

Solutions for Immune Cell Therapy Development

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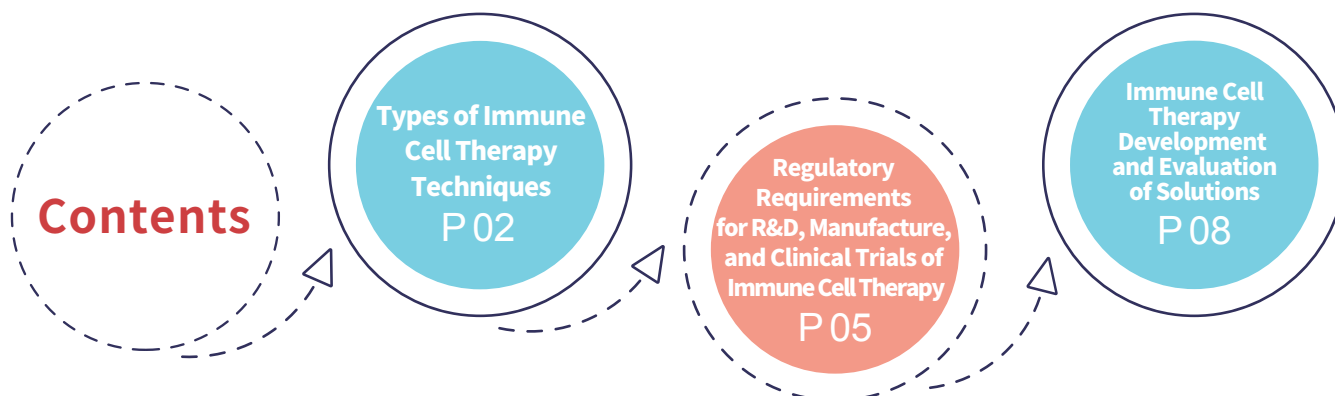
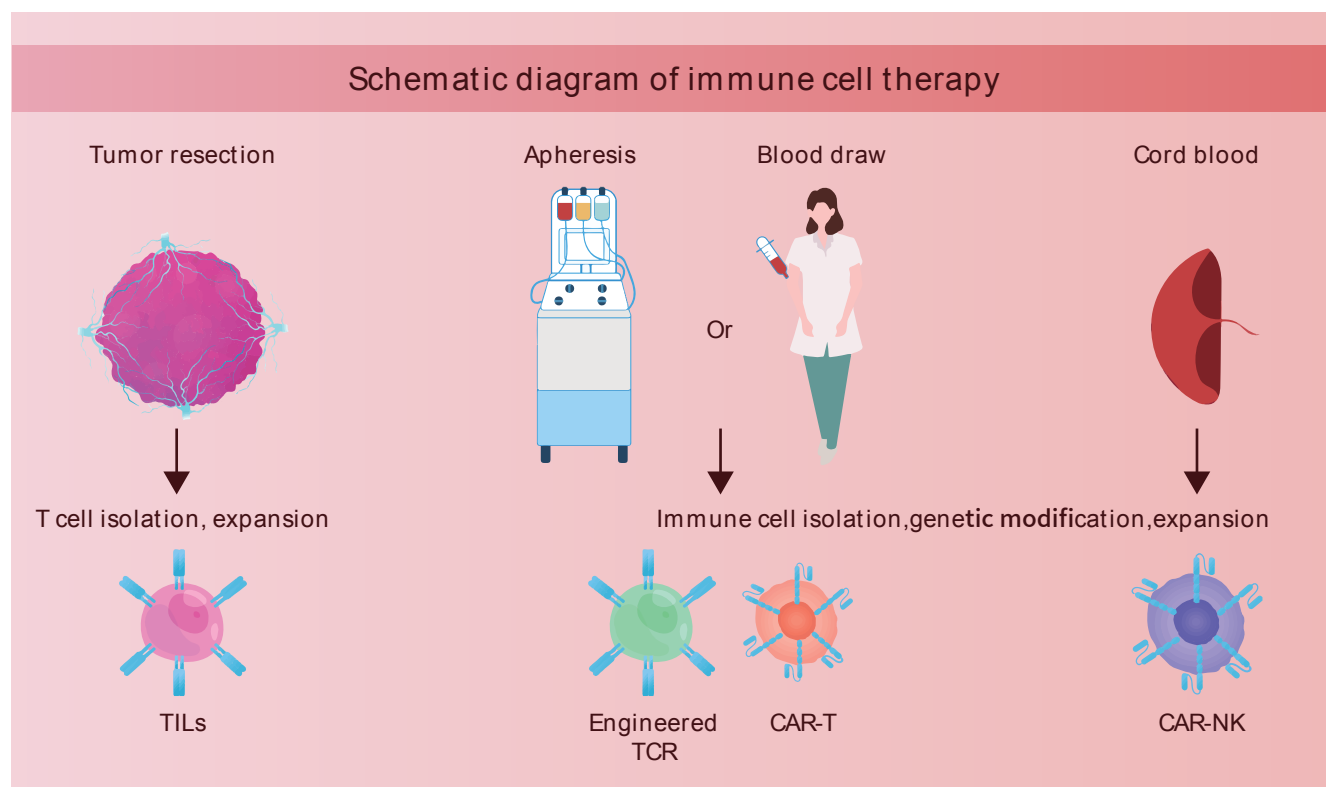
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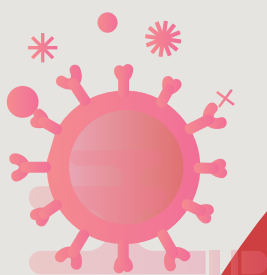
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With the continuous development of tumor biology and immunology in recent years, immune cell therapy has developed into an exciting new field of tumor treatment.

Immune cell therapy refers to isolating the patient's own or donor-derived immune cells, which are modified *in vitro* and then reinfused into the patient's body. These modified immune cells are better able to identify and kill tumor cells and generate a memory-type immunity. The described process creates a significant advantage in preventing tumor recurrence and metastasis. The most common immune cell therapy modalities include CAR-T, TCR-T, TIL, and CAR-NK. These therapies have their advantages in different types of tumors and immune fields.

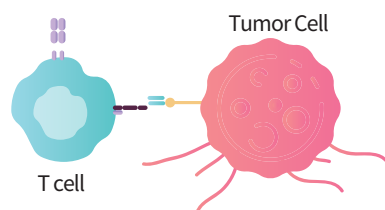


Types of Immune Cell Therapy Techniques



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Chimeric Antigen Receptor T Cell Therapy (CAR-T)



Principle: The Chimeric Antigen Receptor (CAR) consists of an antibody-derived targeting domain fused with T-cell signaling domains. It is expressed by a T-cell, endows the T-cell with antigen specificity as determined by the targeting domain of the CAR.

Manufacturing process: The production of autologous CAR T cells is carried out by various manufacturing approaches, all comprising the same common steps. First, the patient's white blood cells (WBCs) are isolated by leukapheresis, washed, and then T cells are isolated. The T cells are then activated, transduced with the CAR transgene, expanded to the required cell numbers for therapy, formulated, and filled. After quality control testing and preparatory lymphoid-depleting chemotherapy for the patient, the product is injected.

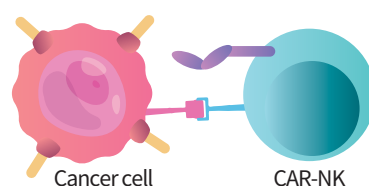
Representative products:

At present, there are 7 approved CAR-T cell therapies globally, including Novartis' Kymriah, Gilead's Yescarta, and so on. In addition, 1007 CAR-T projects are currently at the clinical research stage (Clinical Trials.gov, October 25, 2021).

Kymriah(Novartis): CAR-T cell therapy targeting CD19, a drug used to treat children and adolescents with acute lymphoblastic leukemia (ALL). This drug is the world's first FDA-approved CAR-T cell therapy product.

Yescarta(Gilead): CAR-T cell therapy targeting CD19 to treat adult patients with recurrent or refractory large B-cell lymphoma (LBCL).

Chimeric antigen receptor natural killer cell therapy (CAR-NK)



Principle: CAR-NK cell strategy involves isolating a patient's own NK cells, engineering these NK cells to express CAR, which recognizes the tumor-specific target.

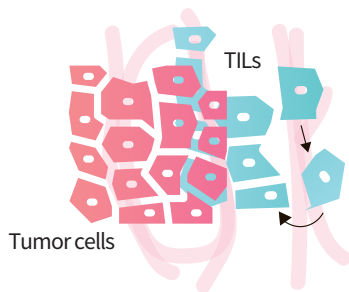
Manufacturing process: Primary NK cells can be isolated directly from peripheral blood mononuclear cells (PBMCs) of healthy donors or umbilical cord blood (UCB) and induced pluripotent stem cells (iPSCs). Isolated primary NK cells can be activated genetically engineered with CAR-expressing vectors (e.g., lentivirus [LVs] or retrovirus [RVs]). After the CAR-NK cells are amplified in vitro, they can be transfused back into the patient.

Representative products:

NKX101 (Nkarta Therapies): An "off-the-shelf" CAR-NK cell therapy targets NKG2D. It is composed of NK cells engineered to express a chimeric NKG2D receptor that targets a tumor cell's NKG2D ligands and a membrane-bound interleukin-15 to increase persistence. Compared with non-engineered NK cells, NKX101's ability to recognize and kill tumor cells in preclinical models has been significantly improved.

FT596 (Fate Therapies): Spot-type, iPSC-derived CAR-NK therapy. Among the 14 patients who received a dose of FT596 with more than 90 million cells, 10 (71%) out of 14 patients achieved objective remission, of which 7 (50%) achieved complete remission. It is not currently approved for the market.

Tumor-infiltrating lymphocyte therapy (TIL)



Principle: Tumor-infiltrating lymphocyte (TIL) therapy is a type of adoptive cellular therapy achieved by harvesting infiltrated lymphocytes from tumors, culturing and amplifying them *in vitro*, and, then infusing them back into patients. Some of these lymphocytes are T cells that target tumor-specific mutant antigens. They are immune cells that can penetrate deep into the tumor and exhibit the most effect.

Manufacturing process: The most used widely TIL production method is to isolate infiltrating lymphocytes from tumor tissues and then culture and expand these cells *in vitro*.

The patient's tumor cells can then interact with the enlarged TIL cells to screen effector TIL cells that can kill tumor cells. Dendritic cells loaded with tumor-specific antigen (DC) are used for further amplification and cultivate tumor-specific TIL. Finally, cells are transfused back into patients for treatment.

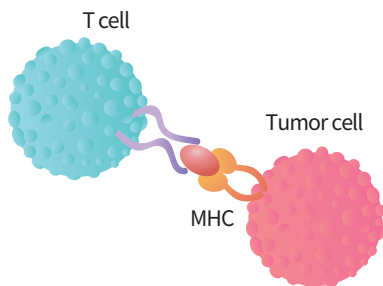
Representative products:

LN-145 (Iovance Biotherapeutics): A TIL therapy developed to treat metastatic non-small cell lung cancer. LN-145 monotherapy has achieved a total remission rate of 21.4% and a disease control rate (DCR) of 64.3%.

ITIL-168 (Instil Bio): ITIL-168 was developed to treat melanoma, with an overall objective response rate of 67%. Among them, the complete remission rate (CR) was 19%, the partial remission rate (PR) was 48%, and the disease control rate (DCR) was as high as 86%.

It is not currently approved for the market.

T cell antigen receptor T cell therapy (TCR-T)



Principle: T-cell receptor (TCR)-based adoptive therapy employs genetically modified lymphocytes directed against specific tumor markers. T cells (or heterologous T cells), derived from the patient's peripheral blood, are modified via genetic engineering by adding identified TCR sequences. These TCR sequences can specifically bind to target antigens. The modified T cells are then transfused back into the patient's body to recognize and kill tumor cells expressing the antigen specificity.

Manufacturing process: The manufacturing process for TCR therapy is virtually the same as the one for CAR T cell therapy. T lymphocytes must be collected from the patient and purified. After purification, the sample is expanded, drastically increasing the number of TCR-T cells, and then transfused back into the patient.

Representative products:

KIMMTRAK (Immunocore) is the first FDA-approved treatment for unresectable or metastatic uveal melanoma. It is also the first regulatory approved T cell receptor (TCR) therapy and the first FDA-approved bispecific T cell connector to treat solid tumors.

Comparison of different immune cell therapies

	CAR-T/UCAR-T	CAR-NK	TIL	TCR-T
Description	Isolated T cells from peripheral blood are reinfused after introducing the CAR genes that specifically recognize tumor antigens	Introduction of CAR gene into NK cells from different sources and transfusion	Tumor-infiltrating T cells are amplified in vitro and then reinfused into the body	Transfusions of TCR genes specific for tumor antigen recognition into T cells isolated from peripheral blood
Main targets	Tumor cell surface proteins, such as CD19, BCMA	Tumor cell surface proteins, such as CD19, HER2	There are no requirements for the target. Anti-tumor effect of multiple targets can be stimulated at the same time	Recognition of MHC antigen-peptide complexes after processing and presentation of tumor surface and internal antigens, such as MAGE-A1, NY-ESO-1, WT1
Characteristics	Haematoma is highly effective, with severe side effects	Powerful anti-hematomas, side effects, and solid tumor efficacy need more research.	The intensity and incidence of side effects are the lowest; almost no non-target tissue side effects occur in the target	There are strong non-target tissue side effects on the target, and the effect on solid tumors has yet to be tested
Hurdles	CAR gene transduction /HLA gene knockout, cell sorting	CAR gene transduction	TIL cell sorting/expansion culture	TCR screening/gene transduction
Indications	Mainly for haematoma, such as Hodgkin lymphoma, lymphocytic leukemia, etc.	Hematologic malignancies and solid tumors, such as lymphocytic leukemia, mammary cancer, glioblastoma, etc.	Solid tumors, cervical cancer, melanoma, lung cancer, etc	Hematologic Malignancies and solid tumors, such as lymphocytic leukemia, synovial sarcoma, etc.


Regulatory Requirements for R&D, Manufacture, and Clinical Research of Immune Cell Therapy



Immune cell therapy drugs had developed rapidly since 2017 when two CAR-T cell therapy drugs were approved by FDA. However, quality research and quality control are more complicated due to the large heterogeneity in the cell source, type, and in vitro operation of immune cell therapy products.

In July 2018, the US Food and Drug Administration (FDA) issued six scientific guidelines on human gene therapy products to standardize the research and development of cell therapy products and improve their safety, effectiveness, and quality controllability. As the cornerstone of a modern and comprehensive regulatory framework, these guidelines provide a strong reference for developing new products in this field following the FDA's safety and efficacy pathway. These guidelines cover a series of regulatory issues and special requirements for different gene therapy products. In addition, the EMA (European Medicines Agency) defines cell therapy products as advanced therapeutic products (ATMPs). The EMA has corresponding principles for ATMPs from non-clinical research and clinical trials to industrial production. It includes the clinical trial quality management specification (GCP) for cutting-edge drugs, the quality management specification (GLP) for non-clinical research of cutting-edge drugs, and the production quality management specification (GMP) for cutting-edge drugs.

FDA\EMA Immune Cell Therapy Regulations

Publishers	File name	 Scan the QR code for the FDA\EMA guidelines package
FDA	Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)	
FDA	Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up	
FDA	Long Term Follow-Up After Administration of Human Gene Therapy Products	
FDA	Human Gene Therapy for Retinal Disorders	
FDA	Human Gene Therapy for Rare Diseases	
FDA	Human Gene Therapy for Hemophilia	
FDA	Recommendations for Microbial Vectors used for Gene Therapy	
FDA	Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products	
FDA	Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products	
FDA	Predclinical Assessment of Investigational Cellular and Gene Therapy Products	
FDA	Potency Tests for Cellular and Gene Therapy Products	
EMA	Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials	
EMA	Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products	

Immune Cell Therapy Development Process (take CAR-T cell drugs as an example)

	Early drug discovery	Manufacture/Quality control	Non-clinical studies	Clinical research
Research Content	<ul style="list-style-type: none"> Targets identification and selection. Preparation and screening of scFv or sdAb (single domain antibody). Design and optimization of CAR structure. 	<ul style="list-style-type: none"> Selection of raw materials Preparation of Gene vector. Preparation of CAR-T cell therapy products. 	<ul style="list-style-type: none"> Selection of animal models. Pharmacodynamic studies. Pharmacokinetics. Non-clinical safety. 	<ul style="list-style-type: none"> Exploratory Clinical Trials Safety and tolerability. Assessment of activity in vivo. Confirmatory clinical trials. Clinical efficacy and safety.
Solutions and Products	50 + CAR-T Target Products: Suitable for multiple scenarios such as immunology, single-domain antibody or scFv screening, CAR affinity detection, and species cross-validation.	Raw materials: Anti-CD3/CD28 antibody -coupled magnetic beads, cytokines, GENES™Nuclease, and other products. For quality control release testing: fluorescent-labeled proteins	Pharmacokinetic study: Highly sensitive and specific fluorescent-labeled CAR-T target proteins, anti-idiotypic antibodies. For immunogenicity evaluation: anti-idiotypic antibodies, such as rabbit Anti-FMC63 scFv polyclonal antibody and murine Neutralizing Anti-FMC63 scFv monoclonal antibody. ACROBiosystems can provide customized anti-idiotypic antibody services to meet customers' demands.	

Manufacture and quality control of gene vector substances

The quality control of gene vector substances is an important upstream link in the production of CAR-T cell drugs. The three most commonly used gene vector substances are lentiviral vectors, retroviral vectors, and plasmid vectors. Among them, lentiviral vectors are the most widely used. The determination of viral vector transfer titers is one of the key indicators of lentiviral vector quality control.

Determination of viral vector transfer titer

The ability to transfer cells is usually used as the titer of the viral vector. After the viral vector is transferred to sensitive cell lines (such as 293T cells, HT-1080 cells, etc.) or primary cells (such as PBMC), the positive CAR expression rate or CAR gene copy number of the cell is detected, and the transfer titer (TU/ml) is calculated.

