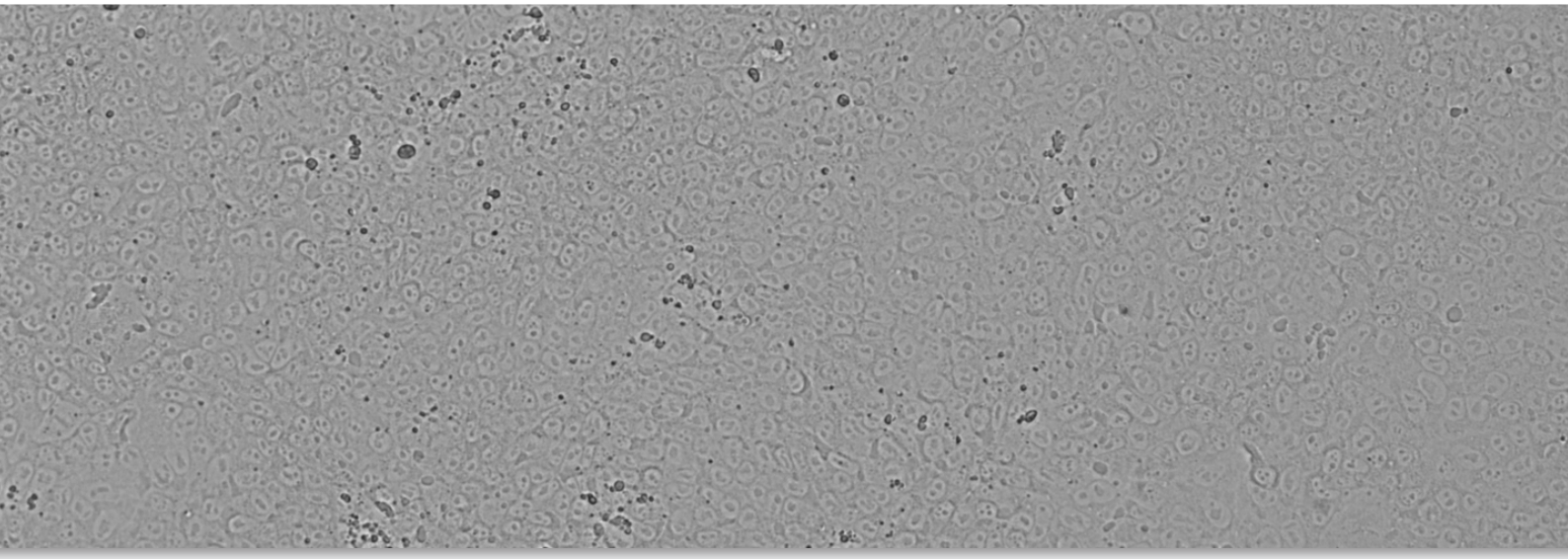
BioLamina
REVOLUTIONIZING CELL CULTURE

APPLICATION NOTE 015

BIOLAMININ 521 CELL THERAPY GRADE

A CLINICALLY RELEVANT CELL CULTURE SUBSTRATE



A CELL CULTURE SUBSTRATE DESIGNED FOR CLINICAL RESEARCH

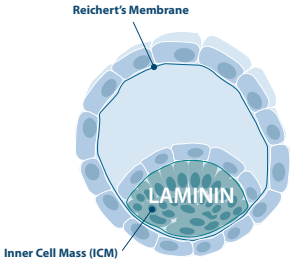
As a complement to our portfolio of defined and animal component-free laminin stem cell substrates, we now offer a cell therapy grade (CTG) Biolaminin™ 521 cell culture substrate For Research Use or Non-commercial Manufacturing of Cell, Gene, or Tissue-Based Products. Biolaminin 521 CTG (CT521) has been developed and manufactured to allow customers to qualify the material for use in the manufacturing of cells for clinical research. USP Chapter 1043: Ancillary materials for cell, gene and tissue-engineered products has been considered in the design of the product. The product is animal origin component free and has supporting documentation, such as Certificate of Analysis and Animal Origin Free Statement provided with every lot to support regulatory filings.

