

VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK

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For the most up to date COVID-19 information, including symptoms, please visit [Coronavirus Disease 2019 \(COVID-19\) | CDC](https://www.cdc.gov/coronavirus/2019-ncov/)

Your sample(s) was tested for COVID-19 using the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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.

WHAT IS COVID-19 (CORONAVIRUS DISEASE 2019)?

COVID-19 is a disease caused by the SARS-CoV-2 virus.

WHAT IS THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK?

The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in direct nasopharyngeal (NP) and anterior nasal swab specimens.

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you may have COVID-19.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during 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 those you come in contact with.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If you have a positive test result with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack test, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Your healthcare provider will work with you to determine how best to care for you based on the test results along

with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

If your initial test result was negative, you should have serial testing performed (see below) and if after serial testing your test result is negative this means that antigens of the virus that causes COVID-19 were not found in your sample.

However, due to the sensitivity of antigen tests compared to molecular COVID-19 tests, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. For example, if you are tested too early during your infection. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than seven (7) days may be more likely to be negative compared to a molecular assay. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and COVID-19 antigen tests have lower sensitivity than COVID-19 molecular tests, false results may occur. Therefore, repeated testing can identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

WHAT ARE THE DIFFERENCES BETWEEN ANTIGEN TESTS AND OTHER COVID-19 TESTS?

There are different kinds of tests for diagnosing 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 would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home 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 5 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/downloads/sick-with-2019-nCoV-fact-sheet.pdf>

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an 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 the declaration is terminated or authorization is revoked sooner.). An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

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>.