

Product Details

GMP Human Laminin 511 Protein (Mix & Scale) is a recombinant human laminin 511 E8 (LN511-E8) protein that provides a defined surface for in vitro feeder-free culture of multiple human pluripotent stem cells (PSCs). 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.

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.

*Importantly, our innovative laminin 511 protein (Mix & Scale) could meanwhile support pre-coating method and suspension method (directly mixing the protein with cell suspensions without coating plates).*

*No coating steps are needed and easy scale-up*

Simplified operation and support automated manufacturing at a large scale.

*Cost-effective*

Significant cost reduction compared to classic coating method.

*Stemness maintenance*

No spontaneous differentiation is observed after several passages of hPSC culture.

*Lot-to-lot consistency*

Produced from a stable cell line, robust purification process, and stringent QC.

*Ready to scale supply*

A new cGMP-compliant facility is ready and supports large scale manufacutring supply.

Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests

The schematic diagram of Laminin in ES/iPS cell culture

Key parameter

Purity (SDS PAGE)	> 95%
Mycoplasma Test	Negative
Sterility Test	Negative
Integrin Binding Assay	1.00 nM < KD < 30.0 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.

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°C or below.

*Please avoid repeated freeze-thaw cycles.*

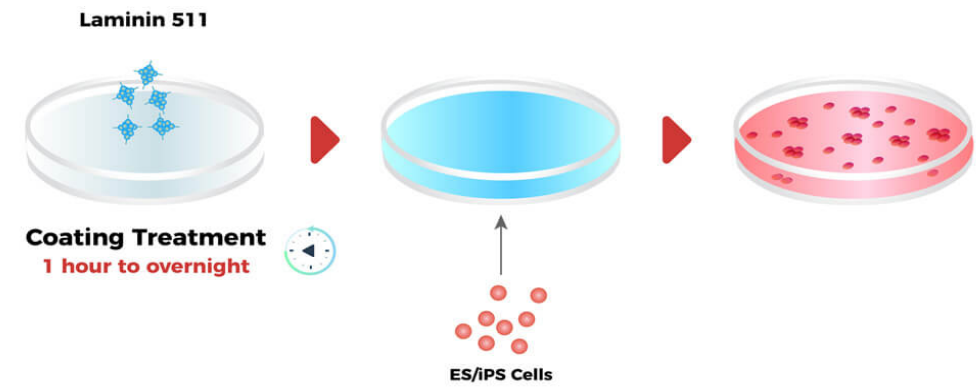
This product is stable after storage at:

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

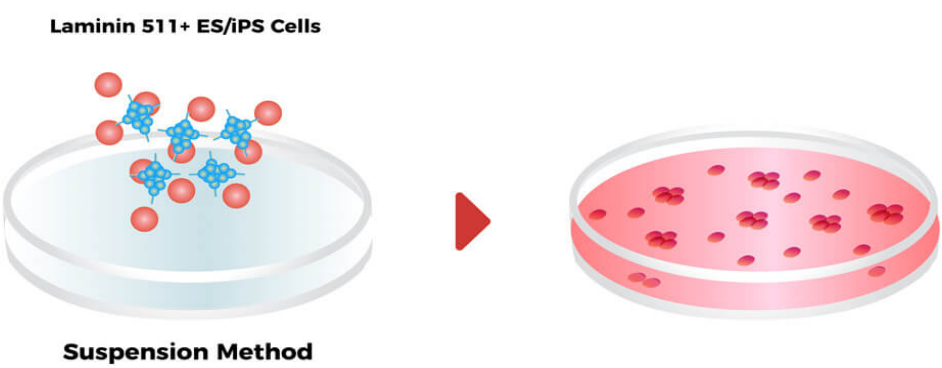


GMP Human Laminin 511 Protein (Mix & Scale)

Catalog # GMP-LA1H36

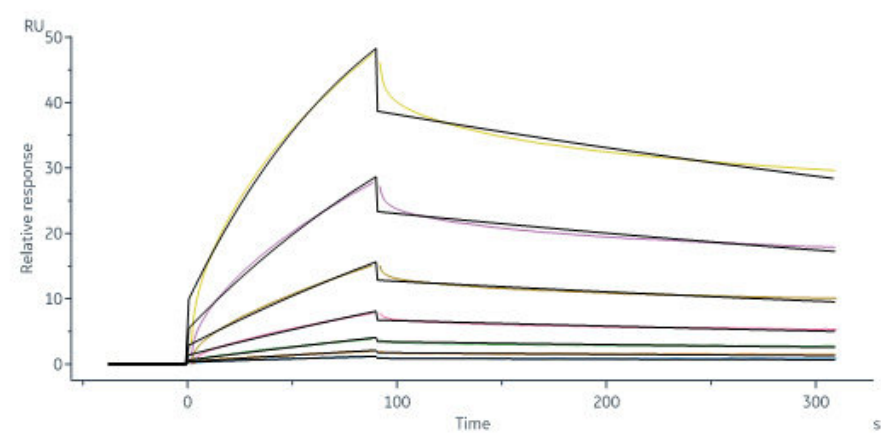


[Download Pre-coating Method Protocol](#)



