When fast action and trusted information matter more than ever, Quest 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 Quest Diagnostics
- Quest Diagnostics personnel are not able to collect the respiratory specimens in Patient Service Centers
- Quest has greatly increased capacity for COVID-19 (test code 39448), and is 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 (IgG), Immunoassay, Test Code 39504

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay test 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.

- The IgG Antibody test is a specific test used to detect IgG antibodies to the SARS-CoV-2 virus in your blood. The IgG Antibody tests currently offered by Quest Diagnostics were granted Emergency Use Authorizations (EUA) by the FDA for public health and clinical use
- These tests have specificity values of 99.6% to 100%, which minimizes false positives, and sensitivity values of approximately 90% to 100%. The CDC recommends the use of antibody testing in conjunction with molecular testing to support the clinical assessment of COVID-19 illness in persons who present 1 to 3 weeks after symptom onset² or 14 days of being symptom-free
- IgG 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)
- Blood specimens for SARS-CoV-2 IgG testing can be collected in any healthcare setting where a licensed phlebotomist can draw blood. Quest is collecting serology specimens by appointment at Patient Service Centers (PSCs) across the country. Appointments can be scheduled online or by calling 1.866.MYQUEST

Note¹: The test is 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 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 test 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.

- 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 IgG antibodies against 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 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

For additional information on Quest’s COVID-19 testing, please visit QuestDiagnostics.com/COVID-19/HCP
Quest Diagnostics offers comprehensive solutions to help you manage your patients.

<table>
<thead>
<tr>
<th>Test name</th>
<th>Test code</th>
<th>CPT code*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 RNA (COVID-19), Qualitative NAAT</td>
<td>39448</td>
<td>87635 (U0003)</td>
</tr>
<tr>
<td>SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay</td>
<td>39504</td>
<td>86769</td>
</tr>
</tbody>
</table>

As always, please refer to the Test Directory 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, contact your Quest Diagnostics sales representative, call 1.866.MY.QUEST (1.866.697.8378), or visit QuestDiagnostics.com/COVID-19/HCP

References: