

Quanterix and Innovita Expand IVD Access in China with National Medical Products Administration Approvals

October 7, 2026

NMPA approvals for Quanterix SIMOA® instruments and key neurology biomarker assays advance access to ultra-sensitive blood-based testing in China

BILLERICA, Mass. & BEIJING--(BUSINESS WIRE)--Oct. 7, 2026-- Quanterix Corporation (NASDAQ: QTRX), a global leader in precision biomarker science, and Innovita Biological Technology Co., Ltd. (SSE: 688253.SH), a leading in vitro diagnostics company in China, today announced regulatory approvals that advance access to the Quanterix SIMOA® technology and neurology biomarker testing in the Chinese market.

Initially formed in 2024, the commercialization arrangement combines Quanterix's ultra-sensitive biomarker detection technology with Innovita's diagnostics development, regulatory and commercialization capabilities in China. Innovita has now received National Medical Products Administration (NMPA) approval for the Quanterix HD-X and SR-X instruments, as well as testing kits for four biomarkers relevant to neurological disease: p-Tau 217, GFAP, p-Tau 181 and NfL.

Together, these approvals establish a broader SIMOA®-powered neurology biomarker portfolio in China and represent an important step toward expanding access to blood-based biomarker testing as the Alzheimer's disease diagnostic and treatment landscape continues to evolve. The four biomarkers provide complementary insights into Alzheimer's disease pathology, neurodegeneration and neuroinflammation, supporting applications across the diagnostic continuum, from early screening to disease monitoring and prognostic assessment. As clinical practice increasingly shifts toward earlier identification and evaluation of Alzheimer's disease, highly sensitive blood-based testing becomes increasingly important. Biomarkers such as p-Tau 217 can be present at very low concentrations, creating sensitivity challenges for conventional immunoassay technologies. SIMOA® ultra-sensitive analytical capabilities help address these challenges, supporting more informed clinical decision-making across the continuum of care.

"Alzheimer's disease can progress quietly for years – too often. Families only get answers after symptoms have progressed and drastically changed their lives," said Xiujie Zhang, Chief Executive Officer of Innovita. "By partnering with Quanterix, we're bringing ultra-sensitive blood-based biomarker testing to China, supporting earlier, more informed clinical decision-making and expanding access to advanced diagnostics for patients and communities who need it most."

Quanterix's SIMOA® technology delivers ultra-sensitive digital immunoassay technology that enables proteins to be quantified at the single-molecule level in blood, serum, and plasma. By enabling detection of biomarkers at concentrations far below traditional limits of quantification (LoQ), SIMOA® is designed to address the challenge of measuring low-abundance biomarkers that may be difficult to detect using traditional immunoassay approaches. Its expanding neurology biomarker portfolio includes markers associated with Alzheimer's disease pathology, neurodegeneration and neuroinflammation, supporting the development of multi-analyte approaches that may provide a more comprehensive view of disease biology than individual biomarkers alone.

"Alzheimer's disease places an enormous burden on patients and families, and earlier, more accessible testing can help clinicians make more informed decisions sooner," said Everett Cunningham, Quanterix Chief Executive Officer. "Our commercialization arrangement with Innovita is a critical step toward expanding access to ultra-sensitive protein biomarker testing globally and underscores the momentum of our strategy to bring SIMOA® powered diagnostics into large, high-impact IVD markets through strong regional partners."

Innovita is planning to make regulatory submissions for additional Quanterix biomarker diagnostic kits in China. Innovita's diagnostic development and commercialization capabilities will support the integration of SIMOA® powered biomarker testing into clinical practice in China, helping bring advanced blood-based Alzheimer's disease diagnostic closer to routine patient care. Looking ahead, Innovita may also expand into additional neurodegenerative diseases as well as infectious diseases, broadening the potential applications of SIMOA® powered diagnostics in the Chinese market and beyond. To learn more about Innovita, visit www.innovitaivd.com. To learn more about Quanterix, visit www.quanterix.com.

