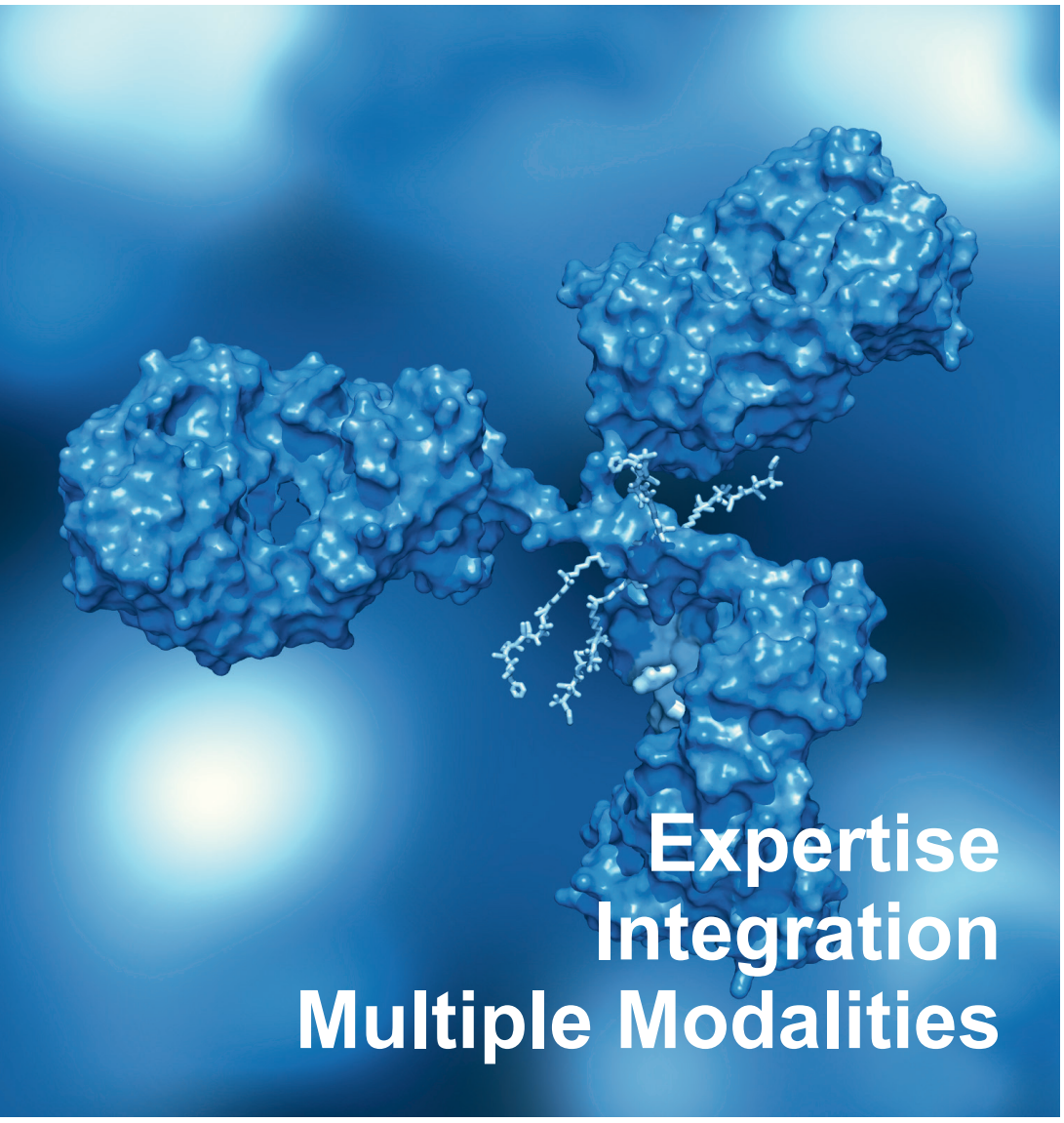
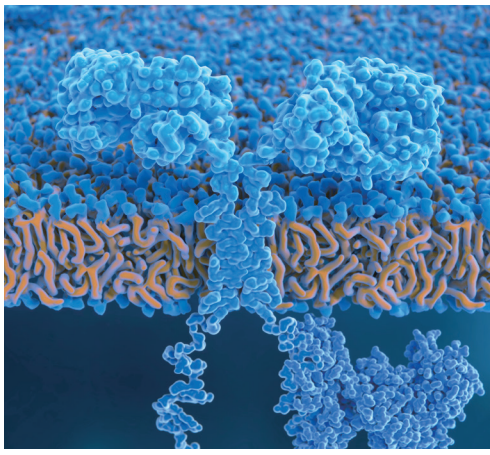
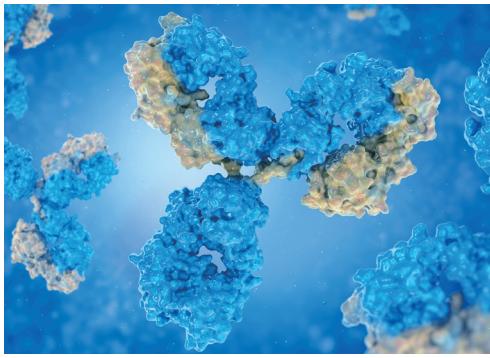
Service Manual

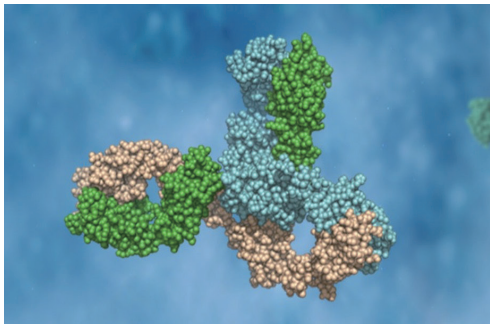
BIOLOGICS DISCOVERY SERVICE

From Target to Preclinical Candidates









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- Antibody Lead Generation Service
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GenScript PROBIO

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About GenScript ProBio Biologics Discovery Center

About GenScript ProBio

GenScript ProBio, a subsidiary of GenScript Biotech Corporation, is a global player dedicated to providing premium end-to-end service from discovery to commercialization with professional solutions and efficient processes to accelerate drug development for customers. GenScript ProBio has established companies in the United States, the Netherlands, South Korea, and China (Hong Kong, Shanghai, and Nanjing) and other regions to serve global customers, and has helped customers in the United States, Europe, Asia Pacific and other regions obtain more than 70 IND approvals since October 2017.

Biologics Discovery Center

GenScript ProBio Biologics Discovery Center leverages 20-year experience in biologics discovery to offer customers end-to-end services from target to preclinical candidates (PCC). **We are dedicated to accelerating your biologics discovery process of getting potential PCCs with functionality and developability.**

Our Core Competences

We are a reputable biologics discovery solution provider offering integrated services with *speed, quality, and cost-efficiency*

Excellence Proven by Impressive Track Record

Highly Integrated Discovery Platforms

Tailored Discovery Strategies for Various Biologics Modalities

Excellence Proven by Impressive Track Record

20 years
EXPERTISE IN BIOLOGICS

20

1800+

1800+
PROJECT EXPERIENCE

2+
PROJECTS MARKETED

2+

1000+

1000+
GLOBAL PARTNERS

14
THERAPEUTIC ANTIBODY LICENSING DEALS

14

15+

15+
PROJECTS IN THE CLINICAL PHASE

*By Jan. 2024

Highly Integrated Discovery Platforms for Faster Advancement to the Clinical Stage!

