Quanterix Expands Reach with IVD and Large Reference Labs

June 23, 2025

Simoa Technology Advances Earlier Disease Detection by Measuring Signature Biomarkers

BILLERICA, Mass.--(BUSINESS WIRE)--Jun. 23, 2025-- Quanterix Corporation (NASDAQ: QTRX), a company fueling scientific discovery through ultrasensitive biomarker detection, today announced that the HD-X Simoa Immunoassay Analyzer has received Class 1 Medical Device registration by the Ministry of Food and Drug Safety (MFDS) in South Korea through its regional distribution partner, HS Biosystems.

The continued expansion of the industry-leading Simoa® technology platform into global markets demonstrates a key milestone in broadening validation of biomarker-based testing and providing clinicians with minimally invasive tools that can help enhance diagnostic accuracy and improve accessibility. Through its unparalleled sensitivity and multi-marker testing capability, the Simoa platform delivers ultrasensitive biomarker detection in blood, serum or plasma, with the ability to quantify proteins that are far lower than the Level of Quantification (LoQ) of traditional measurement platforms.

“Quanterix is the only platform in the neurodegenerative space that can be used in research to discover a biomarker, power an endpoint in a clinical trial and progress to a diagnostic test," said Masoud Toloue, Chief Executive Officer at Quanterix. “Other instruments only address narrow use cases, as they are either only high-plex discovery orientated or diagnostic use only. Quanterix makes discovery to diagnostics happen by powering a critical step in between, biopharma clinical trials. As a result, our ultra-sensitive Simoa technology serves as the backbone for many of the Alzheimer’s tests coming to the market today.”

Quanterix has established several new global collaborations with laboratories and patient testing centers, further strengthening the infrastructure for Alzheimer’s testing and reinforcing its clinical utility. These recent collaborations include:

- ARUP Laboratories - a leading national reference laboratory that recently launched a blood test for phosphorylated tau 217 (P-tau217) to assist in identifying whether cognitive decline symptoms in patients ages 60 years and older are related to Alzheimer's disease (AD) pathology. ARUP’s test will be performed on Quanterix’s SP-X ® platform with the Quanterix Simoa® assay kit, which uses P-tau217 antibody technology licensed from Eli Lilly and Company.
- Neurogen Biomarking – the world’s first ecosystem for memory loss with end-to-end patient support recently announced an easy-to-use at-home blood biomarker collection test that can measure phosphorylated tau 217 (P-tau217), a specific marker for Alzheimer’s disease pathology and MCI, using Quanterix’s highly sensitive technology.
- NSW Health Pathology – the largest public pathology service in Australia, has validated NfL for patient testing.

Rede D’Or, Richet Laboratory (IDOR) – the largest integrated health care network in Brazil, covering over 70 hospitals, was the first Brazilian institution to acquire a Simoa HD-X and implement both P-tau217 and NfL for testing. IDOR recently published their first paper in Nature Communications on their work to reduce the underdiagnosis of AD in Brazil.

According to research, early signs of Alzheimer’s disease (AD) may begin 20 years or more before symptoms appear. The Simoa platform equips customers with advanced insights to help accelerate their research and diagnosis, along with accelerating early detection during this crucial timeframe, allowing patients expanded access to treatments that are not available once the disease has progressed to an advanced stage.

“Our team works primarily on Alzheimer’s Disease and dementia, so from day one, our focus has been on reporting how Simoa biomarkers perform when detecting amyloid status and cognitive decline in a local sample,” said Luis Eduardo da Silva Santos, Scientist, Rede D’Or Institute for Research and Education. “IDOR was the first Brazilian institution to acquire a Simoa HD-X and we are excited to see that our work, published in Nature Communications, is now serving as the basis for the local implementation of two Simoa kits, P-tau217 ALZpath and NfL. We expect these tests to be more affordable than current alternatives and to contribute to reducing the underdiagnosis of AD in Brazil.”

For more information on the Simoa platform, visit https://www.quanterix.com/.

About Quanterix
From discovery to diagnostics, Quanterix’s ultrasensitive biomarker detection fueling breakthroughs only made possible through its unparalleled sensitivity and flexibility. The Company’s Simoa ® technology has delivered the gold standard for earlier biomarker detection in blood, serum or plasma, with the ability to quantify proteins that are far lower than the Level of Quantification (LoQ). Its industry-leading precision instruments, digital immunoassay technology and CLIA-certified Accelerator laboratory have supported research that advances disease understanding and management in neurology, oncology, immunology, cardiology and infectious disease. Quanterix has been a trusted partner of the scientific community for nearly two decades, powering research published in more than 3,400 peer-reviewed journals. Find additional information about the Billerica, Massachusetts-based company at https://www.quanterix.com or follow us on Twitter and LinkedIn.

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