US BioTek LABORATORIES

COVID-19 (SARS-CoV-2 IgG & IgM Antibodies)

Provider:	**Sex:**	**Collected:**
Patient:	**Age:**	**Received:**
Accession #:	**Sample Type:**	**Completed:**

Antibody	Result	AU/mL	Reference Range
IgG	Reactive	3.272	<1.00 AU/mL
IgM	Non-reactive	0.296	<1.00 AU/mL

About This Test

Upon infection with the SARS-CoV-2 virus, the patient's immune system tries to fight the virus by producing blood-circulating molecules known as antibodies. IgM is a class of antibodies that appears as early as three to five days after an infection. IgM is the body's first line of defense against a foreign antigen. IgG is another class of antibodies that appears later and gradually replaces the IgM antibodies. Usually, IgG antibodies appear in the blood circulation within three to four weeks after initial infection.

A Reactive (positive) test for either SARS-CoV-2 IgM or SARS-CoV-2 IgG provides evidence of the infection of a patient with the SARS-CoV-2 virus. A positive test for SARS-CoV-2 IgM indicates that the infection was recent, most likely within a week. A positive test for SARS-CoV-2 IgG indicates that the patient has had an infection for at least three weeks or more. Since most patients do not know the exact time when they contracted the virus, combining both IgM and IgG tests provide much higher test sensitivity and test specificity.

The presence of SARS-CoV-2 IgM or IgG antibodies in the blood of a patient provides secondary evidence of the infection of a patient who may have tested positive with the standard nucleic acid test (RT-PCR test). The serological tests for IgM and IgG can also provide earlier detection of potential positive patients who may not have immediate access to the RT-PCR test.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SAR-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. For samples with concentration near the cut-off or that are positive, follow-up testing should be preformed using molecular testing results to confirm diagnosis. Non-reactive (negative) results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing using RT-PCR should be considered to rule out infection in these individuals.

Note: Based on data from the SARS epidemic, antibody response may be poor in immunocompromised individuals and lower than expected in some pediatric patients.

This test performance has been validated by US BioTek Laboratories according to high-complexity testing under Clinical Laboratory Improvement Amendments (CLIA). The commercial manufacturer of these tests has notified the FDA that they have validated and are offering serology tests as set forth in Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019. The FDA has not reviewed the validation of tests offered by this manufacturer. As stated in Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019, the FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, and notification is provided to the FDA.

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