BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

UltraDx receives first clinical approval of single-molecule analyzer in China

September 5, 2024 | News

Groundbreaking achievement now officially listed on the National Medical Products Administration (NMPA) website



UltraDx Bio has announced that its flagship product, the UD-X Fully Automated Single-Molecule Array Fluorescence Immunoassay Analyzer, has received its first clinical registration approval in China.

This groundbreaking achievement is now officially listed on the National Medical Products Administration (NMPA) website and marks a significant milestone in the field of medical diagnostics. The UD-X Single-Molecule Analyzer is designed for the ultra-sensitive detection and quantification of trace protein biomarkers in body fluids, reaching sensitivity levels at the fg/ml scale. This technology will be utilised alongside soon-to-be-approved companion assay kits, addressing the precision detection needs of clinical diagnostics and community health screenings.

The successful approval and clinical deployment of the UD-X Single-Molecule Analyzer are poised to revolutionise early screening, early diagnosis, companion diagnosis and treatment effectiveness evaluation for diseases such as Alzheimer's Disease (AD). This advancement is not only of immense clinical value but also holds significant social and economic importance.

The company's products leverage state-of-the-art Simoa single-molecule array technology, adapted and approved for clinical use in China. With comprehensive capabilities in R&D, translational research, production, clinical registration, and quality management, UltraDx Bio focuses on developing diagnostic tools for neurological, infectious, immune, cardiovascular, and tumor diseases. The company operates R&D and production centres in Shanghai and Shijiazhuang, offering a robust product portfolio that includes AD early diagnostic instruments, reagents, and complete service solutions.