

# Global Central Laboratories



# Global Integrated Bioanalytical Platform

WuXi AppTec Laboratory Testing Division - Bioanalytical Service (LTD-BAS) has laboratories with integrated global operations, with a comprehensive instrument platform that meets GLP standards, numerous experienced experts, and adherence to the highest regulatory standards in the industry, aiming to provide clients with comprehensive and professional one-stop services for preclinical/clinical mass spectrometry, immunochemistry, molecular/cellular analysis, and central laboratory.



Shanghai, China

**6,600 m<sup>2</sup>**

**Headquarters**

Bioanalytical Services(Clinical)

**Central Lab**



New Jersey, USA

**2,600 m<sup>2</sup>**

Bioanalytical Services  
(Preclinical/Clinical)

**Central Lab**



Chengdu, China

**1,000 m<sup>2</sup>**

Bioanalytical Services  
(Preclinical)



Suzhou, China

**8,100 m<sup>2</sup>**

Bioanalytical Services  
(Preclinical)

Customized antibody production



Qidong, China

**6,000 m<sup>2</sup>**

Bioanalytical Services  
(Preclinical)

## ■ Experience and Capacity

**19+**

Years lab operations in China and the U.S.

**2M+**

Samples analyzed per year

**24,300 m<sup>2</sup>**

Lab space

**1,000+**

Global clients

**3,000+**

Global clinical trials

# Adhering to Global Regulatory Standards

We offer high quality services and conform to all the many major global regulations and guidance, with an excellent track record of global regulatory inspections.

**200+**

**China NMPA inspections**

**30+**

**International regulatory inspections**



**NMPA**



**FDA**



**EUROPEAN MEDICINES AGENCY**  
SCIENCE MEDICINES HEALTH

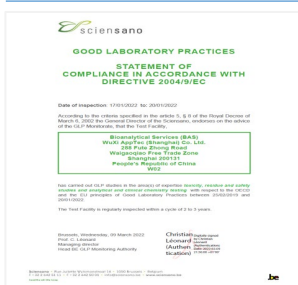


**Pmda**

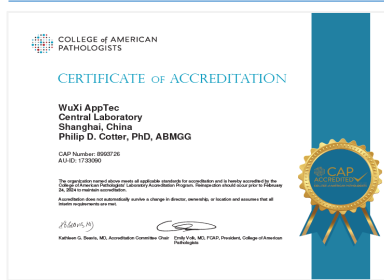


## ■ Certification

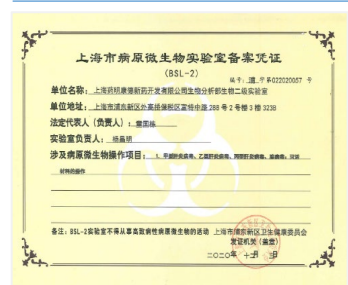
### OECD GLP



### Shanghai CAP



### Shanghai BSL-2



### Shanghai NIFDC EQA



### Shanghai NGSP



### New Jersey CLIA



# Central Lab - Our Scope of Service

Our tailored central lab services empower global clinical studies, ensuring timely and flexible project delivery with our global logistics and seamless data delivery solution.



1

## Project Management

- Full project management and tracking, dedicated project manager
- Responsive and tailored support
- Support for investigator training
- Customized lab manual



2

## Study-Specific Kit

- Industry-leading collection kits:
  - Customized requisition form
  - Pre-labeled vials
  - Organized in collection order
  - Collection/storage supplies



3

## Sample Management

- Information tracking system
- Maintain all sample receiving records
- 24-Hour computerized temperature monitoring systems with alerts
- UPS and generators back-up power



4

## Logistics Coordination

- Global import & export expertise and stay on top of country specific regulatory requirements
- Global logistics partners provide solutions for complex global logistics



5

## Data Delivery

- Our unique client portal provide services online:
  - Real-time report release
  - Place and review lab kits order
  - Review and manage sample reception files



6

## Clinical Safety Testing

- CAP accredited:
  - Hematology
  - Urinalysis
  - Biochemistry
  - Immunoassay
  - Flow cytometry
  - ELISA platform

# We Deliver - With High Efficiency and Quality

We put the customer first and value our clients' special needs in their clinical trials. We are experienced in fast project setup delivery and provide study-specific support with quality control throughout the clinical trials.