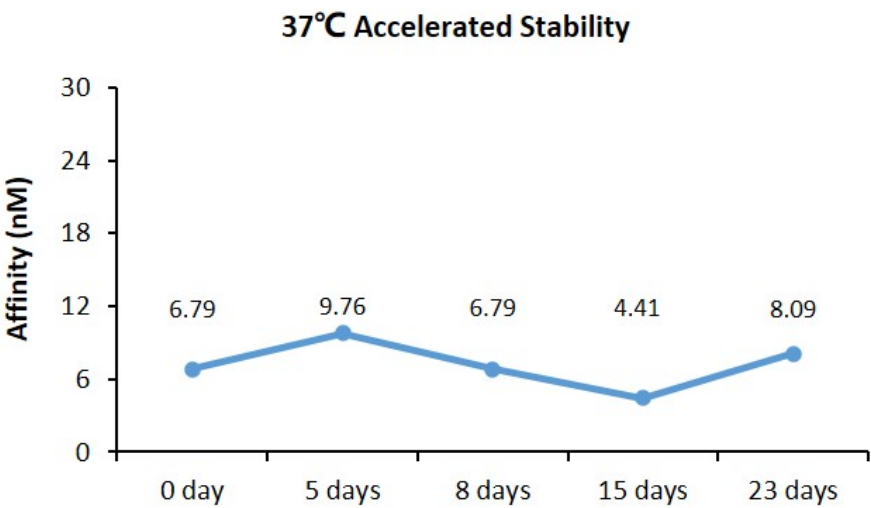
[Download Suspension Method Protocol](#)

Bioactivity-SPR

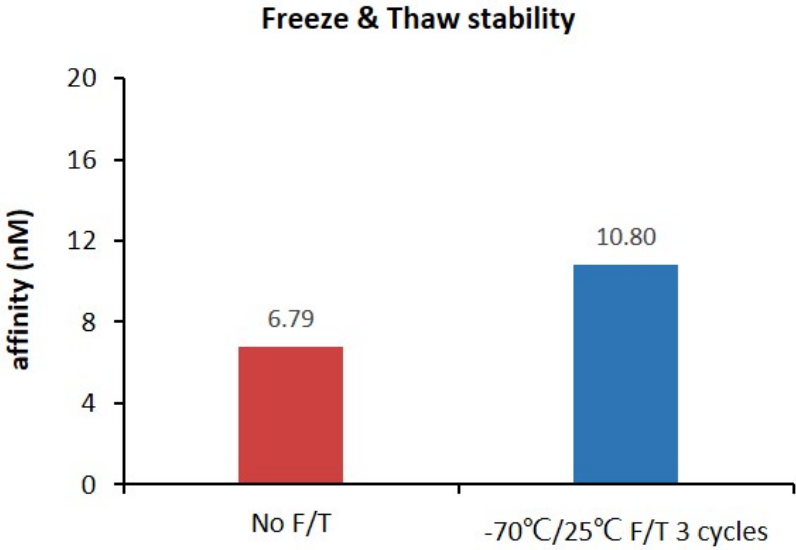


GMP Human Laminin 511 Protein (Mix & Scale) (Cat. No. GMP-LA1H36) immobilized on CM5 Chip can bind Human ITGA6&ITGB1 Heterodimer Protein, His Tag&Tag Free (Cat. No. IT1-H52W7) with an affinity constant between 1.00 nM - 30.0 nM as determined in a SPR assay (Biacore 8K) (QC tested).

Bioactivity-Stability



The SPR based assay shows that GMP Human Laminin 511 Protein (Mix & Scale) (Cat. No. GMP-LA1H36) is stable at 37°C for 23 days.



The SPR based assay shows that GMP Human Laminin 511 Protein (Mix & Scale) (Cat. No. GMP-LA1H36) is stable after freezing and thawing 3 times.



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

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