Lead Generation

- 6 Technology Platforms to Get Leads with Good Qualities

Lead Optimization

- Antibody Sequence Optimization
- Developability and Functionality Optimization

Developability Assessment

- Selection of Final Candidate before CMC

In Vitro Bioassay

- Comprehensive Cell-based Assays to Evaluate the In Vitro Function

In Vivo Pharmacology

- In Vivo Pharmacology Platforms to Assess PK/PD/Potency In Animal Models

Bringing Together Various Technical Campaigns under One-roof

In Vivo Ab Lead Generation

Hybridoma

Single B cell screening

Immunized library

Fully human transgenic mice

In Vitro Ab Lead Generation

Fully human naïve library

Alpaca naïve library

Accelerating the Discovery of “Me-better” Antibody Candidates

Functionality Optimization

Antibody affinity maturation

10-fold affinity improvement guaranteed

Fc engineering

ADCC, CDC, ADCP enhancement , STR Fc silencing technology and half-life extension

Developability Optimizations

Antibody Humanization

Industry-leading timeline **in 2.5 weeks**

Antibody Developability

Prediction, optimization, and assessment

Well-established Pharmacology Platforms in House

Assays & Animal Models

- Ready-to-use bioassays for **100+** popular targets
- **500+** proprietary assay cell lines
- Various efficacy models for different indications:**Oncology, metabolic and autoimmune disease**

Tailored Full-service Capability

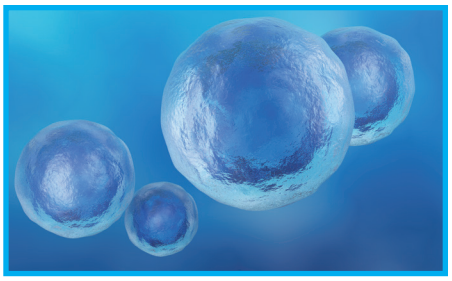
- Customized assay cell lines
- Method development for various bioassays
- Method development for DMPK and bioanalysis (PK\TK, ADA, Biomarkers)

Tailored Discovery Strategies for Various Biologics Modalities, Ensuring the Success Rate!

Cell Therapy

1 approved drug

- Discovery of fully-validated antibody candidates with desirable affinity, epitope and sequence diversity by well-suited discovery strategy for CAR lead candidates
- All-inclusive CAR-T/NK bioassay services from vector construction & cell transduction to functional assay



Monoclonal Antibody

10+ projects in clinical trial

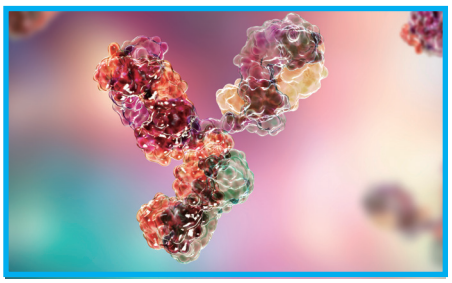
Expertise in Ab discovery for multi-pass membrane targets:

- mRNA and VLP immunization strategies to boost stronger immune response
- Powerdoma™ hybridoma technology to increase positive clone rate with shorter TAT
- Well-established bioassays and in vivo pharmacology platforms to functionally evaluate Ab candidates

Bispecific Antibody

2+ projects in clinical trial

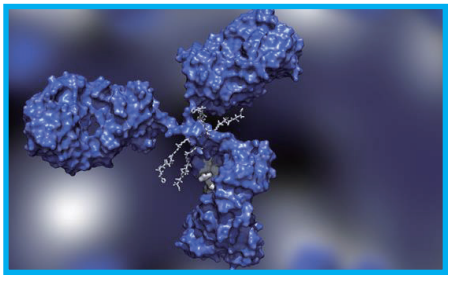
- Customized bsAb formats based on the target, MOA, and customer's needs
- 4 types of bsAb bioassay platforms: （cell-engager, dual-target blockade, dual immunomodulators, and cell surface protein bridging）
- An array of ready-to-use building blocks (mAbs and sdAbs) for fast and convenient construction & testing of bsAbs of interest



Antibody Drug Conjugate

2+ projects in clinical trial

- Identifying functional Abs with "precise targeting, efficient internalization" in the early screening stage
- Large payload-linker library: 150+ cytotoxins, 950+ linkers and 190+ conjugates
- Live-cell imaging-based internalization assay with speed, high-throughput and consistency



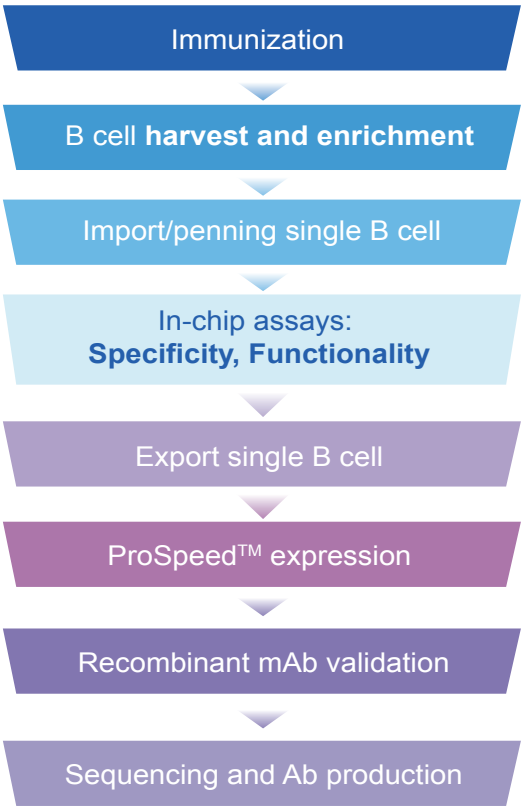
*By Jan. 2024

02

Antibody Lead Generation Service

ProSpeed™ Single B Cell Antibody Discovery Service

Unparalleled Speed! Screening Completed in 1 Day
High-throughput, High-resolution Screening for Diverse Desirable Antibody



1 Month!
To Get Functional Antibody Sequence

A EXPEDITED TIMELINE

- Multiple sequential in-chip screening completed in 1 day
- 2 weeks from B cell exporting to final validated Ab sequences acquisition

B HIGH DIVERSITY

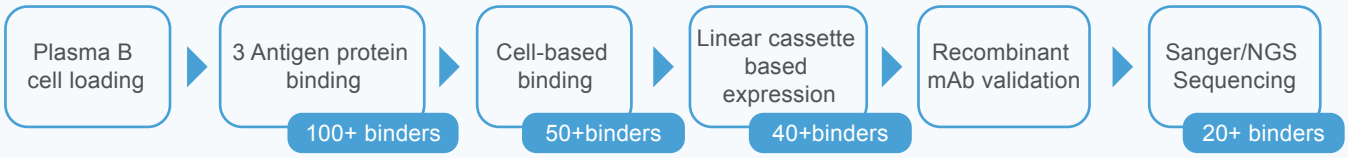
- Forward functional screening for the largest B cell pool possible, minimal diversity loss
- High throughput binder assays using ProSpeed™ expression, avoid missing high-quality leads!

Why Choose GenScript ProBio?

