SARS-CoV-2 (COVID-19)

Molecular (NAAT) and serology 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 tests are intended as aids in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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.[1]

- 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
- A semi-quantitative spike antibody test can be useful in providing evidence of an immune response over time. This may be especially valuable insight for individuals enrolled in ongoing clinical trials and vulnerable patient populations. Results obtained with this assay may not be used interchangeably with values obtained with different manufacturers' test methods[1]

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

A SARS-CoV-2 semi-quantitative IgG test result is interpreted as a positive value at an index[2,3] of ≥1.00. This positive result means that an individual has developed an immune response to recent/prior SARS-CoV-2 infection within the limit of detection of the assay.[2-5]

- 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[2,3]
- Estimated assay sensitivity is >99.9%[2,3] based on positive percent agreement (PPA)[6] and specificity of 99.9%,[2-3] based on negative percent agreement (NPA)[6]

SARS-CoV-2 Total Antibody, Spike, Semi-Quantitative | test code 39820

The result of the total semi-quantitative SARS-CoV-2 antibody immunoassay test is reported as positive at an index of ≥0.8 (index detection interval[7] 0.4-250.0 U/mL). Conversely, a negative result is reported at an index[7] of <0.8 U/mL.

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 PPA[6] and specificity of >99.9%[8] based on NPA[6]

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

The results from this qualitative test for SARS-CoV-2 IgM can be positive (reactive) or negative (non-reactive).[9-10] Separate results are provided for IgG and IgM.

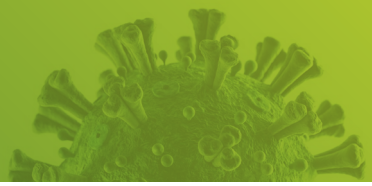
- Estimated assay sensitivity is 95%[9] based on PPA[6] and specificity of >99%[9] based on NPA[6]

Compared to IgG antibodies, IgM antibodies are typically detected earlier, during the acute phase of an infection. 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.[11,12]

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 recovery[13]

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 Total Antibody, Spike, Semi-Quantitative	39820	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**

The IgG and IgM antibody tests are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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.

- The antibody tests and the molecular tests (together "All tests") have not been FDA cleared or approved;
- All tests have been authorized by FDA under EUAs for use by authorized laboratories;
- The antibody tests have been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens;
- The molecular tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- All 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. 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
2. Atellica® IM SARS-CoV-2 IgG (COV2G; spike). Instructions for use. Siemens Healthcare Diagnostics Inc; 2020. Accessed April 7, 2021. https://www.fda.gov/media/140699/download
3. ADVIA® Centaur® SARS-CoV-2 IgG (COV2G; spike). Instructions for use. Siemens Healthcare Diagnostics Inc; 2020. Accessed April 7, 2021. https://www.fda.gov/media/140704/download
4. FDA. Fact sheet for healthcare providers: Siemens Healthcare Diagnostics Inc Atellica® IM SARS-CoV-2 IgG (COV2G; spike). Updated July 31, 2020. Accessed April 7, 2021. https://www.fda.gov/media/140698/download
5. FDA. Fact sheet for healthcare providers: Siemens Healthcare Diagnostics Inc ADVIA Centaur® SARS-CoV-2 IgG (COV2G; spike). Updated July 31, 2020. Accessed April 7, 2021. https://www.fda.gov/media/140702/download
6. FDA. EUA authorized serology test performance. Updated January 8, 2021. Accessed April 7, 2021. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance
7. Cobas® Elecsys Anti-SARS-CoV-2 S (spike). Instructions for use. Roche Diagnostics Inc; 2021. Accessed April 7, 2021. https://www.fda.gov/media/144037/download
8. Architect SARS-CoV-2 IgG (nucleocapsid). Package insert. Abbott Laboratories; 2020. Accessed April 7, 2021. https://www.fda.gov/media/137383/download
9. Architect AdviseDx SARS-CoV-2 IgM (spike). Package insert. Abbott Laboratories; 2020. Accessed April 7, 2021. https://www.fda.gov/media/142940/download
10. FDA. Fact sheet for healthcare providers: Abbott Laboratories AdviseDx SARS-CoV-2 IgM. Updated October 9, 2020. Accessed April 7, 2021. https://www.fda.gov/media/142938/download
11. 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
12. 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
13. 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

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.

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