BIOCARD® Pro

COVID-19 Rapid Antigen Test

NewDay Diagnostics

For In Vitro Diagnostics (IVD) Use Only • For use with anterior nasal swab specimens • For Emergency Use Authorization Only
This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA)

INSTRUCTIONS FOR USE

Please carefully read and follow all instructions. It is important that you complete the test steps as carefully as possible to ensure your specimen can be processed in the lab.

IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the device will produce a false negative result.

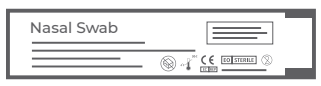
Ensure all test components are at room temperature before use.

STEP 1

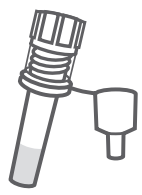
Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.

STEP 2

Check your test kit for the following components. Follow the instructions below and **DO NOT OPEN ANY OF THE TEST KIT COMPONENTS.**



Nasal swab



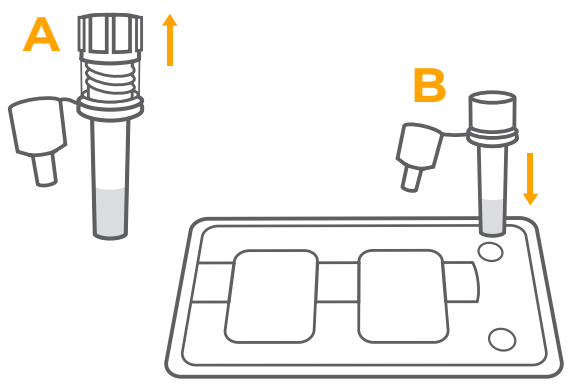
Sample extraction tube with filter nozzle

Test card

Watch or timer (not included)

STEP 3

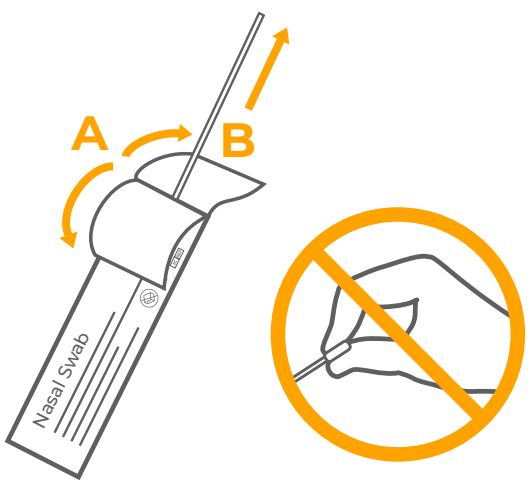
Each sample extraction tube comes with a cap and has extraction solution prefilled to the required level. Remove the cap carefully from the tube, discard the cap and place tube in the tray holder.



NOTE: DO NOT pour out the liquid. If the liquid spills, discard the test and use a new test.

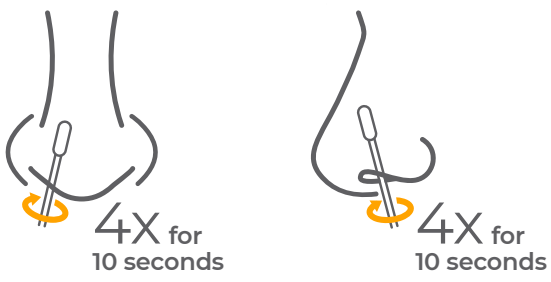
STEP 4

Remove the nasal swab from the wrapper by pulling the ends apart. Be careful to only touch the swab handle, not the tip.



STEP 5

Gently insert the entire soft tip of the swab ½ to ¾ of an inch into the nostril, depending on the size of the person's nose. Firmly rub the swab in a circular motion around the inside wall of **EACH NOSTRIL** at least 4 times for a total of 10 seconds. Be sure to rub **BOTH** nostrils with the **SAME SWAB.**



NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostrils. For very young children, you may need another person to steady the child's head while swabbing.

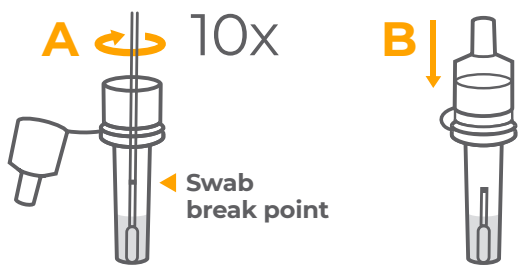
NOTE: Failure to swab properly may cause false negative results.

STEP 6

Insert the nasal swab sample into the extraction solution tube and ensure it is touching the bottom. Then, swirl swab **at least 10 times.**

While in the extraction solution tube, gently bend the swab to break it at the "swab break point" as shown below. Dispose the remainder of the swab in the trash.

