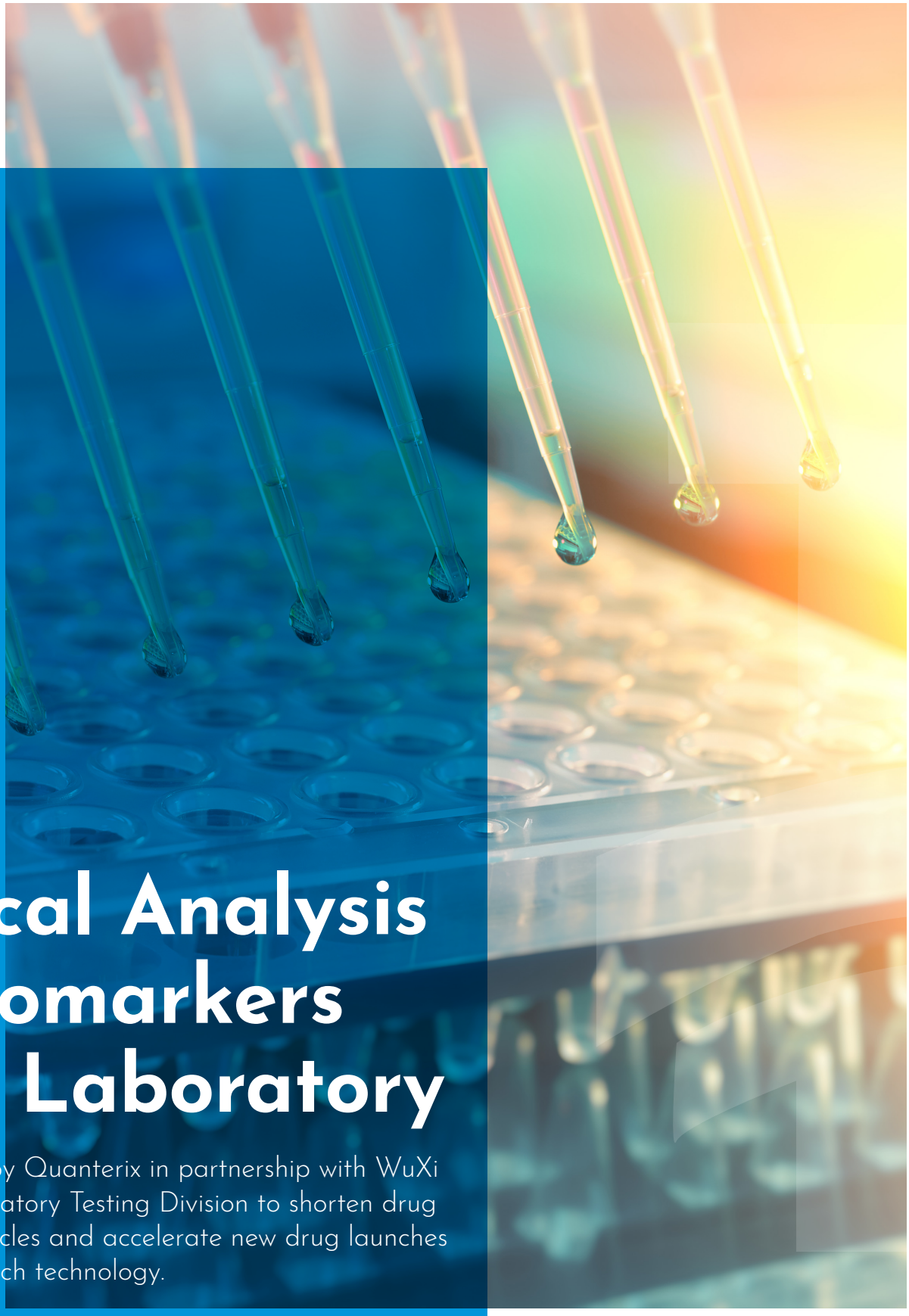

Clinical Analysis of Biomarkers Joint Laboratory

Co-developed by Quanterix in partnership with WuXi AppTec's Laboratory Testing Division to shorten drug development cycles and accelerate new drug launches through top-notch technology.

药明康德
WuXi AppTec

About WuXi AppTec's Laboratory Testing Division (LTD)

WuXi AppTec's Laboratory Testing Division (LTD) is a global, comprehensive, integrated testing platform supporting the entire continuum of the drug development journey. From discovery through preclinical to clinical and beyond, scientists are enabled to transform their ideas into healthcare products that ultimately improve the quality of and extend human life.

