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QIAGEN, DiaSorin collaborate for early detection of Lyme disease

07 June 2019 | News

The companies plan multi-site clinical validations during the 2020 Lyme disease season, with regulatory submissions expected at the end of the same year in the United States and Europe.



QIAGEN and DiaSorin have announced the expansion of their QuantiFERON collaboration to develop an ultra-sensitive diagnostic test for Lyme disease, which is expected to address a significant unmet medical need.

The companies plan multi-site clinical validations during the 2020 Lyme disease season, with regulatory submissions expected at the end of the same year in the United States and Europe. The QuantiFERON technology comes in two components: the QuantiFERON sample collection component with the proprietary assay stimulus/initiation and QuantiFERON read-out component to measure the signal created by the stimulus. The QuantiFERON read-out component of the assay will be run on DiaSorin's widely used LIAISON family of fully automated analyzers and both components will be designed for use on these platforms.

Lyme disease, also called borreliosis, is an infection caused by the Borrelia burgdorferi bacterium, which is transmitted to humans through the bite of blacklegged ticks. Typical symptoms include fever, headache, fatigue and a skin rash called erythema migrans. Left untreated, the Lyme infection can spread to joints, the heart and the nervous system. Lyme disease is most often contracted during the warmer months of the year.

Approximately 30,000 confirmed cases of Lyme disease per year are reported to the U.S. Centers for Disease Control (CDC), but the CDC notes that recent estimates suggest about 300,000 individuals may get Lyme disease annually in the U.S. Meanwhile, the latest available ECDC data in Europe showed approximately 35,000 confirmed cases in 2010, but is considered to be significantly underestimated by many experts amid expectations for a significant 100% increase in the spread of this disease in Europe during the last decade.

The current diagnostic algorithm for Lyme diagnosis foresees the use of IgG and IgM detection, produced via B cell immune response, in association with Western Blot as a confirmative tool.

However, there is often a risk for a false negative result due to the fact that patients often visit their doctor very early during the onset of the disease given the appearance of visible signs of the tick bite or the presence of the tick itself, but before the B cell response has not been activated. T cell response, as measured through the QuantiFERON technology, precedes B cell response and has the potential to provide significantly better sensitivity and earlier detection of the infection.

The QuantiFERON-Lyme test is planned for use in conjunction with LIAISON Borrelia IgG and IgM assays, risk assessment, and other medical and diagnostic evaluations, making it highly synergistic to DiaSorin's IgM assays on LIAISON.

QIAGEN and DiaSorin's collaboration in Lyme disease builds on the co-development and commercialization of in vitro diagnostics combining QIAGEN's industry-leading QuantiFERON technology for sensitive detection of infectious diseases using novel interferon gamma release assays (IGRAs) with DiaSorin's established Lyme disease testing assays.

As part of their collaborations, the two companies already launched a fully automated workflow for the QuantiFERON-TB Gold Plus (QFT-Plus) test for latent tuberculosis (TB) infection in Europe, and are planning for launch in the United States later in 2019 and in China in the future.

The QuantiFERON-based tests for TB and Lyme disease detection are designed to be processed on the more than 8,000 LIAISON systems in place globally, and primarily in hospital laboratories.

"We are excited about the potential to bring the power of QuantiFERON technology to the very large unmet need in Lyme disease, a serious and under-diagnosed infection afflicting hundreds of thousands of patients a year," said Thierry Bernard, Senior Vice President, Head of the Molecular Diagnostics Business Area at QIAGEN. "Early detection of the initial infection and testing for recurrence of Lyme disease are critical to protect patients from debilitating long-term effects. We believe QuantiFERON-Lyme can provide a valuable solution for these needs."

Carlo Rosa, Chief Executive Officer of DiaSorin Group, commented: "Starting from the successful collaboration with QIAGEN on the use of QuantiFERON technology combined with our CLIA solutions to detect latent tuberculosis, this new project targets the first in a pipeline of additional innovations for our clients. I'm profoundly convinced that our joint forces can provide a solid response to labs' daily needs, leveraging the top-notch QuantiFERON technology, our advanced automation on LIAISON and the breadth of our CLIA menu across several clinical areas. Developing QuantiFERON-Lyme will leverage DiaSorin's strong presence in Lyme with our line of serological tests based on the IgG and IgM antibodies."

Both companies estimate that the current IgG- and IgM-based Lyme disease testing market in the United States and Europe is as high as 20 million tests annually and that while the conversion of this market from existing standards will take time, this assay represents a significant addition to the joint QuantiFERON assay portfolio.