



## Features

- 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 CD3 Antibody (OKT3).

## Isotype

Mouse IgG2a/kappa

## Conjugate

Unconjugated

## Specificity

This product is a specific antibody specifically reacts with CD3 epsilon.

## 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.

## Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

## Sterility

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

## Mycoplasma

Negative.

## Formulation

Supplied as 0.2 μm filtered solution in PBS, 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.*

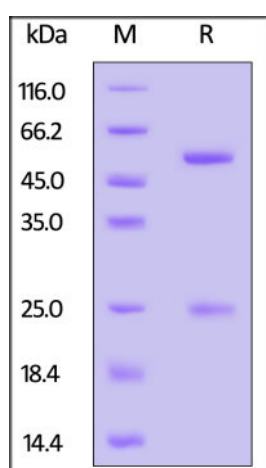
## Storage

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

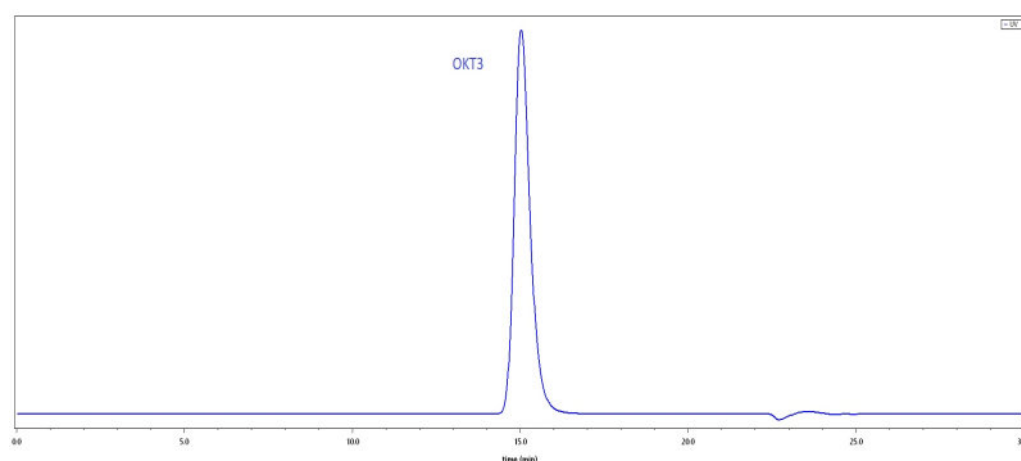
This product is stable after storage at:

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

## SDS-PAGE



## SEC-HPLC



Discounts, Gifts,  
and more!



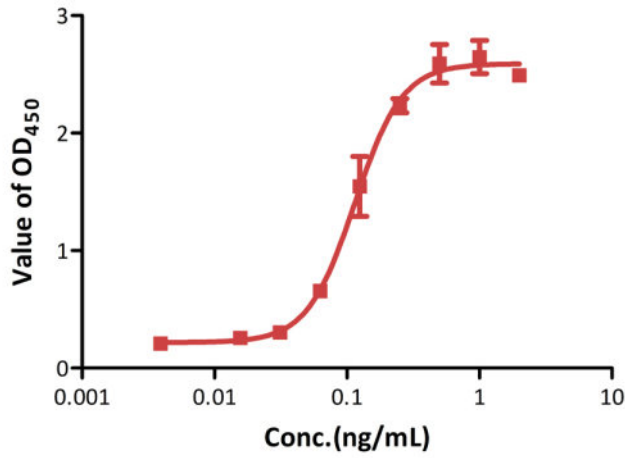


GMP Monoclonal Anti-Human CD3 Antibody (OKT3) on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

The purity of GMP Monoclonal Anti-Human CD3 Antibody (OKT3)(Cat. No. GMP-MC0323) is more than undefined and the molecular weight of this protein is around undefined verified by SEC-MALS.

