

BD Veritor™ At-Home COVID-19 Test

For Emergency Use
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://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

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: www.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 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over 2 or 3 days with at least 24 hours and no more than 48 hours between tests. 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 (unobserved) direct anterior nasal swab specimens from individuals aged 14 years or older, or with adult collected anterior nasal swab specimens from individuals aged 2 years or older.

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. Antigen is generally detectable in anterior nasal (nares) swabs 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.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of COVID-19 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-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their 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 aged 2 years or older in a non-laboratory setting. BD Veritor™ At-Home COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

3 Hazardous Ingredients

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 %

WHAT IS SERIAL TESTING?
COVID-19 serial testing is when one person tests themselves multiple times for COVID-19, such as every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce the spread of infection.

WHAT DO I NEED TO KNOW ABOUT RESULTS FROM SERIAL TESTING?
If your first or second test is positive, then proteins from SARS-CoV-2 (the virus that causes COVID-19) have been found in your specimen and you likely have COVID-19. If you test positive with the BD Veritor™ At-Home COVID-19 Test, you should self-isolate and seek follow-up care with your healthcare provider to determine next steps. You may need additional testing or treatment, depending on your personal health history and other factors. If your first test is negative, you must test again in 24-48 hours. If both your first and second tests are negative, it's unlikely that you have COVID-19, however, you should follow-up with your healthcare provider if you are at high risk for COVID-19 infection or have known contacts with COVID-19. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you do not have symptoms of COVID-19, and this was your second negative (serial) test, you may stop testing. If you continue to be at risk of possible exposure to COVID-19, you may choose to continue serial testing at an interval of every 3-7 days.

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 detect proteins from the virus. Antigen tests are very specific for the virus but are 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 whether an additional molecular test is appropriate, and when you should discontinue self-isolation.

HOW ACCURATE IS THIS TEST?
Based on the results of a clinical study where the BD Veritor™ At-Home COVID-19 Test was compared to an FDA emergency use authorized high sensitivity SARS-CoV-2 test, the BD Veritor™ At-Home COVID-19 Test identified 84.6% of positive specimens and 99.8% of negative specimens. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for screening by serial testing. Performance may differ in these populations. Based on this information, negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing.

4 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 Results section).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

PDF results of this test may help limit the spread of COVID-19 to your family and others in your community.

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 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 App requires an internet connection (either WiFi or cellular) to login, 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 login on a different phone, you will not be able to see those test results.

5 Warnings & Precautions

- Follow the Scanwell Health App directions exactly as presented. Failure to do so may affect test performance and/or produce incorrect results.
- Leave the swab inside its packaging until instructed to swab the nose. Keep the swab clean. Do not allow anything to touch the soft tip of the swab until instructed to swab the nose.
- 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.
- You must apply the 3 drops of sample to the marked location on the test stick within 5 minutes of opening the test stick packaging.
- 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.
- Use only the contents provided in the test kit.
- Do not reuse any test kit components.
- Do not use this test kit beyond the expiration date printed on the outside of the box.
- Do not use if any of the test kit contents or packaging is damaged.
- The tube liquid contains sodium azide. Do not inhale, swallow, or expose to skin and eyes. If the liquid contacts skin, wash immediately with plenty of soap and water. If the liquid contacts eyes, flush with plenty of water. Do not flush the tube liquid down the drain.
- Do not use the test on children under 2 years of age.

6 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.



WHAT DOES IT MEAN IF I HAVE A NEGATIVE TEST RESULT?

A negative test result means that proteins from the virus that causes COVID-19 were **not** found in your specimen and that you are unlikely to have COVID-19. It is possible for the test to give a negative result that is incorrect (false negative result) in some people with COVID-19. This means you could possibly still

have COVID-19 even though the test is negative. The amount of antigen in nasal specimens may decrease the longer you have symptoms of infection. If you contact your healthcare provider they will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and places you have recently traveled) in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps you should take.



WHAT DOES IT MEAN IF I HAVE A POSITIVE TEST RESULT?

If you have a positive test result, it is likely you have COVID-19. There is a small chance the test can give an incorrect positive result (a false positive result). If you contact your healthcare provider, your healthcare provider

will work with you to determine how best to care for you based on your test result along with your medical history and your symptoms.

WHAT SHOULD I DO NEXT?

Please consult your healthcare provider to discuss your positive test result. You should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus



WHAT DOES AN INVALID RESULT MEAN?

Your test has experienced an error. The Scanwell Health App will guide you through the next steps. The most common reasons for an invalid result are not collecting enough specimen from your nose, applying

too little liquid to the test stick or applying the sample to the wrong area of the test stick. If your result is invalid, a new test must be performed with another set of test materials to get a valid result.

WHAT SHOULD I DO NEXT?

If you develop COVID-19 symptoms or your symptoms become severe, seek medical attention immediately.

7 Limitations

- In children, ages 2-13 years, specimens must be collected and tested by an adult (18+ years old). The test has only been tested in children age 2 and above.
- Do not use the test on children under 2 years of age.
- False negative results are possible, especially if you have symptoms or recently had significant close contact with a person with COVID-19.
- False positive results are possible, especially if you do not have any symptoms.
- The test performance has only been assessed for use with human nasal swabs.
- Test results for COVID-19 do not rule out the possibility of other infections.
- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications, and performance may differ in these populations.

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 www.bdveritorathome.com. Additional information is also available for you and your healthcare provider at www.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 www.bd.com/e-labeling.

Manufacturing Information

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[bd.com/e-labeling](https://www.bd.com/e-labeling)



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