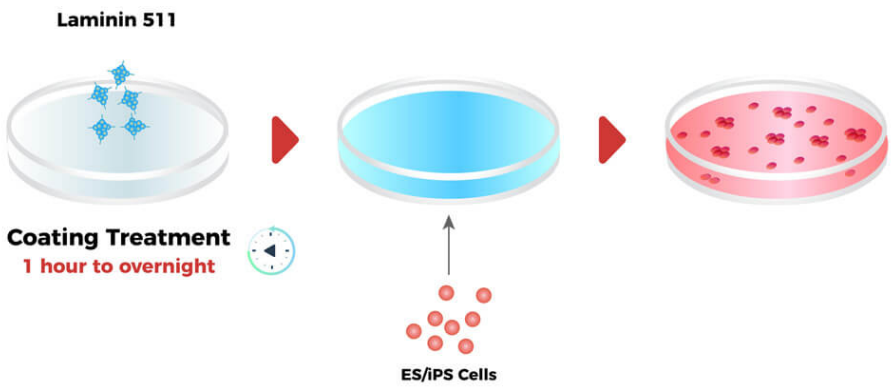
GMP Human Laminin 511 Protein

Catalog # GMP-LA1H25

The schematic diagram of Laminin in ES/iPS cell culture



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.

This product is designed and developed utilizing our proprietary AI technology, which is protected by patent rights. We retain full commercial rights to this product.

Product Features and Advantages

- **Excellent Performance**: Enables rapid expansion and superior stemness maintenance of hPSCs with strong, uniform adhesion support.
- **Superior Biological Functionality**: LN511-E8 fragment enhances cell adhesion, supports differentiation, and mimics in vivo signaling via α6β1 integrin binding.
- **Comprehensive Safety Assurance**: ECACC-compliant HEK293 host cell origin and comprehensive testing (28 items), animal-origin-free (AOF) production process, dual virus reduction measures, and comprehensive viral clearance validation.
- **Defined & Consistent Quality**: Produced from a stable cell line with a robust purification process and stringent QC for exceptional lot-to-lot consistency.

GMP Platform Advantages

- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support**: Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain**: Intelligent modular facilities ensure a stable global supply.
- **Professional Support**: Extensive manufacturing and application expertise to accelerate development.

Expression System

HEK293

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 ng/μg
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.

Vial Specification

2R (13 mm neck finish)

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 -20℃ or below.

Please avoid repeated freeze-thaw cycles.

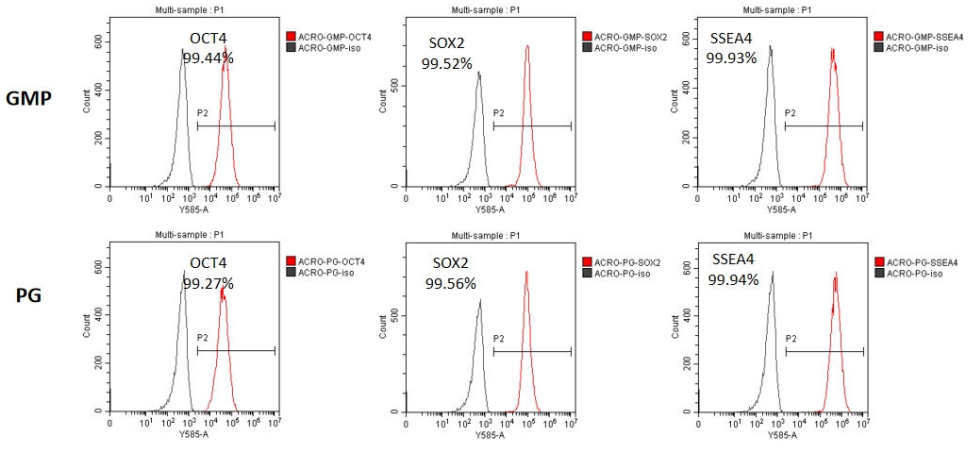
This product is stable after storage at:

