

QIAGEN secures European CE-IVDR certification for full QIAstat-Dx portfolio

- **Full portfolio of QIAstat-Dx panels now CE-IVDR certified for use in clinical syndromic testing, underscoring commitment to highest-quality diagnostics**
- **CE-IVDR clearance granted for QIAstat-Dx Meningitis/Encephalitis (ME) Panel, sets standard with 16 targets for central nervous system infections and broadest coverage for fast and accurate diagnosis**
- **QIAstat-Dx panels offer unique advantages, including exclusive and medically valuable targets combined with a one-step workflow amid plans to expand test portfolio**

Venlo, the Netherlands, September 10, 2025 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced that it has achieved CE-IVDR certification for its full portfolio of QIAstat-Dx syndromic testing systems and panels, including an expanded Meningitis/Encephalitis (ME) Panel that sets a new benchmark in the diagnosis of central nervous system (CNS) infections.

The QIAstat-Dx system now offers CE-IVDR certified panels for respiratory, gastrointestinal and CNS infections that help clinicians diagnose infectious diseases with greater speed and accuracy.

Marking the latest clearance, the expanded CE-IVDR QIAstat-Dx ME Panel provides the broadest coverage available for CNS infections with 16 clinically relevant targets. These include cytomegalovirus (CMV) and *Streptococcus pyogenes*. The inclusion of CMV further aligns the panel with current clinical needs, while *S. pyogenes* detection – exclusive to QIAstat-Dx – addresses an increasingly important and often overlooked pathogen in meningitis cases. The launch of this enhanced panel is expected in September 2025.

The clearance comes ahead of World Meningitis Day on October 5, underscoring the commitment of QIAGEN to advancing rapid and reliable diagnostics for life-threatening CNS infections.

QIAstat-Dx can deliver fast and comprehensive results in about an hour, empowering clinicians to make early and accurate treatment decisions that help avoid unnecessary antibiotic use and support shorter hospital stays and bringing clear value to both patients and healthcare systems.

"Achieving IVDR certification for our complete QIAstat-Dx portfolio marks a major milestone for QIAGEN and the laboratories and clinicians we serve," said Nadia Aelbrecht, Vice President, Head of Infectious Diseases at QIAGEN. "This certification demonstrates our commitment to meeting the highest regulatory standards while reinforcing our dedication to delivering innovative diagnostics that improve patient care."

CE-IVDR certification of these impactful tests reflects QIAGEN's commitment to providing reliable diagnostics that meet the highest quality standards. The European Union has implemented a new law that harmonizes the requirements for in vitro diagnostics (IVD) devices in Europe, replacing the old directive to improve patient safety and transparency. For more information about QIAGEN's transition from IVDD to IVDR and the corresponding time frame, please visit the [IVDR support site](#).

QIAstat-Dx provides unique advantages for clinicians and laboratories, including exclusive, medically valuable targets and the market's easiest workflow. The simple process requires no reagent preparation and minimal hands-on time, helping reduce the risk of contamination, especially critical when working with limited-volume samples that need to be collected invasively, like cerebrospinal fluid.

Media Release

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 2024, more than 4,600 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.

The widely used QIAstat-Dx system is available in two formats: The QIAstat-Dx Analyzer 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. Both platforms received CE-marking under IVDR framework late last year.

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 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.

Source: QIAGEN N.V.
Category: Infectious Diseases

Media Release



Contacts QIAGEN:

Investor Relations

e-mail: ir@QIAGEN.com

Public Relations

e-mail: pr@QIAGEN.com