

# **SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), IA**

**CPT Code:** 86769 (x2)

**Order Code:** 31672

**Tests Included:** SARS-CoV-2 Ab (IgG), Nucleocapsid, Qualitative; SARS-CoV-2 Ab (IgM), Spike, Qualitative

**ABN Requirement:** No

**Specimen:** Serum

**Volume:** 1.0 mL

**Minimum Volume:** 1.0 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

**Causes for Rejection:** Gross hemolysis, gross lipemia; gross icterus; frozen SST specimen

**Methodology:** Immunoassay (IA)

**Turn Around Time:** 3 to 5 days

**Reference Range:** See Laboratory Report

**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:** Detection of IgG and IgM antibodies may indicate exposure to SARS-CoV-2 (COVID-19). IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, with IgG antibodies typically reaching detectable levels simultaneously or 1-2 days later. Separate results will be provided for IgM and IgG. A positive antibody result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between 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. 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.*