



- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- FDA DMF filed
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests

Source

HEK293 cells-expressed human GMP Monoclonal Anti-Human CD28 Antibody.

Isotype

Mouse IgG1/Kappa

Specificity

The cross-reactivity with other species has not been tested yet.

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

Endotoxin

Less than 2 EU/mg by the LAL method.

Protein A

<5 ppm of protein tested by ELISA.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Formulation

Supplied as 0.2 μm filtered solution in PBS, polysorbate 80, pH7.4 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with dry ice, please inquire the shipping cost.

Storage

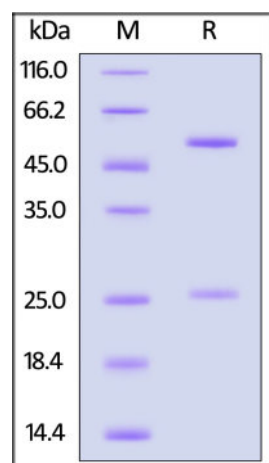
For long term storage, the product should be stored at liquid state at -70°C.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

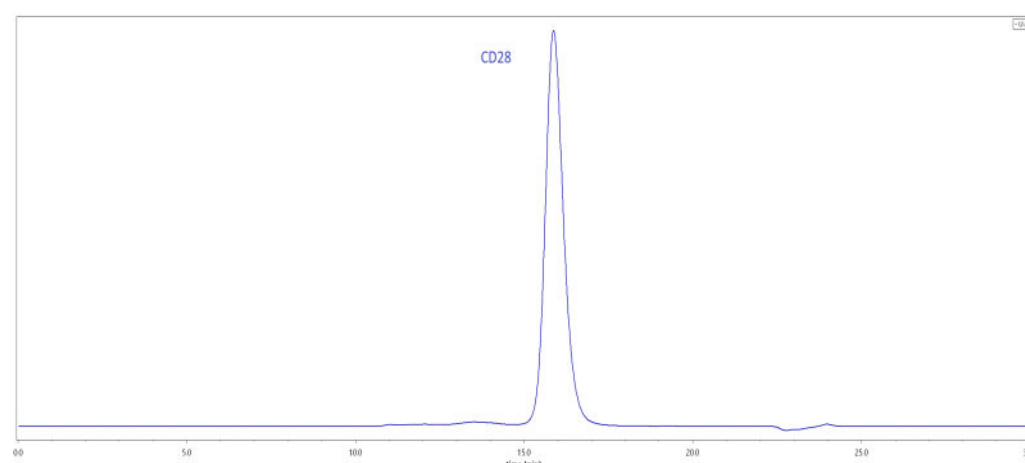
- 2-8°C for 12 months under sterile condition;
- -70°C for 5 years.

SDS-PAGE



GMP Monoclonal Anti-Human CD28 Antibody on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the

SEC-HPLC



The purity of GMP Monoclonal Anti-Human CD28 Antibody(Cat. No. GMP-MC2824) is more than undefined and the molecular weight of this protein is

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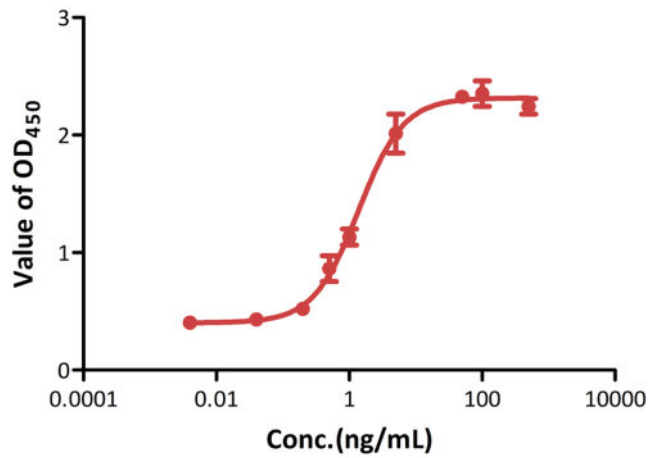


protein is greater than 95%.

around undefined verified by SEC-MALS.

