MAYO CLINIC LABORATORIES

Test Definition: FSARO

Immuno-CRON SARS-CoV-2 Omicron Neutralizing Antibody Test

Overview

Useful For

Measurement of specific neutralizing antibodies capable of inhibiting SARS-CoV-2 Omicron variant.

Method Name

Virus Neutralizing Antibody Test

NY State Available

No

Specimen

Specimen Type

Serum

Ordering Guidance

Molecular testing is recommended for diagnosis of coronavirus disease 2019 (COVID-19) in symptomatic patients.

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Draw blood in a serum gel tube(s), plain red-top tube(s) is acceptable. Centrifuge and aliquot serum; send one aliquot. DO NOT heat-inactivate. Ship 1 mL serum in a plastic vial, frozen.

Specimen Minimum Volume

0.2 mL

Reject Due To

Gross Hemolysis	Reject
Gross Lipemia	Reject
Gross Icterus	Reject
Other	NA

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Refrigerated	5 days	
	Ambient	72 hours	

Clinical & 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 3 to 14 days. Typically, immunocompetent individuals with COVID-19 develop detectable antibodies against SARS-CoV-2 approximately 8 to 11 days following onset of symptoms or vaccination. Patients tested prior to this time may be negative for SARS-CoV-2 antibodies. SARS-CoV-2 Omicron variant, is a viral variant of ancestral SARS-CoV-2, which contains numerous mutations in the spike glycoprotein. As a result, neutralizing antibodies generated from prior infection with SARS-CoV-2 (ancestral or other variants) or vaccination with an approved anti-SARS-CoV-2 spike vaccine, are not as effective at neutralizing SARS-CoV-2 Omicron variant. However, cross protection is observed, particularly in individuals receiving three doses of an approved vaccine. IMMUNO-CRON is specifically designed to measure neutralizing antibodies against SARS-CoV-2 Omicron variant.

Reference Values

Negative (applies to all ages)

Interpretation

POSITIVE: SARS-CoV-2 Omicron variant neutralizing antibodies detected. Results suggest recent or prior infection with SARS-CoV-2 Omicron variant or vaccination against SARS-CoV-2, resulting in the generation of neutralizing antibodies against SARS-CoV-2 Omicron variant. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended.

NEGATIVE: No neutralizing antibodies to SARS-CoV-2 Omicron variant detected. Negative results may occur in samples collected too soon following infection or vaccination, in immunosuppressed patients, in some individuals with prior mild illness, in individuals with waning immunity.
BORDERLINE: An borderline result means no determination regarding the presence or absence of neutralizing antibodies to SARS-CoV-2 Omicron variant can be made.

INFORMATION ABOUT TITER VALUES

The titer value represents the level of neutralizing antibodies present in a blood sample, which is determined as the amount of sample required to inhibit 50% of the virus used in the IMMUNO-CRON test. Titer values are expressed as 50% inhibitory concentrations, where the concentration is the reciprocal of the dilution used for testing, such that samples with higher titer have more neutralizing antibodies against SARS-CoV-2 Omicron variant. Please refer to the

Imanis website for the most up to date information: www.imanis-immunocov.com.

INFORMATION ABOUT THE IMMUNO-COV TEST

This test was performed in the Imanis CLIA laboratory as a high complexity laboratory developed test. The test quantitatively measures the level (titer) of antibodies in a blood sample capable of blocking a live SARS-CoV-2 mimic virus from infecting Vero-ACE2 cells. The test limit of detection (LOD) is an IC50 of 40. The test upper limit of quantitation is an IC50 of 5120.

More detailed information about the test is available at the Imanis website: www.imanis-immunocov.com.

Convert from	Convert to	Multiply by
IU/mL	VNT	1.4380
VNT	IU/mL	0.6954

Cautions

Negative results do not rule out SARS-CoV-2 infection or prior vaccination against SARS-CoV-2. The IMMUNO-COV test measures neutralizing antibodies against SARS-CoV-2 ancestral strain and can be used to detect neutralizing antibodies against SARS-CoV-2 that may not have neutralizing activity against SARS-CoV-2 Omicron. IMMUNO-COV is offered as a stand alone test or as an add on to the IMMUNO-CRON test aspart of IMMUNO-CRON(+).

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or inform infection status.

Positive results may be due to vaccination, prior infection with other SARS-CoV-2 variants, or prior infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC63, or 229E.

Performance

Method Description

The Neutralizing Antibody Assay is a functional assay that detects the presence of specific neutralizing antibodies capable of inhibiting VSV-SARS2(Omi)-Fluc infection. Vero cells (African green monkey-derived kidney epithelial cells) that have been stably transduced to overexpress angiotensin converting enzyme 2 (ACE2) are infected with a virus displaying the SARS-CoV-2 Omicron variant spike glycoprotein on its surface and encoding the same SARS-CoV-2 Omicron variant spike glycoprotein and a firefly luciferase (Fluc) reporter in its genome. When this virus infects the Vero cells, the cells begin to produce firefly luciferase. A luciferase substrate is then added to assay plates to allow for a luminescence readout, wherein total luminescence (relative light units, RLU) corresponds to the extent of virus infection. The ability of antibodies in human serum to block infection of Vero-ACE2 cells by VSV-SARS2-Fluc, and thereby to prevent luciferase expression serves as a proxy readout for antibodies capable of neutralizing SARS-CoV-2 infection.

PDF Report

Referral

Day(s) Performed
Monday through Friday

Report Available
9-11 days

Performing Laboratory Location
Imanis Life Sciences

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 Regional Manager. For assistance, contact Customer Service.

Test Classification
This test was developed, and its performance characteristics determined by Imanis Life Sciences in a manner consistent with CLIA regualtions. This test has not been reviewed, cleared, or approved by the U.S. Food and Drug Administration.

CPT Code Information
86409

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FSARO	SARS-CoV-2 (Omicron) NAb	Not Provided

Result ID	Test Result Name	Result LOINC® Value
FSARO	SARS-CoV-2 (Omicron) NAb	95410-7