

Coronavirus Disease 2019 (COVID-19)

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack Ortho-Clinical Diagnostics, Inc. (June 1, 2020)

You are being given this fact sheet because your sample was tested for potential exposure to the Coronavirus Disease 2019 (COVID-19) using the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack Ortho-Clinical Diagnostics, Inc. .

This fact sheet contains information to help you understand the risks and benefits of using this test for detecting the presence of antibodies to 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 General Webpage: [cdc.gov/coronavirus/2019-ncov/lab/serology-testing](https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing).

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick, or even without having any symptoms (e.g., fever, coughing, difficulty breathing, etc.).

The SARS-CoV-2 total antibody laboratory test was developed to assist with efforts that determine how much of the U.S. population has been exposed to COVID-19.

What is the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack Ortho-Clinical Diagnostics, Inc. test?

The test is designed to detect antibodies against the virus that causes COVID-19 in serum. **This test is not used to diagnose the COVID-19 virus.**

What are the known and potential risks 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 others in your community.
- The results of this test may help determine prevalence of COVID-19 within the community.

What does it mean if I have a test result of "Present"?

If you have antibodies present, it is very likely that you had exposure to or have had COVID-19 and have developed an antibody response to the virus.

For interpretation of your result, you should work with a healthcare provider to determine how to best care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also the small chance that this test can give a "Present" result that is incorrect (a false positive result).

What does it mean if I have a test result of "Not Present"?

If your test result is "Not Present," it means that antibodies to the virus that causes COVID-19 were not found in your specimen. However, it is possible for this test to give a "Not Present" result that is incorrect (false negative) in some people who have had exposure to or have had COVID-19. A "Not Present" result may occur if you are tested early in your illness and your body has not had time to produce antibodies to infection. This means that you could have been exposed to or have had COVID-19 even though the test states "Not Present". If this is the case, 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.

It is important that you work with your healthcare provider to help you understand the next steps, if any, you should take.



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Does this test detect immunity?

No. This is not a test for detecting "immune" individuals. No serologic tests are currently available to serve this purpose. The relationship between the presence or absence of antibodies and the resistance to subsequent infection has not been established.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When FDA-approved tests are limited, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS) 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 of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

Where do I go to find my results?

- Your results are expected to be reported on the NRHS portal within 3 days.
- Visit mynrhs.com to access the NRHS Hospital Portal. Be sure to click on the **Hospital Portal** button.
- For returning users, log in as usual.
- For new users, self-enrollment instructions will be provided to you at time of test.
- Having trouble? Please email us at mynrhs_info@nrh-ok.com or call us at **405-515-6747**.

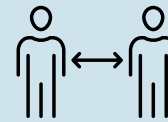
Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the CDC General Webpage: cdc.gov/COVID19. In addition, contact your healthcare provider with any questions/concerns.

Regardless of test results, it is very important to help prevent the spread of COVID-19.



Everyone should wear a cloth mask in public



Keep six feet away from others



Avoid large groups of people



Wash hands frequently for 20 seconds

If at any time you feel sick, call your doctor and follow their instructions. If you do not have a primary care provider, please call our Community Call Center at 405-515-5000. Our Community Call Center helps connect you with the best provider based on your health needs.