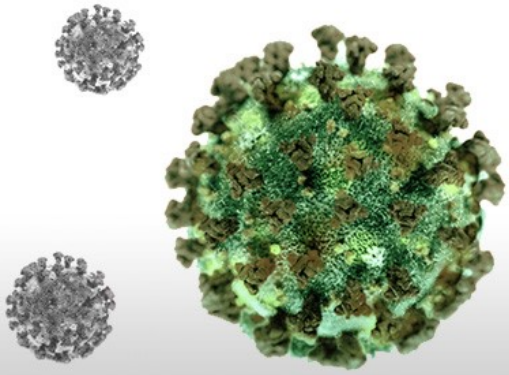

COVID-19

Molecular and Serology Testing Information

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 a qualitative multi-target molecular diagnostics test that aids in the detection of COVID-19. This test is intended to be performed on respiratory specimens collected from individuals who meet the Centers for Disease Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing.

- This testing detects the presence of the virus that causes COVID-19 and should be ordered for patients who meet the recommended guidance for evaluation of infection with COVID-19
- 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 fast turnaround times, often in less than 2 days

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

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay test is a qualitative test to detect IgG antibodies to the SARS-CoV-2 virus in your blood. IgG antibody testing should be performed to help identify people who may have been previously exposed to SARS-CoV-2 and may indicate prior infection which may be resolved or is still resolving, and/or protection against re-infection ("protective immunity").

- IgG testing provides insights into an individual's prior exposure to the virus that causes COVID-19 and the potential for protective immunity, which ultimately may help to identify people who may be able to resume work and other daily activities in society. While the role of antibodies in preventing COVID-19 disease has yet to be established, antibody testing for other respiratory illnesses (SARS, flu) provides insight into immunity to future diseases.
- **IgG antibody testing should not be used to diagnose active infection, and symptomatic patients should always be diagnosed using a molecular COVID-19 test (Test Code 39448)**
- Blood specimens for SARS-CoV-2 antibody testing can be collected in any healthcare setting where a licensed phlebotomist can draw blood. Quest will be collecting serology specimens by appointment at Patient Service Centers (PSCs) across the country, outside of the first hour of the day designated for the Peace of Mind Program, for those patients at greatest risk for COVID-19. Appointments can be scheduled online or by calling 1.866.MYQUEST

Note: This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non–SARS-CoV-2 coronavirus strains, such as HKU1, NL63, OC43, or 229E.

For additional information on Quest's COVID-19 testing, please visit **QuestDiagnostics.com/COVID-19/HCP**

Quest Diagnostics®

Quest Diagnostics™

Quest Diagnostics offers comprehensive solutions to help you manage your patients.

Test name	Test code	CPT code*
SARS-CoV-2 RNA (COVID-19), Qualitative NAAT	39448	87635 (U0003)

Test name	Test code	CPT code*
SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay	39504	86769

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.

These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories. These tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, 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 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.

For more information, contact your Quest Diagnostics sales representative, call 1.866.MY.QUEST (1.866.697.8378), or visit QuestDiagnostics.comCOVID-19/HCP

References:

1. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clin Infect Dis*. 2020 Mar 28. doi: 10.1093/cid/ciaa344
2. Euroimmun. SARS-CoV-2 test systems from EUROIMMUN. Accessed April 17, 2020. https://www.coronavirus-diagnostics.com/faq.html/
3. United States Food and Drug Administration. FAQs on diagnostics testing for SARS CoV-2. Accessed April 17, 2020. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

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