PDL UPDATE:

Coronavirus (COVID-19) Serological Antibody Tests

April 28, 2020

WHAT IS NEW

Effective April 28, 2020, Pacific Diagnostic Laboratories (PDL) is offering serological antibody tests for the 2019 Novel Coronavirus (COVID-19) through LabCorp, our primary reference laboratory.

Serological testing for SARS-CoV-2 is intended for individuals who may have had COVID-19 symptoms but are no longer symptomatic. The tests determine the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19, and can help to identify individuals who have been exposed to the virus. Serology testing should not be used as the sole basis for a diagnosis nor assurance of immunity.

Note: Serologic testing is not intended for the diagnosis of acute COVID-19 infection. As such, please do not send symptomatic patients to the PSC for serologic testing. The RT-PCR is the only diagnostic test for COVID-19.

TEST INFORMATION

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAB10733</td>
<td>SARS-CoV-2 Antibody, IgG</td>
</tr>
<tr>
<td>LAB10732</td>
<td>SARS-CoV-2 Antibody, IgM</td>
</tr>
<tr>
<td>LAB10734</td>
<td>SARS-CoV-2 Antibody, IgA</td>
</tr>
</tbody>
</table>

Specimen Type/Container: Serum; Gel-barrier tube or serum from red-top tube or serum transfer tube

Specimen Volume: 0.5 mL (for each test requested)

Transport Temperature: Room Temperature

Turnaround Time: 3-5 days

Methodology: Immunoassay

Results: Qualitative
- **Positive** serologic result indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus.
- **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.

Billing: AMA CPT 86769
LabCorp has not set pricing for this testing at the time of this notice

Limitations: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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

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