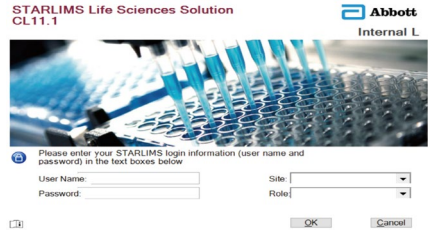
## 1. Project Setup Activities

- Study-specific need inquiry
- Customized lab manual drafting
- Study-specific database design
- On-line training session
- On average 6-12 weeks TAT from study award to initial kit supply



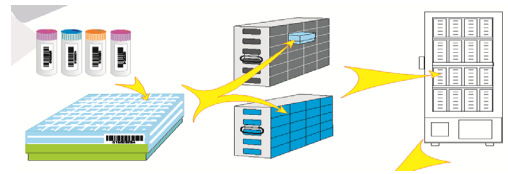
## 2. Kit Production

- Pre-labelled vials, ready to use
- On average 6-10 working days for kit assembly
- 100% quality control before dispatch
- Client system request and query kits



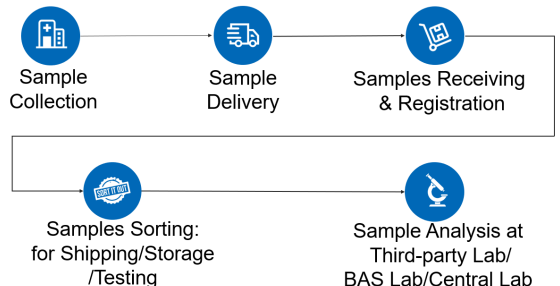
## 3. Sample Management and Biorepository

- Barcode system for sample identification
- Sample life-cycle management
- Sample log-in, verification with QC
- Short-term and long-term storage (-20°C to -80°C) with 7x24-hour computerized temperature monitoring systems



## 4. Sample Shipment Service

- Regularly assessed logistics vendor provide qualified cold-chain service with complete temperature monitoring coverage

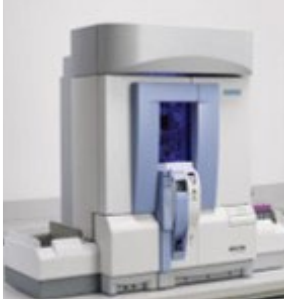




# Central Laboratory Testing Platforms

Our technology platforms support most safety testing and specialized biomarker detections, following CAP standards.

ADVIA 2120i



SYSMEX CS2000i

Coulter AU680



TOSOH HLC-723G8

cobas 6000 c501



cobas 6000 e601

BN Prospec



Centaur XP

## ■ Testing Assay Capabilities

### Biomarker Detection

- Bone
- Tumor Biomarker
- PK Endogenous Biomarker

### Hematology

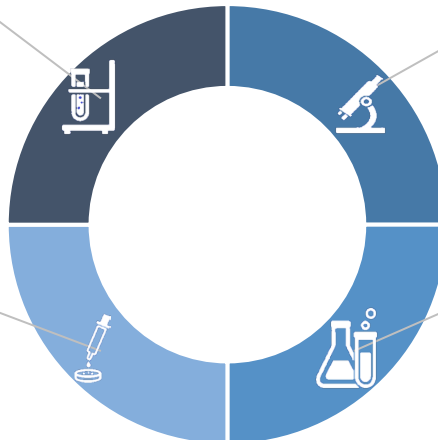
- CBC
- Blood Coagulation
- Flow Cytometry

### Immunology

- Allergy
- Immunoglobulin
- Hepatitis

### Biochemistry

- Lipid
- Hormones
- Pregnancy
- Urinalysis



# Our Global Footprint

We supports clinical studies across the world with our direct presence or cooperation with our entrusted partner labs.

## ■ Clinical Study Experiences

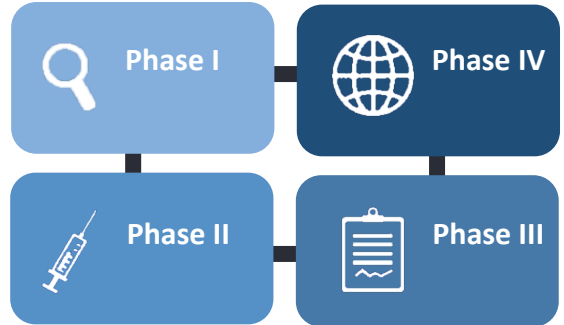
**1887**

Total clinical trials

**102**

Global clinical trials

\*Based on trial summary from 2016 – 2024.10.



## ■ Global Presence





## Our Strength:

- Our global integrated operations and analytics platform can provide comprehensive one-stop services for clients worldwide to support global multi-center clinical trials.
- Our core technology team and professional management team have an average experience of over 10 years supporting clinical trials in the global pharmaceutical industry.
- We serve and value our clients; our team of experienced project managers delivers tailored, specialized services to meet the unique needs of the sponsor.
- Our testing platforms cover over 400+ safety biomarker assays.
- From analytical method development and validation to sample collection, analysis and data reporting, our experienced professionals collaborate with your team to optimize synergies and efficiencies that produce reliable data and reduce the risk of delays.



LEARN MORE

[LABTESTING.WUXIAPPTec.COM/BIOANALYTICAL-SERVICES](http://LABTESTING.WUXIAPPTec.COM/BIOANALYTICAL-SERVICES)



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