# BinaxNOW COVID-19 SCREENING TEST

**District 117 (updated 7/22/2021)**

District 117 has been authorized to administer BinaxNOW COVID-19 antigen tests during the COVID-19 pandemic under the FDA. Testing may be administered for staff and students who are asymptomatic or become symptomatic while on our campus as a screening tool to help us keep our staff and students safe while at school. In conducting this screening test, the district is not providing medical care or giving medical diagnoses. The nasal swab antigen test, which takes approximately 15 minutes, is designed to determine if individuals have COVID-19 by detecting the proteins that make up the virus. The BinaxNOW test is intended to be done during the acute phase of the infection within the first 7 days of symptom onset. Results will be shared with the test subject, Lake County Health Department, and the State of Illinois, as required. Tests are donated by the Illinois Board of Education so there is no cost for the individual being tested.

**Who will be tested?**

Once a consent form and waiver to allow testing has been obtained, staff or students while at school, may be offered testing using the BinaxNOW test.
Spouses/parents/guardians/children/siblings are not eligible for testing through the school.

**What is the consent form and waiver?**

The staff member or parent/guardian will need to sign a consent/waiver form to allow testing. Questions regarding ethnicity and race in the waiver form do not have to be answered. Due to the inequality of opportunity for testing of certain ethnicities and races during this pandemic, information is being collected to help identify lapses in care.

**How are results communicated?**

The nurse will communicate with the staff member or parent/guardian whether the result of the BinaxNOW antigen test is positive or negative. District 117 is not providing medical care or giving a medical diagnosis with this screening test. Staff members and parents/guardians should consult with their medical provider or go to an emergency room if they have questions, serious symptoms and/or to obtain medical advice as to the result of the test.

**Who is responsible for contact tracing?**

District 117 works with the health department to collect case data. Positive test results and/or identified close contacts are reported to the Lake County Health Department for contact tracing. Individuals are strongly encouraged to cooperate with the health department and follow up phone calls.

**Who mandates the isolation/quarantine guidelines?**

District 117 follows the guidelines provided by the Lake County Health Department, in coordination with the CDC and the Illinois Department of Public Health.

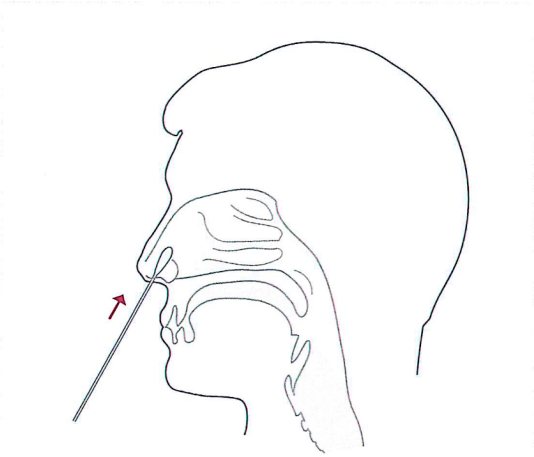
**How is the nasal swab specimen collected and tested?**

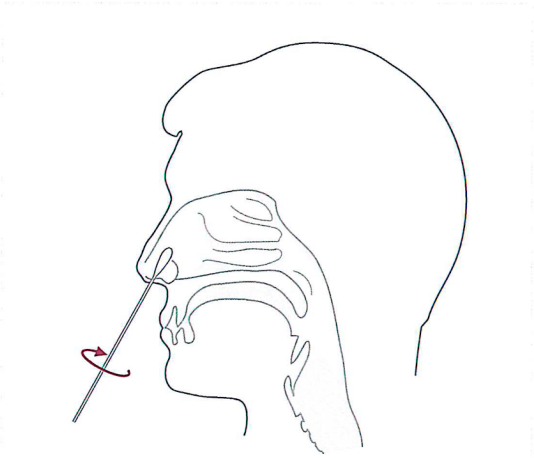
The state of Illinois recommends that those administering the test and performing the swabbing be a **licensed** healthcare professional (any level) if it is within their scope of practice.

