SUNRISE MEDICAL LABORATORIES
A Sonic Healthcare Company

Client Communication

May 11, 2020
New Test Announcement

Sunrise Medical Laboratories is offering a new antibody serology for SARS-CoV-2, the causative agent of COVID-19. 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.

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 or 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.

Test Information:

Test Code: 26506

Test Name: SARS-CoV-2 Antibodies

Ordering Recommendations:

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.

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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

Specimen Requirements:

Sample Type:
- 1.0 ML Serum

Container Type: **Prefer dedicated collection device*
- Serum Separator tube (SST®) preferred

Handling Instructions:

Collect specimen per tube manufacturer's instructions. Centrifuge sample and separate from cells ASAP or within 2 hours of collection.

Transport:	Refrigerated
Unsuitable Specimens:	Heat-inactivated specimens. Specimens grossly hemolyzed. Specimens with obvious microbial contamination. Specimens with fungal growth.

Testing Details:

- Schedule: Sunday to Saturday
- TAT: 48 hours
- Stability: 3 days room temperature, 7 days refrigerated, 28 days frozen

CPT Code: **86769**

LOINC Codes: **94762-2**

Sunrise Medical Laboratories

Notification Date: 05/08/2020

New Test Offering

Effective Date: 05/11/2020

SARS-CoV-2 Antibodies

Order Code: 26506

Summary of changes: NEW test offering.

Specimen Requirements: 1.0 ML Serum collected from Serum Separator tube (SST®)
(Min:0.5 ML – minimum does not allow for repeat testing).
Prefer dedicated collection device.

Transport Temperature: Refrigerated

Result Fields:

	LOINC
26562: SARS-CoV-2 Abs Interp.	
26563: SARS-CoV-2 Abs Index	94762-2

Methodology: Electrochemiluminescence Immunoassay (ECLIA)

Reference Range:

SARS-CoV-2 Abs Interp.	Negative
SARS-CoV-2 Abs Index:	<1.0

CPT: 86769

Additional Notes: Collection Instructions: Collect specimen per tube manufacturer's instructions. Centrifuge sample and separate from cells ASAP or within 2 hours of collection.

Rejection Criteria: Heat-inactivated specimens. Specimens grossly hemolyzed. Specimens with obvious microbial contamination. Specimens with fungal growth.

Stability: 3 days room temperature; 7 days refrigerated; 28 days frozen

Frequency/Turn Around Time Sunday – Saturday/ 48 hours

Testing Location: Sunrise Medical Laboratories
250 Miller Pl., Hicksville, NY 11801

Sunrise Medical Laboratories
250 Miller Place - Hicksville, NY 11801
Client Service 800-782-0282

Report Status: Final

Specimen Information		Patient Information		Ordering Physician
Specimen:	**B2305817**	**BE, BEE**		.TEST, DOCTOR
E Order:		DOB:	03/23/1973	**Client Information**
Collected:	05/07/2020 12:00	Age:	47	**JOHN DOE,MD** **9687**
Received:	05/07/2020 15:16	Gender:	F	123 MAIN ST
Reported:	05/07/2020 15:27	Fasting:	No	ANYWHERE,
Printed:	05/07/2020 15:29	ID:		(631) 435-1515
		Phone:		

Test Name	In Range	Out Range	Reference Range
SARS-CoV-2 ANTIBODIES			
SARS-CoV-2 Abs Interp.	Negative		Negative
SARS-CoV-2 Abs Index	0.4		<1.0 COI

INTERPRETATIVE INFORMATION

Index (COI) Value	Interpretation
< 1.0	Negative for anti-SARS-CoV-2 antibodies
> or = 1.0	Positive for anti-SARS-CoV-2 antibodies

This test is intended for the qualitative detection of antibodies to SARS-CoV-2 in human serum and 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 to what degree the presence of antibodies confers protective immunity. The Roche Elecsys Anti-SARS-CoV-2 assay should not be used to diagnose acute SARS-CoV-2 infection.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct PCR testing is recommended. False positive results may occur due to cross reactivity from pre-existing antibodies or other possible causes. This assay has overall sensitivity of 100% and specificity of 99.8% in patients >=14 days post-PCR confirmation.

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.

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		Phone:		

Test Name	In Range	Out Range	Reference Range

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