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

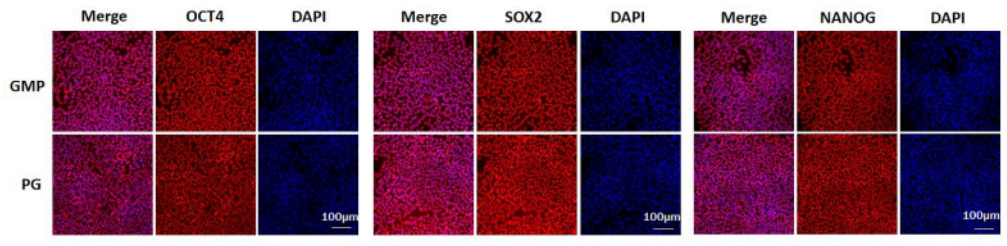
ACRO Quality Management System

- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

Bioactivity-Stem Cell Culture

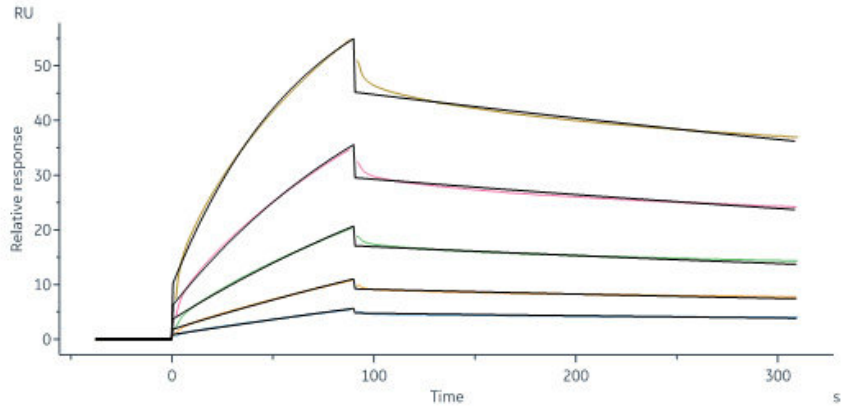


GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) and Human Laminin 511 Protein, premium grade (Cat. No. LA8-H5283L) could maintain the stemness of iPSC at least Passage 5 and has similar performance. FACS data indicated that the iPSCs expressed high levels of pluripotency associated markers OCT4,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



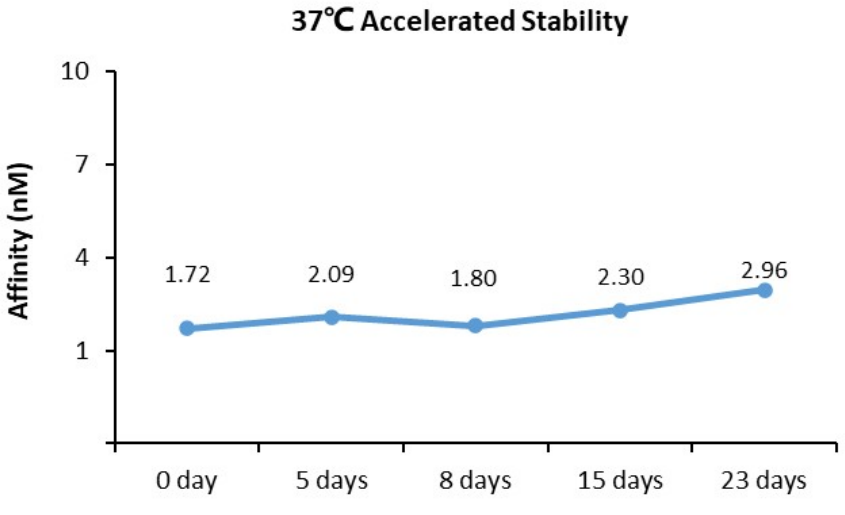
GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) and Human Laminin 511 Protein, premium grade (Cat. No. LA8-H5283L) could maintain the stemness of iPSC at least Passage 5 and have similar performance. Immunofluorescence staining indicated that the iPSCs expressed high levels of pluripotency associated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

