Recombinant Human IL-1β/IL-1F2 GMP

Catalog Number: 201-GMP

DESCRIPTION

Source	*E. coli*-derived Ala117-Ser269 Accession # NP_000567 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ala-Pro-Val-Arg-Ser-Leu-Asn-(Cys)-Thr-Leu Pro-Val-Arg-Ser-Leu-Asn-(Cys)-Thr-Leu-Arg
Predicted Molecular Mass	17 kDa

SPECIFICATIONS

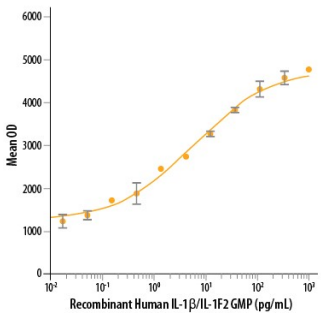
Activity	Measured in a cell proliferation assay using D10.G4.1 mouse helper T cells. Symons, J.A. *et al.* (1987) in Lymphokines and Interferons, a Practical Approach. Clemens, M.J. *et al.* (eds): IRL Press. 272. The ED_{50} for this effect is <12 pg/mL. The specific activity of recombinant human IL-1β is approximately 1.4 x 10^5 IU/µg, which is calibrated against recombinant human IL-1β WHO International Standard (NIBSC code: 86/680).
Endotoxin Level	<0.01 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with silver staining, under reducing conditions.
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 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 6 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.

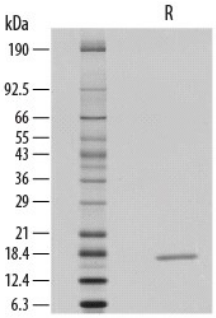
DATA

Bioactivity



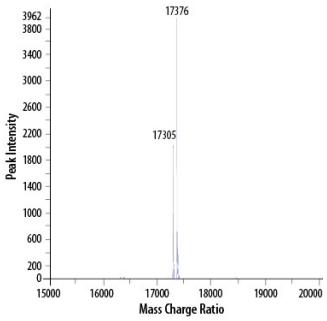
GMP-grade Recombinant Human IL-1β/IL-1F2 (Catalog # 201-GMP) stimulates proliferation of the D10.G4.1 mouse helper T cell line. The ED_{50} for this effect is <12 pg/mL.

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human IL-1β/IL-1F2 (Catalog # 201-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 17 kDa.

Mass Spectrometry



ESI analysis of GMP-grade Recombinant Human IL-1β/IL-1F2 (Catalog # 201-GMP). The labeled peaks at 17376 Da and 17305 Da correspond to the calculated molecular masses, 17377 Da (aa 117-269) and 17306 Da (aa 118-269), respectively.

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BACKGROUND

IL-1 is a name that designates two pleiotropic cytokines, IL-1α (IL-1F1) and IL-1β (IL-1F2), which are the products of distinct genes. IL-1α and IL-1β are structurally related polypeptides that share approximately 21% amino acid (aa) identity in human. Both proteins are produced by a wide variety of cells in response to inflammatory agents, infections, or microbial endotoxins. While IL-1α and IL-1β are regulated independently, they bind to the same receptor and exert identical biological effects. IL-1 RI binds directly to IL-1α or IL-1β and then associates with IL-1 R accessory protein (IL-1 R3/IL-1 R AcP) to form a high-affinity receptor complex that is competent for signal transduction. IL-1 RII has high affinity for IL-1β but functions as a decoy receptor and negative regulator of IL-1β activity. IL-1ra functions as a competitive antagonist by preventing IL-1α and IL-1β from interacting with IL-1 RI (1-4). The human IL-1β cDNA encodes a 269 aa precursor. A 116 aa propeptide is cleaved intracellularly by the cysteine protease IL-1β-converting enzyme (Caspase-1/ICE) to generate the active cytokine (5-7). The 17 kDa mature human IL-1β shares 96% aa sequence identity with rhesus and 67%-78% with canine, cotton rat, equine, feline, mouse, porcine, and rat IL-1β.

References:

1. Allan, S.M. *et al.* (2005) Nat. Rev. Immunol. **5**:629.
2. Boraschi, D. and A. Tagliabue (2006) Vitam. Horm. **74**:229.
3. Kornman, K.S. (2006) Am. J. Clin. Nutr. **83**:475S.
4. Isoda, K. and F. Ohsuzu (2006) J. Atheroscler. Thromb. **13**:21.
5. March, C.J. *et al.* (1985) Nature **315**:641.
6. Auron, P.E. *et al.* (1984) Proc. Natl. Acad. Sci. **81**:7907.
7. Martinon, F. and J. Tschopp (2007) Cell Death Differ. **14**:10.

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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.

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- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
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- 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.

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- 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.
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- High quality product obtained under stringent conditions.
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