

SARS-CoV-2 Antibody Test for Post Vaccination

February 2021

WHAT IS NEW

Effective February 11, 2020, Pacific Diagnostic Laboratories (PDL) has added a new test as part of the pandemic response: **SARS-CoV-2 Antibody, Spike Protein, Post Vaccination (LAB10895)**. The intended use of this new test is for the detection of S antibody consistent with post COVID-19 vaccination antibody production.

SARS-COV-2 ANTIBODIES, SPIKE PROTEIN, POST VACCINATION	
Lab Code: LAB10895 Test Code: 1230118917	TAT: 24 hours
Specimen Requirements	Method Details
<u>Specimen Type:</u> Serum or Plasma <u>Specimen Container:</u> Gold top, Red Top, Green Top <u>Specimen Handling:</u> <ul style="list-style-type: none"> Allow to clot 30 min; Centrifuge Aliquot serum or plasma to transport tube <u>Transport Temperature:</u> Refrigerated	<u>Vendor:</u> Siemens SARS-CoV-2 Total (COV2T) <u>Sensitivity:</u> 100% <u>Specificity:</u> 99.81% <u>Detects:</u> IgM and IgG <u>Antibody to:</u> S1RBD Spike protein receptor binding domain

BACKGROUND INFORMATION

Serologic methods have important public health and clinical uses for monitoring and responding to the COVID-19 pandemic. The serology test determines the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19. Serology testing is not intended as the diagnostic test for acute COVID-19 infection.

The FDA EUA approved SARS-CoV-2 antibody tests utilized by PDL include:

Vendor	Antibodies to Protein	Test Code	Test Name
Siemens	S protein	LAB10895	SARS-CoV-2 Antibodies, Spike Protein, Post Vaccination
Roche	N protein	LAB10741	SARS-CoV-2 Antibodies with Confirmation, Post Infection <i>Includes confirmation with Siemens assay (CDC orthogonal algorithm)</i>

The Siemens antibody test to the S protein has been determined to be highly effective in detecting post vaccination COVID-19 antibody production for either the Pfizer (BNT162b2) or the Moderna (mRNA-1273) vaccines. PDL recently tested 57 vaccinated individuals utilizing both the Siemens and Roche assays. The test results demonstrated antibody detection in 57 out of 57 vaccinated individuals with the Siemens assay (S antigen) and no antibody detection utilizing the Roche assay (N antigen). ***This observed antibody pattern is highly correlated with an adaptive immune response to prior vaccine administration. Please note: The claim for COVID-19 immunity has not been demonstrated or approved by the FDA with any other test but a complex neutralizing antibody test.***

Test Name	Order Code	Test Code	CPT	CDM
SARS-CoV-2 Antibodies, Spike Protein, Post Vaccination	LAB10895	1230118917	86769	30200845
Result Name	Result Code	LOINC	Client Price	
SARS-CoV-2 Abs, Spike, Post Vaccination	1230018524	94762-2	\$58.98	

Billing guidance: Please refer to PDL COVID-19 Billing Tip Sheet on www.pdllabs.com

FUTURE OF SARS-COV-2 ANTIBODY TESTING

PDL is currently validating an advanced semi-quantitative test to S proteins that is a collaboration between Siemens and the CDC. This test is correlated to neutralizing antibodies plaque assay to COVID-19, which correlates with immunity. We anticipate a March go-live. Please note that as the vaccine options expand, PDL will be updating serology test options for *post vaccination in alignment with the specific vaccine and respective targets.*

FOR MORE INFORMATION PLEASE CONTACT CLIENT SERVICES AT (805) 879-8100

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