BINAXNOW™
COVID-19 ANTIGEN SELF-TEST

For Rapid Detection of SARS-CoV-2
At home or for sale over-the-counter

BinaxNOW™ is
FSA/HSA
eligible and reimbursable through most health insurance plans

- Detects active COVID-19 infection
- Detects multiple strains, including the DELTA variant*
- Results in 15 minutes
- Easy to follow illustrated step-by-step instructions
- Requires a minimally invasive nasal swab sample
- Know your result now, without the need to wait for results from your healthcare provider
- Each kit box contains two test cards to enable you to test yourself twice within 3 days, with at least 36 hours between tests
- Compatible with the NAVICA app to capture your results for self reporting

- 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.
- A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens
- Test Kit Dimensions: 9.125” L x 0.938” D x 5.063” H
- Kit contains all necessary components for testing, including: 2 BinaxNOW™ COVID-19 Antigen Test Cards, 2 Nasal Swabs, 2 Reagent Bottles
- Store between 35.6-86° F (2-30° C) until use.

Visit our Website

WhatsApp a Team Member

CONTACT US TODAY
203.930.2154
hello@liloclean.com

NAVICA

Capture your results in NAVICA for self reporting.

Discover the fast, proven and trusted COVID-19 antigen test that is readily available over-the-counter at retailers across the country. Purchase the BinaxNOW™ COVID-19 Antigen Self Test at a retail store near you and perform the test with a simple nasal swab in the comfort and convenience of your home.

#1 COVID-19 Self Test in the US: BinaxNOW™ COVID-19 Antigen Self Test uses the same technology used by doctors and is Made in the USA.

· SIMPLE AND EASY TO USE: Requires just a shallow nasal swab that you can do yourself; includes easy-to-follow instructions.

· SEE RESULTS IN 15 MINUTES: Convenient, fast results anytime, anywhere; no need for a prescription or send to a lab.

· FOR AGES 2 TO ADULT: Indicated for children as young as 2 years old when administered by an adult, and for all people 15 and older to self-administer.

· DETECTS ACTIVE COVID-19 INFECTION: Includes 2 tests that are indicated for serial testing-simply test yourself twice within 3 days, at least 36 hours apart; designed to detect active infection with or without symptoms. Detects multiple strains, including the DELTA variant.*

· FOR PERSONAL USE: This test does NOT meet the CDC testing requirements to enter the U.S. when returning from a trip abroad. For proof of negative COVID-19 test, the BinaxNOW COVID-19 Ag Card Home Test may be a better choice.

1

PURCHASE

Buy the test kit (contains 2 tests) at your local retailer

2

TEST

Complete your test, or help others administer if they require assistance

3

SEE RESULTS

Wait 15 minutes and view the results.

4

TEST AGAIN

Test again within three days (with at least 36 hours between tests)

November 8, 2021

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Device:	BinaxNOW COVID-19 Antigen Self Test
EUA Number:	EUA210264
Company:	Abbott Diagnostics Scarborough, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven days of symptom onset. Adult collected anterior nasal (nares) swab samples from individuals aged two years or older with symptoms of COVID-19 within the first seven days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged two years or older, 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.

Dear Ms. Drysdale:

On March 31, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the BinaxNOW COVID-19 Antigen Self Test pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] Based on your request, FDA granted updates to the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Diagnostics Scarborough, Inc.

[2] The March 31, 2021, letter authorized your product for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test was authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

EN
ENGLISH

BinaxNOW™ COVID-19 ANTIGEN SELF TEST

For Use Under an Emergency Use Authorization (EUA) Only
For use with anterior nasal swab specimens

For ***in vitro*** Diagnostic Use Only

The NAVICA app allows you to track results for your BinaxNOW COVID-19 tests.

- Download the app by scanning the QR code
- Create an account
- Perform a COVID-19 test (digital instructions available)
- Record your result in the app

Go to **www.binaxnow-selftest.abbott** for digital instructions.

INSTRUCTIONS

Flip sheet over to view instructions prior to starting the test.

