	3	17.6%
22 to 59 years	312	79	25.3%
≥ 60 years	131	35	25.4%

Patient demographics, time elapsed since onset of symptoms for all patients enrolled, are presented in the table below. Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW COVID-19 Ag 2 Card Positive (+)	PPA	95 % Confidence Interval	
1	12	10	83.3%	51.6%	97.9%
2	34	28	82.4%	65.5%	93.2%
3	50	41	82.0%	68.6%	91.4%
4	63	50	79.4%	67.3%	88.5%
5	78	63	80.8%	70.3%	88.8%
6	90	75	83.3%	74.0%	90.4%
7	117	99	84.6%	76.8%	90.6%
8 to 10	144	118	81.9%	74.7%	87.9%
11 to 14	161	126	78.3%	71.1%	84.4%
All specimens	167	129	77.2%	70.1%	83.4%

A cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 161). The positive agreement in patients with symptoms greater than seven days was 60% (30/50) and negative agreement was 98% (109/111). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time.

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

BinaxNOW COVID-19 Ag 2 Card limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Presumed negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure.

The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The BinaxNOW COVID-19 Ag 2 Card LOD in natural nasal swab matrix was confirmed as 140.6 $TCID_{50}$/mL.

Limit of Detection (LoD) Study Results

Concentration $TCID_{50}$/mL	Number Positive/Total	% Detected
140.6	20/20	100%

Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW COVID-19 Ag 2 Card was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 $TCID_{50}$/swab). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross-Reactant		Test Concentration
Virus	Adenovirus	1.0×10^5 $TCID_{50}$/mL
	Human metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/mL
	Rhinovirus	1.0×10^5 PFU/mL
	Enterovirus/Coxsackievirus B4	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL
	Influenza A	1.0×10^5 $TCID_{50}$/mL
	Influenza B	1.0×10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus A	1.0×10^5 PFU/mL
Bacteria	*Bordetella pertussis*	1.0×10^6 cells/mL
	Chlamydia pneumoniae	1.0×10^6 IFU/mL
	Haemophilus influenzae	1.0×10^6 cells/mL
	Legionella pneumophila	1.0×10^6 cells/mL
	Mycoplasma pneumoniae	1.0×10^6 U/mL
	Streptococcus pneumoniae	1.0×10^6 cells/mL
	Streptococcus pyogenes (group A)	1.0×10^6 cells/mL
	Mycobacterium tuberculosis	1.0×10^6 cells/mL
	Staphylococcus aureus	1.0×10^6 org/mL
	Staphylococcus epidermidis	1.0×10^6 org/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0×10^6 cells/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45% homology across 18% of the sequence, making cross-reactivity in the BinaxNOW COVID-19 Ag 2 Card highly unlikely.

- No protein sequence homology was found between *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and human coronavirus HKU1 revealed that cross-reactivity cannot be ruled out. Homology for KHU1 and MERS-CoV is relatively low, at 37.8% across 95% of the sequence and 57.14% across 87% of the sequence, respectively.

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.6×10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW COVID-19 Ag 2 Card.

Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW COVID-19 Ag 2 Card at the concentrations listed below and were found not to affect test performance.

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin[1]	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

[1] Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes.

ORDERING AND CONTACT INFORMATION
Reorder Numbers:
195-005: BinaxNOW COVID-19 Ag 2 Card (40 Tests)
195-080: BinaxNOW COVID-19 Ag Control Swab Kit
190-010: Swab Transport Tube Accessory Pack

US +1 877 441 7440

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

US
+ 1 800 257 9525 ts.scr@abbott.com

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Scarborough, Maine 04074 USA
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IN195005 Rev. 2 2022/02

Abbott

BinaxNOW™ COVID-19 Ag 2 CARD

A second test should be obtained within three days with at least 24 hours between tests.

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

US +1 800 257 9525 ts.scr@abbott.com

PROCEDURE CARD

For Use Under an Emergency Use Authorization (EUA) Only.

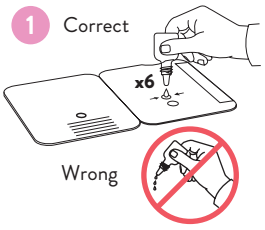
The BinaxNOW COVID-19 Ag 2 Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2. This test is authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with symptoms of COVID-19 within the first seven days of symptom onset. This test is also authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Testing is limited to authorized laboratories.

IMPORTANT: See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations.
False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection.
Open the test card just prior to use, lay it flat, and perform assay as follows.

Part 1 - Sample Test Procedure

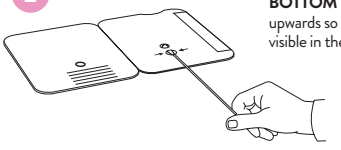
Patient Samples require 6 drops of Extraction Reagent.

1



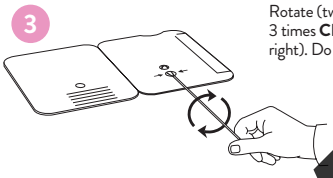
Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



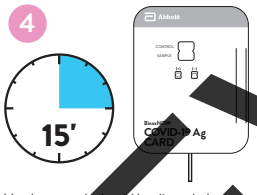
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3



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

4



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.

Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Part 2 - Result Interpretation

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. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. ***Note:*** *If the patient does not have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) between tests.*

Negative Result

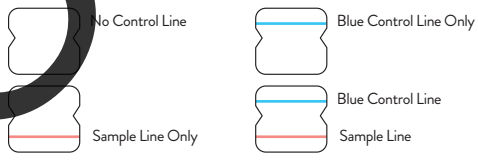
For serial testing, (when tested twice over three days with at least 24 hours and no more than 48 hours between tests) additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19 such as, an individual with a close contact or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19 such individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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.

Positive Result

If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result



Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

1. 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 2 – 4 of the Test Procedure shown.

In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet 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. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of 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 the virus that causes 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 authorization is terminated or revoked sooner.

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IVD

IN195401 Rev. 1 2022/02

Abbott
BinaxNOW
COVID-19 Ag 2

ProCard

Size:
5.5" x 8.0"

Printed Colors

CMYK

Incoming Inspection Colors (For Reference Only)
Colors below are not used for printing

- PMS 2995 U Primary Blue
- PMS 2995 U Primary Blue 70%
- PMS 224 U Magenta Pink
- PMS 303 U Dark Blue
- PMS 185 U Red
- PMS 185 U Red 70%

PN: IN195401
Rev: 1

Date of Last Revision:
1.4 2022/02/04