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Test Announcement:
SARS-CoV-2 Antibodies, Spike Protein

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PathGroup is pleased to announce the availability of a new serologic test for the detection of human antibodies to the **SARS-CoV-2 spike protein (S) receptor binding domain (RBD)**, the viral pathogen associated with SARS-CoV-2 (COVID-19). The Roche Elecsys® Anti-SARS-CoV-2 S antibody test is for the qualitative and semi-quantitative detection of total antibodies (IgG, IgA and IgM) to SARS-CoV-2 in serum from individuals with prior COVID-19 infection and is intended to aid in identification of patients with an adaptive immune response to SARS-CoV-2 indicating prior infection to the SARS-CoV-2 virus. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for this test.

The manufacturer's stated **sensitivity** is 96.6%, 15 days post-confirmation of Covid-19 infection. This test has a reported **specificity** of 99.98% with no reported cross-reactivity to other similar coronaviruses. An antibody (serology) test may be used to assist in the determination of acquired immunity following exposure to a pathogen. Determination of antibody status may assist in the assessment of patient status and for epidemiological purposes. High sensitivity and specificity performance characteristics of the test are important for such determinations especially in low prevalence populations.

Antibodies to SARS-CoV-2 have been detected several days after initial infection. However, expected antibody concentration and duration of elevation are still being investigated. In addition, some patients may not generate detectable antibodies after infection because of an underlying immune disorder or immunosuppression, and individual immune responses may vary based on infective dose or viral burden upon exposure to the virus.

To date, no study has provided conclusive evidence that the presence of antibodies after infection confers immunity to subsequent infection by the same or other strains of SARS-CoV-2. In addition, a non-reactive (negative) test result does not rule out the possibility of SARS-CoV-2 infection as negative results may be obtained prior to seroconversion. Therefore, this test is not intended for use to diagnose an acute infection.

For more information see the fact sheets for providers and test recipients on the FDA website.
Providers: https://www.fda.gov/media/144035/download
Recipients: https://www.fda.gov/media/144036/download

SARS-CoV-2 Antibodies, Spike Protein	
Test Code	**COVIDSP**
Test Name	SARS-CoV-2 Antibodies, Spike Protein
Methodology	Electrochemiluminescence immunoassay
Specimen Type/Volume	Human Serum, 0.5mL
Specimen Container	Serum Separator Tube (SST)
Specimen Stability/Storage/Transport	Room temperature: 3 days Refrigerated (2-8°C): 7 days Frozen (-20°C): 28 days
Unacceptable Conditions	Grossly hemolyzed specimens
Turnaround Time	24 - 48 hours (may vary with increased demand)
Billing	86769

For additional information about this test, please visit the online Directory of Services at https://pathconnect.pathgroup.com/testmenu/#/testinfo/Q09WSURTUA%3D%3D.

For further questions, contact PathGroup Client Services at 1-888-4PG-LABS (1-888-474-5227).