SONIC HEALTHCARE USA

SARS-CoV-2 (COVID-19) Client Communication

PROMEDICA PATHOLOGY LABORATORIES

A Partnership of ProMedica and Sonic Healthcare

July 10, 2020 **Effective July 13, 2020**

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

Patient Information Link: www.fda.gov/media/137382/download

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Orderable Test Code: 39433 SARS-COV-2 IGG (ABBOTT)

Result Codes:

- **394333** - 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.

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www.pathlabs.org

Orderable Code	Test Name	Retired Test Codes	Replacement Code	Replacement Test Codes	Revised Result Field	Specimen Requirements Handling Instructions	Expected Turn Around	Reference Ranges	CPT Change	Other
39433	SARS-COV-2 IGG (ABBOTT)				X	X	X	X		

Replacement Test Codes								
		EMR Interface Mapping		Other				
Orderable Code	Test Name	Result Code	Result Name (Test Components)	AOE	Reportable	LOINC	UOM	CPT
39433	SARS-COV-2 IGG (ABBOTT)	394333	SARS-CoV-2 IGG	N	Y	94507-1		86769

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