

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 Human Laminin 521 Protein (Liquid) (GMP-LA5H24GA02) is the GMP version of Human Laminin 521 Protein, premium grade (Liquid) (LA5-H5213L), 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.

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  $\alpha 6 \beta 1$  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.

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
- 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 | 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       |

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

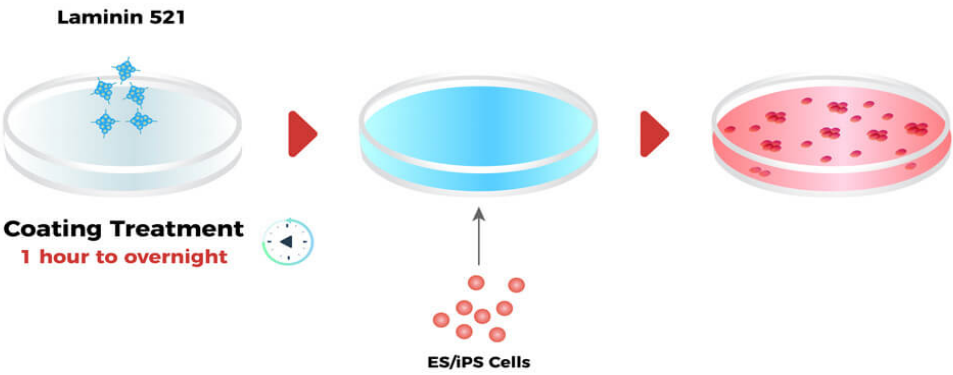
Upon receipt, store it immediately at -20°C or lower for long term storage.  
*Please avoid repeated freeze-thaw cycles.*

- This product is stable after storage at:
- -20°C or below for 3 years under sterile conditions;
  - 1 month at 2-8°C after thaw if within expiry date.



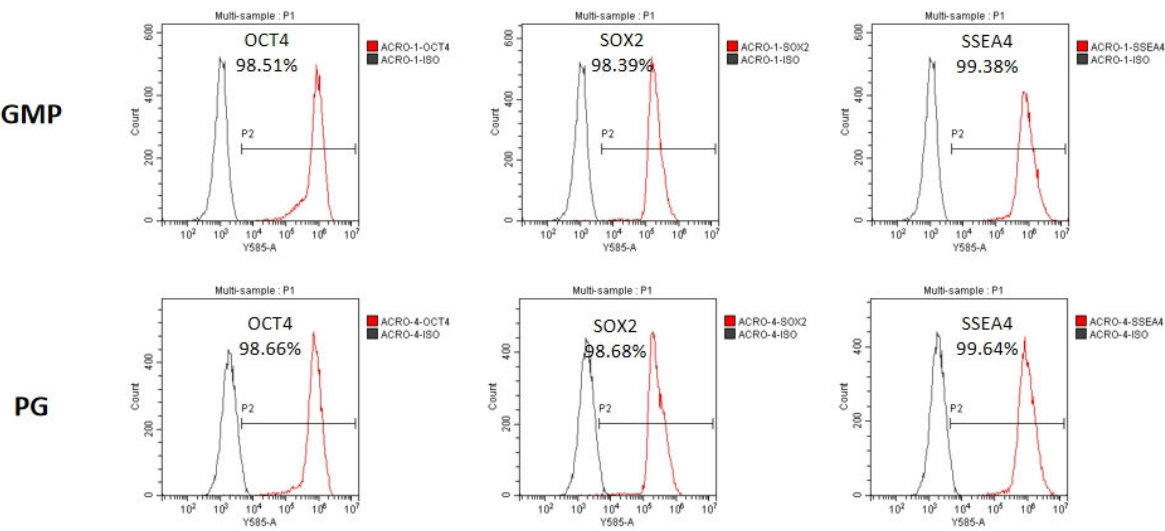
GMP Human Laminin 521 Protein (Liquid)

