BinaxNOW™ COVID-19 ANTIGEN SELF TEST

EN
ENGLISH

IN195150WEB Rev. 6 2023/01

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.

- Compatible smart phone includes Apple iPhone running Operation System (iOS): latest major version and two prior major versions (iPhone running iOS v12 or later), and Android Phones: latest major version and two prior major versions (Android phone running Android OS v9 or later).
- 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

Alternatively go to www.binaxnow-selftest.abbott for digital instructions.

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INSTRUCTIONS

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

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.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal (nares) swab samples from individuals 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

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 which 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.

All negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. 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.

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 report their test result through the NAVICA app **and** provide all results obtained with this product to their healthcare provider in order to receive appropriate medical care. 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. This product has not been FDA cleared or approved.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

FREQUENTLY ASKED QUESTIONS

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.

For more information on EUAs go here: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization

What is the Difference Between an Antigen and Molecular Test?
There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19.

Molecular tests detect genetic material from the virus. Antigen tests, such as the BinaxNOW COVID-19 Antigen Self Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How Accurate is this Test?
Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use available at www.globalpointofcare.eifu.abbott.

What if I Have a Positive Test Result?
A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a Negative Test Result?
A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an Invalid Test Result mean?
An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT
Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

LIMITATIONS

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January, 2021, and May, 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time.

All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

Incorrect test results may occur if a specimen is incorrectly collected or handled.

This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

WARNINGS, PRECAUTIONS and SAFETY INFORMATION

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. In the USA, this product 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. Incorrect test results may occur if a specimen is incorrectly collected or handled.
9. Do not use if any of the test kit contents or packaging is damaged.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. Once opened, the test card should be used immediately.
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. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
19. An anterior nasal swab sample can be self-collected by an individual age 15 years and older. Children age 2 to 15 years should be tested by an adult.
20. If you have had symptoms longer than seven days, you should consider testing at least three times over five days with at least 48 hours between tests.
21. Do not use on anyone under 2 years of age.
22. Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
23. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
24. The Reagent Solution contains a harmful chemical (see table below). Do not ingest any kit components. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: www.poisonhelp.org 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%

For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

WHAT YOUR RESULTS MEAN

Positive Result

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is wrong (a false positive result).

Negative Result

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid Result

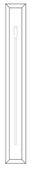
An invalid result means this test was unable to determine whether you have COVID-19 or not. Re-test with a new swab and new test device. Please contact Technical Support at +1 833-637-1594.

TEST KIT COMPONENTS OVERVIEW

Testing supplies are provided in each box.

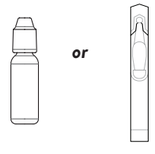
Test Kit Contains:

Swab



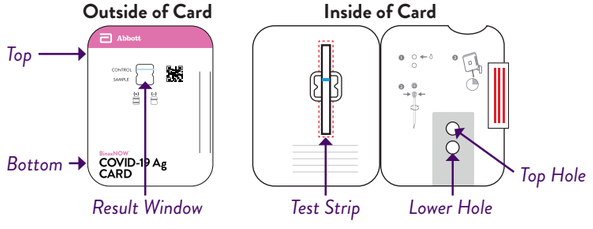
Test Card in Pouch

Dropper Bottle



! Do not open any parts before reading instructions.

Test Card Parts:



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.

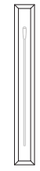
BEFORE STARTING

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

A. PREPARE FOR THE TEST

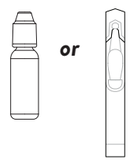
Your box may contain more than one test kit.
Use only 1 of each of the following for each test:

1 Swab

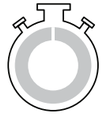


1 Test Card in Pouch

1 Dropper Bottle

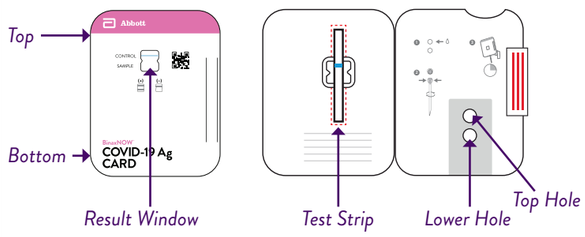


Timing Device
(not included)



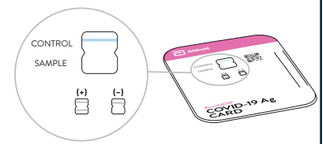
! DO NOT touch any parts on the inside. Handle card only by edges.

