ATTACHMENT XII-C: BinaxNOW Rapid COVID Antigen Testing

Recommended Action: Approve the BinaxNOW Rapid COVID Antigen Testing

Recommended Action: Approve as presented.

Rapid Point-Of-Care testing for COVID-19 in the school setting can be administered onsite by trained healthcare workers under the standing orders by a health care provider. The BinaxNOW Rapid COVID test can diagnose current COVID-19 infections quickly when staff or students are showing symptoms.

Since the BinaxNOW Rapid COVID-19 test can give results within 15 to 30 minutes, the District can use it to help diagnosis and inform those impacted quickly to help slow the spread.

It is being recommended that North Boone CUSD 200 become a Point-Of-Care testing site.

North Boone
Community Unit School District 200
Dr. Michael Greenlee, Superintendent
Melissa Geyman, Director of Business Services

North Boone School District Standing Orders for Administering BinaxNOW Rapid Antigen Test

Purpose: Rapid, portable testing for COVID19 as approved by the FDA under its current EUA.

Policy: Under these standing orders, health professionals, as allowed by state law, may test people who meet the criteria below.

Procedure (Full BinaxNow Procedure Attached):

1. Individuals meet the criteria for testing if they are within the first seven days of symptom onset.
2. Test Administration
    a. Staff performing test will don proper PPE
    b. Each nostril will be swabbed.
    c. Lay test card flat just prior to use
    d. Hold extraction reagent bottle vertically. Hover ½ inch about the top hole and slowly add 6 drops to the TOP HOLE. Do NOT touch the card with the bottle tip.
    e. Insert swab into the BOTTOM HOLE and push firmly until the swab is visible in the top hole.
    f. Rotate the swab **3** times CLOCKWISE. Do NOT remove the swab.
    g. Peel off liner from the right edge of the test card. Close and seal the card. Read results in the window 15 minutes after closing the card. Results should be read promptly at 15 minutes and no later than 30 minutes.
3. Interpreting the Results
    a. A **NEGATIVE** result will give a single pink/purple colored control line in the top half of the window.
    b. A **POSITIVE** result will give 2 pink/purple colored lines. Those with low levels of antigen may give a faint line. Any visible double line is considered positive.
    c. If no lines are seen or the sample line, the test is considered invalid and should be repeated.
4. Document the results on the North Boone Result Report Form. Place a copy of the result form in the student's physical health chart. Document the test information on the Contact Tracing Spreadsheet.
5. Results should be sent via email to Julie Brosnan at jbrosnan@nbcusd.org to be sent to BCHD. Also provide results to the healthcare provider listed on the testing consent form.
6. Refer the student/staff for the appropriate testing and follow-up. Provide the BinaxNow Fact Sheets (Attached) for both patient and provider and any other educational resources.

This policy and procedure shall remain in effect for all patients under the direction of the medical director until rescinded and/or change of medical director.

Medical Director's signature: Effective Date:

Printed Title:

North Boone School District
6248 North Boone School Rd.
Poplar Grove, IL 61065

North Boone COVID-19 Rapid Test Result Report Form (Staff)

Staff Name:_____ Date of Birth:_____ Test Date:_____

Contact Number:_____Position:_____School/Building:_____

Address:_____ City:_____ State:_____ Zip:_____

Are you symptomatic? Yes or No Date of Symptom Onset:_____

Date of possible exposure to COVID-19: _____

Please indicate all of the symptoms that you are exhibiting:

- ❑ Feeling feverish or a measured temperature greater than or equal to 100.4 degrees Fahrenheit
- ❑ Loss of taste or smell
- ❑ Cough
- ❑ Difficulty breathing
- ❑ Shortness of breath
- ❑ Fatigue
- ❑ Headache
- ❑ Chills
- ❑ Sore throat
- ❑ Congestion or runny nose
- ❑ Shaking or exaggerated shivering
- ❑ Significant muscle pain or ache
- ❑ Diarrhea
- ❑ Nausea or vomiting
- ❑ Other:_____

Section Below is for Nursing Staff Only:

Test Kit Lot Number:_____ Exp Date:_____

Test Start Time:_____ Test End Time:_____

Test Result (circle): Positive Negative

Referred for COVID-19 PCR Testing/Follow-up with Provider: Yes or No

Date Referred:_____ Date Results Reported to BCHD:_____

Healthcare Provider:_____Date Reported to Healthcare Provider:_____

Nurse Administering Test:_____ Nurse Signature:_____ Date:_____

North Boone School District
6248 North Boone School Rd.
Poplar Grove, IL 61065

North Boone COVID-19 Rapid Test Result Report Form (Student)

