

Korea approves US-based Quanterix's biomarker assay for Alzheimer's disease detection

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Simoa technology advances earlier disease detection by measuring signature biomarkers



US-based Quanterix Corporation, a company fueling scientific discovery through ultrasensitive biomarker detection, has announced that the HD-X Simoa Immunoassay Analyser 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.