

QIAGEN receives U.S. FDA clearance for first QIAstat-Dx bloodstream infection panel

- **QIAstat-Dx BCID GPF Plus AMR Panel detects 20 pathogen targets and 10 antimicrobial resistance markers from positive blood cultures in about one hour**
- **FDA clearance marks QIAGEN's entry into U.S. bloodstream infection testing and establishes the first member of a planned QIAstat-Dx BCID panel family**
- **Bloodstream infections can rapidly progress to sepsis, a life-threatening condition affecting about 1.7 million adults annually in the U.S., underscoring the need for rapid detection**

Germantown, Maryland, and Venlo, the Netherlands, August 10, 2026 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced that the U.S. Food and Drug Administration (FDA) has cleared the QIAstat-Dx BCID GPF Plus AMR Panel, the first QIAstat-Dx panel for bloodstream infections to receive FDA clearance.

The clearance expands QIAGEN's U.S. syndromic testing portfolio into bloodstream infection diagnostics, the fourth major infectious disease area covered by the QIAstat-Dx platform, which is available in more than 100 countries and with more than 5,200 cumulative placements as of the end of 2025.

The QIAstat-Dx BCID GPF Plus AMR Panel detects 20 gram-positive bacterial and fungal pathogen targets as well as a broad pan gram-negative target together with 10 genetic antimicrobial resistance markers from positive blood culture samples in about one hour. The rapid identification of pathogens and resistance gene markers can support informed treatment decisions, antimicrobial stewardship and infection prevention measures.

Bloodstream infections are associated with significant morbidity and mortality and can rapidly progress to sepsis, a life-threatening reaction to an infection that causes your immune system to harm healthy tissues and organs. An estimated 1.7 million adults in the U.S. develop sepsis each year¹, highlighting the importance of providing clinicians with timely diagnostic information.

"Every hour, even minutes, count with bloodstream infections," said Nitin Sood, Senior Vice President and Head of Product Portfolio & Innovation at QIAGEN. "This clearance gives U.S. laboratories a fast and integrated way to identify pathogens and key genetic antimicrobial resistance markers, supporting more informed treatment decisions and responsible antibiotic use. It also establishes the first member of a broader QIAstat-Dx bloodstream infection panel family planned for the U.S."

The QIAstat-Dx system integrates sample preparation, multiplex PCR testing and data analysis into a single workflow. It is designed to provide rapid and easy-to-interpret results while reducing hands-on time for laboratory professionals.

The FDA clearance also lays the foundation for the continued expansion of QIAGEN's bloodstream infection testing portfolio in the U.S. A complementary QIAstat-Dx BCID GN Plus AMR Panel, designed to detect gram-negative pathogens and associated genetic antimicrobial resistance markers, is currently under FDA review.

¹ Centers for Disease Control and Prevention (CDC). About Sepsis. Available at: <https://www.cdc.gov/sepsis/about/index.html> (accessed August 2026).

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QIAGEN has been consistently expanding the QIAstat-Dx menu for the U.S., broadening the platform across four major infectious disease areas: respiratory, gastrointestinal, central nervous system and now bloodstream infections. The portfolio includes the QIAstat-Dx Respiratory Panel Plus, the QIAstat-Dx Respiratory Panel Mini, the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B, the QIAstat-Dx GI Panel 2 Mini B&V, the QIAstat-Dx Meningitis/Encephalitis Panel and the newly FDA-cleared QIAstat-Dx BCID GPF Plus AMR Panel. This reflects QIAGEN's strategy of building a comprehensive infectious disease testing menu on a single integrated platform.

For more information about the QIAstat-Dx BCID GPF Plus AMR Panel and the QIAstat-Dx system, visit 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, 2026, QIAGEN employed about 5,500 people across more than 35 locations. For more information, visit 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. These statements can be identified by the use of forward-looking terminology such as "believe", "hope", "plan", "intend", "seek", "may", "will", "could", "should", "would", "expect", "anticipate", "estimate", "continue", "target" or other similar words. To the extent that any of the statements contained herein relating to QIAGEN's products, timing for launch and development, marketing and/or regulatory approvals, financial and operational outlook, growth and expansion, acquisitions, collaborations, markets, strategy or operating results, including without limitation its expected net sales, net sales of particular products, net sales in particular geographies, adjusted net sales, expansion of adjusted operating income margin, returns to shareholders, progressive dividend payments, product portfolio management, product launches (including anticipated launches of our sequencing solutions, testing platforms, panels and systems), leveraging AI technology, improvements in operating and financial leverage, currency movements against the U.S. dollar, plans for investment in our portfolio and share repurchase commitments, our expectations relating to our adjusted tax rate, debt maturity and repayment, our ability to grow adjusted earnings per share at a greater rate than sales, our ability to improve operating efficiencies and maintain disciplined capital allocation, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. These include, but are not limited to, risks associated with our dependence on the development and success of new products; management of growth and expansion of operations (including the effects of currency fluctuations, tariffs, tax laws, regulatory processes and supply chain dependencies); variability of operating results; integration of acquired businesses; changes in 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, including delays or limits in the amount of reimbursement approvals or public health funding); our ability to obtain and maintain product regulatory approvals; 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

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from competitors' products; market acceptance of new products and the integration of acquired technologies and businesses; actions of governments, global or regional economic developments, including inflation and changing interest rates, weather or transportation delays, natural disasters, cyber security breaches, political or public health crises and the resulting impact on the demand for our products and other aspects of our business, or other force majeure events; litigation risk, including patent litigation and product liability; debt service obligations; volatility in the public trading price of our common shares; 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" in our most recent Annual Report on Form 20-F. For further information, please refer to QIAGEN's filings with the U.S. Securities and Exchange Commission.

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