Recombinant Human IGF-I/IGF-1 GMP

Catalog Number: 291-GMP

DESCRIPTION

Source	*E. coli*-derived human IGF-I/IGF-1 protein Gly49-Ala118 Accession # P05019 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Gly-Pro-Glu-Thr-Leu-(Cys)-Gly-Ala-Glu-Leu
Predicted Molecular Mass	7.6 kDa

SPECIFICATIONS

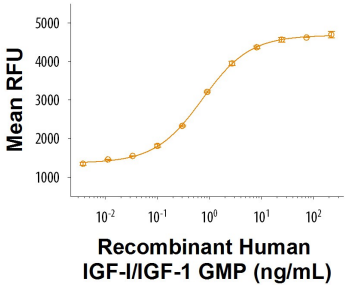
Activity	Measured in a serum-free cell proliferation assay using MCF-7 human breast cancer cells. Karey, K.P. *et al.* (1988) Cancer Research **48**:4083. The ED_{50} for this effect is 0.3-1.5 ng/mL. The specific activity of recombinant human IGF-I/IGF-1 is >1000 IU/mg, which is calibrated against the human IGF-I/IGF-1 WHO International Standard (NIBSC code: 91/554).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE visualized with Silver Staining and quantitative densitometry by Coomassie® Blue Staining.
Host Cell Protein	<1.0 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
Host Cell DNA	<0.0015 ng per µg of protein when tested by PCR.
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 with polar packs. 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.

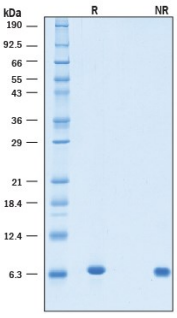
DATA

Bioactivity



Recombinant Human IGF-I/IGF-1 GMP Protein Bioactivity GMP-grade Recombinant Human IGF-I/IGF-1 (Catalog # 291-GMP) stimulates cell proliferation in the MCF-7 human breast cancer cell line in a dose-dependent manner. The ED_{50} for this effect is 0.3-1.5 ng/mL.

SDS-PAGE



Recombinant Human IGF-I/IGF-1 GMP Protein SDS-PAGE 2 µg/lane of Recombinant Human GMP-grade IGF-I/IGF-1 (Catalog # 291-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing R and NR bands at 7 kDa.

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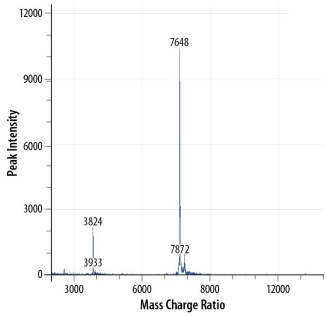
Mass Spectrometry



Recombinant Human IGF-I/IGF-1 GMP Protein Mass Spectrometry MALDI-TOF analysis of GMP-grade Recombinant Human IGF-I/IGF-1 (Catalog # 291-GMP). The major peak at 7648 Da corresponds to the measured molecular weight of the intact protein. The calculated mass is 7655 Da.

BACKGROUND

Insulin-like growth factor 1 (IGF-1 or IGF-I), also known as somatomedin C, is the dominant effector of growth hormone and is structurally homologous to proinsulin. Human IGF-1 is synthesized as two precursor isoforms with N- and alternate C-terminal propeptides (1). These isoforms are differentially expressed by various tissues (1). The 7.6 kDa mature IGF-1 is identical between isoforms and is generated by proteolytic removal of the N- and C-terminal regions. Mature human IGF-1 shares 94% and 96% aa sequence identity with mouse and rat IGF-1, respectively (2), and exhibits cross-species activity. It shares 64% aa sequence identity with mature human IGF2. Circulating IGF-1 is produced by hepatocytes, while local IGF-1 is produced by many other tissues in which it has paracrine effects (1). IGF-1 induces the proliferation, migration, and differentiation of a wide variety of cell types during development and postnatally (3). IGF-1 regulates glucose and fatty acid metabolism, steroid hormone activity, and cartilage and bone metabolism (4-7). It plays an important role in muscle regeneration and tumor progression (1, 8). IGF-1 binds IGF1R, IGF2R, and the insulin receptor, although its effects are mediated primarily by IGF1R (9). IGF-1 association with IGF binding proteins increases its plasma half-life and modulates its interactions with receptors (10).

References:

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2. Sandberg-Nordqvist, A.C. *et al.* (1992) Brain Res. Mol. Brain Res. **12**:275.
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5. Bluher, S. *et al.* (2005) Best Pract. Res. Clin. Endocrinol. Metab. **19**:577.
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10. Denley, A. *et al.* (2005) Cytokine Growth Factor Rev. **16**:421.

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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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- 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

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- 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 testing according to USP
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

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