QIAGEN and DiaSorin widen access to latent TB testing in the U.S. with FDA approval of QuantiFERON®-TB Gold Plus assay on LIAISON® XS

- *Additional U.S. approval for LIAISON® XS platform builds on FDA approval in 2019 for QuantiFERON assay running on DiaSorin's LIAISON® XL analyzer*
- *Collaboration now provides full range of automation platforms for TB testing options to customers, ranging from small healthcare clinics to larger hospitals and reference laboratories*
- *QIAGEN's QuantiFERON Interferon Gamma Release Assay (IGRA) technology the leading assay for detection of latent TB with high clinical sensitivity*

Hilden, Germany, and Saluggia, Italy, November 29, 2021 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) and DiaSorin (FTSE MIB: DIA) today announced that the U.S. Food and Drug Administration (FDA) has approved the LIAISON® QuantiFERON®-TB Gold Plus assay for use on DiaSorin's automated LIAISON® XS platform.

The approval widens the accessibility of U.S. customers to automation solutions for processing QIAGEN's leading blood-based test for latent tuberculosis (TB) detection and support the conversion from the traditional tuberculin skin tests that were developed over a century ago.

The highly automated workflow on LIAISON® platforms gives QuantiFERON® customers a powerful, flexible automated option for all throughput ranges. The addition of the fully automated LIAISON® XS platform to the already approved use of this assay on the LIAISON® XL version expands the range of potential customers to include experts at smaller healthcare clinics alongside those at larger hospitals and medical centers and reference laboratories.

"QuantiFERON-TB Gold Plus continues to set new standards in the global fight against TB, a disease that remains a persistent killer and impacts people around the world," said Thierry Bernard, CEO of QIAGEN N.V. "Our partnership with DiaSorin has enabled customers to absorb the increasing 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 joint opportunities for us to reach new customer segments requiring lower-throughput options."

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."

LIAISON® QuantiFERON®-TB Gold Plus is an interferon-gamma release assay (IGRA) developed by QIAGEN and DiaSorin to offer streamlined laboratory automation for latent TB screening. QuantiFERON-TB – which tests for interferon-gamma released from T-cells that have encountered TB bacteria – has been available on LIAISON® XL platforms in the U.S. since 2019.

QIAGEN and DiaSorin will continue to cooperate closely on the promotion and sale of their joint solutions for TB testing to make sure their customers reap the full benefit of their collaboration.

TB is one of the biggest global healthcare problems. About one third of the world's population is estimated by the World Health Organization (WHO) to carry the infection in its latent form – about 2.5 billion people. Left untreated, up to 10% of them will become active TB sufferers. The disease is one of world's top 10 causes of death, claiming around 1.7 million victims each year.

The highly contagious bacterial infection is spread primarily through coughing by patients with the active, lung-based form of the disease. But the bacterium can also cause infection without disease symptoms, a condition known as latent tuberculosis (LTBI). As part of programs to eradicate TB, the WHO and other international organizations have expanded guidelines for screening high-risk individuals and treating those with LTBI to help prevent further contagion.

Further information on the product can be found here.

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.

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.

Forward-Looking Statement QIAGEN

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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