PDL UPDATE: Coronavirus (COVID-19)

Serological Antibody Testing

PACIFIC DIAGNOSTIC LABORATORIES Guiding Health™

WHAT IS NEW

Effective June 17, 2020, Pacific Diagnostic Laboratories (PDL) is pleased to announce that the SARS-CoV-2 Antibody testing for the 2019 Novel Coronavirus (COVID-19) will be performed in-house.

BACKGROUND INFORMATION

Serological testing for SARS-CoV-2 is intended for individuals who may have had COVID-19 symptoms but are no longer symptomatic. The test determines the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19, and can help to identify individuals who may have been exposed to the virus.

Internal studies at PDL with COVID positive patients confirmed the appearance of antibodies 10 to 14 days after infection. The FDA has stated that there is no identified advantage of assays testing for IgG, IgM and IgG, or total antibody.

Serology testing is not intended as a primary diagnostic test for COVID-19. The RT-PCR (PDL Test Code LAB10716) is the only diagnostic test for COVID-19. Serology testing should not be used as the sole basis for a diagnosis nor assurance of immunity.

TEST INFORMATION	
LAB10739 SARS-CoV-2 Total Antibodies	
Specimen Requirements	**Specimen Type:** Serum (preferred) or Plasma **Volume:** 1 mL **Container:** Gold, Red, Green (Lithium Heparin), or Lavender (EDTA) Top **Transport Temperature**: Refrigerate
Result Detail **SARS-CoV-2 Total Antibodies**	**Reported**: **Positive, Negative or Equivocal** (*qualitative only, no titer provided*) ***A positive serologic result*** *indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus. This assay is for the qualitative detection of total antibodies including IgG, IgM and to a lesser extent IgA. The test does not differentiate antibody isotypes.* ***A negative serologic result suggests*** *that an individual has not developed detectable antibodies at the time of testing. While contingent on a variety of factors, a negative result could be due to testing too early in the course of infection, the absence of exposure to the virus, or the lack of adequate immune response, which can be due to conditions or treatments that suppress immune function.*
Method Specifications	Specificity – **99.65%** Sensitivity >13 days – **100%** Turnaround Time – **24 hours**
Billing & Insurance	**Price:** $99 **AMA CPT:** 86769 **Uninsured Patients**: Qualify under HRSA https://www.hrsa.gov/coviduninsuredclaim

FOR MORE INFORMATION PLEASE CONTACT CLIENT SERVICES AT (805) 879-8100

Stewart W. Comer, MD FCAP Medical Director Pacific Diagnostic Laboratories June 17, 2020