

Information for Patients

COVID-19 Serologic Testing

What is COVID-19?

COVID-19 is an illness caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness, including symptoms such as fever, cough, and shortness of breath. It was first identified in Wuhan, China in late 2019 and has now spread globally. It appears to be spread primarily through person to person contact.

Why am I being tested?

This test can help determine if you have developed immunity to the SARS-CoV-2 virus. You may have mild to severe symptoms such as a fever of 100.4°F or greater, and/or respiratory symptoms such as a cough, sore throat, shortness of breath, or difficulty breathing, or you may have had these symptoms in the past 2 months. Another reason you may be tested is following potential exposure to other positively tested COVID-19 patients.

What is the test?

This test does not directly test for the presence of the virus. The Rapid IgM-IgG Combined Antibody Test for COVID-19 detects the presence of antibodies to the virus in your blood. Your body makes antibodies when it has been exposed to a virus. This type of testing is widely used for many different conditions. A small amount of your blood will be collected and used to run the test in our laboratory.

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

Potential risks include discomfort and or bruising at the site of the blood draw. There is also a potential risk of an incorrect test result (see below for more information.)

Potential benefits include providing more information of the diagnosis and treatment of your symptoms. The results may also help you limit the spread of the infection to others you may come in contact with.

How soon are results available?

The test itself only takes 10 minutes to perform. Your results will usually be available within 24 hours of your blood draw and will be provided to your health care provider. You can contact your health care provider directly for your results and follow up recommendations. Please do not contact Cole Diagnostics directly for your results.

What does it mean if I have a negative result?

If you have a negative result, it is very likely that you do not have antibodies to the SARS-CoV-2 virus at this time. Studies show that it can take 7-10 days from initial exposure to onset of symptoms. Antibodies begin to develop within 5-7 days of symptoms. It is possible that it is too early to tell if you have antibodies to the virus. If you have a negative test, but have symptoms such as a fever, cough, or shortness of breath, you and your provider should consider follow up testing by PCR or testing for other illnesses such as influenza. If you are in immediate distress, call the emergency room and seek care right away. Repeat antibody testing in 7-10 days may be helpful if you think you have been exposed or if you have had symptoms of COVID-19.

What does it mean if I have a positive IgM result?

A positive IgM result means the test has detected IgM antibodies to the virus in your blood. IgM antibodies typically begin to appear within 5-7 days of onset of symptoms. You may be in the acute (early) phase of infection. You should self-isolate and any close contacts should be notified and also be tested. If you have severe symptoms such as difficulty breathing, you should contact the emergency room. About half of patients who test positive do not have noticeable symptoms. You can still be contagious even if you do not have symptoms. In some less common cases, the IgM antibody test is positive due to a cross reaction with another antibody or protein such as rheumatoid factor. A follow-up test in 7-10 days is recommended.

What does it mean if I have a positive IgM and IgG result?

This means that you were most likely exposed to the virus within the last 3 weeks, and that you still have some acute (IgM) antibodies at the same time you are developing long term (IgG) antibodies. You may be experiencing symptoms or have had symptoms in the recent past, such as a fever, cough, or shortness of breath. If you have severe symptoms, such as difficulty breathing you should contact your provider or call the emergency room. You may still be contagious at this point. You should continue to self-isolate, and any close contacts should be tested. A follow-up test in 7-10 days is recommended to see if you are past the acute IgM phase.

What does it mean if I have a positive IgG result?

IgG antibodies are the body's long-term immunity. A positive IgG antibody result means you have been exposed to the virus in the past and your body has mounted an immune response. If you have no symptoms and are IgG positive, you most likely have some immunity to COVID-19. At this time, it is unclear how long that immunity lasts. It is also possible that this result is from another coronavirus you may have been exposed to in the past.

If you have other questions about your results, or about COVID-19, you can contact your healthcare provider, or see the information available at www.cdc.gov/COVID19

How does this compare to PCR screening?

PCR testing is considered the gold standard for testing. The PCR test detects the presence of the virus in your nasal passages. The challenges of PCR testing include the availability of equipment, reagents, and trained testing personnel. PCR testing is also prone to false negative tests, particularly outside of the 5-10 day window when symptoms are most acute, and is less reliable when the patient is not exhibiting upper respiratory symptoms.

Is additional testing necessary?

This test is a snapshot in time to measure your antibodies today. If your test is negative for both antibodies, but you have significant upper respiratory symptoms, follow up testing may be necessary. This could include PCR testing for COVID-19 and/or testing for Influenza or other respiratory illnesses. Repeat antibody testing may be helpful if you have subsequent exposure to the SARS-CoV-2 virus, or to follow the progression of your antibody response.

Required notification - While the FDA EUA application is under review, please note the following information:

- This test has not been reviewed by FDA
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- 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.

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