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. This test is intended for use by individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or 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 infected 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:


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 SARS-CoV-2 viral proteins in direct anterior nasal swab specimens from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or 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 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.

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.
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FACT SHEET FOR INDIVIDUALS
BD Veritor™ At-Home COVID-19 Test
August 24, 2021

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 emergency use of IVDs, 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)
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REF 256094
500055845(01)
2021-08
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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 infection than testing just once. By repeating the test, it may be possible to identify cases of COVID-19 infection 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 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.

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.