## Product Details

GMP Human Laminin 521 Protein (GMP Laminin 521) is a recombinant human protein that provides a defined surface for in vitro feeder-free culture of multiple human pluripotent stem cells (PSCs). GMP Laminin 521 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, GMP Laminin 521 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.
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 521 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 521 protein (GMP-LA5H24) is the GMP version of laminin 521 protein premium grade (LA5-H5261), and they have exactly the same performance for seamless transition.

***Flexible & Compatible***
GMP Laminin 521 could work well in any commercial stem cell media. Meanwhile, it could support the attachment and expansion of hPSCs both in single cells or small colonies.

***Stemness maintenance***
GMP Laminin 521 is the biologically relevant hPSCs extracellular matrix. It is crucial for the growth and stemness maintenance of hPSCs in human through its binding to cell receptors a6β1 integrin.

***Enhance cell differentiation***
Due to the diverse biorelevant environment, GMP Laminin 521 could also enhance cell differentiation, polarization and organization of target cell types, including neurons, hepatocytes, cardiomyocytes, retinal pigmented epithelial cells, pancreatic β-cells, and so on.

***Reduce Variability***
GMP Laminin 521 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
- FDA DMF filed
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency

## Key parameter

| | |
|---|---|
| **Purity (SDS PAGE)** | > 95% |
| **Mycoplasma Test** | Negative |
| **Sterility Test** | Negative |
| **Integrin Binding Assay** | 0.5 nM < KD < 5 nM |
| **Endotoxin Test** | < 10 EU/mg |
| **Host Cell Protein** | < 0.5 ng/μg |
| **Host Cell DNA** | < 0.02 ng/μg |
| **In vitro virus assay** | Negative |

## Formulation

Lyophilized from 0.22 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 blue ice, please inquire the shipping cost.***

## Storage

Upon receipt, store it immediately at -20°C or lower for long term storage.

***Please avoid repeated freeze-thaw cycles.***

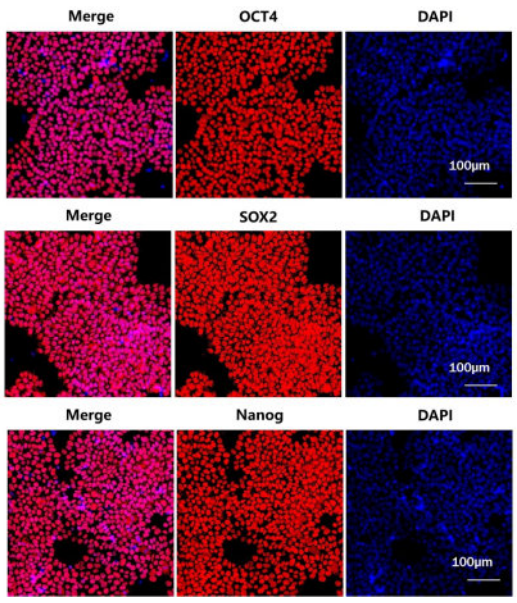
This product is stable after storage at:

- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

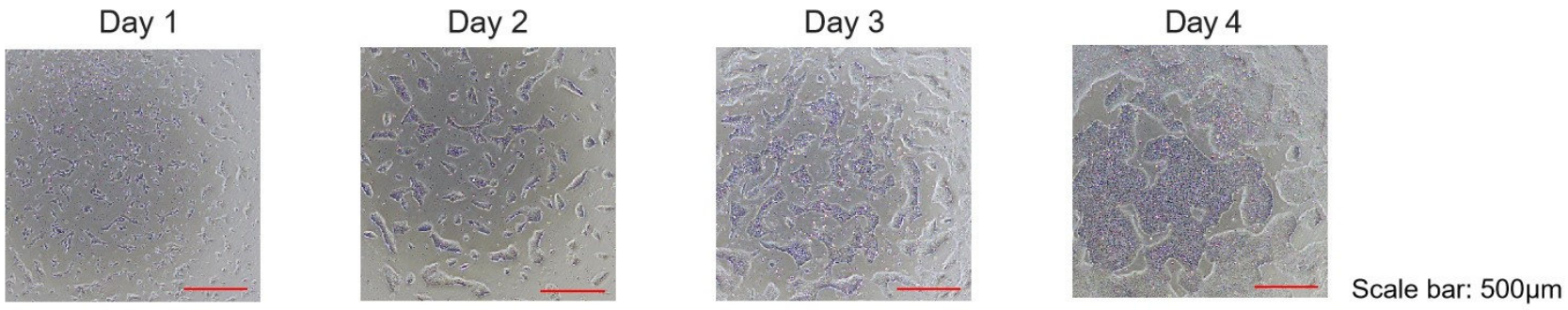
- Stringent quality control tests

## Bioactivity-Stem Cell Culture

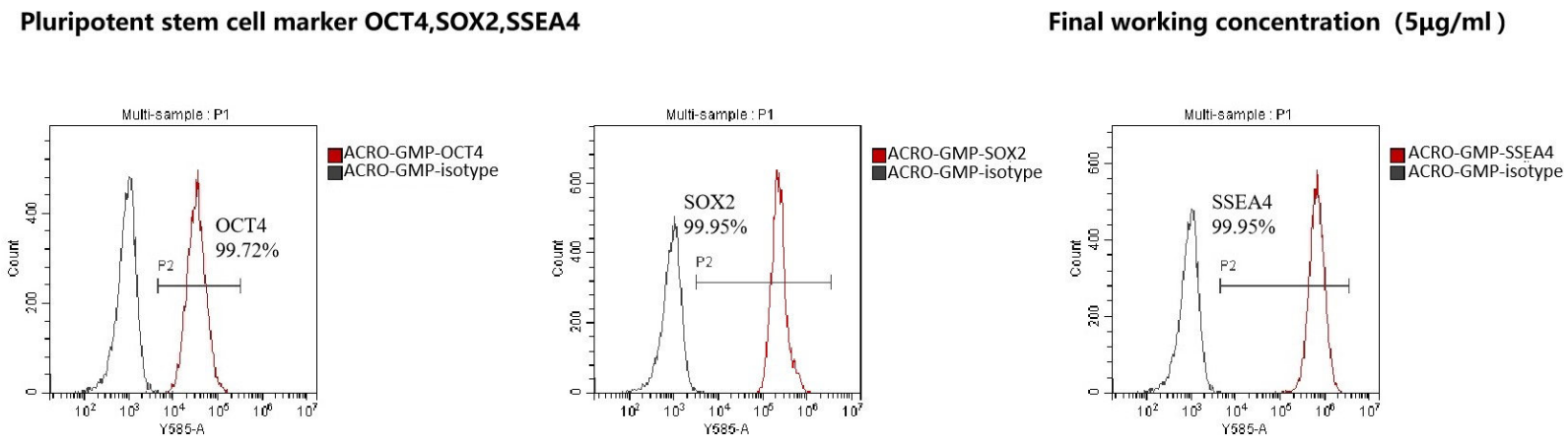
View Protocol




GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) could maintain the stemness of iPSC after several passages.

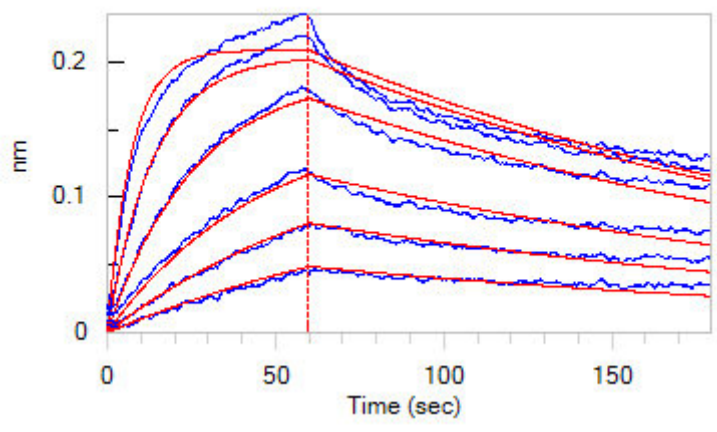



GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) could support the rapid expansion of single cell hPSCs.



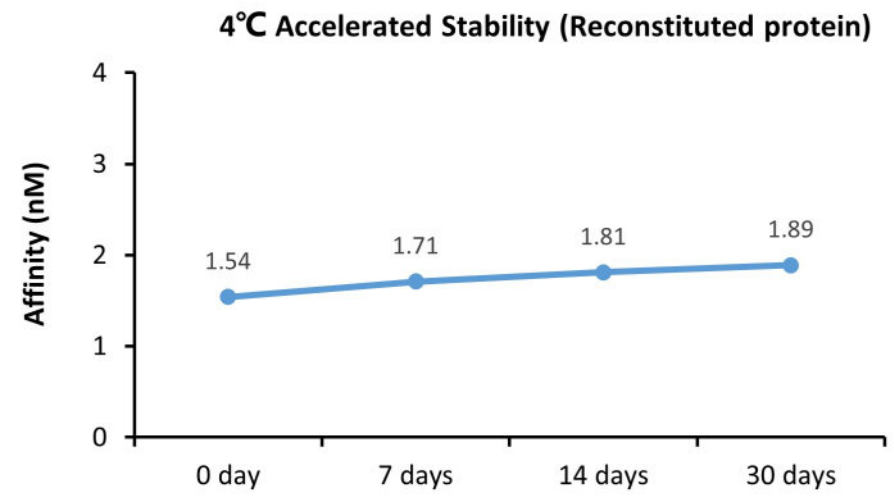

GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) could maintain the stemness of iPSC after several passages.

