



GMP Platform Advantages

- **Quality Assurance:** Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance:** Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents:** Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support:** Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain:** Intelligent modular facilities ensure a stable global supply.
- **Professional Support:** Extensive manufacturing and application expertise to accelerate development.

Source

GMP Monoclonal Anti-Human 4-1BB Antibody (GMP-M41B35) is a chimeric monoclonal antibody recombinantly produced from CHO cells, which combines the variable region of a human monoclonal antibody with mouse IgG1 constant domain.

Isotype

Mouse IgG1 | Mouse Kappa

Conjugate

Unconjugated

Specificity

This product is a specific antibody specifically reacts with 4-1BB.

Endotoxin

Less than 2 EU/mg, tested by the rFC method in compliance with USP <86> and Ph. Eur. 2.6.32.

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.

Sterility

Sterility testing was performed using the membrane filtration method in compliance with 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.

Vial Specification

2R (13 mm neck finish)

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 -20°C or below.

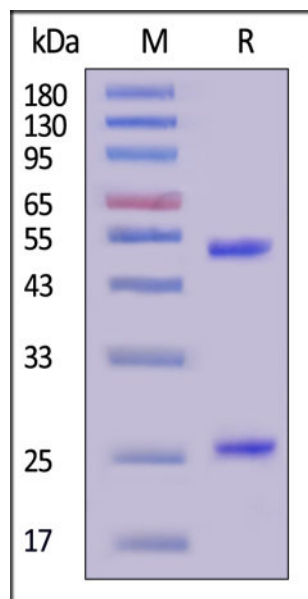
This product is stable after storage at:

- -20°C or below for 24 months under sterile conditions;
- 2-8°C for 24 months after thaw if within expiry date.

ACRO Quality Management System

- [QMS\(ISO, GMP\)](#)
- [Quality Advantages](#)
- [Quality Control Process](#)

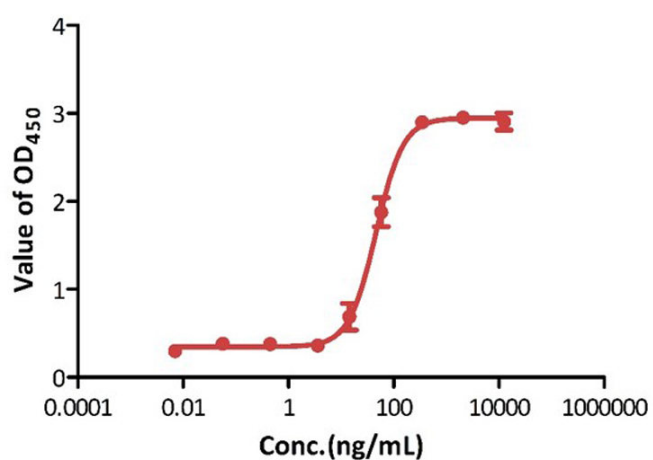
SDS-PAGE



GMP Monoclonal Anti-Human 4-1BB Antibody on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With [Star Ribbon Pre-stained Protein Marker](#)).

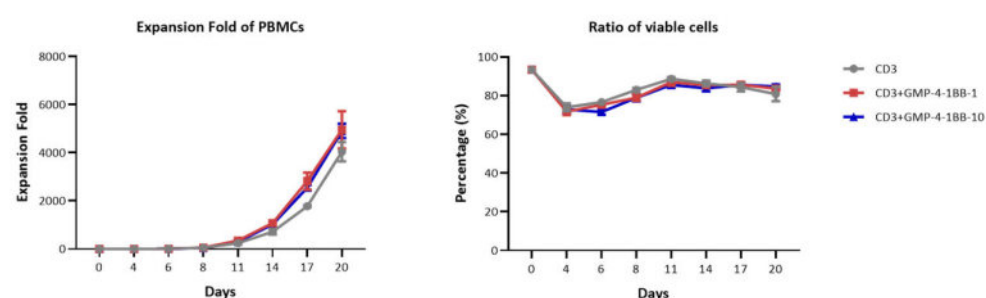
Bioactivity-CELL BASE

GMP Monoclonal Anti-Human 4-1BB Antibody stimulates the secretion of IL-8 by HT1080-CD137

