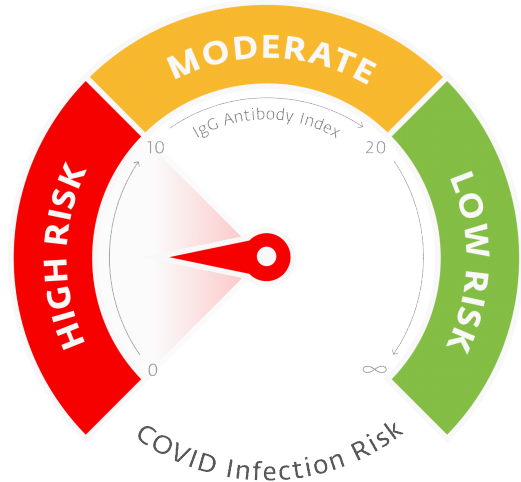


Patient		Specimen		Physician	
Name	HighRisk, 231	Case Number	ID22-000171	Name	Test, Physician
DOB	1999-01-01	Date Collected	2022-03-21	Institution	Office
Gender		Date Received	2022-03-21	Phone	+1 (201) 644-0229
Phone		Date Reported	2022-03-21	Ext. Accession ID	7868707
Indication		Specimen Type	Serum		

COVID-19 IMMUNE INDEX™ TEST

Antibodies to spike protein S1 receptor-binding domain

Antibody	Value	Result
IgA	2	Positive
IgG	1.6	Positive
IgM	0.12	Negative



Reference cut-off index values:

- <0.8.....Negative
- 0.8 - <1.0.....Indeterminate
- ≥1.0.....Positive

Methodology

Chemiluminescence

Comment

Positive results for IgG, IgA and IgM antibodies against SARS-CoV-2 are generally indicative of an individual's current or prior infection with the COVID-19 virus, However, the duration that antibodies remain in circulation is not yet established.

Positive IgM and IgA indicates recent infection with COVID-19. IgA also confers mucosal immunity. However, IgM and IgA do not provide long-term immunity against the virus.

IgG contributes to the long-term immunity. Internal studies comparing antibody assay cutoff values with the plaque reduction neutralization test, the "Gold Standard" for virus neutralization, showed the following results: There is 100% neutralization of virus above IgG titers of 20. IgG titers from 10-20 reduces effective virus neutralization by 25%. Below IgG titers of 10 the effectiveness of virus neutralization decreases considerably.

Negative or indeterminate results indicate lack of circulating antibodies.

Booster vaccinations could be considered when there is lack of circulating antibodies. However, the test results should always be considered in the context of the patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.



DIAGNOSTICS

References

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Valcourt EJ, Manguiat K, Robinson A, Lin Y-C, Abe KT, Mubareka S, et al., 2021. Evaluating humoral immunity against SARS-CoV-2: validation of a plaque-reduction neutralization test and a multi laboratory comparison of conventional and surrogate neutralization assays. Microbiol Spectr 9: e00886-21. <https://doi.org/10.1128/Spectrum.00886-21>.

Disclaimer

This is a lab developed test. This test has been validated in accordance with New York State Department of Health guidelines and FDA's guidance document (Policy for diagnostic testing in laboratories certified to perform high complexity testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 the public health emergency) issued on February 29th, 2020. This test has not been reviewed by the FDA. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Electronically Signed By:

Zheng, Sophia
2022-03-21

Assistant Laboratory Director:

John J. Rushton, PhD, MBA