

PDL UPDATE: SARS-CoV-2 Antibody Test Options



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SARS-CoV-2 ANTIBODIES & TEST OPTIONS

Pacific Diagnostic Laboratories (PDL) currently offers two FDA EUA SARS-CoV-2 (COVID-19) Antibody test options. The tests are designed to detect specific antibodies to the SARS-CoV-2 virus. We are providing additional information to highlight the differences in the tests as well as provide guidance for COVID-19 Antibody Testing.

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.

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

Test Detects: IgG antibody to the Receptor-binding domain (RBD) spike (S1) protein of SARS-CoV-2.

Result Includes: The absorbance Index as well as a positive/negative interpretation. Studies have shown that the higher the absorbance Index the greater the amount of circulating antibodies.

Test Assesses: The specific post-vaccine antibody production without any current claim by the FDA regarding immunity to future COVID-19 infection. A positive result for the SARS-CoV-2 Spike Antibody (IgG) semi-quantitative test is consistent with the development of antibody production to Spike (S) protein with the Pfizer (BNT162b2), the Moderna (mRNA-1273), or the Johnson & Johnson (JNJ-78436735) vaccines.

Additional Information: Antibodies to the spike (S) protein can also develop post infection.

SARS-COV-2 TOTAL ANTIBODIES WITH CONFIRMATION, POST INFECTION (LAB10741)

Test Detects: IgM and IgG antibodies to the nucleocapsid (N) protein of SARS-CoV-2 with a confirmation reflex *if positive*, to a second test that detects IgM and IgG to the spike (S) protein. This approach follows the CDC orthogonal algorithm to optimize the positive predictive value of the test. *Please note that this test should not be used to assess vaccine immune response.*

Result Includes: Qualitative interpretation of presence or absence of the antibodies.

Test Assesses: The presence of antibodies to the (N) protein and (S) protein. Tests that detect antibodies to the N and S proteins (including the S1 RBD antigen) indicate an immune response to infection.

Additional Information: Antibodies can be detected within 1-3 weeks after infection. IgM and IgG antibodies can arise nearly simultaneously; however, IgM (and IgA) antibodies decay more rapidly than IgG. The clinical significance of IgA in SARS-CoV-2 is not yet established.

CDC INTERIM GUIDANCE FOR COVID-19 ANTIBODY TESTING

In a person never vaccinated:	Testing positive for antibody against either N, S, or RBD indicates prior natural infection.
In a vaccinated person:	1) Testing positive for antibody against the vaccine antigen target, such as the S protein, and negative for other antigens suggests that they have produced vaccine-induced antibody and that they were never infected with SARS-CoV-2. 2) Testing positive for any antibody other than the vaccine-induced antibody, such as the N protein, indicates resolving or resolved SARS-CoV-2 infection that could have occurred before or after vaccination.

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

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

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