Quality control of CAR-T cell products

For CAR-T cells, the active ingredients that play a tumor-killing role are CAR-positive T cells. The packaging specifications and clinical dosage of CAR-T cell products are based on the number of CAR-T-positive cells. Therefore, detecting the positive rate of CAR transfection is one of the key indicators for CAR-T quality control.

The detection of positive CAR transfer and transfection positivity rate:

Flow cytometry usually is used to detect the positive rate of CAR transfection. There are some methods for CAR detection, such as CD19 antigen or anti-scFv antibody for CAR antigen-binding sites, anti-Fab antibody, or Protein L for light chain or hinge regions. Among these choices, target antigens are widely considered the best option because they offer high specificity and minimal background staining.

Non-clinical research

Non-clinical research, using suitable subjects and animal models to carry out *in vivo* and *in vitro* pharmacodynamic, pharmacokinetic, and non-clinical safety research, can provide a supporting basis for follow-up clinical trials.

► Pharmacokinetic study of CAR-T cells

The pharmacokinetic research of CAR-T cells mainly focuses on the proliferation level, distribution, and survival time of target cells *in vivo*. Optional detection techniques are imaging techniques, flow cytometry, immunohistochemistry techniques, quantitative PCR, etc. Different methods are suitable for detection of different samples and detection purposes.

- **Imaging method:** The *in vivo* distribution of CAR-T cells can be visually detected. Cell labeling for *in vivo* imaging can be achieved by a variety of methods, such as radioisotope labeling of cells, genetic modification (e.g., expression of a green fluorescent protein or luciferase) labeling, and nano-particle labeling (e.g., iron-dextran nano-particles), etc.
- **Flow cytometry:** Can detect CAR-T cells in animal blood, bone marrow, and spleen.
- **Immunohistochemistry method:** CD3+ cells or CAR+ T cells in the spleen or other organs can be detected to indicate the distribution and accumulation of human T cells in animal organs.
- **Quantitative PCR method:** It can detect CAR-T cells' DNA or RNA levels in all types of samples. The PCR method recommends CAR instead of CAR-T cells as the specific detection target.

► Pharmacodynamic study of CAR-T cells

Bioluminescent Imaging (BLI) technology is the most intuitive and commonly used method for studying the pharmacodynamic effects of CAR-T cells. This method detects tumor cells expressing luciferase and uses fluorescence intensity to indicate the tumor load. It is currently one of the main techniques for evaluating the pharmacodynamic effects of CAR-T cell products *in vivo*.

Flow cytometry can detect the number of tumor cells in animals.

Immunological methods such as flow cytometry, ELISA, and MSD detect changes in tumor-related cytokines in serum, thereby indirectly reflecting pharmacodynamic results.

Conventional pharmacological or pathological methods detect tumor-related parameters (such as tumor volume, tumor weight, colonization site of tumor cells in animals) and the median survival period of animals.

► Indicators of non-clinical immunotoxicity of CAR-T cells

- **Cytokine storm (CRS):** Use flow cytometry, Luminex, MSD electrochemical luminescence, and other methods to detect serum cytokine levels (such as IL-2, IL-4, IL-6, IL-10, INF- γ , TNF- α , etc.)

Clinical research

Clinical research is divided into exploratory and confirmatory clinical trials. The exploratory clinical trial phase focuses on the safety and tolerance of cell therapy products. The biological activity range or optimal effective dose of cell therapy products is determined through dose exploration. Another purpose in the exploratory clinical trial phase is to conduct a preliminary evaluation of product activity, such as cell proliferation, survival, and biological distribution *in vivo* (such as pharmacokinetics), pharmacodynamic activity (such as cytokine levels after product infusion), immunogenicity, and efficacy such as tumor remission or other types of clinical improvement, etc.

The purpose of confirmatory clinical trials is to confirm the efficacy and safety of preliminary indications in exploratory studies and to provide key benefit/risk assessment evidence for registration.

► Pharmacokinetic (PK) evaluation method of CAR-T cell products

For clinical PK studies of CAR-T cell products, real-time fluorescence quantitative polymerase chain reaction (qPCR) and flow cytometry are usually used for PK analysis. The measurement of exogenous gene copies and changes in the number of CAR positive cells helps to verify the reliability of the detection method with each other. The amplification and survival of the product can be more comprehensively analyzed *in vivo*.

► Immunogenicity evaluation method for CAR-T cell products

Immunogenicity research investigates the correlation between anti-drug antibodies (ADA) produced by cell therapy drugs and pharmacokinetic/pharmacodynamic, efficacy, and safety. Its research content mainly focuses on the detection and characterization of drug-resistant antibodies. Data on drug-resistant antibodies' incidence, titer, survival time, and neutralization ability should be obtained.

Commonly used detection methods: Direct/indirect ELISA, bridged ELISA, electrochemiluminescence (ECL/MSD), radioimmunoprecipitation test (RIPA), surface plasma resonance (SPR), cell-level test (Cell-based assay), and Competitive Ligand Binding Assay (Competitive Ligand Binding Assay).

Immune Cell Therapy Development and Evaluation Solutions



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Early discovery of immune cell products

■ Early discovery for CAR-T cell therapy

ACROBiosystems has developed more than 50 CAR-T targets, including CD19, BCMA, CD22, MSLN, and GPC3 using professional protein research and development to support the CAR-T cell drug development research platform.

► Product features

- 👍 50+ CAR-T targets
- 👍 PE/FITC/Biotin/Unconjugated forms available
- 👍 Variety of tags including His Tag/Human IgG1 Fc Tag/Mouse IgG2a Fc Tag/Llama IgG2b Fc Tag
- 👍 Human, Cynomolgus, mouse, and more species
- 👍 Suitable for various application scenarios such as immunization, antibody screening, antibody affinity measurement, and species cross-verification.
- 👍 Some products have completed the FDA DMF filing (DMF number: 034936), which can support your IND, NDA, and BLA.

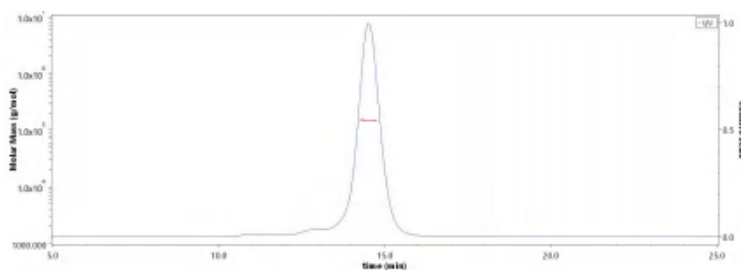
► Hot CAR-T targets

CD19	BCMA	CD22	CD20	CD123	CD33	CD30	CD38	CS1
CD138	CD37	CD4	CD5	CD56	CD7	CD72	CD99	CLL-1
GPC3	LILRB4	HER2	MSLN	EGFR	GPC3	PSMA	EBV	B7-H3
CAIX	CD147	CD47	CEA	CLDN18	DLL3	EGFRVIII	EpCAM	FAP
FOLR1	GUCY2C	HER3	HGFR	IL13RA2	MUC16	Nectin-4	PSCA	uPAR
VEGFR2	CD171	MUC-1	NKG2D	CD133	CD70	ROR1	PD-L1	

The red background represents blood tumor markers, the pink background is for solid while the others are common markers for both.

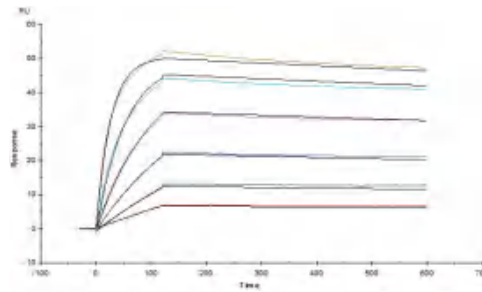
► Featured product – CD19

>>> High purity verified by HPLC-MALS



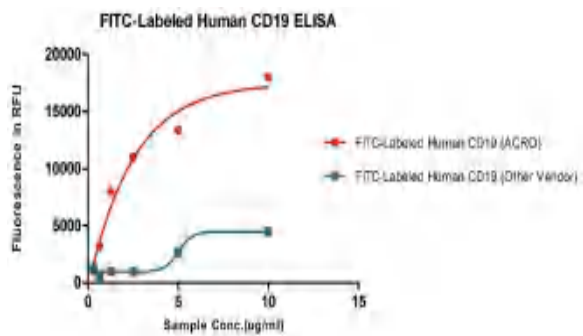
The purity of Human CD19 (20-291), Fc Tag (Cat. No. **CD9-H5251**) was more than 95% and the molecular weight of this protein is around 140-160 kDa verified by HPLC-MALS.

>>> High affinity verified by SPR

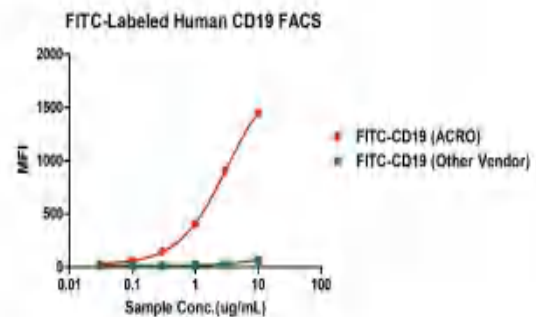


Human CD19 (20-291), Fc Tag (Cat. No. **CD9-H5251**) captured on CM5 chip via Anti-Human IgG Fc antibodies surface, can bind FMC63 MAb (Mouse IgG2a) with an affinity constant of 0.17 nM as determined in a SPR assay (Biacore T200) (Routinely tested).

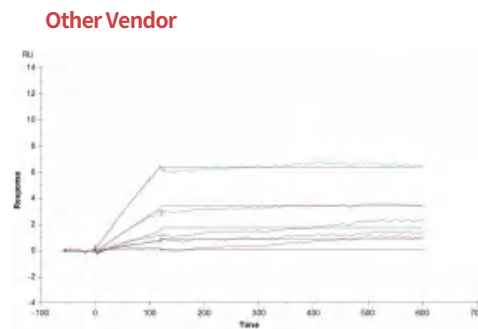
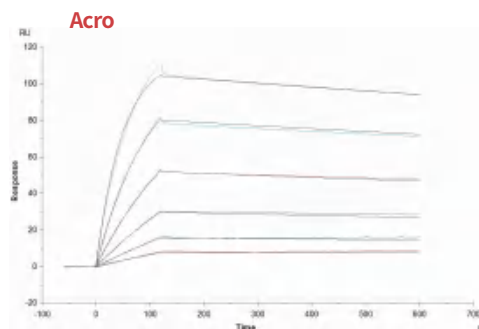
>>> Higher binding activity compared to that of other competitors



Binding activity of FITC-Labeled Human CD19, His Tag from two different vendors were evaluated in the ELISA analysis against FMC63 Mab. The result showed that ACRO's FITC-Labeled Human CD19, His Tag has a much higher binding activity than that of the other vendor.



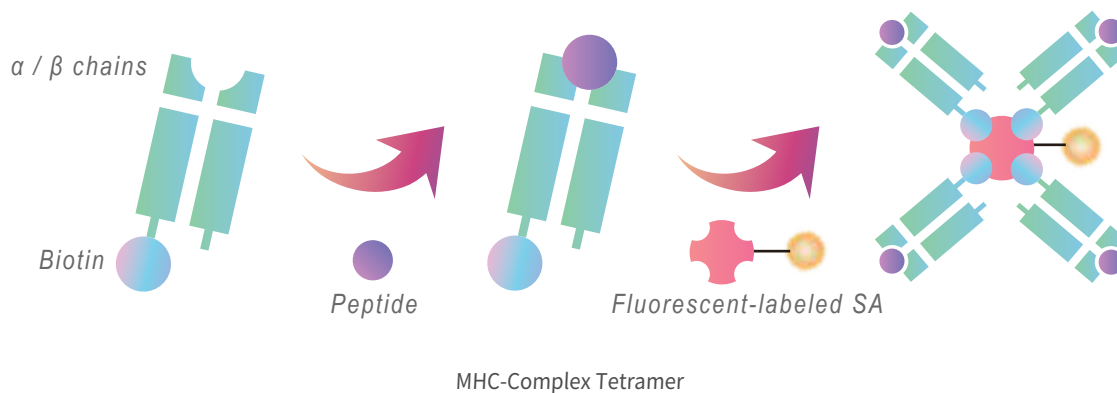
Binding activity of FITC-Labeled Human CD19, His Tag from two different vendors were evaluated in the flow cytometry analysis against anti-CD19-CAR-293 cells. The result showed that ACRO's FITC-Labeled Human CD19, His Tag has a much higher binding activity than that of the other vendor.



Binding activity of Human CD19, His Tag from two different vendors were evaluated by SPR assay against FMC63 mAb. The result showed that ACRO's Human CD19, His Tag can bind FMC63 mAb with an affinity constant of 2.95 nM which is much higher than that of the other vendor.

■ Early discovery of TCR-T cell therapy

Our major histocompatibility complex (MHC) proteins are developed using our mature protein structure design platform alongside our eukaryotic protein expression technology platform to avoid any prokaryotic refolding process instabilities, incorrect complex conformations, and other issues. Using these platforms, we have successfully developed a series of natural MHC complexes with high biological activity in both monomer, tetramer forms with various fluorescent labels available. This includes targets such as NY-ESO-1, WT-1, GP100, GPC, and many others. Furthermore, we also offer custom MHC-peptide complex development services using our technology platforms to ensure natural conformation according to your specific needs and applications.

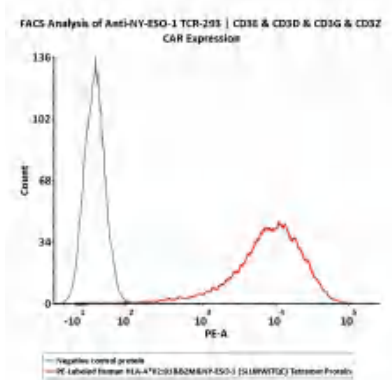


► Customized Product List

MHC Allele				Target			
HLA-A*0101	HLA-A*0201	HLA-A*0301	HLA-A*1101	NY-ESO-1	GP100	MSLN	AFP
HLA-A*2402	HLA-A*30:01	HLA-A*3303	HLA-B*1501	WT-1	MAGE	HPV	HBV
HLA-B*1525	HLA-B*3802	HLA-B*4601	HLA-B*0702	HIV	EBV	RYS	CMV
HLA-C*0102	HLA-C*0303	HLA-C*07:02:01		RHAMM-R3	Glycican 3	KRAS	EW
HLA-DQA1*03:02&DQB1*03:03			HER2	P53	PRAME	PSMA
						

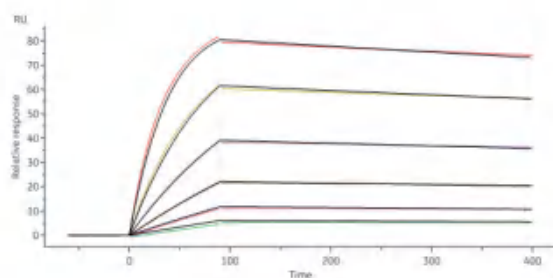


>>> Binding activity of PE-labelled HLA-A*02:01&B2M&NY-ESO-1 tetramers were verified using anti-NY-ESO-1 TCR-293 cells and flow cytometry. Clearly defined populations bound with MHC tetramers were observed in comparison to negative control proteins.



5e5 of anti-NY-ESO-1 TCR-293 were stained with 100 μ L of 1:25 dilution (4 μ L stock solution in 100 μ L FACS buffer) of PE-Labeled Human HLA-A*02:01&B2M&NY-ESO-1 (SLLMWITQC) Tetramer Protein (Cat. No. **HL1-HP2E5**) and negative control protein respectively. PE signal was used to evaluate the binding activity (QC tested).

>>> MHC tetramer binding was evaluated using MHC skeleton (W6/32) targeting antibodies. Proper binding curves were observed using both antibodies, ensuring good specificity and affinity.



Anti-HLA class I Antibody, Human IgG1 (W6/32) captured on Protein A Chip can bind Human HLA-A*11:01&B2M&KRASG12D (VVGADGVGK) Complex Protein (Cat. No. **HLD-H52H4**) with an affinity constant of 1.06 nM as determined in a SPR assay (Biacore 8K) (Routinely tested).

Raw materials for immune cell products

Raw materials at ACROBiosystems	Application
Cytokines (e.g. IL-2, IL-7, IL-15, IL-21)	Activation and amplification of T/NK cells
Antibody/Target-coupled beads, Antibodies	Activation and amplification of T cells
GENIUS™ Nuclease	Nucleic acid removal in the lentivirus purification process
CRISPR-Cas Nuclease	Gene editing
CelThera™ GMP T Cell Expansion Medium	Cell culture
Cell Culture Matrix	Cell culture

► Featured product - GMP Human IL-15

>>> Product Features

★ Strict Quality Control Standards

- 16 quality control standards.
- Excellent safety profile (testing for sterility, mycoplasma, endotoxin, and residual impurities).
- High stability and batch-to-batch consistency.

★ GMP Grade Quality Management System

- ISO 5 cleanrooms used for filling.
- Raw and packing materials are registered.
- Facilities are available for online and on-site audits.

★ Accelerating Global Regulatory Approval of Biological Products

- A comprehensive set of regulatory documents is available.
- Validation reports for analysis methods are available on request.
- FDA DMF filed.