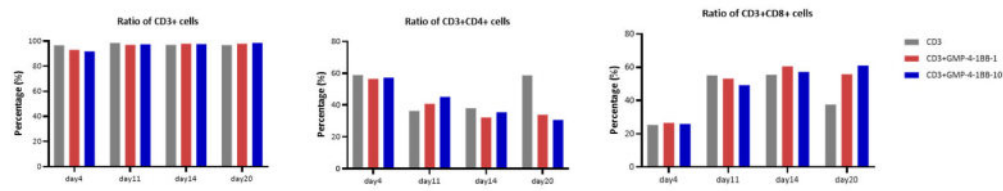


GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) stimulates the secretion of IL-8 by HT1080 human CD137 cell line. The typically EC₅₀ for this effect is 45.30 ng/mL (QC tested).

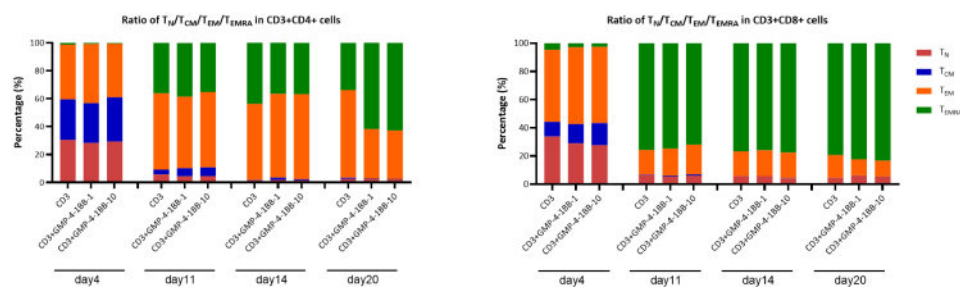
Application Data



Human PBMCs were cultured with GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323), with or without anti-4-1BB for 20 days. GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) exhibits a slight advantage in promoting T cell proliferation.

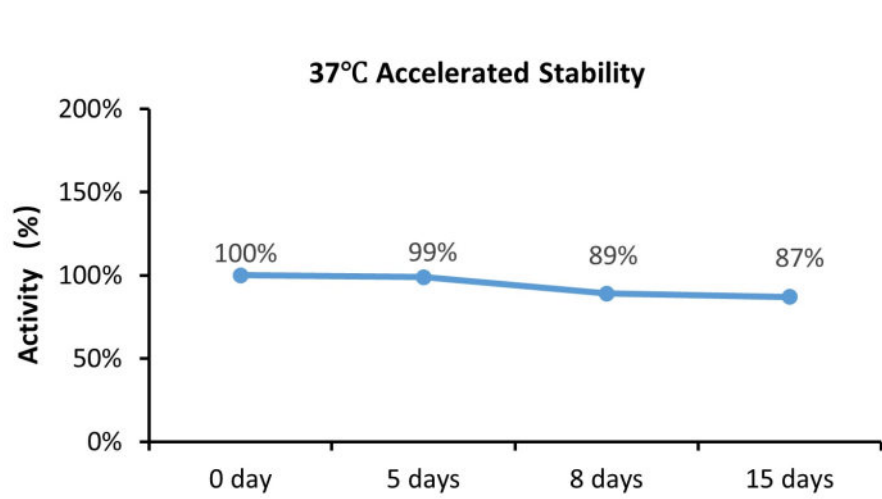


Human PBMCs were cultured with GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323), with or without GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) for 20 days. On the 20th day, the ratio of CD3+CD4+ positive cells after adding anti-4-1BB was lower than that after adding only CD3.

