

Serological Antibody Testing w/Confirmation

August 21, 2020

WHAT IS NEW

Effective August 25, 2020, Pacific Diagnostic Laboratories (PDL) will be shifting all SARS-CoV-2 Antibody testing for the 2019 Novel Coronavirus (COVID-19) to a NEW test code: **SARS-CoV-2 Total Antibodies with Confirmation (LAB10741)**.

Please note: This new code will REPLACE all orders for SARS-CoV-2 Total Antibodies (LAB10739).

BACKGROUND INFORMATION

Serologic methods have important public health and clinical uses for monitoring and responding to the COVID-19 pandemic. The serology 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. Serology testing is not intended as a primary diagnostic test for COVID-19.

According to the CDC Interim Guidelines for COVID-19 Antibody Testing:

- Currently, there is no identified advantage whether the assays test for IgG, IgM and IgG, or total antibody.
- Antibodies most commonly become detectable 1–3 weeks after symptom onset, at which time evidence suggests that infectiousness likely is greatly decreased and that some degree of immunity from future infection has developed.
- “It is important to minimize false positive test results by choosing an assay with high specificity and by testing populations and individuals with an elevated likelihood of previous exposure to SARS-CoV-2. Alternatively, an orthogonal testing algorithm (i.e., employing two independent tests in sequence when the first test yields a positive result) can be used when the expected positive predictive value of a single test is low.” Given the low-intermediate prevalence of antibodies in Santa Barbara County (3-5%), PDL is adjusting our serology testing for COVID to the orthogonal algorithm to increase the positive predicative value to 100%.

The full CDC Interim Guideline is available at the following website:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

LAB10741 SARS-CoV-2 Total Antibodies with Confirmation	
Tests for	Qualitative detection of total antibodies (IgG, IgM, to a lesser extent IgA). Does not differentiate the antibody isotypes.
Specimen Requirements	Specimen type: Serum (preferred) or Plasma Volume: 1 mL Transport Temperature: Refrigerate Container: Gold Top, Red top, Green Top (Lithium Heparin), Lavender Top (EDTA)
Result Detail	<p>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.</p> <p>A positive serologic result indicates that an individual has produced an immune response to the SARS-CoV-2 virus. This will be reported when the result is positive with both methods (reducing false positive rate to 0%).</p> <p>A presumptive positive serologic result indicates that an individual has produced an immune response to the SARS-CoV-2 virus. Presumptive positive will be reported when one method is positive and the other is negative. Given the prevalence of COVID-19 in Santa Barbara County, there is a 5-10% chance of a false positive with this result.</p>
Billing	CPT 86769

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

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