EXTENSIVE EXPERIENCE	• Introduction of the Beacon platform since 2019 • Delivery of over ***110 projects*** • Extensive experience in various targets
A PERFECT COMBINATION WITH PROSPEED™ EXPRESSION AND BEACON® PLATFORM	• Higher throughput Ab expression and assay • Breaking through the technical limitations on Beacon screening • Cutting more than half of the cost and timeline in confirming functional binders

*By Mar. 2024

Case Study: DLL3 mAb Discovery by Beacon



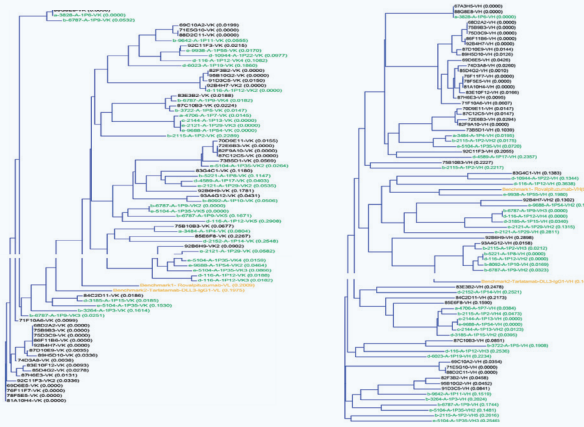
Up to 4 sequential assays were included in the screening workflow

Assay Type	Positive Binders
Human DLL3	98
Cyno DLL3	127
Mouse DLL3	58
Human DLL3 cell	50

Exported Cross	Unique Sequence
61 out of 100	21 out of 23

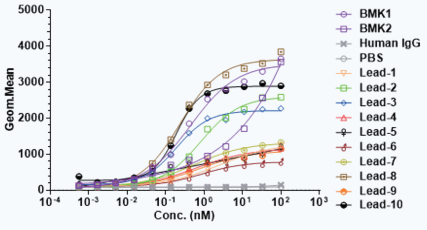
Phylogenetic tree

Sequences discovered from Single B screening (green) are highly diverse and clustered to many different branches of the phylogenetic tree.

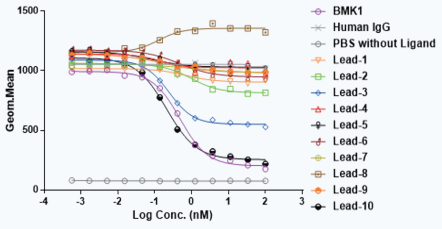


Various binding affinity to cell surface DLL3 and different binding epitopes

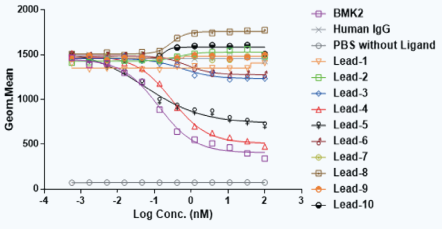
FACS Binding - CHO-K1/human DLL3(+)



Competition with BMK1 by FACS



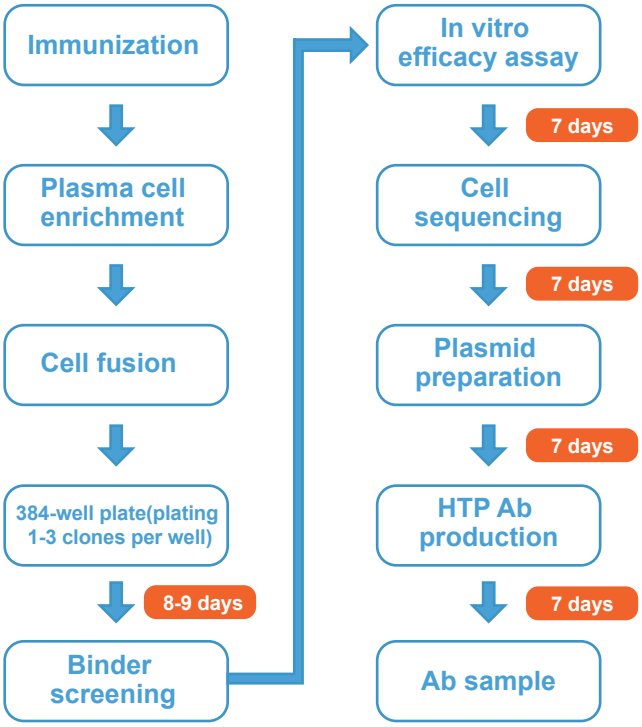
Competition with BMK2 by FACS



BMK1:Rovalpituzumab; BMK2:Tarlatamab-DLL3-IgG1

Powerdoma™ Hybridoma Antibody Discovery Service

An Upgrade of Conventional Hybridoma Technology



3 Months
to Get Functional Ab Sequences

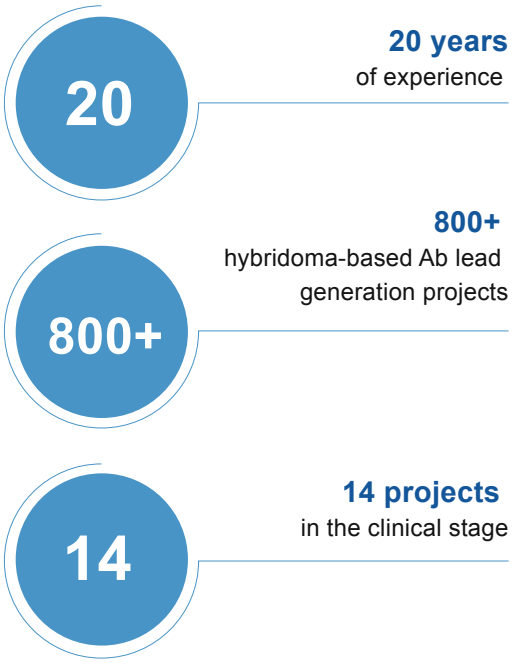
A STREAMLINED PROCESS

- Elimination of cumbersome two-month subcloning steps for greater efficiency
- Powerdoma™ timeline: 3-4 months
- Traditional timeline: 4-6 months

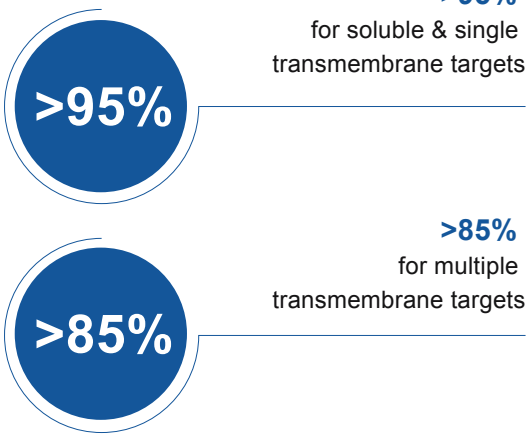
B FUNCTIONAL SCREENING FORWARD

- Use hybridoma supernatant for high-throughput cell-based functional assays (such as internalization assay), identify more high-potential leads at the earliest stage

Why Choose GenScript ProBio?



