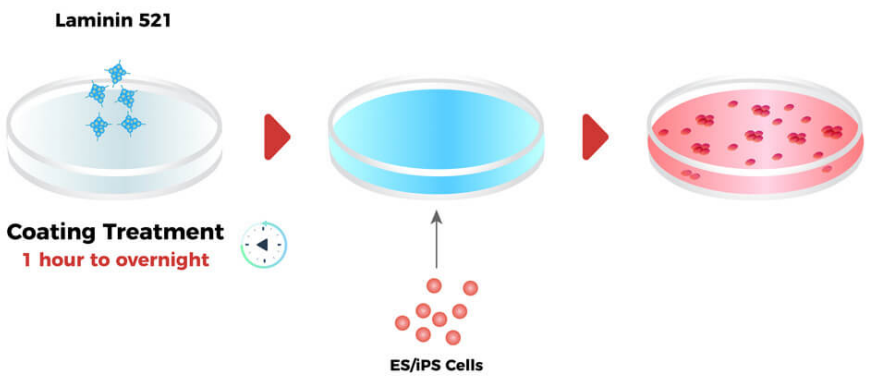
GMP Human Laminin 521 Protein (Liquid)

Catalog # GMP-LA5H24GA02

The schematic diagram of Laminin in ES/iPS cell culture



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.

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

- **High Performance**: Facilitates the rapid expansion and stemness maintenance of hPSC after several passages.
- **Optimal Adhesion**: Maintains good cell adhesion characteristics at concentrations as low as 2 μg/mL.
- **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.
- **Lot-to-Lot Consistency**: Achieved through a stable cell line and robust process, ensuring reliable performance from research to clinical manufacturing.

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
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

6R (20 mm neck finish)

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.

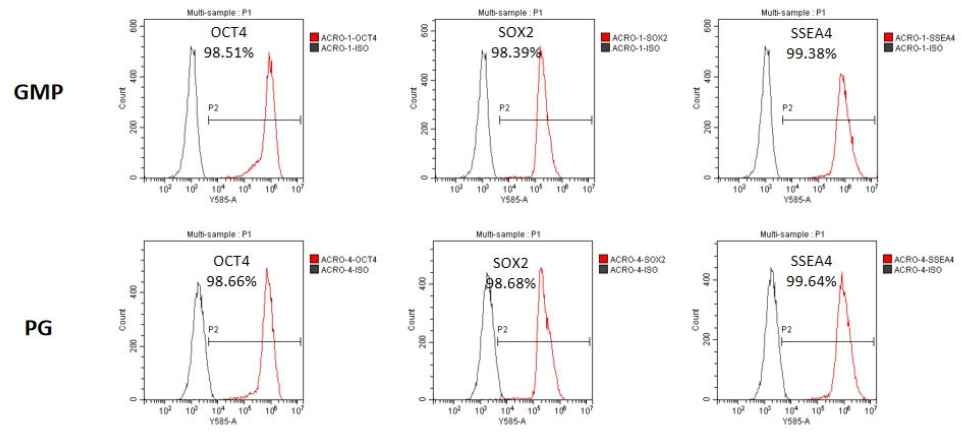
This product is stable after storage at:

- -20°C or below for 3 years under sterile conditions;
- 2-8°C for 3 months under sterile conditions after thaw if within expiry date.

