

QIAGEN receives U.S. FDA emergency use authorization for rapid portable test that can analyze over 30 samples per hour for SARS-CoV-2 antigen

- *Approval gives U.S. healthcare professionals access to a new combination of scalability and speed*
- *QIAreach SARS-CoV-2 Antigen Test, developed in collaboration with Ellume, is easy to use and provides accurate and objective results in 2 to 15 minutes*
- *Each Digital eHub device, with capacity for up to 8 eSticks, can simultaneously run QIAGEN QIAreach SARS-CoV-2 Antigen and Antibody tests*

Germantown, Maryland and Hilden, Germany, August 06, 2021 – QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced it has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its QIAreach® SARS CoV-2 Antigen Test, which is designed for environments that require a high volume of fast and accurate test results.

The rapid portable test can detect SARS-CoV-2 antigen in people with active infections in 2 to 15 minutes and can process an average of around 30 swab samples per hour, providing digital test results that do not require subjective interpretation. Clinical studies have shown the test to have a sensitivity of at least 80% and a specificity of 98.0%.

The QIAreach SARS-CoV-2 Antigen Test is the second QIAGEN COVID-19 test to make use of the digital eHub and eStick system that was developed in partnership with Australian digital diagnostics company Ellume. In May 2021, QIAGEN received an EUA for its QIAreach® Anti-SARS-CoV-2 Total Test that uses the same technology and eHub. Lab professionals will now be able to run tests to detect both previous and active infections on one device at the same time – with each testing slot operating independently of the others.

“Knowledge of past and present infections is key to understanding and inhibiting the spread of the disease”, said Jenny Howard, Head of QIAGEN’s Immune Monitoring Franchise. “The QIAreach SARS-CoV-2 Antigen Test delivers rapid and highly accurate results and addresses the high-volume testing needs for SARS-CoV-2 antigens – and in combination with QIAreach Anti-SARS-CoV-2 Total Test allows labs to run antigen tests and antibody tests at the same time.”

The QIAreach SARS-CoV-2 Antigen Test uses QIAGEN’s UL-certified eHub, a portable reader with backup battery power able to be operated remotely from main power for up to 8 hours. The test has the capacity to analyze nasal and nasopharyngeal swab samples from up to eight symptomatic patients simultaneously. The easy-to-use eStick uses nanoparticle fluorescent detection technology to flag the SARS-CoV-2 nucleocapsid protein, an antigen present on the surface of the virus. The device delivers negative results in 15 minutes – and in as little as two minutes in the case of a strong positive. This means one eHub can process on average about 30 tests per hour with the possibility for one user to operate more than one eHub.

The QIAreach SARS-CoV-2 Antigen Test and the QIAreach SARS-CoV-2 Antibody Test run on the eHub platform that QIAGEN is using for QIAreach® QuantiFERON®-TB, a new solution still in development that will help low-resource and high-burden regions diagnose latent tuberculosis infection.

To find out how QIAreach SARS-CoV-2 Antigen complements QIAGEN’s robust COVID-19 testing portfolio that addresses customer needs from fundamental research to diagnostics, please visit www.qiagen.com/applications/infectious-disease/coronavirus.

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 more than 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, 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).

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