At-Home COVID-19* Test
Quick Start Guide

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.

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).

*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.

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BD Veritor™
At-Home COVID-19 Test
WHAT ARE THE KNOWN RISKS & BENEFITS OF THIS TEST?

Potential benefits include:

• Possible incorrect test results (see Results section).

• Possible discomfort during sample collection.

Potential risks include:

• Possible discomfort during sample collection.

• Possible incorrect test results (see Results section).

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.

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 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 called 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 authorization 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.

For more information on EUAs visit: https://www.fda.gov/emergency-preparedness-and-responses/medical-countermeasures-authorization/authorized-products-list

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID-19
**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 recharging 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.

**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 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.

**Disposal & Storage**

- Dispose of the used test in the household trash.
- Do not flush or pour test liquids down the 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.bdveritortest.com. Additional information is also available for you and your healthcare provider at www.bdveritortest.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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US customers only: For symbol glossary refer to www.bd.com/symbols-glossary

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BD Veritor At-Home COVID-19 Test

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

Scan to get your results.

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.

• If you have COVID-19 symptoms, you can use 1 test
• If you don’t have COVID-19 symptoms, you’ll need at least 2 tests per person
• This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test
• You may need to purchase additional tests to perform serial (repeat) testing

In the US: For use under FDA Emergency Use Authorization (EUA) only.

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