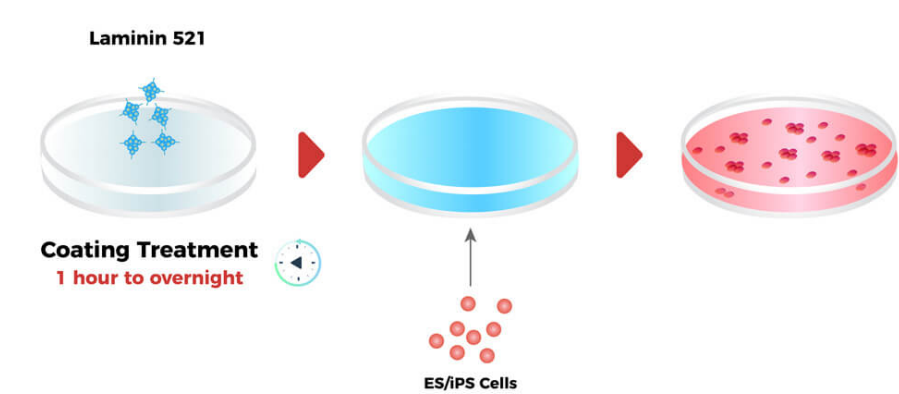


The schematic diagram of Laminin in ES/iPS cell culture



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 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.

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
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.

Vial Specification

2R (13 mm neck finish)

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.

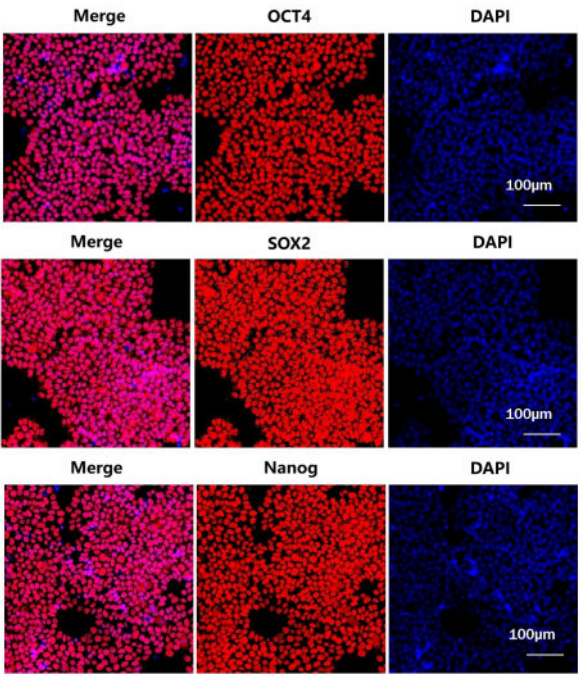
This product is stable after storage at:

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

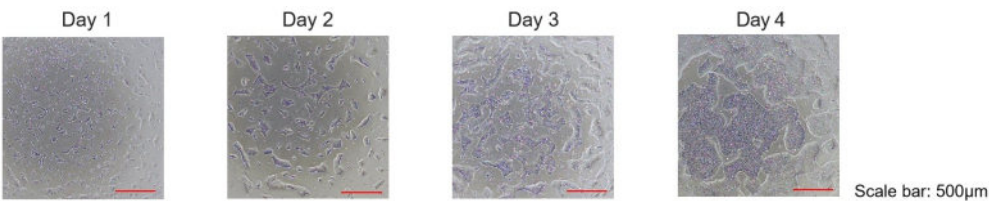
ACRO Quality Management System

- [QMS\(ISO, GMP\)](#).
- [Quality Advantages](#)
- [Quality Control Process](#)

