

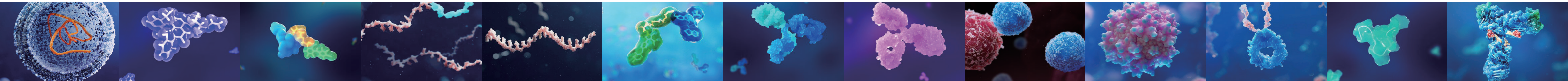


WuXi AppTec
Laboratory Testing Division



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



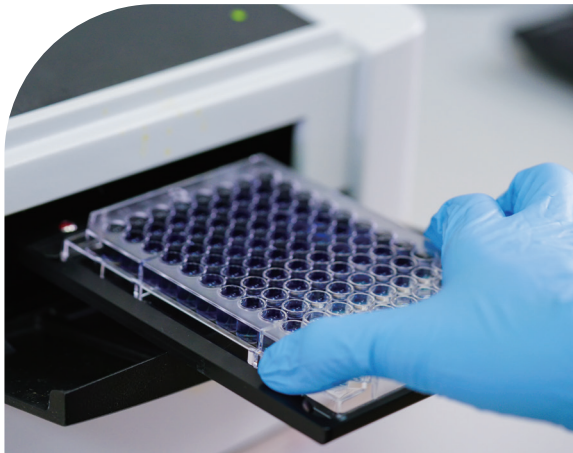
700+ Employees
20+ Years experienced management team
10+ Years experienced bioanalytical team
65%+ Bioanalytical team with master's and doctoral degrees



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	Pharmacokinetics	Immunogenicity	Toxicokinetics	Biomarker	Pharmacodynamics
<ul style="list-style-type: none">ImmunophenotypingCytokines, chemokinesImmunoglobins, ImmunocomplexComplement activationELISpotAllergy	<ul style="list-style-type: none">Plasma-protein binding, ADMEADC, TAb, and free payloadDAR, <i>in vitro</i> stabilityTissue distribution of CAR-T and other cell therapy productsBiodistribution of AAVPre-existing NAb, TAbDelivery (LNP virus vector, etc.)Viral shedding	<ul style="list-style-type: none">Pre-existing NAbTAbs (vector or transgenic product)NAbCellular immunityADA	<ul style="list-style-type: none">ADC, TAb, free payload and main metabolitesC0, T1/2, AUCActivation, maintenance and migration of exogenous cellsBiodistribution of AAVBiodistribution of delivery (e.g., LNP)Protein products of exogenous genesViral shedding	<ul style="list-style-type: none">Disease/pharmaceutical relatedComplement activation relatedOther toxicity biomarkersGrowth factorsHormonesMyocardial injuryBone metabolism	<ul style="list-style-type: none">BiomarkersTarget antigen binding activity/pharmacologyActivation, maintenance and migration of exogenous cellsProtein products of exogenous genesEnzyme activityGene expression (CRISPR target genes)Exosomal RNAs

Bioanalytical Platform–Clinical

LC-MS/MS	Immunochemistry	Flow Cytometry	Molecular Biology	Pathology	Safety Testing
<ul style="list-style-type: none">PKDrug combinationBiomarkerDrug-drug interaction	<ul style="list-style-type: none">PKImmunogenicity/ADA/NAbPDBiomarkerCustomized antibody productionStatistics of cut point for immunogenicityCell-based assays	<ul style="list-style-type: none">Immunophenotyping for TBNK, MDSC, PBMCs, T-regReceptor occupancyCell counting for cell therapy products, e.g., CAR-TImmune responses	<ul style="list-style-type: none">qPCR/ddPCRGene expression/Vector copy numberReplication Competent Lentivirus testingGene mutationsNGS sequencingAAV genome titerViral sheddingTissue distribution	<ul style="list-style-type: none">Cell-based NAb assayCellular immune responsesELISpotFluoroSpotImmunohistochemistry	<ul style="list-style-type: none">Hematology, urinalysisCoagulation, biochemistryHemoglobinImmunoassays, e.g., HBV, insulin and C-peptide, thyroid function, hormones.



Adhering to the Highest Global Regulatory Standards

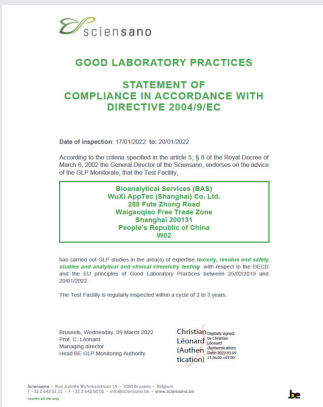
Successfully passed global regulatory inspections