**Lower at least
half of your *GMP*
cytokines cost**

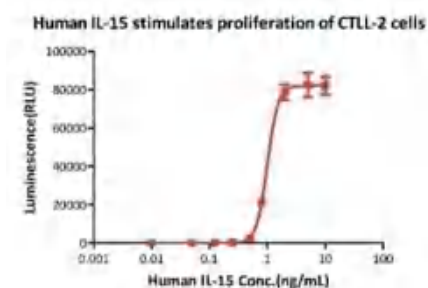
★ Automatic filling equipment



★ Sterilization equipment



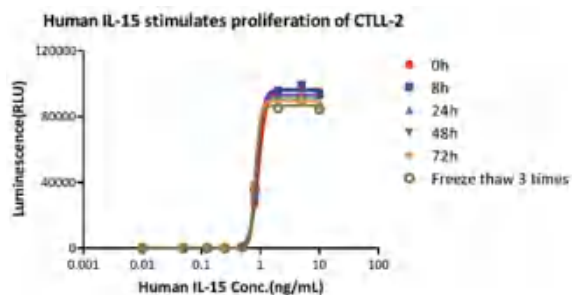
>>> High bioactivity



GMP Human IL-15 (Cat. No. **GMP-L15H13**) stimulates the proliferation of CTLL-2 cells. The EC₅₀ for this effect is 1.004 ng/mL, corresponding to a specific activity of $> 0.8 \times 10^7$ IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554).

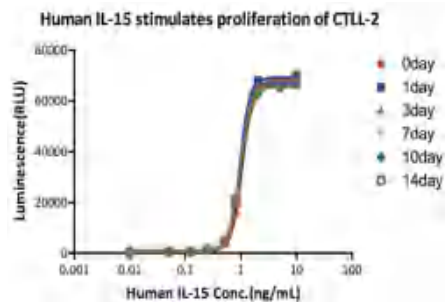
>>> High stability

★ Validation of accelerating and freeze-thaw stability



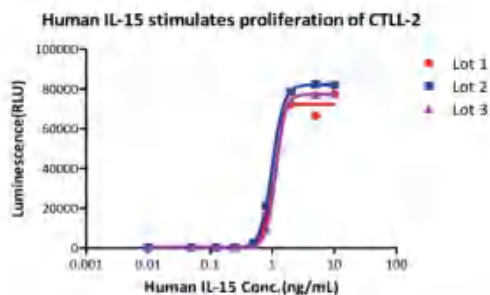
GMP Human IL-15 (Cat. No. **GMP-L15H13**) is stable in undiluted samples at 25 °C for 72 hours and freeze-thaw 3 times without performance reduction.

★ Long-term stability testing (4°C)



GMP Human IL-15 (Cat. No. **GMP-L15H13**) is stable in undiluted samples at 4 °C for 14 days without performance reduction.

>>> High batch-to-batch consistency



Bioactivity of three different lots of GMP Human IL-15 (Cat. No. **GMP-L15H13**) verified by cell-based assay, and the result shows very high batch-to-batch consistency.

► Featured product – CytoPak products

>>>Optimizing Closed Process Manufacturing with CytoPak

CytoPak products are designed to support seamless integration into closed-system cell and gene therapy manufacturing. Our single-use, ready-to-use bag formats minimize contamination risk while ensuring consistency and sterility in critical workflow steps. These products offer a reliable, scalable, and regulatory-compliant solution for various stages of therapy development, from preclinical research to commercial production.



Scan the QR to
learn more

>>>CytoPak Benefits of Closed System Solutions

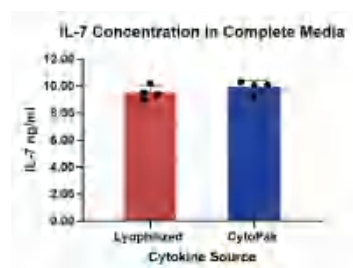
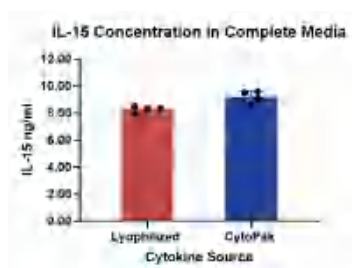
- Closed-System Compatibility: Designed for sterility assurance, minimizing contamination risks and ensuring regulatory compliance in cell therapy workflows.
- Easy to use: Eliminates the need for repeated bag rinsing, simplifying the workflow and reducing preparation time.
- Weldable Tubing Convenience: Facilitates direct integration into existing closed bioreactor systems, such as G-Rex and wave bioreactors, for streamlined operations and reduced contamination risk.
- Optimized Cytokine Dosing: Scientifically validated concentrations to enhance cell culture performance and reproducibility, ensuring robust and consistent expansion of T cells.
- Reduced Manual Handling: Eliminates reconstitution and aliquoting steps, minimizing hands-on technician time and reducing error risks while improving batch-to-batch consistency.
- Stable and Ready-to-Use: Long-term storage at -20°C ensures product integrity, while short-term stability at 2-8°C allows for flexible usage in manufacturing settings.
- Scalability and Versatility: Available in multiple volumes and concentrations to accommodate different stages of cell therapy development, from research to large-scale commercial production.

Cytopak Custom GMP Bags for Closed-System Workflows



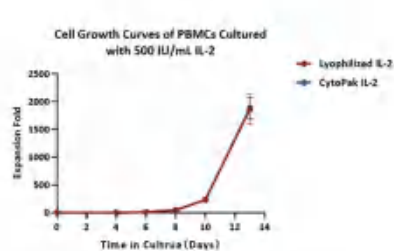
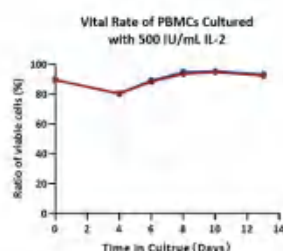
Scan the QR to
Build Your GMP Bag!

>>>Consistent IL-7 & IL-15 Concentration: CytoPak vs Lyophilized

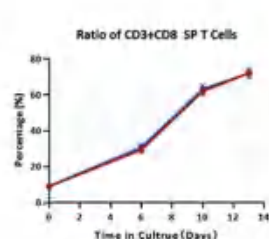
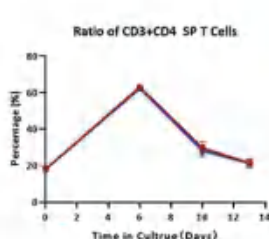
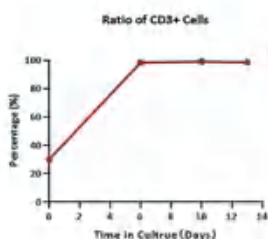


CytoPak GMP Human IL-15/IL-7 Protein (Cat. No. **GMP-L15H13GB01/GMP-L07H24GB01**) and lyophilized IL-15/IL-7 (Cat. No. **GMP-L15H13/GMP-L07H24**) were added to CelThera™GMP T Cell Expansion Medium in parallel. After cytokine addition, the concentration of IL-15/IL-7 were determined by ELISA. Data is the average of 4 independent experiments with error bars \pm SD.

>>>CytoPak Cytokines Powerfully Support Cell Growth



Human PBMCs were cultured with Human IL-2 Protein (ACROBiosystems) with T Cell Expansion Medium for two weeks. No significant differences were observed in cell viability or proliferation between Lyophilized (Cat. No. **GMP-L02H14**) and CytoPak IL-2 (Cat. No. **GMP-L02H14GB01**). Data is the average of 3 independent experiments, error bars \pm SD.

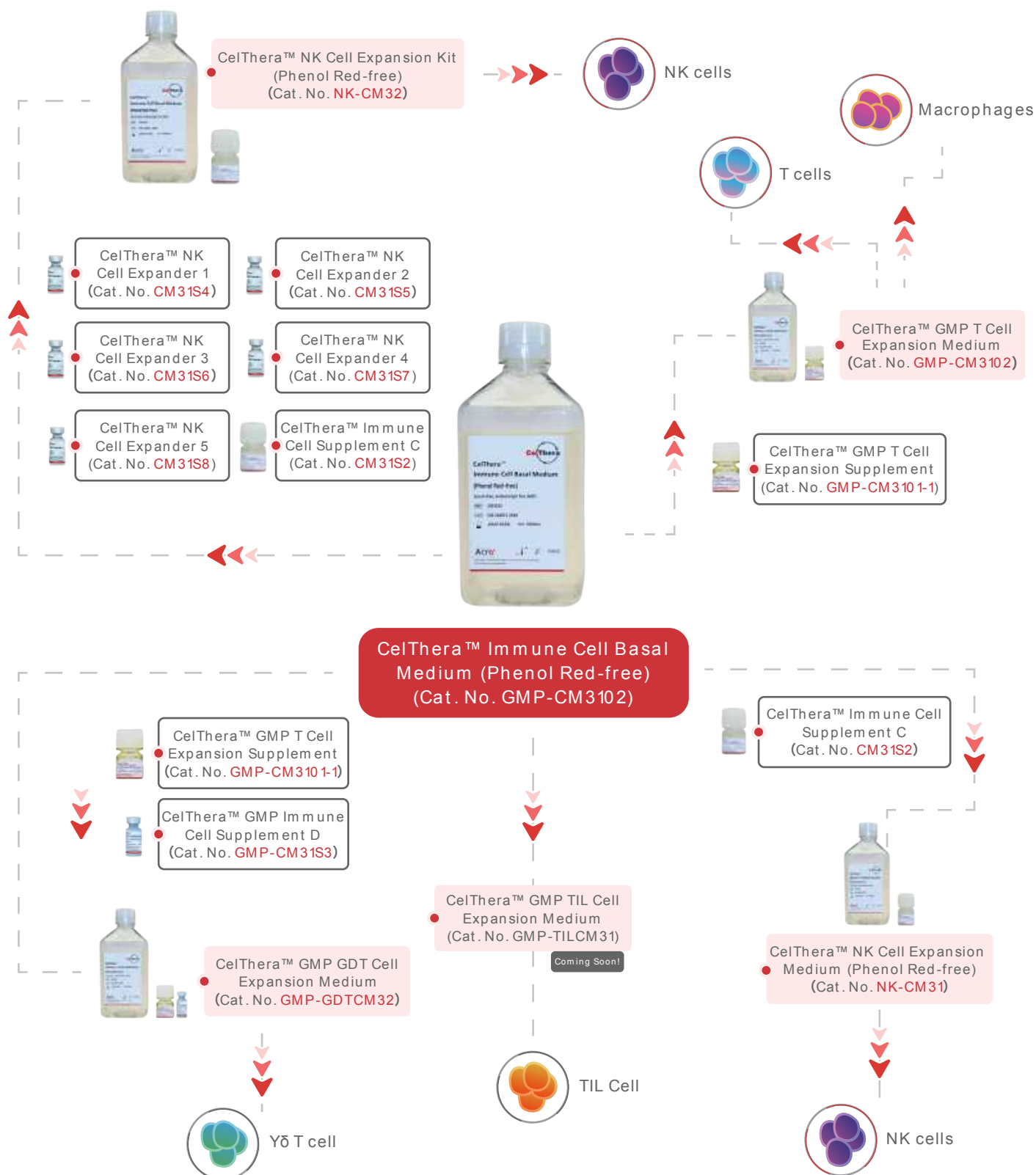


Human PBMCs were cultured with Human IL-2 Protein (ACROBiosystems) with T Cell Expansion Medium for two weeks. No significant differences were observed in the ratio of CD3+ or CD3+ CD4/CD8 positive cells between Lyophilized (Cat. No. **GMP-L02H14**) and CytoPak IL-2 (Cat. No. **GMP-L02H14GB01**). Data is the average of 3 independent experiments, error bars \pm SD.

>>>Hot CytoPak Products

Catalog No.	Product	Host	Size	Grade
GMP-L02H14GB01	CytoPak GMP Human IL-2 Protein	E coli	15×10 ⁶ IU	GMP
GMP-L07H15GB01	CytoPak GMP Human IL-7 Protein (E coli)	E coli	10ug	GMP
GMP-L07H15GB02	CytoPak GMP Human IL-7 Protein (E coli)	E coli	50ug	GMP
GMP-L07H24GB01	CytoPak GMP Human IL-7 Protein	HEK293	10ug	GMP
GMP-L15H13GB01	CytoPak GMP Human IL-15 Protein	E coli	10ug	GMP
GMP-L15H13GB02	CytoPak GMP Human IL-15 Protein	E coli	50ug	GMP
MBS-C038	CytoPak ActiveMax® Human DLL4 μ Beads, premium grade (for cells, 5.5 μ m)	--	25mg	PG

► **Featured product – CelThera™GMP Immune Cell Expansion Medium and Kit**

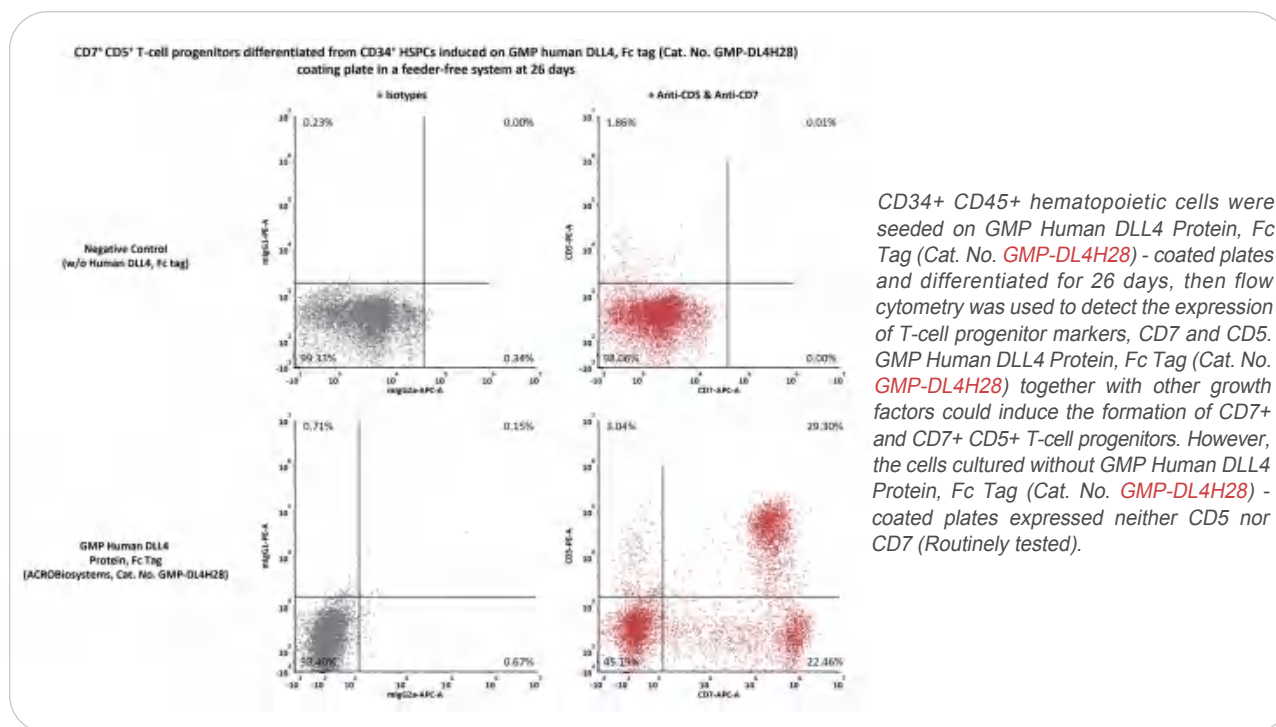


► Featured product- GMP-grade DLL4



ACROBiosystems is dedicated to developing high-quality reagents and raw materials for use in CGT clinical stages. With a robust GMP quality management system, we are pleased to announce the release of our GMP-grade recombinant DLL4 protein, which demonstrates exceptional activity and safety. This protein is ideal for supporting the feeder-cell free approach to iPSC-to-T cell differentiation, particularly for large-scale clinical manufacturing of iPSCs.

>>> Application Data

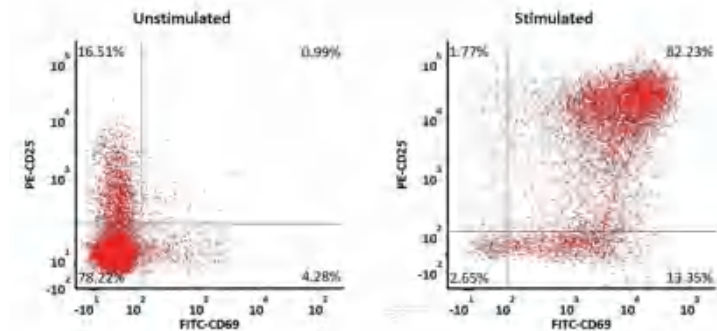


► Featured product- Anti-CD3/CD28 coupled Magnetic Beads

ACROBiosystems focuses on supporting research related to cell therapy. Under a comprehensive GMP quality system, we have developed high-quality ActiveMax[®] GMP-grade CD3/CD28 antibody-coupled magnetic beads (Catalog No: GMP-MBS001). These beads are combined with cell culture platforms, magnetic bead coupling technology, and flow cytometry analysis platforms. Rigorously validated for activity, they efficiently stimulate and expand T cells, accelerating your cell therapy drug development process.

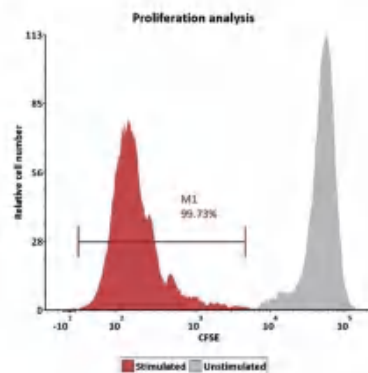
- 👍 Efficient activation and expansion of T cells, superior performance
- 👍 Compliant with GMP quality system, animal component-free for enhanced safety
- 👍 GMP-grade antibodies as raw materials, subjected to rigorous virus removal and testing
- 👍 High stability; high batch-to-batch consistency

★ Efficient Activation of T Cells



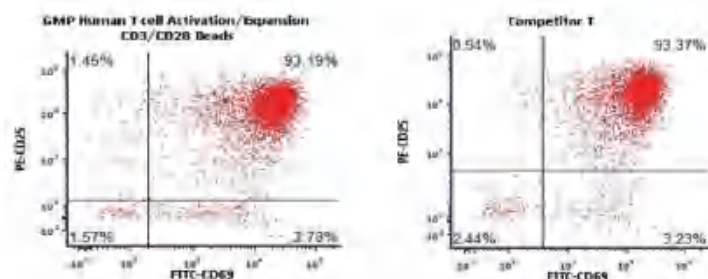
The human T cells were stimulated with GMP ActiveMax® Human T cell Activation/Expansion CD3/CD28 Beads (Cat. No. **GMP-MBS001**) for 24hrs, and the activation was assessed by measuring expression of both activation markers CD25 and CD69 expression on the T cells surface by staining with PE labeled anti-human CD25 antibody and FITC labeled anti-human CD69 antibody respectively (QC tested).

