

SARS-CoV-2 (COVID-19)

Molecular (NAAT) and antibody testing information

SARS-CoV-2 RNA (COVID-19) NAAT testing

The RNA test is for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in upper and lower respiratory specimens collected from individuals suspected of COVID-19 infection by their healthcare provider.

SARS-CoV-2 RNA (COVID-19), Qualitative NAAT | test code 39448

The SARS-CoV-2 RNA (COVID-19), nucleic-acid amplification test (NAAT) is a qualitative multi-target molecular diagnostic test that aids in the detection of COVID-19. Only physicians or authorized healthcare providers can collect respiratory samples and order this test from Quest Diagnostics. Quest personnel are not able to collect the respiratory specimens in Patient Service Centers (PSCs).

SARS-CoV-2 (COVID-19) serology (antibody) testing

SARS-CoV-2 antibody testing can help identify individuals with an adaptive immune response to a recent or prior infection or to a COVID-19 spike-targeted vaccine. Serologic testing should be offered as a method to help support a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.¹ For persons who present 9–14 days after illness onset, serologic testing can be offered in addition to recommended viral direct detection methods such as molecular polymerase chain reaction (PCR) or antigen detection tests. During this time period, the sensitivity of nucleic acid detection may be decreasing, and the sensitivity of serologic testing may be increasing.²

- Antibody testing cannot be used to diagnose or rule out current infection, and symptomatic patients should always be diagnosed using a SARS-CoV-2 RNA test (test code 39448)
- Blood specimens for SARS-CoV-2 serologic testing can be collected in any healthcare setting where a licensed phlebotomist can draw blood. Quest is collecting serology specimens by appointment at PSCs across the country

NEW! SARS-CoV-2 Antibody (IgG), Spike, Semi-Quantitative | test code 34499

A SARS-CoV-2 semi-quantitative IgG test result is reported as positive at an index³ of ≥ 1.00 . This positive result indicates that an individual has developed an immune response to a SARS-CoV-2 infection or a SARS-CoV-2 spike vaccine within the limits of the assay.³

Conversely, a negative result is reported at an index⁴ of < 1.00 . A negative semi-quantitative antibody result means that the patient serum specimen had no SARS-CoV-2 spike IgG antibodies, or that the relative level of antibodies in the patient specimen was below the index cutoff.^{3,4}

- Estimated sensitivity of 99.9%^{5,6} based on positive percent agreement (PPA)⁷ and specificity of 99.9%⁵ based on negative percent agreement (NPA)⁷

SARS-CoV-2 Antibody (IgG), Nucleocapsid, Qualitative (a component of the IgG/IgM panel, test code 31672) | test code 39749

This test is used to detect IgG antibodies in serum (blood) samples, and aids in identifying an immune response to recent or prior natural infection with SARS-CoV-2.

- Estimated sensitivity $> 99.6\%$ ⁸ based on PPA⁷ and specificity of $> 99.9\%$ ⁸ based on NPA⁷

SARS-CoV-2 Serology (COVID-19) Antibodies, (IgG, IgM), Immunoassay test code 31672

Quest only offers SARS-CoV-2 IgM in a panel that includes a separate IgG determination. The results from this qualitative test for SARS-CoV-2 IgM can be positive (reactive) or negative (non-reactive).⁹ Separate results are provided for IgG and IgM.

- Estimated assay sensitivity is 95%¹⁰ based on PPA⁷ and specificity of $> 99\%$ ¹⁰ based on NPA⁷

Compared to IgG antibodies, IgM antibodies are typically detected earlier, during the acute phase of an infection. In the typical infection cycle, the presence of IgM would suggest a more recent or possibly unresolved infection, while the IgG antibody would suggest a prior infection. The use of an IgG/IgM panel can help identify and differentiate those individuals with a recent infection from those who have encountered SARS-CoV-2 and recovered, thus helping to further evaluate disease course.

- Presence of IgM/IgG with symptoms suggests recent infection even if RNA/antigen is not detected
- Presence of IgG alone, absent symptoms, suggests recovery¹¹
- In 1 study, half of IgG-positive participants had functional antibodies that may inhibit reinfection; in several participants, such antibodies were still detectable > 40 days after symptom onset¹²

The antibody response to SARS-CoV-2 usually starts with IgM being detectable first, followed by the longer-lasting and more specific IgG. Data suggest that IgM antibodies can be detected within a few days and IgG antibodies will be detectable from 10 days after SARS-CoV-2 exposure or symptom onset. However, some people do not generate detectable IgG antibodies after infection because of an underlying immune disorder, immunosuppression, or other, as yet unidentified, reasons. Additionally, an individual's immune response can vary in the speed and strength of IgM and IgG production upon exposure to SARS-CoV-2, based on infective dose, viral burden, or other host factors.^{13, 14}

Quest Diagnostics offers comprehensive solutions to help you manage the care of your patients



Quest provides quality, reliability, and accessibility to serve your patients when it comes to SARS-CoV-2 (COVID-19) testing

| Test name | Test code | CPT code |
|---|-----------|---------------|
| SARS-CoV-2 RNA (COVID-19), Qualitative NAAT | 39448 | 87635 (U0003) |
| SARS-CoV-2 Antibody (IgG), Spike, Semi-Quantitative | 34499 | 86769 |
| SARS-CoV-2 Antibody (IgG), Nucleocapsid, Qualitative | 39749 | 86769 |
| SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), Immunoassay | 31672 | 86769 (x2) |

As always, please refer to the Test Directory for the most up-to-date test-specific information.



