ProMedica Pathology Laboratories (PPL) has updated information for SARS-Cov-2/COVID-19 serological test for SARS-Cov-2 IgG Antibody:

Test Code 39433, **SARS-COV-2 IGG (ABBOTT)**, using the Abbott Architect Chemiluminescent Microparticle Immunoassay (CMIA) methodology.

**CLINICAL INFORMATION for 39433, SARS-COV-2 IGG (ABBOTT):**
The Abbott Architect CMIA is designed to detect IgG antibodies to the nucleocapsid protein of SARS-CoV-2 in serum and plasma 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 molecular diagnostic (NAAT; RT-PCR, TMA, others) such as Test Code 39429 SARS-COV-2 (COVID-19) BY RT-PCR 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 FDA cleared or approved and has been authorized by FDA under an Emergency Use Authorization (EUA). NOT FOR THE SCREENING OF DONATED BLOOD.

Per manufacturer performance specifications, SARS-CoV-2 IgG antibody sensitivity is highest 14 days post symptom onset.

Provider Information Link: [www.fda.gov/media/137381/download](http://www.fda.gov/media/137381/download)

Patient Information Link: [www.fda.gov/media/137382/download](http://www.fda.gov/media/137382/download)
Orderable Test Code: 39433 SARS-COV-2 IGG (ABBOTT)

Result Codes: 39433 - SARS-COV-2 IGG

LOINCS: 94507-1

Ordering Recommendations:

To detect SARS-CoV-2 IgG antibodies in serum or plasma from patients who have signs and symptoms of infection, are suspected of coronavirus disease (COVID-19), or in subjects that may have been infected by SARS-CoV-2.

Specimen Requirements:

Sample Type:
- Serum or Plasma
- 1.0 mL (0.5 mL minimum, does not allow for repeat testing)

Container Type:
- Preferred- Serum Separator Tube
- Alternate- Plain Red Top Tube, Green PST Tube, Lavender Tube

Handling Instructions:

Collect specimen per tube manufacturer’s instructions. Centrifuge sample and separate serum from cells ASAP or within 2 hours. Aliquot and refrigerate.

Transport: Refrigerated
Unsuitable Specimens: Grossly hemolyzed specimens
Stability: Ambient: 2 Days; Refrigerated: 1 Week

Testing:

- Testing performed Sunday through Saturday. Expected TAT is 1-3 days.
- Reference Range: SARS-CoV-2 IgG: Negative

CPT Codes: 86769
Methodology: Chemiluminescent Microparticle Immunoassay (CMIA)

Thank you for supporting ProMedica Pathology Laboratories.

2130 W. Central Ave., Suite 300 Toledo, Ohio 43606 419-291-4414 / 833-960-0241

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<table>
<thead>
<tr>
<th>Orderable Code</th>
<th>Test Name</th>
<th>Retired Test Codes</th>
<th>Replacement Code</th>
<th>Replacement Test Codes</th>
<th>Revised Result Field</th>
<th>Specimen Requirements Handling Instructions</th>
<th>Expected Turn Around</th>
<th>Reference Ranges</th>
<th>CPT Change</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>39433</td>
<td>SARS-COV-2 IGG (ABBOTT)</td>
<td></td>
<td></td>
<td></td>
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<td>X</td>
<td>X</td>
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</tbody>
</table>

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<tr>
<th>Orderable Code</th>
<th>Test Name</th>
<th>EMR Interface Mapping</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Result Code</td>
<td>Result Name (Test Components)</td>
</tr>
<tr>
<td>39433</td>
<td>SARS-COV-2 IGG (ABBOTT)</td>
<td>394333</td>
<td>SARS-CoV-2 IGG</td>
</tr>
</tbody>
</table>

If you have any questions, please contact our Customer Service Department at 419-291-4414 / 833-960-0241 or your Account Executive. Thank you.