★ Cell Proliferation Efficacy

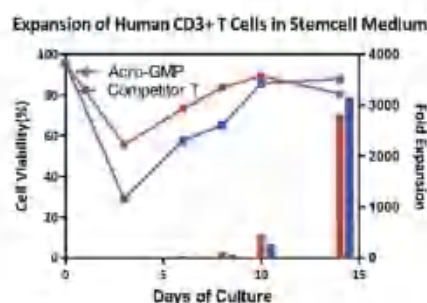
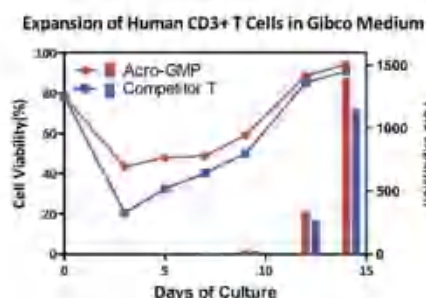


The human T cells were labeled with carboxy fluorescein succinimidyl ester (CFSE) and stimulated with GMP ActiveMax® Human T cell Activation/Expansion CD3/CD28 Beads (Cat. No. **GMP-MBS001**), and then the proliferation of the T cells was assessed with CFSE dilution assay by flow cytometry on day 5 after stimulation (QC tested).

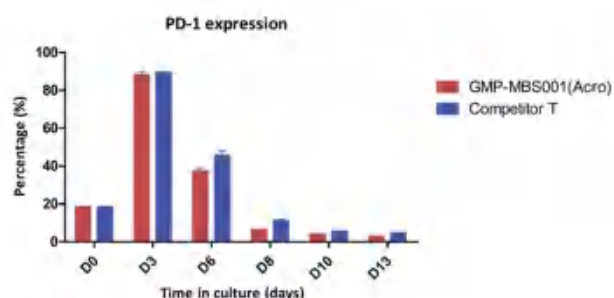
★ Outperforms Competitors



Activation of the purified human T Cells. The purified human T cells were activated using Human T cell Activation/Expansion CD3/CD28 Beads, (ACRO, Cat. No. **GMP-MBS001**) and Competitor-Beads respectively for 24 hours with CTS Optimizer Medium. Cells were fluorescently stained using PE labeled anti-human CD25 antibody and labeled FITC anti-human CD69 antibody and analyzed by flow cytometry.



Expansion of the human CD3+T cells. Human T cells using ACROBiosystems CD3/CD28 Beads (ACRO, Cat. No. **GMP-MBS001**) were expanded under two different medium, respectively. Expansion was performed for two weeks, showing that ACROBiosystems' beads showing better proliferative abilities and comparable competitive ideas compared with competitor product.

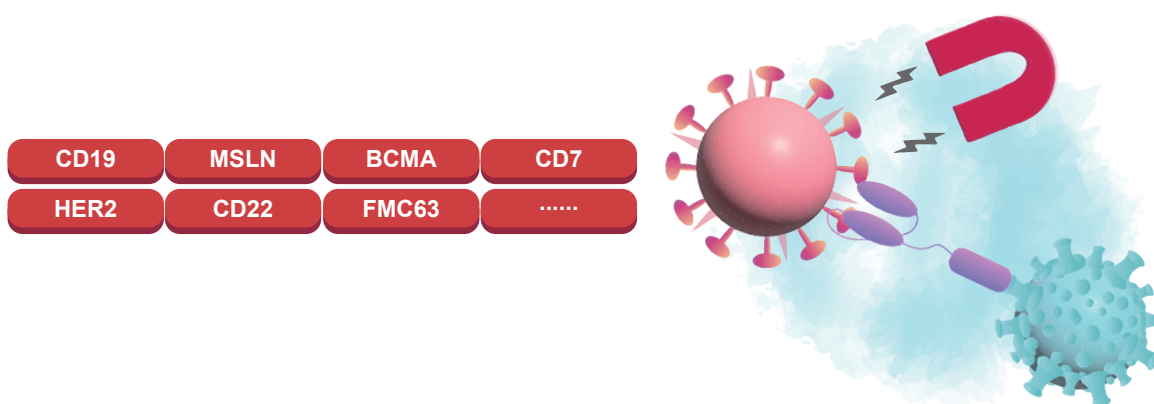


PD-1 expression of the activated human T Cells. The purified human T cells were stimulated using Human T cell Activation/Expansion CD3/CD28 Beads at a ratio of 1:1 beads-to-cells. Cells were expanded in T cell culture medium supplemented with 4ng/mL of rhIL-2 Protein (Acrobiosystems, Cat. No. **IL2-H4113**). Activated T cells were expanded for up to 8 days with low PD-1 expression.

► Featured product – ActiveMax® Target-Specific Activation Beads

To meet market demand, ACROBiosystems has successfully developed a series of Premium grade ActiveMax® Target-Specific Activation Beads based on a comprehensive antigen protein development platform, magnetic bead coupling platform, and flow cytometry platform.

- 👍 High safety: Sterile Ultralow endotoxin (< 2 EU/mg).
- 👍 High CAR target specificity; high batch to batch consistency.
- 👍 Covering multiple targets, such as CD19, MSLN, CD22, HER2, CD7 and so on.
- 👍 Supporting CAR cell-specific activation, expansion, enrichment and in vitro analysis.
- 👍 Readily available and stable for continuous supply.
- 👍 Offering customization of GMP-grade products for your specific needs.

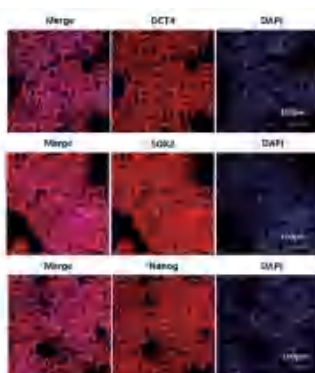


► Featured product—GMP Grade Laminin 521

To support the scalable production of clinical-grade iPSCs, ACROBiosystems is pleased to announce the launch of our new GMP-grade Laminin 521 recombinant protein. Produced under strict GMP quality control, it offers enhanced safety, stable performance, and scalable supply for iPSC culture. Validated for iPSC expansion, it supports pluripotency maintenance, ensuring outstanding quality assurance for your iPSC production.

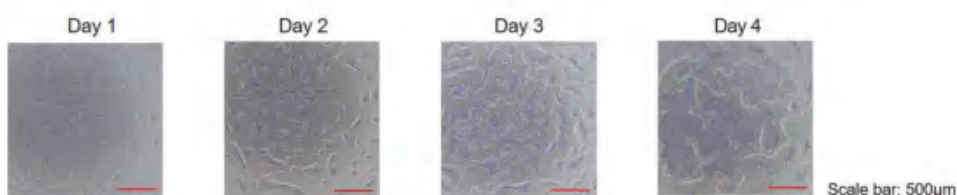
- 👍 Rapid hPSC expansion and efficient differentiation.
- 👍 Better adhesion ability even at 2 µg/ml.
- 👍 No spontaneous differentiation after several passages.
- 👍 Stable production and stringent QC.
- 👍 cGMP-compliant manufacturing.

>>> Following iPSC culture validation, ACROBiosystems' in-house developed GMP-grade Laminin 521 recombinant protein maintains iPSC pluripotency.



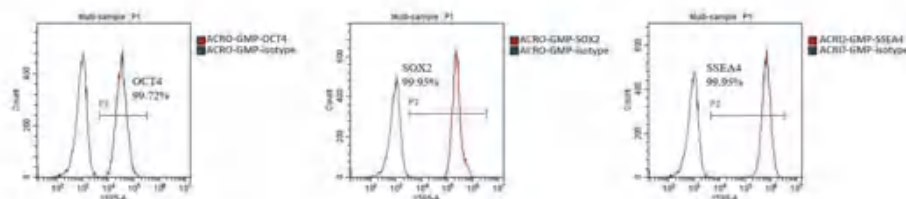
GMP Human Laminin 521 Protein (Cat. No. **GMP-LA5H24**) could maintain the stemness of iPSC after several passages.

>>> Supports rapid monolayer expansion of hPSCs.



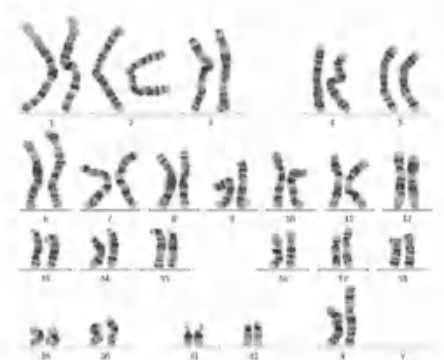
GMP Human Laminin 521 Protein (Cat. No. **GMP-LA5H24**) could support the rapid expansion of single cell hPSCs.

>>> Efficiently maintains iPSC pluripotency even after multiple passages.



GMP Human Laminin 521 Protein (Cat. No. **GMP-LA5H24**) could maintain the stemness of iPSC after several passages.

>>> Following ten passages, hiPSCs encapsulated with GMP-grade Laminin 521 recombinant protein exhibit normal karyotype (46, XX).



Normal karyotype (46, XX) was found in hiPSCs with Laminin 521(GMP-LA5H24) coating after 10 passages.

► Featured product - GENIUS™ Nuclease

GENIUS™ Nuclease is a nucleic acid digestion enzyme used to ensure the removal of any unwanted and residual DNA sequences in your final therapeutics. As a component used to ensure your final therapeutic meets regulatory requirements, we ensure that our nuclease uses no animal-derived components and no added IPTG. The nuclease is unlabeled without any protease activity and is free from viral contaminants that exists in naturally-sourced enzymes. This ensures that our nuclease is of high quality, purity, activity, and most importantly, safety. We currently offer several grades of GENIUS™ Nuclease that comprehensively assists the development process of biopharmaceuticals from discovery to commercialization.

>>> Product Quality Control

Quality Item	Method	GENIUS™ Nuclease, premium	GMP GENIUS™ Nuclease
Appearance	Visual method	Clear	Clear
Visible particle	Light detection method	No foreign objects	No foreign objects
Purity	SDS-PAGE	≥95%	≥95%
Purity	HPLC	≥99%	≥99%
Activity	Standard method	≥250U/μL	≥250U/μL
Specific activity	Standard method	≥1.2x10 ⁶ U/mg	≥1.2x10 ⁶ U/mg

Quality Item	Method	GENIUS™ Nuclease, premium	GMP GENIUS™ Nuclease
Endotoxin	LAL	<0.05EU/KU	<0.05EU/KU
Host cell protein	ELISA	<0.05 ng/μg	<0.05 ng/μg
Protease activity	Standard method	Negative	Negative
Sterility	Membrane Filtration	Negative	Negative
Mycoplasma	Chemiluminescence method	Negative	Negative
Exogenous virus	qPCR	—	Negative
Heavy metal	ICP-MS	—	<10ppm

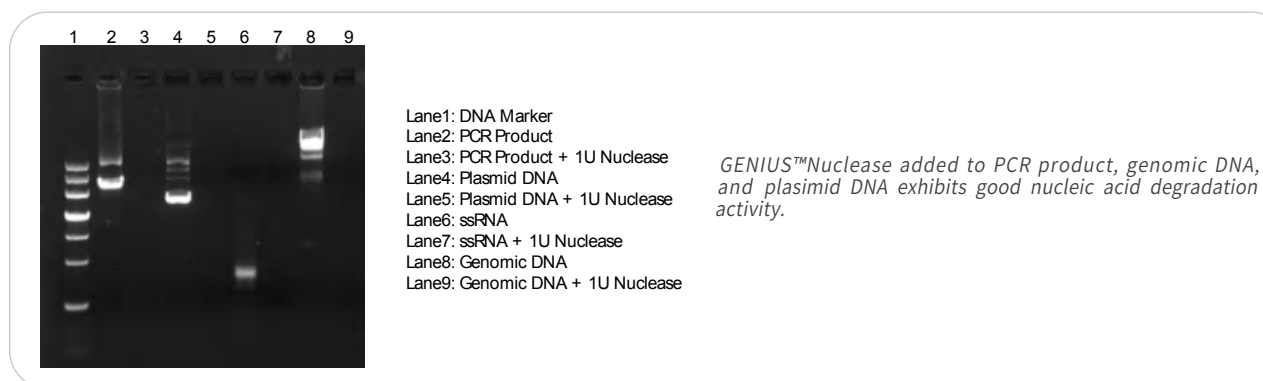
>>> GENIUS™ Nuclease Applicable conditions

Condition	Optimal	Effective
Mg ²⁺	1-2mM	1-10mM
Na ⁺ /K ⁺	0-100mM	0-300mM
pH	8-9.2	6-10
Temperature	37°C	0-50°C
DTT	0-100mM	>100mM
PO ₄ ³⁻	0-10mM	0-100mM
SDS	0mM	0-0.05mM
β-ME	0-200mM	0-200mM

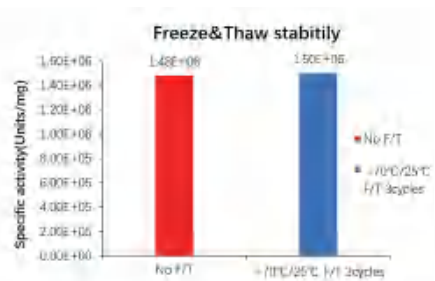
"Optimal" is defined as the condition under which GENIUS™ Nuclease retains > 90% of its activity.
"Effective" is defined as the condition under which GENIUS™ Nuclease retains > 15% of its activity.

>>> Data

★ Nucleic Acid Degradation Activity

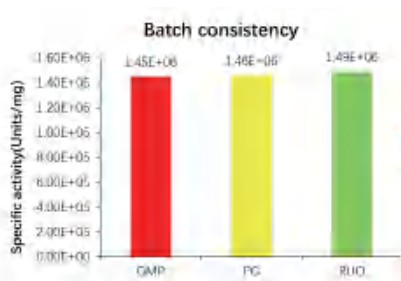


★ High Stability



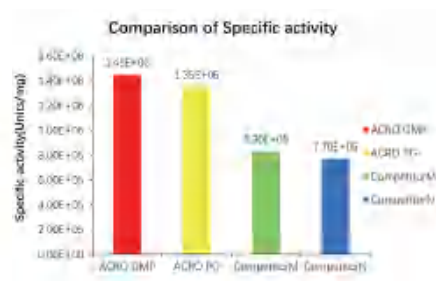
The specific activity shows that GMP GENIUS™ Nuclease is stable after 3 freeze-thaws.

★ High batch to batch consistency



The specific activity shows that GMP GENIUS™ Nuclease is stable in different batches.

★ Competitor Comparison Data



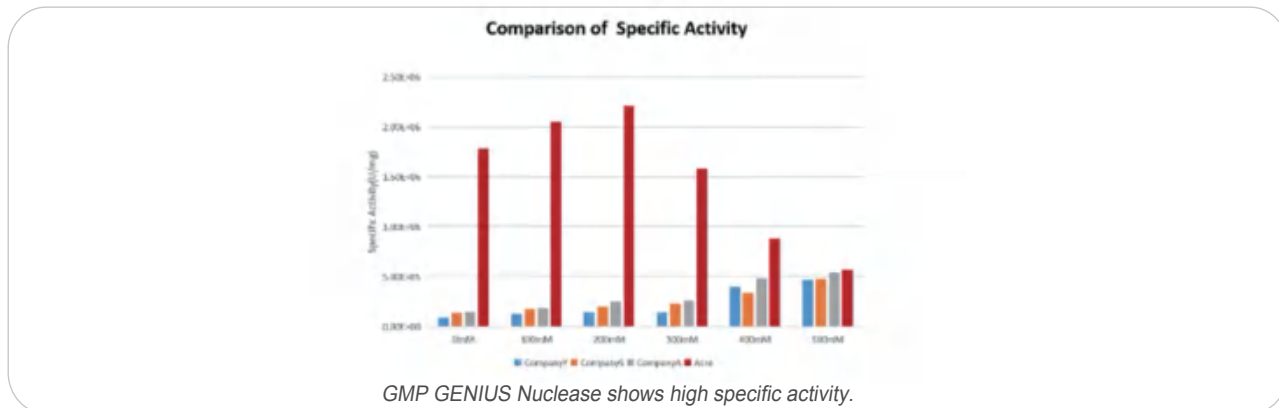
GMP GENIUS™ Nuclease shows high specific activity.