WuXi AppTec's Laboratory Testing Division (LTD) offers three testing platforms – an Investigational New Drug (WIND) platform (WuXi AppTec IND), a clinical drug development platform, and a medical device testing platform. LTD provides pharmacokinetic, toxicology, bioanalytical and medical device testing services and works closely with other divisions of WuXi AppTec, to provide one-stop services for our clients. In particular, for global IND/NDA filing projects, we offer full testing and documentation services or customized research solutions designed to meet the various needs of our clients.

About Quanterix

Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognosis and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease. The company was established in 2007 and is located in Billerica, Massachusetts.

For additional information, please visit ***www.quanterix.com.***

Contact Us to Learn More

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Simoa Joint lab
WuXi AppTec & Quanterix

Biomarker Clinical Analysis Services

Simoa Joint Lab is located at WuXi AppTec's headquarters in Waigaoqiao, Shanghai. Biomarker clinical analysis services are provided by the Bioanalytical services department of the Lab Testing Division.

WuXi AppTec's Bioanalytical services department has GLP laboratories in China and the U.S., relying on mass spectrometry, immunochemistry platforms and central laboratories, and adheres to international quality standards to optimize our clients' new drug development projects and help them make successful filings.

No matter what development stage a client's new drug belongs to, the Bioanalytical services department offers a full range of quantitative and analytical services. With over 15 years of cumulative industry experience and more than 500 team members, they can provide comprehensive system solutions for chemical, biological, gene and cellular therapy to help clients prepare successful IND, NDA and BLA applications.

Equipped with expertise, world-class facilities and the latest instrumentation and technology, we are committed to providing our clients with high-quality data to support and accelerate the new drug development pipeline for the benefit of patients around the world.

Simoa Joint Lab – First Batch of Biomarker Qualification

Nervous System
- NFL
- p-Tau
- a-Synuclein
- Tau

Tumors
- TNFa
- GMCSF

Inflammatory Infection
- IL-6
- IL-12 p70
- IFN-y
- IL-2

Autoimmune Disease
- IL-17A

The Simoa platform offers great advantages in the detection of neurological disease markers. A number of protein markers associated with neurological disorders exist in humans (Tau, P-Tau, NFL, Ab-40, Ab-42). They are closely associated with the early diagnosis of Alzheimer's disease, sequelae of brain injury and other diseases. Most of these protein markers are found in cerebrospinal fluid, which are minimally traceable in peripheral blood and cannot be detected by current conventional protein assays, and the collection of cerebrospinal fluid is complex and dangerous and cannot be used as a screening method.

The application of Simoa's ultra-sensitive assays and kits allows for the detection of concentrations and changes in these neuromarkers in peripheral blood, which is important for the screening and early diagnosis of neurological diseases (e.g. Alzheimer's and Parkinson's disease), and for predicting and monitoring the onset syndromes, progression and prognosis of neurological diseases.

WuXi AppTec's Current Validated Biomarkers

Inflammatory & Immune Diseases
- BMP-9
- C-MET
- HGF
- IL-8
- M-CSF
- MCP-
- PARC
- SDF-1
- TIMP-1
- VEGF1

Pulmonary Emboli
- Adiponectin, Total
- IL 6
- KL-6
- PARC
- Tenascin C
- TGFb 1

Hepatic Impairment
- Adiponectin, Total
- aGST
- CICP
- TGFb 1
- TIMP-1

Osteogenic
- CICP

Kidney Injury
- Cystatin C
- NGAL

Metabolic Diseases
- Adiponectin, Total
- GLP-1, Active
- GLP-1, Total
- GIP
- Leptin
- PYY

Endocrine Functions
- Estradiol
- IGF-1
- TGFb 1

Tumors
- BMP9
- C-MET
- HGF
- IL8

Cardiovascular Disease
- IL6
- MCP-1

Cartilage Diseases & Arthritis
- PIIINP
- YKL-40

Simoa Joint Lab is based on the Bioanalytical platform of WuXi AppTec's Laboratory Testing Division and provides industry-leading biomarker analysis capabilities. With over a hundred validated methodologies, we can develop custom kits for Simoa instruments, based on our clients' needs.

