

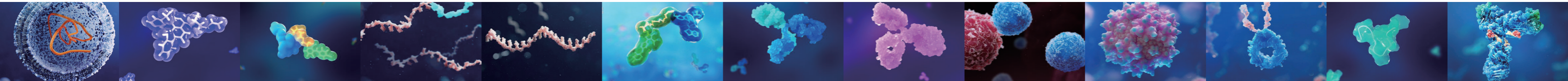


WuXi AppTec
Laboratory Testing Division



WuXi AppTec
Laboratory Testing Division
Bioanalytical Services

WuXi AppTec Bioanalytical Services



Pre-clinical
Bioanalytical Services

Clinical
Bioanalytical Services

Central
Lab

Bioanalytical Services

Shanghai | Suzhou | Qidong | Chengdu | New Jersey

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Global Platform One Vision

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18+ Years lab operations in China
30+ Years lab operations in the U.S.
24,300 Sq. meters lab space

Global Regulatory Standards
Passed inspections by NMPA,
U.S.FDA, OECD, EMA, PMDA, CAP

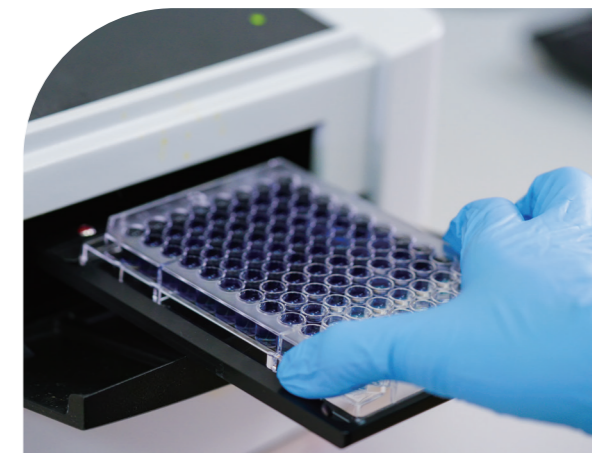
1,000+ Small molecule validated methods
800+ Large molecule validated methods
1M+ Samples analyzed per year

700+ Employees
20+ Years experienced management team
10+ Years experienced bioanalytical team
65%+ Bioanalytical team with master's and doctoral degrees

1,000+ Global clients
3,000+ Global clinical trials

Global Integrated Bioanalytical Platform

WuXi AppTec Bioanalytical Services has leading integrated laboratory operations in China and the US. Our comprehensive instrument platform meets GLP standards with adherence to the highest regulatory standards in the industry. An extensive team of experts provides our clients with comprehensive and professional one-stop services for pre-clinical/clinical mass spectrometry, immunology, molecular/cellular, and central laboratory services.



Bioanalytical Platform—Pre-clinical

Immunotoxicity

- Immunophenotyping
- Cytokines, chemokines
- Immunoglobins, Immunocomplex
- Complement activation
- ELISpot
- Allergy

Pharmacokinetics

- Plasma-protein binding, ADME
- ADC, TAb, and free payload
- DAR, *in vitro* stability
- Tissue distribution of CAR-T and other cell therapy products
- Biodistribution of AAV
- Pre-existing NAb, TAb
- Delivery (LNP virus vector, etc.)
- Viral shedding

Immunogenicity

- Pre-existing NAb
- TAb (vector or transgenic product)
- NAb
- Cellular immunity
- ADA

Toxicokinetics

- ADC, TAb, free payload and main metabolites
- C₀, T_{1/2}, AUC
- Activation, maintenance and migration of exogenous cells
- Biodistribution of AAV
- Biodistribution of delivery (e.g., LNP)
- Protein products of exogenous genes
- Viral shedding

Biomarker

- Disease/pharmaceutical related
- Complement activation related
- Other toxicity biomarkers
- Growth factors
- Hormones
- Myocardial injury
- Bone metabolism