INTENDED USE

The BinaxNOW™ COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Antigen Self Test 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. Individuals who test positive with the BinaxNOW COVID-19 Antigen Self Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, 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 an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

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.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The BinaxNOW COVID-19 Antigen Self Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The BinaxNOW COVID-19 Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

FREQUENTLY ASKED QUESTIONS

Will this Test Hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the Known and Potential Risks and Benefits of this Test?

Potential Risks Include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Results section).

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 is the Difference Between an Antigen and Molecular Test?

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.

How Accurate is this Test?

Based on the interim results of a clinical study where the BinaxNOW™ COVID-19 Antigen Self Test was compared to an FDA authorized high sensitivity SARS-CoV-2 test, BinaxNOW COVID-19 Antigen Self Test correctly identified 91.7% of positive specimens and 100% of negative specimens.

Due to the relatively small sample size for the home use clinical study, the BinaxNOW COVID-19 Antigen Self Test is estimated to correctly identify between 73.0% and 98.9% of positive specimens as reflected in the 95% Confidence Interval. This is consistent with the performance established in a separate multi-site clinical study in the US, where the BinaxNOW COVID-19 Ag Card test was performed and results interpreted by test operators with no laboratory experience. In that study, BinaxNOW COVID-19 Ag Card test correctly identified 84.6% of positive specimens and 98.5% of negative specimens.

The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Based on this information, negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing.

What is Serial Testing?

COVID-19 Serial Testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

What do I need to know about Results from Serial Testing?

If your test is negative you should test again in at least 36 hours. If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your specimen and you likely have COVID-19. If you test positive with the BinaxNOW COVID-19 Antigen Self Test, you should self-isolate and seek follow-up care with your healthcare provider to determine the next steps you should take. You may need additional testing, depending on your personal health history and other factors.

If both your first and second tests are negative, you may not have COVID-19, however, you should follow-up with your healthcare provider if you are at high risk for COVID-19 infection or have known contacts with COVID-19. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19 or need other testing.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
3. Use of gloves is recommended when conducting testing.
4. Keep testing kit and kit components out of the reach of children and pets before and after use.
5. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. 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.
8. Proper sample collection and handling are essential for correct results.
9. Do not use a kit that has been opened and/or tampered with.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
11. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
12. Do not touch swab tip when handling the swab sample.
13. Do not use kit past its expiration date.
14. Do not mix components from different kit lots.
15. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
16. Dispose of kit components and patient samples in household trash.
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 bottle vertically, 1/2 inch above the swab well, and add drops slowly.
18. The Reagent Solution contains a harmful chemical (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name/CAS	GHS Code for each Ingredient	Concentration
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.0125%

STORAGE and STABILITY

Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the outer packaging and containers.

WHAT YOUR RESULTS MEAN

Positive Result

A positive test result means it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. 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). If you test positive with the BinaxNOW COVID-19 Antigen Self Test, you should self-isolate and seek follow-up care with your healthcare provider. 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.

Negative Result

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. Negative results may require additional molecular testing to confirm that you do not have COVID-19.

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 you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath, you should seek follow up care with your healthcare provider. Please consult your healthcare professional if you develop symptoms, symptoms persist or become more severe. 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. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

If the presence of a faint line and/or the presence of a line is uncertain, additional confirmatory testing should be conducted. It is important that you work with your healthcare provider to help you understand the next steps you should take.

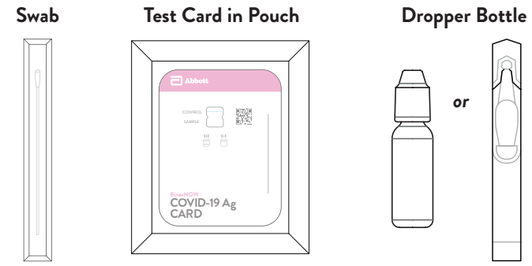
Invalid Result

An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result. Please contact Technical Support at +1 833-637-1594.