Student Name:_____ Date of Birth:_____ Test Date:_____

Grade/Teacher:_____ School/Building:_____

Parent/Guardian Name:_____ Contact Number:_____

Address:_____ City:_____ State:_____ Zip:_____

Is the student symptomatic? Yes or No Date of Symptom Onset:_____

Date of possible exposure to COVID-19: _____

Please circle all of the symptoms that the student is exhibiting:

- ❑ Feeling feverish or a measured temperature greater than or equal to 100.4 degrees Fahrenheit
- ❑ Loss of taste or smell
- ❑ Cough
- ❑ Difficulty breathing
- ❑ Shortness of breath
- ❑ Fatigue
- ❑ Headache
- ❑ Chills
- ❑ Sore throat
- ❑ Congestion or runny nose
- ❑ Shaking or exaggerated shivering
- ❑ Significant muscle pain or ache
- ❑ Diarrhea
- ❑ Nausea or vomiting
- ❑ Other:_____

Section Below is for Nursing Staff Only:

Test Kit Lot Number:_____ Exp Date:_____

Test Start Time:_____ Test End Time:_____

Test Result (circle): Positive Negative

Referred for COVID-19 PCR Testing/Follow-up with Provider: Yes or No

Date Referred:_____ Date Results Reported to BCHD:_____

Healthcare Provider:_____Date Reported to Healthcare Provider:_____

Nurse Administering Test:_____ Nurse Signature:_____ Date:_____

STUDENT CONSENT FORM FOR OPTIONAL COVID-19 TESTING

The North Boone Community Unit School District #200 takes the health and safety of our students and their families very seriously. As such, in addition to steps to screen for the virus and prevent its spread within our schools, we are adding a voluntary Pre-K-12 COVID-19 testing program for students. This program uses Abbott Laboratories BinaxNOW tests provided by the federal government. We will only test with your consent. If you are willing to provide consent for us to administer this test on your child, please fill out this form.

What is the test?

If your child is symptomatic or part of a group that is designated for testing, if you consent, your child will receive a free BinaxNOW rapid test for the COVID-19 virus . Collecting a specimen for testing involves using a swab, similar to a Q-Tip, placed inside the tip of the nose. A school nurse who has been trained to administer this test will collect the specimen and complete the test. Test results will be made available to the parent/guardian who signs this form below. This program is optional for students, although we hope you choose to have the test to keep our schools as healthy & safe as possible. The tests are being offered in addition to existing safety protocols such as mask-wearing, social distancing, and frequent disinfection of surfaces.

What should I do when I receive my/my child's test results?

Positive Result:

If your child tests positive for the virus, your child will be moved to a room away from other students and staff until you can pick him/her up. The student will be excluded from school for at least 10 days from the date symptoms first appear and he or she is symptom-free for 24 hours without any fever-reducing medication.

Negative Result:

If your child's test results are negative and he or she is symptomatic your child will need to get a COVID-19 PCR test completed to confirm the rapid test result. The student will be excluded from school for at least 10 days from the date symptoms first appear and he or she is symptom-free for 24 hours without any fever-reducing medication. This can be done at any of the testing sites (info attached). In a small number of cases, tests sometimes produce incorrect results. For example, showing negative results (called "false negatives") in people who have COVID-19. If your child tests negative but has symptoms of COVID-19, or if you have concerns about your child's exposure to COVID-19, you should have COVID-19 PCR testing completed and call your child's doctor and get further guidance.

Known Symptoms:

People with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Symptoms may appear **2-14 days after exposure to the virus.** People with these symptoms may have COVID-19:

- Feeling feverish or a measured temperature greater than or equal to 100.4 degrees Fahrenheit
- Loss of taste or smell
- Cough
- Difficulty breathing
- Shortness of breath
- Fatigue
- Headache
- Chills
- Sore throat
- Congestion or runny nose
- Shaking or exaggerated shivering
- Significant muscle pain or ache
- Diarrhea
- Nausea or vomiting

This list does not include all possible symptoms.