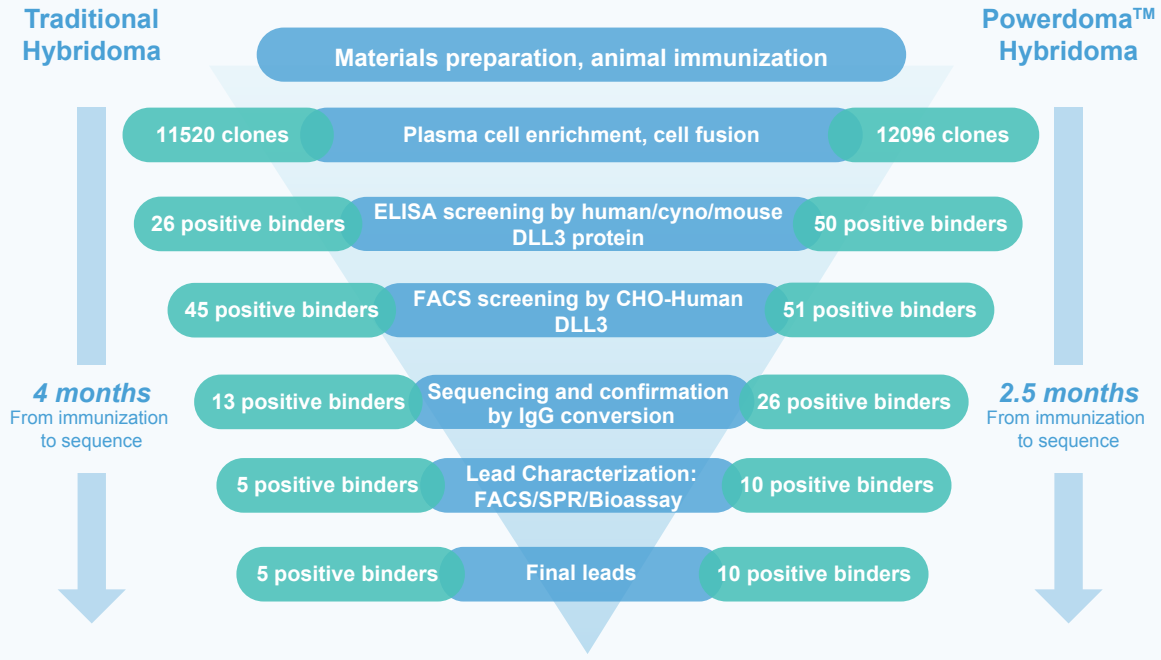
Impressive success rate in mAb lead generation



*By Jan. 2024

Case Study: Faster to Get More Positive Antibody Sequences with Powerdoma™ Platform

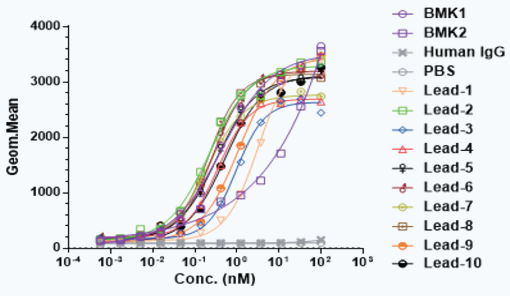
- **Screening funnel**



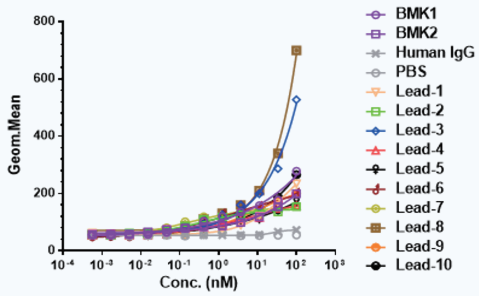
- Fast and efficient cell fusion and the fused hybridoma is monoclonal
- As fast as 1.5 month to get positive sequence
- More positive clones from Powerdoma™ platform

- **Some binders showed higher affinity**

FACS Binding - CHO-K1/human DLL3(+)



FACS Binding - DMS53



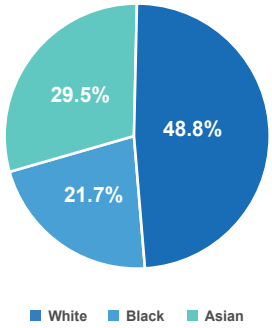
Human Naïve Library Antibody Discovery Service

Large Library Size & Good Donor Diversity to Allow Discovery of High Affinity Leads

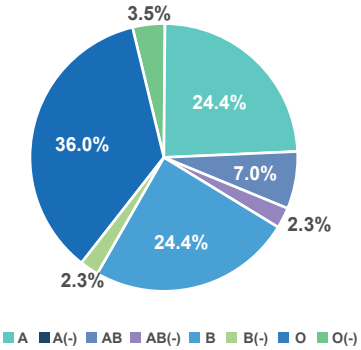
High-quality Human Naïve Library with Good Donor Diversity!

Donors from both sexes, various races & all blood types

Donor ethnicity distribution



Donor blood type distribution

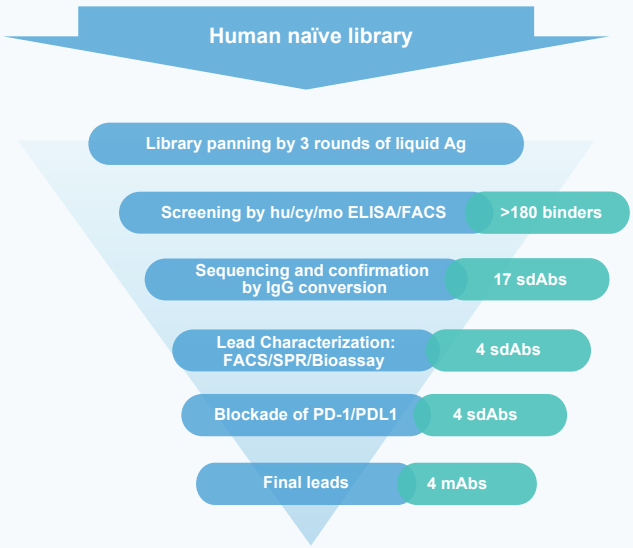


Library Features	
Source	~1000 healthy donors
Material	Human PBMC
Library	Phage Fab library
Total size (cfu)	$1.0x10^{11}$ (in expansion)
Insertion rate	>95%
In-frame rate	>85%
Diversity rate	>95%
CDR3 diversity	Normal distribution
Tag	His & c-Myc
Affinity with SPR	1E-8~1E-10M
Typical TAT	~ 2 months

*By Jan. 2024

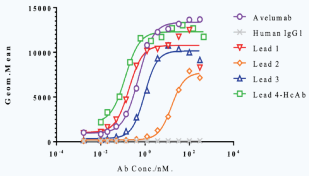
Case Study: PD-L1 mAb Discovery

- **Screening funnel**

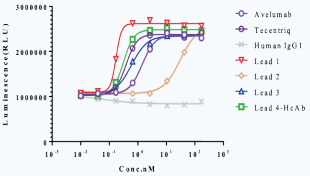


Higher binding and blocking profile than BMK

FACS binding-HuPD-L1



PD-1/PD-L1 Blockade assay



Key indicators of the best Ab lead

Criteria	Lead	BMK1-Avelumab
ELISA EC50 (nM)	0.2	0.7
FACS EC50 (nM)	0.13	0.51
Affinity by SPR (M)	3.05E-10	8.34E-10
Binding to mPDL1 EC50 (nM)	0.18	0.30
Binding to cynoPDL1 EC50 (nM)	0.68	0.88
Epitope binning	overlapping	/
PD1/PD-L1 blockade assay (EC50, nM)	0.17	1.41

Single Domain Antibody Discovery Service

Two sdAb Lead Generation Approaches to Increase Success Rate

sdAb Naïve Library

Faster timeline
Higher diversity

- **300** Alpaca donors;
- Library size: **2×10^{11}**
- In frame rate/ORF rate: **>95%**

1.5-2 months

sdAb Immunized Library

Higher affinity
Higher positive hit rate

- Easy access to Alpaca farm
- Using **only naïve Alpaca** for each project

3 -4 months

SPSSdAb™ Platform

Soluble supernatant based phage screening for sdAb discovery

- 2 antibody formats expressed during the phage display screening phase: phage expression & soluble expression

Advantages

- Inducible sdAb expression in supernatant
- Extremely high affinity of SASA tag (pmol for BSA) to allow high throughput affinity ranking by SPR
- Further elimination of false positive clones by SPR ranking

Why Choose GenScript ProBio?

