

Re: LabCorp Offers No Charge Antibody Testing Program to Accelerate COVID-19 Blood Plasma Donation

Dear Valued Client:

As announced on July 30, 2020, LabCorp is offering a no charge antibody testing program in response to federal health authorities' request to increase donations of COVID-19 blood plasma. Plasma with COVID-19 antibodies could be helpful when treating patients with an active COVID-19 infection and is being evaluated as a possible treatment.

Beginning August 11, 2020, LabCorp will perform the high-affinity antibody test at no charge to patients, insurance companies, or the government over the next three months. For patients who are contemporaneously receiving other medically necessary blood tests as part of a medically necessary exam or treatment, this program allows you to add the **SARS-CoV-2 Antibodies Test [164068]** to the same order and the same blood draw at no charge. **Please note:** the no-charge high-affinity antibody testing program will use only the Roche Elecsys® Anti-SARS-CoV-2 and does not apply to other COVID-19 antibody tests, such as the IgG test.

Patients will be able to access their results through the LabCorp Patient™ portal and through their doctor. Result data from the antibody testing program will also be reported to the CDC and state public health agencies to further support COVID-19 surveillance and response efforts.

Individuals who have tested positive for COVID-19 and have not experienced symptoms for at least two weeks, or who have been confirmed to have antibodies to the virus are likely candidates for plasma donation. Many people who have had COVID-19 do not experience symptoms and may be unaware they have antibodies that can help other patients.

Patients who test positive for COVID-19 antibodies are encouraged to donate their blood plasma. Donating plasma does not affect the donor's immunity, as their body will continue to produce antibodies. More information can be found about plasma donation at [TheFightInUs.org](https://www.fightsinus.org). The website can help check eligibility criteria and connect patients directly to plasma and blood donation centers nearby.

About the High-Affinity Antibody Test Program

Under this program, providers can order the high-affinity antibody test that is based on an in-solution double-antigen sandwich format and can detect antibodies to SARS-CoV-2, the virus that causes COVID-19. The test will be performed at no charge for the next three months. The test is offered only to patients receiving other medically necessary blood tests as part of a medically necessary exam or treatment. Antibodies could signal whether a person has already been infected and potentially developed immunity to the virus. LabCorp's antibody test uses the Roche Elecsys® Anti-SARS-CoV-2 platform, has 99.8 percent specificity and shows no cross-reactivity to the common cold, HIV, and other coronaviruses.¹ This means it can lower the chance of false positives due to the detection of similar antibodies that may be present in an individual. The Anti-SARS-CoV-2 test detected antibodies with 100% sensitivity in samples taken 14 days after a PCR-confirmed infection.¹

Thank you for your continued partnership with LabCorp.

1. 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 July 28, 2020.

The Elecsys Anti-SARS-CoV-2 test has not been FDA cleared or approved. It has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. It 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.