TEST KIT COMPONENTS OVERVIEW

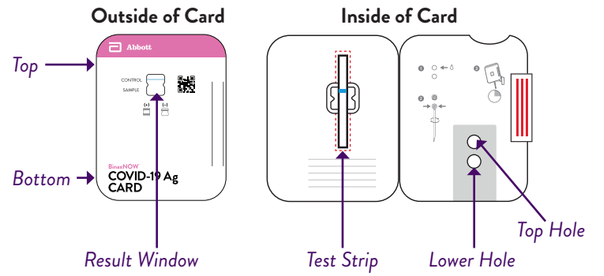
Testing supplies are provided in each box. It is recommended that the same person use two sets, testing at least 36 hours apart.

Test Kit Contains:



! Do not open any parts before reading instructions on other side of this sheet.

Test Card Parts:



Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA

IN195150WEB Rev. 2 2021/06

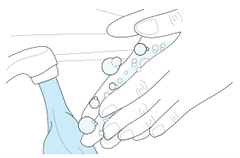
Turn Over

INSTRUCTIONS - START HERE

Carefully read instructions prior to starting test. It is recommended gloves (not provided) also be used during testing. See other side for important information.

BEFORE STARTING

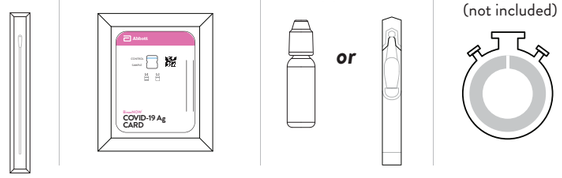
1. Wash or sanitize your hands. Make sure they are dry before starting.



A. PREPARE FOR THE TEST

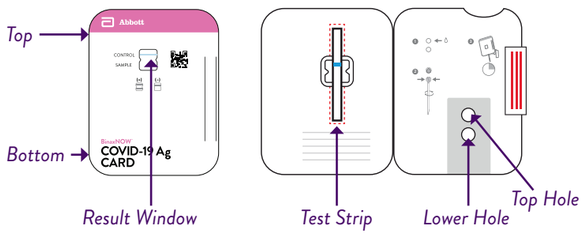
Your box may contain more than one test kit.
Use only 1 of each of the following for each test:

1 Swab | **1 Test Card in Pouch** | **1 Dropper Bottle** | **Timing Device** (not included)



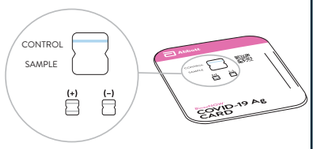
! DO NOT touch any parts on the inside. Handle card only by edges.

Outside of Card | **Inside of Card**

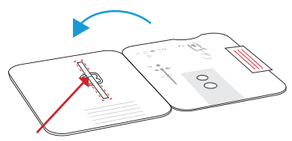


2. Remove test card from pouch.

   Make sure the **blue control line** is present in the result window. **Do not** use the card if it is not.



   Open the card and lay it flat on the table with the pink side down. You may bend the spine in the opposite direction to help the card lay flat.



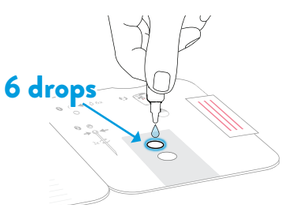
DO NOT touch the test strip.

! Card must stay FLAT on table for entire test.

3. Remove dropper bottle cap.

   Hold dropper bottle straight over **top hole**, not at an angle.

   Put 6 **drops** into **top hole**. Do not touch card with tip.

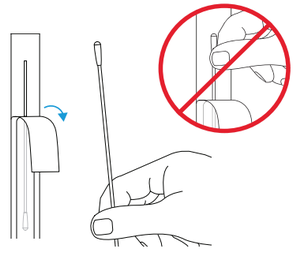


Note: False negative result may occur if more than 6 drops of fluid are put in the hole.

B. COLLECT NASAL SAMPLE

! Keep fingers away from the swab end.

4. Open swab package at stick end. Take swab out.

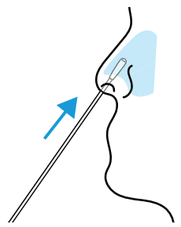


5. **Swab both nostrils carefully as shown.**

   Insert the entire soft tip of the swab into a nostril (usually 1/2 to 3/4 of an inch).