200+
sdAb lead generation projects with good success rate:

100+
sdAb humanization projects, 100% success rate

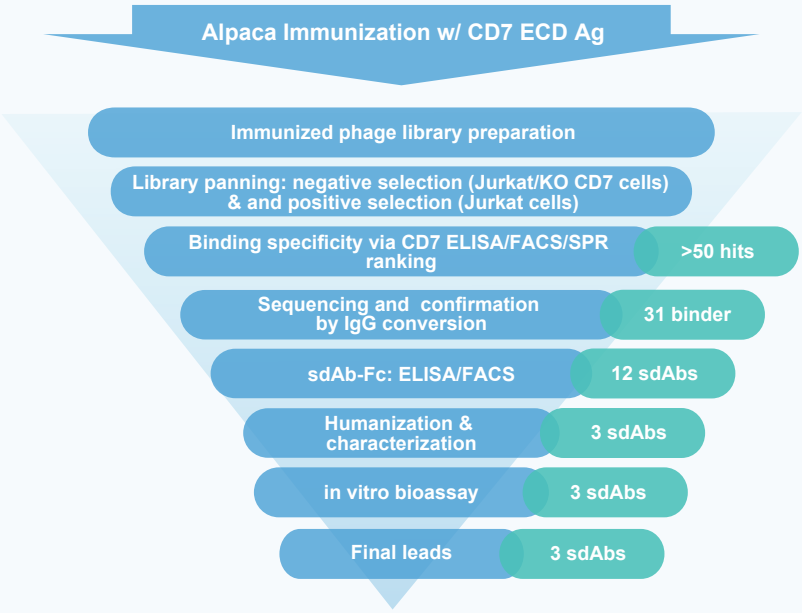
9
global licensing deals

1
FDA approved drug (CARVYKTI® (BCMA CAR-T), Legend/Janssen)

*By Jan. 2024

Case Study: CD7 sdAb Discovery Using Immunized Library

- **Screening funnel**

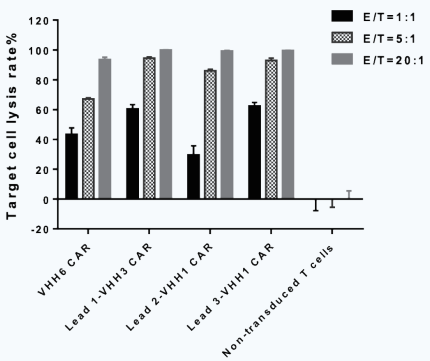


Multiple humanized CD7 VHH leads were discovered showing higher affinity and more potent blockade of CD7 cell surface expression, comparing with the BMK Ab PA3-17-VHH6 (PersonGen).

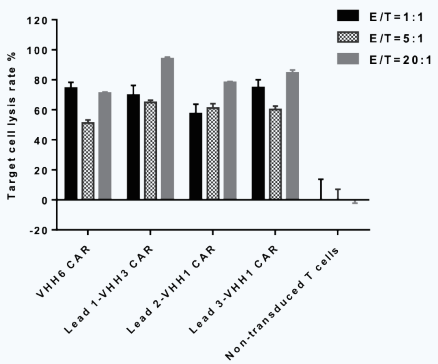
Ligand	Analyte	Chi² (RU²)	ka (1/Ms)	kd (1/s)	KD (M)	Rmax (RU)
Lead 1-VHH3-Fc	CD7	1.05E-01	4.40E+05	5.19E-05	1.18E-10	76.1
Lead 2-VHH1-Fc	CD7	5.79E-02	2.43E+05	3.18E-05	1.31E-10	100.3
Lead 3-VHH1-Fc	CD7	4.87E-01	3.04E+05	3.04E-05	1.00E-10	77.3
PA3-17-VHH6（BMK）	CD7	2.88E-01	9.79E+04	1.25E-04	1.28E-09	210

Potent target cell killing was mediated by CAR-T cells with a CAR composed of these VHH leads, confirming their functionality and good potential as CAR component.

Target :Jurkat/Luc killing assay



Target :CCRF-CEM/Luc killing assay



03

Antibody Lead Optimization Service

Antibody Humanization Service

As Fast as 2.5 Weeks to Get Your Antibody Humanized

2.5 weeks, get humanized antibodies with high expression levels, good thermal stability, and comparable affinity with the parental antibodies

Start — 1 week — 2 weeks — 2.5 weeks

Ab humanization design
Developability prediction
(PTM, Immunogenicity, Aggregation)

Humanization design and feedback in **2 days**

Chimeric antibody and humanized antibody production and purification

High-throughput gene synthesis, **2 weeks** from sequence to purified antibody

Affinity insurance:
Guarantee at least 1 antibody with affinity comparable with parental antibody

Humanized antibody affinity ranking and sequence confirmation

Why Choose GenScript ProBio?

Extensive experience

20-year experience in antibody discovery
Delivered over **500 projects**
The most advanced project is **marketed**

*By 2024.1

Top-notch delivery

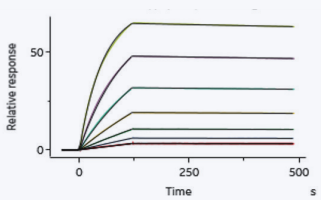
Delivery in as fast as 2.5 Weeks
Guarantee **no loss of affinity**
Humanization rate **>95%**
Provide developability prediction reports including **PTM, aggregation and immunogenicity**

Case Study: Experienced in Various Ab Formats (mAb, scFv and sdAb)

Case Study 1: Mouse IgG Humanization

Affinity kinetic analysis

samples	Chi² (RU²)	ka (1/Ms)	kd(1/s)	KD (M)	Rmax (RU)
humanized antibody	5.03E-02	3.67E+05	6.90E-05	1.88E-10	70.5
parental antibody	2.11E-01	4.02E+05	5.56E-05	1.38E-10	73.6

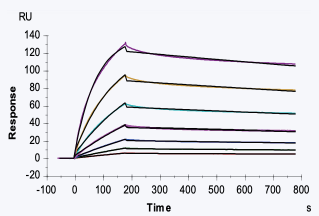


Affinity is maximally retained by rational design

Case Study 2: VHH Humanization

Affinity kinetic analysis

Ligand	Analyte	ka (1/Ms)	kd (1/s)	KD (M)	Rmax (RU)	Chi² (RU²)
VHH WT	Ag	3.57E+04	2.52E-04	7.05E-09	127.1	0.682
VHH2	Ag	1.50E+04	2.75E-04	1.83E-08	148.9	0.315
VHH3	Ag	3.26E+04	2.46E-04	7.54E-09	136.8	0.694
VHH4	Ag	3.46E+04	2.42E-04	6.99E-09	117.4	0.57
VHH5	Ag	3.40E+04	2.19E-04	6.43E-09	172.3	0.99



Affinity is maximally retained by rational design

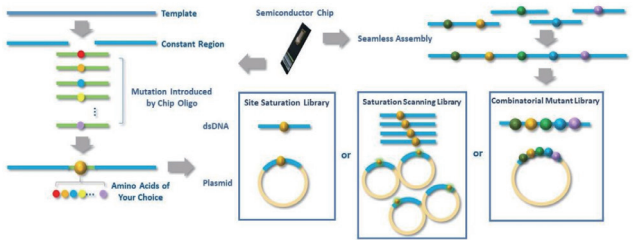
Antibody Affinity Maturation Service

Combination of Proprietary Precise Mutagenesis Library & High-throughput Screening Platform (FASEBA)

More comprehensive screening strategies, guarantee 10-fold improvement!

