Coronavirus (COVID-19) IgM_IgG Rapid 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 that has the virus on it, and then touching their mouth, nose, or eyes.

The rapid test is a qualitative test that detects the IgM/IgG antibodies to SARS-CoV-2 within 15 minutes, 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.

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. *

*https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html

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 finger stick.

AM I REQUIRED TO FAST?

No

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 15 minutes

IF I HAVE QUESTIONS ABOUT MY TEST RESULTS WHO SHOULD I CONTACT?

You can share your results with your healthcare provider or contact our telemedicine partner, DialCare, 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).**

**https://www.vumc.org/coronavirus/latest-news/antibody-testing-covid-19-what-it-tells-us-and-what-it-doesnt

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

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. ****

****https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

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

No, but it has been granted FDA EUA authorization. During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) to provide more timely access to critical medical products that may help during the emergency when there are no adequate, approved, and available options.

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.

***https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts

SHOULD I USE ANTIBODY TESTING TO DETERMINE EMPLOYEE STAFFING?

COVID-19 Antibody Testing should not be the sole determination for staffing. Since 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). *

*https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html

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. ***

***https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts

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, DialCare, 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 that you can use your HSA or FSA for the cost of the test.

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Ekan Essien, MD, MPH, a native Georgian, received his BA from Duke University. Dr. Essien continued his education at Florida A&M University where he received his Masters of Public Health in Epidemiology; received his medical degree from Meharry Medical College in Nashville, Tennessee; and obtained training in general and trauma surgery at Grady Memorial Hospital at Morehouse School of Medicine. He is a candidate in the post graduate fellowship in anti-aging and regenerative medicine from the American Academy of Anti-Aging Medicine.