   You do not need to go deeper.

a Up to 3/4 of an inch

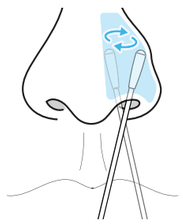


   Using medium pressure, rub the swab against all of the inside walls of your nostril.

   Make at least **5 big circles. Do not** just spin the swab.

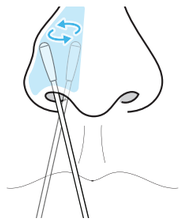
   Each nostril must be swabbed for about **15 seconds.**

b At least 5 big circles



   Using the same swab, repeat step 5 in your other nostril.

c At least 5 big circles



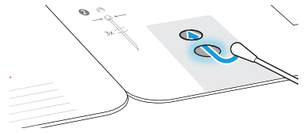
STOP **Check:** Did you swab BOTH nostrils?

Note: False negative result may occur if the nasal swab is not properly collected.

C. PERFORM THE TEST

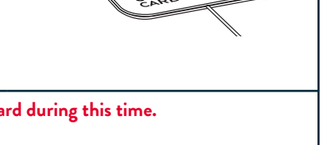
! Keep card FLAT on table.

6. Insert swab tip into **lower hole**.



   Firmly push the swab tip from the lower hole until it is visible in the **top hole**.

   Do not remove the swab from the card.



7. Turn swab to right 3 times to mix the swab with the drops.

   Do not skip this step.

   Leave the swab in the card for the remainder of the test.

Note: False negative result can occur if swab is not turned.

! DO NOT remove swab.

8. Peel adhesive liner off. Be careful not to touch other parts of card.

a Peel

   Close left side of the card over swab. Press firmly on the two lines on right edge of the card to seal.

b Seal

   Keep card face up on table.

! DO NOT move or touch the card during this time.

9. **Wait** 15 minutes.

   Read the result at 15 minutes.

   Do not read the result before 15 minutes or after 30 minutes.

WAIT 15 MINUTES

READ BETWEEN 15-30 MINUTES

Note: A control line may appear in the result window in a few minutes but a sample line may take as long as 15 minutes to appear.

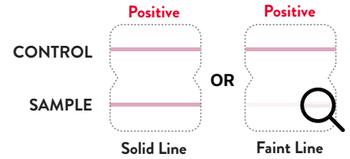
Note: Results should not be read after 30 minutes.

D. INTERPRET RESULTS

Check for Positive COVID-19 Result

Find result window and look carefully for two pink/purple lines.

Positive Result: If you see two pink/purple lines (one on the top half and one on the bottom half), this means **COVID-19 was detected.**



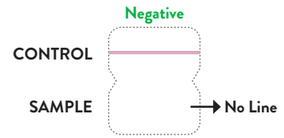
Look very closely! The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

Below are photos of actual positive tests. On the right, note how faint the bottom line can get.

Check for Negative COVID-19 Result

Find result window and look for a single pink/purple line in window.

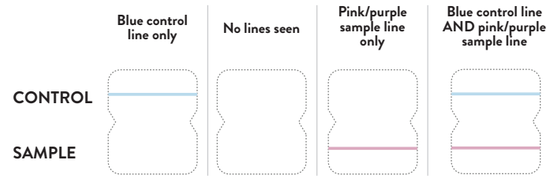
Negative Result: If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected.**



Check for Invalid Result

If you see any of these, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result.

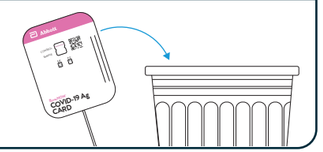
Please contact Technical Support at + 1-833-637-1594.



Note: See other side to read about what your results mean.

E. DISPOSE THE TEST KIT

Throw away all used test kit components in the trash.



F. REPORT YOUR RESULTS

Report your test result through the NAVICA app or by contacting your healthcare provider.

Note: A second test should be taken at least 36 hours after the first test.

Day 1 TEST 1 → Wait 36 hours (1.5 days) → **Day 2 to Day 3** TEST 2