Catalog # GMP-LA5H24GA02

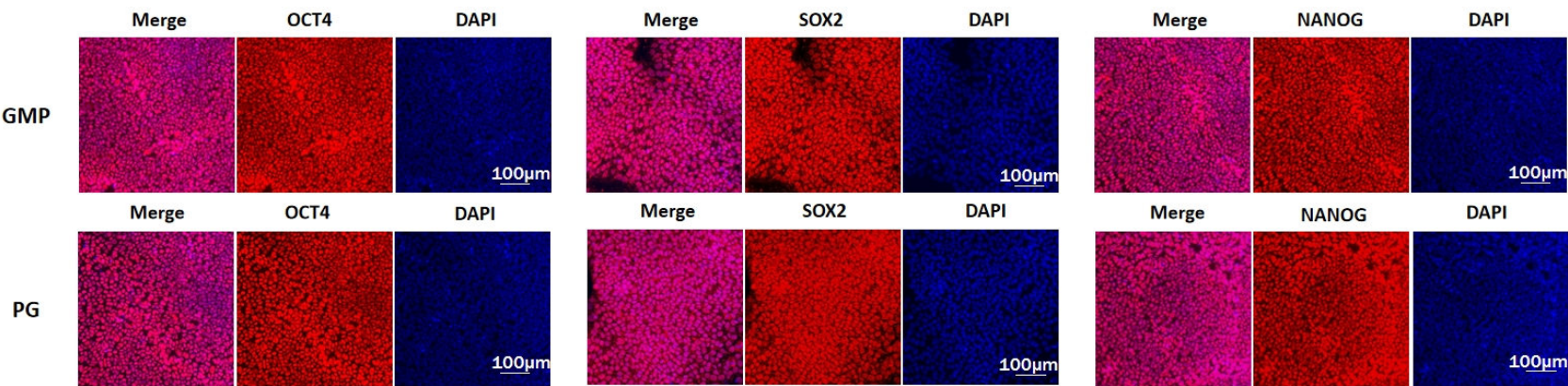


[Download Pre-coating Method Protocol](#)

Bioactivity-Stem Cell Culture



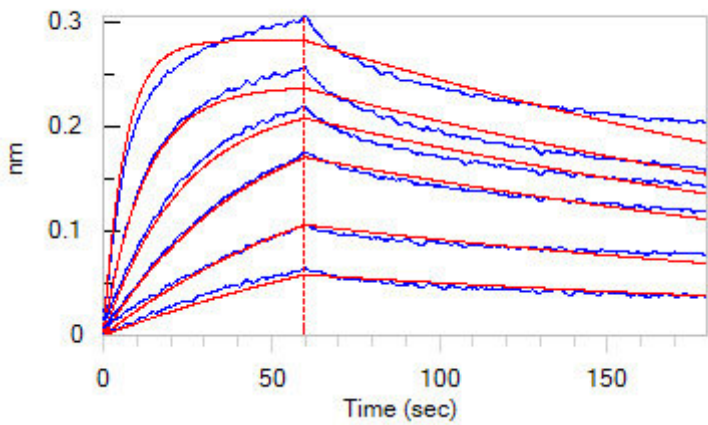
GMP Human Laminin 521 Protein (Liquid) (Cat. No. GMP-LA5H24GA02) and Human Laminin 521 Protein, premium grade (Liquid) (Cat. No. LA5-H5213L) could maintain the stemness of iPSC at least Passage 5, with high expression of stem cell genes OCT4, SOX2 and NANOG in FACS.



GMP Human Laminin 521 Protein (Liquid) (Cat. No. GMP-LA5H24GA02) and Human Laminin 521 Protein, premium grade (Liquid) (Cat. No. LA5-H5213L) could maintain the stemness of iPSC at least Passage 5, with high expression of stem cell genes OCT4, SOX2 and NANOG in immunofluorescence.

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-LA5H24GA02) with an affinity constant between 0.50 nM - 5.00 nM as determined in BLI assay (ForteBio Octet Red96e) (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 521 Protein (Liquid)

Catalog # GMP-LA5H24GA02



- 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