Using both hands, cover the tube with the dropper cap and tighten the lid.



NOTE: Swirling the device less than 10 times may cause invalid or false negative results.

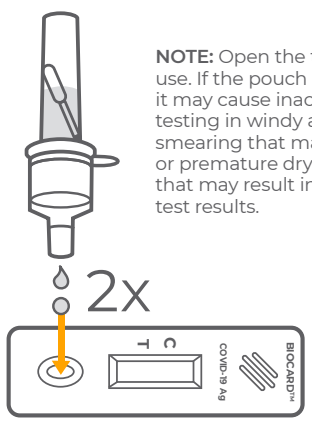
STEP 7

Wait for **2 minutes.** This step is very IMPORTANT.

NOTE: If the swab is in the solution for more than 5 minutes it should not be used.

STEP 8

Remove the test card from its pouch and place it on **a flat surface** in good lighting. Add **2 drops** of the extraction solution with specimen into the sample well of the test card.



NOTE: Open the test card pouch just before use. If the pouch is left unused after opening, it may cause inaccurate results. Avoid testing in windy areas to prevent potential smearing that may obscure the Test Line (T) or premature drying out of the membranes that may result in false negatives or invalid test results.

STEP 9

Read the results after **10 minutes**. Time of result inspection should not be longer than 15 minutes after loading the sample.

NOTE: Do not move or lift the test card during this time.

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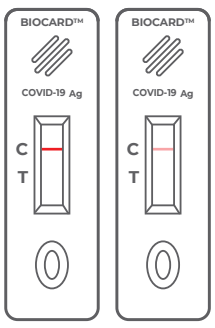
INSTRUCTIONS FOR USE *Continued*

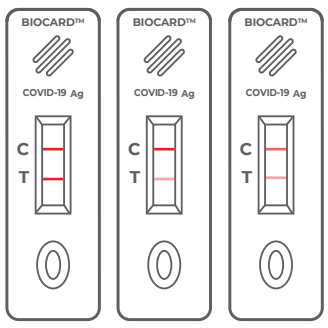
STEP 10

Line color may be red **or** purple.

NEGATIVE

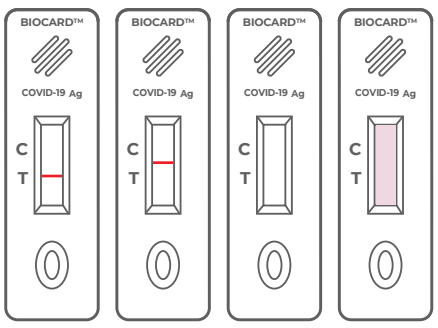


POSITIVE



NOTE: The color intensity of the red or purple test line will vary depending on the amount of antigen present in the sample. Any faint red- or purple-colored line in the test "T" line should be considered positive.

INVALID



INTERPRETATION OF RESULTS

COVID-19 NEGATIVE:
Any visible red or purple color control line (C)

A negative test result means that proteins from the virus that causes COVID-19 were not found in the sample. It is possible for this test to give a false negative result in some people with COVID-19. This means that the person could possibly still have COVID-19 even though the test is negative. If the person tests negative and continues to experience COVID-19-like symptoms of fever, cough and/or shortness of breath, he or she should seek follow-up care with his or her healthcare provider. The healthcare provider will consider the test result together with all other aspects of the individual's medical history (such as symptoms, possible exposures and geographical location of places that person has recently traveled) in deciding how to care for the person. For example, the healthcare provider may suggest that the individual take another test to determine if he or she has contracted the virus causing COVID-19. It is important that the individual works with his or her healthcare provider to help understand the next steps he or she should take.

COVID-19 POSITIVE:
Any visible red or purple color test (T) and control (C) lines.

A positive test result means that proteins from the virus that causes COVID-19 were found in the sample and it is very likely the individual has COVID-19, and it is important for him or her to be under the care of his or her healthcare provider. It is also likely that the individual may be placed in isolation to avoid spreading the virus to others. There is a very small chance the this test can give a false positive result. If the person tests positive with the BIOCARD® Pro COVID-19 Rapid Antigen Test, he or she should self-isolate and seek follow-up care with his or her healthcare provider as additional testing may be necessary. The healthcare provider will work with the individual to determine how best to care for him or her based on the test result, along with the individual's medical history and his or her symptoms.