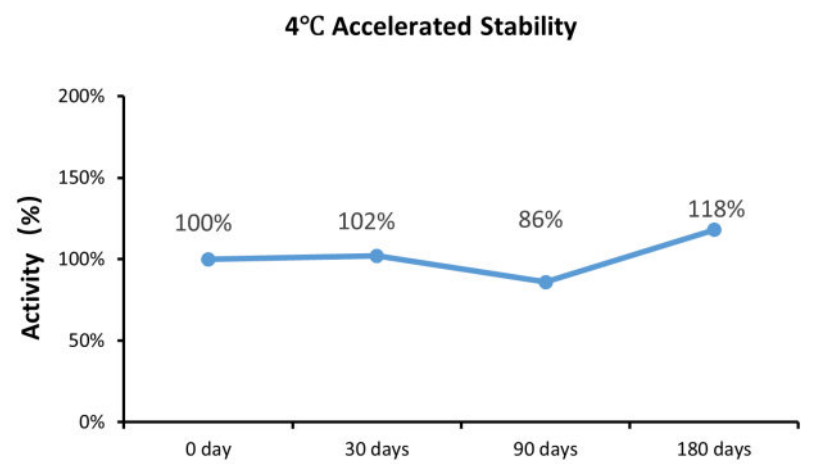


Human PBMCs were cultured with GMP Monoclonal Anti-Human CD3 Antibody (OKT3) (Cat. No. GMP-MC0323), with or without GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) for 20 days. No significant differences were observed in the ratio of T_N/T_{CM}/T_{EM}/T_{EMRA} positive cells, whether anti-4-1BB was added or not.

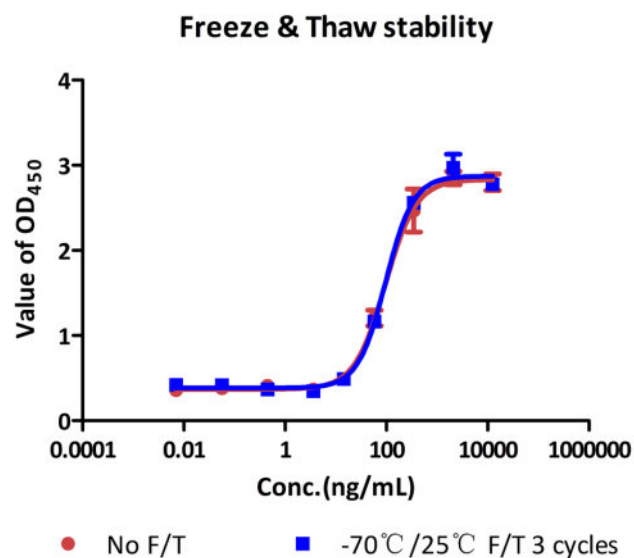
Bioactivity-Stability



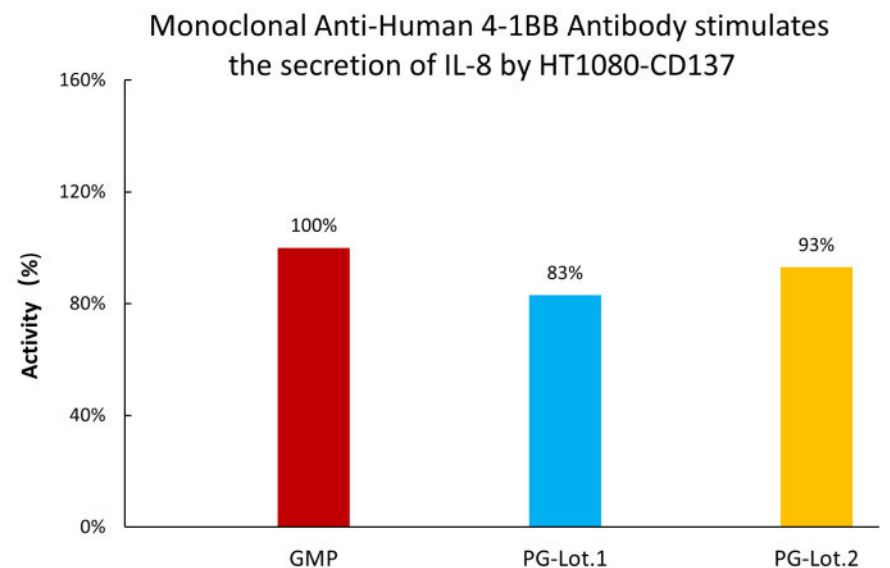
Cell-based assay demonstrates that GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) is stable at 37°C for 15 days.



Cell-based assay demonstrates that GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) is stable at 4°C for 180 days.



