Lab Dept: Serology

Test Name: SARS-CoV-2 NUCLEOCAPSID IGG ANTIBODY

General Information

Lab Order Codes:	COR2G
Synonyms:	Sever Acute Respiratory Syndrome Coronavirus 2 IgG Antibody; SARS-CoV-2 Nucleocapsid Total Antibody
CPT Codes:	86769 – Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
Test Includes:	SARS-CoV-2 nucleocapsid antibody reported as positive or negative.

Logistics

Test indications:	This test provides qualitative detection of serum antibodies against the nucleocapsid protein of SARS-CoV-2, the causative agent of COVID-19. This test will not yield a positive result following vaccination against SARS-CoV-2. This test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
Lab Testing Sections:	Serology - Sendouts
Referred to:	Mayo Clinic Laboratories (Mayo test: COVTA)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1-3 days
Special Instructions:	Serologic testing should not be used to diagnose SARS-CoV-2 infection in symptomatic patients presenting soon after symptom onset due to risk of false-negative serologic results.

Specimen

Specimen Type:	Blood

Container:	SST (Red, marble or gold) tube
Draw Volume:	2 mL (Minimum: 1.5 mL) blood
Processed Volume:	0.6 mL (Minimum: 0.5 mL) serum
Collection:	Routine blood collection
Special Processing:	Lab Staff: Allow specimen to clot. Centrifuge within 2 hours of collection 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 7 days.
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:	Mislabeled or unlabeled specimens; gross hemolysis; gross lipemia; gross icterus.

Interpretive

Reference Range:	Negative INTERPRETATION: Negative: No antibodies to SARS-CoV-2 detected. Negative results may occur in serum collected too soon following infection, in patients who are immunosuppressed, or in patients with mild or asymptomatic infection. This test does not rule out active or recent COVID-19 and will not detect SARS-CoV-2 vaccine-induced antibodies. Follow-up testing with a molecular test is recommended in symptomatic patients. Positive:SARS-CoV-2 antibodies to the nucleocapsid protein detected. Results suggest recent or prior infection with SARS-CoV-2. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. Serologic results should not be used to diagnose recent SARS-CoV-2 infection. Protective immunity cannot be inferred based on these results alone. False-positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
Critical Values:	N/A
Limitations:	The sensitivity of Roche Elecsys Anti-SARS-CoV-2 test in early infection is unknown. Negative results do not preclude SARS-CoV-2 infections. If an acute infection is suspected, direct testing for SARS-CoV-2 virus is necessary. See Ordering Guidance.

This test detects total antibodies against the SARS-CoV-2 nucleocapsid protein. All current SARS-CoV-2 vaccines induce antibodies to the spike glycoprotein only. Therefore, this assay will not detect SARS-CoV-2 vaccine induced anti-spike glycoprotein antibodies and cannot be used to measure vaccine response.

False-positive results for Roche Anti-SARS-CoV-2 IgG test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Extremely high concentrations of biotin in patient serum due to heavy administration or supplementation of biotin may falsely depress anti-SARS-CoV-2 antibody detection.

Performance characteristics have not been established for the following specimen characteristics:

- Potential endogenous interferences, eg, hemolysis, bilirubin, rheumatoid factors, and pharmaceutical compounds other than biotin, have not been tested, and therefore, interference cannot be excluded
- Containing particulate matter
- Cadaveric specimens

Methodology: Chemiluminescence Immunoassay

References: Mayo Clinic Laboratories (June 2023)

Updates: 7/21/2023: Updated Mayo test code, test name, limitations, synonyms, test indications, methodology. Added specimen stability.