Abbott

TECH TIPS

# COLLECTION OF A NASAL SWAB FOR THE **BINAXNOW™ COVID-19 AG CARD** (ANTIGEN TEST)





1 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.

2 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 and then slowly remove from the nostril.

3 Using the same swab, repeat sample collection in the other nostril.

## IMPORTANT REMINDERS

- Please refer to the BinaxNOW COVID-19 Ag Card product insert for full details.
- Use only the swabs provided in the test kit.

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.**

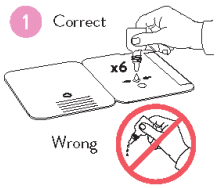
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

**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

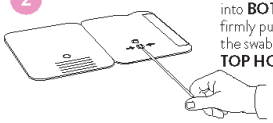
**Patient Samples require 6 drops of Extraction Reagent.**

1 Correct



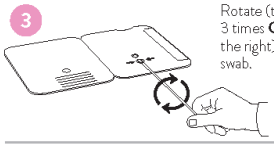

Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



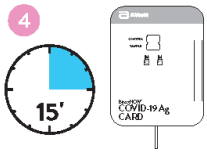
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

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.

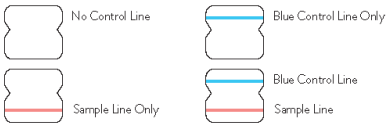
**Negative Result**


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.

**Abbott Diagnostics Scarborough, Inc.**
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott

℞ Only
IVD



IN195001 Rev. 1 2020/08

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**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:**
1.7 2020/08/25

# FACT SHEET FOR PATIENTS

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

**Updated: December 16, 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.

- **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.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means 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 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms of COVID-19 are improving **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation

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.

- **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.

# STUDENT SCREENING CONSENT FORM AND WAIVER FOR BinaxNOW TESTING

**FIRST NAME** _____ **MI**____ **LAST NAME** _____

**DATE OF BIRTH (Month/Day/Year )** _____ / _____ / _____

In consideration for receiving the opportunity to participate in **COVID-19 testing/screening** (hereinafter "Testing"), which is provided by Community High School District 117, 1 hereby release, waive, discharge, covenant not to sue, and agree to hold harmless for any and all purposes Community High School District 117 and their healthcare staff, other staff members, administrators, board members, servants, agents, volunteers, and/or any other employees (herein referred to as "Indemnitees") from any and all liabilities, claims, demands, injuries (including death), or damages, including court costs and attorney's fees and expenses, that may be sustained by me while participating in Testing, while traveling to and from the Testing, or while on the premises owned or leased by Indemnitees.

I am fully aware that the Testing provided by the Community High School District 117may involve COVID-19 tests that have not gone through a full FDA approval process and instead obtained emergency use authorization (EUA) or registered and are pending such processing and that the results could produce false positives or false negatives, or be administered in a way that otherwise produces inaccurate results. I am also fully aware that the organization is not providing medical care or giving a medical diagnosis with Testing and that ***I should consult my doctor or go to an emergency room if I, and/or my child, have any questions, serious symptoms and/or to obtain medical advice from my own doctor as to the results of the Testing.*** ***I understand my student will be sent home immediately if symptomatic, irregardless of the BinaxNow test result. District 117 will follow the guidance of the Lake County Health Department and the Illinois Department of Public Health.***

I hereby waive my rights regarding protected health information under HIPAA, FERPA and/or ISSRA, to the extent necessary to complete the Testing and to allow Community High School District 117 to provide the results (whether positive or negative) of Testing to (1) the organization which has arranged for the testing, and (2) local and state public health authorities (which may result in further direct communication from those entities to me for further follow-up and contact tracing). Protected health information will not be reused or disclosed.

By checking the box in front of the I CONSENT box below, I am agreeing to voluntary Testing for my child. By checking this box, I acknowledge and represent that I have read it, understand it, and sign it voluntarily.

