Test Available: SARS-CoV-2 (COVID-19) Antibody

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Effective May 27, 2020, PathGroup is pleased to announce the availability of a new serologic test for human antibodies to SARS-Cov-2, the viral pathogen associated with COVID-19 (PathGroup Test Code: COVIDAB). On May 3, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Roche Elecsys® SARS-CoV-2 antibody test. The test is for the qualitative detection of total antibodies (including IgG, IgA and IgM) to SARS-CoV-2 in serum from individuals with prior COVID-19 infection. This test may aid in identification of patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection to the SARS-CoV-2 virus.

The manufacturer's stated **sensitivity** is 100%, 14 days post-confirmation of infection by PCR. This test has a reported **specificity** greater than 99.8% with no reported cross-reactivity to other similar coronaviruses that could generate a false positive result and thus wrongly infer potential immunity. An antibody test, also called a 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 determined. 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 confers immunity to subsequent infection by the same or other strains of SARS-CoV-2 in humans. 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/137603/download
Recipients: https://www.fda.gov/media/137604/download

(Test specifications continued on page 2)

SARS-CoV-2 (COVID-19) Antibody	
Test Code	**COVIDAB** **PLEASE NOTE –** PathGroup will no longer offer SARS-CoV-2 IgG Antibody (PathGroup Test Code COVIDIGG). Effective May 27, 2020, all orders for PathGroup Test Code COVIDIGG will be substituted with PathGroup Test Code COVIDAB.

	For clients with EHR ordering interfaces who are not currently ordering COVIDIGG, and would like to order COVIDAB electronically, please contact PathGroup IT at help@pathgroup.com to request the new test code be added to your EHR system. After a transition period, all EHR systems will be updated to permanently substitute the COVIDAB test code for the COVIDIGG test code.
TEST NAME	SARS-CoV-2 Antibodies, Total (IgG/IgA/IgM)
METHODOLOGY	Sandwich ELISA chemiluminescence immunoassay
SPECIMEN TYPE/VOLUME	Human Serum, 0.5mL
SPECIMEN COLLECTION	Serum Separator Tube (SST)
SPECIMEN STABILITY	Room temperature: 3 days Refrigerated (2-8°C): 7 days Frozen: 28 days
SPECIMEN STORAGE/TRANSPORT	Room temperature or refrigerated (2-8°C): 3 Days Frozen (-20°C) for longer storage
UNACCEPTABLE CONDITIONS	Grossly hemolyzed specimens
TURNAROUND TIME	24 hours (TAT may be impacted by high volume)
BILLING	CPT 86769

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