

## Overview

### Useful For

Measurement of specific neutralizing antibodies capable of inhibiting ancestral SARS-CoV-2 and 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

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**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 may be 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. The two assays performed as part of the IMMUNO-CRON(+) test are designed to measure neutralizing antibodies against both ancestral SARS-CoV-2 and SARS-CoV-2 Omicron variant.

**Reference Values**

Negative (applies to all ages)

**Interpretation**

**Note:** a result will be indicated for both ancestral SARS-CoV-2 and SARS-CoV-2 Omicron variant.

**Negative:** No neutralizing antibodies to ancestral SARS-CoV-2 or 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, or in individuals with waning immunity.

**Borderline:** A borderline result means no determination regarding the presence or absence of neutralizing antibodies to ancestral SARS-CoV-2 or SARS-CoV-2 Omicron variant can be made.

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

**INFORMATION ABOUT TITER VALUES**

The titer value represents the level of neutralizing antibodies present in a blood sample. For the IMMUNO-CRON (Omicron variant) assay, titer 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. For the IMMUNO-COV (Ancestral) assay, titers have been calibrated to World Health Organization International Units per milliliter (IU/mL). Please refer to the Imanis website for the most up to date information: [www.imanis-immunocov.com](http://www.imanis-immunocov.com).

**INFORMATION ABOUT THE IMMUNO-COV TEST**

This test is a combination of two independent assays, which were performed in the Imanis CLIA laboratory as high complexity laboratory developed tests. Together, the assays quantitatively measure the level (titer) of antibodies in a blood sample capable of blocking live SARS-CoV-2 mimic viruses (Ancestral or Omicron variant) from infecting Vero-ACE2 cells. For the IMMUNO-CRON assay, the limit of detection (LOD) is an IC50 of 40 and the upper limit of quantitation is an IC50 of 5120. For the IMMUNO-COV assay, the limit of detection (LOD) is 22 IU/mL and the upper limit of quantitation is 20,862 IU/mL.

More detailed information about the test is available at the Imanis website: [www.imanis-immunocov.com](http://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.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to 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-Fluc or 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 ancestral or Omicron variant spike glycoprotein on its surface and encoding the same spike glycoprotein and a firefly luciferase (Fluc) reporter in its genome. When either 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 or VSV-SARS2(Omi)-Fluc, and thereby to prevent luciferase expression serves as a proxy readout for antibodies capable of neutralizing ancestral SARS-CoV-2 or SARS-CoV-2 Omicron variant 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 requirements. 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
FSARM	SARS-CoV-2 (Muiltplex) NAb	Not Provided

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