

Immunology laboratory will start new COVID 19 antibody testing on 11/18/2021.

The new Anti-SARS-CoV-2 S is an electrochemiluminescence immunoassay intended for **qualitative and semi-quantitative detection of total antibodies against SARS-CoV-2 spike (S) protein** receptor binding domain (RBD) in human serum and plasma (Elecsys Anti-Sars-CoV-2 S, Roche Diagnostics, Inc.). It is available under an Emergency Use Authorization (EUA). This assay will be replacing our current assay, detecting IgG antibodies against nucleocapsid protein (NP).

The test is intended as an aid in identifying individuals with immune response to SARS-CoV-2, indicating recent or prior infection. The test also identifies antibodies against the receptor-binding domain (RBD) of the spike protein, which is the target of many vaccines. Currently, it is unknown if the presence of antibodies provides protective immunity. The clinical applicability of a semiquantitative result is currently unknown and cannot be used to indicate degree of immunity or protection from the re-infection or after vaccination. This assay should not be used to diagnose acute SARS-CoV-2 infection. This test should not be used for donor blood screening. It is recommended to use this test in individuals at 10-14 days post symptom onset or at 10-14 days following exposure to individuals with confirmed COVID-19 infection (median seroconversion has been observed at approximately 2 weeks).

This assay is measuring **total antibody against SARS-CoV-2 Spike protein**.

Acceptable specimens: human serum or plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate).

An example of patient's result will be reported as follows:

COVID Spike Total Ab	20.0	U/mL	(2050)
COVID Spike Total Ab	Antibodies against the SARS-CoV-2 spike protein receptor binding domain were detected. This is used as an aid in identifying individuals with an adaptive immune response to SARS-Cov-2. It has yet undetermined what level of antibody to SARS-CoV-2 spike protein correlates to immunity against developing symptomatic		
RESULT	SARS-CoV-2 disease. This test also targets antibodies against the receptor binding domain (RBD) of the spike protein, which is the target of many vaccines.		
-----	(NOTE)		
<0.8 U/mL	INTERPRETATION		
>= 0.8 - <= 250.0 U/mL	-----		
>250.0 U/mL	Negative for anti SARS-CoV-2-S		
	Positive for anti SARS-CoV-2-S within the measuring interval.		
	Positive for anti SARS-CoV-2-S, numeric value as >250.0		
Interpretation:	* Positive [NEG]		(205

Test can be ordered in EPIC as **COVID Spike Total Ab**. Epic code is **LAB9340**

**TAT: This assay will be performed M-W-F (the same way as the current assay).** If our current order numbers increase, it can be run daily.

This new assay will replace the test that is named **COVID-19 IgG Ab**, Epic code LAB9246.

**In case antibodies against SARS-CoV-2 Nucleocapsid need to be evaluated, it will be a send-out, LabCorp SARS-CoV-2 Antibodies, Nucleocapsid: 164068, TAT 24-72 hours.**

If you have any questions, please call the Immunology lab at 464-6764.