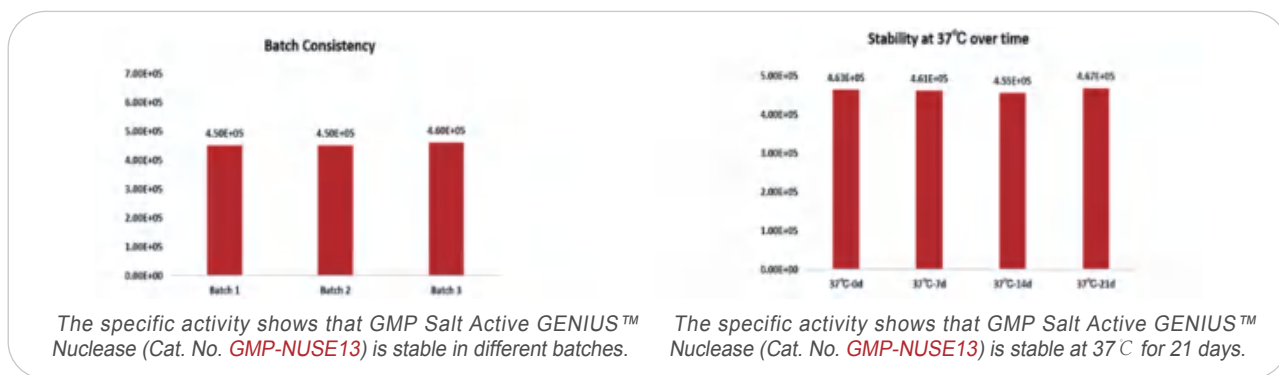
Scan the QR to
explore Salt Active
GENIUS™ Nuclease

► GMP Salt Active GENIUS™ Nuclease

>>> High enzymatic activity



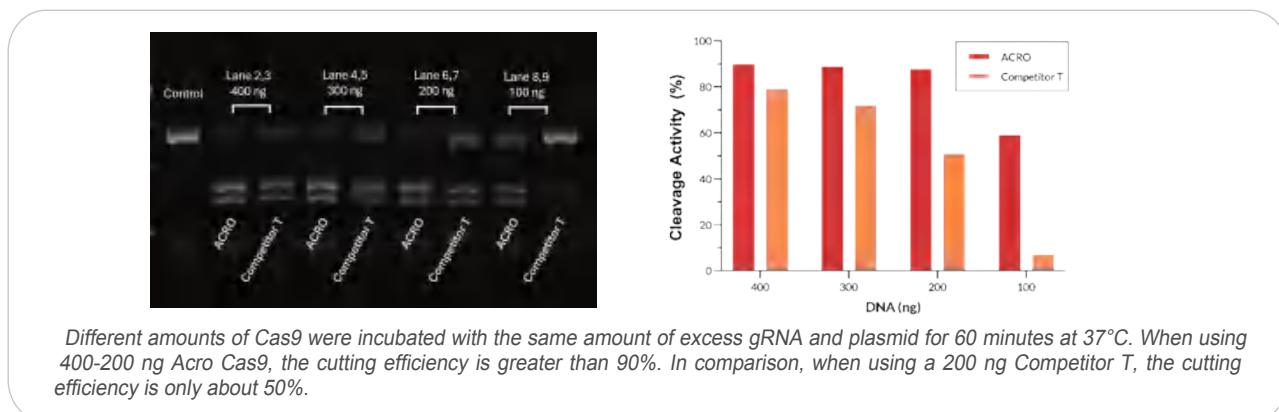
>>> Batch-to-batch consistency and stability

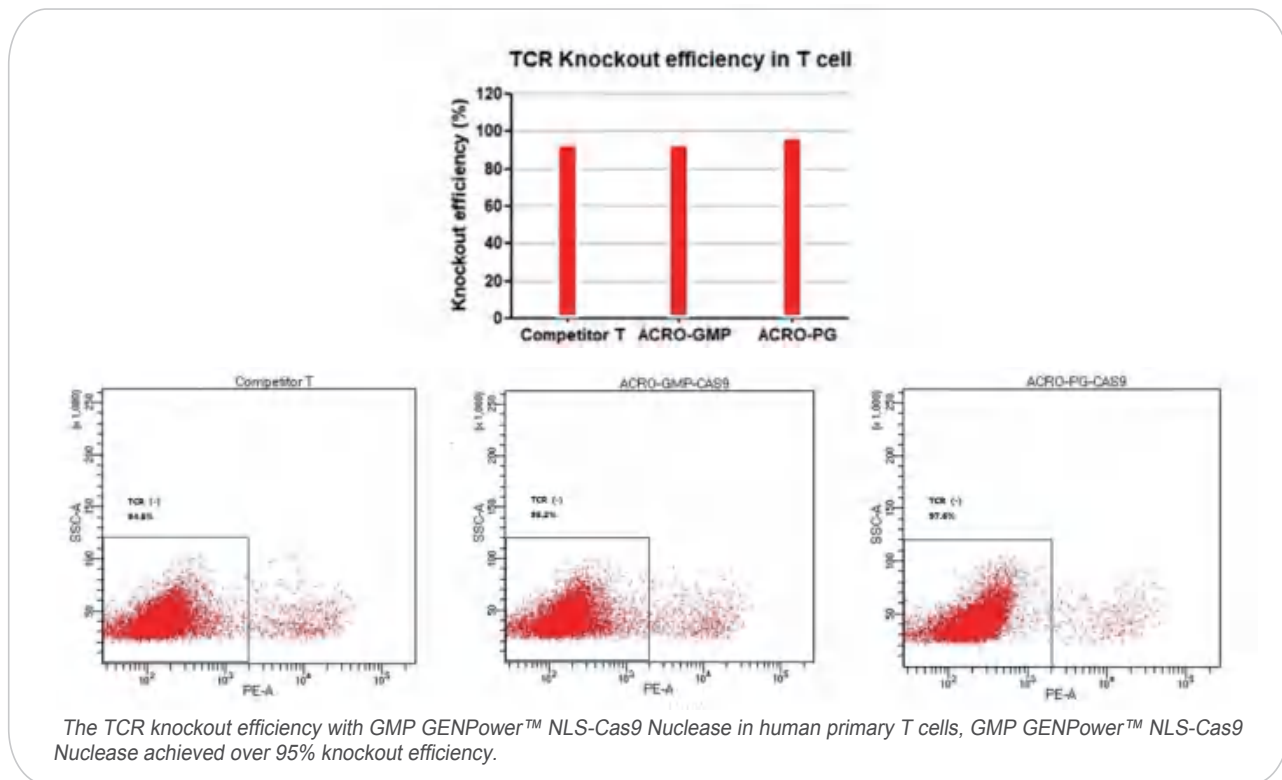


► Featured product- GMP GENPower™ NLS-Cas9 Nuclease

- 👍 High enzyme activity: improve the cutting efficiency to 90% and make it easier to edit gene by CRISPR
- 👍 High purity verified by SDS-PAGE(>95%) and SEC-HPLC(>95%)
- 👍 Sterility and low endotoxin less than 0.01 EU/ug
- 👍 Residual Host Cell Protein ≤10 ng/mg tested by ELISA
- 👍 Host Cell DNA ≤1 ng/mg tested by qPCR

>>> High bioactivity validated in vitro and in vivo, demonstrating high TCR knockout activity.

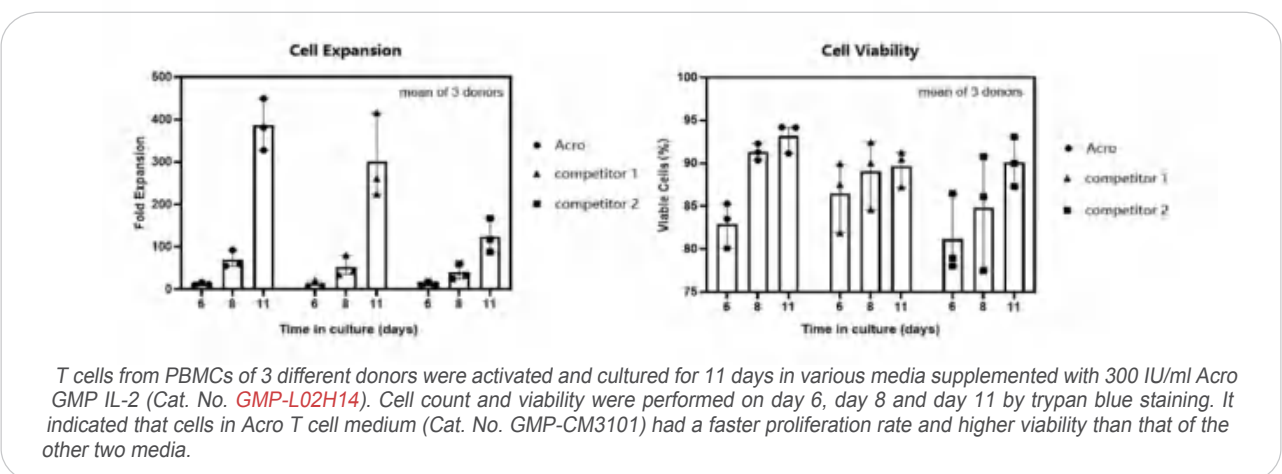




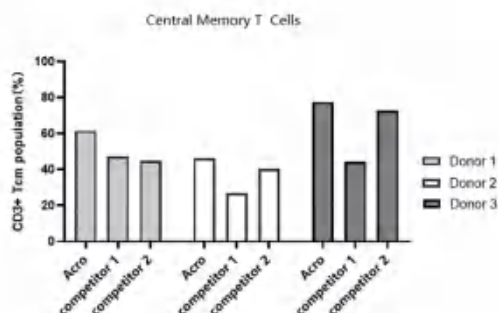
► Featured product—CelThera™ GMP T Cell Expansion Medium

CelThera™ GMP T Cell Expansion Medium is a serum-free culture medium specifically developed to support human T cell culture. It is a serum-free, animal origin-free T cell maintenance and expansion medium produced under GMP conditions.

★ T cell expansion rate and viability

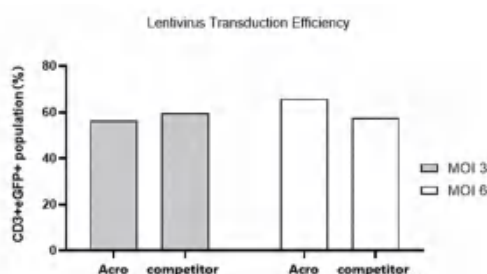


★ Tcm cell proportion



T cells from PBMCs of 3 different donors were activated and cultured in various media supplemented with 300 IU/ml Acro GMP IL-2 (Cat. No. **GMP-L02H14**). Tcm percentage (CD45RO+/CCR7+) was determined by flow cytometry when cells reached about 50-fold expansion. It indicated that cells in Acro T cell medium (Cat. No. **GMP-CM3101**) had a higher percentage of central memory T cells than that of the other two media.

★ Lentiviral transduction efficiency



T cells from PBMCs were activated and cultured in various media supplemented with 300 IU/ml Acro GMP IL-2 (Cat. No. **GMP-L02H14**). 24 hours after activation, the cells were transduced with pLenti-CMV-EGFP-puro lentivirus (MOI=3 or 6). 24hrs after transduction, the lentivirus was removed by centrifugation. Then, the cells were cultured for 48hrs and the CD3+eGFP+ population was detected by flow cytometry. It indicated that cells in Acro T cell medium (Cat. No. **GMP-CM3101**) had a similar lentiviral transduction efficiency to that of the other medium.

Quality control of CAR-T cell products

The detection of the positive rate of CAR transfection is a key test indicator for the quality control of CAR-T cell products. Regulatory authorities recommended flow cytometry to test CAR antigen-binding sites, such as target antigen. However, there is a lack of stable products suitable for this application in the market.

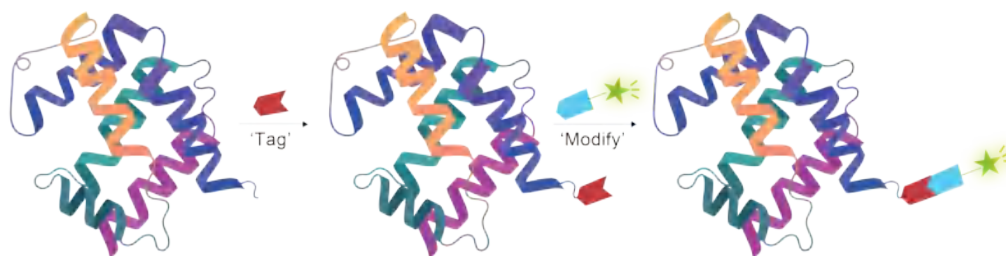
ACROBiosystems has used its professional protein research and development platform, a new fluorescent targeted labeling platform, a stable cell line development platform, and a cell-based assay platform to develop more than 50 kinds of Fluorescent-labeled CAR target antigens. These antigens are verified by flow cytometry to ensure high batch-to-batch consistency and stability.

► Product features

- 👍 50+ CAR-T targets
- 👍 PE/FITC/APC/ Alexa Fluor 647/488/555/Biotin/Unconjugated forms.
- 👍 High batch-to-batch consistency and stability to meet CAR-T cell drugs' strict quality control requirements.
- 👍 Suitable for CAR detection with high sensitivity and specificity.
- 👍 Some products have completed the FDA DMF filing (DMF number: 034936), which can support your IND, NDA, and BLA.

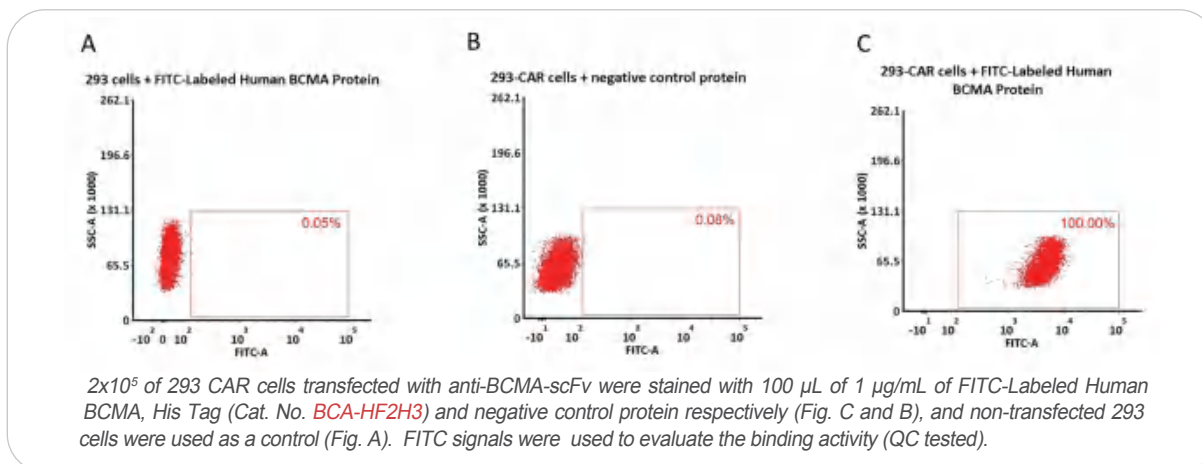
► Featured product—Star Staining FITC-labeled Human BCMA, His Tag

>>> New generation labeling technology to maintain high bioactivity.

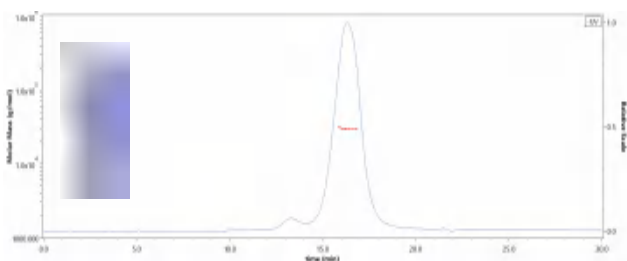


>>> Suitable for CAR detection by flow cytometry

★ FACS Analysis of Anti-BCMA CAR Expression

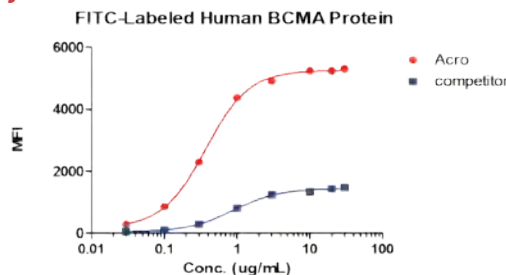


>>> High purity is more than 90% as verified by HPLC-MALS



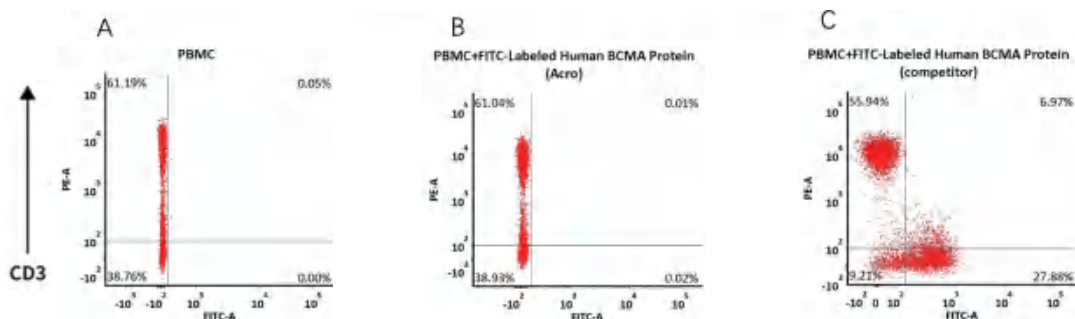
The purity of FITC-Labeled Human BCMA, His Tag (Cat. No. **BCA-HF2H3**) was more than 90%, and the MW of this protein is around 24-34 kDa as verified by HPLC-MALS.

>>> High purity is more than 90% as verified by HPLC-MALS



The binding activity of FITC-Labeled Human BCMA protein from AcroBiosystems and a competing vendor was evaluated by FACS analysis. The result showed that ACRO's Star Staining FITC-Labeled Human BCMA (Cat. No. **BCA-HF2H3**) protein has a much higher binding activity as compared to competitors.