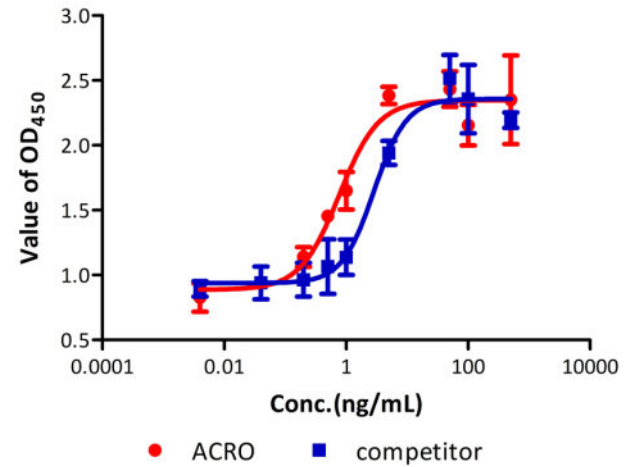
Bioactivity-Bioactivity CELL BASE

GMP Monoclonal Anti-Human CD28 Antibody stimulates secretion of IL-2 by PBMC



GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) stimulates secretion of IL-2 by PBMC stimulated with 4ng/mL GMP Monoclonal Anti-Human CD3 Antibody (OKT3). The typically EC50 for this effect is 1.382 ng/mL (QC tested).

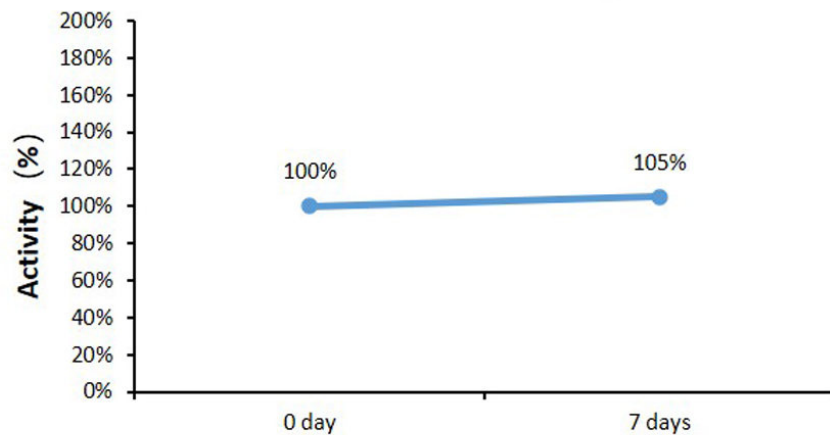
Monoclonal Anti-Human CD28 Antibody, Mouse IgG1 stimulates secretion of IL-2 by PBMC



The activity of GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) was higher than other competing products.

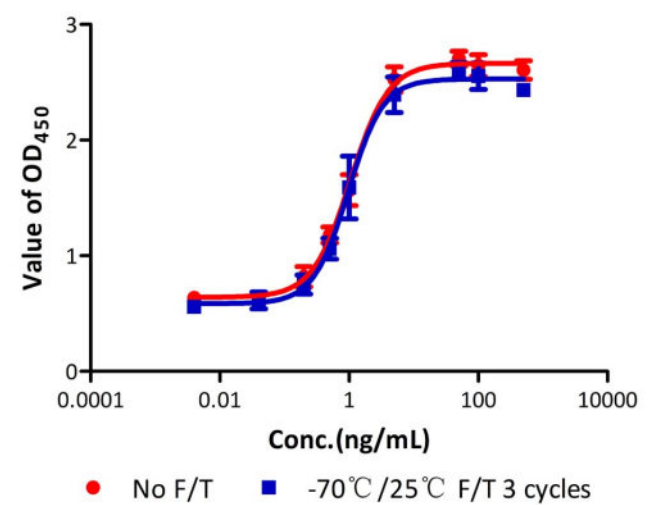
Bioactivity-Stability

37°C Accelerated Stability



The Cell based assay shows that GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) is stable at 37°C for 7 days.

Freeze & Thaw stability



The Cell based assay shows that GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) is stable after freezing and thawing 3 times.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents:

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

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Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files (RSF)

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

SDS-PAGE

Protein content

Endotoxin level

Residual Host Cell DNA content

Residual Host Cell Protein content

Biological activity analysis

Microbial testing

Mycoplasma testing

In vitro virus assay

Batch-to-batch consistency

Background

T-cell-specific surface glycoprotein CD28 is also known as TP44, is a single-pass type I membrane protein which contains one Ig-like V-type (immunoglobulin-like) domain. is one of the molecules expressed on T cells that provide co-stimulatory signals, which are required for T cell activation. CD28 is the receptor for CD80 (B7.1) and CD86 (B7.2). When activated by Toll-like receptor ligands, the CD80 expression is upregulated in antigen presenting cells (APCs). The CD86 expression on antigen presenting cells is constitutive. CD28 is the only B7 receptor constitutively expressed on naive T cells.

Clinical and Translational Updates

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