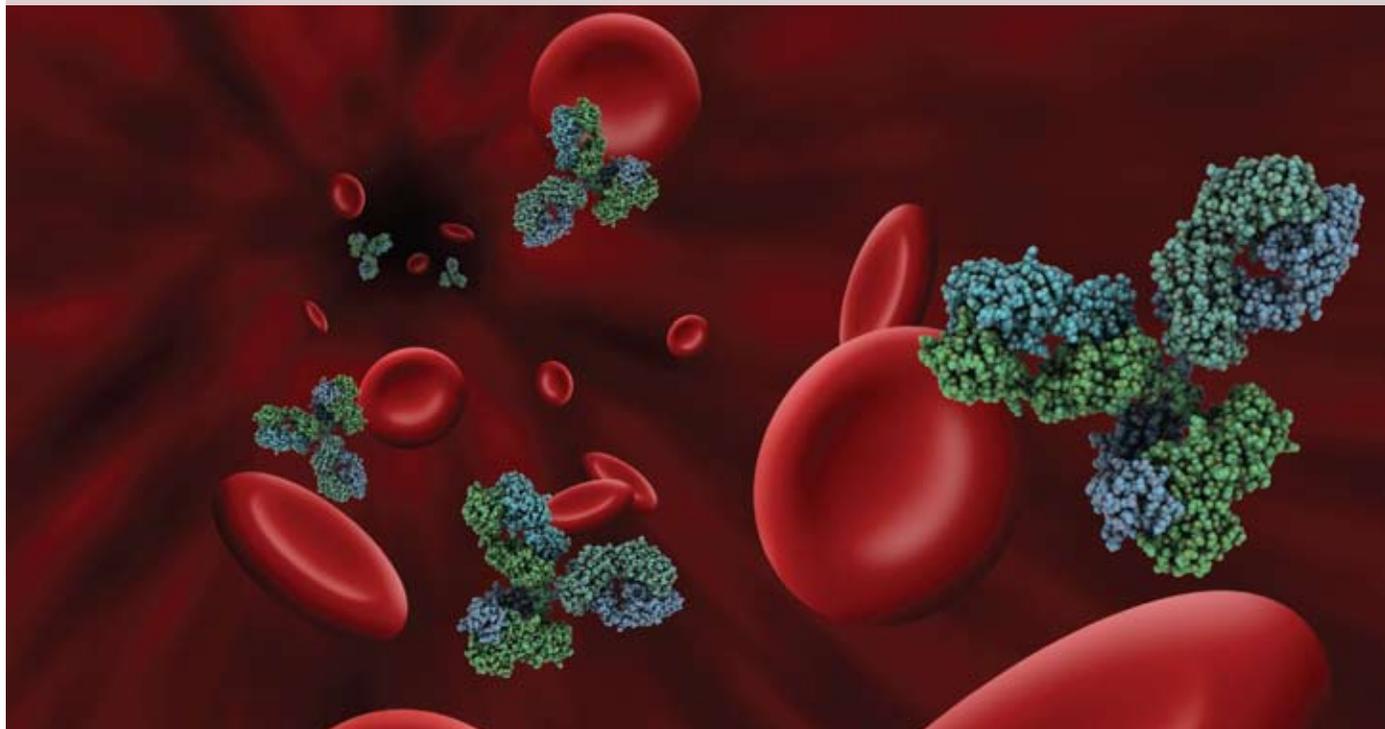


# Bioanalytical Services



**Seamless, comprehensive, multi-site capabilities  
to support submissions worldwide**

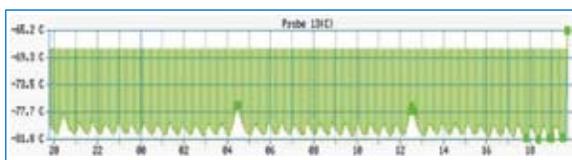
*ILLUSTRATION:  
Blood cells and antibodies*



