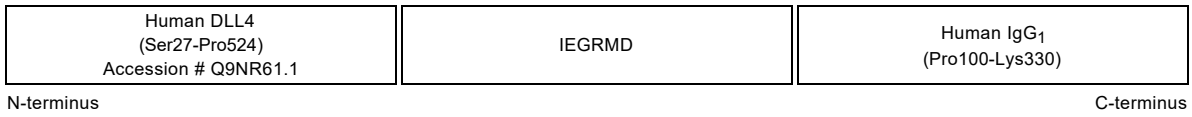
Recombinant Human DLL4 Fc Chimera GMP

Catalog Number: BT-DLL4-GMP

DESCRIPTION

Source

Chinese Hamster Ovary cell line, CHO-derived human DLL4 protein



Manufactured and tested under cGMP guidelines.

N-terminal Sequence Analysis	Ser27-Gly-Val-Phe-Gln-Leu-Gln-Leu-Gln-Glu
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	81 kDa

SPECIFICATIONS

SDS-PAGE	89-98 kDa, under reducing conditions.
Activity	Measured by its binding ability in a functional ELISA. Recombinant Human DLL4 Fc Chimera GMP (Catalog # BT-DLL4-GMP) binds to Recombinant Human Notch-1 Fc Chimera (Catalog # 3647-TK) with an ED_{50} of 2.00-20.0 ng/mL.
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
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 HBS and Tween®-80 with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 500 µg/mL in sterile water.
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.

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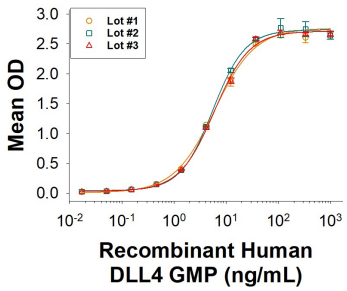
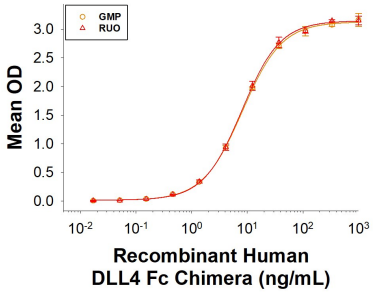
DATA

Binding Activity



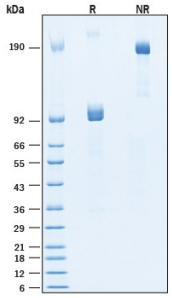
Recombinant Human DLL4 GMP Protein Binding Activity. The binding activity of Recombinant Human DLL4 GMP Protein (Catalog # BT-DLL4-GMP) was measured in a functional ELISA with Recombinant Human Notch-1 Protein. Three independent lots were tested for binding activity and plotted on the same graph to show lot-to-lot consistency of GMP DLL4 protein.

Binding Activity



Equivalent Binding Activity of GMP and RUO grades of Recombinant Human DLL4 Equivalent binding activity of GMP (Catalog # BT-DLL4-GMP) and RUO (Catalog # BT-DLL4) grades of Recombinant Human DLL4 as measured in a functional ELISA with Recombinant Human Notch-1 Protein (orange and red, respectively).

SDS-PAGE



Recombinant Human DLL4 Fc Chimera GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human DLL4 Fc Chimera GMP Protein (Catalog # BT-DLL4-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 89-98 kDa and 180-200 kDa, respectively.

BACKGROUND

Delta-like protein 4 (DLL4) is a type I membrane protein belonging to the Delta/Serrate/Lag2 (DSL) family of Notch ligands. Notch signaling is an evolutionarily conserved pathway that controls cell fate and is required in multiple developmental processes including vascular development, hematopoiesis, somatogenesis, myogenesis, and neurogenesis. In mammals, four Notch homologs (Notch 1 to 4) and five ligands (DLL 1, 3 and 4, Jagged 1 and 2) have been identified. DLL-4 is the only Notch ligand expressed predominantly by the vascular endothelium, making it critical in vascular development. The mature extracellular domain (ECD) of human DLL4 shares 86% amino acid sequence identity with mouse DLL4. The use of DLL4, in conjunction with VCAM1, has been shown as an effective method for generating hematopoietic progenitors and T cells from hPSCs in a serum- and feeder-free environment.

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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.

PRODUCT SPECIFIC NOTICES

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

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