

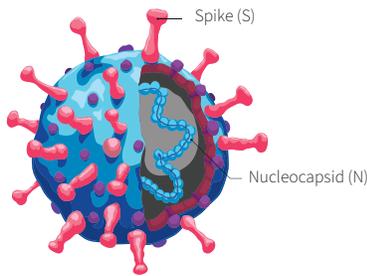


SARS-CoV-2 Antibody Testing Options

Qualitative and semi-quantitative antibody testing can provide insights to a patient's immune response to SARS-CoV-2.

What is the difference between the spike and nucleocapsid proteins?

Nucleocapsid and spike are viral structural proteins. The nucleocapsid protein helps organize viral RNA while the spike protein mediates viral entry into human cells. Antibodies to the SARS-CoV-2 viral spike protein have been shown to have neutralizing effects.¹⁻³ Current vaccines were designed to elicit antibodies to the spike protein. Labcorp offers options for testing antibodies to spike or nucleocapsid proteins.



Spike (S): Antibodies to the spike protein are produced after vaccination or prior infection.¹⁻³

Nucleocapsid (N): Antibodies to the nucleocapsid protein identify individuals who have had a recent or prior COVID-19 infection, but are not useful for detecting antibodies elicited by currently available SARS-CoV-2 vaccines.

If I want to test my patient for...	Consider...	Keep in mind...
<p>Antibodies induced by natural infection and possibly by vaccination</p> <p>AND</p> <p>quantification is desired</p>	<ul style="list-style-type: none"> SARS-CoV-2 Semi-Quantitative Total Antibody [164090] <p>OR</p> <ul style="list-style-type: none"> SARS-CoV-2 Semi-Quantitative IgG Antibody, Spike [164055] 	<p>SARS-CoV-2 Semi-Quantitative Total Antibody [164090] tests for antibodies of any class (IgM, IgG, IgE) to the receptor binding domain (RBD) of the viral spike protein.</p> <p>SARS-CoV-2 Semi-Quantitative IgG Antibody, Spike [164055] tests for IgG antibodies with affinity to any part of the viral spike protein.</p> <p>These tests provide a numerical value on a result report; however, reported values do not have a clear correlation to immunity and the test values are not comparable to one another.</p>
<p>Antibodies resulting ONLY from natural infection...</p>	<p>SARS-CoV-2 Antibodies, Nucleocapsid [164068]</p>	<p>This assay can be used to identify patients with an adaptive immune response to SARS-CoV-2, providing a qualitative indication of a recent or prior infection. But it does not detect antibodies elicited by currently available COVID-19 vaccines.</p>
<p>Multisystem Inflammatory Syndrome</p>	<p>SARS-CoV-2 Antibody Profile, Nucleocapsid and Spike [160236]</p>	<p>This assay provides both a qualitative assessment of nucleocapsid antibodies and a semi-quantitative assessment of RBD-specific spike antibodies to aid in the diagnosis of Multisystem Inflammatory Syndrome in children (MIS-C) or adults (MIS-A).</p>
<p>Research or clinical trial purposes...</p>	<p>In addition to the tests above, consider SARS-CoV-2 Antibody, IgM, Spike [164034]</p>	<p>Following SARS-CoV-2 infection, IgM antibodies emerge at approximately the same time as IgG antibodies. Results from this test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection status. This should be used in conjunction with an IgG assay and may be of best value in an academic or research setting.</p>

SARS-CoV-2 Antibody Testing Guidance

Additional considerations:

- Negative antibody results in persons collected earlier than 21 days after symptom onset may be negative due to the kinetics of seroconversion, specifically, some patients will not have measurable antibody until more than 21 days after symptom onset.
- Results from antibody tests should not be used to diagnose active SARS-CoV-2 infection or to guide quarantine/isolation/PPE decisions.
- Conclusions about protective immunity to infection cannot be made on the basis of the results provided because the mechanisms of protective immunity against SARS-CoV-2 are not yet defined.
- Vendors are providing regular updates in regards to the ability of their assays to detect antibodies to new strains of the virus as they arise. To date, the Labcorp antibody assays in use continue to detect antibodies against the known circulating strains of SARS-CoV-2.
- Labcorp does not flag antibody results, as the presence or absence of antibodies alone should not be used to diagnose active infection. Additionally, the presence of antibodies may be associated with immune or vaccine response, which would not be considered abnormal.