SEAMLESS TRANSITION FROM BENCH TO CLINIC

CT521 is a full-length, human, recombinant laminin 521 substrate, the only one of its kind on the market, providing an optimal environment for feeder-free culture of human PSCs, MSCs and most anchorage-dependent progenitor cell types. With this new clinical grade product, scientists are supported throughout their cell therapy development process – from concept to commercialized therapy.

BIOLOGICALLY RELEVANT CULTURE ENVIRONMENT

Laminin 521 is a key basement membrane protein of the natural stem cell niche, expressed and secreted by hPSCs in the inner cell mass of the embryo. Laminins bind to cell surface receptors activating cell signaling cascades, leading to more functional cells.



The CT521 substrate recreates a more authentic culture environment and supports reliable single-cell or colony expansion of hPSCs as well as efficient differentiation, maturation, polarization and organization of specialized cell types.

FEATURES AND SPECIFICATIONS:

- Cell therapy grade substrate
- Designed for clinical research - USP Chapter 1043*
- Animal component–free to the secondary level**
- Manufacturing control and traceability
- Consistent and reliable performance
- Biologically relevant culture environment
- Easy and flexible culture system
- Homogenous and genetically stable hPSC cultures
- Easily adaptable to automation platforms
- Efficient differentiation and enhanced cell maturation, polarization and organization
- For research use or non-commercial manufacturing of cell, gene, or tissue-based products

Direct link to Biolaminin 521 CTG information online

*U. S. Pharmacopeia. Chapter 1043: Ancillary Materials for Cell, Gene, and Tissue-Engineered Products.
** ISCT guidance document "ISCT Animal-Free Origin Survey Results-Summary"

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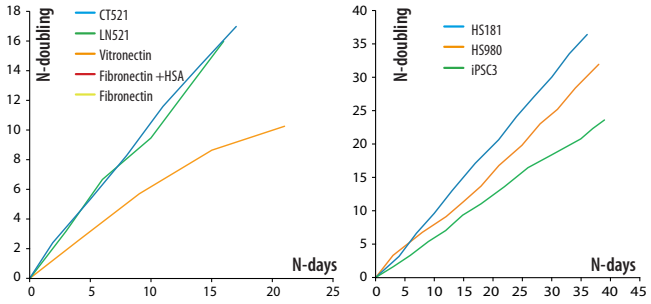
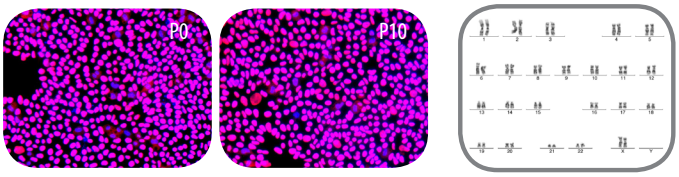
RAPID CELL EXPANSION ON CT521



Left: Cells passaged as single cells (wo ROCKi) on CT521 and LN521 in iPS-Brew medium have similar proliferation rate and accumulate significantly faster compared to cells cultured on Vitronectin. Fibronectin substrates could not support cell growth. Right: Accumulation rate (10 p) for hESC cell lines HS181 and H980 and iPSC cell line iPSC3.

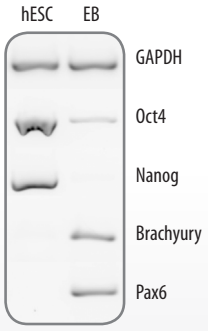
PLURIPOTENT AND WITH A NORMAL KARYOTYPE



hESC cells (HS181) cultured on CT521 as single-cells in iPSC-Brew medium for 10 passages remain pluripotent (Oct4+; pink). The HS181 also have a normal karyotpe after 13 passages on CT521.