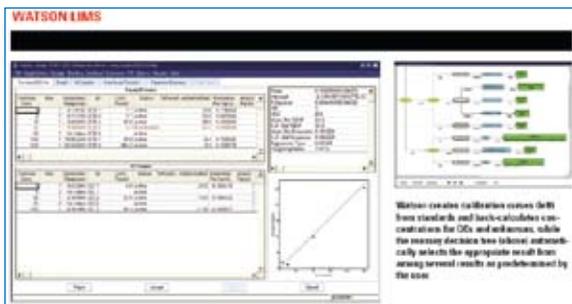
# Bioanalytical Services

*State-of-the-art technologies to deliver high-quality, accurate data*

With over 60,000 sq. ft. of laboratories and nearly 190 staff members in both China and the U.S., WuXi AppTec offers comprehensive bioanalytical services to pharmaceutical and biopharmaceutical companies – from small start-ups to large Fortune 500 companies, innovators to generic. We conduct PK, BE and BA sample analysis using state-of-the-art technology in supporting client submissions to global regulatory agencies. All facilities are US FDA registered and ours is the first US FDA-inspected and certified GLP bioanalytical CRO in China. Our GLP regulatory-compliant laboratories deliver high quality and accurate data under a strict quality control program.



Temperature probe read-out



Watson LIMS features

## OPERATIONS

Both the China and U.S. facilities have simplified procedures in place for receiving biological materials, based on the experience that comes from testing over 400,000 samples annually (the vast majority of which are received from outside China). To ensure the security and integrity of client data, we have established strict IT policies of data and data access, including a centralized security alarm and card-controlled facilities, blinded bar coding of each sample, electronic audit trails, 100% check of QC and QA reports, and dual long-term documentation archives.

Additional operational controls and features include:

- Sample shipment temperature tracking
- Electronic temperature monitoring alarm system 24/7
- -80°C and -20°C freezers and walk-in cold rooms
- On-site back-up generators
- UPS for all LC/MS/MS instruments
- Instrument and computer qualifications - IQ/OQ/PQ
- Instrument and equipment scheduled calibrations
- Watson LIMS Data Management
- Analyst Acquisition Software
- All studies monitored by sponsors from study protocols to reports
- Shared SOPs and Protocols across all WuXi AppTec facilities
- Simple sample importation procedure
- Archive sites with fire suppression system and limited-access authorization

## OUR SERVICE

Utilizing a customer-focused approach and leveraging our facilities in both China and the U.S. – through access to technical experts, sharing SOPs and protocols across all sites and high-throughput sample analysis – we can provide substantial cost savings and expedited timelines to our clients worldwide.

Available services include:

- GLP and non-GLP sample analysis for both small and large molecules
- PK/TK/PD analysis for preclinical and clinical studies
- Antibody immunogenicity assays
- Generic drug BE studies (pilot and pivotal)
- Method transfer, development and validation
- High-throughput LC/MS/MS, UPLC/TOMTEC sample analysis
- Incurred sample re-analysis for each conducted study
- Stability testing
- Metabolite identification and elucidation
- Synthesis of commercially non-available internal standards and metabolites



Temperature probe monitoring samples shipped from Austin, Texas to Shanghai, China

Instrumentation / Equipment	China	U.S.	Application
AB Sciex API 4000/5000/5500 LC/MS/MS	✓	✓	Small Molecule
Thermo TSQ Vantage	✓		
Waters Xevo G2 Q-TOF	✓	✓	
Waters UPLC/Agilent HPLC/Leaps CTC autosampler	✓	✓	
Tecan EVO workstation	✓		Automation and LIMS
Thermo Matrix workstation	✓		
Tomtec Quadra 96/4 workstation	✓	✓	
Eppendorf epMotion workstation	✓	✓	
Watson LIMS v7.2 (accounts)	✓	✓	
Tecan EVO automated ELISA workstation	✓		Large Molecule
Hamilton Microlab Star automated ELISA workstation	✓		
Luminex 200	✓	✓ (2013)	
Meso Scale Discovery (MSD) Sector Imager 6000 ECL analyzer	✓	✓	
Molecular Device M2/M5 ELISA plate reader	✓	✓	
AB Sciex API 4000 Q Trap	✓	✓	
Gyrolab XP	✓		

## QUALITY & COMPLIANCE

WuXi AppTec's bioanalytical laboratories maintain strict adherence to internal and/or client SOPs and quality standards. In addition to an exacting QC process that includes daily in-process inspections, an independent quality assurance unit performs routine and periodic inspections – monitoring the laboratories to ensure data is qualified for regulatory submissions and confirming the labs are in compliance with the following:

- US FDA/OECD/SFDA GLPs
- ICH/SFDA GCP
- FDA 21 CFR part 11 and part 58
- FDA Guidelines to Industry for Bioanalytical Method Validation
- Crystal City Workshop guidelines

The following is a list of WuXi AppTec regulatory agency audits and visits. Numerous studies have been reviewed and accepted by the US FDA and SFDA (with no 483s).