Disclaimer:

While we realize precautions will be taken for the safety of students, please understand that neither the test administrator nor the North Boone Community Unit School District #200, nor any of its trustees, officers, employees, or organization sponsors are liable for any accident or injuries that may occur to your child, as a result of agreeing to the test.

TO BE COMPLETED BY PARENT, GUARDIAN OR ADULT STUDENT

Parent/Guardian Information

You will be notified with test results either via cell phone or in-person when you pick up your student.

Parent/Guardian Print Name:			
Parent/Guardian Cell/Mobile #: *Note: results will be texted to this cell #*			
Parent/Guardian Email Address:			
Student's Healthcare Provider:		**Phone:**	

Child/Student Information

Child/Student Print Name:					
Street Address:		**City:**		**State:**	
Zip Code:		**County:**			
School:			**Grade Level:**		
Date of Birth: *(MM/DD/YYYY)*			**Age:**		
Race/Ethnicity:	☐ Asian ☐ Hispanic ☐ Native American/Indigenous ☐ Black ☐ White ☐ Unknown		**Gender:**	☐ Male ☐ Female ☐ Other/Unknown	

CONSENT

By signing below, I attest that:

A. I authorize the school system to conduct collection and testing of my child for COVID-19 by nasal swab.
B. I acknowledge that a positive test result is an indication that my child must self-isolate for 10 days from symptom onset and until he or she is symptom free for 24 hours without any fever-reducing medication and also continue wearing a mask or face covering as directed in an effort to avoid infecting others.
C. I understand the school system is not acting as my child's medical provider, this testing does not replace treatment by my child's medical provider, and I assume complete and full responsibility to take appropriate action with regards to my child's test results. I agree I will seek medical advice, care and treatment from my child's medical provider if I have questions or concerns, or if their condition worsens.
D. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.
E. **The results of this test will be reported to the Boone County Health Department AND the provider you have indicated above.**

I, the undersigned, have been informed about the test purpose, procedures, possible benefits and risks, and I have received a copy of this Informed Consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time. I voluntarily agree to this testing for COVID-19 for the remainder of the school year. I understand that anytime I can choose to revoke this decision by notifying the school.

Signature of Parent/ Guardian:		**Date:**	

FACT SHEET FOR HEALTH PROVIDERS

Abbott Diagnostics Scarborough, Inc. **August 26, 2020**
BinaxNOW™ COVID-19 Ag Card

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the BinaxNOW COVID-19 Ag Card.

The BinaxNOW COVID-19 Ag Card is authorized for use using nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Abbott Diagnostics Scarborough, Inc. - BinaxNOW COVID-19 Ag Card.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The BinaxNOW COVID-19 Ag Card can be used to test nasal swab samples directly using a dual nares collection (swab inserted in both nares).
- The BinaxNOW COVID-19 Ag Card should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first seven days of onset of symptoms.
- The BinaxNOW COVID-19 Ag Card is only authorized for use in laboratories in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high and 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 test is to be performed only using nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "*Where can I go for updates and more information?*" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The BinaxNOW COVID-19 Ag Card has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection

control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients with symptom onset beyond 7 days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks from a false negative result include: delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "*Where can I go for updates and more information*" section).

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19

Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html

Laboratory Biosafety:
https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html

Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Specimen Collection:
https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

Infection Control:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

Discontinuation of Isolation:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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Scarborough, Maine 04074

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Abbott

FACT SHEET FOR PATIENTS

Abbott Diagnostics Scarborough, Inc.
BinaxNOW™ COVID-19 Ag Card
August 26, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the BinaxNOW COVID-19 Ag Card.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the BinaxNOW COVID-19 Ag Card?

The BinaxNOW COVID-19 Ag Card is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in respiratory specimens, for example nasal swabs.

Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first seven days of the onset of symptoms.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than seven days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 72 hours (that is three full days of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved)

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

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Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

BinaxNOW™ COVID-19 Ag CARD

For Use Under an Emergency Use Authorization (EUA) Only

For use with nasal swab specimens

For *in vitro* Use Only

Rx Only

INTENDED USE

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.

Negative results from patients with symptom onset beyond seven days, 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.

The BinaxNOW™ COVID-19 Ag Card is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests. BinaxNOW™ COVID-19 Ag 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 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.

PRINCIPLES OF THE PROCEDURE

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.

To perform the test, a 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 10 mL of extraction reagent

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

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

Negative Control Swab: 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 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, 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.

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.

