INTENDED USE

The BinaxNOW COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleic acid antigens 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 to detect the presence of SARS-CoV-2 in the first 7 days of symptom onset. Although this test can detect antigen even before the first day of symptom onset, antigen levels are highest between 1-3 days after the onset of symptoms. The test is also authorized for prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 7 years or older with or without symptoms at a maximum of 10 days from symptom onset. This test is not intended for use in pregnant women.

The test is not authorized for non-prescription 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 aged 2 years or older, with or without symptoms or at a maximum of 10 days from symptom onset. This test is also not intended for use in pregnant women.

TEST METHOD

The BinaxNOW COVID-19 Antigen Self Test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

RESULTS

For the identification of SARS-CoV-2 nucleic acid antigens, antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but close correlation with patient history and other diagnostic information is necessary to determine whether this test result is clinically significant. Negative test results do not exclude the possibility of COVID-19 infection.

The BinaxNOW COVID-19 Antigen Self Test is intended for prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or at a maximum of 10 days from symptom onset.

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 as additional testing may be necessary.

Negative results should be treated as precautionary and in conjunction 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 basis for treatment or patient management decisions, including fracture decisions.

Unlike nucleic acid tests, additional confirmatory testing with a molecular test for the positive result may be conducted. However, if there is a low likelihood of COVID-19, such as an individual with a low contact dose with COVID-19 or with suspected exposure to COVID-19 in a community with high prevalence of infection. Adverse reaction and consequences to continue COVID-19 symptoms if fever, cough, shortness of breath or difficulty of breath may still have SARS-CoV-2 infection and should seek follow-up care with your healthcare provider.

Individuals should report their test result through the NAVICA app and provide all results obtained from their healthcare provider in a timely manner.

The BinaxNOW COVID-19 Antigen Self Test is intended for non-prescription home use only, as applicable for a COVID-19 test to detect antigen in 2 years or after using a laboratory testing.

The BinaxNOW COVID-19 Antigen Self Test is for use only by the Food and Drug Administration’s Emergency Use Authorization.

PRECAUTIONS

1. For in vitro diagnostic use.

2. Wear safety mask or other face covering when collecting anterior nasal swab specimen from child or another individual.

3. Use of gloves is recommended when conducting testing.

4. Keep testing kit and components out of reach of children and pets before and after use.

5. 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 the pathogen SARS-CoV-2, which is responsible for COVID-19, not 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 this product in vitro diagnostic tests, and during the period of the public health emergency. Unless it is revoked or rescinded sooner, the declaration and authorization remain in effect until 1 year after the date of the declaration.

8. This product has not been cleared or approved by the FDA.

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10. Use testing supplies are provided in each box.

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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
   1 Timing Device (not included)

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

   Outside of Card
   - Top
   - Bottom

   Inside of Card
   - Result Window
   - Test Strip
   - Lower Hole

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.

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.

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

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

B. COLLECT NASAL SAMPLE

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).
   - Do not go deeper.
   - You do not need to go deeper.

   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.

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

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

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

   **Note:** False negative result may occur if the swab was not
   properly collected.

C. PERFORM THE TEST

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.

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

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

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

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

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

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

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

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.

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 Negative COVID-19 Result

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

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.

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.

**Note:** If you do not have symptoms, a second test should be taken at least
24 hours (and no more than 48 hours) between tests.

**Day 1**

**Wait 24 hours**

**Day 2 to Day 3**

**Test 1**

**Wait 15 minutes**

**Test 2**

**Wait 15-30 minutes**

**Day 1**

**Day 2 to Day 3**

**TEST 1**

**TEST 2**
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA

www.binaxnow-selftest.abbott

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This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, 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.

EASY
A Simple Nasal Swab

FAST
Results in 15 Minutes

DOWNLOAD THE NAVICA™ APP to report your results and view animated instructions

Made in the USA

For use under an Emergency Use Authorization only.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to... This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.

Contents:
- 10 BinaxNOW™ COVID-19 Test Cards
- 10 Nasal Swabs
- 10 Reagent Bottles

Store between 35.6-86° F (2-30° C) until use

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For use under an Emergency Use Authorization only.

Made in the USA

For use under an Emergency Use Authorization only.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to ... This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
Overview

- Perform the test as prompted (approximately 20 minutes).
- Complete your test in one sitting. Interruptions (i.e. phone calls) can lead to inaccurate results.
- It is recommended gloves (not provided) also be used during testing.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- 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 a COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

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BEFORE STARTING

1. Wash Your Hands (for at least 20 seconds)

- Wash or sanitize your hands.
- Make sure they are dry before starting.
PREPARE FOR THE TEST

2A. Set Up

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

I DO NOT touch any parts on the inside of the card. Handle the card only by edges.
PREPARE FOR THE TEST

28. Open Test Card Pouch

- Remove test card from pouch and lay it flat on a table.
PREPARE FOR THE TEST

2C. Check for the Control Line

- Make sure the blue control line is present in the result window. DO NOT use this card if it is not.
- If you do not see the blue line contact Technical Support at +1-833-637-1594.
2D. Open Card

- Open 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.
  
  I DO NOT touch any parts on the inside. Handle card only by edges.
  
  I Card must lay flat on table for entire test

DO NOT touch the test strip.
PREPARE FOR THE TEST

3. Apply Fluid to Top Hole

- Remove dropper bottle cap.
- Hold dropper 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.

Card must stay FLAT on table for entire test.
COLLECT NASAL SAMPLE

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4. Open Swab

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

! Keep fingers away from the swab end.
5. Swab a Nostril

- 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.
- 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.

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

6. Swab the Other Nostril

- Insert the entire soft tip of the SAME swab into the other nostril (usually 1/2 to 3/4 of an inch). You do not need to go deeper.
- 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.

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

< Back | Home | Next >>

! Please make sure you have swabbed BOTH NOSTRILS before you continue to the next step.
7. 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.
  - I Keep card FLAT on the table.
8. Turn Swab 3 Times

- 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.

Keep card FLAT on the table.
PERFORM THE TEST

9A. Peel Strip

- Peel adhesive liner off. Be careful not to touch other parts of card.
  - Keep card FLAT on the table.
  - DO NOT remove swab.
PERFORM THE TEST

9B. Close Card and Start Timer

- 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.

I DO NOT remove swab.
PERFORM THE TEST

10. Wait 15 Minutes

- Read the result at 15 minutes.
- DO NOT read the result before 15 minutes or after 30 minutes.
- I DO NOT move or touch the card during this time.

**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.
11A. 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.

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

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118. Check for Negative COVID-19 Result

- Find result window and look carefully for a single pink/purple line.
- **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.
11C. Check for Invalid COVID-19 Result

- **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
12. Dispose in Trash

- Throw away all used test kit components in the trash.
13. REPORT YOUR RESULTS

- Report your test results through the NAVICA app and provide all results obtained with this product to your healthcare provider in order to receive appropriate medical care.
- Download the NAVICA app from the Google play store or Apple app store. Compatible smart phone includes Apple iPhone running Operation System (IOS) 13 latest major version and two prior major versions (IpOne running IOS v12 or later), and Android Phones: latest major version and two prior major versions (Android phone running Android OS v9 or later).
14. TEST COMPLETE

- If you don’t have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) after the first test.