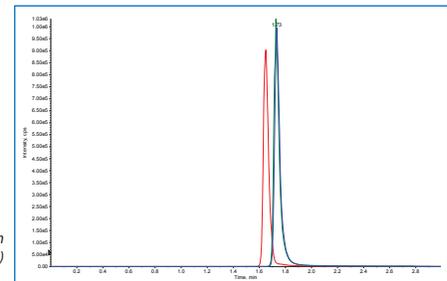
- US FDA
- SFDA
- US GAO
- OECD

## METHODS & ASSAYS

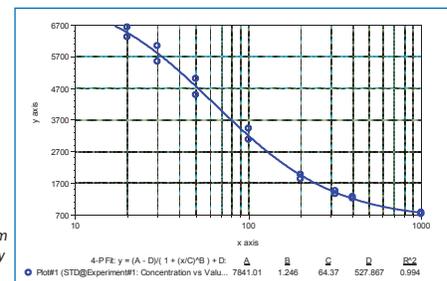
The experienced scientists on WuXi AppTec's bioanalytical services team utilize a diverse set of techniques and equipment to analyze for both large and small molecules. We have developed hundreds of bioanalytical assays – not only for clients' proprietary compounds, but also for commonly co-administered medications (e.g., paclitaxol, TMZ), over-the-counter medications (e.g., warfarin, ketoconazole), and biomarkers (e.g., epinephrine, IL-22).

Our expertise and capabilities in monitoring for numerous large and small molecules can also aid in a variety of preclinical and clinical studies, such as: comparison of an emergent therapy to a previously marketed drug in Phase II trials; use of biomarkers to support proof-of-concept clinical trials; and determination of possible drug-drug interactions during both preclinical and clinical studies.

Example chromatogram (LC-MS/MS)



Example curve from competitive ELISA assay



Tecan automated liquid handling system

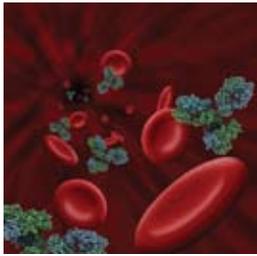


MSD system

Sciex API 4000 LC-MS/MS system



BAS Laboratory – Shanghai, China



# Bioanalytical Services

*WuXi AppTec, a leading global contract services organization, provides services of exceptional quality to help our worldwide customers shorten the time and lower the cost of drug R&D through cost-effective and efficient outsourcing solutions.*

## **PROGRAM FEATURES & BENEFITS**

We know what our clients want from their bioanalytical services: accurate, high-quality data analysis. And we understand that they are often dealing with tight budgets and timelines. As a result, we have developed an environment to help ensure we successfully meet client expectations. With a team of dedicated, knowledgeable employees – including senior lab heads with over 20 years of bioanalytical experience in the U.S., EU and China – WuXi AppTec has the expertise and capability to provide resourceful solutions.

- Strong track record of successful regulatory agency and client audits.
- State-of-the-art equipment to ensure timely high-throughput and high-quality analysis.
- Seamless transfer of methods between U.S. and China to provide consistency for multi-geographic studies.
- Custom assay program with pre-established technology transfer protocols to speed your timelines to final result.
- Ability of clients to access and leverage the expertise in both China and U.S. for study and assay design.
- Daily email/voice communication and weekly teleconferences, providing timely access to study protocols and progress.
- Strict adherence to IT and QC procedures to protect client data and ensure integrity of data capture and analysis.
- Experience testing over 400,000 samples annually in over 250 non-proprietary assays – both small and large molecule – that can be passed on to your program to achieve a high level of success.

**Contact WuXi AppTec for bioanalytical services:**

**(1) 651-675-2000 / 888-794-0077 • [info@wuxiapptec.com](mailto:info@wuxiapptec.com) • [www.wuxiapptec.com](http://www.wuxiapptec.com)**