MAYO CLINIC LABORATORIES

Test Definition: COVSQ

SARS-CoV-2 Spike Ab, Semi-Quant, S

Overview

Useful For

Aiding in the identification of individuals with an adaptive immune response to severe acute respiratory syndrome coronavirus 2 , indicating prior infection or vaccination

Manufacture of coronavirus disease 2019 (COVID-19) convalescent plasma

Highlights

This test provides semi-quantitative detection of serum antibodies against the spike glycoprotein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (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 (EUA) 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 also likely detect antibodies against

spike glycoprotein of severe acute respiratory syndrome coronavirus 2 (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 COVTA / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2), Nucleocapsid, Total Antibody, Serum.

Molecular testing is recommended for diagnosis of coronavirus disease 2019 (COVID-19) in symptomatic patients. For more information see:

-COVOO / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA Detection, Varies

-RSARS / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV-2), Molecular Detection, Rapid, Varies

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

Necessary Information

1. Patient's race and ethnicity, as well as collection date, are required.

2. If ordering electronically, answers must be provided for the order entry questions.

3. If not ordering electronically, patient race and ethnicity must be provided on the request form.

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 1 mL

Forms

If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Gross icterus	OK

Specimen Minimum Volume

0.75 mL

Specimen Stability Information

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

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 semi-quantitative detection of total antibodies (without differentiation between immunoglobulin classes) against the SARS-CoV-2 spike protein, specifically against the receptor binding domain). Antibodies to SARS-CoV-2 are detectable in over 90% of patients by two weeks after symptom onset or vaccination. While antiviral antibodies remain for at least 3 to4 months postinfection, the long-term duration for antibodies continues to be defined. Patients may have detectable virus present for several weeks following seroconversion.

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 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike glycoprotein. Both vaccine and active 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 coronavirus disease 2019 (COVID-19) infection or vaccination. 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. These results suggest recent or prior SARS-CoV-2 infection or vaccination. Antibody levels greater than or equal to 0.80 U/mL are considered positive by this assay. No 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.

For the manufacture of COVID-19 convalescent plasma using the Roche Diagnostics anti-SARS-CoV-2 spike electro-chemiluminescence immunoassays, per current FDA 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

The sensitivity of Roche Elecsys Anti-SARS-CoV-2 test in early infection is unknown. Negative results do not preclude severe acute respiratory syndrome coronavirus 2 (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.

It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

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.

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 Feb 17;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 Apr 8;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 May;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 Jun;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 Feb 20;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 May-Jun;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 Feb 17;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

Specimen Retention Time

3 Months

Performing Laboratory Location

Rochester

Fees & Codes

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	Reporting Name	LOINC®
SRACE	Patient's Race	72826-1
SETHN	Patient's Ethnicity	69490-1
COVIN	SARS-CoV-2 Spike Ab, Interp, S	94762-2
COVQN	SARS-CoV-2 Spike Ab, Quant, S	94769-7