Pharmacodynamics

- Biomarkers
- Target antigen binding activity/pharmacology
- Activation, maintenance and migration of exogenous cells
- Protein products of exogenous genes
- Enzyme activity
- Gene expression (CRISPR target genes)
- Exosomal RNAs

Bioanalytical Platform—Clinical

LC-MS/MS

- PK
- Drug combination
- Biomarker
- Drug-drug interaction

Immunochemistry

- PK
- Immunogenicity/ADA/NAb
- PD
- Biomarker
- Customized antibody production
- Statistics of cut point for immunogenicity
- Cell-based assays

Flow Cytometry

- Immunophenotyping for TBNK, MDSC, PBMCs, T-reg
- Receptor occupancy
- Cell counting for cell therapy products, e.g., CAR-T
- Immune responses

Molecular Biology

- qPCR/ddPCR
- Gene expression/Vector copy number
- Replication Competent Lentivirus testing
- Gene mutations
- NGS sequencing
- AAV genome titer
- Viral shedding
- Tissue distribution

Pathology

- Cell-based NAb assay
- Cellular immune responses
- ELISpot
- FluoroSpot
- Immunohistochemistry

Safety Testing

- Hematology, urinalysis
- Coagulation, biochemistry
- Hemoglobin
- Immunoassays, e.g., HBV, insulin and C-peptide, thyroid function, hormones.



Adhering to the Highest Global Regulatory Standards

Successfully passed global regulatory inspections

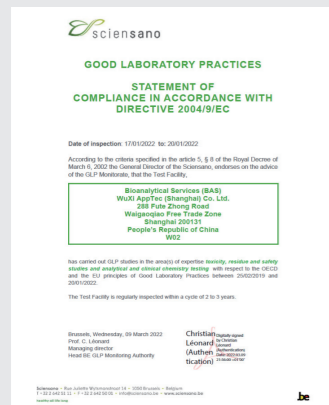
200+ China NMPA

30+ International regulatory agencies
(U.S. FDA, OECD, EMA, PDMA, CAP)



BAS Lab Certification

OECD GLP Certificate



Shanghai CAP Certificate



Shanghai BSL-2 Certificate



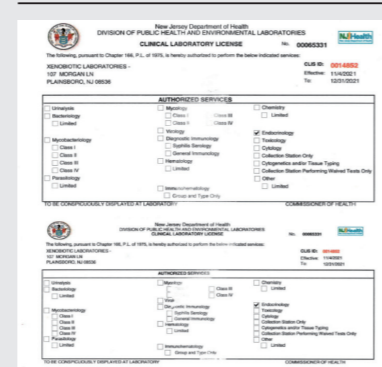
Shanghai NIFDC EQA Certificate



Shanghai NGSP Certificate



New Jersey CLIA Lab Certificate



Hot Topics—Cell and Gene Therapy Bioanalysis

Cell therapy

- VCN, RCL
- FACS
- ADA
- NAB
- PD/Biomarker
- Cytokine
- ELISpot

Gene therapy

- AAV PK
- Viral shedding and Tissue distribution
- AAV ADA
- Transgene protein ADA
- AAV NAb
- PD/Biomarker
- Cytokine
- ELISpot

Oligonucleotide

- PK
- ADA
- Biomarker/Cytokine
- FACS

Vaccine

- IgG/IgM/IgA subtyping
- Anti-vaccine antibody
- ELISpot
- qPCR

Cell therapy/CRISPR

- VCN, RCL
- ADA/NAB
- ELISpot
- FACS

Oncolytic virus

- PK, viral shedding and bio-distribution
- ADA/NAB
- Transgene expression
- Biomarker/Cytokine

Other areas

- Enzymatic activity assay
- Receptor occupancy analysis
- ctDNA mutation analysis

WuXi AppTec & Quanterix – Simoa® Joint Lab

1000x more sensitive than traditional ELISA assays

Ultra-Sensitivity & Multiplex detection

Capable of running up to 10-plex assays. Able to detect different indicators from one sample.

