

Quanterix' Simoa Technology Demonstrates Advancements in COVID-19 Research through Viral Antigen Measurements in Blood and Saliva Samples

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Company's SARS-CoV-2 N-Protein Assay measures viral antigen in plasma, dried blood spots and saliva in more than 90 percent of COVID-19 PCR+ positive donors, including those without symptoms

BILLERICA, Mass .-- (BUSINESS WIRE) -- Mar. 26, 2021 --

Quanterix Corporation (NASDAQ:QTRX), a company digitizing biomarker analysis to advance the science of precision health, today announced that its <u>Simoa® technology</u> has been used in research studies to detect the SARS-CoV-2 virus in serum/plasma, dried blood microsamples (DBS) and saliva samples obtained from polymerase chain reaction (PCR)+ COVID-19 patients. Published in <u>Nature Communications</u>, the research study of these technologies offers further evidence that non-invasive antigen detection in blood or saliva samples, including from asymptomatic and pre-symptomatic individuals, can serve as an important complement to testing of nasal and nasopharyngeal (NP) swab samples. In addition to the benefits of detecting COVID-19 during the pre-symptomatic window when transmissibility is known to be highest, measuring viral load in blood may be particularly relevant in the context of clinical studies, as an indicator of disease severity or progression, and potentially of therapeutic efficacy.

"Despite the rapid proliferation of COVID-19 testing, the global community continues to struggle to overcome critical challenges with the accuracy, cost and availability of diagnostic tests, and with access to research tools that could help to enable a highly tailored approach to COVID-19 patient care," said Kevin Hrusovsky, Chairman, Chief Executive Officer and President, Quanterix and Founder, Powering Precision Health (PPH). "While vaccine deployment continues at an aggressive pace, COVID-19 testing and clinical research tools will remain a global priority in the months to come. Highly sensitive measurements of viral antigen and the adaptive immune response from sample types suitable for collection at point-of-care settings and at home can help facilitate global public health efforts to curtail viral spread and accelerate therapy development clinical research programs."

While current PCR-based testing remains the gold standard for COVID-19 detection, concerns have been raised with respect to false negatives associated with nasal and NP swabs, particularly in asymptomatic and pre-symptomatic patients. According to data published in the <u>Annals of Internal</u> <u>Medicine</u>, on day five of infection – the median time for symptom onset and the peak of viral transmission – molecular tests show a 38 percent probability of producing a false result. Moreover, PCR-based supply chains have been strained by increased testing demands, requiring the need to evaluate new testing paradigms.

Harnessing the high-sensitivity and specificity of the <u>Simoa HD-X AnalyzerTM</u> to quantitate the SARS-CoV-2 nucleocapsid protein and anti-SARS-CoV-2 spike IgG directly in the various sample matrices in this research test, which is authorized for use with NP swabs, but not yet authorized by the FDA for emergency use with saliva or DBS samples, the research team observed a more than 90 percent positive percentage agreement (PPA) of COVID-19 positive patients and a more than 98 percent negative percent agreement (NPA) in all matrices within seven days of a positive PCR test, using sample cohorts which included both asymptomatic and symptomatic patients. The research also demonstrates an inverse correlation between nucleocapsid protein clearance and an increase in SARS-CoV-2 anti-spike IgG in all matrices, suggesting that an early and robust IgG response alleviates severe disease outcomes, even when high levels of viral nucleocapsid protein are initially present.

"The impact of the COVID-19 pandemic will continue to reverberate globally in the months and years ahead." continued Hrusovsky. "With technologies like Simoa, which can measure the concentration of viral proteins in blood and saliva samples obtained non-invasively, new pathways may become available to expand access to accurate and reliable testing, and to extend our understanding of COVID-19 biology. When combined with highly sensitive Simoa assays to measure biomarkers of inflammation and neurodegeneration, we can begin to unravel the mysteries of COVID-19 infection, including the estimated 30% of infections that progress to 'Long COVID', and accelerate development of effective treatment paradigms. We're elated by the results of this research and continue to support the global scientific community in their tireless efforts to address the pandemic."

The results presented in the Nature Communications publication were obtained using Research Use Only (RUO) assays from Quanterix. For details on Simoa assays which have received Emergency Use Authorization, please visit https://www.quanterix.com/covid/.

To learn more about Quanterix' technology, visit https://www.quanterix.com/simoa-technology/.

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.guanterix.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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