SONIC HEALTHCARE USA

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

PROMEDICA PATHOLOGY LABORATORIES

A Partnership of ProMedica and Sonic Healthcare

May 15, 2020

ProMedica Pathology Laboratories (PPL) is now offering an additional serological test for SARS-Cov-2 Antibodies, **Test Code**, **39434, SARS-COV-2 ANTIBODIES (ROCHE).**

CLINICAL INFORMATION for 39434, SARS-COV-2 ANTIBODIES (ROCHE):
The Roche Elecsys Anti-SARS-CoV-2 assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2, including IgG. The assay method is Electrochemiluminescence Immunoassay (ECLIA), whereby coated microparticles are magnetically captured onto the surface of an electrode. Results are determined by comparing the electrochemiluminescence signal from the sample with the signal of the cutoff calibration.

Performance data supplied by Roche in the package insert for sensitivity and specificity:

- Sensitivity 100% in patients >=14 days post-PCR confirmation.
- Specificity 99.8% including no cross-reactivity in patient cohorts tested against other seasonal coronaviruses confirmed via PCR.

Intended for the qualitative detection of antibodies to SARS-CoV-2 in human serum. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Elecsys Anti-SARS-CoV-2 assay should not be used to diagnose acute SARS-CoV-2 infection.

The individual immune response following SARS-CoV-2 infection varies considerably and may give different results with assays from different manufacturers.

Fact Sheet for Healthcare Providers: https://www.fda.gov/media/137603/download
Fact Sheet for Patients: https://www.fda.gov/media/137604/download

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Orderable Test Code: 39434 SARS-COV-2 ANTIBODIES (ROCHE)

Result Codes: **LOINCS:**

- 394341 - SARS-COV-2 ABS INTERP
- 394342 - SARS-COV-2 ABS INDEX 94762-2

Specimen Requirements:

Sample Type:

- Serum ***(only)***
- 1.0 mL (0.5 mL minimum, does not allow for repeat testing)

Container Type:

- Serum Separator 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: Heat inactivated, grossly hemolyzed, contaminated, or fungal growth.
Stability: Ambient: 3 Days; Refrigerated: 7 Days; Frozen: 28 Days

Testing:

- Testing is performed Sunday through Saturday. Expected TAT 3 days.
- Reference Range: SARS-CoV-2 ABS Interp: Negative
  SARS-CoV-2 ABS Index: <1.0

CPT Codes: 86769
Methodology: ELECTROCHEMILUMINESCENCE IMMUNOASSAY (ECLIA)

COMPLIANCE STATEMENT:
The Elecsys Anti-SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA) under section 564 (d) (1) of the Act, 21 U.S. C section 360bb-3 (b) (1) unless authorization is terminated or revoked sooner. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate and high complexity tests. Sunrise Medical Laboratories, an affiliate of Sonic Healthcare USA, Inc., performs this test on behalf of PPL and is a CLIA certified laboratory.

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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
39434	SARS-COV-2 ANTIBODIES (ROCHE)									NEW

		EMR Interface Mapping		Other				
Orderable Code	Test Name	Result Code	Result Name (Test Components)	AOE	Reportable	LOINC	UOM	CPT
39434	SARS-COV-2 ANTIBODIES (ROCHE)	394341 394342	SARS-COV-2 ABS INTERP SARS-COV-2 ABS INDEX	N N	Y Y	 94762-2		86769

Note: CPT codes are provided for information only and are based on ProMedica PathLabs' current understanding of Medicare rules and carrier instructions and in accordance with the current issue of Physicians Current Procedural Terminology published by the American Medical Association. Medicare coding may differ from coding used by other third party payers. Questions regarding coding should be confirmed with the payer being billed. ProMedica PathLabs cannot accept responsibility for the reimbursement clients may or may not receive based on the procedure codes provided.

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