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Korea marks milestone for blood-based Alzheimer's diagnostics ecosystem

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Exclusive distribution agreement with Quanterix-Lucent Diagnostics and Emocog Inc in Korea



Quanterix Corporation, a US.-based biotechnology company specialising in ultrasensitive biomarker detection, and its clinical diagnostics brand Lucent Diagnostics, together with Emocog Inc., a digital healthcare company based in Seoul, South Korea, have entered into an exclusive distribution agreement for the Korean market covering the Simoa® (Single Molecule Array) technology platform — including the ultra-sensitive HD-X immunoassay analyzer and blood-based Alzheimer's biomarker reagents.

This agreement marks the first introduction of the Simoa® platform into Korea as a formally authorized In Vitro Diagnostic (IVD) device rather than a Research Use Only (RUO) instrument, representing an important milestone in the development of Korea's blood-based Alzheimer's diagnostics ecosystem.

In late October 2025, Emocog obtained Class I In Vitro Diagnostic (IVD) Medical Device import clearance from the Ministry of Food and Drug Safety (MFDS) for the Simoa® HD-X analyzer, establishing the regulatory foundation required to introduce IVD-based blood testing into the Korean healthcare system.

The Simoa® platform is an ultra-sensitive digital immunoassay technology capable of detecting and quantifying proteins at the single-molecule level in blood, serum, or plasma - with sensitivity far beyond traditional assay limits. The HD-X Analyzer, Quanterix's flagship model, is widely used by leading pharmaceutical companies, top-tier hospitals, and neuroscience research centers worldwide for Alzheimer's disease and other neurodegenerative biomarker applications.

Emocog is now preparing Korean clinical and IVD regulatory submissions for Quanterix's pTau217 assay and other Simoa®-based Alzheimer's biomarkers. pTau217 is globally regarded as one of the most accurate and rapidly standardizing biomarkers for early Alzheimer's detection.

Once regulatory approval is secured, Emocog plans to introduce a clinical blood-based diagnostic service that can assess Alzheimer's risk from a single blood draw.