MOE based structural modelling → **Precise site-saturation mutagenesis library (PML) construction** → FASEBA screening and SPR affinity ranking → **Combinatorial mutagenesis library and SPR affinity ranking** → Ab production and validation

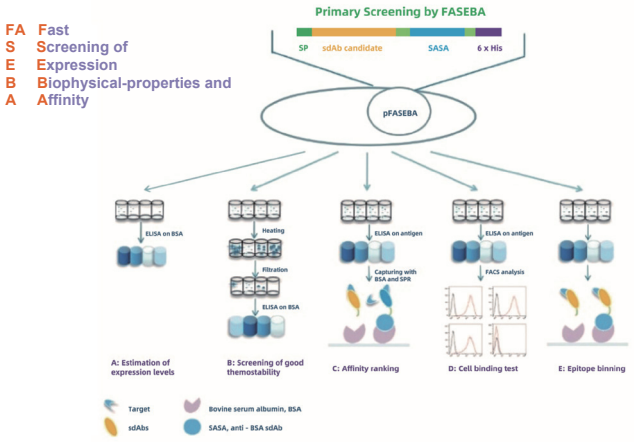
1 Precise Site-Saturation Mutagenesis Library, PML



Exhaustive mutagenesis possibilities

- Semiconductor-based oligo synthesis technology
- Precise site-saturation mutagenesis to ensure even distribution of 18 mutated amino acids at each residue
- No stop codons and unexpected codons

2 FASEBA High-throughput Screening Platform



Quickly screen out molecules with the highest affinity, expression level and the best biophysical properties.

- Technology introduced from National Research Council Canada
- Affinity ranking by SPR was performed with prokaryotic expression supernatant, which greatly reduces the cost and cycle of recombinant expression, and ensure the success rate of screening.

Case Study:1316-fold Affinity Improvement, from 10^{-7} to 10^{-10}

Ligand	Analyte	Chi² (RU²)	ka (1/Ms)	kd (1/s)	KD (M)	Rmax (RU)
WT	Target C	1.33E+00	3.79E+05	2.53E-01	6.66E-07	162.9
variant1	Target C	5.37E-02	3.77E+05	5.50E-04	1.46E-09	45.3
variant2	Target C	8.22E-02	5.87E+05	3.74E-04	6.38E-10	50.5
variant3	Target C	3.76E-02	4.92E+05	2.49E-04	5.06E-10	49.9

Fc Engineering Service

- **Fc engineering service:**
  - √ **Fc silence**
  - √ **ADCC,CDC, ADCP enhancement**
  - √ **Half-life extension**
- **One-stop Fc engineering solution from sequence design to pharmacology study**

Case Study 1: STR Silencing Technology

A cell-based reporter assay (Fig 6a) showed that the STR variant had no activity on all FcγRs compared to wild-type IgG1, LALA, and aglycosylated variants. A cytokine release assay with PBMCs isolated from healthy donors showed (Fig 6b) that STR exhibited no significant activity above buffer alone for all cytokine measured. **STR silencing technology truly abolishes the Fc domain effector function.**

* Data comes from mAbsolve

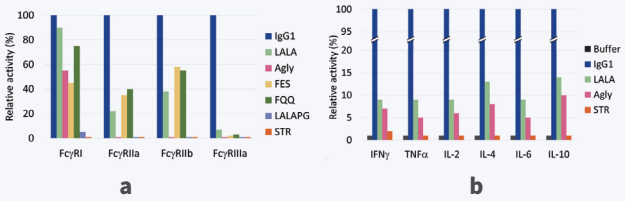


Fig. Cell-based assay for different Fc silence mutants

Case Study 2: ADCC and CDC Enhancement

The potency of ADCC and CDC against PA-1 target cells of two mutated Fc constructs was evaluated. As reported, the published Fc mutation sequences showed enhanced ADCC and CDC activities on PA-1 cells.

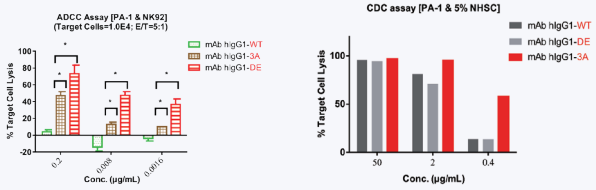


Fig. Cell-based assay for different Fc mutants

Antibody Developability Optimization Service

- **One-stop developability solution from prediction to optimization**
- **PTM optimization: Guarantee no affinity loss**
- **Antibody aggregation optimization: guarantee at least 5-fold yield improvement**

The developability prediction **allows optimization of PTM sites and hydrophobic regions** to obtain antibody candidates with better developability.

Prediction → **Optimization**

Developability Prediction Report

- Immunogenicity
- PTM
- Aggregation

- **PTM site optimization**

PTM analysis → PTM removal → Testing & validation

- **Antibody Aggregation Optimization**

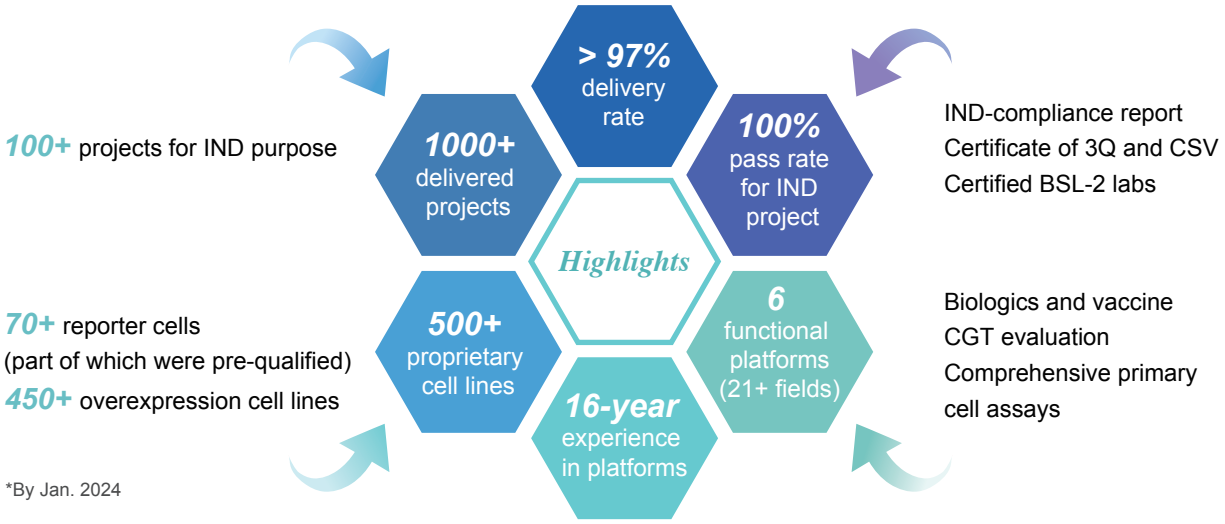
Antibody sequence analysis & modeling analysis → Ab sequence optimization & expression → Testing & validation

04

Biologics Pharmacology Service

In Vitro Bioassay Service

A Versatile Platform for Functional Evaluation



6 Featured Functional Assay Platforms

Bioactivity of monoclonal Ab Fab domain

1.Functional assays
- Binding Assays
- Agonist activity
- Ligand blockade activity
- Neutralization Assays

2.Preclinical safety assessment
- Cytokine release syndrome assessment
- Species cross-reactivity assessment

3.Customized primary cell assays
- T/Treg, NK, macrophage, etc.