Cell-based assay demonstrates that GMP Monoclonal Anti-Human 4-1BB Antibody (Cat. No. GMP-M41B35) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG Anti-Human 4-1BB Antibody.

Background

4-1BB, also known as CD137 and TNFRSF9, is an approximately 30 kDa transmembrane glycoprotein in the TNF receptor superfamily. 4-1BB functions in the development and activation of multiple immune cells. Mature human 4-1BB consists of a 163 amino acid (aa) extracellular domain (ECD) with four TNFR cysteine-rich repeats, a 27 aa transmembrane segment, and a 42 aa cytoplasmic domain . Within the ECD, human 4-1BB shares 60% aa sequence identity with mouse and rat 4-1BB. 4-1BB is expressed as a disulfide-linked homodimer on various populations of activated T cell including CD4, CD8, memory CD8, NKT, and regulatory T cells as well as on myeloid and mast cell progenitors, dendritic cells, mast cells, and bacterially infected osteoblasts . It binds with high affinity to the transmembrane 4-1BB Ligand/TNFSF9 which is expressed on antigen presenting cells and myeloid progenitor cells . This interaction costimulates the proliferation, activation, and/or survival of the 4-1BB expressing cell . It can also enhance the activation-induced cell death of repetitively stimulated T cells . Mice lacking 4-1BB show augmented T cell activation, perhaps due to its absence on regulatory T cells . 4-1BB can associate with OX40 on activated T cells, forming a complex that responds to either ligand and inhibits Treg and CD8 T cell proliferation . Reverse signaling through 4-1BB Ligand inhibits the development of dendritic cells, B cells, and osteoclasts but supports mature dendritic cell survival and costimulates the proliferation and activation of mast cells.

4-1BB activation enhances CD8 T cell and NK cell mediated anti-tumor immunity . It also contributes to the development of inflammation in high fat diet-induced metabolic syndrome . Soluble forms of 4-1BB and 4-1BB Ligand circulate at elevated levels in the serum of rheumatoid arthritis and hematologic cancer patients, respectively .

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:

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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

ACROBIOSYSTEMS - LEGAL NOTICES FOR GMP GRADE PRODUCTS

1. PRODUCT USE RESTRICTIONS & PROHIBITIONS

- 1.1 ACROBiosystems ("ACRO") GMP grade products ("Products") are designed for research, manufacturing use or ex vivo use.
- 1.2 Products are NOT intended for diagnostic purposes or for direct or indirect administration into humans.
- 1.3 Purchaser shall not market, distribute, or resell Products obtained from ACRO without ACRO's prior written consent.

2. REVERSE ENGINEERING PROHIBITED & CONFIDENTIALITY

- 2.1 Purchaser shall not reverse-engineer, decompile, disassemble, sequence, analyze via bioinformatics, or otherwise attempt to discover the structure, sequence, composition, construction, manufacturing process, or any trade secret embodied in the Products. Purchaser shall not permit any third party to undertake such activities.
- 2.2 All specifications, data, and know-how related to the Products provided by ACRO are ACRO's confidential information and shall be protected accordingly.

3. LIMITED WARRANTY & DISCLAIMERS

- 3.1 ACRO warrants solely that Products will conform to their published specifications when used under normal, specified laboratory/manufacturing conditions and within their labeled expiration date. **THIS IS THE ONLY WARRANTY PROVIDED.**
- 3.2 Purchaser assumes ALL risk and responsibility for:
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 - (b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.
 - (c) Compliance with all applicable laws, regulations (including but not limited to cGMP/GLP where claimed), and industry standards.
 - (d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.
 - (e) Proper storage, handling, and use of Products according to ACRO's instructions.
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 - (b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.
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 - (d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

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- 5.2 End User explicitly acknowledges the Products are NOT FOR HUMAN ADMINISTRATION and agrees not to use them in any in vivo human application, directly or indirectly.
- 5.3 End Users unwilling to accept these terms must immediately: (a) cease all use; (b) notify ACRO or their supplier; and (c) return the unopened, unused Products.
- 5.4 ACRO reserves the right to audit End User's compliance with these restrictions upon reasonable notice.

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