Ready-to-use Biomarkers

Neurological disease	Oncology	Inflammation
NFL	TNFa	IL-6
P-Tau	GMCSF	IL-12 p70
A-Synuclein		IFN-γ
Tau		IL-17

Homebrew capabilities

Provide flexibility for clients to develop custom Simoa Beads & Planar Array assays. Highly specialized and experienced team to develop custom assays to meet accelerated timelines.

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GLP Validated Bioanalytical Platforms

LC-MS/MS Platform

- LC-MS/MS(85, the MS includes API 4000/5000, TQ5500/6500/6500+/7500, TOF6600)
- ICP MS(3)
- LC-FLD(3)
- UPCC(1)

Immunochemistry Platform

- Microplate Reader(30)
- EnVision(1)
- EnSpire(1)
- MSD(15)
- GYROS(1)
- 3D Suspension Array System(2)
- SMCxPRO(1)
- ImmunoSpot(2)
- Simple Plex(1)
- Gamma Counter(1)
- Phadia Immunoassay Analyzer(1)

New technology Platform

- Simoa HD-X(2)
- Flow Cytometer(6)
- qPCR(7)
- ddPCR(2)
- Vi-CELL XR(1)

Automated workstations

- Tecan(9)
- Hamilton(2)
- Cybi-Selma(6)
- epMotion(2)
- QIAcube Connect(1)
- Biotage Extrahera(3)
- Thermo KingFisher Flex(1)

Small Molecule Bioanalysis Project Experience

Species	Matrix	Drug Type
<ul style="list-style-type: none"> Human Rodent Rabbit Monkey Pig Dog 	<ul style="list-style-type: none"> Serum Plasma Whole blood Urine Tear CSF Milk Saliva Feces Tissue Tumor 	<ul style="list-style-type: none"> Small molecule drug mAb BsAb Antibody prodrug Polymer Protein PROTAC PDC Stable isotope-labeled drug Oligonucleotide LNP

Challenging Projects	Selected Analytes
Derivatization	Acyeterion: Ethinyl estradiol, Drospirenone
Enzyme Hydrolysis	Ezetimibe
Peptide	GLP-1 drug: Liraglutide, Exenatide Insulin drug: levetiracetam, Lispro
Extremely Unstable Pro-drug/Metabolite(s)	Temozolomide and metabolites
ADC	Fosapitan and Aripitan
Endogenous Drug	Payload, Linker-Payload
Elemental Analysis	Aspartic acid, Ornithine, Arginine, Bile acids
Special Formulation	Arsenic, Bismuth, Platinum, Lutetium
	Amphotericin liposome

Large Molecule Bioanalysis Project Experience

Therapeutic monoclonal antibody	Bispecific and polyvalent antibodies	ADC/PDC
<ul style="list-style-type: none"> COVID-19 S protein CTLA4 LAG3 41BB TIM3 PD-1/PD-L1 OX40 EGFR G-CSF HER2 IL17 PCSK9 RANKL TNFα VEGF CD40/CD70/CD38 PSMA B7H7 TIGIT Siglec15 HER3 	<ul style="list-style-type: none"> 41BB/PD-L1 CD3/CD19 CD3/CD20 HER2/CD3 PD-1/PD-L1 CD3/PSM CD3/BCMA CD3/CLDN18.2 CD3/MUC17 CD3/EPCAM GARP/PD-L1 CD47/HER2 B7H4/4-1BB OX40/PD-L1 PD-L1/CTLA-4 PD-L1/TGF-β1 TIGIT/CD96 EGFR/IL-10 PD-1/IL-15 PD-L1/IL-2 CD28/CLDN18.2 VEGF/TGF-β1 PD-1/LAG3 PD-L1/TIGIT PD-L1/CD47 	<ul style="list-style-type: none"> CD46-MMAE HER2-DM1 HER2-MMAF CD46-MMAF p-Cadherin-MMAE Trop2-DM1 HER2, Clon18.2-MMAE CD138, FGFR3-PBD IL2-DM1 HER3-MMAE UPAR-MMAE CD3-MMAE HER3-Exatecan/DXD Peptide-SN-38