MAINTAINED DIFFERENTIATION CAPACITY AFTER LONG-TERM CULTURE ON CT521

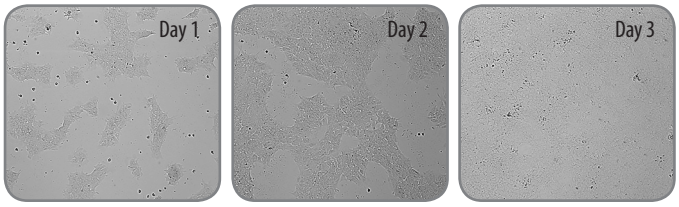
Gene expression analysis of markers for pluripotency (Oct4 and Nanog) and germline-specific markers (Brachyury and Pax6) expressed in hESC cultured as single cells on CT521 for 10 passages (left) and embryoid body (EB) differentiated hESC cells (P10, right) show that hESC cultured on CT521 retain the capacity to differentiate.



REFERENCES

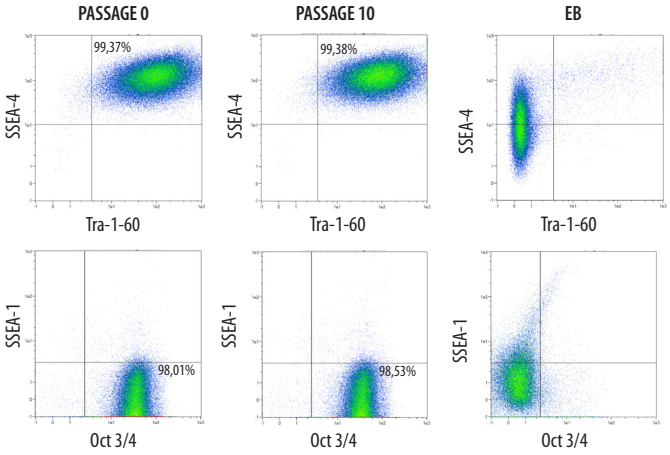
- Clonal culturing of human embryonic stem cells on laminin-521/E-cadherin matrix in defined and xeno-free environment. Rodin et al. Nat Commun. 2014
- a-5 Laminin Synthesized by Human Pluripotent Stem Cells Promotes Self-Renewal. Laperle et al. Stem Cell Reports, 2015
- Laminin 521 stabilizes the pluripotency expression pattern of human embryonic stem cells initially derived on feeder cells. Albalushi et al. Stem Cell International, 2017

HOMOGENOUS MONOLAYER OF hPSCs ON CT521



- Single-cell seeding
- Derivation & gene editing
- No ROCKi needed
- Monolayer growth
- Allows clonal survival
- No spontaneous differentiation
- Can grow near confluence
- Passage with enzyme or EDTA
- Compliant with any medium

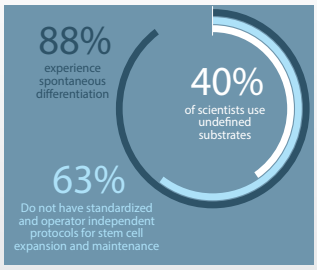
NO SPONTANEOUS DIFFERENTIATION



Flow cytometry analysis shows that HS181 cells cultured on CT521 iPSC-Brew remain pluripotent after 10 passages and with retained capacity to differentiate (EB). Pluripotency markers; SSEA-4, Tra-1-60 and Oct3/4. Differentiation marker; SSEA-1.

THE IMPACT OF CULTURE SUBSTATES ON CELL BEHAVIOUR

The type of substrate used for cell culture will influence cell behaviour and have a great impact on the research results. Yet 40% of scientists use undefined cell culture substrates where >60% are facing issues, such as low cell yield and bad cell quality, and are struggling with laborious, inconsistent and operator-dependent procedures. Moreover, almost 90% of these scientists have issues maintaining a homogenous stem cell population, having to spend time manually removing differentiated cell areas. With the CT521 substrate, you will get a robust and reliable culture method with high cell quality and yield.



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