



## 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 Receptor Binding Domain (RBD) of the spike protein of the SARS-CoV-2 virus.</p> <p>It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or as an aid in assessing the immune response of individuals that have been previously immunized with a SARS-CoV-2 vaccine.</p>
Turnaround Time	2-3 days
<b>Specimen Requirements</b>	
Specimen	Serum, Plasma (EDTA or heparin), dried blood spots (DBS)
Minimum volume	0.5 mL for venous blood, one card for DBS
Collection	Standard aseptic procedures
Storage Instructions	<p>Room Temperature: 2 days</p> <p>Refrigerated: 7 days</p> <p>Frozen: 30 days</p> <p>Freeze/thaw cycles: stable for 3X</p> <p>For venous blood, 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)</p> <p>Citrate or NaF plasma</p> <p>Frozen whole blood</p>
Limitations	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 SARS-CoV-2 infection. Positive results may be due to past or present

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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.

Its performance was determined to be pursuant to the requirements of CLIA '88 for clinical testing and is intended for clinical purposes.

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 indicates that an 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.

After vaccination, it typically takes 15-30 days after dosing is complete for IgG levels to approach peak levels. The protection provided by and durability of antibodies produced by SARS-CoV-2 vaccines are still being studied.

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## References

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