MAYO CLINIC LABORATORIES

Test Definition: COVSQ

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Spike Antibody, Semi-Quantitative, Serum

Overview

Useful For

Aiding in the identification of individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection or vaccination

Highlights

This test provides semi-quantitative detection of serum antibodies against the spike glycoprotein of the SARS-CoV-2, the causative agent of COVID-19.

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.

Fact sheets for this emergency use authorization assay can be found at the following links:
For healthcare providers: www.fda.gov/media/144035/download
For patients: www.fda.gov/media/144036/download

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test will detect antibodies developed due to prior or current infection and will detect antibodies against the spike glycoprotein of SARS-CoV-2 generated following vaccination. This test will not differentiate between the two 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 COVTA / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2), Nucleocapsid, Total Antibody, Serum.

Molecular testing is recommended for diagnosis of COVID-19 in symptomatic patients. For more information see HPCOV / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Molecular Detection, Varies.

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For the most up-to-date coronavirus disease 2019 (COVID-19) epidemiology and testing recommendations, visit www.cdc.gov/coronavirus/2019-ncov/index.html.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	72 hours	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped, single-stranded RNA virus of the family Coronaviridae, genus *Betacoronavirus*. All coronaviruses share similarities in the organization and expression of their genome, which encodes 16 nonstructural proteins and the 4 structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N).

Results are for the semiquantitative detection of total antibodies (without differentiation between immunoglobulin classes) against the SARS-CoV-2 spike protein, and specifically against the receptor binding domain. Antibodies to SARS-CoV-2 are detectable in over 90% of patients by 2 weeks after symptom onset or vaccination and can remain detectable for months to years following resolution of infection and after repeat vaccination.

Reference Values

An interpretative report will be provided.

Interpretation

This assay provides qualitative and semi-quantitative results for the presence of antibodies to the receptor binding domain on the SARS-CoV-2 spike glycoprotein. Both vaccine and recent infection can stimulate antibodies against this domain.

Negative:
No antibodies to SARS-CoV-2 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 COVID-19 infection. Follow-up testing with a molecular test for SARS-CoV-2 is recommended in symptomatic patients.

Positive:
Antibodies to the SARS-CoV-2 spike glycoprotein detected. Results suggest recent or prior SARS-CoV-2 infection or vaccination. Serologic results should not be used to diagnose recent SARS-CoV-2 infection as antibodies remain detectable for months to years after infection/vaccination.

For the manufacture of COVID-19 convalescent plasma using the Roche Diagnostics anti-SARS-CoV-2 spike electro-chemiluminescence immunoassays, per current US Food and Drug Administration Emergency Use Authorization guidelines, high-titer convalescent plasma is defined as plasma units with a semi-quantitative value of 132 U/mL and above (see appendix A: www.fda.gov/media/141477/download).

Cautions

Negative results do not preclude SARS-CoV-2 infections. If an acute infection is suspected, direct testing for SARS-CoV-2 virus is necessary.

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.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin, or ruthenium can occur.

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.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human antimouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium rarely occur and may also interfere with this assay. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Zhang W, Du RH, Li B, et al. Molecular and serologic investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerg Microbes Infect. 2020;9(1):386-389. doi:10.1080/22221751.2020.1729071
2. Okba N, Muller MA, Li W, et al. Severe acute respiratory syndrome coronavirus 2-specific antibody responses in coronavirus disease 2019 patients. Emerg Infect Dis. 2020;26(7). doi:10.3201/eid2607.200841
3. Guo L, Ren L, Yang S, et al. Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). Clin Infect Dis. 2020;ciaa310. doi:10.1093/cid/ciaa310
4. Wolfel R, Corman VM, Guggemos W, et al. Virological assessment of hospitalized patients with COVID-2019. Nature. 2020;581(7809):465-469. doi:10.1038/s41586-020-2196-x
5. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol. 2016;24(6):490-502. doi:10.1016/j.tim.2016.03.003
6. Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020;382(8):727-733. doi:10.1056/NEJMoa2001017
7. Liu L, Liu W, Zheng Y, et al. A preliminary study on serological assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 admitted hospital patients. Microbes Infect. 2020;22(4-5):206-211. doi:10.1016/j.micinf.2020.05.008
8. Zhang W, Du RH, Li B, et al. Molecular and serologic investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerg Microbes Infect. 2020;9(1):386-389. doi:10.1080/22221751.2020.1729071

Performance

Method Description

Testing is performed on a Roche cobas e801. The Roche Elecsys Anti-SARS-CoV-2 S assay uses a double-antigen sandwich principle. This assay predominantly detects anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG but anti-SARS-CoV-2 IgA and IgM as well. Patient specimen is added to biotinylated SARS-CoV-2 S-receptor binding domain (RBD)-specific recombinant antigen and SARS-CoV-2 S-RBD-specific recombinant antigen labeled with a ruthenium complex to form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. This reaction mixture is aspirated into the measuring cell where the bound microparticles are magnetically captured onto the surface of the electrode, and unbound substances are removed. Voltage is applied to the electrode inducing a chemiluminescent emission, which is then measured against a calibration curve to determine the amount of SARS-CoV-2 S antibody in the patient specimen.(Package insert: cobas Elecsys Anti-SARS-CoV-2 S Antibody. Roche Diagnostics; V 1.0 English, 12/2020)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has received Emergency Use Authorization (EUA) by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86769

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COVSQ	SARS-CoV-2 Spike Ab, Semi-Quant, S	94769-7

Result ID	Test Result Name	Result LOINC® Value
COVIN	SARS-CoV-2 Spike Ab, Interp, S	94661-6
COVQN	SARS-CoV-2 Spike Ab, Quant, S	94769-7