On May 19, 2021, the FDA issued a safety communication reiterating that “antibody testing should not be used to evaluate a person’s level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.”⁴ Currently authorized SARS-CoV-2 antibody tests, including the SARS-CoV-2 Semi-Quantitative Total Antibody assay (164090), have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination. Additionally, the components of a protective immune response against infection or re-infection with SARS-CoV-2 have not been fully characterized (e.g., antibody, T cell, etc.). Clinical trials and other studies are underway to elucidate the correlates of immunity to SARS-CoV-2.

Labcorp antibody result reports will continue to include a comment indicating that the antibody level that correlates with immunity has not yet been determined. If antibody test results are interpreted incorrectly, people may take fewer precautions against SARS-CoV-2, which may result in increased risk of infection and spread of the virus. Please refer to the FDA website for further guidance around antibody testing recommendations and to these FAQs.

What test should I order to determine if the COVID-19 vaccine worked?

The U.S. Centers for Disease Control and Prevention (CDC) does not currently recommend antibody testing (or any other laboratory testing) to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, and the FDA has not yet approved a test for determination of vaccine protection.⁵ Additionally, testing is not recommended to assess for the need for vaccination in an unvaccinated person or for a booster vaccination in a vaccinated person.

What does the numerical result mean for test 164090 (SARS-CoV-2 Semi-Quantitative Total Antibody, Spike)?

The reported numerical value indicates the amount of antibody present in the specimen (e.g., titer) however, the amount of antibody needed to confer protection against infection or reinfection with SARS-CoV-2 is not yet known.

What is a “good” antibody response following COVID-19 vaccination?

The amount of antibody needed to confer protection against infection or reinfection with SARS-CoV-2 is not yet known and as such, the CDC does not currently recommend antibody laboratory testing to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. Studies are ongoing to elucidate correlates of immunity to SARS-CoV-2.

What is the intended use for SARS-CoV-2 semi-quantitative antibody testing?

Antibody tests, including the SARS-CoV-2 Semi-Quantitative Total Antibody, spike (164099) test can be used to detect previous infection with SARS-CoV-2, can aid in the diagnosis of Multisystem Inflammatory Syndrome in children (MIS-C) and adults (MIS-A), and play an important role in surveillance activities. Semi-quantitative antibody assays can be used to measure the antibody response and aide in longitudinal monitoring of the dynamics of the antibody response to support characterization of the kinetics of the immune response to vaccination and/or infection.

Labcorp is providing serology testing based on tests from various manufacturers. These tests have not been FDA cleared or approved. The tests have been authorized by the FDA under an emergency use authorization for use by authorized laboratories. These tests have been authorized only for the detection of antibodies against SARS-CoV-2, and not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

References

1. Zost SJ, Gilchuk P, Case JB, et al. Potently neutralizing and protective human antibodies against SARS-CoV-2. *Nature*. 2020;584(7821):443-449. doi:10.1038/s41586-020-2548-6.
2. Seydoux E, Homad LJ, MacCamy AJ, et al. Characterization of Neutralizing Antibodies from a SARS-CoV-2 Infected Individual. *Immunology*. 2020. doi:10.1101/2020.05.12.091298.
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4. U.S Food & Drink Administration. Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety. <https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety>. Accessed May 19, 2021.
5. Centers for Disease Control and Prevention. Overview of Testing for SARS-CoV-2 (COVID-19). <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

For more information, visit labcorp.com/coronavirus-disease-covid-19/providers/antibody-test

