

## COVID-19 IgM Detection by ELISA Antibody Test

You are being given this TestFact because your sample was tested using the National Jewish Health COVID-19 IgM Detection by ELISA Antibody Test.

This TestFact contains information to help you understand the risks and benefits of using this test for diagnosing prior infection with 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.

### What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. This virus, which can cause mild to severe respiratory illness, has now spread globally, including to the United States. There is limited information available to fully describe the different types of clinical illness associated with COVID-19. This illness likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.) or in the few days leading up to symptoms.

### What is the COVID-19 IgM Detection by ELISA Antibody test?

The test is designed to detect antibodies (also known as immunoglobulins) against the virus that causes COVID-19. Antibodies are proteins produced by the immune system in response to an infection and are specific to that particular infection. They are found in the liquid part of blood specimens which is called serum or plasma, depending on the presence of clotting factors. Today your sample will be tested for immunoglobulin M (IgM).

This test detects IgM antibodies. IgM is usually the first antibody produced by the immune system when a virus attacks. A positive IgM test indicates that you may have been infected and that your immune system has started responding to the virus. When IgM is detected you may still be infected or you may have recently recovered from a COVID-19 infection.

### Why was my sample tested?

You were tested because:

- 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; or
- you have recovered from COVID-19.

Testing of the sample may help find out if you may have antibodies to 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:

- The results, along with other information, can help your health care provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

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

The presence of IgM suggests that the infection happened within the last few weeks. It also suggests that you could still be infectious to others. Having a nasopharyngeal swab test may confirm if you are infectious.

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 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.

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. 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 FDA. 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 Secretary of Health and Human Service's (HHS's) declaration 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 developed and validated this test and submitted it for emergency use authorization from the U.S. Food and Drug Administration (FDA).

## 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: <https://www.cdc.gov/COVID19>. 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:

1. The outdoors site is for testing only, not treatment of sick individuals
2. 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 may also 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. <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

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. <https://covid19.colorado.gov/covid-19-in-colorado/isolation-and-quarantine>

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

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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.

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