SARS-CoV-2 ANTIBODY TESTING OPTIONS

Helping you provide better patient care

Qualitative and quantitative 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 who were never symptomatic or no longer symptomatic. The tests determine the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19, and can help to identify individuals who have been infected with the virus. Antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

LabCorp now offers multiple options for SARS-CoV-2 antibody testing:

SARS-CoV-2 Semi-Quantitative Total Antibody [**164090**]:

This semi-quantitative assay can help assess the level of antibodies in people who have been infected with the SARS-CoV-2 virus. The test looks for antibodies against the receptor binding domain (RBD) of the spike protein, which is the target of many candidate vaccines.

SARS-CoV-2 Antibodies [**164068**]:

This qualitative assay uses a modification of standard ELISA methodology to detect the presence of high affinity antibodies to the SARS-CoV-2 nucleocapsid protein.[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]

SARS-CoV-2 Antibody, IgG [**164055**]:

This qualitative assay uses a modification of standard ELISA methodology to detect the presence of IgG antibodies to the SARS-CoV-2 spike protein.

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Comparative Test Overview

Test Name	SARS-CoV-2 Antibodies	SARS-CoV-2 Antibody, IgG	SARS-CoV-2 Quantitative Total Antibody
Test Number	164068	164055	164090
CPT Code	86769	86769	TBD
Intended Use	Qualitative detection of anti-SARS-CoV-2 antibodies. This test detects the presence of high affinity antibodies to the SARS-CoV-2 virus nucleocapsid protein.	Qualitative detection of IgG antibodies to SARS-CoV-2, the virus that causes COVID-19. This test detects the presence of IgG antibodies to SARS-CoV-2 virus spike protein.	This assay uses a recombinant protein representing the RBD of the S antigen for the quantitative determination of antibodies against SARS-CoV-2. Quantification of the antibody response can help to determine the specific antibody titer and aid in longitudinal monitoring of the dynamics of the antibody response in individual patients.
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, with >14 days being optimal.		
Sensitivity	100%*	100%*	96.6% (PPV at >14 days)[2]
Specificity	99.8%*	99.6%*	100%[2]
Sample Type	Serum		
Sample Volume	0.8 mL	0.5 mL	1.5 mL
Sample Container	Gel-barrier tube, 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.

Do not order more than one test in the chart above on the same patient; select one only.

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

References
1. Elecsys® Anti-SARS-CoV-2 Immunoassay. Package insert. Roche Diagnostics; 2020.
2. Elecsys® Anti-SARS-CoV-2 S. Package insert. Roche Diagnostics; 2020.

LabCorp is providing serology testing based on tests from various manufacturers. These tests have not been FDA cleared or approved. The 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 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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