Cell therapy	Recombinant fusion protein	Peptide/Hormone	Insulin/GLP-1 analog	Gene therapy/Oligonucleotide
<ul style="list-style-type: none"> BCMA CAR-T CD19 CAR-T GPC3 CAR-T Claudin 18.2 CAR-T CD30 CAR-T CAR-NK 	<ul style="list-style-type: none"> CTLA4: Fc Factor VIII GLP-1: Fc LAG-3 rhTNFR: Fc rHuEPO EPO-PEG CD80,CD86 PD-L1: IL-15 PEG-IL-12 IL-2: Fc SAA: Fc GCase 	<ul style="list-style-type: none"> Exenatide PEG-GH rHCG rIFN rPSH rPTH NGF Dopamine T & P & E TSH Total T3/T4 DHA & EPA 	<ul style="list-style-type: none"> Aspart Delgludec Glargine Lispro Insulin Icodec Semaglutide 	<ul style="list-style-type: none"> AAV2 AAV9 AAV8 HSV Milasen ASO siRNA IL-15/IL-15Ra SMN1 GCase

Biomarker Bioanalysis Experience



17+
years of experience



120+
R&D drug
products supported

300+
Clinical trails



260+
Clinical method validation
or qualification

200+
Preclinical method
validation

Type of disease

- Cancer
- Inflammation and immunology
- Metabolic disease
- Cardiovascular disease
- Kidney injury
- Nervous system
- Bile acid malabsorption

- Dermatitis
- Osteoblast
- Osteochondropathy and Arthritis
- Endocrine system
- Pulmonary disease
- Liver injury
- Immunology

- Eye disease
- Blood disease
- SCOMT
- Cancer and Prognosis
- Diabetes

LTD-BAS of WuXi AppTec has established advanced and comprehensive testing platforms for the bioanalysis of biomarkers that are involved in a variety of diseases. We are capable of analyzing biomarkers at small molecule, large molecule, genetic and cellular levels.

Please scan the QR code for more information.



Central Laboratory Services

Project Management

- Global integrated project management
- Global clinical trial operation experiences
- Dedicated project management team throughout the life cycle of the study
- Quick study start-up and response with 24-48 hours

Sample Management

- Sample management (including log in and out, storage, etc.)
- Cold storage (-20°C)
- Ultra low temperature storage (-70°C to -80°C)
- 7x24-Hour computerized temperature monitoring systems with alerts
- UPS and generator as back up power

Data Management

- Leading laboratory information management system (STARLIMS)
- Data storage and transfer

Safety testing

- 400+ safety testing assays
- Technology platform: Hematology, Urinalysis, Coagulation, Biochemistry, Hemoglobin Testing, Immunoassay, ELISA Platform, Flow Cytometry
- Capable of handling BE, lipids, diabetes, hormones, tumors and hepatitis
- Particular Solutions: BE acarbose detection, PK biomarkers (Calcium, Iron, HBsAg, etc.), hemagglutination and inhibition, QuantiFRON TB Glod combined with TB virus screening test

Logistics coordination and management

- Solutions for complex global logistics
- Global, consolidated logistics network with standardized service points
- Conduct global kit supply and sample reception
- Dedicated import and export management team
- Assist in handling customs clearance documents

Kits supply and lab manual

- Study-specific kit assembly / distribution
- Customized laboratory manual



Instrument platform

- Siemens Advia 2120i
- Beckman Coulter AU680
- Siemens BN Prospec
- Siemens Clinitek Status+
- Roche cobas 6000 c501 module
- Siemens Centaur XP
- Sysmex CS2000i
- Tosoh HLC-723G8(2)
- Roche cobas 6000 e601 module

