PRODUCT INFORMATION LEAFLET - In the USA, for use under an Emergency Use Authorization only

BD Veritor™ At-Home COVID-19 Test

For Emergency Use Authorization (EUA) only
For *In Vitro* Diagnostic (IVD) Use

This document provides you with more information about this test. Please **READ** this information completely before starting the test. The Quick Start Guide presents steps required to download the Scanwell® Health App, create a Scanwell® account and get started. When performing the test, follow the step-by-step instructions presented in the Scanwell® Health App.

In the USA:
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 more information on EUAs visit: https://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.
- For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

1 Kit Contents

- 1 kit box with tube holder
- 2 nasal swabs
- 2 tubes (with liquid) in foil pouch
- 2 test sticks
- 2 scan cards
- Quick Start Guide
- Product Information Leaflet (this document)
- Fact Sheet for Individuals

DO NOT OPEN KIT COMPONENTS UNTIL INSTRUCTED BY THE APP

The following are required to perform the test but are not included in the test kit:
- A compatible smartphone – For a full list of compatible smartphones visit: bdveritorathome.com/devices
- Scanwell® Health App – Download the free app from your smartphone.

Do not begin if you do not have at least 20 minutes available to focus on performing the test. Before you begin, wash your hands for at least 20 seconds and then dry your hands. Perform the test indoors, at room temperature (59 °F–86 °F/15 °C–30 °C) on a clean, flat surface away from fans or open windows.

Perform the test in a brightly lit area, but away from direct sunlight. Ensure a light source is in front of you, and not directly overhead. Make sure your smartphone is not in silent mode and is charged or charging. Turn the phone's volume up so you can hear the app alerts/timers. Ensure your smartphone is not in a protective case, the camera lens is clean and free of dirt and that you have a cellular or Wi-Fi connection.

2 Intended Use

The BD Veritor™ At-Home COVID-19 Test is a chromatographic, digital immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test results are interpreted by the Scanwell® Health App and displayed on a compatible smartphone.

This test is 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 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over 3 days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over 5 days with at least 48 hours between tests.

The BD Veritor™ At-Home COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens 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 BD Veritor™ At-Home COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation 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 sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. 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.

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 physician or healthcare provider.

Test results are reported 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 the CDC. Test result reporting from the BD Veritor™ At-Home COVID-19 Test occurs via the Scanwell® Health App software application. Individuals should also report their test result to their healthcare provider to receive appropriate medical care.

The BD Veritor™ At-Home COVID-19 Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The BD Veritor™ At-Home COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

3 Frequently Asked Questions

WILL THIS TEST HURT?
No, the nasal swab may tickle but should not hurt.
You may experience watery eyes, feel some itchiness, or the need to sneeze. If you feel pain or your nose starts to bleed, remove the swab, and contact a medical professional.

WHAT ARE THE KNOWN RISKS & BENEFITS OF THIS TEST?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Warnings and Results interpretation sections for more information).

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.

Frequency Asked Questions (continued)

WHAT IS SERIAL TESTING?
COVID-19 serial testing is when 1 person tests themselves multiple times for COVID-19, such as every other day. Serial testing is more likely to detect COVID-19 and reduce the spread of infection, especially when you do not have symptoms.

WHAT IS THE DIFFERENCE BETWEEN A COVID-19 ANTIGEN AND MOLECULAR TEST?
There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as this test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

HOW ACCURATE IS THIS TEST?
Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at bd.com/e-labeling.

WHAT IF I HAVE A POSITIVE TEST RESULT?
A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

WHAT IF I HAVE A NEGATIVE TEST RESULT?
A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT DOES AN INVALID TEST RESULT MEAN?
An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT
Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

HOW DO I GET THE MOST ACCURATE RESULTS?
The best way to obtain accurate results is to follow the directions for nasal swab collection and test procedure exactly as described in the Scanwell® Health App.

