QIAGEN expands QIAstat-Dx testing menu with respiratory four-plex panel that differentiates between flu, RSV and SARS-CoV-2

- Easy-to-use cartridge receives CE-marking in Europe and will launch soon
- Syndromic test differentiates between influenza A and B, RSV and SARS-CoV-2, a critical test for upcoming flu seasons
- Test broadens QIAGEN’s large portfolio of PCR solutions fighting the COVID-19 pandemic

Hilden, Germany, and Germantown, Maryland, November 2, 2021 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch and CE-marking of the QIAstat-Dx Respiratory 4 Plex Flu A-B/RSV/SARS-CoV-2 test for the QIAstat-Dx system to quickly identify whether patients have common seasonal respiratory infections or SARS-CoV-2.

QIAGEN’s new Respiratory 4 Plex Flu A-B/RSV/SARS-CoV-2 test is a powerful diagnostic tool in the COVID-19 pandemic, especially in influenza like illness (ILI) or “flu” seasons. It leverages the easy-to-use QIAstat-Dx modular cartridge-based system to deliver fast results that require no additional sample preparation.

The polymerase chain reaction (RT-PCR) multiplex test detects and differentiates between influenza A and B, respiratory syncytial virus (RSV) and SARS-CoV-2 infections in about an hour – a vital capability in the fight against the COVID-19 pandemic. The viruses produce similar respiratory symptoms, making it challenging to clinicians to diagnose exactly which one a patient is suffering from to make the right treatment decisions.

“The COVID-19 pandemic has highlighted the indisputable need for accurate, reliable and time-sensitive diagnostics” says Amy S. Fox, M.D., M.S., Clinical Virologist and Vice Chair for Clinical Research, Department of Pathology, Montefiore Medical Center, Montefiore Health System, Bronx, NY. “The ability to provide rapid and accurate diagnosis through syndromic testing with multiplex PCR has significantly changed the way Infectious Disease clinicians and laboratorians manage patients and optimize workflow. An accurate early diagnosis may allow for informed, earlier, and more precise therapeutic decisions, and may aid in the implementation of public health measures such as isolation or contact precautions.”

“This new test expands the capabilities of our QIAstat-Dx system with a much-needed COVID-19 application that differentiates between respiratory infections quickly without lab infrastructure,” said Jean-Pascal Viola, Senior Vice President, Head of the Molecular Diagnostics Business Area and Corporate Business Development at QIAGEN. “With flu season and COVID-19 case numbers still high, this test provides a crucial tool that can be used close to patients and in decentralized environments like ICUs, emergency rooms and satellite labs. By adding this new test to our growing QIAstat-Dx testing menu, we are taking another step to increase the platform’s value for customers beyond the pandemic.”

Recent publications in the Journal of Antimicrobial Chemotherapy have highlighted the value of syndromic testing for clinicians and laboratorians. The publications in the supplement highlight various considerations such as how to maximize impact of infectious diseases syndromic panels, collaboration between laboratories and antimicrobial stewardship programs, utilizing syndromic panels outside of the central laboratory and what factors impact clinical decisions to utilize syndromic versus low-plex PCR.

These papers can be accessed here [https://academic.oup.com/jac/issue/76/Supplement_3](https://academic.oup.com/jac/issue/76/Supplement_3)
QIAGEN currently offers the QIAstat-Dx Respiratory+ test and the QIAstat-Dx Gastrointestinal test. It also has a strong pipeline of additional tests in development, including one for Meningitis. As of H1 2021, QIAGEN has over 2400 QIAstat-Dx instruments in the market worldwide. In March, QIAGEN announced additional digital diagnostics and connectivity features for QIAstat-Dx through QIAsphere.

The QIAstat-Dx system was introduced in Europe in 2018 after receiving the region’s CE marking and in the United States in mid-2019 after being cleared by the Food and Drug Administration (FDA). The easy-to-use device enables fast and cost-effective syndromic testing with novel Sample to Insight workflows.

The system streamlines molecular testing from beginning to end. A technician simply loads a clinical sample – for example, on a swab – into a single-use QIAstat-Dx cartridge and places it in the analyzer. With QIAGEN chemistries for sample processing and analysis built in, the QIAstat-Dx instrument delivers results in about one hour.

A video on QIAstat-Dx can be found [here](#).

Further information on QIAGEN’s response to the coronavirus outbreak can be found [here](#).

For more information about QIAGEN, please visit [https://qiagen.com](https://qiagen.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 [http://www.qiagen.com](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.

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