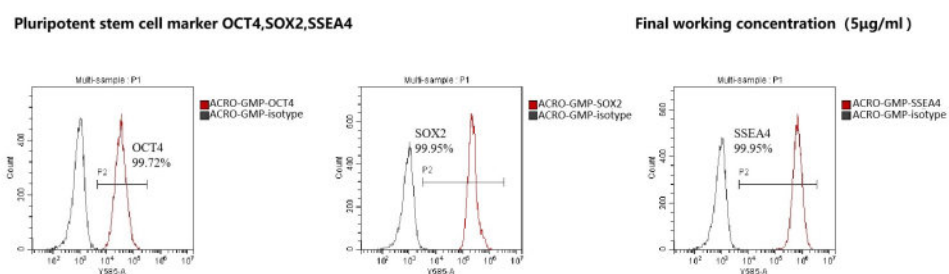
Bioactivity-Stem Cell Culture



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

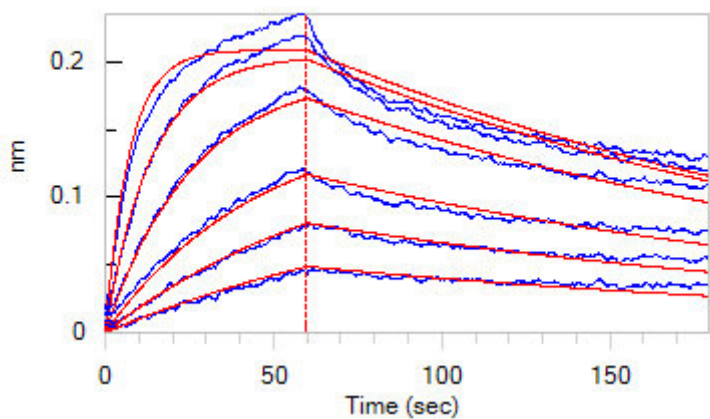


GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24) could support the rapid expansion of hPSCs.



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) (Routinely 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:

- 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
- Residual moisture
- Batch-to-batch consistency

ACROBIOSYSTEMS - LEGAL NOTICES FOR GMP GRADE PRODUCTS

1. PRODUCT USE RESTRICTIONS & PROHIBITIONS

- 1.1 ACROBiosystems ("ACRO") GMP grade products ("Products") are designed for research, manufacturing use or ex vivo use.
- 1.2 Products are NOT intended for diagnostic purposes or for direct or indirect administration into humans.
- 1.3 Purchaser shall not market, distribute, or resell Products obtained from ACRO without ACRO's prior written consent.

2. REVERSE ENGINEERING PROHIBITED & CONFIDENTIALITY

- 2.1 Purchaser shall not reverse-engineer, decompile, disassemble, sequence, analyze via bioinformatics, or otherwise attempt to discover the structure, sequence, composition, construction, manufacturing process, or any trade secret embodied in the Products. Purchaser shall not permit any third party to undertake such activities.
- 2.2 All specifications, data, and know-how related to the Products provided by ACRO are ACRO's confidential information and shall be protected accordingly.

3. LIMITED WARRANTY & DISCLAIMERS

- 3.1 ACRO warrants solely that Products will conform to their published specifications when used under normal, specified laboratory/manufacturing conditions and within their labeled expiration date. THIS IS THE ONLY WARRANTY PROVIDED.
- 3.2 Purchaser assumes ALL risk and responsibility for:
 - (a) Determining the suitability of Products for Purchaser's intended application(s).
 - (b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.
 - (c) Compliance with all applicable laws, regulations (including but not limited to cGMP/GLP where claimed), and industry standards.
 - (d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.
 - (e) Proper storage, handling, and use of Products according to ACRO's instructions.
- 3.3 ACRO EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING BUT NOT LIMITED TO: (A) WARRANTIES OF MERCHANTABILITY; (B) WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE; (C) WARRANTIES OF NON-INFRINGEMENT; AND (D) WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

4. LIMITATION OF LIABILITY

- IN NO EVENT SHALL ACRO, ITS AFFILIATES, OR SUPPLIERS BE LIABLE FOR ANY OF THE FOLLOWING, HOWSOEVER ARISING (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, STATUTE, OR OTHERWISE):
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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.
 - (c) DAMAGES ARISING FROM: (i) MISUSE, ABUSE, OR UNAUTHORIZED MODIFICATION OF PRODUCTS; (ii) USE BEYOND THE EXPIRATION DATE; (iii) IMPROPER STORAGE OR HANDLING; (iv) ACCIDENTAL DAMAGE; (v) FAILURE TO CONDUCT ADEQUATE VALIDATION OR TESTING BY PURCHASER; (vi) INFRINGEMENT CLAIMS RELATED TO PURCHASER'S USE; OR (vii) THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES.
 - (d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

5. END USER ACKNOWLEDGEMENT & COMPLIANCE

- 5.1 By accepting, opening, or using the Products, the End User (Purchaser or its downstream recipient) agrees to be irrevocably bound by all terms herein.
- 5.2 End User explicitly acknowledges the Products are NOT FOR HUMAN ADMINISTRATION and agrees not to use them in any in vivo human application, directly or indirectly.
- 5.3 End Users unwilling to accept these terms must immediately: (a) cease all use; (b) notify ACRO or their supplier; and (c) return the unopened, unused Products.
- 5.4 ACRO reserves the right to audit End User's compliance with these restrictions upon reasonable notice.

ACRO has the right, at its sole discretion, to modify, add or remove any terms herein without notice to Purchaser and/or End User. Any changes to these terms are effective immediately following the updating of such changes on ACRO’s website or published specifications or product-related documents.

Discounts, Gifts,
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