

QIAGEN receives European IVDR certification for QIAstat-Dx syndromic testing instruments and assays

- **Product line earns CE-marking under new EU IVDR framework – including QIAstat-Dx Analyzer, QIAstat-Dx Rise and panels for detection of gastrointestinal and respiratory infections**
- **Certification confirms that QIAGEN's devices meet the stringent safety, quality and performance standards for in-vitro diagnostics in Europe**
- **QIAGEN on track to transition over 180 products to new IVDR regulatory framework**

Venlo, the Netherlands, September 26, 2024 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced that its QIAstat-Dx syndromic testing systems and associated assays have received CE-marking under the European Union's new In-Vitro Diagnostic Medical Devices Regulation (IVDR).

This certification includes the widely-used QIAstat-Dx Analyzer, QIAstat-Dx Rise, and panels for detecting gastrointestinal and respiratory illnesses. The achievement underscores QIAGEN's commitment to meeting the highest standards of safety, quality, and performance, as it has already transitioned 80 percent of over 180 products to the new regulatory framework.

The new IVD regulation aims to ensure the safety, quality and effectiveness of in-vitro diagnostic (IVD) devices, overseen by independent organizations in the EU known as Notified Bodies. Devices are now classified by risk level, from A (lowest risk) to D (highest risk). The QIAstat-Dx instruments, QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise, are classified as Class A devices, while the QIAstat-Dx Gastrointestinal Panel 2 is classified as a Class C device. The QIAstat-Dx Respiratory Panel Plus is classified as a Class D device – the highest risk category – highlighting QIAGEN's capabilities to meet highest regulatory thresholds in Europe. The submission for IVDR certification of the QIAstat-Dx Meningitis/Encephalitis Panel is expected in the coming months.

"Achieving IVDR certification for our QIAstat-Dx systems and panels is a significant milestone for QIAGEN," said Fernando Beils, Senior Vice President and Head of QIAGEN's Molecular Diagnostics Business Area. "This certification under the new, more rigorous EU regulatory framework underscores our commitment to provide healthcare professionals with reliable and rapid syndromic testing solutions they can trust. As we continue to transition over 180 products to the IVDR framework, we remain dedicated to enhancing patient care by offering clinical customers a broad portfolio of diagnostic solutions that meet the highest standards of safety, quality, and performance."

The QIAstat-Dx system leverages multiplex real-time PCR technology to rapidly detect and identify multiple pathogens simultaneously, delivering results in approximately one hour. It provides comprehensive data, including cycle threshold (Ct) values and amplification curves, directly on the instrument's touch screen. These fast and precise results enable healthcare providers to make informed

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treatment decisions, such as discontinuing unnecessary antibiotic use when viral infections are detected, thereby contributing to better patient outcomes and antimicrobial stewardship.

Available in over 100 countries, including the U.S. and throughout Europe, QIAstat-Dx solutions play a critical role in disease diagnosis worldwide. By the end of 2023, more than 4,000 QIAstat-Dx systems had been installed globally. Hospitals, laboratories, and clinics value the QIAstat-Dx range for its ease of use and reliable detection of a wide array of pathogens.

QIAstat-Dx is available in two formats: The QIAstat-Dx version that brings together up to four Analytical Modules into one integrated system, and the QIAstat-Dx Rise higher-capacity version that provides comprehensive testing for up to 160 tests per day using eight Analytical Modules.

For more information about the transition from IVDD to IVDR and the corresponding time frame, please visit QIAGEN's [IVDR support site](#).

Further information about QIAstat-Dx can be found on <https://www.qiagen.com/de-gb/applications/syndromic-testing>.

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) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of June 30, 2024, QIAGEN employed more than 5,900 people in over 35 locations worldwide. Further information can be found at <http://www.qiagen.com>.

Forward-Looking Statement

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, including those products used in the response to the COVID-19 pandemic, timing for launch and development, marketing and/or regulatory approvals, financial and operational outlook, growth and expansion, 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; actions of governments, global or regional economic developments, weather or transportation delays, natural disasters, political or public health crises, including the breadth and duration of the COVID-19 pandemic and its impact on the demand for our products and other aspects of our business, or other force majeure events; as well as the possibility that expected benefits related to recent or pending acquisitions may not materialize as expected; and the other factors discussed under the heading "Risk Factors" contained in Item 3 of our most recent Annual Report on Form 20-F. 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.

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