Bioactivity-SPR

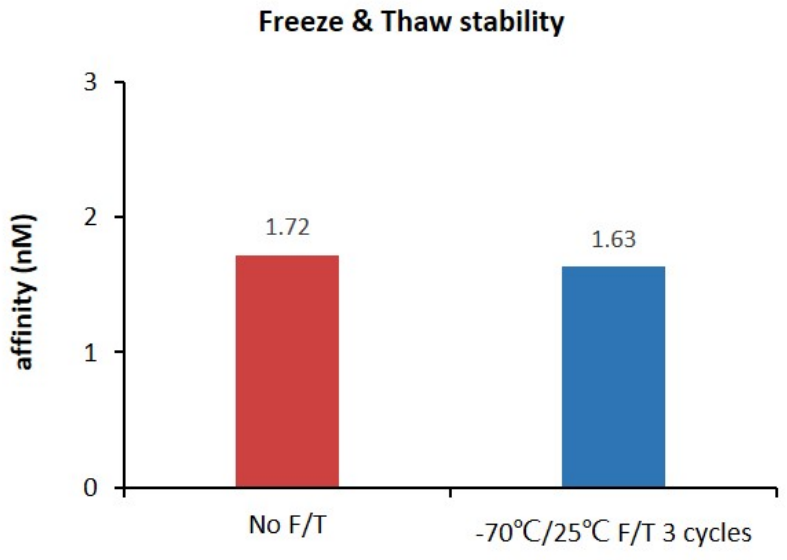


GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) immobilized on CM5 Chip can bind Human Integrin alpha 6 beta 1 (ITGA6&ITGB1) Heterodimer Protein, His Tag&Tag Free with an affinity constant between 1.00 nM - 15.0 nM as determined in a SPR assay (Biacore 8K) (QC tested).

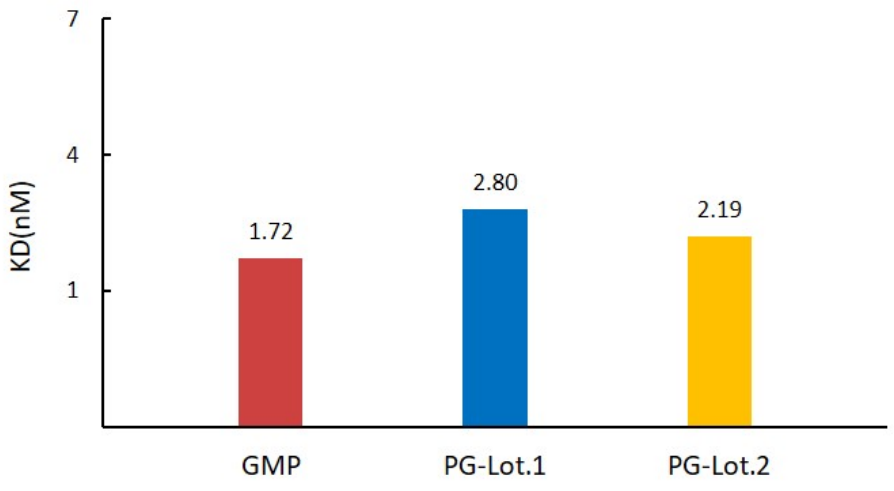
Bioactivity-Stability



SPR assay demonstrates that GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) is stable at 37℃ for 23 days.



SPR assay demonstrates that GMP Human Laminin 511 Protein (Cat. No. GMP-LA1H25) is stable after 3 freeze-thaw cycles.



SPR assay demonstrates batch-to-batch consistency between Acro's GMP and PG Laminin 511.

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：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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
- 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

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