Outside of Card **Inside of Card**

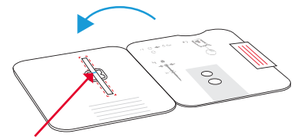


2. Remove test card from pouch.

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.



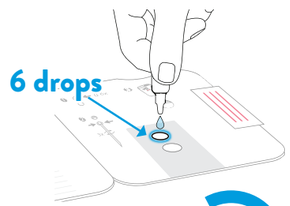
DO NOT touch the test strip.

! 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.



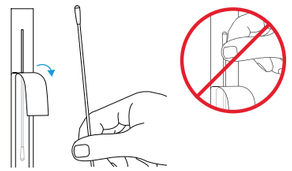
Note: False negative result may occur if more than 6 drops of fluid are put in the hole.

Turn Over

B. COLLECT NASAL SAMPLE

! **Keep fingers away from the swab end.**

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

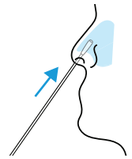


5. Swab both nostrils carefully as shown.

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

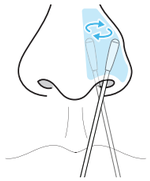


Using medium pressure, rub the swab against all of the inside walls of your nostril.

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

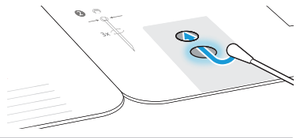
STOP **Check:** Did you swab BOTH nostrils?

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

C. PERFORM THE TEST

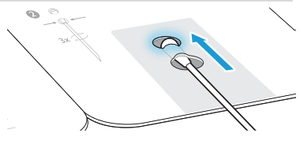
! **Keep card FLAT on table.**

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



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

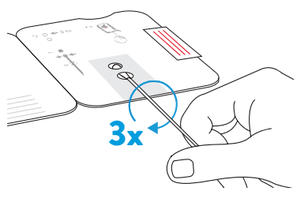
Do not remove the swab from the card.



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.



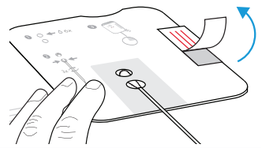
Note: False negative result can occur if swab is not turned.

C. PERFORM THE TEST continued

! **DO NOT remove swab.**

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

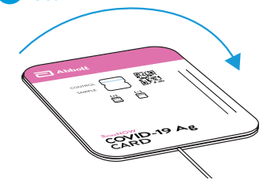
a Peel



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

Keep card face up on table.

b Seal



! **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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

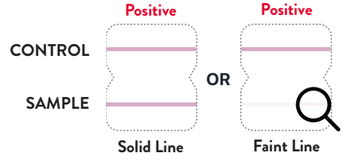
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

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.

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

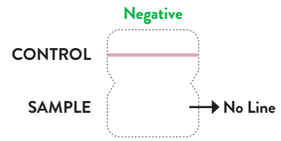
You do not need to perform repeat testing if you have a positive result at any time.

D. INTERPRET RESULTS continued

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.**



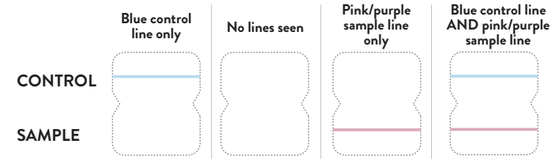
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

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 and by contacting your healthcare provider.