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



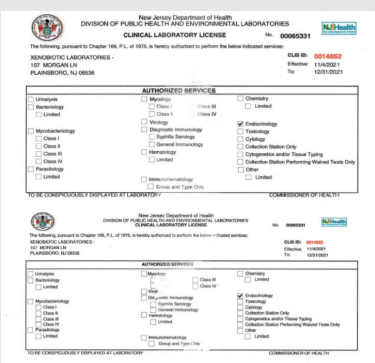
Shanghai NIFDC EQA Certificate



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

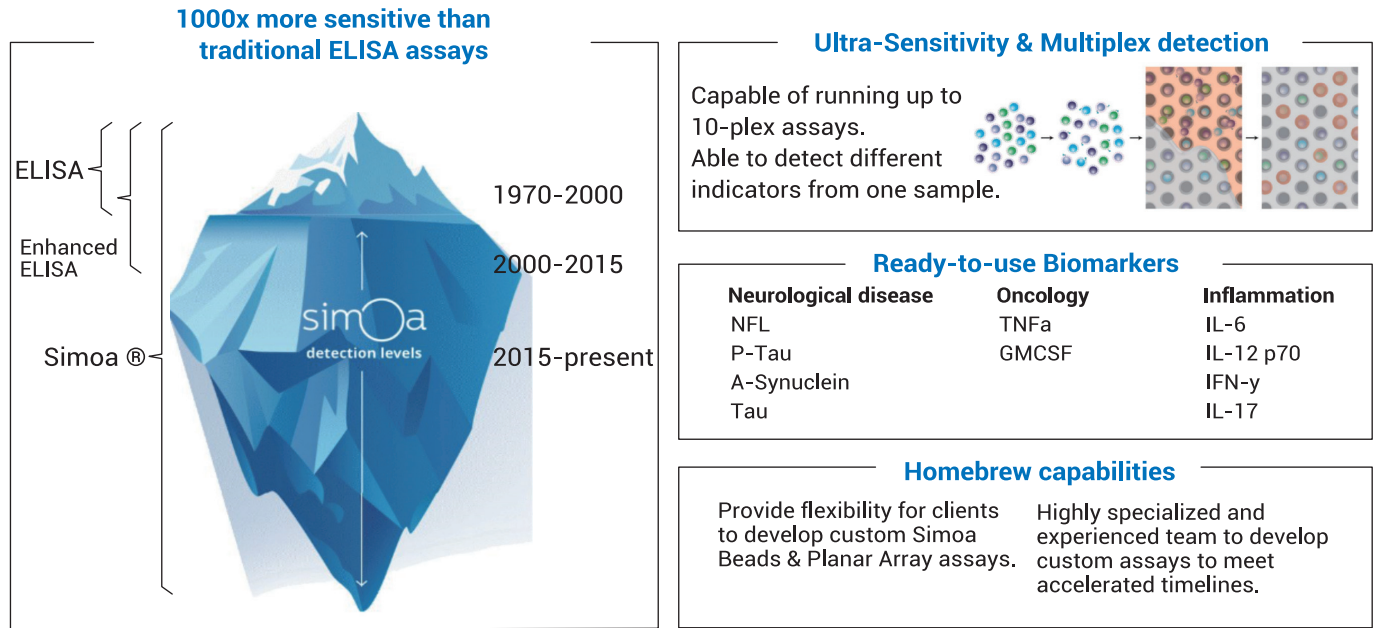
Oncolytic virus

- 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



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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	
Human	Serum	Milk	Small molecule drug	PROTAC
Rodent	Plasma	Saliva	mAb	PDC
Rabbit	Whole blood	Feces	BsAb	Stable isotope-labeled drug
Monkey	Urine	Tissue	Antibody prodrug	Oligonucleotide
Pig	Tear	Tumor	Polymer	LNP
Dog	CSF		Protein	

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 Payload, Linker-Payload
Endogenous Drug	Aspartic acid, Ornithine, Arginine, Bile acids
Elemental Analysis	Arsenic, Bismuth, Platinum, Lutetium
Special Formulation	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 proteinCTLA4LAG341BBTIM3PD-1/PD-L1OX40EGFRG-CSFHER2IL17PCSK9RANKLTNFα	<ul style="list-style-type: none">VEGFCD40/CD70/CD38PSMAB7H7TIGITSiglec15HER3	<ul style="list-style-type: none">41BB/PD-L1CD3/CD19CD3/CD20HER2/CD3PD-1/PD-L1CD3/PSMCD3/BCMACD3/CLDN18.2CD3/MUC17CD3/EPCAMGARP/PD-L1CD47/HER2B7H4/4-1BBOX40/PD-L1PD-L1/CTLA-4PD-L1/TGF-β1TIGIT/CD96EGFR/IL-10PD-1/IL-15PD-L1/IL-2CD28/CLDN18.2VEGF/TGF-β1PD-1/LAG3PD-L1/TIGITPD-L1/CD47	<ul style="list-style-type: none">CD46-MMAEHER2-DM1HER2-MMAFCD46-MMAFp-Cadherin-MMAETrop2-DM1HER2,Cldn18.2-MMAECD138, FGFR3-PBDIL2-DM1HER3-MMAEUPAR-MMAECD3-MMAEHER3-Exatecan/DXDPeptide-SN-38

Cell therapy	Recombinant fusion protein	Peptide/Hormone	Insulin/GLP-1 analog	Gene therapy/Oligonucleotide
<div><ul style="list-style-type: none">BCMA CAR-TCD19 CAR-TGPC3 CAR-TClaudin 18.2 CAR-TCD30 CAR-TCAR-NK</div>	<div><ul style="list-style-type: none">CTLA4: FcFactor VIIIGLP-1: FcLAG-3rhTNFR: FcrHuEPOEPO-PEGCD80,CD86PD-L1: IL-15PEG-IL-12IL-2: FcSAA: FcGCase</div>	<div><ul style="list-style-type: none">ExenatidePEG-GHrHCGrIFNrPSHrPTHNGFDopamineT & P & ETSHTotal T3/T4DHA & EPA</div>	<div><ul style="list-style-type: none">AspartDelgludecGlargineLisproInsulin IcodecSemaglutide</div>	<div><ul style="list-style-type: none">AAV2AAV9AAV8HSVMilasenASOsiRNAIL-15/IL-15RαSMN1GCase</div>

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

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

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.