WHAT SHOULD I DO IF MY PHONE BATTERY RUNS OUT DURING THE TEST?
It is important to make sure that your phone is charged or charging before beginning the test. If your phone runs out of battery power after starting the test and the app quits, your test kit will be marked as used and the test cannot be restarted.

WHAT SHOULD I DO IF MY PHONE CANNOT CONNECT TO THE INTERNET?
The Scanwell® Health App requires an internet connection (either Wi-Fi or cellular) to log in, start the test, and upload results. If you lose internet connection while testing, you can continue and complete the test. Your results will be stored on your phone and will be visible in your Test History. However, your results will not be uploaded to Scanwell's server. This means that if you delete the app or log in on a different phone, you will not be able to see those test results.

For more information on EUAs go here:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

4 How to Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the second test is also negative, a third time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

5 Warnings, Precautions, and Safety Information

- Follow the Scanwell® Health App directions exactly as presented. Failure to do so may affect test performance and/or produce incorrect results.
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- **Serial testing should be performed in individuals with negative results at least twice over 3 days (with 48 hours between tests) for symptomatic individuals and three times over 5 days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 7 days you should consider testing at least three times over 5 days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years or older. Children age 2 to 13 years should be tested by an adult.
- Do not use the test on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not reuse.
- Use only the contents provided in the test kit.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test stick should be used within 5 minutes.
- For more information on EUAs please visit: 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.
- Perform the test as soon as possible after swabbing both nostrils, but no more than 1 hour after swabbing and within 30 minutes after adding the swab to the tube.
- Keep the test stick on a flat, well-lit surface during the test. Take care not to drop the test stick.
- Do not use the test if the liquid in the tube spills.
- Stay near your smartphone during the 15 minutes the test is running so you can hear the timer alarms. The Scanwell® Health App will generate timing alerts during testing that are important to hear.
- Scan the test stick as soon as the 15-minute alert sounds. You have 5 minutes to complete your scan after the end of the 15-minute incubation or the test becomes invalid.
- Do not force quit the Scanwell® Health App until your result is available.
- Do not attempt to determine test results visually. Only use the Scanwell® Health App, on a smartphone, to determine test results.
- Keep testing kit and kit components away from children and pets before and after use. Do not inhale, swallow or ingest any kit components. Avoid contact with your skin and eyes. The reagent solution contains harmful chemicals (see Hazardous Ingredients table below). If the solution contacts your eyes, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or** 1-800-222-1222.

Chemical Name/CAS	GHS Code	Concentration
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.095%
Triton X-100/9002-93-1	Causes skin irritation (H315) Causes serious eye irritation (H319)	2%

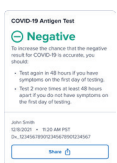
6 Test Interpretation – What Do My Results Mean?

The Scanwell® Health App will display the test result on your smartphone screen and provide further directions. A record of your test result and detailed information will remain accessible in the Scanwell® Health App. Your test results will be reported to public health authorities. You should also report your test result to your healthcare provider to receive appropriate medical care.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.



COVID-19 NEGATIVE (-)
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test two more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms (e.g., fever, cough, and/or shortness of breath) you should seek follow-up care with your healthcare provider.

COVID-19 POSITIVE (+)
You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

WHAT SHOULD I DO NEXT?
You should self-isolate from others and contact a healthcare provider for medical advice about your positive result. A confirmatory test may be recommended.

INVALID
An invalid result means that an error occurred and you should retest with a new test kit. Errors can occur when collecting, mixing, or adding the sample to the test stick. Please follow the instructions in the app carefully to decrease the chances of an invalid test result.

WHAT SHOULD I DO NEXT?
You should retest with a new test. If you have COVID-19 symptoms, you should self-isolate from others until you can retest.

7 Limitations

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in Spring 2021. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- The test performance has only been assessed for use with human nasal swabs.
- Samples collected in viral transport media should not be used with this test.

Disposal & Storage

- Dispose of the used test in the household trash. Do not flush or pour test liquids down a drain.
- Store between 35 °F–86 °F (2 °C–30 °C) until use.