Bispecific Ab characterization

1.In trans cell bridging assay
- T cell engager
- NK cell engager
- Anti-TAA x immune checkpoint
- (stimulatory or inhibitory)

2.Dual target blockade/modulatory assay
- Immune cell activation
- Downstream signaling pathway analysis

3.In cis cell surface protein bridging assay

Cell line engineering

1.Target overexpression cells

2.Reporter gene cell and assay development

3.Customized bioactivity assays based on cell lines

4.Customized primary cell engineering
- T, NK, macrophage, etc.

Bioactivity of monoclonal Ab Fc domain

1.ADCC effect evaluation
- PBMC
- Reporter gene cell
- Primary NK cell/NK cell line

2.ADCP effect evaluation
- Primary macrophage cell
- Reporter gene cell

3.CDC effect evaluation
- Complement proteins
- Normal human pooled serum

4.Customized primary cell assays
- T/Treg, NK, macrophage, etc.

ADC lead characterization

1.Antibody internalization assay
- Live-cell imaging based Internalization
- pH-indicator-based internalization
- Toxin-conjugated mAb-based cytotoxicity assay
- Temperature shift-based internalization

2.Cytotoxicity assay
- Cell viability assay
- Cell apoptosis assay
- Cell cycle analysis assay

3.By-stander effect
- Medium transfer or co-culture assay

Other functional analysis platforms

1.CGT functional characterization
- CAR-T, CAR-NK
- AAV

2.Virus packaging and testing & VLP display

3.GPCR drug screening and evaluation
- Calcium flux;cAMP;beta-arrestin

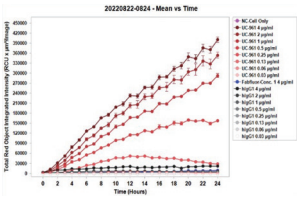
4.Cell apoptosis/cycle analysis/growth
- Annexin-V/PI staining
- Caspase-3 activity

Case Study

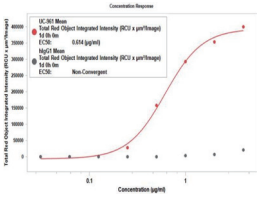
ADC Lead Characterization: 8 Assay Formats Available for ADC Evaluation

Upgraded strategy: real-time live cell imaging-based internalization and bystander effect assay

Time course study

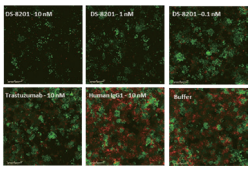


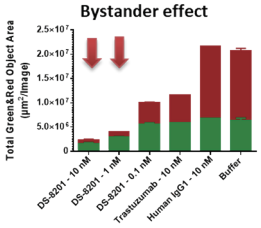
Dose response study



The **Incucyte® live-cell analysis system** enables direct detection of antibody internalization in a 96-well plate. Cells were treated with either Incucyte® FabFluor labeled anti-ROR1 antibody (UC-961) or hIgG1 isotype control. Dose response study showed a rapid increase in red object area in CHO-K1/ROR1 cells treated with anti-ROR1 antibody (UC961).

Bystander effect study





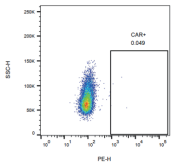
Her2+ and Her2- cells expressing red and green fluorescence, respectively, were co-cultured with ADC for 7 days, and fluorescence imaging was performed using a live-cell imaging system.
Green fluorescence and bar graphs demonstrated specific killing of Her2- cells.

CAR-T Lead Characterization: A Versatile Platform for Functional Evaluations of CAR Leads

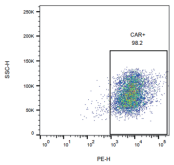
From vector construction & T cell transduction to functional evaluation

CAR Expression | **Cytotoxicity Evaluation** | **Cytokine Release**

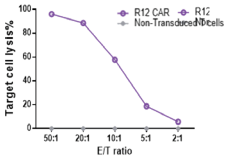
Non-transduced primary T cells



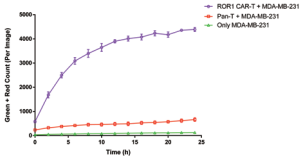
CAR-transduced primary T cells



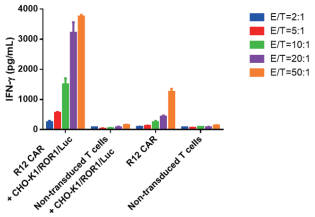
Luciferase-based killing assay



Live Cell imaging based killing assay (Incucyte)

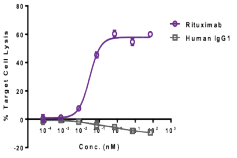


IFN-γ production

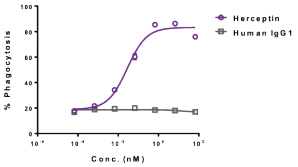


More Case Studies: 1000+ Delivered Projects

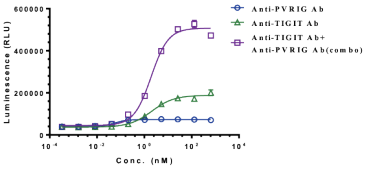
PBMC-based ADCC assay



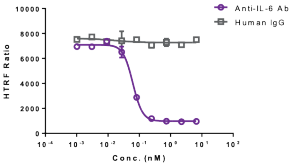
Macrophage-based ADCP assay



Immune checkpoint assay



Cytokine neutralization assay



In Vivo Pharmacology Service

Comprehensive Services from Discovery to Clinical Development

Drug Discovery	Drug Development	Clinical Trials
Animals Model Development	In vivo biological activity	IIT/IIR & IST
Early PD	PD	Preclinical supplementary research
Early PK	PK	Extended indications research
Early toxicity	Toxicity	

Key Features

Various Modalities

- Monoclonal antibodies
- Bispecific antibodies
- Antibody drug conjugates
- Cell and gene therapy
- Recombinant Proteins
- Vaccines

One-stop Platform

- In vivo efficacy & DMPK studies
- Safety evaluation
- Diverse bioanalytical detection
- CMC+ Ecology, GMP+GLP
- Customized services

Extensive R&D Experience

- 30+ drug discovery projects
- 8+ CGT discovery projects
- 10+ integrated projects
- 5+ global IND approvals
- NMPA/FDA/EMA compliance

In Vivo Pharmacology Platforms

In Vivo Efficacy and Biological Activity Study

Antitumor mouse models

- Syngeneic model
- Transgenic model
- CDX model
- PBMC immune humanization model
- Metastasis or orthotopic model

Non-tumor disease models

- Metabolic disease models
- Autoimmune disease models
- In vivo bioactivity assay
- Assisted reproductive drug efficacy
- Regenerative treatment
- Customized services

In Vivo DMPK & Bioanalysis

In vivo DMPK

- Plasma stability
- Method development and validation
- PK or PK-PD test
- ADA & Nabs test
- Tissue distribution
- Receptor occupancy

Bioanalysis

- Tumor Infiltrating Lymphocytes
- Pathological
- Tissue Cross-Reactivity
- Immuno-phenotyping
- Cytokine testing
- Tissue chip
- Customized services

In Vivo Toxicity

Early toxicity (Non-GLP)

- Drug tolerance
- Animal survival rate
- Predict toxic effects
- Other customized services

GLP toxicity

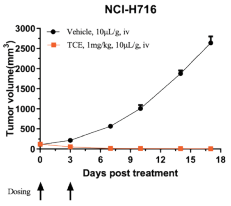
- Acute toxicity
- Long-term toxicity
- Safety pharmacology
- Tissue cross reactivity
- Preparation safety
- Immunotoxicity
- Genotoxicity
- Reproductive toxicity