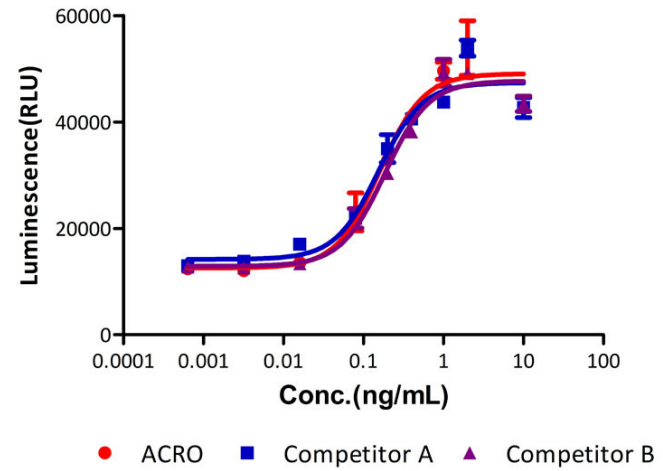
**Bioactivity-Bioactivity CELL BASE**

**GMP Monoclonal Anti-Human CD3 Antibody (OKT3) stimulates secretion of IL-2 by PBMC**



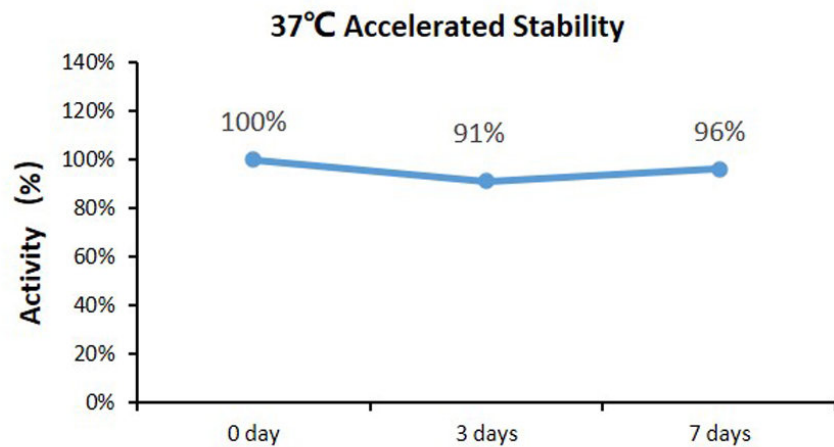
GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323) stimulates secretion of IL-2 by PBMC stimulated with 10 ng/mL Monoclonal Anti-Human CD28 Antibody, Mouse IgG1. The typically EC50 for this effect is 0.11 ng/mL (QC tested).

**Monoclonal Anti-Human CD3 Antibody, Mouse IgG2a (Clone: OKT3), Ultra-low endotoxin stimulates proliferation of PBMC**



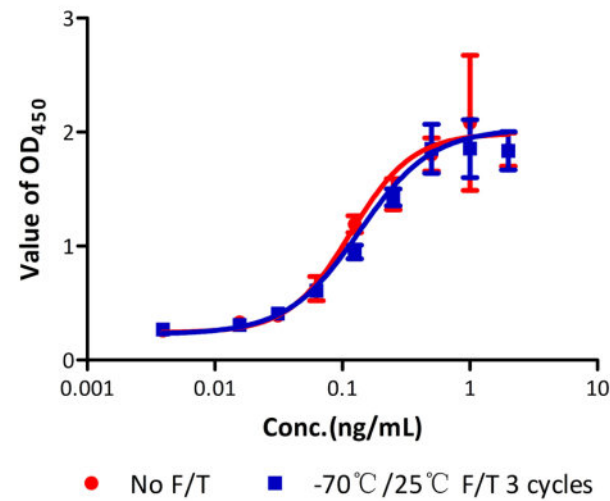
The activity of GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323) was higher than other competing products.

**Bioactivity-Stability**



The Cell based assay shows that GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323) is stable at 37°C for 7 days.

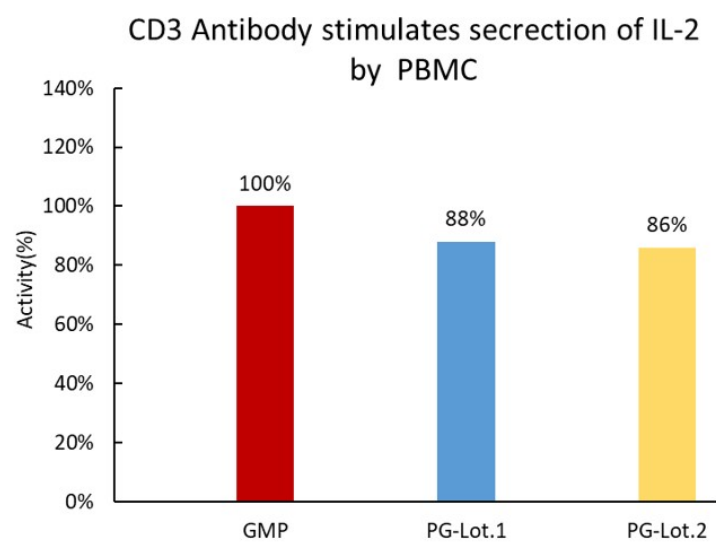
**Freeze & Thaw stability**



The Cell based assay shows that GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323) is stable after freezing and thawing 3 times.

Discounts, Gifts, and more!





The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG CD3 Antibody.

## 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.

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



# GMP Monoclonal Anti-Human CD3 Antibody (OKT3)

Catalog # GMP-MC0323



- 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

CD3ε molecule, epsilon is also known as CD3E, is a T-cell surface single-pass type I membrane glycoprotein. CD3E contains 1 Ig-like (immunoglobulin-like) domain and 1 ITAM domain. CD3E, together with CD3-γ, CD3-δ and CD3-ζ, and the T-cell receptor α/β and γ/δ heterodimers, forms the T cell receptor-CD3 complex. This complex plays an important role in coupling antigen recognition to several intracellular signal-transduction pathways. The genes encoding the epsilon, gamma and delta polypeptides are located in the same cluster on chromosome 11. The epsilon polypeptide plays an essential role in T-cell development. CD3E plays an essential role in T-cell development, and defects in CD3E gene cause severe immunodeficiency. CD3E gene has also been linked to a susceptibility to type I diabetes in women. CD3E has been shown to interact with TOP2B, CD3EAP and NCK2.

## Clinical and Translational Updates

Discounts, Gifts,  
and more!

