

**DESCRIPTION**

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

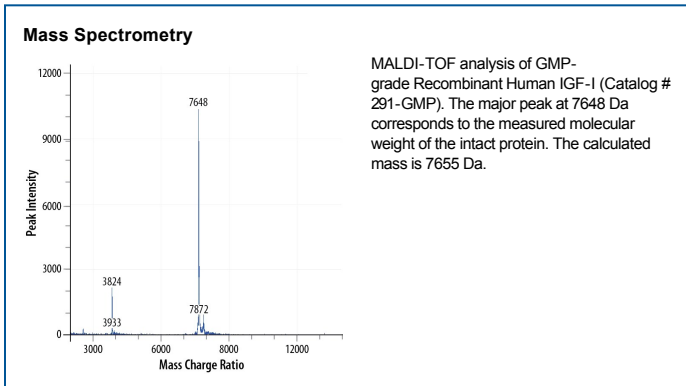
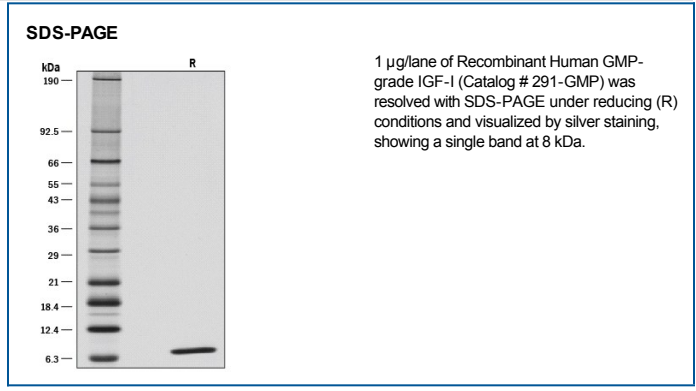
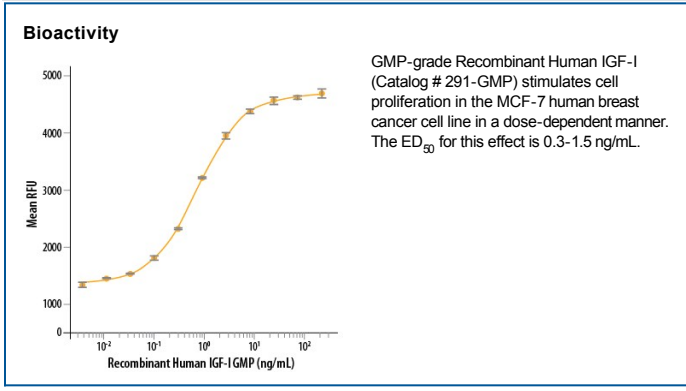
**SPECIFICATIONS**

<b>Activity</b>	Measured in a serum-free cell proliferation assay using MCF-7 human breast cancer cells. Karey, K.P. <i>et al.</i> (1988) Cancer Research 48:4083. The ED <sub>50</sub> 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).
<b>Endotoxin Level</b>	<0.10 EU per 1 μg of the protein by the LAL method.
<b>Purity</b>	>97%, by SDS-PAGE with silver staining, under reducing conditions.
<b>Host Cell Protein</b>	<1.0 ng per μg of protein when tested by ELISA.
<b>Mycoplasma</b>	Negative when tested in a ribosomal RNA hybridization assay.
<b>Formulation</b>	Lyophilized from a 0.2 μm filtered solution in PBS. See Certificate of Analysis for details.

**PREPARATION AND STORAGE**

<b>Reconstitution</b>	Reconstitute at 100 μg/mL in PBS.
<b>Shipping</b>	The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.
<b>Stability &amp; Storage</b>	<b>Use a manual defrost freezer and avoid repeated freeze-thaw cycles.</b> <ul style="list-style-type: none"> <li>• A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.</li> <li>• 1 month, 2 to 8 °C under sterile conditions after reconstitution.</li> <li>• 3 months, ≤ -20 °C under sterile conditions after reconstitution.</li> </ul>

**DATA**



**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.

## 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](#)

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