

QIAGEN gains U.S. clearance of higher-throughput QIAstat-Dx Rise, expanding patient access to rapid syndromic testing

- **U.S. market entry set to begin for QIAstat-Dx Rise – a version of QIAstat-Dx for syndromic testing that combines unparalleled throughput with the easiest workflow**
- **QIAstat-Dx Rise launch can process up to 160 samples per day, initial launch includes Respiratory Panel Plus and Respiratory Panel Mini and additional panels in development**
- **Expansion of QIAstat-Dx instrument portfolio in the U.S. builds on the availability of both system options in Europe and other regions of the world**

Germantown, Maryland and Venlo, the Netherlands, September 2, 2025 – QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch of QIAstat-Dx Rise – a version of the QIAstat-Dx automated syndromic testing system that offers unparalleled throughput with the easiest workflow available to customers worldwide.

The new system, which received clearance from the U.S. Food and Drug Administration (FDA), is designed to meet the needs of hospitals and reference laboratories seeking highly automated syndromic testing with automated loading and unloading of cartridges, access to priority handling of urgent samples and only a minimum of hands-on time.

“The launch of QIAstat-Dx Rise marks a significant step forward in our commitment to expand access to infectious disease diagnostics across the U.S., and builds on the expansion efforts for this system in other areas of the world,” said Nadia Aelbrecht, Vice President and Head of Infectious Diseases at QIAGEN. “QIAstat-Dx builds on the strong customer response to the lower-throughput version, empowering labs to automate and scale up testing with minimal hands-on time while delivering the detailed diagnostic insights needed for timely treatment decisions.”

This clearance marks QIAGEN’s third FDA-cleared QIAstat-Dx product in 2025, and builds on a growing portfolio of six panels cleared for the QIAstat-Dx family over the last 12 months. The system is already available in more than 100 countries, with over 4,600 instruments placed globally through the first half of 2025.

The first two panels for respiratory conditions are already available. QIAGEN also plans to add to the QIAstat-Dx Rise system in the coming months its family of gastrointestinal panels including the QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx Gastrointestinal Mini B&V and QIAstat-Dx Gastrointestinal Panel Mini B. Additional panels for both QIAstat-Dx and QIAstat-Dx Rise are in development.

QIAstat-Dx Rise delivers automated, real-time PCR-based detection of multiple pathogens from a single sample, significantly increasing testing capacity while maintaining the speed and ease of use that QIAstatDx is known for. With the ability to run up to 160 tests per day across eight analytical modules – including 16 batch samples and two urgent slots per run – the system enables fast and accurate diagnoses in settings where turnaround time is critical.

Media Release

QIAstat-Dx quickly multiplies many genetic targets using real-time PCR technology in the same reaction, delivering results in about one hour and with less than one minute of hands-on time. Cycle threshold (Ct) values and amplification curves provide laboratories with additional information in the context of co-infections, and are instantly viewable on the instrument touchscreen with no additional software required.

To learn more about QIAGEN's range of QIAstat-Dx devices and testing panels, visit <https://www.qiagen.com/applications/syndromic-testing>.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is a global leader in Sample to Insight solutions that enable customers to extract and analyze molecular information from biological 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 prepare these biomolecules for analysis, while bioinformatics support the interpretation of complex data to deliver actionable insights. Automation solutions integrate these steps into streamlined, cost-effective workflows. QIAGEN serves more than 500,000 customers worldwide in the Life Sciences (academia, pharmaceutical R&D and industrial applications such as forensics) and Molecular Diagnostics (clinical healthcare). As of June 30, 2025, QIAGEN employed approximately 5,700 people across more than 35 locations. For more information, visit www.qiagen.com.

Forward-Looking Statement

Certain statements in this press release may constitute 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. These statements, including those regarding QIAGEN's products, development timelines, marketing and/or regulatory approvals, financial and operational outlook, growth strategies, collaborations and operating results, such as expected adjusted net sales and adjusted diluted earnings, are based on current expectations and assumptions. However, they involve uncertainties and risks. These risks include, but are not limited to, challenges in managing growth and international operations (including the effects of currency fluctuations, tariffs, tax laws, regulatory processes and logistics and supply chain dependencies), variability in operating results, and the commercial development of products for customers in the Life Sciences and clinical healthcare markets; changes in relationships with customers, suppliers or strategic partners; competition and rapid technological change; fluctuating demand for QIAGEN's products due to factors such as economic conditions, customer budgets and funding cycles; obtaining and maintaining product regulatory approvals; and challenges in integrating QIAGEN's products into manufacturing process workflows and manufacturing at scale. Additional risks include market acceptance of new products, integration of acquisitions, governmental actions, global or regional economic developments, natural disasters, political or public health crises, and other force majeure events. There is also no guarantee that anticipated benefits from restructuring programs and acquisitions will materialize as expected. For a more complete discussion of risks and uncertainties, please refer to the "Risk Factors" section in our most recent Annual Report on Form 20-F and other reports filed with or furnished to the U.S. Securities and Exchange Commission.

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