**INTENDED USE**

The BinaxNOW COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid proteins of viruses that cause SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal/nares) swab specimens from individuals aged 15 years or older, with or without symptoms or under the care of a healthcare provider. It is intended for use in the first 3 days of symptoms or asymptomatic persons. To determine if you have COVID-19, BinaxNOW COVID-19 Antigen Self Test should be self-administered and self-read by the same individual.

The BinaxNOW COVID-19 Antigen Test is not equivalent to SARS-CoV-2 and BinaxNOW COVID-19 Antigen Test Results are for the identification of SARS-CoV-2 nucleocapsid protein antigens. Antigens are generally detectable in anterior nasal (nasal/nares) swabs during the acute phase of infection. Positive results indicate the presence of antigens, but false-negative results and other diagnostic information are necessary to determine if you have COVID-19. False-negative test results may not rule out the diagnosis of COVID-19, especially in elderly individuals or those with weakened immune systems. Many factors may affect the ability of this test to detect a viral infection. False-negative results may occur in some individuals with COVID-19. Do not use the test to determine whether you have COVID-19.

**TEST KIT COMPONENTS OVERVIEW**

<table>
<thead>
<tr>
<th>Swab</th>
<th>Test Card in Pouch</th>
<th>Dropper Bottle</th>
</tr>
</thead>
</table>

**TEST KIT COMPONENTS OVERVIEW**

- **Swab**
- **Test Card in Pouch**
- **Dropper Bottle**

**INSTRUCTIONS**

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

**STORAGE and STABILITY**

Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use.

**WHAT YOUR RESULTS MEAN**

**Positive Result**

A positive test result means that proteins from the virus that causes COVID-19 were found in your specimen and you likely have COVID-19. A negative test result means that proteins from the virus that causes COVID-19 were not found in your specimen. A positive test result may help limit the spread of COVID-19 to your family and others in your community. However, testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than forty-eight hours between tests. You may need to purchase additional tests to perform the serial testing.”

**Negative Result**

A negative test result means that proteins from the virus that causes COVID-19 were not found in your specimen. It is important that you work with your healthcare provider to help you understand the next steps you should take.

**National Institutes of Health**

The National Institutes of Health (NIH) is the nation’s medical research agency. Established in 1887, the NIH focuses on basic research to understand the causes of disease and develop cures and treatments. The NIH is composed of 27 Institutes and Centers and is a component of the United States Department of Health and Human Services.

**Abbott Diagnostics Technical Support**

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**Abbott Diagnostics**

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INSTRUCTIONS - START HERE

Carefully read instructions prior to starting testing. 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 (not included)
Timing Device

1. DO NOT touch any parts on the inside. Handle card only by edges. Out of Card

2. Remove test card from pouch. Make sure the blue control line is present in 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.

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.

B. COLLECT NASAL SAMPLE

1. Keep fingers away from the swab end.

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

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

Make at least 5 big circles.
Using the same swab, repeat step 5 in your other nostril.

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

C. PERFORM THE TEST

1. Keep card FLAT on table.

2. 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.

3. 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 may occur if swab is not turned.

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

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

Do NOT remove swab.

6. Keep card face up on table.

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.

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.

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.
A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.

Contents:
- 2 Case 2 BinaxNOW™ COVID-19 Test Cards
- 2 Case 2 Nasal Swabs
- 2 Case 2 Reagent Bottles
- 1 Case 1 Patient Instructions
- 1 Case 1 Fact Sheet for Individuals

Not provided:
- Timer

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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.

For infection detection
Antigen
Self Test
COVID-19

For use under an Emergency Use Authorization only.

2 Tests

Self Test
COVID-19

This product is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

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

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A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.

Contents:
- BinaxNOW™ COVID-19 Test Cards
- Nasal Swabs
- Reagent Bottles
- Patient Instructions
- Fact Sheet for Individuals

Not provided:
- Timer

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FOR INFECTION DETECTION
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Download the NAVICA™ APP to report your results and view animated instructions.

Made in the USA
Ages 2 and up

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

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.

Contents:
- 5 BinaxNOW™ COVID-19 Test Cards
- 5 Nasal Swabs
- 5 Reagent Bottles
- 1 Patient Instructions
- 1 Fact Sheet for Individuals

Not provided:
- Timer

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FOR INFECTION DETECTION

ANTIGEN

SELF TEST

COVID-19

For use under an Emergency Use Authorization only.

For in vitro diagnostic use

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

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.

FOR INFECTION DETECTION

ANTIGEN

SELF TEST COVID-19

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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

Not provided:
- Timer

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