Recombinant Human TGF-beta 3 GMP

Catalog Number: BT-TGFB3-GMP

DESCRIPTION

Source	*E. coli*-derived human TGF-beta 3 protein Ala301 - Ser412 Accession # P10600.1 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ala301-Leu-Asp-Thr-Asn-Tyr-(Cys)-Phe-Arg-Asn
Predicted Molecular Mass	13 kDa (monomer)

SPECIFICATIONS

SDS-PAGE	10 kDa, under reducing conditions.
Activity	Measured by its ability to inhibit the IL-4-dependent proliferation of HT-2 mouse T cells. Tsang, M. *et al.* (1995) Cytokine **7**:389. The ED_{50} for this effect is 7.50-75.0 pg/mL. The specific activity of Recombinant Human TGF-β3 is >1.9 x 10^7 IU/mg, which is calibrated against the Human TGF-β3 WHO International Standard (NIBSC code: 09/234).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
Mass Spectrometry	The molecular weight by mass spectrometry is 25411 Da ± 5 Da.
Host Cell Protein	<0.500 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative for Mycoplasma.
Host Cell DNA	<0.00150 ng per µg of protein when tested by PCR.
Formulation	Lyophilized from a 0.2 µm filtered solution in Acetonitrile and TFA with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 500 µg/mL in 4 mM HCl.
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.

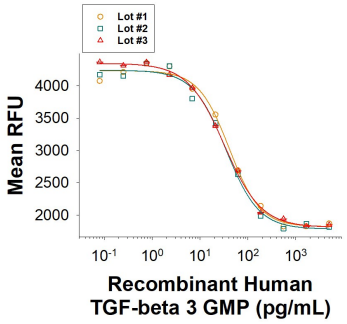
Bio-Techne®
Global | bio-techne.com info@bio-techne.com techsupport@bio-techne.com TEL: 1.612.379.2956
USA | TEL: 800.343.7475 Canada | TEL: 855.668.8722 Europe | Middle East | Africa TEL: +44.0.1235.529449
China | info.cn@bio-techne.com TEL: 400.821.3475

Recombinant Human TGF-beta 3 GMP

Catalog Number: BT-TGFB3-GMP

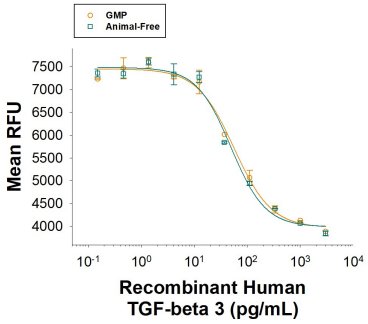
DATA

Bioactivity



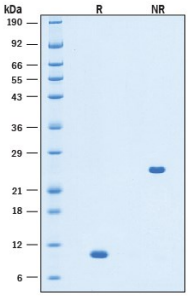
Recombinant Human TGF-beta 3 GMP Protein Bioactivity. The bioactivity of Recombinant Human TGF-beta 3 GMP Protein (Catalog # BT-TGFB3-GMP) was measured by its ability to inhibit the IL-4-dependent proliferation of HT-2 mouse T cells. Three independent lots were tested for bioactivity and plotted on the same graph to show lot-to-lot consistency of GMP TGF-beta 3 protein.

Bioactivity



Equivalent Bioactivity of GMP and Animal-Free grades of Recombinant Human TGF-beta 3. Equivalent bioactivity of GMP (Catalog # BT-TGFB3-GMP) and Animal-Free (Catalog # BT-TGFB3-AFL) grades of Recombinant Human TGF-beta 3 as measured by its ability to inhibit the IL-4-dependent proliferation of HT-2 mouse T cells (orange and green, respectively).

SDS-PAGE



Recombinant Human TGF-beta 3 GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human TGF-beta 3 GMP Protein (Catalog # BT-TGFB3-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 10 kDa, under reducing conditions.

