MAYO CLINIC LABORATORIES

Test Definition: COVTA

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Nucleocapsid, Total Antibody, Serum

Overview

Useful For
Aiding in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection

Highlights
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.

Fact sheets for this emergency use authorization assay can be found at the following links:
For healthcare providers: www.fda.gov/media/137603/download
For patients: www.fda.gov/media/137604/download

Method Name
Chemiluminescence Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Ordering Guidance
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

For the most up to date 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: 0.6 mL
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume
0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Ambient	7 days	
	Refrigerated (preferred)	14 days	
	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).

Detection of antibodies against the SARS-CoV-2 nucleocapsid indicates recent or prior infection with the virus. This assay will not detect an immune response to SARS-CoV-2 vaccination as the N antigen is not in current vaccine preparations.

Reference Values
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 infection and will not detect SARS-CoV-2 vaccine-induced antibodies. Follow-up testing with a

molecular test is recommended in symptomatic patients.

Positive:
Severe acute respiratory syndrome coronavirus 2 antibodies to the nucleocapsid protein detected. Results suggest recent or prior infection with SARS-CoV-2. Serologic results should not be used to diagnose recent SARS-CoV-2 infection.

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. 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

Clinical Reference

1. Zhang W, Du RH, Li B, et al. Molecular and serological 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 NMA, Müller MA, Li W, et al. Severe acute respiratory syndrome coronavirus 2-specific antibody responses in coronavirus disease patients. Emerg Infect Dis. 2020;26(7):1478-1488. 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;71(15):778-785. 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 serological 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 assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2. In the first incubation the sample, biotinylated SARS-CoV-2-specific recombinant antigen and SARS-CoV-2-specific recombinant antigen labeled with a ruthenium complex form a sandwich complex. During the second incubation, after addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed. Application of a voltage to the electrode induces chemiluminescent emission, which is measured by a photomultiplier. Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.(Package insert: Elecsys Anti-SARS-CoV-2. Roche Diagnostics; v 4.0, 08/2020)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

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

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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
COVTA	SARS-CoV-2 Nucleocapsid Total Ab, S	94762-2

Result ID	Test Result Name	Result LOINC® Value
COVTI	SARS-CoV-2 Nucleocapsid Total Ab, S	94762-2