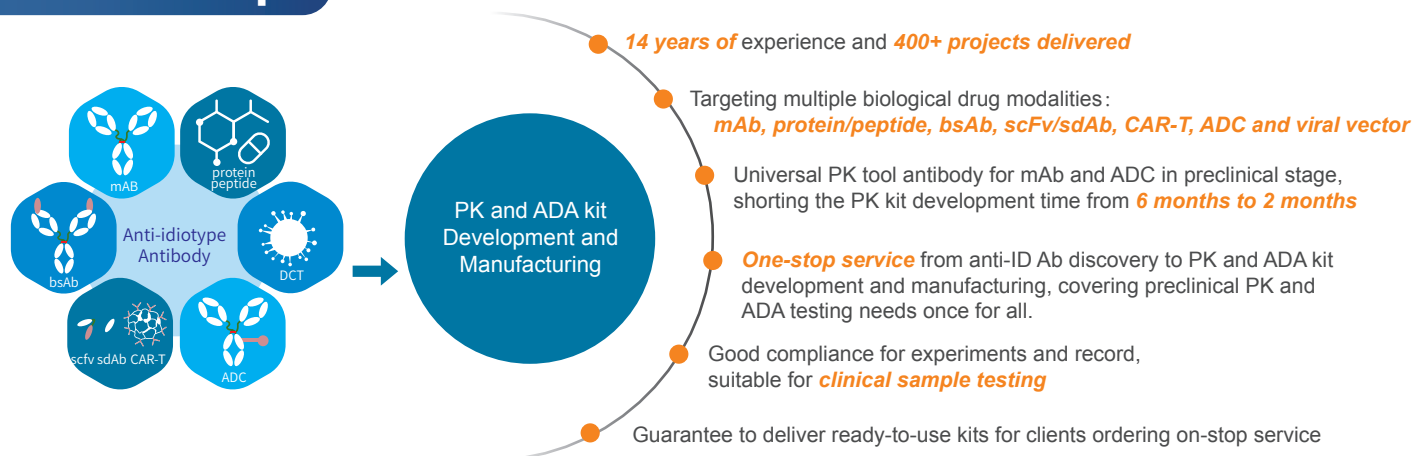


# ANTI-IDIOTYPE ANTIBODY SERVICE

Anti-idiotype antibody generation & PK/ADA kit development and manufacturing

## Service Scope



## Package Overview

Anti-idiotype antibody production			
Apply	PK capture ELISA	PK sandwich ELISA	ADA
Applicable molecule type	mAb, protein/peptide, bsAb, scFv/sdAb(CAR-T), ADC		mAb, protein/peptide, bsAb, scFv/sdAb(CAR-T), ADC, viral vector
Deliverable	3-5 blocking or non-blocking antibodies/sequences	5-10 blocking or non-blocking antibodies/sequences	pAb
TAT	Express immunization: 3-4 months Standard immunization: 5-6 months		Human IgG1: 8-10 Human IgG2/IgG4: 10-12 Other Type#: >13

\*This service applies to PK analysis in preclinical and clinical stages

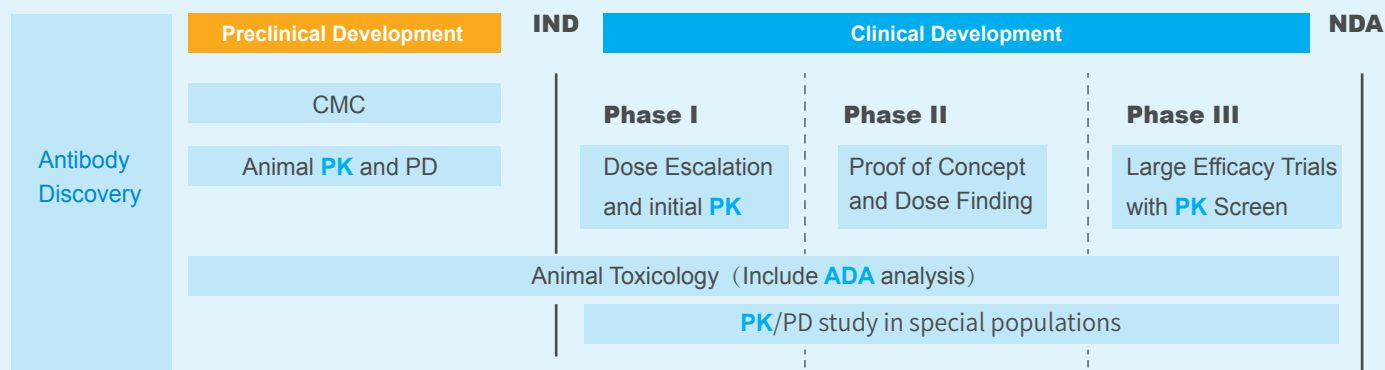
Universal PK Tool Antibody Pairs Package			
Apply	PK sandwich ELISA		
Applicable molecule type	mAb, sdAb		
Deliverable	<ul style="list-style-type: none"> <li>1 mg Biotin Labelled antibody</li> <li>1 mg unlabeled antibody</li> </ul>	<ul style="list-style-type: none"> <li>Sensitivity&lt;10ng</li> <li>Stability: &gt;5 years</li> </ul>	<ul style="list-style-type: none"> <li>Report of antibody pairing</li> </ul>
TAT	1-4w		

\*This service applies to PK analysis on preclinical stage

PK/ADA Kit Development and Manufacturing Package for Preclinical Use		
	PK	ADA
Deliverable	<ul style="list-style-type: none"> <li>100 PK kits</li> <li>Report of feasibility analysis</li> <li>Final report of kit development</li> <li>0.5 mg Biotin Labelled anti-ID antibody &amp; 1 mg unlabeled anti-ID antibody</li> </ul>	<ul style="list-style-type: none"> <li>150 ADA kits</li> <li>Report of feasibility analysis</li> <li>Final report of kit development</li> <li>0.5 mg Biotin labeled drug antibody</li> </ul>
TAT	2-3 months	

## Timing of Kit Development and Manufacturing

PK/ADA kit development at *late discovery stage* or *cell line development stage*



- PK data is necessary for IND application, thus PK assay/kit development is the rate limiting step in drug development
- ADA assessment runs throughout the biologic drug development stages

## Compliance Guidance

### Data management

- Well-established operating procedures and management systems to regulate the recording and review requirements of data generated during the production process.
- Regular calibration and verification of data-generating measuring instruments to ensure data reliability.
- Raw Data are backed up in accordance with data management requirements.

### Records management

- Complete paper-based operating procedure documents and experimental record forms.
- A complete quality management system for documents and records, including processes for approval and review of documents and records, printing and issuance, record requirements, filing and preservation, copying and destruction, etc.
- Complete electronic record management system, including regular inspection of computerized system, time and time zone management, backup of system data, operation authority and user authority management, etc.



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