

The Diagnostic Specialist

Press Release

DIASORIN LAUNCHES THE NEW LIAISON QUANTIFERON-TB GOLD PLUS ASSAY AS AN AID FOR LATENT TUBERCULOSIS DETECTION IN PARTNERSHIP WITH QIAGEN

September 17, 2018 - Saluggia, Italy and Hilden, Germany; **DiaSorin** (FTSE Italy Mid Cap: DIA) and **QIAGEN N.V.** (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch in the CE market of the LIAISON QuantiFERON-TB Gold Plus as an aid to detect latent tuberculosis infection (LTBI) on LIAISON analyzer systems.

The new test was developed in a partnership between DiaSorin and QIAGEN to help address accelerating conversion of the global LTBI testing market to the modern blood-based QuantiFERON technology.

LTBI is today a major healthcare problem with around one third of worldwide population carrying the infection, and with about 5-10% of this number progressing to active tuberculosis (TB) if untreated¹, thus causing around 1.7 million deaths every year and making it one of the top 10 causes of death worldwide.

Tuberculosis is a contagious bacterial infection spread primarily through coughing by patients with the active pulmonary form of the disease. In LTBI, the bacterium infects a person but produces no symptoms unless it progresses to active disease, at which stage the patient is highly contagious. As part of comprehensive programs to eradicate TB, WHO and other international organizations have expanded their guidelines for screening high-risk individuals and treating those with latent infection to help prevent further contagion and reduce the disease burden.

TB is currently diagnosed either through a skin test or a blood test technology, the latter working in two steps: (1) blood collection and consequent stimulation of T-cells immuno-response to TB through in-tube incubation, executed with QuantiFERON Blood Collection Tubes, thus releasing interferon gamma that (2) needs to be measured with an immunoassay solution, today executed with QuantiFERON test read-out components on the ELISA technology.

The launch of the new LIAISON QuantiFERON-TB Gold Plus is meant to provide laboratories with the first and only available CLIA detecting solution in the European market on the LIAISON family platforms, simplifying and speeding-up the second step of the TB testing process, as a consequence of the incremental strong demand of the TB testing volumes worldwide.

The test will be launched in the U.S. by 2019 and in China by 2020 and will enable customers of both companies to process QuantiFERON-TB Gold Plus (QFT-Plus), the fourth-generation modern gold standard for latent tuberculosis (TB) detection, on more than 7,000 LIAISON platforms worldwide.

Through the partnership signed on the QuantiFERON technology, DiaSorin and QIAGEN want to drive the conversion from existing skin test detection to a fully automated testing process and, at the same time, provide labs with the opportunity to lead the testing process with a complete, fast and robust fully-integrated solution.

Customers will continue to purchase the QuantiFERON Blood Collection Tubes kit from QIAGEN, while DiaSorin will be responsible for commercialization of the QuantiFERON read-out test components, also leveraging on a dedicated software developed to allow complete traceability, result management and full integration with the IT solutions available today in most of the diagnostic laboratories.

¹ World Health Organization estimates



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Furthermore, the collaboration between the two companies initiated in 2017 to develop new tests for the LIAISON family analyzers based on QIAGEN assay technologies is leading to assess and develop new potential opportunities based on QuantiFERON technology, providing a unique, efficient way to detect asymptomatic infections and other risks that cannot be discovered with standard diagnostic technologies.

Carlo Rosa, Chief Executive Officer of DiaSorin Group, commented "I'm really excited about the tremendous opportunity we have in front of us through this alliance with QIAGEN. The collaboration between the two companies can provide a very unique solution to the current LTBI tests demand in the labs all over the world. Our existing LIAISON platforms installed base, combined with the launch of our new CLIA platform, LIAISON XS, in early 2019, will provide new labs the opportunity to approach this relevant testing routine with a very robust and fully-automated solution. I'm convinced that this collaboration with QIAGEN can bring our companies to find additional diagnostic applications where we can leverage on the QuantiFERON technology and the LIAISON installed base, strengthening our positioning in the diagnostic market".

Thierry Bernard, Senior Vice President, Head of the Molecular Diagnostics Business Area at QIAGEN, commented: "We are pleased to offer customers this compelling, fully automated solution for QuantiFERON-TB Plus, enabling an improved workflow of the world's leading test for latent TB infection. Increasingly, public health initiatives around the world are using QFT-Plus in screening at-risk patients to safeguard against progression from latent infection to active, life-threatening tuberculosis. LIAISON users will benefit from adding our unique latent TB test to their laboratory menus and will thereby be able to provide highly accurate screening and novel diagnostic insights. QuantiFERON-TB customers will benefit from LIAISON's best-in-class, random access, continuous loading and fully automated workflow. We look forward to working closely with our partners at DiaSorin"

About DiaSorin Group

Headquartered in Italy and listed in the FTSE Mid Cap Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field. For over 50 years the Company has been developing, producing and marketing reagent kits for IVD worldwide. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnostics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnostics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the IVD "Diagnostics Specialist."

For additional information, please contact:

Riccardo Fava Investor Relations & Corporate Communication Senior Director Tel: +39.0161.487988 <u>riccardo.fava@diasorin.it</u> Ines Di Terlizzi Investor Relator Tel: +39.0161.487567 ines.diterlizzi@diasorin.it