Recombinant Human IGF-I GMP

Catalog Number: 291-GMP

DESCRIPTION

Source	*E. coli*-derived 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

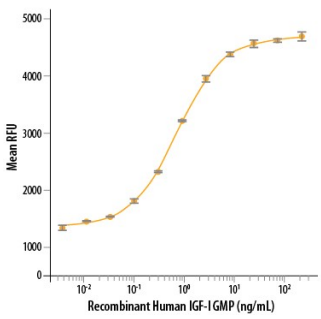
Activity	Measured in a serum-free cell proliferation assay using MCF-7 human breast cancer cells. Karey, K.P. *et al.* (1988) Cancer Research **48**:4083. The ED_{50} for this effect is 0.3-1.5 ng/mL. The specific activity of recombinant human IGF-I is approximately 2.5 IU/µg, which is calibrated against recombinant human IGF-I 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 with silver staining, under reducing conditions.
Host Cell Protein	<1.0 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 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.

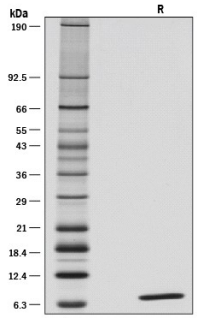
DATA

Bioactivity



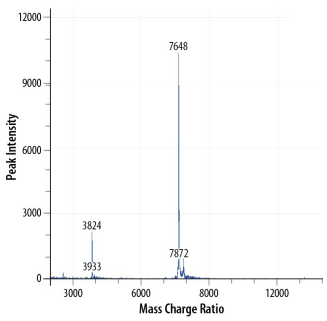
GMP-grade Recombinant Human IGF-I (Catalog # 291-GMP) stimulates cell proliferation in the MCF-7 human breast cancer cell line in a dose-dependent manner. The ED_{50} for this effect is 0.3-1.5 ng/mL.

SDS-PAGE



1 µg/lane of Recombinant Human GMP-grade IGF-I (Catalog # 291-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 8 kDa.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human IGF-I (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.

bio-techne®
Global bio-techne.com info@bio-techne.com techsupport@bio-techne.com TEL +1 612 379 2956
USA TEL 800 343 7475 Canada TEL 855 668 8722 China TEL +86 (21) 52380373
Europe | Middle East | Africa TEL +44 (0)1235 529449

BACKGROUND

Insulin-like growth factor I, also known as somatomedin C, is the dominant effector of growth hormone and is structurally homologous to proinsulin. Human IGF-I 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-I is identical between isoforms and is generated by proteolytic removal of the N- and C-terminal regions. Mature human IGF-I shares 94% and 96% aa sequence identity with mouse and rat IGF-I, respectively (2), and exhibits cross-species activity. It shares 64% aa sequence identity with mature human IGF-II. Circulating IGF-I is produced by hepatocytes, while local IGF-I is produced by many other tissues in which it has paracrine effects (1). IGF-I induces the proliferation, migration, and differentiation of a wide variety of cell types during development and postnatally (3). IGF-I 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-I binds IGF-I R, IGF-II R, and the insulin receptor, although its effects are mediated primarily by IGF-I R (9). IGF-I association with IGF binding proteins increases its plasma half-life and modulates its interactions with receptors (10).

References:

1. Philippou, A. *et al.* (2007) In Vivo **21**:45.
2. Sandberg-Nordqvist, A.C. *et al.* (1992) Brain Res. Mol. Brain Res. **12**:275.
3. Guvakova, M.A. (2007) Int. J. Biochem. Cell Biol. **39**:890.
4. Clemmons, D.R. (2006) Curr. Opin. Pharmacol. **6**:620.
5. Bluher, S. *et al.* (2005) Best Pract. Res. Clin. Endocrinol. Metab. **19**:577.
6. Garcia-Segura, L.M. *et al.* (2006) Neuroendocrinology **84**:275.
7. Malemud, C.J. (2007) Clin. Chim. Acta **375**:10.
8. Samani, A.A. *et al.* (2007) Endocrine Rev. **28**:20.
9. LeRoith, D. and S. Yakar (2007) Nat. Clin. Pract. Endocrinol. Metab. **3**:302.
10. Denley, A. *et al.* (2005) Cytokine Growth Factor Rev. **16**:421.

bio-techne®
Global bio-techne.com info@bio-techne.com techsupport@bio-techne.com TEL +1 612 379 2956
USA TEL 800 343 7475 Canada TEL 855 668 8722 China TEL +86 (21) 52380373
Europe | Middle East | Africa TEL +44 (0)1235 529449

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.

