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**Lab Dept:** Serology

**Test Name:** SARS COV-2 SPIKE ANTIBODY

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***General Information***

**Lab Order Codes:** COVSQ

**Synonyms:** SARS-CoV-2 Spike Ab, Semi-Quant

**CPT Codes:** 86769 - Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

**Test Includes:** SARS COV-2 Spike Antibody reported as Negative or Positive This test provides semi-quantitative detection of serum antibodies against spike glycoprotein of the severe acute respiratory syndrome coronavirus. Both vaccine and active infection can stimulate antibodies against this domain.

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***Logistics***

**Test indications:** Aiding in the identification of individuals with an adaptive immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), indicating prior infection or vaccination. Manufacture of COVID-19 convalescent plasma.

This test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection and/or vaccination.

This test will detect antibodies developed due to prior or current infection and will likely detect antibodies against spike glycoprotein of SARS-CoV-2 generated following vaccination. This test will not differentiate between the 2 events. The absence of antibodies in this assay does not rule out recent infection.

For confirmation of prior infection in the presence of vaccination, order Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2), Nucleocapsid, Total Antibody, Serum.

**Lab Testing Sections:** Serology - Sendouts

**Referred to:** Mayo Clinic Laboratory (Mayo Test Code: COVSQ)

**Phone Numbers:** MIN Lab: 612-813-6280

STP Lab: 651-220-6550

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 1 – 3 days, performed Monday - Saturday

**Special Instructions:** Molecular testing is recommended for diagnosis of coronavirus disease COVID-19 in symptomatic patients.

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### ***Specimen***

**Specimen Type:** Blood

**Container:** SST (Gold, marble or red) tube

**Draw Volume:** 3 mL (Minimum: 2.25 mL) blood

**Processed Volume:** 1 mL (Minimum: 0.75 mL) serum

**Collection:** Routine blood collection

**Special Processing:** Lab Staff: Allow specimen to clot. Centrifuge and aliquot serum to plastic vial. Ship and store at refrigerated temperatures.

Serum specimen stable refrigerated (preferred) for 14 days, frozen for 28 days, ambient for 72 hours.

**Patient Preparation:** For 24 hours before specimen collection, avoid high doses of supplements containing biotin (vitamin B7), which is commonly found in hair, skin and nail supplements and multivitamins.  
See [Limitations](#)

**Sample Rejection:** Gross hemolysis; mislabeled or unlabeled specimens

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### ***Interpretive***

<b>Reference Range:</b>	<p>Negative – No antibodies to SARS-CoV2 spike glycoprotein detected. Negative results may occur in serum collected too soon following infection or vaccination, in immunosuppressed patients or in patients with mild or asymptomatic infection. This test does not rule out active or recent coronavirus disease COVID-19 infection or vaccination. Follow-up testing with a molecular test for SARS-CoV-2 is recommended in symptomatic patients.</p> <p>Note: This assay provides qualitative and semi-quantitative results for the presence of antibodies to the receptor binding domain on the severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) spike glycoprotein. Both vaccine and active infection can stimulate antibodies against this domain.</p> <p>Positive: antibodies to the SARS-CoV2 spike protein detected These results suggest recent or prior SARS-CoV2 infection or vaccination. Antibody levels greater than or equal to 0.80 U/mL are considered positive in this assay. Not minimum antibody level or threshold has been established to indicate long-term protective immunity against re-infection. Serologic results should not be used to diagnose recent SARS-CoV-2 infection. False-positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.</p>
<b>Critical Values:</b>	N/A
<b>Limitations:</b>	<p>The sensitivity of this assay in early infection is unknown. Negative results do not preclude severe respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. If an acute infection is suspected, direct testing for SARS-CoV-2 virus is necessary.</p> <p>False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.</p> <p>It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.</p> <p>In rare cases, interferences due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur.</p> <p>Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Extremely high concentrations of biotin in in patient serum due to heavy administration or supplementation of biotin may falsely depress Anti-SARS-CoV-2 antibody detection.</p>
<b>Methodology:</b>	Electrochemiluminescence Immunoassay (ECLIA)
<b>References:</b>	<a href="#">Mayo Clinic Laboratory</a> (July 2023)
<b>Updates:</b>	7/5/2023: Updated limitations, synonyms, test indications. Added Mayo test code and specimen stability.