

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay

CPT Code: 86769

Order Code: 39504

ABN Requirement: No

Specimen: Serum

Volume: 1.0 mL

Minimum Volume: 0.5 mL

Container: Gel-barrier tube (SST)

Collection:

1. Collect and label sample according to standard protocols.
2. Gently invert tube 5 times immediately after draw. DO NOT SHAKE.
3. Allow blood to clot 30 minutes.
4. Centrifuge for 10 minutes.

Transport: Store specimen at 2°C to 8°C after collection and ship the same day per packaging instructions included with the provided shipping box.

Requisition Form and Ordering Instructions:

Completion of patient demographic information is required for state reporting of COVID-19 testing. These include patient name, address, phone number, date of birth, and gender.

Stability:

Ambient (15-25°C): 4 days

Refrigerated (2-8°C): 7 days

Frozen (-20°C): 30 days

Collection Instructions: Do not freeze any samples stored in a primary tube.

Causes for Rejection: Improper labeling; samples not stored properly; samples older than stability limits; gross hemolysis; gross lipemia; gross icterus; frozen Serum Separator Tube (SST)

Methodology: Immunoassay (IA)

Turn Around Time: 3 to 5 days

Reference Range:

*This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic method should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to exclude SARS-CoV-2 infection or to inform infection status.

Clinical Significance: Detection of IgG antibodies may indicate exposure to SARS-CoV-2 (COVID-19). It usually takes at least 10 days after symptom onset for IgG to reach detectable levels. An IgG positive result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between IgG positivity and immunity to SARS-CoV-2 has not yet been firmly established. Antibody tests have not been shown to definitively diagnose or exclude SARS-CoV-2 infection. Positive results could also be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by molecular testing methods, consistent with a patient's clinical findings.

The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.