

SAS™ COVID-19 IgG/IgM Antibody Detection test- Patient Information

You were tested for immune response with SAS™ COVID-19 IgG/IgM Antibody Detection test.

COVID-19 is caused by the SARS-CoV-2 virus.

The virus spreads quickly and does not cause symptoms in everyone. It can cause mild to severe respiratory illness and can be a serious threat to certain individuals. Quantifiable information to characterize the full spectrum of clinical illness associated with COVID-19 is limited.

SAS™ COVID-19 IgG/IgM Antibody Detection tests detect immune response.

Antibodies are developed in our immune systems against the virus that causes COVID-19. Your healthcare provider may recommend this antibody test if he/she believes you may have been exposed to the virus that causes COVID-19. This could be based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

You live in or have recently traveled where transmission of COVID-19 is known to occur, and/or
You have been in close contact with someone suspected of or someone confirmed to have or have had COVID-19 and/or
You are returning to work and are participating in a testing program for your safety

Additional testing should always be required to confirm or rule out a diagnosis of COVID-19. See below.

Known Potential Risks and Benefits of Test Usage

Potential Benefits Include:

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

Potential Risks Include:

- Discomfort or other complications due to fidgetstick and sample collection
- Incorrect test interpretation - refer to information below
- Incorrect test result - refer below

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Report All Adverse events, including problems with test performance or results, by submitting the online FDA Form 3500 or by calling 1-800-FDA-1088.

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There are several ways to interpret negative Rapid Test results.

A negative result on the test cassette(s) indicates that antibodies to the virus that causes COVID-19 were not found in your sample. This may not necessarily mean you do not have the virus, especially if you are showing symptoms. A negative result may occur if you are tested early in your illness and your body has not had time to produce antibodies to infection. This means that you could possibly still have COVID-19, even though the test is negative.

Additional testing should be required to confirm or rule out a diagnosis of COVID-19. Your healthcare provider may recommend serology testing often as part of your carefully monitored care plan. You may be enrolled in a program through your employer that facilitates repeated testing. Your ability to adhere to safety protocol and protect yourself is most important to prevent being exposed to COVID-19.

When determining care, your healthcare provider will consider the test results along with other factors of your medical history, symptoms, potential exposures, and geographic location of recent travels. Regular, or follow-up testing may provide you with continued peace of mind.

It is important that you work with your healthcare provider to fully understand how to comply with prescribed recommendations. Stay informed of safety protocol in your region, state and workplace. The FDA and CDC websites contain helpful, up to date information. Stay informed.

There are several ways to interpret positive Rapid Test results.

A positive result on the test cassette(s) indicates that antibodies to the virus that causes COVID-19 were found in your sample. This may mean you have had COVID-19 before. A positive result (s) may occur if you were infected previously and the antibodies produced in response have remained in your body.

Depending on your situation and symptoms, it may be most likely that you have COVID-19 and isolation should be required immediately to avoid spreading the virus to others. Additional testing is recommended to confirm.

Your healthcare provider will consider the test results along with other factors of your medical history, symptoms, potential exposures, and geographic location of recent travels when determining your care plan.

There is also the small chance that this test can give a false positive result. Your healthcare provider may request that more than one Rapid Test be administered to you. Additional testing should be required to confirm or rule out a diagnosis of COVID-19, and your healthcare provider will consider a positive test cassette result when prioritizing additional (PCR) testing procedures.

This product has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing should be considered to rule out infection in these individuals. Results from one antibody test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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