Support

For questions, or to report a problem, please call 1-844-4-VERITOR (844-483-7486) or visit bdveritorathome.com. Additional information is also available for you and your healthcare provider at bdveritorathome.com. This Product Information Leaflet, Quick Start Guide, Fact Sheet for Individuals, Fact Sheet for Health Care Providers, and Health Care Provider Instructions for Use are also available at bd.com/e-labeling.

Manufacturing Information

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 USA

30 °C
2 °C

IVD bd.com/e-labeling REF 256094 500054437(04) 2023-04

US customers only: For symbol glossary refer to bd.com/symbols-glossary

BD Veritor™ At-Home COVID-19 Test

Quick Start Guide

For *In Vitro* Diagnostic Use. For Emergency Use Authorization Only. Read the Product Information Leaflet for more information before starting the test. This test is intended to be used as an aid in the clinical diagnosis of COVID-19, but it should not be the only guide to manage your illness. Please consult a healthcare professional if your symptoms persist or become worse. Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

WARNING: DO NOT OPEN the packaged kit items until instructed to do so by the app.

Getting started

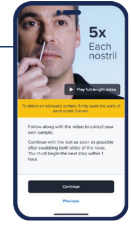
The testing process takes 20 minutes to complete. The app will guide you through every step.
You will need to have an active cellular connection or Wi-Fi to progress through the test.

1 Download the Scanwell® Health app

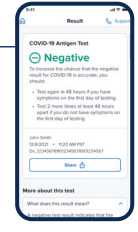
Search for "Scanwell Health" in your app store or scan this QR code using your camera app.

2 Sign up or log in to the app

3 Follow the video steps



4 Result provided in 15 minutes



Need help? Contact us at 844-4-VERITOR (844-483-7486).

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Sparks, Maryland 21152 USA

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2023-02

US customers only: For symbol glossary, refer to bd.com/symbols-glossary

BD Veritor™

At-Home COVID-19 Test

RAPID RESULTS
YOU CAN SEE IN 15 MINUTES

DIGITALLY READ RESULTS
ON YOUR COMPATIBLE SMARTPHONE

2 tests per box

For Emergency Use Authorization (EUA) only
For in vitro diagnostic use

Qualitative test for the detection of SARS-CoV-2 viral proteins in nasal swabs.

Compatible smartphone and Scanwell® Health app required.
Please refer to instructions on back or visit www.bdveritorathome.com/devices

Powered by Scanwell®

Kit Contents
- Swab (2)
- Tube (contains liquid) (2)
- Test Stick (2)
- Scan Card (2)

Materials required but not provided
- Compatible iPhone or Android smartphone; see bdveritorathome.com/devices
- Scanwell® Health App – Available for download from the Apple App Store or Google Play Store.

BD Veritor™

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From the makers of the BD Veritor™ Plus System–
the antigen test trusted by doctors, nurses, and hospitals.

The BD Veritor™ At-Home Test in 5 Clear Steps

1. Swab 2. Mix 3. Drop 4. Wait 5. Scan

Compatible smartphone not included.

For a full list of compatible smartphones, and how to download the free Scanwell® Health app, scan this QR code or visit www.bdveritorathome.com/devices

Please read the materials included inside for more information.

Please note: use of this test requires you to accept the BD and Scanwell privacy policies and terms of use. Visit www.bdveritorathome.com/policies for details.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

BD Veritor™

For ages 2 and up

Need help? Contact us at 844-4-VERITOR (844-483-7486)

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REF 256094

bd.com/e-labeling

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

Test Stick made in USA with US & foreign materials, Tube & Liquid made in China, Swab made in Italy & USA, Scan Card made in USA.
US customers only: For symbol glossary, refer to www.bd.com/symbols-glossary

FPO
Refer to Label #L012501

For the most current expiration dates of this test, please refer to https://www.fda.gov/covid-tests.

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BD Veritor™