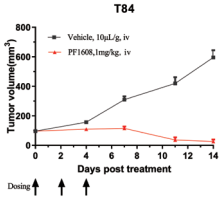
Various Ready-to-use Tumor Models for Efficacy Study

200+ tumor cell lines, 80+ tumor cell models, covering 24 tumor indications

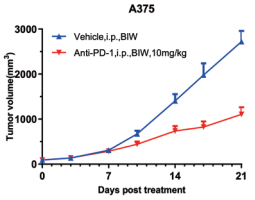
24 tumor indications	
Bladder cancer	Lymphoma
Brain cancer	Liver cancer
Breast cancer	Lung cancer
Cervical cancer	Myeloma
Colon cancer	Melanoma
Esophageal cancer	Oral cancer
Endometrial	Ovary cancer
Fibrosarcoma	Pancreas cancer
Gastric cancer	Prostate cancer
Kidney cancer	Rectum cancer
Leukemia	Skin cancer

Efficacy of CD3 bispecific antibody in CDX model with huPBMC transplant

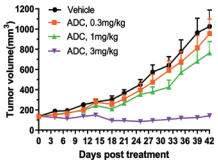




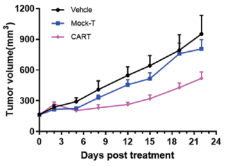
Efficacy of CPIs in CDX model with huPBMC transplant



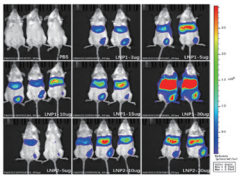
Efficacy of ADC in CDX model



Efficacy of CART in CDX model

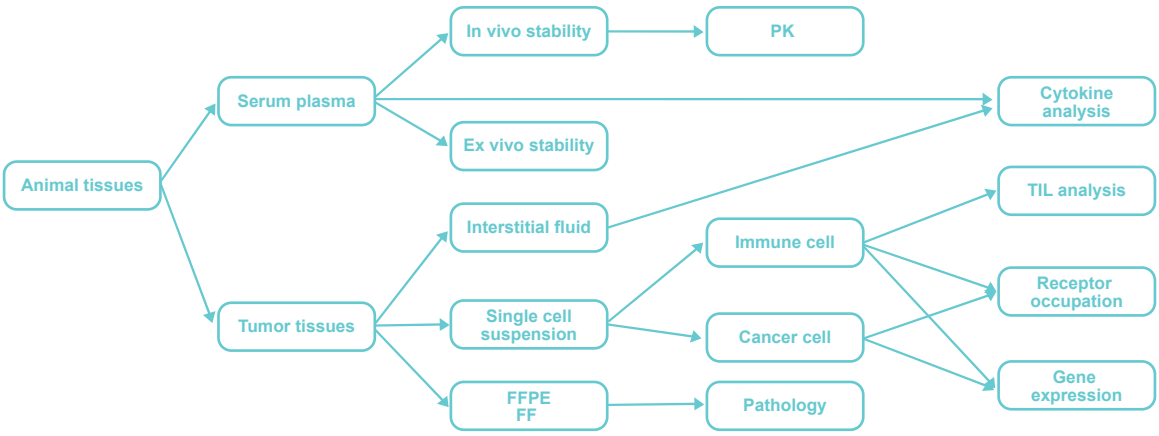


IVIS of mice

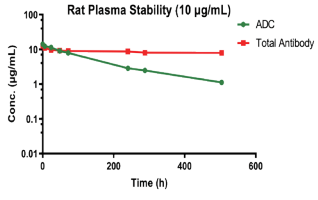


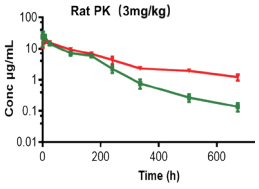
Comprehensive Biological Analysis Empowers Drug Discovery

ProBio's typical workflow

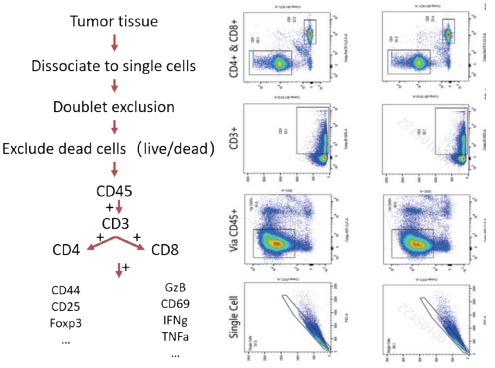


PK service for ADC modalities

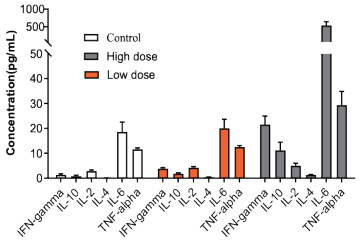




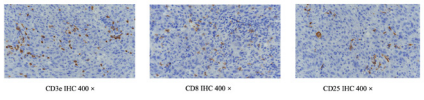
Immune typing by FACS



ICRS panel



IHC panel



05

Preliminary Developability Assessment

Preliminary Developability Assessment Service

A Critical Step for Both Antibody Discovery and CMC Development

Developability assessment is one of the most important evaluations in the development of biologics at both the drug discovery and CMC stage. The developability assessment services offered at GenScript ProBio may help identify the potential developability risk of Ab lead candidates and select the CMC candidates at discovery stage, and provide critical information to guide the process development & optimization at CMC stage.

Typical Instruments

HPLC/UHPLC System

LC-MS System

DLS System

DSF System

Imaged Capillary Electrophoresis System

Biacore 8K

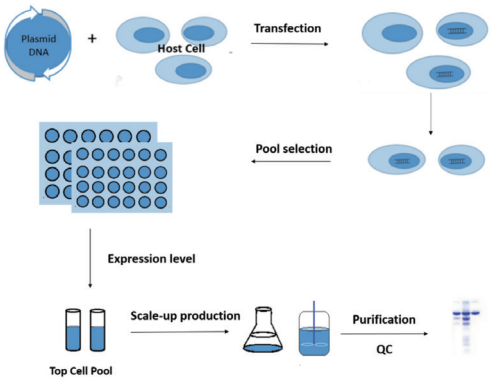
Service Package (for mAb)

Service	Service content					Deliverables	Timeline
Basic	Quality attributes	Test item	Stressed conditions			Report: • Tagg • Conc. • Purity	6-8 weeks
			None	40°C	Low pH 3.5		
	Tagg	DLS	√	-	-		
	Conc.	UV280	√	√	√		
	Purity	SEC-HPLC	√	√	√		
	Purity	CE-SDS-NR	√	√	√		
Premium	Quality attributes	Test item	Stressed conditions			Report: • Tagg • Tm • Conc. • Purity • Charge variant profiles	6-8 weeks
			None	40°C	Low pH 3.5	Freeze-thaw	
	Tagg	DLS	√	-	-	-	
	Tm	DSC	√	-	-	-	
	Conc.	UV280	√	√	√	√	
	Purity	SEC-HPLC	√	√	√	√	
	Purity	CE-SDS-NR	√	√	√	√	
	Charge variants	icIEF	√	√	√	√	

Want to Get More Informative Data on Developability?

Try our **ProGram** platform to generate high quality material for developability assessment!

- Product quality close to **CMC sample**
- High productivity stable pool: **2-3g/L**
- High batch to batch **consistency** compared to transient
- **12 weeks** from gene synthesis to purified material



GenScript ProBio - Innovation Through Collaboration

Together, we transform the world with science & innovation

Contact us

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