CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

New Test Announcement: SARS-CoV-2 (COVID-19) IgG Serology

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

Effective April 28, 2020, Clinical Pathology Laboratories (CPL) will offer IgG serology for SARS-CoV-2, the causative agent of COVID-19 clinical illness. The Abbott Architect chemiluminescent microparticle immunoassay (CMIA) is designed to detect IgG antibodies to the nucleocapsid protein of SARS-CoV-2 in serum from patients who have signs and symptoms of infection, are suspected of coronavirus disease (COVID-19) or have been infected by SARS-CoV-2. It is important to note that negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in 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 IgG antibodies against SARS-CoV-2 and not for any other viruses or pathogens. This 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_IgGAssay_FactSheet_HealthcareProvider**

Fact Sheet for Patients: **www.cpllabs.com/COVID19_IgGAssay_FactSheet_Patient**

Please contact your Account Representative should you have any questions.

TEST INFORMATION:	
Test Code / Name:	**7301 SARS-CoV-2 IgG**
SPECIMEN REQUIREMENTS:	
Preferred Sample:	2 mL serum from SST *Allow SST to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection. Refrigerate.* *For phlebotomy service to a recently symptomatic patient, please have patient present at least 3 days beyond end of symptoms, at least 7 days from symptom onset for phlebotomy.* *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 *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. Cearly label tube as serum from a plain red top tube.*
Transport Temperature:	Refrigerated
Specimen Stability:	2 Days Room Temperature; 7 Days Refrigerated; 1 Month Frozen
Rejection Criteria:	2 freeze/thaw cycles, heat inactivated specimens, pooled specimens, grossly hemolyzed specimens, obvious microbial contamination specimens.
TESTING:	
Expected Turn Around:	2 Days
Testing Frequency:	Monday through Friday
CPT:	86769
Methodology:	Chemiluminescent Microparticle Immunoassay (CMIA)

Thank you for supporting Clinical Pathology Laboratories