Test Definition: COR2G

SARS Coronavirus 2 IgG Ab, S

Overview

Useful For

Detection of IgG-class antibodies against severe acute respiratory syndrome coronavirus 2, agent of coronavirus disease 2019 (COVID-19)

Highlights

This test provides qualitative detection of serum IgG-class antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19).

Test should not be used to detect recent or acute COVID-19.

Testing is only recommended in individuals at least 10 days post-symptom onset or following exposure to individuals with confirmed COVID-19.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Advisory Information

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

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

-SARS2 / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA, Varies

Specimen Required

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.6 mL

Collection Instructions: Centrifuge and aliquot serum.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat inactivated serum	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	30 days	

Clinical and Interpretive

Clinical Information

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-stranded RNA virus that causes coronavirus disease 2019 (COVID-19). Like other coronaviruses that infect humans, SARS-CoV-2 can cause both upper and lower respiratory tract infection. Symptoms can range from mild (ie, the common cold) to severe (ie, pneumonia) in both healthy and immunocompromised patients. SARS-CoV-2 transmission occurs primarily via respiratory droplets. During the early stages of COVID-19, symptoms maybe nonspecific and resemble other common respiratory tract infections, such as influenza.

The incubation period for COVID-19 ranges from 5 to 7 days. Typically, immunocompetent individuals with COVID-19 develop detectable IgG-class antibodies against SARS-CoV-2 approximately 8 to 11 days following onset of symptoms. Patients tested prior to this time may be negative for SARS-CoV-2 IgG antibodies.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Negative:

No IgG antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) detected. Negative results may occur in serum collected too soon following infection, in immunosuppressed patients, or in some individuals with prior mild illness. Follow-up testing with a molecular test is recommended in symptomatic patients. This test should not be used to exclude active/recent coronavirus disease 2019 (COVID-19).

Indeterminate (Index of > or =1.01 to <1.21):

Repeat testing in 7 to 10 days may be considered to determine definitive serologic status.

Positive:

SARS-CoV-2 IgG antibodies 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. Infrequently, false-positive results may be due to prior infection with other human coronaviruses.

Cautions

Symptomatic patients suspected to have acute coronavirus disease 2019 (COVID-19) should be tested using a molecular assay to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA. For more information see:

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

-SARS2 / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA, Varies

Serologic testing should not be used to diagnose SARS-CoV-2 infection in symptomatic patients presenting soon after symptom onset due to the risk of false-negative serologic results.

False-negative serologic results may occur in serum collected too soon after symptom onset. Typically, the majority of patients seroconvert between 8 to 11 days post-symptom onset; specimens collected and tested prior to this time point may be negative.

False-positive results may occur in a small percentage of individuals. Preliminary data indicate minimal cross-reactivity between antibodies to SARS-CoV-2 and the commonly circulating coronavirus strains, OC43, 229E, NL63, and HKU1.

Clinical Reference

1. OKBA N,Muller MA,Li W,et al: SARS-CoV-2 Specific Antibody Responses in COVID-19 Patients. medRxiv2020.03.18.20038059. doi: 10.1101/2020.03.18.20038059

2. Amanat F,Nguyen T,Chromikova V,et al: A Serologic Assay to Detect SARS-CoV-2 Seroconversion in Humans. medRxiv2020.03.17.20037713.doi: 10.1101/2020.03.17.20037713

3. Liu L: A preliminary study on serological assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 admitted hospital patients. 2020, in press. doi: 10.1101/2020.03.06.20031856

4. Zhang W: Molecular and serologic investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerging Microbes Infect 2020, in press. doi: 10.1080/22221751.2020.1729071

Performance

Method Description

This enzyme-linked immunosorbent assay (ELISA) kit is designed, developed, and produced for the qualitative measurement of the human anti-SARS-CoV-2 IgG antibody in serum. This assay utilizes the microplate based enzyme immunoassay technique. Assay controls and 1:100 diluted serum samples are added to the microtiter wells of a microplate that was coated with SARS-CoV-2 recombinant full length nucleocapsid protein. After the first incubation period, the unbound protein matrix is removed with a subsequent washing step. A horseradish peroxidase (HRP)-labeled polyclonal goat antihuman IgG tracer antibody is added to each well. After an incubation period, an immunocomplex of SARS-CoV-2 recombinant antigen-human anti-SARS-CoV-2IgG antibody-HRP labeled antihuman IgG tracer antibody is formed if there is specific coronavirus IgG antibody present in the tested specimen.

The unbound tracer antibody is removed by the subsequent washing step. HRP-labeled tracer antibody bound to the well is then incubated with substrate solution in a timed reaction and then measured in a spectrophotometric microplate reader. The enzymatic activity of the tracer antibody bound to the anti-SARS-CoV-2 IgG on the wall of the microtiter well is proportional to the amount of the anti-SARS-CoV-2 IgG antibody level in the tested specimen.(Package insert: EDI Novel Coronavirus COVID-19 IgG ELISA Kit, Epitope Diagnostics, Inc., KT-1032/IVD/US-ONLY-1. 03/2020)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Sunday; 10 a.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

86769

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
COR2G	SARS Coronavirus 2 IgG Ab, S	94563-4

Result ID	Test Result Name	Result LOINC Value
CR2G	SARS-CoV-2 IgG Ab	94563-4
DEXRG	SARS-CoV-2 IgG Index	94505-5