Animal-Free Manufacturing Conditions
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.

Please read our complete Animal-Free Statement

bio-techne®
Global bio-techne.com info@bio-techne.com techsupport@bio-techne.com TEL +1 612 379 2956
USA TEL 800 343 7475 Canada TEL 855 668 8722 China TEL +86 (21) 52380373
Europe | Middle East | Africa TEL +44 (0)1235 529449

PRODUCT SPECIFIC NOTICES

END USER TERMS OF USE OF PRODUCT

The following terms are offered to you upon your acceptance of these End User Terms of Use of Product. By using this product, you indicate your acknowledgment and agreement to these End User Terms of Use of Product. If you do not agree to be bound by and comply with all of the provisions of these End User Terms of Use of Product, you should contact your supplier of the product and make arrangements to return the product.

We suggest you print and retain a copy of these End User Terms of Use of Product for your records.

The End User is aware that R&D Systems, Inc. sells its GMP products for research use only or further manufacturing and not for *in vivo* use, the production of therapeutics or other drugs or for biologic products or devices. The End User further agrees, as a condition of the sale of R&D Systems' GMP products that: a) the End User will not use this GMP Product in any procedure wherein the product may be directly or indirectly administered to humans, unless the End User has obtained, or prior to their use will have obtained, an Investigational New Drug (IND) exemption from the FDA and will use the product only in accordance with the protocols of such IND and of the Institutional Review Board overseeing the proposed research, or b) the End User will use the products outside of the United States in accordance with the protocols of research approved by the Institutional Review Board or authorized ethics committee and regulatory agencies to which the End User is subject to in their territory.

R&D Systems, Inc. has the right, at its sole discretion, to modify, add or remove any terms or conditions of these End User Terms of Use without notice or liability to you. Any changes to these End User Terms of Use are effective immediately following the printing of such changes on this product insert. The most recent version of these End User Terms of Use of Product may be found at: RnDSystems.com/Legal.

You agree to review these End User Terms of Use of Product to ensure any subsequent use by you of R&D Systems' GMP Products following changes to these End User Terms of Use of Product constitutes your acceptance of all such changes.

TERMS AND CONDITIONS

The following limitation applies to R&D Systems' warranty and liability for damages: All products are warranted to meet R&D Systems' published specifications when used under normal laboratory conditions.

R&D SYSTEMS DOES NOT MAKE ANY OTHER WARRANTY OR REPRESENTATION WHATSOEVER, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO ITS PRODUCTS. IN PARTICULAR, R&D SYSTEMS DOES NOT MAKE ANY WARRANTY OF SUITABILITY, NONINFRINGEMENT, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

NOTWITHSTANDING ANY OTHER PROVISIONS OF THESE TERMS AND/OR ANY OTHER AGREEMENT BETWEEN R&D SYSTEMS AND PURCHASER FOR THE PURCHASE OF THE PRODUCTS, R&D SYSTEMS' TOTAL LIABILITY TO PURCHASER ARISING FROM OR IN RELATION TO THESE TERMS, AN AGREEMENT BETWEEN THE PARTIES OR THE PRODUCTS, WHETHER ARISING IN CONTRACT, TORT OR OTHERWISE SHALL BE LIMITED TO THE TOTAL AMOUNT PAID BY PURCHASER TO R&D SYSTEMS FOR THE APPLICABLE PRODUCTS. IN NO EVENT WILL R&D SYSTEMS BE LIABLE FOR THE COST OF PROCUREMENT OF SUBSTITUTE GOODS.

Full details of R&D Systems' Terms and Conditions of Sale can be found online at: RnDSystems.com/Legal.

bio-techne®
Global bio-techne.com info@bio-techne.com techsupport@bio-techne.com TEL +1 612 379 2956
USA TEL 800 343 7475 Canada TEL 855 668 8722 China TEL +86 (21) 52380373
Europe | Middle East | Africa TEL +44 (0)1235 529449