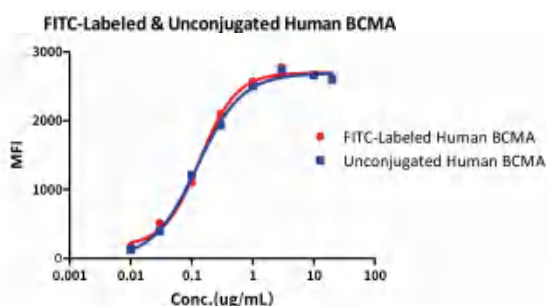
>>> No non-specific binding to non-transduced PBMCs



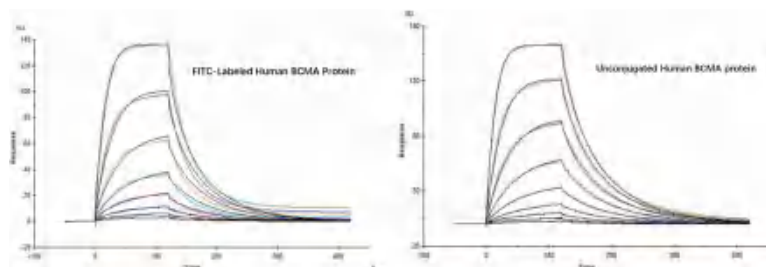
Non-specific binding to non-transduced PBMCs between FITC-Labeled Human BCMA Protein of Acro and competitor. 5e5 of non-transduced PBMCs were stained with FITC-Labeled Human BCMA Protein and anti-CD3 antibody, washed and then analyzed with FACS. PE signal was used to evaluate the expression of CD3+ T cells in non-transduced PBMCs, and FITC signal was used to evaluate the non-specific binding activity to non-transduced PBMCs.

>>> Maintain natural bioactivity

- ★ High binding capacity before and after conjugation, as verified by FACS and SPR



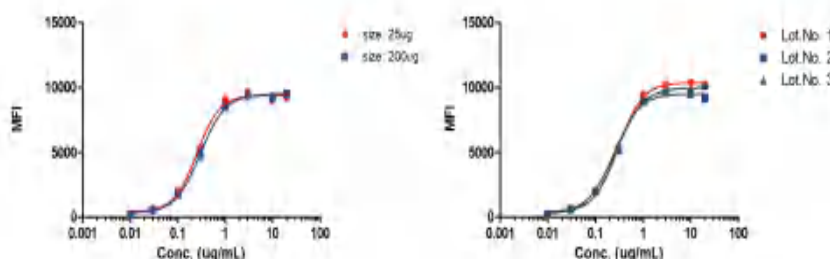
The binding activity of the Human BCMA before and after FITC labeling was evaluated in the above FACS analysis. The result shows that FITC-Labeled BCMA (Cat. No. **BCA-HF2H3**) and unconjugated Human BCMA have similar levels of binding activity.



Binding affinity of the Human BCMA before and after FITC labeling was evaluated in the above SPR analysis (Biacore T200). The result shows that FITC-Labeled (Cat. No. **BCA-HF2H3**) and unconjugated Human BCMA, His Tag have almost the same level of affinity.

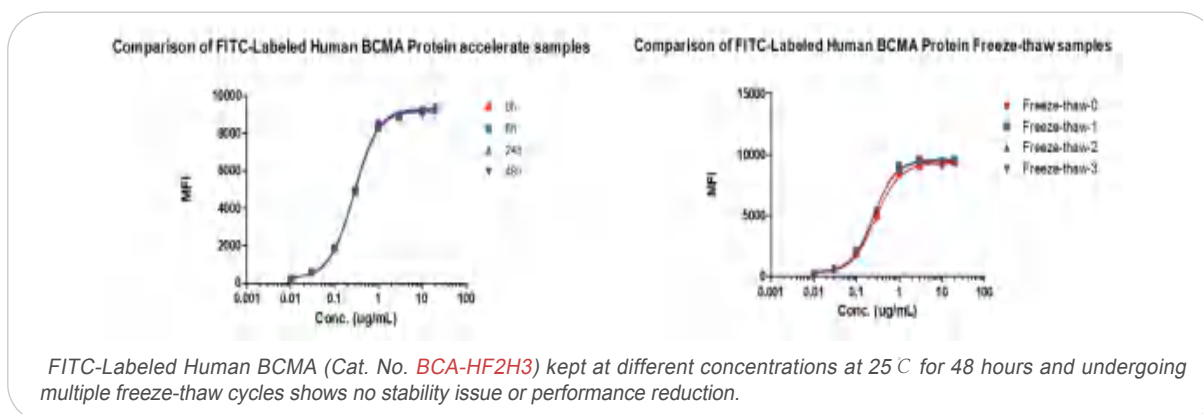
>>> High batch-to-batch consistency

- ★ FACS verified the binding activity of different lots of FITC-labeled Human BCMA protein



Binding activity of two different sizes (left) and three different lots (right) of FITC-Labeled Human BCMA (Cat. No. **BCA-HF2H3**) against anti-BCMA CAR-293 cells was evaluated by flow cytometry. The result shows very high batch-to-batch consistency.

>>> High stability



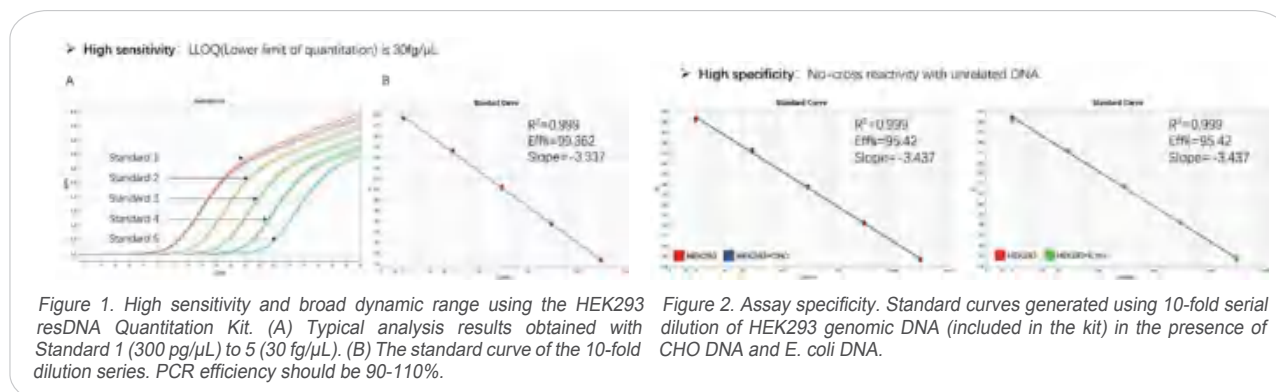
Cell and Gene therapies (CGT) face significant manufacturing challenges due to their complex processes, intrinsic safety risks, and regulatory compliance mandates. Throughout the CMC (Chemistry, Manufacturing, and Controls) production phase, residual materials such as ancillary/raw materials, additives, and host cell DNA can persist as impurities, posing safety and efficacy concerns for the final products. Stringent regulations necessitate comprehensive testing and clearance of these process-related residuals to ensure both quality and regulatory compliance. Robust residuals testing strategies are therefore essential for the successful development of CGT therapies.

Our brand, resDetect™, offers comprehensive solutions for quality control of process-related residuals, empowering and supporting your CGT drug discovery journey.

>>> Host Cell Residual Nucleic Acid Detection

HEK293/HEK293T cells and E. coli are widely used for viral and plasmid vector production in CGT manufacturing. However, residual host cell DNA (resDNA) from these systems can pose safety risks, including carcinogenicity and infectious agents. Detecting resDNA is crucial for ensuring CGT therapy safety and efficacy.

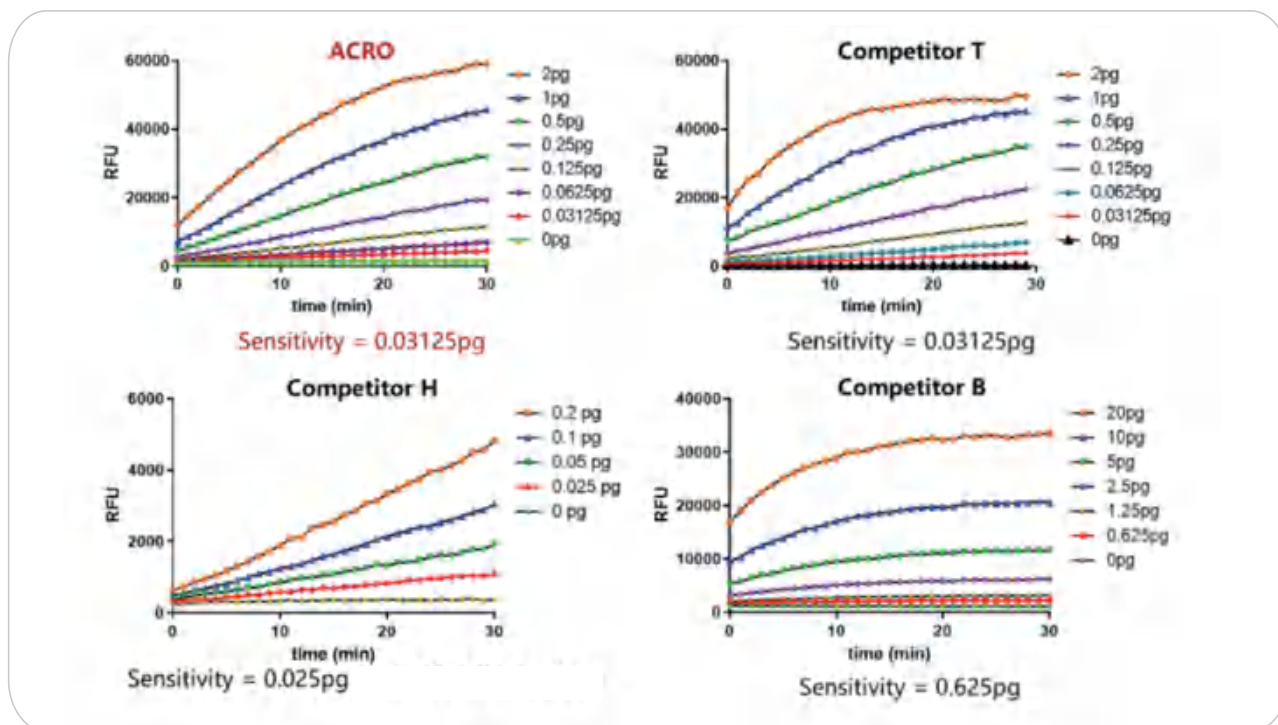
resDetect™ provides a comprehensive range of highly sensitive detection kits for various host cell types, supporting robust resDNA quality control.



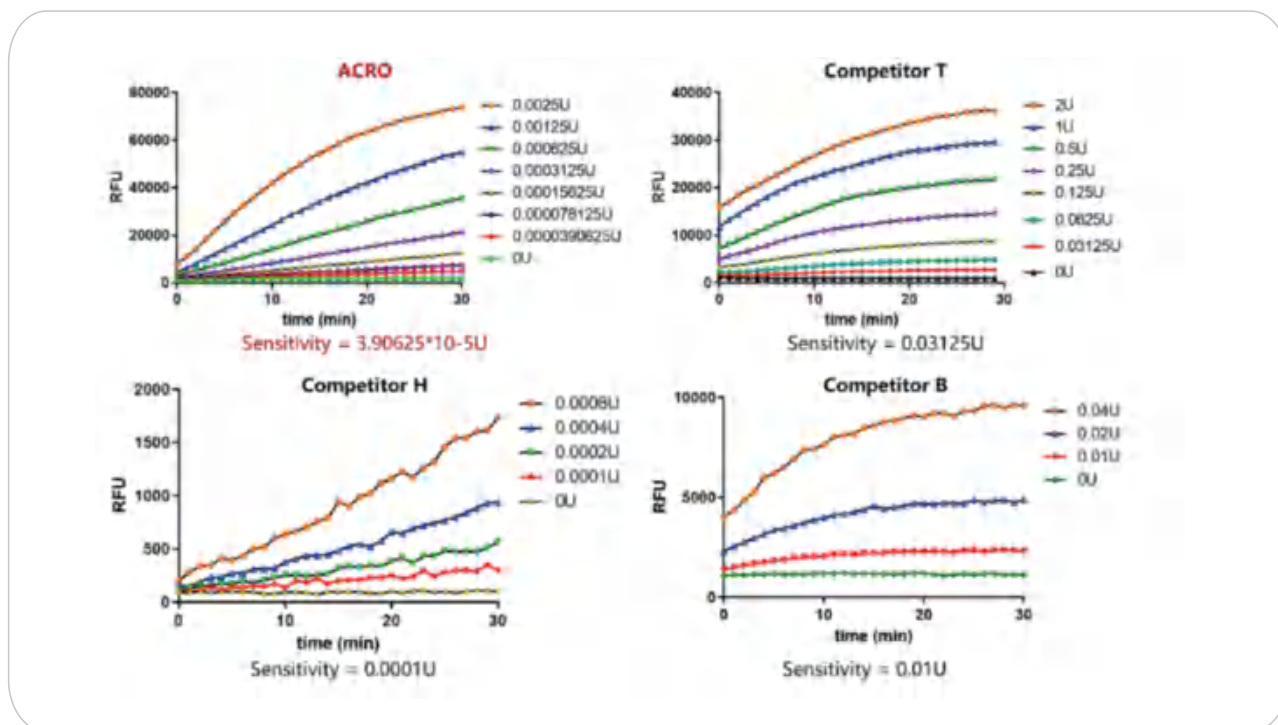
>>> Enzyme Residue Detection

During CGT production, DNase and RNase impurities can trigger strong immunogenicity and degrade DNA/RNA if introduced into the body. Therefore, it is crucial to detect residual nucleases in the experimental environment, materials, and products.

The RNase Activity Assay Kit (Fluorescence) (ASE-A001) achieves a sensitivity of 0.03125 pg, similar to the imported Competitor T brand, and superior to the majority of other brands on the market.



The DNase Activity Assay Kit (Fluorescence) (ASE-A002) achieves a sensitivity of 3.90625×10^{-5} U, surpassing the majority of other brands on the market.



>>> Antibiotic Residue Detection

Antibiotics, commonly used additives in CGT production, require strict residue control to avoid compromising drug safety and efficacy. Substances like kanamycin and gentamicin can harm the cochlear nerve, cause nephrotoxicity, and trigger allergic reactions. Regulations mandate clear guidelines on this issue. Our range of antibiotic residue detection kits boasts high sensitivity, strong specificity, minimal usage, broad applicability, and user-friendly operation.

Standard Conc. (μg/mL)	Optical Density	Optical Density	Average
1000	0.281	0.285	0.283
500	0.103	0.105	0.104
100	0.043	0.045	0.044
50	0.028	0.029	0.0285
10	0.005	0.006	0.0055

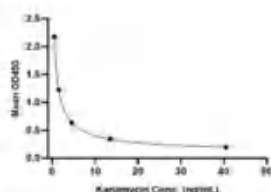


Figure 1. For each experiment, a standard curve needs to be set for each micro-plate, and the specific OD value may vary depending on different laboratories, testers, or equipments. The following example data is for reference only. (Cat. No. RES-A004)

Cross Reactant	Cross-reactivity
Kanamycin (500μg/mL)	100%
Ampicillin (500μg/mL)	<1%
Tetracycline (500μg/mL)	<1%
Chloramphenicol (500μg/mL)	<1%

Figure 2. It has been verified that no significant cross-reactivity was observed when 500 μg/mL of ampicillin, tetracycline, and chloramphenicol were individually added to the sample diluent.

Preclinical and clinical pharmacokinetics (PK) research



Scan to learn more about our residue-related products

The purpose of preclinical and clinical PK research on CAR-T cell products is to analyze the amplification and survival of CAR-T cells in vivo. Real-time fluorescence quantitative polymerase chain reaction (qPCR) and flow cytometry are usual used for such analysis, and the changes in exogenous gene copies and the number of CAR-positive cells are measured separately.

However, due to the complex cell composition of preclinical and clinical samples, low CAR-T cell content and strong non-specific background, currently available flow detection reagents cannot readily meet the needs of PK research.

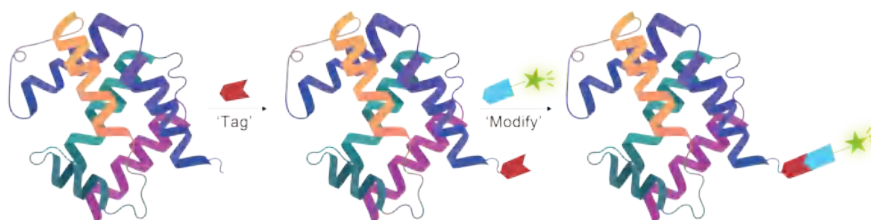
To solve this problem, ACROBiosystems has developed a series of high-sensitivity and high-specificity CAR-T target proteins and anti-unique antibodies, which are suitable for flow cytometry to detect CAR-T preclinical and clinical samples.

► Product features

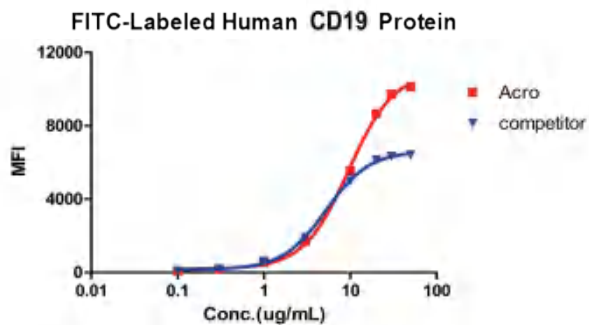
- 👍 50+ CAR-T targets
- 👍 PE/FITC/APC/ Alexa Fluor 647/488/555 forms
- 👍 High sensitivity and specificity verified by FACS
- 👍 Nonspecific binding to non-transduced PBMCs
- 👍 High batch-to-batch consistency and stability that meet the requirements of clinical sample analysis
- 👍 Some products have completed FDA DMF filing (DMF number: 034936), which can be used to support your IND, NDA, and BLA.

