

QIAGEN adds new biopharma products to QIAcuity digital PCR portfolio and launches Expert Custom Assay Design Service

- **13 new kits and assays allow for quantification of AAV viral titer and residual host cell DNA in cell and gene therapy**
- **Custom assay design provides dPCR users with access to tailored multiplex assays for use beyond biopharma applications**
- **Milestone achieved with over 1,000 cumulative placements of the standard-setting QIAcuity systems**

Hilden, Germany, and Germantown, Maryland, July 27, 2022 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) announced today a series of enhancements for its QIAcuity series of digital PCR (dPCR) instruments designed to drive greater use among customers, particularly those involved in the biopharma industry:

- New solutions are now available with ten new QIAcuity Cell and Gene Therapy (CGT) dPCR Assays for use in adeno-associated virus (AAV) titer quantification and three new QIAcuity Residual DNA Quantification Kits for checking carryover of host cell DNA.
- A new version of the QIAcuity Software Suite has been released with expanded functionality to support good manufacturing practice (GMP) compliance.

The major expansion of QIAGEN's dPCR assay offerings comes after a milestone was achieved with more than 1,000 cumulative placements of the QIAcuity system since launch in late 2020. QIAcuity's approach to digital PCR is based on using nanoplates to partition the samples more quickly than other systems. The instruments – available in one, four and eight-plate versions – integrate partitioning, thermocycling and imaging into one workflow, cutting processing times to only two hours from six.

"We tested QIAGEN's QIAcuity dPCR for quantification of viral titer, vector copy number and residual host cell DNA – all critical to in-process quality control in gene therapy. It is easy to use, fast, scalable and complies with requirements for GMP," said Dana Cipriano, Senior Vice President, Testing and Analytical Services, Center for Breakthrough Medicines in King of Prussia, PA, in the U.S. "The system is a great addition to our analytical development and testing services, process development and R&D platforms which is available to our clients now."

"The new cell and gene therapy applications will increase the utility of QIAcuity for biopharma customers, meeting their need for high-throughput analytical methods, rapid turnaround times, wet-lab verified catalog assays, multiplexing and more," said Thomas Schweins, Senior Vice President and Head of QIAGEN's Life Sciences Business Area. "Our custom assays for dPCR build on decades of expertise in assay design for traditional qPCR. The Expert Custom Assay Design Service will extend customer choice beyond the existing catalog of assays, especially in key application areas that require simultaneous detection of up to five molecular markers."

Biopharma customers will benefit from the launch of ten wet-lab verified QIAcuity Cell and Gene Therapy (CGT) Assays which can be designed with multiple fluorophores, and quickly produce results of superior accuracy and reproducibility, with a dynamic range of at least four orders of magnitude.

The biopharmaceuticals sector is also the target group for the QIAcuity Residual DNA Quantification Kits for detecting residual host cell DNA (resDNA) of CHO, *E. coli* and HEK293 cells used in CGT, even when PCR contaminants and other inhibitory reagents are present in samples. These three new kits work in conjunction with the new QIAcuity UCP Probe PCR Kit that has an ultra-clean master mix to minimize contaminating DNA background and enable residual DNA testing among other quality control applications.

When paired with the updated QIAcuity Software Suite, biopharma customers can benefit from a turnkey workflow for the development and manufacturing of cell and gene therapies. Version 2.1 of the software, among other things, includes client-defined user management with customized permissions, improved plate ownership, an electronic signature for reports (to meet the FDA 21 CFR Part 11 requirement), an audit trail status indicator and robust cybersecurity.

Complementing the menu expansion is the introduction of the Expert Custom Assay Design Service, to be made available globally from the end of July, allowing dPCR users to source custom multiplex assays – for detecting various pathogens, rare mutations, copy number variations and other molecular phenomena. From design freeze to assay shipment reduced to only two weeks, customers will save time and cost. Customers will be able to access, manage and order their assays through QIAGEN's GeneGlobe Design & Analysis Hub. On top of that, they will have access to the QIAGEN Genomic Services Team for wet-lab assay verification.

Biopharmaceutical customers developing next-generation therapies are increasingly adopting dPCR to enhance drug safety and efficacy. Compared to qPCR, the dPCR technology provides a much higher level of sensitivity and accuracy that can be leveraged for multiple applications in the drug development process – from drug discovery and clinical trials to manufacturing. The market for dPCR in biopharma is currently growing at a solid double-digit pace and becoming a multi-billion dollar market in the coming years, according to recent market research reports.

For more information, please visit <https://www.qiagen.com/applications/pharma-biotech>.

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), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of March 31, 2021, QIAGEN employed more than 6,000 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, 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. 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 (SEC).

Contacts QIAGEN:

Investor Relations

John Gilardi +49 2103 29 11711
Phoebe Loh +49 2103 29 11457
e-mail: ir@QIAGEN.com

Public Relations

Thomas Theuringer +49 2103 29 11826
e-mail: pr@QIAGEN.com