FDA provides EUA to PerkinElmer for COVID-19 serological test

May 7, 2020—<u>PerkinElmer</u> announced that the FDA has provided emergency use authorization for <u>Euroimmun</u>'s Anti-SARS-CoV-2 ELISA (IgG) serology test. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, and has 99 percent specificity and 100 percent 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," Prahlad Singh, president and chief executive officer, PerkinElmer, said in a press release. "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."