Solentim

MatriClone™ and Clinical Manufacturing Grade Laminin

In-solution matrices for high efficiency, high viability iPSC single-cell cloning and outgrowth

ADVANCED INSTRUMENTS

Product specifications[1]

Product name	MatriClone**	Clinical Manufacturing Grade Laminin
Product guide	RS-2100 - MatriClone 2 x 175µg RS-2101 - MatriClone 6 x 175µg	RS-4100 – Clinical Manufacturing Grade Laminin*^ 6 x 175ug
Product claims	Research Grade	Clinical Grade
Declaration	For research use only	For research use or clinical manufacturing^
Product specification	Human recombinant Laminin-511, truncated E8 fragment A trimeric protein of 150kDa	
Content	Recombinant human Laminin-511 E8 fragment protein in PBS(-)	
Quality control	• Bacterial endotoxins test • Sterility test • Mycoplasma test (PCR) • Purity (SDS-PAGE) • Integrin bindng assay (kd) • Concentration	• Bacterial endotoxins test • Sterility test • Mycoplasma test (PCR) • Purity (SDS-PAGE) • Integrin binding assay (kd) • Concentration • Virus testing
Documentation	CoA & Animal Origin Statement (AO)	CoA & Animal Origin Statement (AO) TSE/BSE Statement Certificate of Standard Biological Ingredients
Storage and shipping	Store at 2-8°C Shipped on ice packs direct from Advanced Instruments	Store at 2-8°C Shipped on ice packs Drop shipped from Japan to customer with agreed courier

Table: Clinical Manufacturing Grade Laminin* is only available to customers under supply agreement with Advanced Instruments for use with Solentim VIPS and/or Cell Metric. Clinical Manufacturing Grade Laminin is a product of Matrixome, Japan, supplied via Advanced Instruments to its customers under supply agreement.

** MatriClone is not available for sale in Japan, South Korea or Taiwan via Advanced Instruments

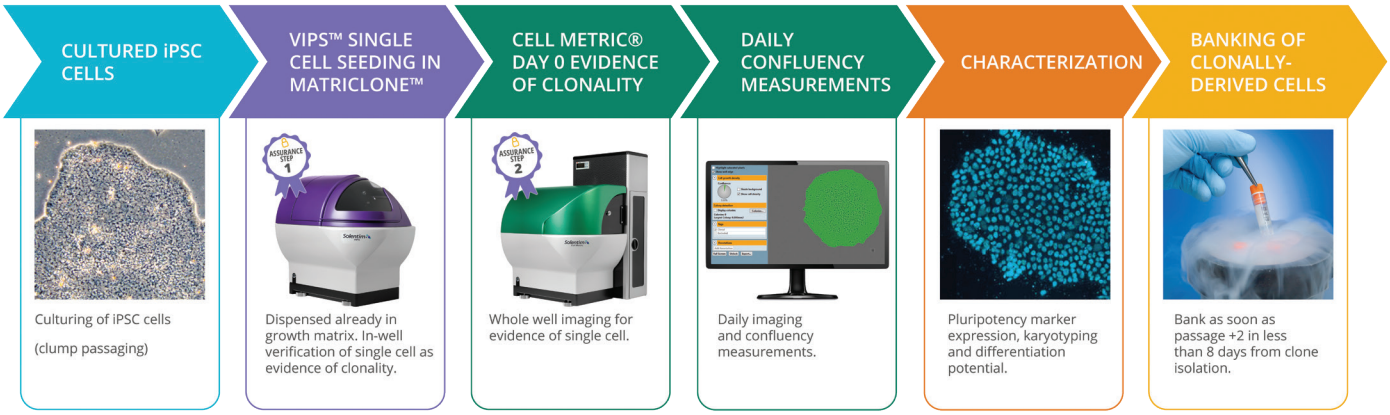
Enhancing iPSC Single-Cell Cloning and Outgrowth

Induced pluripotent stem cells (iPSCs) have tremendous potential and capability to differentiate into any cell type in the human body. However, single iPSCs often fail to grow into colonies without the addition of growth factors. Traditional matrices on the market today pose limitations. First, they are sourced from animal tumor-derived components, which carry the risk of xenopathogenic transmission. Second, they require pre-coating plates, a labor intensive, time-consuming and variable method.

In-solution format: The new standard matrix for iPSC single-cell cloning

Solentim MatriClone™ (research-grade) and Clinical Manufacturing Grade Laminin* take single-cell cloning of iPSCs to a new level of efficiency. These defined, animal component-free matrices support single-cell cloning workflows for making master cell banks, while maintaining pluripotency in research and clinical settings. Optimized for in-solution use, MatriClone and Clinical Manufacturing Grade Laminin eliminate the need for pre-coating plates, saving time and conserving product.

The matrices are composed of a truncated recombinant Laminin-511 protein, the Essential 8 fragment, enabling iPSC cell lines to be cultured in single or multi-cell formats under feeder-free conditions. The truncated version of Laminin-511 promotes greater adhesion than full-length Laminin protein and allows for less movement of cells during growth, which assists single cell and colony imaging.



