

Why did I receive this Information Guide?

You received this Patient Information Guide as your sample(s) was tested for COVID-19 (also referred to as Coronavirus Disease 2019 or the SARS-CoV-2 virus) using the BIOTRINETIX COVID-19 IgG/IgM Antibody Test.

This information will help you understand the risks and benefits associated with using the BIOTRINETIX COVID-19 IgG/IgM Antibody Test for the diagnosis of a potential COVID-19 infection. It is recommended that you consult your doctor or healthcare provider if you have any additional questions after reading this sheet.

What is COVID-19?

First identified in Wuhan, China, COVID-19 is caused by the SARS-CoV-2 virus. This virus can cause mild to severe respiratory illness. This virus has now spread worldwide, including the United States. While there is limited information available at this time to characterize the spectrum of clinical illness associated with COVID-19, it likely transmits to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the BIOTRINETIX COVID-19 IgG/IgM Antibody Test?

The BIOTRINETIX COVID-19 IgG/IgM Antibody Test is designed to detect antibodies against the virus that causes COVID-19 in blood specimens (i.e. serum, plasma or whole blood).

Why was my sample tested?

Due to one of more of the following factors your healthcare provider believes you may have been exposed to the COVID-19 virus:

- You displayed signs and symptoms (e.g., fever, cough, difficulty breathing), and/or
- You recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You live in or near a location where COVID-19 has been detected and/or
- You have come into close contact with an individual diagnosed with or suspected of or having COVID-19.

Testing your sample(s) will help determine if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential benefits include:

- Your healthcare provider can make informed recommendations regarding your care or treatment based on the results of this test along with other information.
- The results of this test may help limit the spread of the Coronavirus.

Potential risks include:

- Possible false positive or negative test result (see page 2 for more information).
- The possible discomfort or other complications associated with sample collection.

What does it mean if I have received a positive test result?

A positive result could be related to the following:

- Your results indicate that you may have contracted COVID-19 and that you may need to quarantine to avoid spreading the virus to other individuals.

- Some results may indicate you were previously infected.
- There is also the small chance that this test provided a false positive result (incorrect positive result).

Your doctor or healthcare provider will assist you in determining how best to care for you based on the test results, symptoms, medical history, possible exposures, and geographic location of places you have recently traveled or frequented.

What does it mean if the test provided a negative test result?

A negative test result could mean the following:

- The antibodies to the virus that cause COVID-19 were not detected in your sample.
- A false negative result (incorrect negative result for some people with COVID-19) may occur if you are tested too early in your illness and your body has not had the opportunity to produce antibodies to the infection. This means that you could possibly still have contracted COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other parameters of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled or frequented) in the deciding how to provide care.

In order to best understand the next steps you should take, it is important that you work with your doctor or healthcare provider.

Important Notification:

Due to the Coronavirus Public Health Emergency, the FDA updated its Policy for Diagnostic Tests for COVID-19 on March 16, 2020. Included in this update is guidance for commercial manufacturers, for screening tests that identify antibodies (e.g., IgG, IgM) to SARS-CoV-2 from clinical specimens. This updated policy allows for testing by healthcare workers at the point of care or in laboratories. At-home testing is not covered by this guidance. Please note the following information:

- This test has not been reviewed by the FDA.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Negative results do not rule out SARS-CoV-2 infection, especially in those who have been exposed to the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in those individuals.
- The results from antibody testing should not be used as the sole basis to diagnose or exclude a COVID-19 infection or to determine an individual's infection status.

Biotrinetix
1020 Holland Drive STE 115
Boca Raton, FL 33487
www.biotrinetix.com
+1 (561) 571-2601