SARS-CoV-2 Antibody (IgG) Testing: New Assay

Date: May 26, 2020

Effective Date: June 1, 2020

Antibody testing for IG to the SARS-CoV-2, the causative agent of COVID-19, will be available to order. While RT-PCR testing remains the gold standard for COVID-19 diagnosis, antibody testing may aid in the assessment of previous infection.

Test Methodology: Qualitative chemiluminescent immunoassay (CLIA) for detection of IgG against the SARS-CoV-2 nucleocapsid protein.

Test Performance: The clinical sensitivity of the SARS-CoV-2 IgG antibody test is approximately 95% in individuals who are at least 14-21 days post symptom onset. The clinical specificity of the SARS-CoV-2 IgG antibody testing is 99%

Notes:

- This test is for use under FDA Emergency Use Authorization only.
- A positive IgG result may indicate that an individual was previously infected by SARS-CoV-2, though it is currently unknown whether this means that they are protected against future infections.
- **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 rule out SARS-CoV-2 infection, particularly in those who have been recently in contact with the virus. Follow-up testing with RT-PCR should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-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, or 229E.
- This test is not for screening of donated blood.
- Fact sheets for healthcare providers and test recipients are available on the UR Medicine Labs Test Menu: www.testmenu.com/rochester

Test Code: C2IGG
Specimen Type: Serum, 2 mL (Min: 0.5mL)
Testing: UR Medicine Central Laboratory
Turnaround Time: 1-2 days upon receipt

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

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