

COVID-19 / SARS Laboratory Testing: Immunoassay Test

Notice

The Food and Drug Administration (FDA) has not licensed this test. The FDA has agreed that we can use this test under an investigational device exemption (IDE).

Background

SARS is a respiratory illness that can start as fever and cough. It may go on to pneumonia in some people. SARS seems to be spread by close person-to-person contact. This can occur when a person who is sick with SARS coughs or sneezes onto themselves, other people, or nearby surfaces. Droplets from the cough or sneeze can travel a short distance through the air and land on the mouth, nose, or eyes of persons who are nearby. The virus also can spread when a person touches a surface or object with infectious droplets and then touches his or her mouth, nose, or eye(s). It also is possible that SARS can be spread through the air or by other ways that are not known.

Why Should I Be Tested?

In order to ensure the best outcome from your elective surgery, you may be asked to have SARS testing done prior to the surgery. In order to protect the patients and staff members of Heart of Texas Eye Institute, you may be asked to have SARS testing done if you are having symptoms consistent with SARS, or have been in recent contact with someone who has either confirmed diagnosis of SARS, or symptoms consistent with SARS.

Are There Any Risks From Taking My Samples?

To do this test, a small drop of blood will be taken. You may feel a slight sting as the blood sample is drawn.

The blood will be placed on an immunoassay cartridge and processed to look for antibodies to the COVID-19 SARS virus. Results will be available after 10 minutes.

Your doctor may also ask to take more samples in the future, or refer you to your primary care doctor for additional testing.

When Do I Learn My Results?

The Immunoassay Test tests the presence of antibodies present in the small blood sample. The testing takes about 10 minutes for results to be available. Your results and the implications will be reviewed by your doctor.

Are There Other Choices?

PCR nasal swab tests, and other antibody tests besides Confirm Biosciences Immunoassay are available at other doctors offices, hospitals, and testing centers.

What About Privacy?

We will keep all facts about you as private as the law allows. If requested, the CDC, FDA, the Local/State Health Department staff may see your results.

What Are the Costs?

The test will be billed to your medical insurance. If you do not have medical insurance, there will be a \$60 fee for administering and interpreting the test.

Right to Refuse

It is your choice to have this testing done. Should you choose to refuse the test, your doctor may decide that it is best to defer your surgery until such time that a vaccine is available, or the risk of exposure is lower.

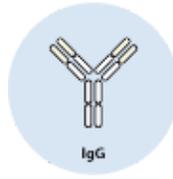
Whom to Call If You Have Questions

Please call your doctor if you have any questions about this testing.

What Is the Difference Between IgM and IgG?



IgM antibodies



IgG antibodies

IgM antibodies are the [largest](#) antibodies in the body and are typically produced first when an individual gets infected by a virus. IgM antibodies make up about 5% to 10% of all the antibodies in the body. They are found in the blood and lymph fluid.

Because the body typically produces IgM antibodies first, the IgM panel can detect the SARS-CoV-2 virus early. Therefore, IgM panels can accurately detect “acute infection.”

IgG antibodies are the [smallest and most common](#) antibodies. They make up about 75% to 80% of all the antibodies in the body. They are also the only type of antibody that can travel across the placenta from a pregnant woman to her unborn child. IgG antibodies can be found in all body fluids.

Unlike IgM antibodies, the body produces IgG antibodies much later. As a result, IgG antibodies can only be detected in the later course of the illness. Scientists use the IgG panels to detect “recent infection” or “in-recovery” states. An antibody testing with positive IgG with negative IgM results indicates that a person who has been exposed to or infected with COVID-19 and now has protection against COVID-19.

Reading of the IgM vs. IgG Panels and How They Distinguish Acute vs. In-Recovery States

There are a few different types of results with (serological) antibody testing. 4 different possible outcomes:

	IgM Neg (-)	IgM Pos (+)
IgG Neg (-)	The patient has never been infected with COVID-19 or is still in the incubation period.	The patient is having an early phase, active COVID-19 infection.
IgG Pos (+)	The patient has been infected with COVID-19 and now has protection against COVID-19.	The body has an active COVID-19 infection and is trying to build up protection against it.

It is important to note that a positive test from both IgM and IgG panels means that the patient is still fighting infection and healthcare practitioners must follow all CDC guidelines for this patient.