Media Release

QIAGEN expands QIAstat-Dx syndromic testing menu in the U.S. with launch of molecular test to improve gastrointestinal care

- **U.S. FDA clears QIAstat-Dx Gastrointestinal Panel 2 for use in clinical settings**
- **New panel offers fast and accurate identification of up to 16 common gastrointestinal pathogens**
- **Generates results in about one hour based on real-time PCR technology, easy access to Ct values and amplification curves**

Germantown, Maryland, and Venlo, the Netherlands, June 3, 2024 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch of the QIAstat-Dx Gastrointestinal Panel 2 in the United States. The launch comes after the recent clearance of the syndromic test for clinical use by the U.S. Food and Drug Administration (FDA) and marks a significant step forward in improving the accuracy and efficiency of gastrointestinal (GI) infection diagnosis.

The QIAstat-Dx Gastrointestinal Panel 2 takes about an hour to simultaneously look for up to 16 clinically relevant bacterial, viral and parasitic pathogens that cause most GI infections. Acute infectious gastroenteritis is a common reason for hospitalizations and outpatient physician visits in the U.S., with an estimated 180 million cases per year.[1]

The panel leverages QIAstat-Dx's ability to quickly multiply many genetic targets using real-time PCR technology in the same reaction – an important advance compared to traditional microbiological testing, which often requires samples to be incubated for at least 24 hours and up to 10 days of specimen collection. Software interprets signals from the reaction and provides positive or negative results for each pathogen. QIAstat-Dx additionally provides easy-to-view cycle threshold (Ct) values and amplification curves that can offer additional insights not available with end-point PCR or other techniques.

"The QIAstat-Dx Gastrointestinal Panel 2 allows medical professionals to identify which GI pathogen they are dealing with quickly," said Fernando Beils, Senior Vice President and Head of the Molecular Diagnostics Business Area at QIAGEN. "This is QIAGEN's answer to two major problems in treating GI infections: diagnosis of overlapping symptoms and laborious testing methods."

"It can be very difficult to clinically distinguish between viral, bacterial and parasitic causes of GI illness. We can easily set up and get a full panel of results back faster than culture and microscopy, and access to Ct values for each detected pathogen can provide valuable information when interpreting when interpreting multiple pathogen detections," added Romney Humphries, Ph.D., professor of Pathology, Microbiology, and Immunology and division director for Laboratory Medicine at Vanderbilt University Medical Center in the U.S. about the clinical utility of QIAstat-Dx.

The new panel expands QIAGEN's U.S. menu for syndromic testing, building on the use of the QIAstat-Dx Respiratory Panel Plus that can identify 21 pathogens causing respiratory infections from viral and bacterial pathogens. Both Panels are available as cost-efficient, single-use cartridges that slot easily into

[1] Moon RC, Bleak TC, Rosenthal NA, et al. "Epidemiology and Economic Burden of Acute Infectious Gastroenteritis Among Adults Treated in Outpatient Settings in US Health Systems", Am J Gastroenterol. 2023;10.14309: https://doi.org/10.14309/ajg.0000000000002186

the QIAstat-Dx Analyzer 1.0. As they contain all reagents, set up takes less than a minute and requires no precision pipetting.

The U.S. launch supports healthcare providers with diagnosing and treating patients quickly and accurately. They will be able to quickly isolate those at risk of transmitting infections and identify negative cases sooner, reducing the burden of unnecessary testing and treatment costs on the healthcare system and patients. Syndromic tests have also been shown to improve the detection of co-infections, reducing the need for additional testing like endoscopies. By providing fast results, syndromic testing enables healthcare providers to make informed decisions and discontinue empiric antibiotic treatment when viral pathogens are detected, reducing overall antibiotic usage and supporting the goal of responsible antimicrobial stewardship.

Syndromic testing with cloud-based connectivity and epidemiological insights

QIAstat-Dx solutions and syndromic tests to support diagnosing diseases are available in more than 100 countries worldwide, including the U.S. and many across Europe. More than 4,000 cumulative systems were installed worldwide at the end of 2023. Hospitals, laboratories and clinics value the QIAstat-Dx range as an easy-to-use automated solution for the reliable detection of various 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. QIAstat-Dx Rise is available with CE-IVD marking in Europe and other countries that accept this marking.

With a QIAstat-Dx Connectivity plan, QIAstat-Dx connects to the QIAsphere cloud-based platform that provides remote monitoring of the instruments and test status, allowing customers to receive push notifications on their personal devices. It can monitor an unlimited number of instruments across different hospitals or satellite labs, reducing system downtime and enabling fast and accurate syndromic testing. Connectivity is achieved through the Qbase hub, which can be connected to QIAstat-Dx in minimal time through hospitals' LAN or Wi-Fi network, ensuring sensitive patient data remains within the hospital network.

QIAsphere also allows users to view and export reports on real-time local, regional and global epidemiology data through QIAsphere Insights to support epidemiological surveillance. Further, with the recent release of a medical reference app for QIAstat-Dx users, the Pathogen Guide, QIAstat-Dx is poised as a leader in digital diagnostic technology for customers around the world.

Learn more about QIAstat-Dx and the Gastrointestinal Panel 2 at https://www.qiagen.com/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 March 31, 2024, QIAGEN employed approximately 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.

Contacts QIAGEN:

Investor Relations		**Public Relations**	
John Gilardi	+49 2103 29 11711	Thomas Theuringer	+49 2103 29 11826
Domenica Martorana	+49 2103 29 11244	Lisa Mannagottera	+49 2103 29 14181
e-mail: ir@QIAGEN.com		e-mail: pr@QIAGEN.com	