

Quanterix' Simoa Technology Sets New Standard in Protein Detection

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New research published in Lab on a Chip demonstrates 100x sensitivity improvement on Simoa; marks significant advancement in sensitivity for industry leading detection platform

BILLERICA, Mass.--(BUSINESS WIRE)--May 13, 2020-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis to advance the science of precision health, today announced that it has successfully applied its <u>Simoa</u>® technology to achieve a 100x sensitivity improvement of the digital enzyme-linked immunosorbent assay (ELISA) using an advanced version of the technology that powers the Company's <u>HD-X</u> TM and<u>SR-X</u> TM Ultra-Sensitive Biomarker Detection Systems. The breakthrough enables a significant increase to the signal-to-background of these assays, further expanding the measurement of a wider range of soluble protein biomarkers. The results were recently published in *Lab on a Chip.**

Quanterix has pioneered the detection of ultra-low concentrations of proteins to greatly improve the sensitivity of immunoassays via its Simoa technology. In this work, Quanterix' Senior Vice President of Research & Development and Chief Technology Officer, David C. Duffy, and his team of researchers sought to maximize the sensitivity of Simoa technology by optimizing the number of beads used to capture proteins in a sample and developing methods that greatly improve the efficiency of bead analytics. This breakthrough enables ultra-high sensitivity digital ELISAs for a number of proteins in serum and plasma from healthy individuals and further progresses Simoa's capability for measuring dry blood spots, expanding its reach to home care applications.

"We believe that this work is highly relevant to those in the biomedical industries striving for sensitive detection of protein biomarkers, including researchers developing novel therapeutics and next-generation diagnostics, and clinicians performing cutting-edge translational biomarker research," said Duffy. "We also believe that the immunoassays developed using this advance in Simoa are the most sensitive reported to date, by enabling detection at never-before-seen sub-attomolar concentrations. Greater sensitivity of protein measurements, when combined with high specificity, can enable greater diversity in the measurement of proteins found and the samples paving the way for significant discoveries across a range of diseases and health conditions."

The paper also describes a novel method called magnetic-meniscus sweeping (MMS) that increased by 10-fold the number of beads loaded into arrays of microwells in the Simoa disk. Improved optics and image analysis algorithms also contributed to improved sensitivity. Quanterix researchers used these approaches to develop an assay for IL-17A, a pro-inflammatory cytokine, with a limit of detection (LOD) of 0.7 attomolar (aM), 437-fold more sensitive than the first generation Simoa assay technology. The new Simoa methodology also yielded digital ELISAs with improved LODs for IL-12p70 (0.046 aM), p24 (9.1 aM), and interferon alpha (45.9 aM).

The 100x advance solidifies Simoa's leadership position as an enabling technology in new types of measurements of proteins. For example, detection of neurological biomarkers in plasma and serum, offering the potential of "blood tests for the brain" for the first time. In particular, greater sensitivity allows the detection of low abundance post-translational modifications of proteins, such as the detection of abnormal accumulation of a phosphorylated tau protein, the presence of which is consistent with the neurodegenerative changes associated with Alzheimer's disease. Improved sensitivity also unlocks new capabilities for the detection of inflammatory cytokines in the blood of healthy and diseased patients, and the detection of proteins important in the early and accurate detection of inflammators.

"Achieving this important innovation goal is key for Quanterix to continue unlocking the power of biomarkers for revolutionizing precision health," said Kevin Hrusovsky, Chief Executive Officer, President and Chairman, Quanterix. "Several years ago, Quanterix established breakthrough ultrasensitivity in protein detection with the launch of the Simoa digital ELISA technology. Since that time, many researchers around the world have shown the importance of this advance for detecting disease earlier, sometimes pre-symptomatically, and with minimally invasive blood testing. It has also been shown that sensitivity can lead to improved specificity and quantitation, helping to reduce false positives and false negatives in biomarker detection. These advances are being realized today in promising new COVID-19 serology tests under development. Achieving even greater sensitivity further advances the field of high-fidelity biomarker detection by enabling biomarker subtypes to be measured and quantified, further stratifying disease cohorts and enabling precision health studies. This advance may also benefit point-of-care solutions and drug and vaccine research, diagnostics and disease prevention sciences."

The greater sensitivity carries particular significance in the fight against COVID-19 by powering greater detection of proteins central to infectious diseases, namely, viral antigens, and the antibodies and cytokines that are generated during host response. For example, improved sensitivity will further improve Simoa's ability to measure cytokine concentrations associated with cytokine release, a severe immune response to the virus. European researchers in the <u>Powering Precision Health (PPH)</u> community identified a deficiency of interferon (IFN) type I in the blood early in the disease cascade, which has shown to have predictive value for patients that are at greater risk for deregulation of the inflammatory response leading to cytokine storm, providing a rationale for new treatment strategies in response to the COVID-19 pandemic. IFN-alpha was one of the proteins with improved sensitivity reported in this work.

Quanterix is offering researchers early access to this 100x assay capability through its state-of-the-art <u>Accelerator Lab</u>, a dedicated CLIA-certified laboratory environment for custom assay development and clinical sample testing. Since its launch in 2014, the Accelerator Lab has powered considerable advancements in disease detection and drug development, helping researchers obtain quick, robust data that would otherwise take more time and added resources.

Learn more about the Quanterix Accelerator Lab and click here for information about the SR-X Ultra-Sensitive Biomarker Detection System.

*Manuscript Title: "Digital Enzyme-Linked Immunosorbent Assays with Sub-Attomolar Detection Limits Based on Low Numbers of Capture Beads Combined with High Efficiency Bead Analysis."

This technology is patent pending.

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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