

DESCRIPTION

Source *E. coli*-derived
His25-Ser153, with an N-terminal Met
Accession # P05112
Produced using non-animal reagents in an animal-free laboratory.
Manufactured and tested under cGMP guidelines.

N-terminal Sequence Analysis Met-His₂₅-Lys-(Cys)-Asp-Ile-Thr-Leu-Gln-Glu

Predicted Molecular Mass 15.1 kDa

SPECIFICATIONS

SDS-PAGE 14 kDa, reducing conditions

Activity Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) *J. Cell Physiol.* **140**:323.
The ED₅₀ for this effect is 0.05-0.2 ng/mL.
The specific activity of recombinant human IL-4 is approximately 2.9 x 10⁴ IU/μg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656).

Endotoxin Level <0.10 EU per 1 μg of the protein by the LAL method.

Purity >97%, by SDS-PAGE under reducing conditions and visualized by silver stain.

Host Cell Protein <0.5 ng per μg of protein when tested by ELISA.

Mycoplasma Negative when tested in a ribosomal RNA hybridization assay.

Formulation Lyophilized from a 0.2 μm filtered solution in PBS. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution Reconstitute at 100-200 μg/mL in PBS.

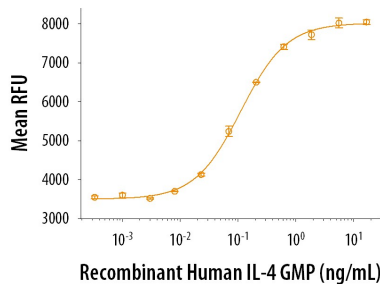
Shipping The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.

Stability & Storage Use a manual defrost freezer and avoid repeated freeze-thaw cycles.

- A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.
- 1 month, 2 to 8 °C under sterile conditions after reconstitution.
- 3 months, ≤ -20 °C under sterile conditions after reconstitution.

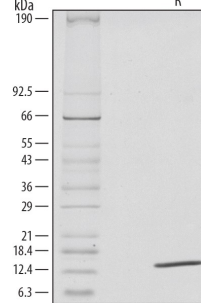
DATA

Bioactivity



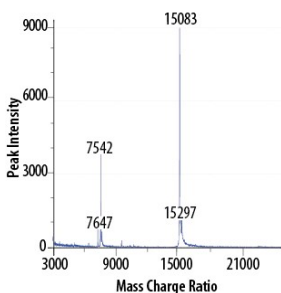
GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) stimulates proliferation of TF-1 human erythroleukemic cells. The ED₅₀ is 0.05-0.2 ng/mL.

SDS-PAGE



1 μg/lane of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 14 kDa.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP). The major peak at 15083 Da corresponds to the calculated molecular mass, 15094 Da. The minor peak at 15297 Da is a matrix-associated artifact of the MALDI-TOF.

BACKGROUND

Interleukin-4 (IL-4), also known as B cell-stimulatory factor-1, is a monomeric, approximately 13 kDa-18 kDa Th2 cytokine that shows pleiotropic effects during immune responses (1-3). It is a glycosylated polypeptide that contains three intrachain disulfide bridges and adopts a bundled four α -helix structure (4). Human IL-4 is synthesized with a 24 aa signal sequence. Alternate splicing generates an isoform with a 16 aa internal deletion. Mature human IL-4 shares 55%, 39% and 43% aa sequence identity with bovine, mouse, and rat IL-4, respectively. Human, mouse, and rat IL-4 are species-specific in their activities (5-7). IL-4 exerts its effects through two receptor complexes (8, 9). The type I receptor, which is expressed on hematopoietic cells, is a heterodimer of the ligand binding IL-4 R α and the common γ chain (a shared subunit of the receptors for IL-2, -7, -9, -15, and -21). The type II receptor on nonhematopoietic cells consists of IL-4 R α and IL-13 R α 1. The type II receptor also transduces IL-13 mediated signals. IL-4 is primarily expressed by Th2-biased CD4⁺ T cells, mast cells, basophils, and eosinophils (1, 2). It promotes cell proliferation, survival, and immunoglobulin class switch to IgG4 and IgE in human B cells, acquisition of the Th2 phenotype by naive CD4⁺ T cells, priming and chemotaxis of mast cells, eosinophils, and basophils, and the proliferation and activation of epithelial cells (10-13). IL-4 plays a dominant role in the development of allergic inflammation and asthma (12, 14).

References:

1. Benczik, M. and S.L. Gaffen (2004) *Immunol. Invest.* **33**:109.
2. Chomarat, P. and J. Banchereau (1998) *Int. Rev. Immunol.* **17**:1.
3. Yokota, T. *et al.* (1986) *Proc. Natl. Acad. Sci.* **83**:5894.
4. Redfield, C. *et al.* (1991) *Biochemistry* **30**:11029.
5. Ramirez, F. *et al.* (1988) *J. Immunol. Meth.* **221**:141.
6. Leitenberg, D. and T.L. Feldbush (1988) *Cell. Immunol.* **111**:451.
7. Mosman, T.R. *et al.* (1987) *J. Immunol.* **138**:1813.
8. Mueller, T.D. *et al.* (2002) *Biochim. Biophys. Acta* **1592**:237.
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11. Corthay, A. (2006) *Scand. J. Immunol.* **64**:93.
12. Ryan, J.J. *et al.* (2007) *Crit. Rev. Immunol.* **27**:15.
13. Grone, A. (2002) *Vet. Immunol. Immunopathol.* **88**:1.
14. Rosenberg, H.F. *et al.* (2007) *J. Allergy Clin. Immunol.* **119**:1303.

MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in *ex vivo* cell therapy applications. They are not for *in vivo* use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

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Our dedicated controlled-access animal-free laboratories ensure that at no point in production are the products exposed to potential contamination by animal components or byproducts. Every stage of manufacturing is conducted in compliance with R&D Systems' stringent Standard Operating Procedures (SOPs). Production and purification procedures use equipment and media that are confirmed animal-free.

Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.
- For *ex vivo* research or bioproduction, [additional documentation](#) can be provided.

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