

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

CPT Code: 86769

Order Code: 34499

ABN Requirement: No

Tests Included: SARS-CoV-2 Ab (IgG), Spike, Semiquantitative

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.

Collection Instructions: Do not freeze whole blood or any specimen stored in a primary tube.

Transport: Store serum 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.

Completion of 11 patient assessment questions required for order entry of the test. These questions will assess if this is the first test for the patient, if the patient is employed in healthcare, if they are symptomatic, date of symptom onset, hospitalization, ICU admission, residency in congregate care setting, pregnancy status, race, ethnicity, and specimen source.

A document with the patient assessment questions can be accessed [here](#).

Please print, complete, and attach this document to Cleveland HeartLab requisition forms when ordering COVID-19 testing.

Stability:

Ambient (15-25°C): 4 days

Refrigerated (2-8°C): 7 days

Frozen (-20°C): 30 days

Methodology: Immunoassay (IA)

Turn Around Time: 3 to 5 days

Reference Range:

NOTE: 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 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, OC43, or 229E.

Clinical Significance: This test is intended as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. This test may be positive in vaccinated patients. It is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. This assay should not be used to diagnose acute SARS-CoV-2 infection.

The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from reinfection. Individuals that have been vaccinated with a SARS-CoV-2 spike or receptor-binding domain vaccine may be positive in this test, and their sero-positivity may or may not be due to a SARS-CoV-2 infection.

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.