



## SARS-CoV-2 (RBD) IgG Antibody

Test Number: 19723      CPT Code: 86769

Synonyms	COVID-19 Serology
Use	<p>SARS-CoV-2 (RBD) IgG Antibody test is an immunoassay intended for the qualitative and semi-quantitative detection of antibodies binding to the SARS-Cov-2 Spike Receptor Binding Domain (RBD).</p> <p>It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.</p>
Turnaround Time	2-3 days (from receipt specimen)
<b>Specimen Requirements</b>	
Specimen	Serum, Plasma (EDTA or heparin), Dried Blood Spots (DBS)
Minimum volume	0.5 mL for Serum, Plasma (EDTA or heparin), one card for DBS
Collection	Standard aseptic procedures
Storage Instructions	<p>Room Temperature: 2 days</p> <p>Refrigerated: 7 days (14 days for DBS)</p> <p>Frozen: 30 days</p> <p>Freeze/thaw cycles: stable for 3X</p> <p>For Serum, Plasma (EDTA or heparin), do not freeze samples in original collection tubes</p>
Causes for Rejection	<p>Gross hemolysis for plasma and serum samples</p> <p>Insufficient sample (&lt; 0.5mL of venous blood, Dried Blood Spots less than 9mm in diameter)</p> <p>Citrate or NaF plasma</p> <p>Frozen whole blood</p>
Limitations	<p>This test is not approved, cleared, or issued an Emergency Use Authorization (EUA) by the FDA.</p> <p>Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. Results from antibody testing should not be used to diagnose or exclude acute</p>

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SARS-CoV-2 infection. 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.

This test was established and its performance characteristics determined by ProterixBio, 1 Fortune Drive, Billerica, MA 01821.

Test performance was determined to meet the requirements of CLIA '88 for clinical testing, and as such this test is intended for clinical use.

The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

Testing is performed at ProterixBio, 1 Fortune Drive, Billerica, MA 01821 under CLIA certificate #22D2189261; Laboratory Director Mark D. Kellogg, PhD, MT(ASCP), DABCC

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### Additional Information

After infection, it typically takes at least 10 days after the onset of symptoms for IgG levels to be detectable. A positive result in an unvaccinated individual indicates that the individual has likely been infected by SARS-CoV-2 and has produced an immune response. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

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### References

CDC Overview of Testing for SARS-CoV-2 (COVID-19), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>, Aug 2020.

FDA Policy for COVID-19 Tests During the Public Health Emergency (Revised), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>, Aug 2020

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Okba et al, Severe Acute Respiratory Syndrome Coronavirus 2–Specific Antibody Responses in Coronavirus Disease Patients *Emerg Infect Dis*, 2020; 26(7).

Atjeo et al, Distinct early serological signatures track with SARS-CoV-2 survival, *Immunity* 53, 1-9, 2020.

Premkumar et al, The receptor binding domain of the viral spike protein is an immunodominant and highly specific target of the antibodies in the SARS-CoV-2 patients, *Science Immunology*, 11June 2020.

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