



EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA Receives FDA Emergency Use Authorization

October 5, 2021

Assay enabling the measurement of IgG antibodies could yield future discoveries and insights on immune responses to SARS-CoV-2

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 5, 2021-- [EUROIMMUN](#), a [PerkinElmer, Inc.](#) company (NYSE: PKI), announced today that the U.S. Food and Drug Administration has provided Emergency Use Authorization (EUA) for its [Anti-SARS-CoV-2 S1 Curve™ ELISA \(IgG\)](#). This assay allows for the qualitative and semi-quantitative detection of IgG antibodies formed against the SARS-CoV-2 S1 antigen, in human serum and plasma. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) can immediately begin using this ELISA for the detection of antibodies of the immunoglobulin class G.

The Anti-SARS-CoV-2 S1 Curve ELISA (IgG) – based on EUROIMMUN's [Anti-SARS-CoV-2 QuantiVac™ ELISA \(IgG\)](#) that received CE mark in November 2020 – measures the concentration of antibodies against the S1 domain of the spike protein including the receptor binding domain (RBD), which represents an important target antigen for virus neutralizing antibodies. Due to the low protein homologies within the coronavirus family, the existence of IgG antibodies specifically indicates recent or prior infection and is to be used as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. For this reason, S1 based tests play a critical role in ongoing vaccine development programs and in research efforts to examine the immunity of individuals previously infected by SARS-CoV-2.

“Assays that enable the detection of IgG antibodies are an important tool in the arsenals of scientists and researchers working to understand the nature of SARS-CoV-2 and prevent the spread of other highly infectious viruses like it in the future,” said Dr. Wolfgang Schlumberger, CEO of EUROIMMUN. “With this latest EUA of our semi-quantitative antibody test, more laboratories will have the ability to generate in-depth insights on immunity that advance future antibody therapies and vaccines for COVID-19.”

The assay can run manually or using the [EUROLab™ Workstation ELISA](#), [Sprinter XL™](#) and other third party ELISA platforms.

The Anti-SARS-CoV-2 S1 Curve ELISA (IgG) is one of many solutions in EUROIMMUN's [SARS-CoV-2 specific portfolio](#), which also includes real-time [PCR tests](#), an [antigen](#) detection assay and multiple [antibody](#) tests, a [dried blood spot](#) solution, as well as [automation](#) systems for small, medium and high sample throughput.

About PerkinElmer

PerkinElmer enables scientists, researchers, and clinicians to address their most critical challenges across science and healthcare. With a mission focused on innovating for a healthier world, we deliver unique solutions to serve the diagnostics, life sciences, food, and applied markets. We strategically partner with customers to enable earlier and more accurate insights supported by deep market knowledge and technical expertise. Our dedicated team of about 15,000 employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the wellbeing and longevity of people globally. The Company reported revenue of approximately \$3.8 billion in 2020, serves customers in 190 countries, and is a component of the S&P 500 index. Additional information is available at www.perkinelmer.com.

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