For more information on Quest's COVID-19 testing, contact your **Quest Diagnostics sales representative**, call **1.866.MYQUEST** (1.866.697.8378), or visit **QuestDiagnostics.com/COVID-19/HCP**

Antibody tests are intended for use as an aid in identifying individuals with a recent or prior infection of SARS-CoV-2 (which may be resolved or is still resolving), or an immune response to a COVID-19 spike-targeted vaccine. Results are for the detection of SARS-CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARS-CoV-2 is necessary. The tests should not be used to diagnose acute SARS-CoV-2 infection. False-positive results for the test may occur due to cross reactivity from pre-existing antibodies or other possible causes. The sensitivity of the IgM test early after infection is unknown. Due to the risk of false-positive results, confirmation of positive results should be considered using a second, different IgM assay or an IgG assay. Samples should only be tested for IgM from individuals with 15 days to 30 days post-symptom onset. SARS-CoV-2 antibody negative samples collected 15 days or more post-symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG. The results of the semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from reinfection.

- These tests have not been FDA cleared or approved;
- These tests have been authorized by FDA under EUAs for use by authorized laboratories;
- These tests have been authorized only for the detection of nucleic acid or IgG and IgM antibodies from SARS-CoV-2, not for any other viruses or pathogens, and;
- 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. CDC. Recommendations for use of serologic tests. Updated August 1, 2020. Accessed October 25, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html#anchor_1590264293982
2. CDC. Interim Guidelines for COVID-19 antibody testing. Updated August 1, 2020. Accessed March 3, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>
3. FDA. Fact sheet for healthcare providers: Siemens Healthcare Diagnostics Inc. Atellica® IM SARS-CoV-2 IgG (COV2G). SARS-CoV-2 IgG semi-quantitative and ADVIA Centaur® SARS-CoV-2 IgG (COV2G). Updated July 31, 2020. Accessed January 22, 2021. <https://www.fda.gov/media/140698/download>; <https://www.fda.gov/media/140702/download>
4. FDA. Atellica® IM SARS-CoV-2 IgG (COV2G) and ADVIA Centaur® SARS-CoV-2 IgG (COV2G). Instructions for use. Siemens Healthcare Diagnostics Inc; 2020. Accessed February 14, 2021. <https://www.fda.gov/media/140699/download>; <https://www.fda.gov/media/140704/download>
5. Siemens Atellica SARS-CoV-2 IgG [package insert]. Siemens Laboratories; 2020.
6. Siemens Centaur SARS-CoV-2 IgG [package insert]. Siemens Laboratories; 2020.
7. FDA. EUA authorized serology test performance. Updated January 8, 2021. Accessed January 25, 2021. <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>
8. SARS-CoV-2 IgG [package insert]. Abbott Laboratories; 2020. Accessed January 21, 2021. <https://www.fda.gov/media/137383/download>
9. FDA. Fact sheet for healthcare providers: Abbott Laboratories AdviseDx SARS-CoV-2 IgM. Updated October 9, 2020. Accessed January 22, 2021. <https://www.fda.gov/media/142938/download>
10. AdviseDx SARS-CoV-2 IgM [package insert]. Abbott Laboratories; 2020. Accessed January 21, 2021. <https://www.fda.gov/media/142940/download>
11. Jacofsky D, Jacofsky EM, Jacofsky M. Understanding antibody testing for COVID-19. *J Arthroplasty*. 2020;35(7s):S74-S81. doi:10.1016/j.arth.2020.04055
12. Payne DC, Smith-Jeffcoat SE, Nowak G, et al. SARS-CoV-2 infections and serologic responses from a sample of US Navy service members—USS Theodore Roosevelt, April 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(23):714-721. doi:10.15585/mmwr.mm6923e4
13. Espejo AP, Akgun Y, Al Mana AF, et al. Review of current advances in serologic testing for COVID-19. *Am J Clin Pathol*. 2020;154(3):293-304. doi:10.1093/ajcp/aqaa112
14. Li Z, Yi Y, Luo X, et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. *J Med Virol*. 2020;92(9):1518-1524. doi:10.1002/jmv.25727

The CPT® codes provided are based on American Medical Association guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Test codes may vary by location. Please contact your local laboratory for more information.

QuestDiagnostics.com

Quest, Quest Diagnostics, any associated logos, and all associated Quest Diagnostics registered or unregistered trademarks are the property of Quest Diagnostics. All third-party marks—® and ™—are the property of their respective owners. © 2021 Quest Diagnostics Incorporated. All rights reserved. SB9408 3/2021