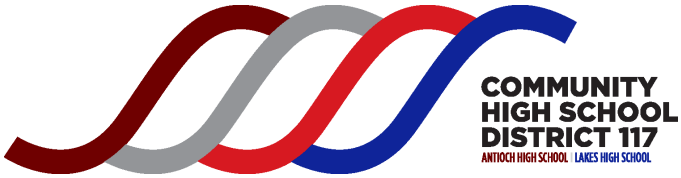
- ❑ I hereby DO consent and DO agree to voluntarily allow my child to be tested for COVID-19 using the Binax Now COVID-19 Test. I acknowledge and represent that I have read this consent, understand and sign it voluntarily. By signing below, I am agreeing to voluntary Testing, as offered, through June 30, 2022. I understand that to revoke my consent, I must designate it in writing to District 117.

By checking the box in front of the I DO NOT CONSENT box below, I am stating that I do not want my child to be tested. By checking this box, I acknowledge and represent that I have read it, understand it, and sign it voluntarily.

- ❑ I DO NOT consent and DO NOT agree to voluntarily allow my child to be tested for COVID-19 using the Binax Now COVID-19 Test. I acknowledge and represent that I have read this consent, understand and sign it voluntarily.

**Parent/ Legal Guardian Signature:** _____ **Date:**_____

**Student Signature if over age 18:** _____ **Date:**_____




# STAFF SCREENING CONSENT FORM AND WAIVER FOR BinaxNOW TESTING

**FIRST NAME _____ MI____ LAST NAME _____**

**DATE OF BIRTH (Month/Day/Year ) _____ / _____ / _____**

This consent form and waiver allows District 117, with my permission, to perform the BinaxNow Rapid COVID-19 test (hereinafter "Testing"). The BinaxNOW Rapid antigen test is a minimally invasive nasal swab of the lower nasal cavity which is then tested using the BinaxNOW COVID-19 Ag Card to detect the proteins that make up the virus. The goal of the screening test is to quickly identify those individuals who may be COVID-19 positive so that necessary measures for controlling the exposure and spread of others to the virus can be implemented, including but not limited to isolating positive cases and quarantining close contacts. I am fully aware that the Testing provided by the Community High School District 117 may involve COVID-19 tests that have not gone through a full FDA approval process and instead obtained emergency use authorization (EUA) or registered and are pending such processing and that the results could produce false positives or false negatives, or be administered in a way that otherwise produces inaccurate results. I am also fully aware that the organization is not providing medical care or giving a medical diagnosis with Testing and that ***I should consult my doctor or go to an emergency room if I have any questions, serious symptoms and/or to obtain medical advice from my own doctor as to the results of the Testing***.

In consideration for receiving the opportunity to participate in COVID-19 infection testing, which is provided by Community High School District 117, I hereby release, waive, discharge, covenant not to sue, and agree to hold harmless for any and all purposes Community High School District 117 and their healthcare staff, other staff members, administrators, board members, servants, agents, volunteers, and/or any other employees (herein referred to as "Indemnitees") from any and all liabilities, claims, demands, injuries (including death), or damages, including court costs and attorney's fees and expenses, that may be sustained by me while participating in Testing, while traveling to and from the Testing, or while on the premises owned or leased by Indemnitees.

I hereby waive my rights regarding protected health information under HIPAA, FERPA, and/or ISSRA, to the extent necessary to complete the Testing and to allow Community High School District 117 to provide the results (whether positive or negative) of Testing to (1) the organization which has arranged for the testing, and (2) local and state public health authorities (which may result in further direct communication from those entities to me for further follow-up and contact tracing). Protected health information will not be reused or disclosed by the organization to any person or entity other than above, except as required by law.

By signing below, I am agreeing to voluntary Testing, as offered, through June 30, 2022. I understand that to revoke my consent, I must designate it in writing to District 117.

In signing this Testing consent form and waiver, I acknowledge and represent that I have read it, understand it, and sign it voluntarily.

**Signature: _____ Date: _____**

**School: _____Position:_____**