NEWS RELEASE

FDA Provides Emergency Use Authorization to PerkinElmer for Serological Test to Identify COVID-19 Antibodies

5/5/2020

PDF Version

WALTHAM, Mass.--(BUSINESS WIRE)--May 5, 2020-- **PerkinElmer, Inc.** (NYSE: PKI), a global leader committed to innovating for a healthier world, announced today that the U.S. Food and Drug Administration (FDA) has provided Emergency Use Authorization (EUA) for EUROIMMUN's (a PerkinElmer company) **Anti-SARS-CoV-2 ELISA (IgG) serology test.** Clinical laboratories certified to perform high complexity tests under Clinical Laboratory Improvement Amendments (CLIA) can immediately begin using this ELISA for the detection of antibodies of the immunoglobulin class G.

Serological tests detect antibodies in the blood and are detected when an immune reaction to the pathogen has already taken place. These tests can determine who had previously been infected with COVID-19 (2-4 weeks or more prior to testing) and may have developed immunity. How long antibodies last and whether they are protective is being actively studied. The EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) has 99% specificity and 100% sensitivity after 21 days following the onset of symptoms.

"Leading with science is a fundamental part of our DNA at PerkinElmer, and the EUROIMMUN team recognized early on that understanding the pathogenesis of COVID-19 from a cellular biology level is paramount to developing a highly accurate and reliable antibody test," said Prahlad Singh, president and chief executive officer, PerkinElmer.

“As a result, the antigen used in the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG), the spike protein S1 domain, is more likely to reflect virus neutralizing antibodies than antibodies to N capsid nucleoprotein. This is also supported by the fact that most of the COVID-19 vaccine development programs in the U.S. and worldwide have chosen the spike protein as their target.”

“It is possible that 50 percent* or more of people who have been infected with COVID-19 might not display symptoms, making it difficult to identify those who have previously contracted COVID-19,” said Prahlad Singh. “That’s why serological testing that utilizes an antigen highly specific to SARS-CoV-2 is such an important tool in understanding how pervasive this virus is.”

EUROIMMUN has the capacity to manufacture millions of assays per month. Since March, it has already started shipping its Anti-SARS-CoV-2 ELISA (IgG) to leading laboratories across the globe. EUROIMMUN intends to further build production capacity to meet heightened demand.

For more information about COVID-19 solutions from EUROIMMUN, a PerkinElmer company, please visit **www.coronavirus-diagnostics.com**.

The Anti-SARS-CoV-2 ELISA (IgG) EUA has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by authorized laboratories. The test has been authorized only for the detection of SARS-CoV-2 antibodies (the antibodies detected should be specified, e.g., total, IgA, IgG and IgM) not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

*Data attributed from COVID-19 **studies**

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 13,000 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 $2.9 billion in 2019, serves customers in 190 countries, and is a component of the S&P 500 index. Additional information is available through 1-877-PKI-NYSE, or at **www.perkinelmer.com**.

Factors Affecting Future Performance

This press release contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements relating to estimates and projections of future earnings per share, cash flow and revenue growth and other financial results, developments relating to our customers and end-markets, and plans concerning business development opportunities, acquisitions and divestitures. Words such as "believes," "intends," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions, and references to guidance, are intended to identify forward-looking statements. Such statements are based on management's current assumptions and expectations and no assurances can be given that our assumptions or expectations will prove to be correct. A number of important risk factors could cause actual results to differ materially from the results described, implied or projected in any forward-looking statements. These factors include, without limitation: (1) markets into which we sell our products declining or not growing as anticipated; (2) fluctuations in the global economic and political environments; (3) our failure to introduce new products in a timely manner; (4) our ability to execute acquisitions and license technologies, or to successfully integrate acquired businesses and licensed technologies into our existing business or to make them profitable, or successfully divest businesses; (5) our failure to adequately protect our intellectual property; (6) the loss of any of our licenses or licensed rights; (7) our ability to compete effectively; (8) fluctuation in our quarterly operating results and our ability to adjust our operations to address unexpected changes; (9) significant disruption in third-party package delivery and import/export services or significant increases in prices for those services; (10) disruptions in the supply of raw materials and supplies; (11) the manufacture and sale of products exposing us to product liability claims; (12) our failure to maintain compliance with applicable government regulations; (13) regulatory changes; (14) our failure to comply with healthcare industry regulations; (15) outbreaks of communicable diseases such as COVID-19; (16) economic, political and other risks associated with foreign operations; (17) our ability to retain key personnel; (18) significant disruption in our information technology systems, or cybercrime; (19) our ability to obtain future financing; (20) restrictions in our credit agreements; (21) discontinuation or replacement of LIBOR; (22) the United Kingdom’s withdrawal from the European Union; (23) our ability to realize the full value of our intangible assets; (24) significant fluctuations in our stock price; (25) reduction or elimination of dividends on our common stock; and (26) other factors which we describe under the caption "Risk Factors" in our most recent annual report on Form 10-K and in our other filings with the Securities and Exchange Commission. We disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20200505005611/en/**

Media Relations:
Brian Willinsky

(781) 663-5728
brian.willinsky@perkinelmer.com

Investor Relations:
Bryan Kipp
(781) 663-5583
bryan.kipp@perkinelmer.com

Source: PerkinElmer, Inc.