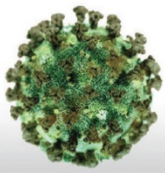

SARS-CoV-2 (COVID-19)

Molecular and Serology Testing Information

DIAGNOSTIC LABORATORY OF OKLAHOMA

When fast action and trusted information matter more than ever, Diagnostic Laboratory of Oklahoma (DLO) is committed to aiding in the response.

SARS-CoV-2 RNA (COVID-19), Qualitative NAAT, Test Code 39448

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 by their healthcare provider.

- Samples must be collected and testing must be ordered by a physician or authorized healthcare provider and sent to DLO
- DLO personnel are not able to collect the respiratory specimens in Patient Service Centers
- DLO and Quest Diagnostics have greatly increased capacity for COVID-19 (test code 39448), and are providing results with improved turnaround times

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.[1]

SARS-CoV-2 Serology (COVID-19) Antibody Testing

SARS-CoV-2 (COVID-19) antibody testing can help identify recent or prior infection with SARS-CoV-2 (which may be resolved or is still resolving), versus the molecular test which is used to help identify an active infection.

- Antibody testing cannot be used to diagnose or rule out active infection, and symptomatic patients should always be diagnosed using a SARS-CoV-2 RNA test (test code 39448)
- The CDC states that "serologic testing can be offered as a method to support diagnosis of acute COVID-19 illness for persons who present late. 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 polymerase chain reaction or antigen detection tests. During this time period, the sensitivity of nucleic acid detection is decreasing, and the sensitivity of serologic testing is increasing"[2]
- Blood specimens for SARS-CoV-2 serologic testing can be collected in any healthcare setting where a licensed phlebotomist can draw blood. DLO is collecting serology specimens at Patient Service Centers (PSCs) across Oklahoma. Appointments are available

SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), Immunoassay, Test Code 31672

- The IgM/IgG antibody panel will be performed on the Abbott® platform, and expands on the current IgG offering to also include the IgM antibody component.[3] The panel is used for the qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in serum (blood) samples, and separate results will be provided for IgM and IgG
- 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 IgM/IgG 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[4]
  - New data suggests that individuals with some level of IgG antibody may impart a level of immunity to reinfection[5]
- The antibody response to SARS-CoV-2 usually starts with IgM and/or IgA 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[6,7]
  - SARS-CoV-2 IgG: Estimated assay sensitivity is 90% to 100% for samples collected at least 15 days post-symptom onset,[8-10] based on positive percent agreement (PPA)[11] of SARS-CoV-2 IgG serology results on COVID-19 RNA positive patients.[8-10] Estimated assay specificity is >99%,[8-10] based on negative percent agreement (NPA)[11] assessed by performing cross-reactivity studies utilizing serum samples positive for antibodies to other respiratory viruses pre- and post-COVID-19 time periods[8-10]
  - SARS-CoV-2 IgM: Estimated assay sensitivity is 95% for samples collected at least 15 days post-symptom onset,[3] based on PPA[11] of SARS-CoV-2 IgM serology results on SARS-CoV-2 RNA positive patients.[3] Estimated specificity is >99%[3] based on NPA[11] assessed by performing SARS-CoV-2 IgM tests on serum samples collected from patients during a pre-COVID-19 time period[3]

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay, Test Code 39504

- The IgG antibody test is used to detect IgG antibodies to the SARS-CoV-2 virus in serum (blood) samples
- For specificity and sensitivity values, see details above for the IgG component of the IgG/IgM panel
- Please note that a SARS-CoV-2 IgM-only test is not available for ordering

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.

- 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 IgG and IgM antibodies against 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

DIAGNOSTIC LABORATORY OF OKLAHOMA.

DLO offers comprehensive solutions to help you manage the care of your patients.

Test name	Test code	CPT code*
SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	39448	87635 (U0003)
SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay	39504	86769
SARS-CoV-2 Serology (COVID-19) Antibodies (IgG, IgM), Immunoassay	31672	86769 (x2)

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

* The CPT code provided is based on AMA guidelines and is for informational purposes only. CPT coding is the sole responsibility of the billing party.

For more information on DLO's COVID-19 testing, contact your **DLO sales representative**, call **1.800.891.2917**, or visit **dlolab.com/COVID**

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