

Product Details

Laminin 511 E8 (LN511-E8) is a recombinant human protein that provides a defined surface for the in vitro feeder-free culture of multiple human pluripotent stem cells (PSCs). As a truncated form of laminin 511, LN511-E8 is a functionally minimal form that retains the full capability for binding to integrins. LN511-E8 has been proven to maintain normal growth characteristics and stemness in multiple PSC lines without simultaneous differentiation, which includes ESC, iPSC, MSC, etc. In addition, LN511-E8 has been demonstrated to support PSC growth for >10 passages without any signs of karyotypic abnormalities and to maintain the ability of PSCs to differentiate into all three germ line lineages. As published by Takamichi Miyazaki et al., the LN511-E8 variant of laminin 511 shows higher efficiency for supporting the adhesion of dissociated cells than did wild-type laminin 511 which makes it a cost-effective choice.

High-quality products and regulatory support files are essential for the smooth transition from preclinical research & development to cell therapy clinical study. Designed for clinical research, GMP Laminin 511 is manufactured by an animal-free process in a GMP-compliant facility. A full battery of QC testing is implemented to ensure product quality, including purity, bioactivity, sterility, mycoplasma, endotoxin, etc. GMP Laminin 511 protein (GMP-LA1H25) is the GMP version of laminin 511 protein premium grade (LA8-H5283L), and they have the same performance for a seamless transition.

Optimized and defined surface

Laminin 511 E8 (LN511-E8) has been proven to allow single-cell seeding at low density. In a feeder-free culture system, the seeded cells demonstrate high motility with higher clonal survival.

Physiology-related

The laminin 511 isoform is crucial to the growth and maintenance of hPSCs in human through its binding to cell receptors a6B1 integrin. LN511-E8 is truncated laminin 511 isoform which works in multiple stem cell lines, from iPSC to hESC and MSC.

Better Adhesion

LN511-E8 variant of laminin 511 shows higher efficiency for supporting the adhesion of dissociated cells than did wild-type laminin 511.

Enhance cell differentiation

Due to the diverse biorelevant environment, GMP Laminin 511 could also enhance cell differentiation, polarization and organization of target cell types, including retinal pigmented epithelial cells, neurons, hepatocytes, cardiomyocytes, pancreatic β -cells, and so on.

Reduce Variability

LN511-E8 is a defined, recombinant human protein with better lot-to-lot consistency that reduces variability in your PSC cultures.

Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory

Key parameter

Purity (SDS PAGE) > 95%

Mycoplasma Test Negative

Sterility Test Negative

Integrin Binding Assay 1.0 nM < KD < 15 nM

Endotoxin Test < 10 EU/mg

Host Cell Protein $< 0.5 \text{ ng/}\mu\text{g}$

Host Cell DNA < 0.02 ng/µg

Formulation

Supplied as 0.2 µm filtered solution in PBS, pH7.4 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with dry ice, please inquire the shipping cost.

Storage

For long term storage, the product should be stored at liquid state at -70°C.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

- 2-8°C for 6 months under sterile condition;
- -20°C or below for 3 years.



GMP Human Laminin 511 Protein

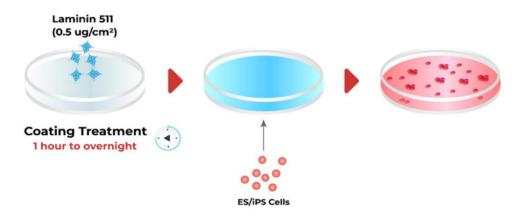
Catalog # GMP-LA1H25





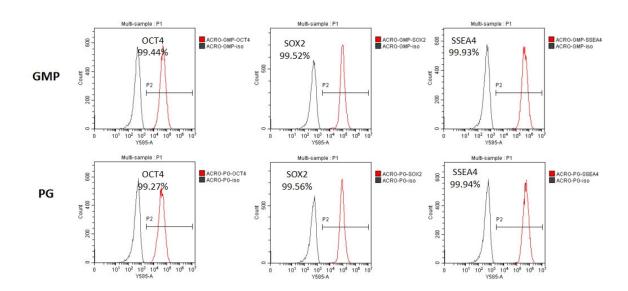
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests

The schematic diagram of Laminin 511 in ES/iPS cell culture.

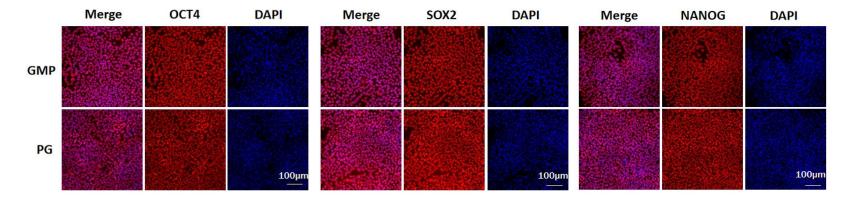


Pre-coating Method

Bioactivity-Stem Cell Culture



GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) and Human Laminin 511 Protein, premium grade (Cat. No. LA8-H5283L) could maintain the stemness of iPSC at least Passage 5 and has similar performance. FACS data indicated that the iPSCs expressed high levels of pluripotency associated markers OCT4, SOX2, and SSEA4.



GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) and Human Laminin 511 Protein, premium grade (Cat. No. LA8-H5283L) could maintain the stemness of iPSC at least Passage 5 and have similar performance. Immunofluorescence staining indicated that the iPSCs expressed high levels of pluripotency associated markers OCT4, SOX2, and NANOG.

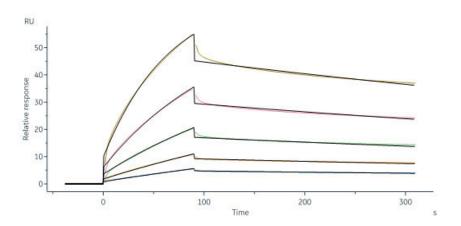
Bioactivity-SPR



GMP Human Laminin 511 Protein

Catalog # GMP-LA1H25





GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) immobilized on CM5 Chip can bind Human Integrin alpha 6 beta 1 (ITGA6&ITGB1) Heterodimer Protein, His Tag&Tag Free with an affinity constant between 1.00 nM - 15.0 nM as determined in a SPR assay (Biacore 8K) (QC tested).

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents:

- Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.
- Animal-Free materials
- Materials purchased from the approved suppliers by QA
- ISO 5 clean rooms and automatic filling equipment
- Qualified personnel
- Quality-related documents review and approve by QA
- Fully batch production and control records
- Equipment maintenance and calibration
- Validation of analytical procedures
- Stability studies conducted
- Comprehensive regulatory support files

Request For Regulatory Support Files (RSF)

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

- SDS-PAGE
- Protein content



GMP Human Laminin 511 Protein

Catalog # GMP-LA1H25



- Endotoxin level
- Residual Host Cell DNA content
- Residual Host Cell Protein content
- Biological activity analysis
- Microbial testing
- Mycoplasma testing
- In vitro virus assay
- Batch-to-batch consistency



>>> www.acrobiosystems.com