



## **EUROIMMUN is one of first European manufacturers of diagnostic tests to provide CE-marked antibody detection systems to support COVID-19 diagnostics**

March 25, 2020

The [Anti-SARS-CoV-2 ELISAs](#) for immunoglobulin classes A and G from EUROIMMUN, a PerkinElmer, Inc. company (NYSE:PKI), have received the CE mark and can now be applied to COVID-19 diagnostics. The PCR test EURORealTime SARS-CoV-2 has been submitted for CE mark.

COVID-19 is currently significantly affecting the lives of people worldwide. At the end of January 2020, the World Health Organization declared the new infectious disease COVID-19 a global emergency. The Johns Hopkins University has reported more than 441,000 infections and 19,700 deaths as of 25 March 2020.

Coronaviruses form a large family of viruses which can cause mild colds, but also severe, sometimes fatal diseases of the respiratory tract. In the case of COVID-19, the infection has a mild course in the majority of patients. However, it may also cause severe, life-threatening pneumonia with acute respiratory distress syndrome.

As is the case with other infectious diseases, RT-PCR and serological tests are suited to investigate patients with suspected infections with SARS-CoV-2. RT-PCR technology plays a role especially in the early stage of a viral infection, in which the virus reproduces quickly. It enables direct detection of the pathogen. Serological tests, on the other hand, detect neutralizing antibodies in the blood. This means they are applied when an immune reaction to the pathogen has already taken place. Using this test, researchers may be able to determine how quickly antibodies to the virus are made, which could have implications in identifying individuals who have developed immunity.

At EUROIMMUN, the development of tests was initiated promptly after the virus became known, resulting in the introduction of two ELISAs for the detection of anti-SARS-CoV-2 antibodies of classes IgA and IgG. These are two of the first antibody detection tests to be CE marked in Europe and available for COVID-19 testing. While IgG antibodies indicate a persisting or even past infection, IgA antibodies are described as early markers of acute respiratory tract infections. In a recent study (Okba et al., doi: 10.1101/2020.03.18.20038059; March 2020) the additional value of specific IgA detection for early diagnostics of acute SARS-CoV-2 infections was confirmed. The good sensitivity and specificity of the ELISAs have also been proven. The developers underline that the antigen used in the EUROIMMUN Anti-SARS-CoV-2 ELISAs (IgA and IgG), the spike protein S1 domain, is more specific for the serological detection of SARS-CoV-2 antibodies than the more highly conserved N- or full-length S-proteins.

"The ELISAs are suited for screening on a large scale in order to identify persons who may have had contact with the virus even without noticing, have had an immune response, and have probably developed immunity," explains Katja Steinhagen, Head of EUROIMMUN's Business Division Immunobiochemistry Infectious Serology. They can also be applied to collect epidemiological data. Like almost all other ELISAs from EUROIMMUN, the Anti-SARS-CoV-2 ELISAs can be processed automatically using laboratory instruments.

The SARS-CoV-2 product range is completed by the EURORealTime SARS-CoV-2 for direct virus detection. This PCR-based test is currently only available for research use and has been submitted for CE mark.

Dr. Ulf Steller, Head of EUROIMMUN's Business Division Molecular Genetic Diagnostics explains: "The EURORealTime SARS-CoV-2 was developed for specific detection of COVID-19. Because the test detects two different genetic sequences of the virus simultaneously, it is very sensitive."

As the demand for reliable COVID-19 diagnostic tests is steadily increasing, EUROIMMUN is working to expand the test production. "The worldwide demand for these tests is very high. We will do our best to respond to this need with effective testing solutions," says EUROIMMUN's CEO, Dr. Wolfgang Schlumberger.