

SARS-CoV-2 Antibody (IgG), Spike Protein

Date: June 9, 2021

Effective Date: June 16, 2021

Test Name: SARS-CoV-2 Antibody (IgG), Spike Protein

Test Methodology: Qualitative and semi-quantitative chemiluminescent immunoassay (CLIA) for detection of IgG antibodies against the SARS-CoV-2 spike protein.

Test Performance: The clinical sensitivity is approximately 98% in individuals who are at least ≥ 15 days post-symptom onset; the clinical specificity is approximately 99%.

Reference intervals:

- AU/mL < 50.0: Negative.
- AU/mL ≥ 50.0 : Positive.

Notes and Limitations:

- This test is for use under FDA Emergency Use Authorization only.
- A positive IgG result may indicate previous infection with SARS-CoV-2 or immunization with current vaccines. The performance of this test, however, has not been established in individuals that have received a COVID-19 vaccine.
- The test should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. COVID-19 PCR should be performed to evaluate for acute infection.
- This test should only be used for testing specimens collected ≥ 15 days after symptom onset. It may take 3 or more weeks after infection for an individual to be positive for antibody to SARS-CoV-2.
- Negative results do not preclude SARS-CoV-2 infection. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies in the specimen is below the detection limits of the assay, or if the antibodies are not present during the stage of disease in which a specimen is collected.
- **Although this assay is authorized as a semi-quantitative assay, the clinical applicability of semi-quantitative numerical results is currently unknown and cannot be interpreted as an indication or degree of immunity, nor protection from infection.**
- This test should not be used for blood donor screening.

Fact sheets for healthcare providers and test recipients are available on the UR Medicine Labs Test Menu:
<https://www.testmenu.com/rochester>

Test Code: CSPIG.

Specimen Type: Serum, 1 mL (Min: 0.5mL).

Testing: UR Medicine Central Laboratory.

Turnaround Time: 1-2 days upon receipt.



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Please direct questions to Lindsay Ryan-Muntz, Serology Supervisor, at 585-275-7801.

From: Dwight J. Hardy, PhD
Director, Clinical Microbiology
UR Medicine Central Laboratory
Phone: 585-275-1408
E-mail: dwight_hardy@urmc.rochester.edu