## Bioactivity-BLI

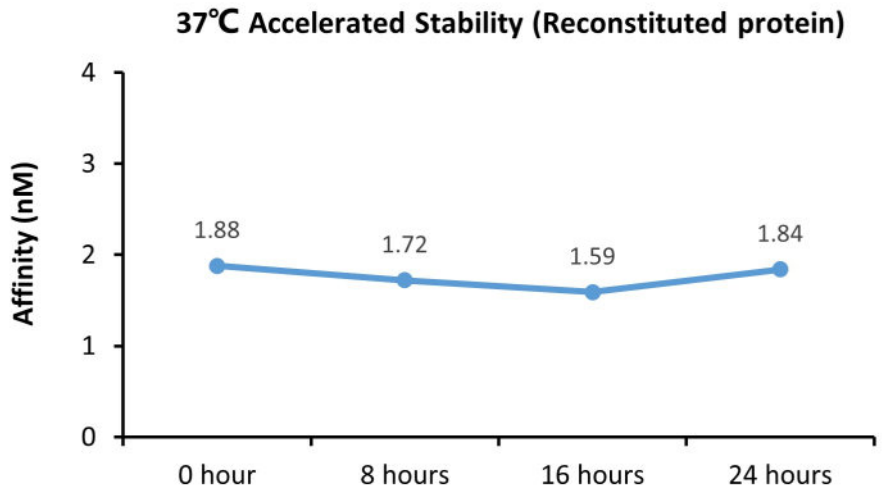


Loaded Human ITGA6&ITGB1 Heterodimer Protein, His Tag&Tag Free (Cat. No. IT1-H52W7) on HIS1K Biosensor, can bind GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) with an affinity constant between 0.50 nM - 5.00 nM as determined in BLI assay (ForteBio Octet Red96e) (QC tested).

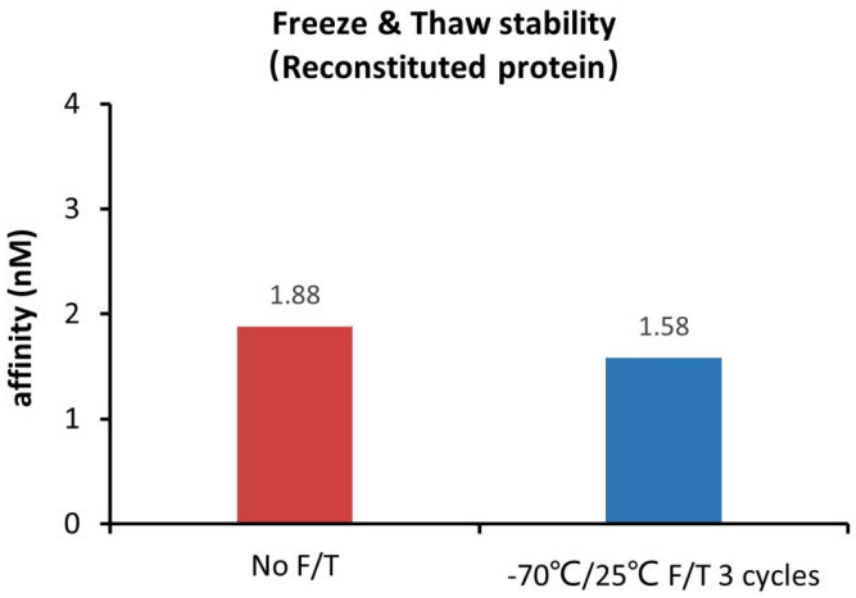
## Bioactivity-Stability



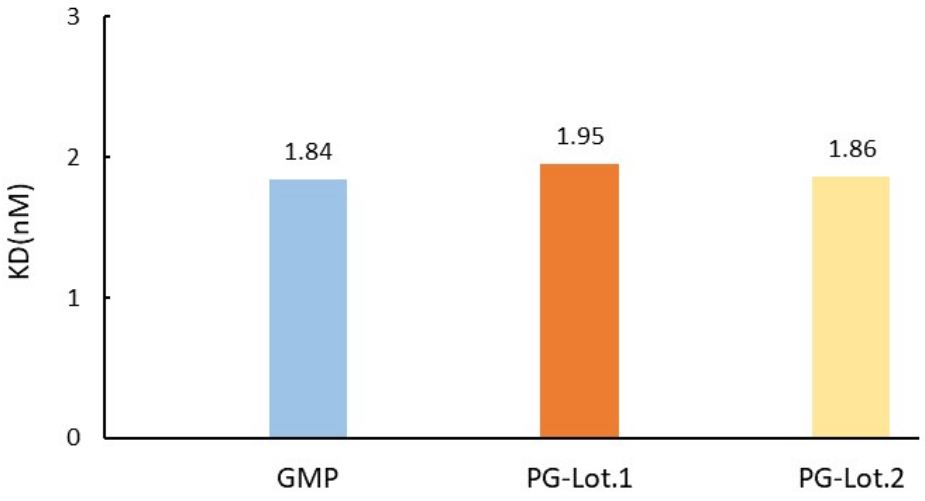

The BLI based assay shows that GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) is stable at 4℃ for 30 days.




The BLI based assay shows that GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) is stable at 37℃ for 24 hours.




The BLI based assay shows that GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) is stable after freezing and thawing 3 times.




The BLI based assay shows batch-to-batch consistency between Acro's GMP and PG Laminin 521.

## 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

Residual moisture

Batch-to-batch consistency

## Clinical and Translational Updates