



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.</p>
Turnaround Time	2-3 days
Specimen Requirements	
Specimen	Serum or Plasma (EDTA or heparin)
Minimum volume	0.5 mL
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>Do not freeze samples in original collection tubes</p>
Causes for Rejection	Gross hemolysis
Limitations	<p>This test has not been reviewed by the FDA. Consistent with FDA guidance for high-complexity CLIA laboratories offering COVID-19 serology testing, ProterixBio notified and submitted validation data to 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 SARS-CoV-2 infection. Positive results may be due to past or present</p>

infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Additional Information

Typically, it 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.

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.

Gudbjartsson et al., Humoral Immune Response to SARS-CoV-2 in Iceland, *NEJM*, 1Sept 2020.
