For use with anterior nasal swab specimens

The NAVICA app allows you to track results for your COVID-19 test and receive digital instructions to perform a COVID-19 test (digital instructions available). To download the app, scan the QR code provided by CDC.

What is Serial Testing?
Serial testing involves testing multiple times with an antigen test, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with a minimum of twenty-four hours and no more than forty-eight hours between tests. You may need to purchase additional tests to perform the serial (repeat) testing.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. The NAVICA app tracks your test results and assists in decision making.

POTENTIAL RISKS INCLUDE:
• Do not use unless the test card clearly states “Valid for use with anterior nasal swab specimens”.
• Test card needs to be in aseptic conditions.
• Perform the COVID-19 test (digital instructions available) before use.
• Remember to record the result in the app.
• Record negative test result.

Intructions for Serial Testing:
1. Test twice in the first 24-48 hours.
2. If both tests are negative, perform serial testing every 48 to 72 hours or every other day for a total of 7 serial tests.
3. If you test negative and continue to experience COVID-19 symptoms, you should consult with your healthcare provider to determine the next steps.

STORAGE AND STABILITY
Store kit between 35-86°F (2-30°C). Ensure all components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the packaging and container.

WHAT YOU NEED TO KNOW ABOUT RESULTS FROM SERIAL TESTING:
If you test negative twice, you should test again at least two to four times (no more than 48 hours) between test results. If your first test is negative, you are less likely to have COVID-19, but you may still choose to be tested again. If your second test is negative, you are even less likely to have COVID-19, but you may still choose to be tested again.

If both your first and second tests are negative, you are not likely to have COVID-19, however, you should follow-up with your healthcare provider if you develop COVID-19 symptoms.

If both your first and second tests are positive, you may have COVID-19 and should self-isolate and seek care with your healthcare provider. Your healthcare provider may suggest you undergo confirmatory testing with a molecular test for positive results. A positive result may also be necessary, if there is a low likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 in a community with high prevalence of infection. Additional confirmatory testing with a molecular test for result may be necessary, if there is a low likelihood of COVID-19, such as in an individual with exposure to COVID-19 in a community with high prevalence of infection.

What is the Difference Between an Antigen and Molecular Test?
An antigen test is a rapid test that uses a sample (nasal or throat swab) to detect antigens (proteins) or other components of the virus that are present in your body. An molecular test is a test that detects the presence of nucleic acids (DNA or RNA) from the virus.

What to Do If You Need to Report Results From Serial Testing:
If you test negative twice and then you test positive, you should test again at least 24 to 48 hours (no more than 48 hours) between test results. If your first test is positive, you are likely to have COVID-19. If you test positive with the BinaxNOW COVID-19 Antigen Test, you should self-isolate and seek care with your healthcare provider to determine the next steps.

Intructions to prepare for serial testing:
1. Obtain negative test result.
2. Start to serial testing.
3. Perform serial testing.

Intructions to perform serial testing:
1. Perform the COVID-19 test (digital instructions available) before use.
2. Remember to record the result in the app.
3. Record negative test result.

Intructions for serial testing:
1. Test twice in the first 24-48 hours.
2. If both tests are negative, perform serial testing every 48 to 72 hours or every other day for a total of 7 serial tests.
3. If you test negative and continue to experience COVID-19 symptoms, you should consult with your healthcare provider to determine the next steps.

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Intructions for serial testing:
1. Test twice in the first 24-48 hours.
2. If both tests are negative, perform serial testing every 48 to 72 hours or every other day for a total of 7 serial tests.
3. If you test negative and continue to experience COVID-19 symptoms, you should consult with your healthcare provider to determine the next steps.
INSTRUCTIONS - START HERE

Before starting:
1. Wash or sanitize your hands.

Carefully read instructions prior to starting test.

It is recommended gloves (not provided) also be used.

Carefully read instructions prior to starting test.

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

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.

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. Insert swab into a nostril (usually 1/2 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.

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.

B. Collect nasal sample

1. 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.

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

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.

C. Perform the test

1. Keep card FLAT on table.

6. 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.

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

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.

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.

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

D. Dispose the test kit

Throw away all used test kit components in the trash.

E. 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.

Note: Results should not be read after 30 minutes.

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.

Note: Results should not be read after 30 minutes.
A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.

Contents:
- BinaxNOW™ COVID-19 Test Card
- Nasal Swab
- Reagent Bottle
- Patient Instructions
- Fact Sheet for Individuals

Not provided:
- Timer

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

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FOR INFECTION DETECTION
ANTIGEN SELF TEST COVID-19

EASY
A Simple Nasal Swab

FAST
Results in 15 Minutes

15

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

Not provided:
- Timer

For use under an Emergency Use Authorization only.

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 in vitro diagnostic use

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

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 do a third test to confirm your result.

This drawing is approved for all three of the following:
- Size & Style
- Coating Pattern
- Code Date

DIRECT FOOD CONTACT:
- Yes
- No

By:

Date:

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

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

Not provided:
- Timer

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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:
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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.

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