# FACT SHEET FOR INDIVIDUALS

## BD Veritor™ At-Home COVID-19 Test

## November 22, 2021

**Coronavirus Disease 2019 (COVID-19)**

This Fact Sheet is provided because you obtained the BD Veritor™ At-Home COVID-19 Test for testing yourself or dependents for proteins from the virus that causes COVID-19. The intended use of this test is for testing individuals within 7 days of symptom onset or individuals 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.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

**For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19**

**What is COVID-19?**
COVID-19 is a contagious respiratory illness caused by the SARS-CoV-2 virus. COVID-19 can present as a mild to severe illness, although some people with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link:

https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

**What is the BD Veritor™ At-Home COVID-19 Test?**
The BD Veritor™ At-Home COVID-19 Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs. The BD Veritor™ At-Home COVID-19 Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals within 7 days of symptom onset or individuals 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 may be used for individuals age 2–13 years with an adult collecting the specimen and utilizing the test, and age 14 and older with self-sampling. Individuals older than 14 may also have collection by another adult, if necessary. The BD Veritor™ At-Home COVID-19 test reports all test results to public health authorities. Individuals should also report their test result to their healthcare provider to receive appropriate medical care.

**What are the known and potential risks and benefits of the test?**
Potential risks include:

- Possible discomfort or other complications that can happen during nasal specimen collection.
- Possible incorrect test result (see below 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.

**What does it mean if I have a positive test result?**
A positive test result indicates that you are very likely to have COVID-19 because proteins from the virus that causes COVID-19 were found in your specimen. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result).

If you test positive with the BD Veritor™ At-Home COVID-19 Test, you should self-isolate from others and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results(s) along with your medical history and your symptoms.

**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. It is possible for this test to give a negative result that is incorrect (a false negative result) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a specimen may decrease the longer you have symptoms of infection. See also the "What is serial testing?" section below.

If you test negative and experience COVID-19-like symptoms of fever, cough and/or shortness of breath, you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 status after testing or think you may need follow up testing, please contact your healthcare provider.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in 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.

**What does it mean if I have an invalid test result?**
An invalid test result means that a testing error occurred, and a result could not be reported. An invalid test result can occur for reasons such as not collecting enough specimen from your nose or applying too little liquid to the test stick. Following the app instructions carefully decreases the chance of an invalid test result.
If your result is invalid, a new test must be performed with another set of test materials to get a valid result. If you have symptoms of COVID-19, you should self-isolate from others per CDC COVID-19 guidance and contact a healthcare provider for medical advice about your symptoms.

**What is serial testing?**
Serial testing is when an individual is tested for COVID-19 more than once using the same type of test. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur and also because the amount of antigen in specimens may change over the course of the illness, repeated testing may identify more individuals with COVID-19 than testing just once. By repeating the test, it may be possible to identify cases of COVID-19 more quickly and reduce the spread of infection. When using this test for serial testing, it is important that you work with your healthcare provider to help you understand the next steps you should take.

If you are not experiencing symptoms and this was your first test, you must perform a second test with at least 24 and no more 48 hours between tests. If 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. You may need to purchase additional tests to perform this serial (repeat) testing.

**What are the differences between antigen tests and other COVID-19 tests?**
There are different kinds of diagnostic tests for COVID-19. Molecular tests (PCR is the most common type of molecular test) 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 would help with your care, and when you should discontinue quarantine.If you have symptoms of COVID-19 and your test result is negative, the CDC currently recommends that you should stay home under quarantine until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved) . Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation.

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html.

**Is this test FDA-approved or cleared?**
No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency use of *in vitro* diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

**What are the approved alternatives?**
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

**TECHNICAL SUPPORT**

For questions, or to report a problem, please call BD Customer Care at 1.844.4Veritor (1.844.483.7486)

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

This document also available at: BD.com/e-labeling



REF 256094
500055845(02)
2022-03

**Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.