QIAGEN announces the commercialization of the PreAnalytiX PAXgene® Saliva Collector for non-invasive sample collection, storage, and transportation with stabilization of nucleic acid

- *Newly launched PAXgene Saliva Collector stabilizes collected sample to avoid preanalytical errors and thereby increases reproducibility and reliability of results*
- *Non-invasive and painless sample collection tool permitting seamless self-collection; initial applications include SARS-CoV-2 research*
- *PreAnalytiX, a BD and QIAGEN joint venture, combines expertise to provide an integrated and standardized workflow solution from saliva sample collection and stabilization to analyte preparation for varied downstream applications and valuable data interpretation*

Hilden, Germany, and Germantown, MD, August 26, 2021 – QIAGEN N.V. (NYSE: QGEN; Frankfurt, Prime Standard: QIA) today announced the commercialization of the new PreAnalytiX PAXgene Saliva Collector, a non-invasive and painless method of sample collection. The PAXgene Saliva Collector is part of a standardized pre-analytical workflow for human saliva collection, stabilization, transportation, and storage through nucleic acid extraction and analyses.

The collection device contains a preservation solution that stabilizes the DNA levels in human saliva samples by protecting the DNA from degradation and inhibiting bacterial growth over storage time, and was developed by PreAnalytiX GmbH, a joint venture between QIAGEN N.V. and BD (Becton, Dickinson and Company; NYSE: BDX).

One initial area of additional application is sample collection for SARS-CoV-2 research. In addition to DNA stabilization, SARS-CoV-2-derived RNA copy numbers are preserved when saliva is collected in the PAXgene Saliva Collector. SARS-CoV-2 RNA present in a saliva sample is stabilized for at least four days at 20°C. The genome of SARS-CoV-2 consists of RNA and can be isolated using QIAamp Viral RNA Mini Kit and quantified with QIAGEN's QuantiTect® Probe RT-PCR and QIAGEN's Rotor-Gene® Q. While the PAXgene Saliva Collector stabilizes SARS-CoV-2 particles for detection and quantification, it efficiently inactivates the capability of the virus to infect and replicate itself in a cell culture model.

"During the current pandemic saliva has been gaining ground as an emerging non-invasive specimen type for analysis of respiratory infections. However, the outcome of the analytical test results is highly dependent on the sample quality. Therefore, a standardized sample handling during the entire pre-analytical phase is key," said Prof. Kurt Zatloukal, Head of the Diagnostic and Research Center for Molecular Biomedicine, Medical University of Graz. "We have successfully tested the PAXgene Saliva Collector in a European SARS-CoV-2 research project and are looking forward to applying the device to additional applications."

"Post collection stabilization of analyte profiles is imperative to ensure the reliability and reproducibility of test results. With the PAXgene Saliva Collector we are thrilled to answer an urgent market demand for sample stabilization immediately after collection and during transport and storage," said Dr. Uwe Oelmueller, Vice President, Head of MDx Development Sample Tech at QIAGEN, Coordinator of SPIDIA and SPIDIA4P.

The PAXgene Saliva Collector adds to QIAGEN's gold standard sample preparation portfolio of kits and instruments for manual and automated extraction. For manual DNA extraction, the device can be used in combination with the QIAamp DNA Mini and Gentra® Puregene Cell Kits. Saliva collected in the PAXgene

Saliva Collector can be used to process DNA automated with the QIAsymphony DNA Midi Kit on the QIAsymphony SP instrument or the QIAamp DNA Mini Kit on the QIAcube Connect. The isolated DNA is compatible with downstream analytical PCR assays, including digital PCR with the QIAcuity Digital PCR System and next-generation sequencing (NGS) molecular test methods. Saliva samples collected with the PAXgene Saliva Collector have stable DNA levels for at least 24 months at temperatures up to 25°C, because bacterial growth and chemical as well as enzymatical DNA degradation are prevented. After 24 months of storage, DNA is still of high yield and high quality if isolated with the QIAGEN DNA extraction kits and protocols.

For more information about the PAXgene Saliva Collector, please visit the product page: https://www.preanalytix.com/products/saliva/dna/paxgene-saliva-collector-mba/US?cHash=2319179f194effee506bf153b79554d2

About PreAnalytiX, GmbH
PreAnalytiX was formed in 1999 by QIAGEN and BD with the purpose of developing, manufacturing, and marketing integrated systems for the collection, stabilization, and purification of nucleic acids (DNA and RNA) for molecular diagnostic testing. More information about PreAnalytiX and the PAXgene Saliva Collector can be found at https://www.preanalytix.com

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 June 30, 2021, QIAGEN employed approximately 5.900 people in over 35 locations worldwide. Further information can be found at https://www.qiagen.com.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care. The company supports the heroes on the frontlines of healthcare by developing innovative technology, services, and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease, and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety, and expand access to health care. For more information on BD, please visit bd.com or connect on LinkedIn at http://www.linkedin.com/company/bd1/ and Twitter @BDandCo.

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		**Public Relations**	
John Gilardi	+49 2103 29 11711	Thomas Theuringer	+49 2103 29 11826
Phoebe Loh	+49 2103 29 11457	Robert Reitze	+49 2103 29 11676
e-mail: ir@QIAGEN.com		e-mail: pr@QIAGEN.com	

Category: Product

Source: QIAGEN N.V.