About Quanterix

Quanterix is a global leader in precision biomarker science, making biology measurable to deliver earlier insights and support breakthroughs in disease research, diagnostics, and drug development. Its SIMOA® technology delivers industry-leading sensitivity, allowing researchers to detect and quantify biomarkers in blood and other fluids at concentrations far below traditional limits. Through the acquisition of Akoya Biosciences, Quanterix Spatial solutions deliver high-plex, quantitative protein analysis in tissue at single-cell resolution. Combined with Accelerator Laboratory services, Quanterix gives researchers the tools and expertise to translate discovery into precision diagnostics. Learn more at www.quanterix.com.

About Innovita

Founded in 2006 and listed on the Shanghai STAR Market (Stock: 688253.SH), Innovita Biotechnology is a leading company in rapid infectious disease diagnostics. Guided by the mission "Diagnostics, Wherever Care is Needed," Innovita builds upon six core technology platforms — antigen-antibody preparation, viral culture, colloidal gold, ELISA, fluorescence chromatography, and immunofluorescence — to become a globally recognized brand in multiplex pathogen detection.

The company's portfolio of 50+ IVD rapid tests spans respiratory pathogens, tropical diseases, hepatitis and sexually transmitted infections, maternal/TORCH screening, and gastrointestinal infections. CE marked and ISO 13485 certified, Innovita products are sold in 70+ countries. The company operates Class 100,000 cleanroom manufacturing facilities in China, holds multiple national invention patents, and is actively pursuing IVDR

and US FDA registration to accelerate international growth. Learn more at www.innovitaivd.com.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements included in this press release that are not historical in nature or do not relate to current facts are intended to be, and are hereby identified as, forward-looking statements for purposes of the safe harbor provided by Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include, among other things, statements about the development and availability of new diagnostic biomarker blood-tests in China and expansion of the clinical impact of Quanterix's technologies. Words and phrases such as "may," "approximately," "continue," "should," "expects," "projects," "anticipates," "is likely," "look ahead," "look forward," "believes," "will," "intends," "estimates," "strategy," "plan," "could," "potential," "possible" and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are subject to certain risks and uncertainties that are difficult to predict with regard to, among other things, timing, extent, likelihood and degree of occurrence, which could cause actual results to differ materially from anticipated results. Such risks and uncertainties include, among others, the following possibilities with respect to Quanterix's future business, operations, strategy and financial performance: risks related to the impact of changes in U.S. government policies, including impacts of tariffs and reductions in federal research funding; risks associated with the anticipated timing for launch of, and features of, Quanterix's next-generation instruments to upgrade its existing platforms; risks related to Quanterix's ability to improve existing diagnostics and develop new diagnostic tests and tools; risks related to Quanterix's ability to successfully penetrate the diagnostics market; risks related to Quanterix's ability to retain and expand its customer base and achieve sufficient market acceptance of its products; risks related to the ability of Quanterix's contract manufacturers and suppliers to reliably and consistently manufacture and supply our instruments; risks that Quanterix may fail to realize the anticipated benefits and synergies of its recent acquisitions of Emission, Inc. and Akoya Biosciences Inc.; risks that Quanterix's estimates regarding expenses, future revenues, capital requirements, and needs for additional financing could be incorrect; risks related to Quanterix's ability to maintain effective internal control over financial reporting and disclosure controls and procedures; and risks related to defects or other quality issues in Quanterix's products that could lead to unforeseen costs, product recalls, adverse regulatory actions, negative publicity and litigation. Additional factors that could cause results to differ materially from those described above can be found in the periodic reports filed by Quanterix with the SEC, including the "Risk Factors" sections contained therein, which are available on the SEC's website at www.sec.gov.

All forward-looking statements expressed or implied, included in this press release are expressly qualified in their entirety by the cautionary statements contained or referred to herein. If one or more events related to these or other risks or uncertainties materialize, or if Quanterix's underlying assumptions prove to be incorrect, actual results may differ materially from what Quanterix anticipates. Quanterix cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made and are based on information available at that time. Quanterix does not assume any obligation to update or otherwise revise any forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements were made or to reflect the occurrence of unanticipated events except as required by federal securities laws.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20261007841334/en/>

Quanterix Media Contact:

media@quanterix.com

Investor Relations Contact:

IR@quanterix.com

Source: Quanterix Corporation