► Featured product—Star Staining FITC-labeled Human CD19, His Tag

>>> New generation labeling technology to maintain high bioactivity

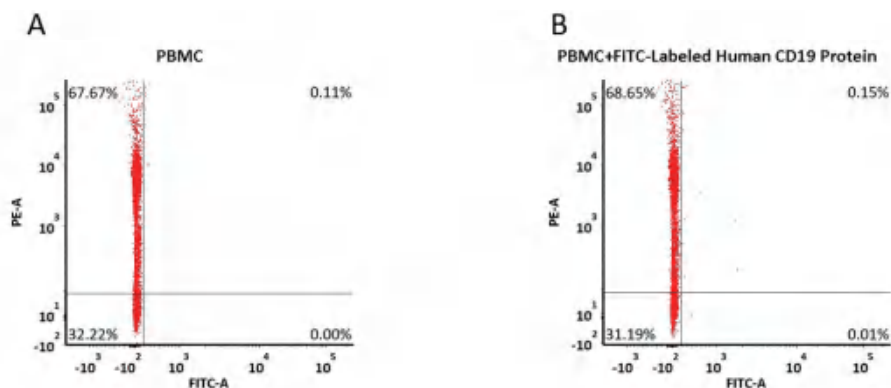


>>> Higher binding activity as compared to that of other competitors



The FACS analysis evaluated the binding activity of FITC-Labeled Human CD19 protein from two different vendors. The result shows that ACRO's Star Staining FITC-Labeled Human CD19 (Cat. No. **CD9-HF2H3**) protein has a much higher binding activity than other competitors.

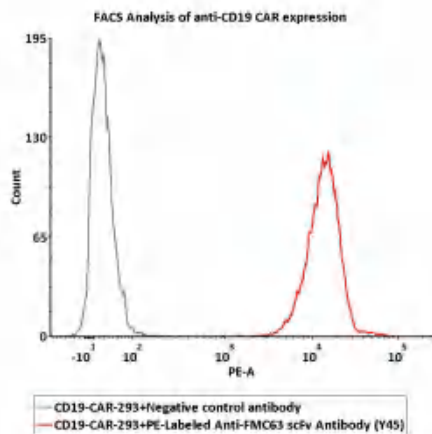
>>> No non-specific binding to non-transduced PBMCs



5e5 PBMCs were stained with FITC-Labeled Human CD19 (20-291), His Tag (Cat. No. **CD9-HF2H3**), and anti-CD3 antibody, washed and then analyzed with FACS. PE signal was used to evaluate the expression of CD3+ T cells in PBMCs. FITC signal was used to evaluate the nonspecific binding activity to PBMCs (QC tested).

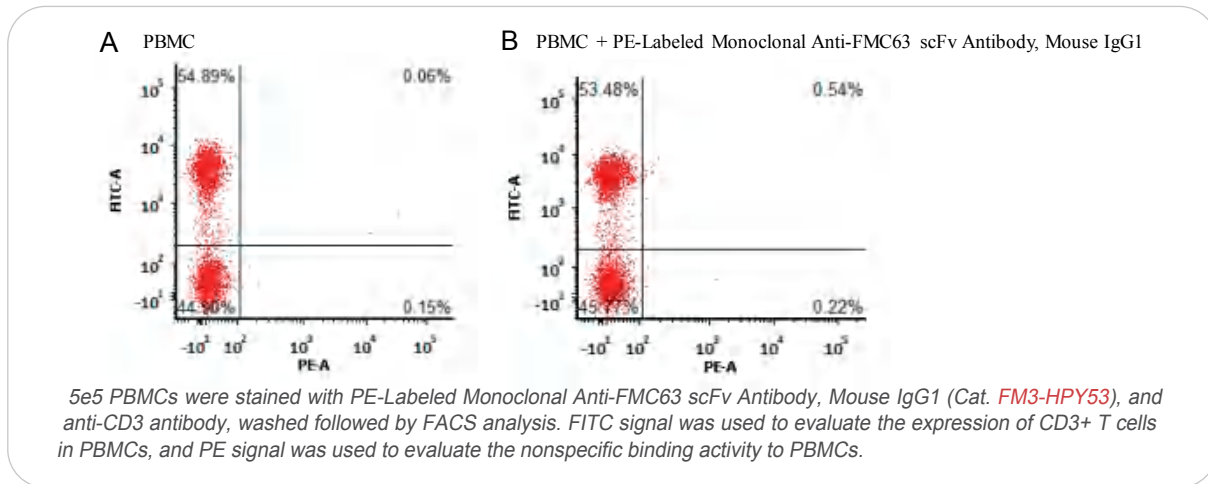
► Featured product—PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45)

>>> High sensitivity validated by FACS

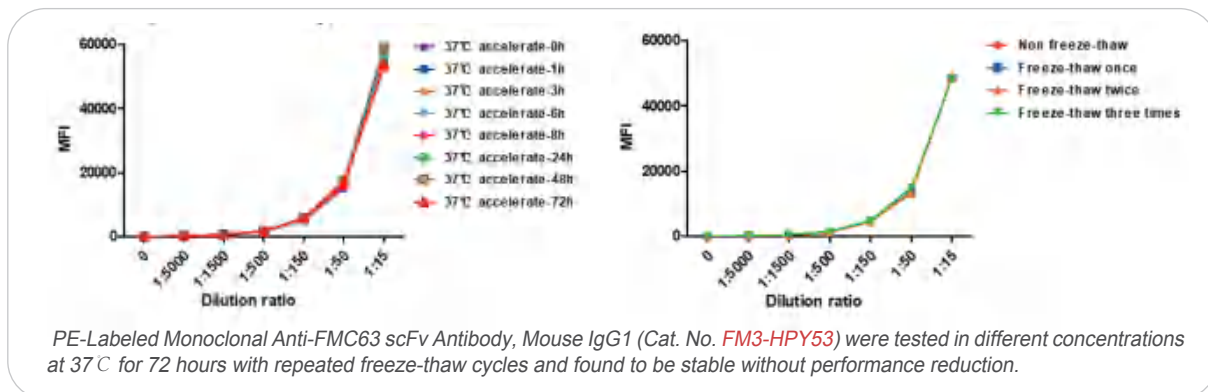
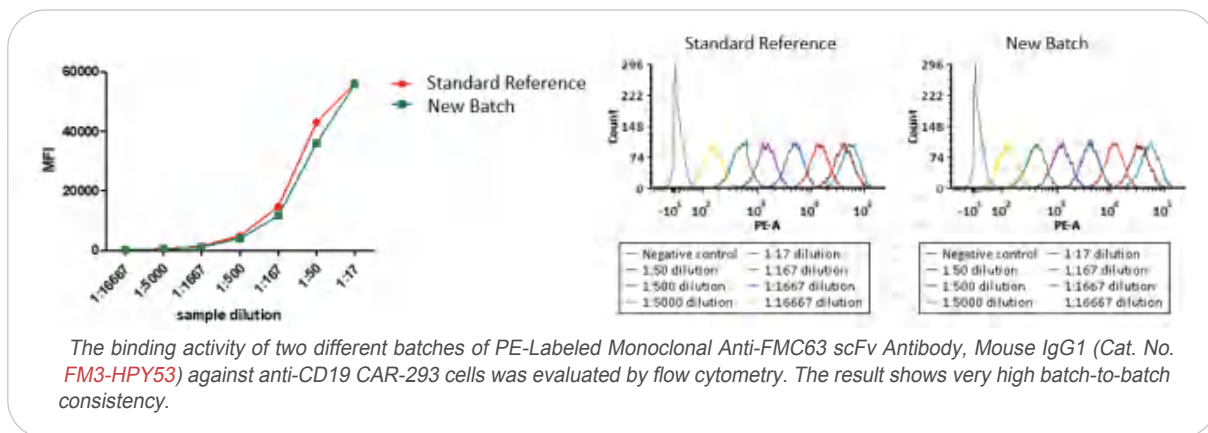


1e6 of the Anti-CD19 CAR-293 cells were stained with 100 μ L of 1:50 dilution (2 μ L stock solution in 100 μ L FACS buffer) of PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Cat. No. **FM3-HPY53**) and negative control antibody respectively. PE signal was used to evaluate the binding activity (QC tested).

>>> No non-specific binding to non-transduced PBMCs



>>> High batch-to-batch consistency and stability meet the requirements of clinical sample analysis



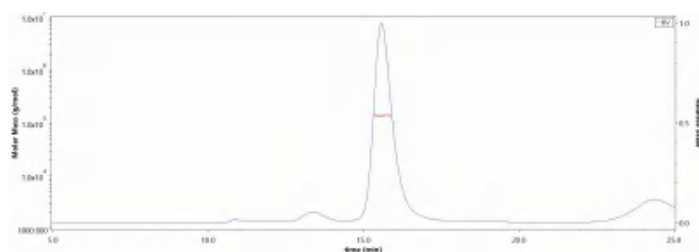
Preclinical and clinical immunogenicity evaluation

Immunogenicity is a key indicator in CAR-T cell therapy non-clinical and clinical safety research. It is mainly used to investigate the correlation between Anti-drug antibodies (ADA) produced by cell therapy drugs and pharmacokinetics, efficacy, and safety. The research content mainly focuses on the detection and characterization of anti-drug antibodies. Data on anti-drug antibodies' incidence, titer, survival time, and neutralization ability should be obtained.

Using a professional anti-idiotypic antibody research platform, ACROBiosystems has developed anti-idiotypic antibody products such as Anti-FMC63 scFv antibodies that can evaluate CAR-T cell drugs and provide customized ADA services.

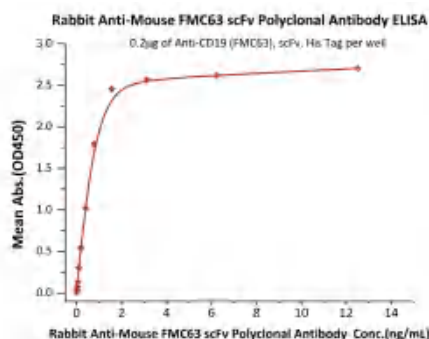
► Featured product—Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody

>>> High purity is more than 90%

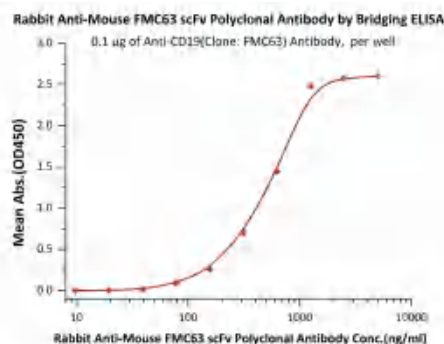


The purity of Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody (Cat. No. **FM3-S93**) was more than 90%, and the molecular weight of this protein is around 130-145 kDa, as verified by HPLC-MALS.

>>> Suitable for ADA assay development



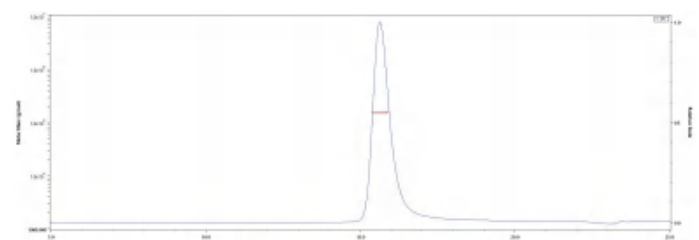
Immobilized FMC63 scFv at 2 µg/mL (100 µL/well) can bind Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody (Cat. No. **FM3-S93**) with a linear range of 0.098-0.78 ng/mL (QC tested).



Immobilized anti-CD19 antibody (Clone: FMC63) at 1 µg/mL, add increasing concentrations of Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody (Cat. No. **FM3-S93**) and then add Biotinylated anti-CD19 antibody (Clone: FMC63) at 2 µg/mL. Detection was performed using HRP-conjugated streptavidin with sensitivity of 78 ng/mL (QC tested).

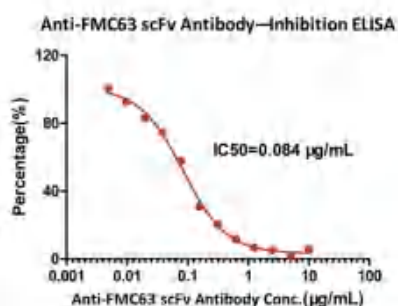
► Featured product—Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Carrier-free)

>>> >95% purity as verified by SEC-MALS



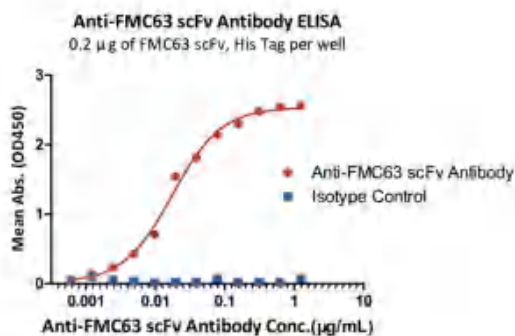
The purity of Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Carrier-free) (Cat. No. **FM3-Y45A1**) was more than 95%, and the molecular weight of this protein is around 140-160kDa as verified by SEC-MALS.

>>> Competitive inhibition ELISA verified Anti-FMC63 antibodies neutralizing activity.
Suitable for development of Neutralising ADA Detection Assay



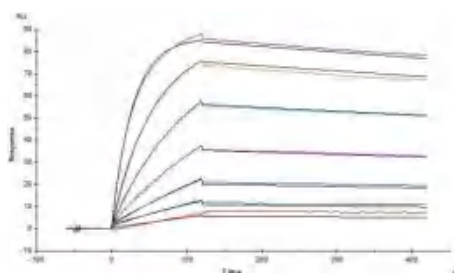
ELISA analysis shows that the binding of Human CD19, Fc Tag (Cat. No. **CD9-H5251**) to FMC63 scFv, His Tag was inhibited by increasing concentration of Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Clone Y45). The concentration of Human CD19, Fc Tag used is 5 µg/mL (100 µL/well). The IC₅₀ is 0.084 µg/mL (Routinely tested).

>>> Binding activity and specificity verified by Indirect ELISA



Immobilized FMC63 scFv, His Tag at 2 µg/mL (100 µL/well) can bind Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Clone Y45) with a linear range of 1-19 ng/mL. Anti-DNP antibody, mouse IgG1 (Cat. No. **DNP-M1**) was used as an isotype control (QC tested).

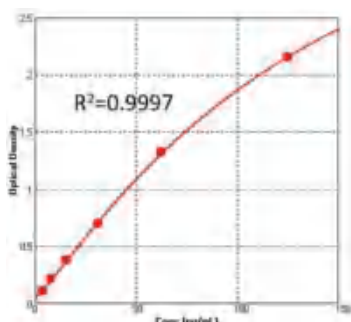
>>> High affinity verified by SPR



Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Cat. No. **FM3-Y45**) captured on CM5 chip via anti-mouse antibodies surface can bind FMC63 scFv with an affinity constant of 1.08 nM as determined in an SPR assay.

► Featured product- Anti-CD19 (FMC63) CAR Immunogenicity ELISA Kit

>>> Typical Data Please refer to DS document for The assay protocol



Detection of FMC63 ADA titer by bridging-ELISA Assay. Immobilized Mouse FMC63 scFv can bind FMC63 ADA in 1:10 human serum, and then add Biotin-Mouse FMC63 scFv. Detection was performed using HRP-conjugated streptavidin with sensitivity of 78 ng/mL (QC tested).

ACRO provides cell therapy researchers with one-stop services from antigen preparation to polyclonal anti-idiotypic antibody and immunogenicity test kit developments.

Anti-Idiotypic Antibody Development Service

One-stop services from antigen preparation to test kit developments

ACRO proteins supplied for free

miAb, CAR-T, PK/ADA assay, BiAb, ADC

Neutralizing, Non-neutralizing, Drug target complex

Please Scan the QR code for more information

Product list

► GMP Grade Products

Type	Cat.No.	Molecule	Product Description
Cytokines	GMP-L02H14	IL-2	GMP Human IL-2 Protein
	GMP-L04H26	IL-4	GMP Human IL-4 Protein
	GMP-L06H27	IL-6	GMP Human IL-6 Protein
	GMP-L07H24	IL-7	GMP Human IL-7 Protein
	GMP-L15H13	IL-15	GMP Human IL-15 Protein
	GMP-L21H25	IL-21	GMP Human IL-21 Protein
	GMP-ILBH16	IL-1 beta	GMP Human IL-1 beta Protein
	GMP-FLLH28	Flt-3 Ligand	GMP Human Flt-3 Ligand Protein
	GMP-FGBH16	FGF-8b	GMP Human FGF-8b Protein
	GMP-FGCH17	FGF basic	GMP Human FGF basic Protein
	GMP-IFGH24	IFN-gamma	GMP Human IFN-gamma Protein
	GMP-GMFH28	GM-CSF	GMP Human GM-CSF Protein
	GMP-TNAH23	TNF-alpha	GMP Human TNF-alpha Protein
	GMP-SCFH25	SCF	GMP Human SCF Protein
	GMP-PDBH19	PDGF-BB	GMP Human PDGF-BB Protein
	GMP-VE5H23	VEGF165	GMP Human VEGF165 Protein
Antibodies	GMP-MC0323	CD3	GMP Monoclonal Anti-Human CD3 Antibody (OKT3)
	GMP-MC2824	CD28	GMP Monoclonal Anti-Human CD28 Antibody
Beads	GMP-MBS001	CD3 & CD28	GMP ActiveMax® Human T cell Activation/Expansion CD3/CD28 Beads
Nuclease	GMP-CA9S18	CAS9	GMP GENPower™ NLS-Cas9 Nuclease
	GMP-NUES19	Nuclease	GMP GENIUS™ Nuclease
	GMP-NUES13	Nuclease	GMP Salt Active GENIUS™ Nuclease
Protein	GMP-DL4H28	DLL4	GMP Human DLL4 Protein, Fc Tag
	GMP-DL4H23	DLL4	GMP Biotinylated Human DLL4 Protein, His,Avitag™
	GMP-VC1H25	VCAM-1	GMP Human VCAM-1 Protein, Fc Tag
	GMP-LA5H24	Laminin 521	GMP Human Laminin 521 Protein
	GMP-41LH26	4-1BB Ligand	GMP Human 4-1BB Ligand Protein, Fc Tag
Media	GMP-CM3101	-	CelThera™ GMP T Cell Expansion Medium