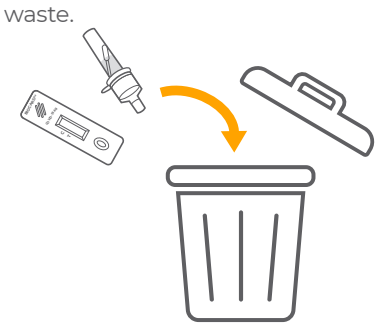
INVALID:
Test results are invalid if:

- There is NO visible red or purple line at control line (C)
- A visible red or purple line appears between the control line (C) and test line (T)
- NO visible red or purple line appears
- The test strip is discolored or smudged making it difficult to read the test

If the test result is invalid, a new swab should be collected, and the test should be performed again with a new prefilled tube and test card.

STEP 11

Dispose used test in the trash. All used test components should be disposed of in your household waste.



STEP 12

After completing all steps, wash hands or use hand sanitizer.

Please notify your prescribing healthcare provider of the results of your BIOCARD® Pro COVID-19 Rapid Antigen Test.

LIMITATION OF THE PROCEDURE

- The BIOCARD® Pro COVID-19 Rapid Antigen Test Kit is a screening test only. The results should not be the sole basis for treatment or patient management. The infection should be confirmed with other tests, clinical symptoms, epidemiology and additional clinical data, as per the guidelines by a specialist.
- This kit detects both SARS-CoV and SARS-CoV-2, regardless of their viability. This kit does not differentiate between SARS-CoV and SARS-CoV-2.
- In the early stages of infection, low levels of antigen expression can result in negative results.
- Due to the limitation of the assay methods, negative results cannot entirely rule out the possibility of infection.
- This product can only qualitatively detect SARS-CoV-2 antigen in human nasal specimens and cannot determine the specific antigen quantity in the sample.

ADDITIONAL INFORMATION

New Day Diagnostics is seeking FDA Emergency Use Authorization (EUA) for the BIOCARD® Pro COVID-19 Rapid Antigen Test.

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- 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 IVDs 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 more information on EUAs, go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- For the most up-to-date information on COVID-19, please visit: www.cdc.gov/COVID19.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read the written instructions fully before starting the test procedure.
- To ensure correct results, you must follow the instructions.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Wear safety mask or other face covering when collecting swabs from children or others.
- Use of personal protection materials such as gloves are recommended.
- Do not open the materials until ready for use.
- If the test card is open for an hour or longer, invalid test results may occur.
- Improper swab collection may result in incorrectly negative (false negative) results.
- If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate, and the test should be repeated.
- Do not use a test kit that is expired.
- Do not touch the swab head when handling the swab.
- Avoid exposure of your skin, eyes, nose or mouth to the solution in the tube.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

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 STEP 10).

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.

What is the difference between an antigen and molecular test?

An antigen test, such as the BIOCARD® Pro COVID-19 Rapid Antigen Test, detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home.

How accurate is this test?

The performance of BIOCARD® Pro COVID-19 Rapid Antigen Test was established in an all-comers prospective clinical study conducted between January-February 2022 at five (5) sites in the US. The study enrolled 242 participants (age 2 years to over 65 years). Positive Percent Agreement (PPA) for symptomatic subjects within 0-14 days of symptom onset was 87.2% and the Negative Percent Agreement (NPA) was 100%. For all subjects combined, symptomatic and asymptomatic, the PPA was 81.4%, and the NPA was 99.5%.

INTENDED USE

The BIOCARD® Pro COVID-19 Rapid Antigen Test is a lateral flow immunoassay intended for the rapid, qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus that causes COVID-19.

This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 14 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 14 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over three days with at least 24 hours and no more than 48 hours between tests.

The BIOCARD® Pro COVID-19 Rapid Antigen 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 swab specimens 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 BIOCARD® Pro COVID-19 Rapid Antigen 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 and do not rule out SARS-CoV-2 infection. A negative test result 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 a person's recent exposure to infected individuals and the presence of clinical signs and symptoms consistent with COVID-19 infection. Confirmation with a molecular assay may be performed if necessary for patient management. For serial testing programs, confirmatory testing with a molecular test may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as suspected exposure or having prolonged close contact with an individual(s) with COVID-19 or in communities having a high prevalence of infection. The addition of confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of SARS-CoV-2 infection, 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-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with 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 BIOCARD® Pro COVID-19 Rapid Antigen Test is intended for non-prescription self-use and/or, as applicable, for an adult lay user testing another aged 2 years or older.

The BIOCARD® Pro COVID-19 Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

CATALOG #	Test Quantity
40100	1 test/pack
40200	2 tests/pack
40300	25 tests/pack

Manufactured for and Distributed by New Day Diagnostics, LLC 138 NW 16th Street, Boca Raton, FL 33432 (877) 639-3293 www.newdaycovidtest.com
ND0001EN (R13)