SARS-COV-2 ANTIBODY TESTING OPTIONS

Helping you provide better patient care

You Have **Quality Choices**

Qualitative antibody testing can provide information on SARS-CoV-2 immune response in previously diagnosed patients and can help identify individuals who have been exposed to the virus.

Serologic tests for SARS-CoV-2 are intended for individuals who may have had COVID-19 symptoms but are no longer symptomatic. The tests determine the presence of antibody to SARS-CoV-2, the virus that causes COVID-19, and can help to identify individuals who have been exposed to the virus. Understanding if an individual has developed the antibodies and a potential immune response can be useful in the determination of important decisions such as the ability for hospital staff to care for patients. Antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

To address the increasing demand for testing, optimal turnaround time for results, and access to advanced methodologies, LabCorp now offers an additional option for qualitative SARS-CoV-2 antibody testing:

NEW: SARS-CoV-2 Antibodies **(164068)**:

This is a new qualitative assay that uses a modification of standard ELISA methodology to determine the presence of high affinity antibodies to the SARS-CoV-2 nucleocapsid antigen.[1] While the assay does not differentiate between antibody types, it preferentially detects IgG antibodies since these are most likely to evolve to become high affinity.[1]

This new test is in addition to our existing SARS-CoV-2 Antibody, IgG test, which is a qualitative assay that uses a modification of standard ELISA to signal the presence of IgG antibodies bound to the SARS-CoV-2 antigen. This approach creates a test with high sensitivity and specificity to detect IgG antibodies only.

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Comparative Test Overview

Test Name	SARS-CoV-2 Antibodies	SARS-CoV-2 Antibody, IgG
Test Number	164068	164055
CPT Code	86769	86769
Intended Use	Qualitative detection of anti-SARS-CoV-2 antibodies. This test detects and reports on the presence of high affinity antibodies to the SARS-CoV-2 virus.	Qualitative detection of IgG antibodies to SARS-CoV-2, the virus that causes COVID-19. This test detects and reports specifically on the presence of IgG antibodies to SARS-CoV-2 virus.
Clinical Setting	These tests are recommended in individuals at least 10-14 days post symptom onset or at least 10-14 days following exposure to individuals with confirmed COVID-19.	
Sensitivity*	100%	100%
Specificity*	99.8%	99.6%
Sample Type	Serum	
Sample Volume	0.8 mL	0.5 mL
Sample Container	Gel-barrier tube, serum from red-top tube, or serum transfer tube	
Expected Turnaround time	1-3 days	

*Source: EUA Authorized Manufacturers' Serology Test Performance Data, summarized by the FDA: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance, content current as of May 13, 2020.

Note: LabCorp is providing a choice in antibody test options.
Do not order both tests in the chart above on the same patient; select one only.

Antibody test collections (blood draw) can be performed in office and sent via courier and are available through LabCorp patient service centers, including LabCorp at Walgreens locations.

References
1. Roche. (2020). Elecsys® Anti-SARS-CoV-2 Immunoassay.

These tests have not been FDA cleared or approved. These tests have been authorized by the FDA under an emergency use authorization for use by authorized laboratories. These tests have been authorized only for the detection of the presence of antibodies against SARS-CoV-2, and 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 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.

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