Customized Reagent Kits → ***Feasibility Testing*** → ***Prototype Development*** → ***Assay Optimization*** → ***Assay Validation***

WuXi AppTec Clinical Trial Testing Services

- Prior medications
- Diagnostic tests: Pathological, immunological, cellular-molecular level
- Blood analysis, urinalysis
- Coagulation, biochemistry
- Hemoglobin
- Humoral immunity: Drug-resistant/ neutralizing antibodies
- Immunoassays, e.g. hepatitis B virus, insulin and c-peptide, thyroid function, hormones
- Resistant profile
- Target interference
- Threshold setting in special groups
- Cellular immunity

Inclusion/ Exclusion Testing

Safety Testing

Immunogenic

Biomarkers

- Biomarkers (e.g. Receptor Occupancy, Target Engagement)
- Clinical markers

Pharmacodynamics

- Efficacy
- Safety
- Patient stratification
- Diagnosis
- Prognosis

Pharmacokinetics

- Single dose, repeated administration
- Free state, bound state
- Special group
- Co-administration of drugs
- (DDI, drug interferences)

Simoa Joint lab

WuXi AppTec & Quanterix

About Simoa Joint Lab

Co-developed by Quanterix in partnership with WuXi AppTec's Laboratory Testing Division, Simoa Joint Lab provides global, industry-leading services and solutions to customers in the Asia-Pacific region.

These solutions are applicable to biomarker analysis, biopharmaceutical research, custom analytical development, clinical sample testing and precision data delivery.

Single-molecule immunoarray technology makes it possible to detect proteins and nucleic acids with extreme precision, thereby greatly enhancing the results of protein bioanalysis studies.

Why Choose Simoa Joint Lab

The team has over 10 years of experience in preclinical and clinical biomarker analysis, providing services in method development, method verification, and sample analysis under GLP and Non-GLP.

The Lab is equipped with a digital single-molecule immunoarray Simoa HD-X analyzer, providing ultra-sensitive multi-protein detection technology, with 1000 times greater analytical sensitivity compared to standard enzyme-linked immunosorbent assay (ELISA) kits.

The result is the ability to quantify proteins below the limit of quantification in a unique immunoassay platform, and obtain baseline analytes of healthy subjects and disease indicators for exploratory biomarker analysis of enhanced PK/PD studies for drug development.

Customized Reagent Kits

Simoa Joint Lab has the advantage of offering industry-leading technology. Unlike regular laboratories, Simoa Joint Lab is not only able to provide clients with custom testing services but also custom kit services.

Quanterix provides leading technical support for kit customization services as a laboratory partner. Clients can achieve ultra-sensitive protein marker detection, and kit research and development with their own antibodies.

Simoa HD-X Digital Single Molecule Immunoarray Analyzer

Ultra-Sensitive:
More than 1000 times higher, on average, than existing conventional immunoassays. Detection of very low concentrations of analytes also provides a powerful tool for the discovery and detection of new biomarkers.

Fully Automated:
The system automates all assay tasks such as spiking, washing, incubation and detection, and automatically handles large volumes of samples by high throughput, shortening test times and reducing error rates.

High Precision:
Resulting coefficients of variation CVs <10%.

Multiple Testing:
Simultaneously completing tests of up to 10 unique target molecules in the same reaction well.

Wide Range of Linearity:
Both digital and analog data analysis were used for low- and high-concentration samples, respectively, in the concentration range >4 log.

Independent R&D:
System Homebrew kits to help users develop and optimize their own test kits.

Service Group

Simoa Experimental Team

Simoa's experimental team consists of a large molecule PD/Biomarker team and a PK team. All five experimentalists have a Master's degree or higher (one Ph.D. and four MSc) and extensive experience in method development, validation and analysis of biological samples in biochemical immunology, biomarkers and pharmacokinetics. All team members are qualified and experienced in GLP bioanalytical laboratories and skilled in GLP compliance.

The large-molecule PD/biomarker team currently conducts bioanalytical and pharmacodynamics assays of a variety of markers covering oncology, inflammation and metabolism for dozens of clients worldwide.

Simoa's experimental team uses the most advanced protein analysis platform available to provide the most sensitive and high-quality protein assays to R&D personnel in pharmaceutical corporations, research institutions, and medical facilities worldwide.

Instrument Support Team

The instrument support team consists of 15 professionals with extensive GxP compliance laboratory experience and over 100 customer and regulatory audits. The standardized maintenance process, compliant with regulatory agencies such as U.S FDA, NMPA and OECD GLP Principal, supported by complete equipment validation and computerized system verification, ensures smooth operation and data integrity requirements of specialized instrumentation in the compliance laboratory.

Quality Assurance Team

The QA team is an international team operating in both the U.S. and China, to provide comprehensive quality assurance services to the laboratory. The team members have rich cross-background experience in GMP, GLP, GCP, GCLP, CSV, etc. and closely follow the relevant laws and regulations to ensure the compliance of bioanalytical business. QA activities use standardized processes to ensure consistency and integrity of operation, and go live with the industry's advanced Track-Wise quality management system for a paperless office, to ensure accuracy and efficiency. The QA team has assisted the laboratory in passing more than 200 official audits by U.S FDA, OECD, EMA, PMDA, NMPA, etc., without critically flawed items affecting the research project.