Quanterix Receives Label Expansion on Emergency Use Authorization for COVID Antigen Test

September 13, 2021

Simoa SARS-CoV-2 N Protein Antigen Test is first antigen test validated to detect all Variants of Concern currently designated by CDC, including Delta variant, and first authorized for use in saliva samples

EUA label expansion demonstrates additional evidence showing potential for Simoa technology across range of clinical tests, including less-invasive testing

BILLERICA, Mass.--(BUSINESS WIRE)--Sep. 13, 2021-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis with the goal of advancing the science of precision health, announced that the Food and Drug Administration (FDA) has expanded the Emergency Use Authorization (EUA) label for its Simoa® SARS-CoV-2 N Protein Antigen Test to include testing with nasal swab and saliva samples, and for asymptomatic serial testing with nasal swab samples. The expanded label establishes this test as the first antigen test authorized for use with saliva samples. The test is validated to detect all Variants of Concern currently designated by the Centers for Disease Control (CDC) and is the first non-NGS test validated and independently confirmed to detect the highly transmissible Delta variant (B.1.617.2) in sequence-confirmed clinical samples. The test can be run on Quanterix' Simoa HD-X Analyzer®, a fully automated high-throughput immunoassay instrument.

The Simoa SARS-CoV-2 N Protein Antigen Test detects the presence of the SARS-CoV-2 virus nucleocapsid protein (or N protein), which is known to be elevated in respiratory fluids during the initial acute phase of the infection. The National Institutes of Health (NIH) Variant Task Force has independently validated the assay's ability to detect all currently designated Variants of Concern including the Delta variant in sequence-confirmed, clinical nasal swab samples, including those with low viral load. Direct detection of antigen proteins from the virus may be a more meaningful measure of infection status than detection of RNA by rRT-PCR because genetic material can linger even after the virus has left the body, resulting in increased risk of false positives[1].

"The Delta variant is contributing to rising case counts across the globe, and COVID-19 testing remains a priority as schools and workplaces attempt to protect against the spread of the virus while normalizing their operations," said Kevin Hrusovsky, Chairman and Chief Executive Officer, Quanterix. "We are pleased to receive this EUA label expansion on our antigen test and demonstrate another advance in the body of evidence supporting Simoa's potential for asymptomatic, less-invasive clinical testing. While PCR testing remains the primary COVID-19 diagnostic modality, we believe antigen testing with simple sample collection in both symptomatic and asymptomatic individuals is a complementary longer-term opportunity to help control the spread of COVID-19 and protect our most vulnerable citizens."

The expanded FDA authorization of the Simoa SARS-CoV-2 N Protein Antigen Test is an important next step in a project funded by the NIH Rapid Acceleration of Diagnostics (RADx) initiative to apply Simoa digital biomarker technology to decentralized SARS-CoV-2 antigen detection in non-invasive sample types. The aim of this NIH program is to improve clinical laboratory tests that will increase the capacity of SARS-CoV-2 testing in the U.S.

Simoa RUO assays for COVID-19 Research
Quanterix offers a family of assays tailored to Research Use Only (RUO) applications. In addition to its EUA assay, Quanterix has commercialized a SARS-CoV-2 N Protein Antigen Advantage Assay. Quanterix has tailored this quantitative ultra-sensitive assay for research applications in sample matrices including NP swabs, nasal swabs, serum, plasma, capillary dried blood, and saliva. The assay complements the Simoa SARS-CoV-2 IgG serology assay which represents an important tool in ongoing vaccine development efforts, particularly as the community seeks to understand serological signatures of protective immunity.

Kevin Hrusovsky commented: "The global research community continues to invest in resources to deepen the longer-term understanding of SARS-CoV-2 biology, including COVID-19 disease progression, innate and adaptive immune responses, and biomarkers indicative of disease pathology, including a growing appreciation for the potential role of neurological markers. Our RUO portfolio of ultra-sensitive assays includes a broad panel of markers linked to SARS-CoV-2 biology and disease progression and severity. Our technology is enabling research on patients with acute disease, and those with long-term non-resolving symptoms ("COVID-19 long haulers"), including those with neurological dysfunction. Blood-based biomarkers show promise for predicting disease severity and addressing this important evolving research need."

Simoa Technology
Simoa (single molecule array technology) is a revolutionary digital approach to immunoassays, which allows single molecules to be counted for protein biomarker research applications, changing the way scientists study the biology of health and disease by giving them the ability to closely examine critical biomarkers. In doing so, Quanterix enables development of methods providing much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for applications in a majority of therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease.

For more information on Quanterix' Simoa technology, visit https://www.quanterix.com/technology. To learn more about Quanterix' infectious disease research and RUO assay development solutions, visit https://www.quanterix.com/therapeutic-areas/infectious-disease.

About Quanterix
Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa®, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the

continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease. The company was established in 2007 and is located in Billerica, Massachusetts. For additional information, please visit https://www.quanterix.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release are based on Quanterix' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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[1] https://www.medrxiv.org/content/10.1101/2020.10.02.20205708v1

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Media:
PAN Communications
Paige Romine
(321) 652-8370
quanterix@pancomm.com

Investor Relations:
Stephen Hrusovsky
(774) 278-0496
shrusovsky@quanterix.com

Source: Quanterix Corporation