

COVID-19 Spike Protein IgM Antibody Test

You are being given this TestFact because your sample was tested using the National Jewish Health COVID-19 Spike Protein IgM antibody test.

This TestFact contains information to help you understand the risks and benefits of using this test for SARS-CoV-2, the virus that causes COVID-19. After reading this TestFact, if you have questions or would like to discuss the information provided, please talk with your health care provider.

Why was my sample tested?

You were tested because:

- Testing of the sample may help find out if you may have IgM antibodies to COVID-19 as a result of infection or vaccination with one of the vaccines containing the virus spike protein.
- Your health care provider believes you may have been exposed to the virus that causes COVID-19 based on your current or previous signs and symptoms (e.g., fever, cough, difficulty breathing).
- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur.
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

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

Potential risks include:

- Possible discomfort, bruising, infection or other complications that can happen during sample collection (Serious complications are very rare.)
- Possible incorrect test result (See below for more information.)

Potential benefits include:

- Results and other information can help your health care provider make informed recommendations about your care
- Test results may help limit the spread of COVID-19 to your family and others

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

If you have a positive test result (antibodies are detected), you may have been recently infected with the virus that causes COVID-19, or you have made antibodies as a response to recent vaccination with one of the current SARS-CoV-2 vaccines. There is still a chance that the antibodies indicate past infection due to other coronaviruses. These other coronaviruses cause the common cold. There is also a small chance that a positive result is incorrect (false positive).

The presence of IgM suggests that the infection or vaccination happened recently. How much IgM antibodies might protect you from getting sick with COVID-19 in the future is unknown.

Your health care provider will work with you to determine how best to care for you based on the test results

along with other factors of your medical history, including any previous symptoms, possible exposure to COVID-19 and the location of places you have recently traveled.

What does it mean if I have a negative test result?

A negative test result means that the antibodies to the virus that causes COVID-19 or to the vaccine were not found in your sample. Some health conditions might make it difficult for your body to produce antibodies to an infection or vaccination. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people.

A negative result may occur if you are tested early in your illness or shortly after vaccination and your body hasn't had time to produce antibodies to the spike protein. This means that you could possibly still have COVID-19 even though the test is negative or that it too early after vaccination to detect antibodies. If this is the case, your health care 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 health care provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States Food and Drug Administration (FDA). However, when there are no FDA-approved or cleared tests available, and other criteria are met, the 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 declaration from the Secretary of Health and Human Service (HHS) 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 use of in vitro diagnostic tests (IVDs), unless it is terminated or revoked by FDA (after which the test may no longer be used).

National Jewish Health researchers and clinicians validated this test for use in antibody testing.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the [Centers for Disease Control and Prevention website](#). In addition, please also contact your health care provider with any questions/concerns.

IF YOU ARE CURRENTLY SICK – You should not have antibody testing for COVID-19 at the National Jewish Health testing tent site because:

- The outdoors site is for testing only, not treatment of sick individuals.
- You may not yet have started to make antibodies.

Symptomatic individuals (regardless of physician referral) needing urgent medical evaluation or who are recovering from COVID-19 may also have this test drawn as part of their evaluation in COVID-19-related clinics. Please call National Jewish Health if you would like more information.

People who are sick should seek medical attention by calling their doctor. They also may call National Jewish Health to determine if they need to be seen in a clinic or emergency department, or qualify to have a test for active COVID-19 (i.e., a nasopharyngeal swab) at our outdoor testing site before returning home. People who are sick with COVID-19 or may have COVID-19 need to self-isolate themselves from others until recovered, according to the [CDC guidelines](#).

People who have been exposed to COVID-19 should [quarantine for 14 days to avoid infecting others](#) in this time period when they might be becoming sick themselves.

Visit our website for more information about support groups, clinical trials and lifestyle information.

© Copyright 2020

NOTE: This information is provided to you as an educational service of National Jewish Health. It is not meant to be a substitute for consulting with your own physician.

National Jewish Health is the leading respiratory hospital in the nation. Founded 123 years ago as a nonprofit hospital, National Jewish Health today is the only facility in the world dedicated exclusively to groundbreaking medical research and treatment of patients with respiratory, cardiac, immune and related disorders. Patients and families come to National Jewish Health from around the world to receive cutting-edge, comprehensive, coordinated care. To learn more, visit njhealth.org.