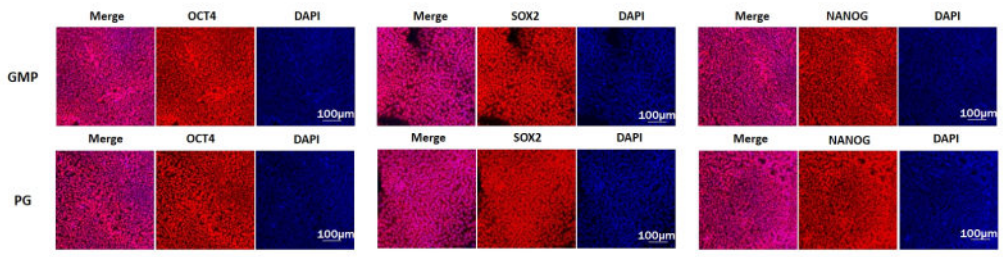
ACRO Quality Management System

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

Bioactivity-Stem Cell Culture

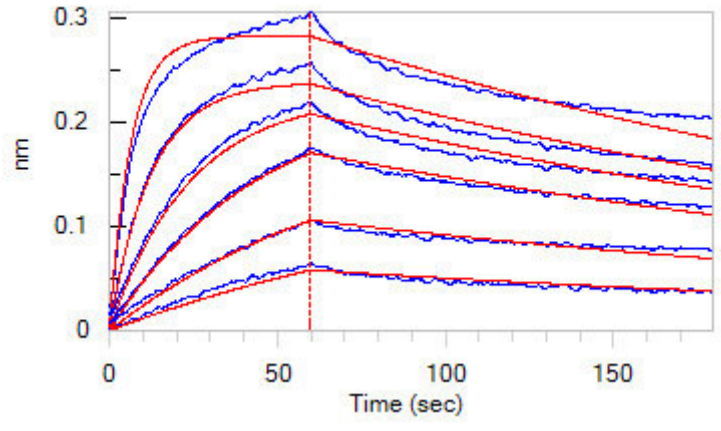


GMP Human Laminin 521 Protein (Liquid) (Cat. No. GMP-LA5H24GA02) and Human Laminin 521 Protein, premium grade (Liquid) (Cat. No. LA5-H5213L) could maintain the stemness of iPSC at least Passage 5, with high expression of stem cell genes OCT4, SOX2 and NANOG in FACS.



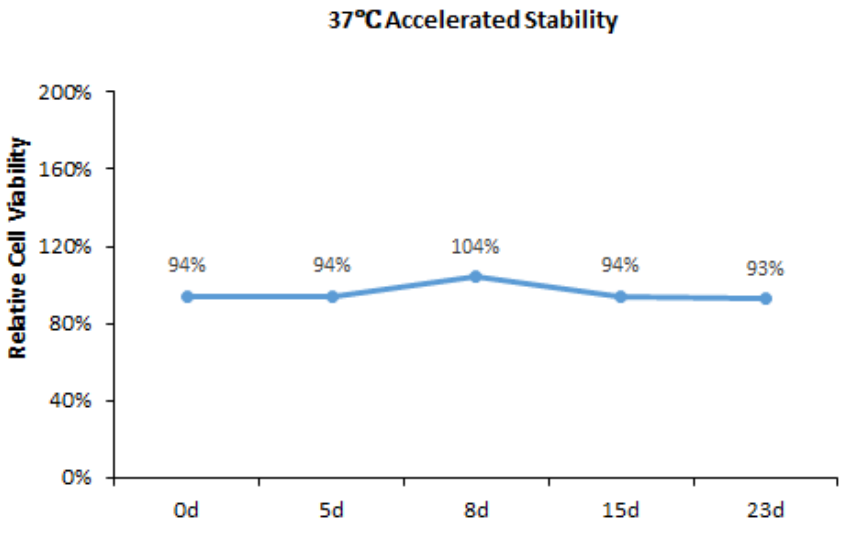
GMP Human Laminin 521 Protein (Liquid) (Cat. No. GMP-LA5H24GA02) and Human Laminin 521 Protein, premium grade (Liquid) (Cat. No. LA5-H5213L) could maintain the stemness of iPSC at least Passage 5, with high expression of stem cell genes OCT4, SOX2 and NANOG in immunofluorescence.

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 (Liquid) (Cat. No. GMP-LA5H24GA02) with an affinity constant between 0.50 nM - 5.00 nM as determined in BLI assay (ForteBio Octet Red96e) (Routinely tested).

Bioactivity-Stability



GMP Human Laminin 521 Protein (Liquid) (Cat. No. GMP-LA5H24GA02) maintains activity within 90-110% of the internal standard in stem cell culture assay at 37°C for 23 days.

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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(b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.
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(d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

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5.4 ACRO reserves the right to audit End User's compliance with these restrictions upon reasonable notice.

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