BACKGROUND

TGFβ3 (transforming growth factor-beta 3) is a member of a TGF-β superfamily subgroup that is defined by their structural and functional similarities (1-5). TGF-β3 and its closely related proteins, TGF-β1 and -β2, act as cellular switches to regulate immune function, cell proliferation, and epithelial-mesenchymal transition (4, 6, 7). The non-redundant biological effects of TGF-β3 include involvement in palatogenesis, chondrogenesis, and pulmonary development (1, 2, 7-9). Human TGF-β3 cDNA encodes a 412 amino acid (aa) precursor that contains a 20 aa signal peptide and a 392 aa proprotein. The proprotein is processed by a furinlike convertase to generate a 220 aa latencyassociated peptide (LAP) and a 112 aa mature TGF-β3 (10, 11). Mature human TGF-β3 shows 100%, 99%, and 98% aa identity with mouse/dog/horse, rat, and pig TGF-β3, respectively. TGF-β3 is secreted as a complex with LAP. This latent form of TGF-β3 becomes active upon cleavage by plasmin, matrix metalloproteases, thrombospondin-1, and a subset of integrins (12). TGF-β3 binds with high affinity to TGF-β RII, a type II serine/threonine kinase receptor. This receptor then phosphorylates and activates type I serine/threonine kinase receptors, TGF-β RI or ALK-1, to modulate transcription through Smad phosphorylation (13-15). The divergent biological effects exerted by individual TGF-β isoforms is dependent upon the recruitment of co-receptors (TGF-β RIII and endoglin) and the subsequent initiation of Smad-dependent or -independent signaling pathways (14, 16, 17).

References:

1. Barrio, M.C. *et al.* (2014) Cells Tissues Organs. [Epub ahead of print; PMID 24861080].
2. Doetschman, T. *et al.* (2012) Genesis **50**:59.
3. Mittl, P.R. *et al.* (1996) Protein Sci. **5**:1261.
4. Sporn, M.B. (2006) Cytokine Growth Factor Rev. **17**:3.
5. Wahl, S.M. *et al.* (2006) Immunol. Rev. **213**:213.
6. Chang, H. *et al.* (2002) Endocr. Rev. **23**:787.
7. Dunker, N. and K. Krieglstein (2000) Eur. J. Biochem. **267**:6982.
8. Jin, J.Z. *et al.* (2014) Dev. Dyn. [Epub ahead of print; PMID 25104574].
9. Tang, Q.O. *et al.* (2009) Expert Opin. Biol Ther. **9**:689.
10. Derynck, R. *et al.* (1988) EMBO J. **7**:3737.
11. Miyazono, K. *et al.* (1988) J. Biol. Chem. **263**:6407.
12. Oklu, R. and R. Hesketh (2000) Biochem. J. **352 Pt 3**:601.
13. Cui, X.M. and C.F. Shuler (2000) Int. J. Dev. Biol. **44**:397.
14. de Caestecker, M. (2004) Cytokine Growth Factor Rev. **15**:1.
15. Nakajima, A. *et al.* (2007) Dev. Dyn. **236**:791.
16. Iwata, J. *et al.* (2012) J. Clin. Invest. **122**:873.
17. Gatza, C.E. *et al.* (2010) Cell. Signal. **22**:1163.

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 Europe | Middle East | Africa TEL: +44.0.1235.529449
China | info.cn@bio-techne.com TEL: 400.821.3475

MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and Eu. Ph. 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products.

R&D Systems' quality focus includes:

- Designed, manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented and controlled manufacturing process
- Control of documentation and process changes by QA
- Personnel training programs
- Raw material inspection and vendor qualification/monitoring program
- Validated equipment, processes and test methods
- Equipment calibration and maintenance schedules using a Regulatory Asset Manager
- Facility/Utilities maintenance, contamination controls, safety and pest control programs
- Material review process for variances
- Robust product stability program following relevant ICH guidelines

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 application. Each product is provided with a lot-specific Certificate of Analysis that contains the product's specifications and test results. Quality control testing may include, but is not limited to:

- N-terminal amino acid analysis
- SDS-PAGE purity analysis
- Molecular weight analysis via mass spectrometry
- Endotoxin assessment per USP <85> and Ph. Eur. 2.6.14 guidelines
- Bioassay analysis
- Microbial testing per USP <71> and Ph. Eur. 2.6.1 guidelines
- Host cell protein assessment
- Host cell DNA assessment
- Mycoplasma assessment

Additional testing and documentation requested by the customer can be arranged at an additional cost.

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

R&D Systems sells GMP grade products for preclinical or clinical *ex vivo* use. They are not for *in vivo* use. 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.

Please read our complete Animal-Free Statement

PRODUCT SPECIFIC NOTICES

Full terms and conditions of sale can be found online in the Protein Sciences Segment T&Cs at: Terms & Conditions.

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 Europe | Middle East | Africa TEL: +44.0.1235.529449
China | info.cn@bio-techne.com TEL: 400.821.3475