

Coronavirus (COVID-19) IgM/IgG Antibody Test

DESCRIPTION

Coronavirus (COVID-19) is an illness caused by a virus that is transmitted from person to person. Symptoms can range from mild (or no symptoms) to severe illness. One can be infected from respiratory droplets when an infected person sneezes or coughs. Other ways that one can be infected is by touching a surface or object has the virus on it, and then touching their mouth, nose, or eyes.

The lab test is a qualitative test that detects the IgM/IgG antibodies to SARS-CoV-2, the virus that causes COVID-19. IgM antibodies are the first type of antibody produced by the immune system. The IgM antibody is detected if you have an active infection or have recently been exposed to the virus. IgG antibodies can usually be detected 10 days from suspected infection or post symptom onset. The IgG antibodies will remain in the blood after an infection has passed.

Customers that have active COVID-19 or COVID-19 related symptoms such as fever, cough, or shortness of breath, should not visit Any Lab Test Now locations. Customers who believe that they may have COVID-19 are strongly encouraged to contact their physician or other medical professional.

TEST DETAILS:

This test will identify both IgM and IgG antibodies if present. The IgM antibody is detected if you have an active virus or have recently been exposed to the virus. The IgG antibody test will identify if you have had past exposure to the virus.

This is not a test for an active infection.

Free options for testing are available. The COVID-19 Antibody Test may be covered by your insurance plan or the government, with no out-of-pocket costs to you. If you are looking for that no-cost option, contact your healthcare provider.

You may be able to submit the expense associated with this test to your Health Savings Account, Flexible Spending Account, Health Reimbursement Account, or similar account for reimbursement. Please check with your health account administrator.

Note: This test can sometimes detect antibodies from other coronaviruses, which can cause a false positive result if you have been previously diagnosed with or exposed to other types of coronaviruses. Additionally, if you test too soon, your body may not have

produced enough IgG antibodies to be detected by the test yet, which can lead to a false negative result.

FAQs

WHAT IS AN ANTIBODY TEST?

Antibody blood tests, also called serologic tests, check your blood for antibodies that would show if you have had a previous infection. Antibodies are proteins that help fight off germs. A serologic test may not be able to show if you have a current infection, because it can take 1 to 3 weeks to make antibodies after symptoms occur.

We do not know yet if having antibodies to SARS-CoV-2 can protect someone from getting infected with that virus again, or how long that protection might last. Scientists are doing studies to answer those questions.

If you test positive or negative for COVID-19, no matter the type of test, you still should take preventive measures to protect yourself and others. *

WHY DO I NEED THIS TEST?

If you believe you have been exposed to COVID-19 or have had symptoms in the past, you may be a good candidate for this test. You **must** be asymptomatic (free of symptoms) for at least seven (7) days prior to testing.

WHAT TYPE OF SPECIMEN WILL BE COLLECTED FOR THIS TEST?

This test requires a simple blood draw.

AM I REQUIRED TO FAST?

No. You are not required to fast for this test.

IS A DOCTOR'S ORDER REQUIRED?

Any Lab Test Now's ordering physician will provide the required physician's order on your behalf.

HOW LONG WILL IT TAKE TO GET MY LAB TEST RESULTS?

Results from the COVID-19 IgG/IgM test are generally available within 1 to 3 business days after you specimen is received by the lab.

<u>IF I HAVE QUESTIONS ABOUT MY TEST RESULTS WHO SHOULD I</u> CONTACT?

You can share your results with your healthcare provider or contact our telemedicine partner, <u>DialCare</u>, and they will assist you in interpreting the results. Any Lab Test Now does not diagnose or interpret results.

WHAT IS THE DIFFERENCE BETWEEN AN IGM AND IGG ANTIBODY TEST?

Early after infection (usually after the first week), a class of antibodies known as immunoglobulin M (IgM) develop, although they typically do not last long. Later, after the first 2-4 weeks following infection, IgG, a more durable antibody, is produced.

Detection of microbe-specific IgM and IgG in circulating blood (a 'serologic' test) serves as a traditional method to determine whether a person has been infected with that pathogen, either recently (IgM) or more distantly (IgG).**

<u>IF ANTIBODY TESTS ARE NOT USED FOR DIAGNOSIS OR EXCLUSION OF COVID-19 INFECTION, WHAT IS THEIR PURPOSE?</u>

Antibody tests can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who have been exposed to SARS-CoV-2 virus and may have develop an immune response. In the future, this may potentially be used to help determine, together with other clinical data, whether these individuals may be less susceptible to infection. ****

IS THIS TEST APPROVED BY THE FOOD AND DRUG ADMINISTRATION (FDA)?

No. According to the FDA "more flexibility was needed during a pandemic of this scale and speed, and incorporating feedback from the medical community, states and test developers, we have also provided regulatory flexibility for serological tests in an effort to provide laboratories and health care providers with early access to these tests with the understanding that the FDA had not reviewed or authorized (or "approved") them, at least not initially, and these tests should not be used for diagnosing or excluding active SARS-CoV-2 infection. Specifically, last month, as part of our broader strategy, the FDA issued a policy explaining that FDA does not intend to object when developers of serological tests market or use their tests without prior FDA review where: 1) the tests are validated

by the developer to determine that they are accurate and reliable, 2) notification of the developer's validation is provided to FDA, and 3) the tests are labeled appropriately, including that they are not to be used as a sole basis for diagnosis. "***

The test you receive follows the above referenced FDA guidelines.

SHOULD I USE ANTIBODY TESTING TO DETERMINE EMPLOYEE STAFFING?

COVID-19 Antibody Testing should not be the sole determination for staffing. Since the we do not know if COVID-19 antibodies protect someone from future infection, you cannot be assured that they will not get re-infected.

WHAT DOES IT MEAN IF I HAVE A POSITIVE TEST RESULT?

If you have a positive test result, it is likely that you may have had COVID-19 and might have developed an antibody response to the virus. There is a small chance that this test can give a positive result that is wrong (a false positive result). *

WHAT DOES IT MEAN IF I HAVE A NEGATIVE TEST RESULT?

A negative test results means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. A negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. ***

WHAT IF I WANT TO DISCUSS THE RESULTS WITH A PHYSICIAN?

You can share your results with your healthcare provider or contact our telemedicine partner, <u>DialCare</u>, and they will assist you in interpreting the results. Any Lab Test Now does not diagnose or interpret results.

WHAT IF I WANT TO GET A FREE COVID-19 ANTIBODY TEST?

Free options for testing are available. The COVID-19 Antibody Test may be covered by your insurance plan or the government, with no out-of-pocket costs to you. If you are interested in this option, please contact your healthcare provider. Any Lab Test Now provides transparent pricing and an option for consumers who want fast and convenient access to laboratory testing. Please note the you can use your HSA or FSA for the cost of the test.

- * https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html
- $\hbox{** $\underline{$https://www.vumc.org/coronavirus/latest-news/antibody-testing-covid-19-what-it-tells-us-and-what-it-doesnt}}$
- ***https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts
- **** https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

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