

Institute of Biologics

ONE-STOP SERVICE FOR PROTEIN DRUG DEVELOPMENT

Potential Drug Target Validation

Preclinical Biologics Drug Development

Preclinical Biologics Drug Development CRS

Immune Cell Therapy

Therapeutic Monoclonal Antibody

Protein Drug Engineering

Biologics Production and Process

Protein Drug Characterization

Institute of Biologics

RNA Therapeutics

Bioassay Development

Antibody-Drug Conjugate

Test Items

Service Introduction

Antibody Generation

1. Human antibody : Human synthetic antibody library screening, automatic panning and screening, expression plasmid construction, antibody expression, purification and affinity analysis.
2. Mouse antibody: mouse immunization, hybridoma generation or phage library construction, screening, expression plasmid construction, antibody expression, purification and affinity analysis.
3. Nanobody antibody: camelid immunization, phage library construction, screening, expression plasmid construction, antibody expression, purification and affinity analysis.

Antibody Engineering

Antibody computer modeling, humanization and bi/trifunctional antibody/protein construction.

The Next-Generation Antibody Engineering and Production

Antibody-drug conjugate and preparation, bispecific antibody/protein engineering and production, drug activity screening (ELISA、Flow、Internalization、Cytotoxicity、Reporter).

High-Titer Cell Line Development

Well-established traditional antibody and homogenate glycan antibody CHO-S cell line development.

Process Development of Mammalian Cell Expression System

Upstream process development and production : development of culture process using microbioreactor (Ambr¹⁵) and 5 L bioreactors. Contract manufacturing services for a variety of target proteins.

Downstream process development (chromatography and TFF): optimizing purification strategies to achieve high product yield, purity, and critical quality attributes.

Process Development of Microbial Expression System

Expression system screening and establishment of *E. coli* and *Pichia*.

Process development of 250 mL to 5L fed-batch culture and purification. Contract manufacturing services for a variety of target proteins.

Immune Cell Therapy

Immune cell isolation and activation, CAR design and construction, CAR virus/CAR-T cell production, CAR-T characterization and functional assay, and CAR antibody screening.

Therapeutic mRNA Development & Production

Process development and production of mRNA, samRNA, and circRNA.

1、Biologics Drug Characterization

Test Item

Service Introduction

Physicochemical Properties

- Molecular weight information: Gel electrophoresis, Capillary electrophoresis, SEC- MALS.
- Structural characterization and confirmation : Peptide mapping、Intact MS、PTM、Disulfide bond mapping, N-glycosylation site, Glycan profile.
- Isomer and variant analysis: IEX, CE-IEF, RP-HPLC, HIC.
- Preformulation: DLS, DSF, Osmolarity.

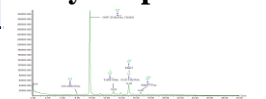
Product Related Impurities

- Aggregation, Host cell DNA, Host cell protein, ELISA.

Analytical Method Development

- DAR, Protein identification, PTM, Acceleration stability, Long-term stability.

Glycan profile



Peptide mapping



DAR

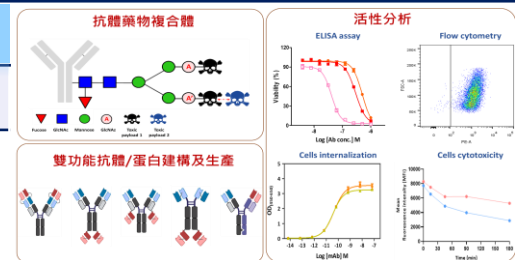


2、Assay Development for Biologics Drug Screening

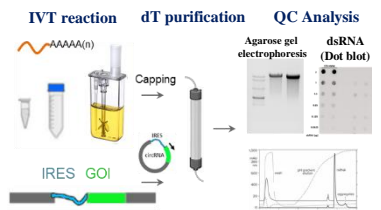
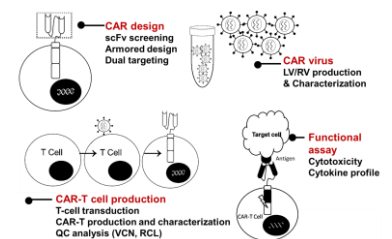
Test Item	Service Introduction
SPR Based Protein-Protein Interaction Assay	Antibody-antigen affinity evaluation.
Cell Surface Protein Expression Analysis	Flowcytometry and image based method for protein expression analysis and antibody-antigen interaction evaluation.
Antibody CDC/ADCC Activity Evaluation	Cell-based method for antibody-mediated CDC/ADCC function analysis, i.e., tumor killing activity.
Bioactivity Assessment	Cell proliferation, cytokine releasing, cytotoxicity, reporter assay, cellular internalization, receptor internalization, opsonophagocytic killing (OPK) assay, agonistic or antagonistic antibody mediated signaling transduction and cellular activity.

3、The New-Generation Biologics Drug Technology Platform

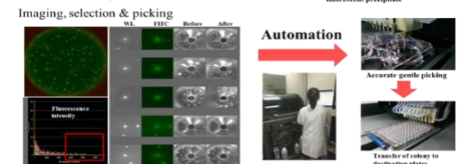
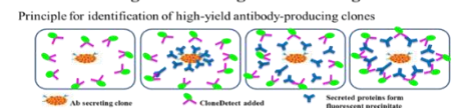
Test Item	Service Introduction
ADC Bioactivity Analysis	<ul style="list-style-type: none"> Affinity and Binding Analysis: Assessment of ADC binding affinity and specificity to target antigens or cells including molecular interaction strength and binding kinetics. Internalization Assay: Evaluation of the internalization efficiency of ADCs into target cells, including internalization rate and uptake percentage. Cytotoxicity Assay: Measurement of ADC-induced cell death, including cell viability, half-maximal inhibitory concentration (IC₅₀), and cytotoxic efficiency.
Novel Antibody Screening for CAR-T Cell Development	<ul style="list-style-type: none"> T cell isolation. T cell activation, subset analysis and characterization. CAR design and construction. CAR virus production & titration. CAR-T production and characterization (VCN, RCL). CAR-T cell <i>in vitro</i> cytolytic assay. CAR-T cell cytokine production analysis.
mRNA and Novel RNA In Vitro Production	<ul style="list-style-type: none"> Linear mRNA design and IVT production (1-10 Kb). Linear mRNA or samRNA dT column affinity. Circular RNA design and production (1-3 Kb).
4、Biologics Production and Process	
Test Item	Service Introduction
High-Titer Cell Line Development	<ul style="list-style-type: none"> Transient transfection (Expi293、ExpiCHO-S). Stable cell pools generation (CHO-S). Establishment of single-clone stable cell line (CHO-S). Trimannosylated antibody-producing cell line (CHO-S). Stability test of single-clone cell. Establishment of microbial expression platform.
Upstream Process Development	<ul style="list-style-type: none"> Microbioreactor for parameter screening (Ambr¹⁵). Culture parameters in 5 L bioreactor. Non-GLP Production in bioreactor. Small-scale production in shaking flask. Metabolite analysis. Protein production in microbial expression system.
Downstream Process Development	<ul style="list-style-type: none"> Purification process development. Protein purification service. Quality control : UV280 nm、SDS-PAGE、SEC-HPLC、Endotoxin.
Plasmid Production	<ul style="list-style-type: none"> Establishment of plasmid production cell line. Plasmid extraction (< 5 mg using kit extraction, > 5 mg using column chromatography). Plasmid linearization. Process development and quality control.



CAR-T cell therapy development platform



Automated imaging and picking system for single cell cloning and screening



Development and production of upstream and downstream processes