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

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.

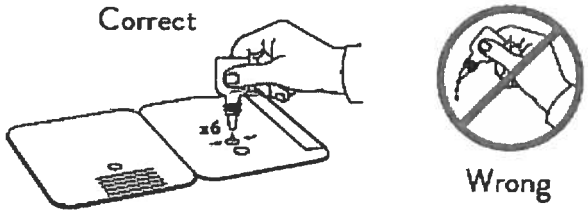
For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient 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.

TEST PROCEDURE

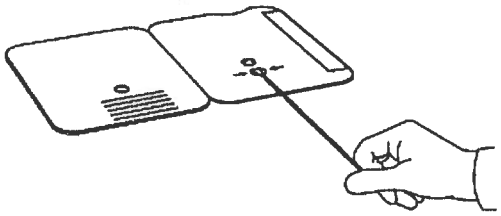
Procedure for Patient Specimens

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.**

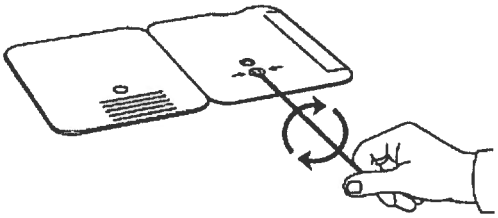
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



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

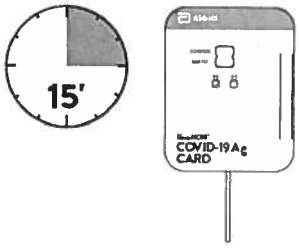


3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.



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.

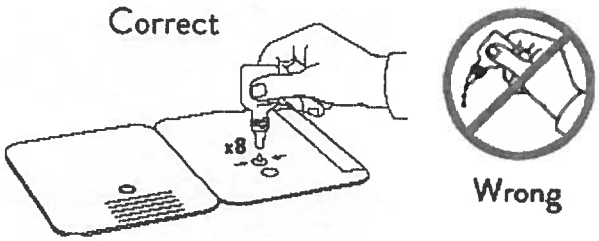


Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

Procedure for BinaxNOW™ Swab Controls

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

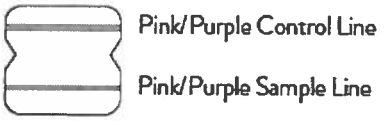
1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the **TOP HOLE,** slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

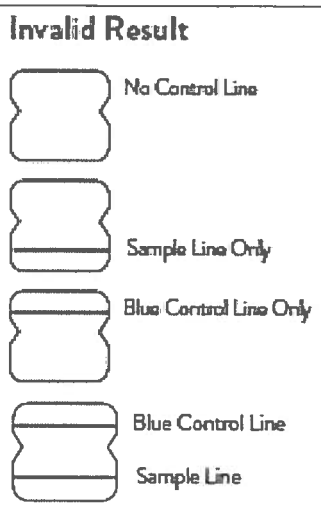


2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

RESULT INTERPRETATION

Note: In an untested BinaxNOW COVID-19 Ag 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.	

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.
- 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 seven 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.

CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS

The BinaxNOW™ COVID-19 Ag 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/vitro-diagnostics-euas.

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

- Authorized laboratories[1] using your product will 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 will use your product as outlined in the "BinaxNOW™ COVID-19 Ag 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 will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will 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 will 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 Card was evaluated in a multi-site prospective study in the U.S in which patients were sequentially enrolled and tested. A total of seven (7) 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 thirty-two (32) intended users. No training on the use of the test was provided to the operators. 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, as only seven asymptomatic patients were enrolled. Of the seven asymptomatic patients, only two patients were positive for SARS-CoV-2. Two nasal swabs were collected from patients and tested using the BinaxNOW™ COVID-19 Ag 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 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 Card Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The performance of BinaxNOW™ COVID-19 Ag Card was established with 102 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

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

BinaxNOW™ COVID-19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	34	1	35
Negative	1	66	67
Total	35	67	102
Positive Agreement: 34/35	97.1% (95% CI: 85.1% - 99.9%)		
Negative Agreement: 66/67	98.5% (95% CI: 92.0% - 100%)		

Patient Demographics

Patient demographics (gender, age, time elapsed since onset of symptoms) are available for the 102 samples used in the analysis. The table below shows the positive results broken down by age of the patient:

Age	BinaxNOW COVID-19 Ag Card		
	Total #	Positive	Prevalence
≤ 5 years	0		
6 to 21 years	0		
22 to 59 years	77	28	36.4%
≥ 60 years	25	7	28.0%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW COVID-19 Ag Card Positive (+)	PPA	95 % Confidence Interval	
1	4	4	100.0%	39.8%	100.0%
2	10	10	100.0%	69.2%	100.0%
3	15	15	100.0%	78.2%	100.0%
4	18	18	100.0%	81.5%	100.0%
5	23	22	95.7%	78.1%	99.9%
6	27	26	96.3%	81.0%	99.9%
7	35	34	97.1%	85.1%	99.9%

The following data is provided for informational purposes:
The performance of BinaxNOW™ COVID-19 Ag Card with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW™ COVID-19 Ag Card is higher with samples of a Ct count <33.

BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

BinaxNOW™ COVID-19 Ag Card	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	29	5
Negative	0	1
Total	29	6
Positive Agreement (95% CI)	100.0 (88.1, 100.0)	83.3 (35.9, 99.6)

A limited cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 28). Although the sample size was relatively small, the positive agreement in this cohort was 75% (9/12) and negative agreement was 92% (11/12). Therefore, negative results in patients with symptom onset greater than seven days should be treated as presumptive and confirmed with a molecular assay if needed for clinical management.

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

BinaxNOW™ COVID-19 Ag 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 Card LOD in natural nasal swab matrix was confirmed as 22.5 $TCID_{50}$/swab.

Limit of Detection (LoD) Study Results

Concentration $TCID_{50}$/Swab	Number Positive/Total	% Detected
22.5	20/20	100%

Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW™ COVID-19 Ag 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

Potential Cross-Reactant		Test Concentration
	Human parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL
	Human parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL
	Human parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL
	Human parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/mL
	Influenza A	1.0 x 10^5 $TCID_{50}$/mL
	Influenza B	1.0 x 10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus A	1.0 x 10^5 PFU/mL
Bacteria	*Bordetella pertussis*	1.0 x 10^6 cells/mL
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
	Haemophilus influenzae	1.0 x 10^6 cells/mL
	Legionella pnuemophila	1.0 x 10^6 cells/mL
	Mycoplasma pneumoniae	1.0 x 10^6 U/mL
	Streptococcus pneumoniae	1.0 x 10^6 cells/mL
	Streptococcus pyogenes (group A)	1.0 x 10^6 cells/mL
	Mycobacterium tuberculosis	1.0 x 10^6 cells/mL
	Staphylococcus aureus	1.0 x 10^6 org/mL
	Staphylococcus epidermidis	1.0 x 10^6 org/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0 x 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 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 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW™ COVID-19 Ag 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 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.

SYMBOLS

℞ Only	Prescription Only

ORDERING AND CONTACT INFORMATION

Reorder Numbers:

195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)
195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit

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

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.abbott.com/poct

IN195000 Rev. 1 2020/08

Abbott BinaxNOW COVID-19 Ag CARD

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.

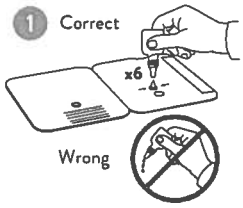
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

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

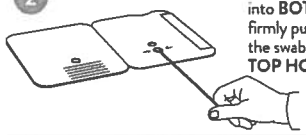
Patient Samples require 6 drops of Extraction Reagent.

1 Correct



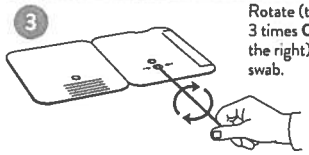
Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



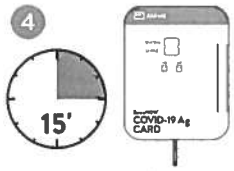
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

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, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

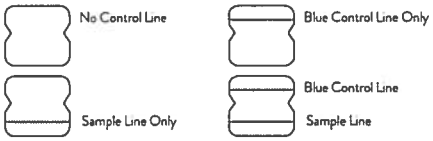
Negative Result

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 test has not been FDA cleared or approved; this test 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 test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this test 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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℞ Only
IVD

IN195001 Rev. 1 2020/08

Abbott
BinaxNOW
COVID-19 Ag

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: IN195001
Rev: 1

Date of Last Revision:
1.6 2020/08/24