Abbott

BinaxNOW™ COVID-19 ANTIGEN SELF TEST

Healthcare Provider Instructions for Use

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

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

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 past medical 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.

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.

The BinaxNOW COVID-19 Antigen Self Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The BinaxNOW COVID-19 Antigen Self Test kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES of the PROCEDURE

The BinaxNOW COVID-19 Antigen Self Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, an anterior nasal swab specimen is collected by the patient, then 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 (2): A cardboard, book-shaped hinged test card containing the test strip
Extraction Reagent (2): Bottle containing <1 mL of extraction reagent
Nasal Swabs (2): Sterile swab for use with BinaxNOW COVID-19 Antigen Self Test
Patient Instructions for Use (1)
Individual Fact Sheet (1)

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
3. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
4. Use of gloves is recommended when conducting testing.
5. Keep testing kit and kit components out of the reach of children and pets before and after use.
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 or swab.
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

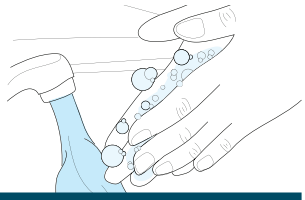
Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the outer packaging and containers.

DIRECTIONS FOR RUNNING THE BINAXNOW COVID-19 AG CARD SELF TEST

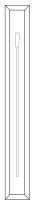
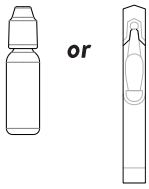
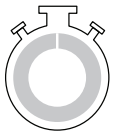
Carefully read instructions prior to starting test. It is recommended gloves (not provided) also be used during testing.

BEFORE STARTING

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



A. PREPARE FOR THE TEST

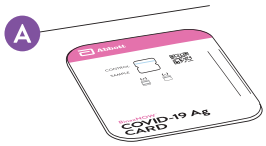
1 Swab	1 Test Card in Pouch	1 Dropper Bottle	Timing Device (not included)
			

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

! Card must stay FLAT on table for entire test.

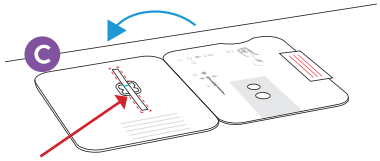
2. Remove test card from pouch and lay flat on table.

The card must stay flat on the table for the entire test.



Make sure the **blue control line** is present in the result window. If a blue line is not present, **do not** use this card.

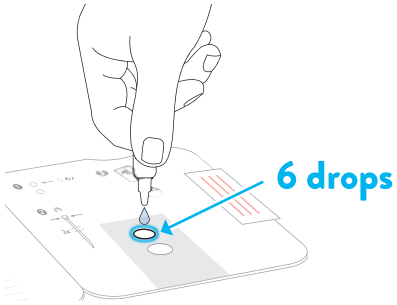
Open card flat on table. You may bend the spine in the opposite direction to help the card lay flat.



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.

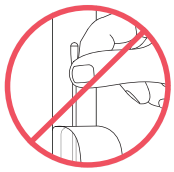


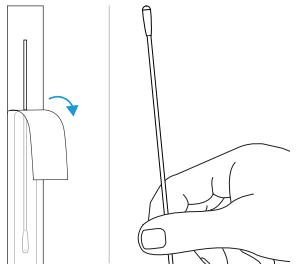
Note: False negative result may occur if less than 6 drops of fluid are put in the hole.

B. COLLECT NASAL SAMPLE

! Keep fingers away from the swab end.

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



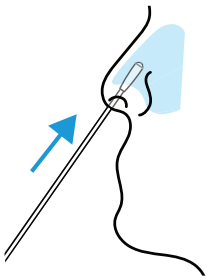


5. **Swab both nostrils carefully as shown.**

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**

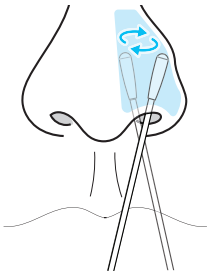


Using medium pressure, rub the swab against all of the inside walls of your nostril.

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

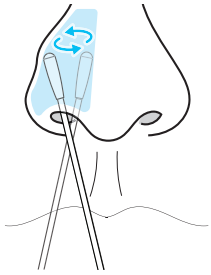
Each nostril must be swabbed for about **15 seconds.**

B **At least 5 big circles**



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

C **At least 5 big circles**



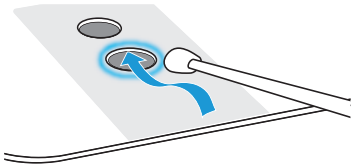
STOP **Check:** Did you swab BOTH nostrils?

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

C. PERFORM THE TEST

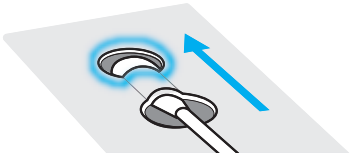
! **Keep card FLAT on table.**

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



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

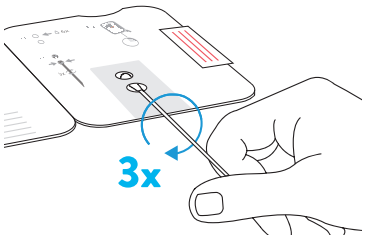
Do not remove the swab from the card.



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

Do not skip this step.

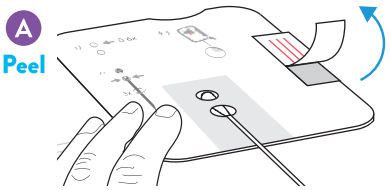
Leave the swab in the card for the remainder of the test.



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.



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

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.

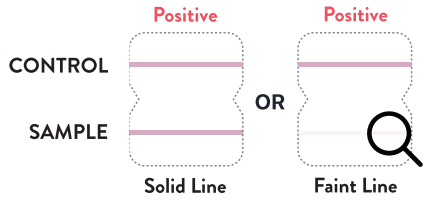
Note: Results should not be read after 30 minutes.

D. INTERPRET RESULTS

A. 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.**



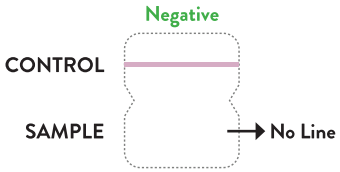
Look very closely!
The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

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

B. Check for Negative COVID-19 Result

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

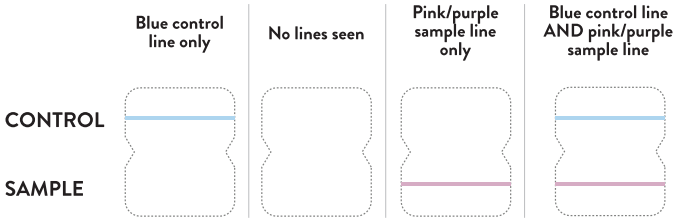
Negative Result: If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected.**



C. 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.

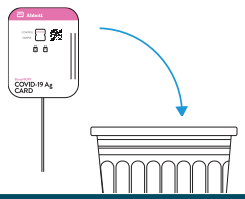
Please contact Technical Support at + 1 833-637-1594



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

Please share your test result with your health care provider.