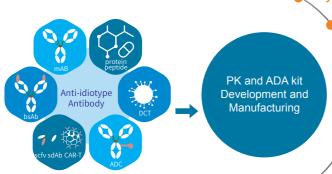


# ANTI-IDIOTYPE ANTIBODY SERVICE Anti-idiotype antibody generation & PK/ADA kit development and manufacturing



# Service Scope



14 years of experience and 400+ projects delivered

Targeting multiple biological drug modalities:

mAb, protein/peptide, bsAb, scFv/sdAb, CAR-T, ADC and viral vector

Universal PK tool antibody for mAb and ADC in preclinical stage, shorting the PK kit development time from 6 months to 2 months

One-stop service from anti-ID Ab discovery to PK and ADA kit development and manufacturing, covering preclinical PK and ADA testing needs once for all.

Good compliance for experiments and record, suitable for *clinical sample testing* 

Guarantee to deliver ready-to-use kits for clients ordering on-stop service

## **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			

<sup>\*</sup>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><li>1 mg Biotin Labelled antibody</li><li>1 mg unlabeled antibody</li></ul>	<ul><li>Sensitivity&lt;10ng</li><li>Stability: &gt;5 years</li></ul>	Report of antibody pairing				
TAT		1-4w					

<sup>\*</sup>This service applies to PK analysis on preclinical stage

PK/ADA Kit Development and Manufacturing Package for Preclinical Use						
	PK	ADA				
Deliverable	<ul> <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> <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					



# ANTI-IDIOTYPE ANTIBODY SERVICE

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

### **Timing of Kit Development and Manufacturing**

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

	Preclinical Development	IND			Clinical Development			NDA
Antibody Discovery	CMC		Phase I		Phase II		Phase III	
	Animal PK and PD		Dose Escalation and initial PK		Proof of Concept and Dose Finding	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Large Efficacy Tria with PK Screen	Is
	Animal Toxicology (Include ADA analysis)							
			PK/PD study in special populations					
		ı		1		1		

- · 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.



#### — Address/

Genscript ProBio USA Inc. 20 Kingsbridge Rd, Piscataway, NJ 08854, USA

Phone / 1-732-885-9188
 Toll-Free / 1-877-436-7274
 Fax / 1-732-885-5878

#### — Contact/

cdmo.us@genscriptprobio.com cdmo.eu@genscriptprobio.com cdmo.apac@genscriptprobio.com