GMP Monoclonal Anti-Human CD16 Antibody (3G8)

Catalog # GMP-MC1639

Product Features and Advantages

- **Wide-ranging functions**: Acts as a key functional reagent to support the specific activation and expansion of natural killer (NK) cells in adoptive cell therapy workflows, while enhancing antibody-dependent cellular cytotoxicity (ADCC) and effector function in CAR-NK, TIL, and NK cell cultures.
- **High Performance**: Exhibits superior binding specificity to CD16 and potent biological activity, making it the preferred choice for numerous pharmaceutical enterprises in preclinical and clinical-stage NK cell therapy development and cancer immunotherapy research.
- **Comprehensive Safety Assurance**: ATCC-compliant CHO host cell origin and comprehensive testing (52 items), animal origin-free (AOF) production process, with stringent final product quality control and release specifications to support clinical-grade applications.
- **Lot-to-Lot Consistency**: Achieved through a stable cell line and robust manufacturing process, ensuring reliable, reproducible functional performance from early-stage research through clinical manufacturing.

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 CD16 Antibody (3G8) (GMP-MC1639) is recombinantly produced from CHO cells.

Isotype

Mouse IgG1 | Mouse kappa

Conjugate

Unconjugated

Specificity

This product is a specific antibody that specifically reacts with CD16/Fc gamma RIII.

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 -70°C.

Please avoid repeated freeze-thaw cycles.

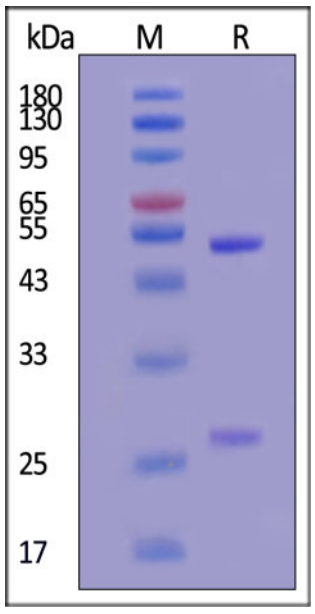
This product is stable after storage at:

- -70°C for 5 years;
- -20°C for 12 months under sterile conditions;
- 2-8°C for 6 months under sterile conditions.

ACRO Quality Management System

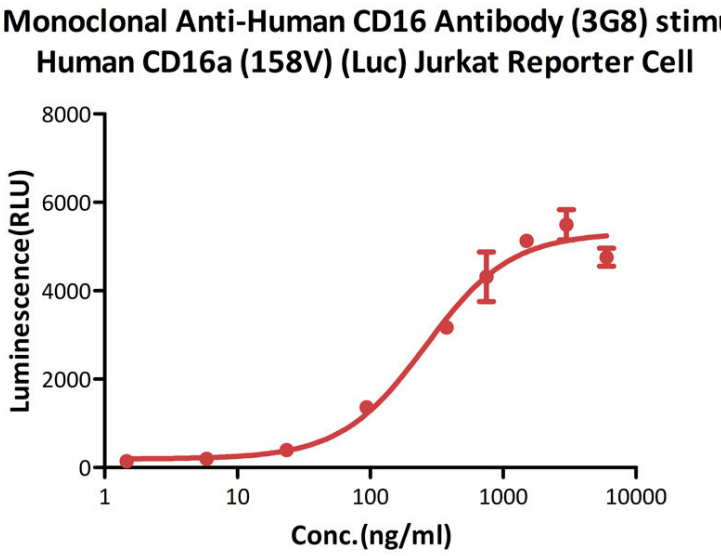
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



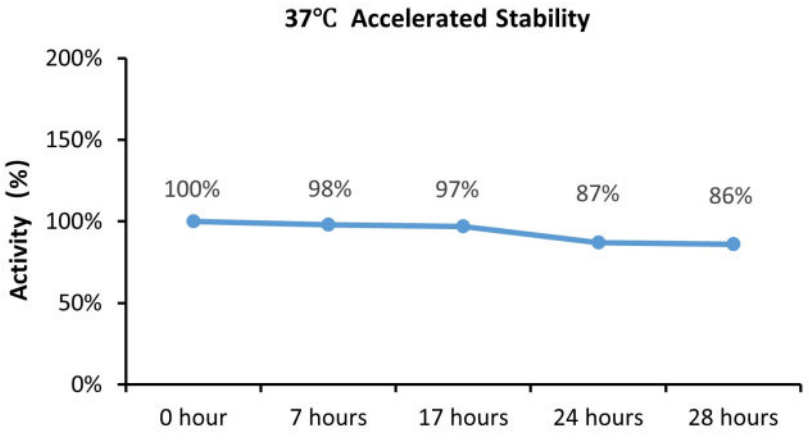
GMP Monoclonal Anti-Human CD16 Antibody (3G8) on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

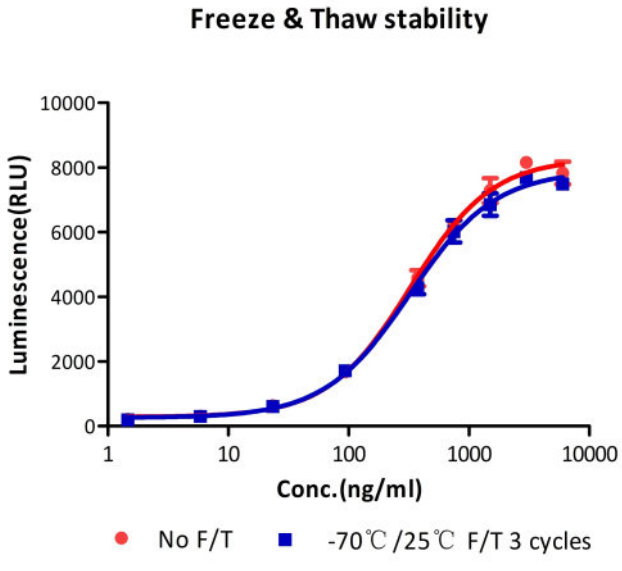


GMP Monoclonal Anti-Human CD16 Antibody (3G8) (Cat. No. GMP-MC1639) stimulates Human CD16a (158V) (Luc) Jurkat Reporter Cell. The typical EC50 for this effect is 260.8 ng/mL (QC tested).

Bioactivity-Stability



Cell-based assay demonstrates that GMP Monoclonal Anti-Human CD16 Antibody (3G8) (Cat. No. GMP-MC1639) is stable at 37°C for 28 hours.



Cell-based assay demonstrates that GMP Monoclonal Anti-Human CD16 Antibody (3G8) (Cat. No. GMP-MC1639) is stable after 3 freeze-thaw cycles.

Background

CD16 encodes a receptor that recognizes the Fc portion of immunoglobulin G and is involved in the clearance of immune complexes from the circulation, as well as other functions such as cellular mediated cytotoxicity and enhancement of virus infections. This gene, FCGR3A, shares a high degree of similarity with another nearby gene, FCGR3B, located on chromosome 1. The receptor encoded by this gene is expressed on natural killer (NK) cells as an integral membrane glycoprotein anchored through a transmembrane peptide, while FCGR3B is expressed on polymorphonuclear neutrophils (PMN) where the receptor is anchored through a phosphatidylinositol (PI) linkage. Mutations in this gene have been associated with immunodeficiency 20 and have been linked to susceptibility to recurrent viral infections, susceptibility to systemic lupus erythematosus, and alloimmune neonatal neutropenia. Alternatively spliced transcript variants encoding different isoforms have been found for this gene. Diseases associated with FCGR3A include Immunodeficiency 20 and Herpes Zoster.

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

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