

BD Veritor™ At-Home COVID-19* Test

Quick Start Guide

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**
- 2 **Sign up or log in to the app**



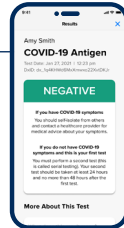
Search for "Scanwell Health" in your app store or scan this QR code using your camera app.



- 3 **Follow the video steps**



- 4 **Result provided in 15 minutes**



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

*This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. 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 *In Vitro* Diagnostic Use. In the USA: For use under an 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.

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bd.com/e-labeling



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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. 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 swab samples from individuals aged 14 years or older within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older, with symptoms of COVID-19 within the first 7 days of symptom onset.

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

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

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 DO I NEED TO KNOW ABOUT RESULTS FROM SERIAL TESTING?

If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19, 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.

Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. 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. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. You may need to purchase additional tests to perform serial (repeat) testing.

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. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. 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.

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 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.

COVID-19 Antigen

Test Date: Jan 25, 2021 10:23 AM

BD Veritor Antigen Test

NEGATIVE

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

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

A negative result means that proteins from the virus that causes COVID-19 were not found in your sample and you are unlikely to have COVID-19.

It is possible for this test to give you a negative result that is incorrect (false negative). There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. Serial testing (ie, testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. You may need to purchase additional tests to perform serial testing.

WHAT SHOULD I DO NEXT?

If you do not have COVID-19 symptoms and this is your first test, you should perform a second test between 24 and 48 hours after the first test.

If you have COVID-19 symptoms, you should self-isolate from others and contact a healthcare provider for medical advice about your symptoms.

COVID-19 Antigen

Test Date: Jan 25, 2021 10:23 AM

BD Veritor Antigen Test

POSITIVE

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

WHAT DOES IT MEAN 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. It is possible for this test to give a positive result that is incorrect (false positive), particularly when used in a population without many cases of COVID-19. Contact a healthcare provider for medical advice about your positive result. A confirmatory test may be recommended.

It is possible for this test to give a positive result that is incorrect (false positive), particularly when used in a population without many cases of COVID-19. Contact a healthcare provider for medical advice about your positive result. A confirmatory test may be recommended.

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.

COVID-19 Antigen

Test Date: Jan 25, 2021 10:23 AM

BD Veritor Antigen Test

INVALID

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

3-Panel COVID-19 Antigen Test

Has been validated for use in the detection of COVID-19.

WHAT DOES AN INVALID RESULT MEAN?

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

- 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.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform serial (repeat) testing.

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (ie, testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

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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