CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

# New Test Announcement: SARS-CoV-2 (COVID-19) Total Antibody

*Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.*

Effective May 11, 2020, Clinical Pathology Laboratories (CPL) will offer SARS-CoV-2 total antibody assay using the Roche COBAS Electrochemiluminescence Immunoassay (ECLIA) method. The immunoassay is designed to detect IgG, IgA and IgM antibodies to recombinant nucleocapsid protein of SARS-CoV-2 in serum intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity. It is important to note that negative results do not rule out acute SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Testing with a nucleic acid amplification test (NAAT; RT-PCR, TMA, others) should be considered to evaluate for active 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.

This test has not been Food and Drug Administration (FDA) cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This test has been authorized only for the detection of antibodies against SARS-CoV-2, not for any other viruses or pathogens. The 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 SARS-CoV-2 under Section 564(d)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Clinical Pathology Laboratories is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests. This assay is not for the screening of donated blood.

Fact Sheet for Healthcare Providers: **www.cpllabs.com/COVID19_TotalAntibody_FactSheet_HealthcareProvider**

Fact Sheet for Patients: **www.cpllabs.com/COVID19_TotalAntibody_FactSheet_Patient**

Please contact your Account Representative should you have any questions.

| **TEST INFORMATION:** | |
|---|---|
| **Test Code / Name:** | **7304 Anti-SARS-CoV-2** |
| **SPECIMEN REQUIREMENTS:** | |
| **Preferred Sample:** | 2 mL serum from SST<br>*Allow SST to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection. Refrigerate.*<br>*For phlebotomy service to a recently symptomatic patient, please have patient present at least 3 days beyond end of symptoms, at least 10 days from symptom onset for phlebotomy.*<br>*Please instruct all patients ordered for COVID-19 antibody to wear a facemask for phlebotomy.* |
| **Acceptable Sample:** | 2 mL serum from a plain red top tube<br>*Allow sample to clot in an upright position for at least 60 minutes, then centrifuge sample and transfer serum to a plastic transport tube within 2 hours of collection. Clearly label tube as serum from a plain red top tube.* |
| **Transport Temperature:** | Refrigerated |
| **Specimen Stability:** | 3 Days Room Temperature; 7 Days Refrigerated; 28 Days Frozen |
| **Rejection Criteria:** | 1 freeze/thaw cycle or heat inactivated serum |
| **TESTING:** | |
| **Expected Turn Around:** | 3 Days |
| **Testing Frequency:** | Monday through Friday |
| **CPT:** | 86769 |
| **Methodology:** | Electrochemiluminescence Immunoassay (ECLIA) |

*Thank you for supporting Clinical Pathology Laboratories*