PDL UPDATE: SARS-CoV-2 Spike Antibody

October 20, 2021

SARS-CoV-2 SPIKE ANTIBODY

This update is to provide you with additional information on the following test currently being offered by Pacific Diagnostic Laboratories (PDL):

SARS-COV-2 (COVID-19) SPIKE (S) ANTIBODY, SEMI-QUANTITATIVE, POST VACCINATION LAB10910

This test is FDA EUA authorized and is designed to detect a specific antibody to the SARS-CoV-2 virus. Serologic methods have public health value for monitoring and responding to the COVID-19 pandemic, and clinical utility in providing care for patients. Antibody testing is not a diagnostic test for acute COVID-19 infection.

TEST DETAIL:

SARS-CoV-2 Spike Antibody (S) test is a semi-quantitative assay that is consistent with the development of antibody production to SARS-CoV-2 Spike (S1) protein Receptor Binding Domain (RBD).

TEST RESULT:

It is recognized that this test correlates well with circulating neutralizing antibody titers[1,2] and can assess specific post vaccine antibody production without any current claim by the FDA regarding immunity to future COVID-19 infection, which was reaffirmed when the FDA issued their safety communication on 19 May 2021. Of note, however, many recent studies[3,4] reported during the summer of 2021 have clearly demonstrated waning levels of circulating antibodies to SARS-CoV-2 over the course of several months post vaccination. This is the rationale for the FDA[5] authorizing a booster dose for select populations at least 6 months after completion of the primary series of Pfizer BioNTech COVID-19 vaccine. Serologic methods have important clinical uses for monitoring and responding to the COVID-19 pandemic.

This semi-quantitative serology test includes a positive or negative interpretation, as well as the absorbance value (listed as an index value unique to this particular assay). The index value has a reproducibly distinct relationship to the amount of circulating SARS-CoV-2 antibody present. Studies have shown that with this semiquantitative antibody, the higher the index value the greater the amount of circulating antibodies present in the patient. A positive result for the SARS-CoV-2 Spike Antibody (S1 RBD) semi-quantitative test is consistent with the development of antibody production to SARS-CoV-2 Spike (S1) protein receptor binding domain (RBD) with the Pfizer (BNT162b2), the Moderna (mRNA-1273), or the Johnson & Johnson (JNJ-78436735) vaccines.

For Health Care Providers, PDL reaffirms the FDA position with the added context of this new research and recognizes that index values < 1.00 should continue to be interpreted as Negative for circulating antibodies. Specifically, this means that the level of circulating Spike (S1 RBD) antibody cannot be analytically distinguished from the cohort of normal individuals tested as part of the original PDL validation studies, performed prior to the release of vaccination, in which 57 of 57 uninfected individuals had index values < 1.00 consistent with the performance characteristics as submitted to the FDA by Siemens. In addition, the Siemens SARS-CoV-2 Spike (S1 RBD) Antibody performed on the Siemens ADVIA Centaur must generate an index value ≥ 4.8 in order to meet the FDA requirement to be categorized as a high-titer COVID-19 Convalescent Plasma donor.[2]

References:

1 USA. Food and Drug Administration (FDA). Hinton DM. The Authorized COVID-19 Convalescent Plasma. Available at: Convalescent Plasma EUA Letter of Authorization 06032021 (fda.gov)

2 Hematology Transfusion Cellular Therapy 2021; 43(2): 212-213.

3 Lancet Vol 398 (31 Jul 2021): 385-386.

4 Nature Medicine 27 (Jul 2021): 1205-1211.

5 USA. Food and Drug Administration (FDA) Press Release of 22 September 2021. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations.

SARS-COV-2 SPIKE ANTIBODY (IGG), SEMI-QUANTITATIVE, POST VACCINATION
Lab Code: LAB10910 Test Code: 1230118995
Specimen Requirements
Specimen Type: Serum or Plasma
Specimen Container: Gold Top, Red Top or Green Top
Specimen Handling:
• Allow to clot 30 min; Centrifuge
• Transfer serum or plasma to transport tube
Transport Temperature: Refrigerated
Turnaround Time: 24 hours

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