► Star Staining New Generation Fluorescent-labeled Products

Molecule	Cat.No.	Product Description
BCMA	BCA-HF2H3	FITC-Labeled Human BCMA / TNFRSF17 Protein, His Tag ^{Star Staining}
CD19	CD9-HF2H3	FITC-Labeled Human CD19 (20-291) Protein, His Tag ^{Star Staining}
Mesothelin	MSN-HF2H3	FITC-Labeled Human Mesothelin / MSLN (296-580) Protein, His Tag ^{Star Staining}
Siglec-2	SI2-HF2H4	FITC-Labeled Human Siglec-2 / CD22 Protein, His Tag ^{Star Staining}
FMC63	FM3-FY57P1	FITC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) ^{Star Staining}
CD19	CD9-HP2H5	PE-Labeled Human CD19 (20-291) Protein, His Tag ^{Star Staining}
BCMA	BCA-HP2H7	PE-Labeled Human BCMA / TNFRSF17 Protein, His Tag ^{Star Staining}
Mesothelin	MSN-HP2H8	PE-Labeled Human Mesothelin / MSLN (296-580) Protein, His Tag ^{Star Staining}
CD19	CD9-HA2H9	APC-Labeled Human CD19 (20-291) Protein, His Tag ^{Star Staining}
BCMA	BCA-HA2H4	APC-Labeled Human BCMA / TNFRSF17 Protein, His Tag ^{Star Staining}
Mesothelin	MSN-HA2H6	APC-Labeled Human Mesothelin / MSLN (296-580) Protein, His Tag ^{Star Staining}

★ More Star Staining Products

>>> Alexa Fluor 647 Label

BCMA	CD19	Mesothelin	Glypican 3	CD147	CD300e
HER2	Siglec-2	Siglec-3	PD-1	OX40	MUC-1
TSLP R					

>>> Alexa Fluor 555 Label

BCMA	CD19	Mesothelin	Glypican 3	NKG2D	FAP
Nectin-4	CD37	protein L			

>>> Alexa Fluor 488 Label

BCMA	CD19	Mesothelin	Glypican 3	CD147	CD300e
HER2	Siglec-2	Siglec-3	PD-1	OX40	MUC-1
TSLP R					

>>> FITC Label

Glypican 3	HER2	CD7	Siglec-3	CD30	EGF R
EGFRVIII	GUCY2C	NKG2D	FAP	Nectin-4	CD37
protein L					

>>> PE Label

Glypican 3	NKG2D	FAP	Nectin-4	CD37	protein L
CD147	CD300e	HER2	Siglec-2	Siglec-3	PD-1
OX40	MUC-1	TSLP R			

>>> APC Label

Glypican 3	CD147	CD300e	HER2	Siglec-2	Siglec-3
PD-1	OX40	MUC-1	TSLP R		

► Targets for Cell Therapy

>>> Blood tumor

BCMA	CD19	CD123	CD138	CD20	CD22
CD30	CD33	CD37	CD38	CD4	CD5
CD56	CD7	CD72	CD99	CLL-1	CS1
GPRC5D	LILRB4	CD123	CD138	CD20	CD22

>>> Solid tumor

VEGF R2	uPAR	ROR1	PSMA	PSCA	NKG2D
Nectin-4	MUC16	MUC1	MSLN	IL13RA2	HGF R
HER3	HER2	GUCY2C	GPC3	FOLR1	FAP
EpCAM	EGFRVIII	EGFR	EBV	DLL3	CLDN18
CEA	CD70	CD47	CD147	CD133	CAIX
B7-H3					

>>> PE Label

Glypican 3	NKG2D	FAP	Nectin-4	CD37	protein L
CD147	CD300e	HER2	Siglec-2	Siglec-3	PD-1
OX40	MUC-1	TSLP R			

>>> APC Label

Glypican 3	CD147	CD300e	HER2	Siglec-2	Siglec-3
PD-1	OX40	MUC-1	TSLP R		

► Targets for Cell Therapy

>>> Blood tumor

BCMA	CD19	CD123	CD138	CD20	CD22
CD30	CD33	CD37	CD38	CD4	CD5
CD56	CD7	CD72	CD99	CLL-1	CS1
GPRC5D	LILRB4	CD123	CD138	CD20	CD22

>>> Solid tumor

VEGF R2	uPAR	ROR1	PSMA	PSCA	NKG2D
Nectin-4	MUC16	MUC1	MSLN	IL13RA2	HGF R
HER3	HER2	GUCY2C	GPC3	FOLR1	FAP
EpCAM	EGFRVIII	EGFR	EBV	DLL3	CLDN18
CEA	CD70	CD47	CD147	CD133	CAIX
B7-H3					

>>> MHC peptide complex related alleles and targets

MHC Allele				Target			
HLA-A*0101	HLA-A*0201	HLA-A*0301	HLA-A*1101	NY-ESO-1	GP100	MSLN	AFP
HLA-A*2402	HLA-A*30:01	HLA-A*3303	HLA-B*1501	WT-1	MAGE	HPV	HBV
HLA-B*1525	HLA-B*3802	HLA-B*4601	HLA-B*0702	HIV	EBV	RYR	CMV
HLA-C*0102	HLA-C*0303	HLA-C*07:02:01		RHAMM-R3	Glycican 3	KRAS	EW
HLA-DQA1*03:02&DQB1*03:03				HER2	P53	PRAME	PSMA
.....						

► Anti-idiotypic Antibodies

Cat.No.	Species	Product Description	Application
FM3-AY54P1	Mouse	APC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation)	CAR expression by flow cytometry in preclinical and clinical samples
FM3-HPY53	Mouse	PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation) DMF Filed	
FM3-PY54A2	Mouse	PE-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Site-specific conjugation) DMF Filed (0.03% Proclin)	
FM3-FY45P1	Mouse	FITC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (HEK293)	
FM3-FY45	Mouse	FITC-Labeled Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) DMF Filed	
FM3-BY54	Mouse	Biotinylated Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1, Avitag™ (Y45) DMF Filed	ADA assay development
FM3-BY45	Mouse	Biotinylated Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) DMF Filed	
FM3-Y45P1	Mouse	Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (HEK293) DMF Filed	
FM3-Y45	Mouse	Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) DMF Filed	
CD9-BV4324b	Mouse	Biotinylated Anti-CD19 scFv, Fc, Avitag™ (FMC63) (MALS verified)	

Cat.No.	Species	Product Description	Application
FM3-Y45A1	Mouse	Monoclonal Anti-FMC63 scFv Antibody, Mouse IgG1 (Y45) (Carrier-free) (recommended for ADA assay) DMF Filed	ADA assay development
FM3-S93	Rabbit	Rabbit Anti-Mouse FMC63 scFv Polyclonal Antibody (recommended for ADA assay) (MALS verified)	

► Magnetic Beads

Cat.No.	Product Description
MBS-C001	ActiveMax® Human T cell Activation/Expansion CD3/CD28 Beads, premium grade DMF Filed
MBS-C002	ActiveMax® Human CD19 µBeads, premium grade (for cells)
MBS-C003	ActiveMax® Human MSLN µBeads, premium grade (for cells)
MBS-C004	ActiveMax® Human BCMA µBeads, premium grade (for cells)
MBS-C005	ActiveMax® Human CD7 µBeads, premium grade (for cells)
MBS-C006	ActiveMax® Human Her2 µBeads, premium grade (for cells)
MBS-C007	ActiveMax® Human CD22 µBeads, premium grade (for cells)
MBS-C008	ActiveMax® Anti-FMC63 Antibody µBeads, premium grade (for cells)
MBS-C009	ActiveMax® Streptavidin µBeads, premium grade (for cells)
MBS-C012	ActiveMax® Human 4-1BB Ligand / TNFSF9 (71-254) µBeads, premium grade (for cells)
MBS-C013	ActiveMax® Human DLL4 µBeads, premium grade (for cells)
MBS-C014	ActiveMax® Human CEACAM-5 / CD66e µBeads, premium grade (for cells)
MBS-C018	ActiveMax® Human DLL3 µBeads, premium grade (for cells)

► Nucleases

Molecule	Cat.No.	Product Description
Cas9	CA9-S5149	NLS-Cas9 Nuclease
Cas9	GMP-CA9S18	GMP GENPower™ NLS-Cas9 Nuclease
Cas12a	CAA-L5149	NLS-Cas12a Nuclease
Nuclease	BEE-N3116	GENIUS™ Nuclease DMF Filed
Nuclease	NUE-S5119	GENIUS™ Nuclease, premium grade
Nuclease	GMP-NUES19	GMP GENIUS™ Nuclease DMF Filed
Nuclease	NUE-S5118	Salt Active GENIUS™ Nuclease
Nuclease	GMP-NUES13	GMP Salt Active GENIUS™ Nuclease

► Residue Testing Kits

Type	Cat.No.	Molecule	Product Description
Host Cell Residual Nucleic Acid Detection	OPA-O002	DNA	resDetect™ <i>E. coli</i> resDNA Quantitative Kit (qPCR)
	OPA-R010	DNA	resDetect™ HEK293T resDNA Quantitation Kit (qPCR)
	OPA-R006	DNA	resDetect™ HEK293 resDNA Quantitation Kit (qPCR)
	OPA-R007	DNA	resDetect™ E1A&SV40LTA resDNA Quantitation Kit (qPCR)
	OPA-R008	DNA	resDetect™ E1A resDNA Quantitation Kit (qPCR)
	OPA-R009	DNA	resDetect™ Plasmid resDNA Quantitation Kit (qPCR)
	OPA-R004	DNA	resDetect™ CHO resDNA Quantitation Kit (qPCR)
	OPA-R017	DNA	resDetect™ Pichia pastoris resDNA Quantitation Kit (qPCR)
	OPA-R005	DNA	resDetect™ resDNA Sample Preparation Kit (Magnetic Beads)
	OPA-R024	DNA	resDetect™ resDNA Sample Preparation Kit II (Magnetic Beads)
	OPE-32S	-	resDetect™ Automated Nucleic Acid Extraction System
	OPA-R013	-	resDetect™ 96 V-Bottom Deep-well Plate
	OPA-R014	-	resDetect™ 8-Strip V-Bottom Tip Comb

Type	Cat.No.	Molecule	Product Description
Enzyme Residue Detection	ASE-A002	DNase I	resDetect™ DNase Activity Assay Kit (Fluorescence)
	ASE-A001	RNase A	resDetect™ RNase Activity Assay Kit (Fluorescence)
	CAS-C001	Cas9	resDetect™ Cas9 (CRISPR Associated Protein 9) ELISA Kit (Residue Testing)
	RES-A054	Nuclease	resDetect™ Salt Active GENIUS™ Nuclease Nuclease ELISA Kit (Residue Testing)
	CRS-A031	Nuclease	resDetect™ GENIUS™ Nuclease ELISA Kit (Residue Testing)
	RES-A018	T7 RNA polymerase	resDetect™ T7 RNA Polymerase ELISA Kit (Residue Testing)
	RES-A005	Pyrophosphatase	resDetect™ Pyrophosphatase ELISA Kit
Affinity Ligand Residue Detection	RES-A024	protein A (SuRe)	resDetect™ Universal Protein A Quick ELISA kit
	RES-A029	protein A (SuRe)	resDetect™ Universal Protein A Quick ELISA Kit (Boiling-free)
Antibiotic Residue Detection	RES-A004	Kanamycin	resDetect™ Kanamycin ELISA Kit
	RES-A025	Gentamicin	resDetect™ Gentamicin ELISA Kit
Cytokine & Antibody Residue Detection	CRS-A003	IL-2	resDetect™ Human Interleukin-2 (IL-2) ELISA Kit (Residue Testing)
	CRS-A004	IL-4	resDetect™ Human Interleukin-4 (IL-4) ELISA Kit (Residue Testing)
	CRS-A005	IL-6	resDetect™ Human Interleukin-6 (IL-6) ELISA Kit (Residue Testing)
	CRS-A025	IL-7	resDetect™ Human Interleukin-7 (IL-7) ELISA Kit (Residue Testing)
	CRS-A024	IL-15	resDetect™ Human Interleukin-15 (IL-15) ELISA Kit (Residue Testing)
	CRS-A010	IL-21	resDetect™ Human Interleukin-21 (IL-21) ELISA Kit (Residue Testing)
	RES-A027	TNF-alpha	resDetect™ Human Tumor Necrosis Factor Alpha (TNF-α) ELISA Kit (Residue Testing)
	RES-A028	IFN-gamma	resDetect™ Human Interferon-γ (IFN-γ) ELISA Kit (Residue Testing)
	RES-A009	FGF2	resDetect™ Human FGF2 ELISA Kit (Residue Testing)
	RES-A052	DLL4	resDetect™ Human Fc Tag DLL4 ELISA KIT (Residue Testing)
	RES-A022	DLL4	resDetect™ Biotinylated Human DLL4 ELISA Kit (Residue Testing)
	CRS-A015	CD3	resDetect™ Anti-CD3 Antibody ELISA Kit
	CRS-A014	CD28	resDetect™ Anti-CD28 Antibody ELISA Kit

► Cytokine ELISA Kits

Cat.No.	Product Description
CEA-B030	Human Soluble Mesothelin ELISA Kit, PRO
CEA-B032	Human Soluble TROP2 ELISA Kit, PRO
CEA-B033	Human Granzyme B ELISA Kit
CEA-B034	Human Perforin ELISA Kit
CEA-B036	Human MCP-1 / CCL2 ELISA Kit
CEA-B038	Human Soluble Delta Like Protein 4 (DLL4) ELISA Kit, PRO
CEA-B039	Human Soluble CD38 ELISA Kit
CEA-B040	Human NKp46/NCR1 ELISA Kit, PRO
CEA-B046	Human Soluble Siglec-2 / CD22 ELISA Kit, PRO
CEA-B048	Human Soluble CD73 / NT5E ELISA Kit, PRO
CEA-B050	Human Soluble ROR1 ELISA Kit, PRO
CEA-B089	Human ANGPTL3 ELISA Kit, PRO
CEA-C004	Human IL-8 ELISA Kit, PRO
CEA-C006	Human IFN- γ ELISA Kit, PRO
CEA-C027	Human Erythropoietin (EPO) ELISA Kit, PRO
CEA-C028	Human CXCL10/IP-10 ELISA Kit
CEA-C029	Human TARC/CCL17 ELISA Kit
CEA-C068	Human VEGF ELISA Kit
CEA-C074	Human TSLP ELISA Kit
CEA-C077	Human GDF-15 ELISA Kit
CEA-C078	Human SCF ELISA Kit
CEA-C080	Human EGF ELISA Kit
CEA-C092	Human IL-17A / CTLA8 ELISA Kit
CEA-C203	Human IL-12/IL-23 p40 ELISA Kit
CRS-A002	Human Tumor Necrosis Factor Alpha (TNF- α) ELISA Kit
CRS-A017	Human Interferon- γ (IFN- γ) ELISA Kit
CRS-B001	Human IL-6 ELISA Kit
CRS-B002	Human IL-1 β ELISA Kit
CRS-B003	Human IL-4 ELISA Kit
CRS-B004	Human IL-8 ELISA Kit
CRS-B005	Human IL-10 ELISA Kit
CRS-B007	Human GM-CSF ELISA Kit
CRS-B008	Human IL-2 ELISA Kit
CRS-B009	Human IL-12p70 ELISA Kit
CRS-B012	Human HGF ELISA Kit
CRS-B016	Human C-Reactive Protein (CRP) ELISA Kit

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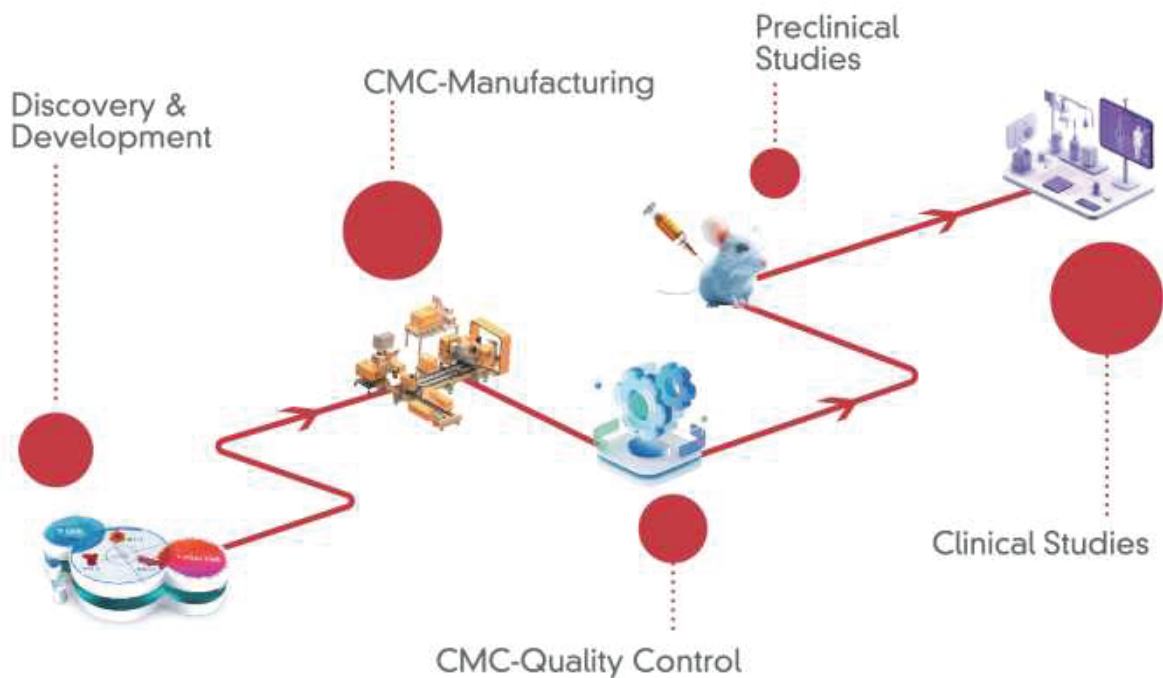
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