

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.