



DIASORIN RECEIVES FDA APPROVAL FOR ITS LIAISON® QUANTI FERON®-TB GOLD PLUS ASSAY FOR USE ON THE LIAISON® XS ANALYZER, WIDENING THE ACCESSIBILITY OF BLOOD-BASED LATENT TUBERCULOSIS INFECTION TESTING IN THE U.S.

LIAISON® QUANTI FERON®-TB GOLD PLUS

- IS A TEST FOR THE DETECTION OF *M. TUBERCULOSIS* INFECTIONS AND INTENDED TO ASSIST THE CLINICIANS IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS IN CONJUNCTION WITH OTHER DIAGNOSTIC TOOLS AND MEDICAL EVALUATIONS
- IS BASED ON THE PATENTED AND WELL ESTABLISHED QIAGEN QUANTI FERON® INTERFERON GAMMA RELEASE ASSAY (IGRA) TECHNOLOGY
- PROVIDES HIGH CLINICAL SENSITIVITY FOR THE DETECTION OF LATENT TUBERCULOSIS INFECTION (LTBI)
- IS NOW ALSO APPROVED FOR USE ON THE LIAISON XS® CLIA PLATFORM, EXPANSION BUILDS ON 2019 APPROVAL FOR USE ON THE LIAISON® XL PLATFORMS AND NOW PROVIDES HIGHLY FLEXIBLE AUTOMATION OPTIONS FOR ALL THROUGHPUT RANGES INCLUDING HOSPITALS

Saluggia (Italy) and Hilden (Germany), November 29, 2021 - DiaSorin (FTSE MIB: DIA) and QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) announced today the approval of LIAISON® Quanti FERON®-TB Gold Plus on the fully automated LIAISON® XS platform in the U.S. market. LIAISON® Quanti FERON®-TB Gold Plus is the modern blood-based leading assay for the detection of *M. tuberculosis* infection.

The U.S. Food and Drug Administration (FDA) approved the LIAISON® Quanti FERON®-TB Gold Plus Test for use on the newly launched benchtop platform LIAISON® XS, thus widening the accessibility of the novel Quanti FERON® technology in the U.S. market and supporting the conversion from testing based on tuberculin skin tests, which were first developed over a century ago.

LIAISON® Quanti FERON®-TB Gold Plus is an Interferon Gamma Release Assay (IGRA) developed by QIAGEN and DiaSorin to offer streamlined laboratory automation for latent TB screening. It has been available in the U.S. since 2019 on the automated LIAISON® XL system.

The highly automated workflow on LIAISON® platforms provides Quanti FERON® customers a powerful, flexible automated option for all throughput ranges. With the addition of the fully automated LIAISON® XS platform, the range of customers has been dramatically expanded to range from smaller healthcare clinics to larger hospitals and medical centers.

Tuberculosis is a major healthcare problem with about one third of the world's population estimated by the World Health Organization (WHO) to carry the infection. If left untreated, up to 10% of these infections



progress to active tuberculosis (TB). TB is one of the top 10 causes of death worldwide¹ causing around 1.7 million deaths every year.

Tuberculosis is a contagious bacterial infection, spread primarily through coughing by patients with the active pulmonary form of the disease. The bacterium can cause infection without disease symptoms, a condition known as latent tuberculosis (LTBI), and those who are infected are at risk of future progression to active disease, at which stage the patient is highly infectious. 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 LTBI to help prevent further contagion and reduce the disease burden.

DiaSorin and QIAGEN will cooperate closely on the promotion and sale of the complete solution to TB testing to assure their customers get the full benefit of this collaboration.

Carlo Rosa, CEO of DiaSorin Group, commented: *“Today we announce the approval of our first PMA assay available on the LIAISON® XS platform. This solution is a key milestone of our LIAISON® XS strategy in the U.S., where the test was already successfully launched in 2019 on our LIAISON® XL platform. Making this test available with our partner QIAGEN for use on the LIAISON XS benchtop solution is part of our plan to increase adoption of this highly automated solution on a platform that is suitable for smaller-size laboratories.”*

Thierry Bernard, CEO of QIAGEN, commented: *“QuantiFERON-TB® Gold Plus continues to set new standards in the global fight against TB, a disease that remains a persistent killer. Our partnership with DiaSorin has enabled customers to absorb the increasing test demand for TB detection with access to a proven automation solution on the LIAISON® XL platform, especially in larger reference labs and hospitals. The addition of the LIAISON® XS platform will open up new opportunities for us together to reach new customer segments requiring lower-throughput options.”*

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¹ World Health Organization (WHO) estimates



The Diagnostic Specialist

PRESS RELEASE



About DiaSorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 45 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the “Diagnostic Specialist”.

More info at www.diasoringroup.com

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of September 30, 2021, QIAGEN employed approximately 6,000 people in over 35 locations worldwide. Further information can be found at <http://www.qiagen.com>.