A simple, automated workflow

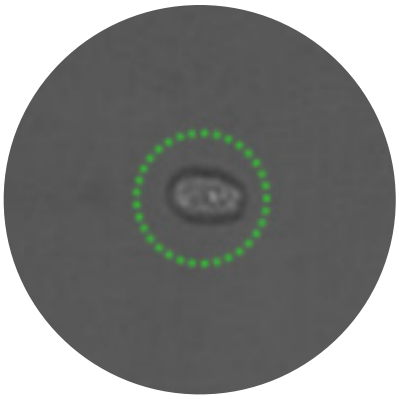
When used as part of the Verified In-Situ Plate Seeding (VIPS™) protocol, MatriClone and Clinical Manufacturing Grade Laminin offer high single-cell survival and outgrowth, all in a simple, automated workflow. iPSC cells easily adapt to in-solution MatriClone and Clinical Manufacturing Grade Laminin in a stepwise passaging process. Then, the reagents are simply added to the cell culture medium for the rest of the workflow, eliminating the need to coat the plates.

Unparalleled efficiency, quality and performance

Enhance cell line development workflows with MatriClone and Clinical Manufacturing Grade Laminin. These matrices help improve cloning efficiency, confidence and consistency of clonality across research and development and clinical settings.

Simple, fast and cost-effective

The in-solution formulation of MatriClone and Clinical Manufacturing Grade Laminin eliminates the need for manually pre-coating plates. The reagent is simple to prepare and use with the cells. The format also eliminates the incubation period and requires only half the concentration of reagent compared to pre-coating methodologies.



VIPS seeded iPS single cell adapted to MatriClone matrix

Higher productivity

When using VIPS as a combination platform with MatriClone or Clinical Manufacturing Grade Laminin, a higher percentage of clonal outgrowth wells is achieved per plate as a result of higher single-cell seeding efficiency and higher cloning efficiency. Processing fewer plates saves time, which is crucial for gene editing projects where several hundred colonies may be required.

Superior quality

No stresses are placed on the cell line, preventing differentiation and maintaining pluripotency.
The supplements are present in the detachment plate, the cell reservoir and the clone outgrowth plates

Consistent and reliable performance ready for clinical manufacturing

MatriClone and Clinical Manufacturing Grade Laminin are manufactured under the same conditions, using the same equipment and processes, ensuring that the protocols for use and products will transition consistently from process development (PD) to clinical manufacturing. This means the same SOP developed in PD with MatriClone can be exactly replicated in manufacturing with the Clinical Manufacturing Grade Laminin.

Batch-to-batch consistency

Users can ensure a high batch-to-batch consistency of Clinical Manufacturing Grade Laminin, which is not typically the case for other matrices.

Animal component-free

MatriClone and Clinical Manufacturing Grade Laminin are defined, animal component-free reagents, which removes the potential for contaminants and improves consistency of quality and performance.

Optically suited for automated imaging

Compatibility with automated imaging platforms enables easy detection of single cells, preventing ambiguity due to debris in the well and lack of movement of cells.

Validating the in-solution performance of MatriClone and Clinical Manufacturing Grade Laminin

Application Note:

A study assessed the in-solution performance of MatriClone at different concentrations.

- MatriClone outperformed a leading competitor, supporting a higher confluence level over the five-day period for both in-solution and pre-coated plate formats.
- Only half the concentration of MatriClone is required for in-solution use.
- After the iPSC line was passaged with the in-solution MatriClone, various pluripotency assessments showed no differentiation, and the cells retained their ability to differentiate successfully.

The study also looked at clonal outgrowth results using VIPS to dispense iPSC cells with MatriClone in-solution versus using limiting dilution with MatriClone.

- VIPS single-cell seeding combined with in-solution MatriClone further enhanced the percentage of clonal outgrowth achieved in a single workflow.

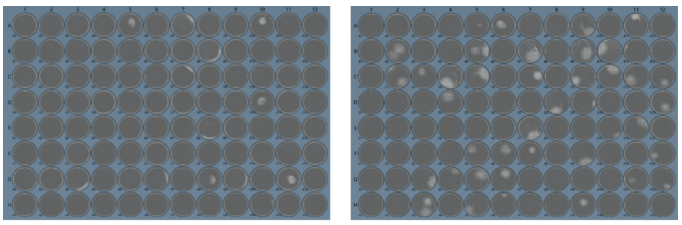
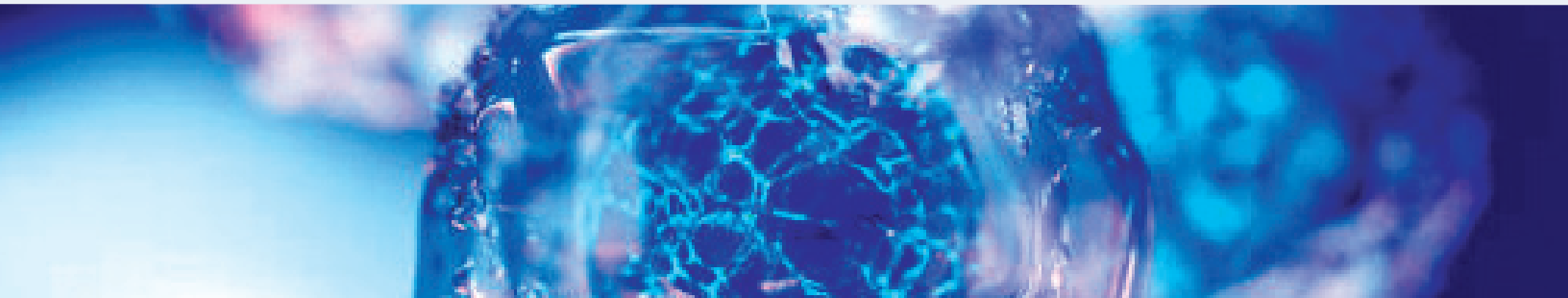
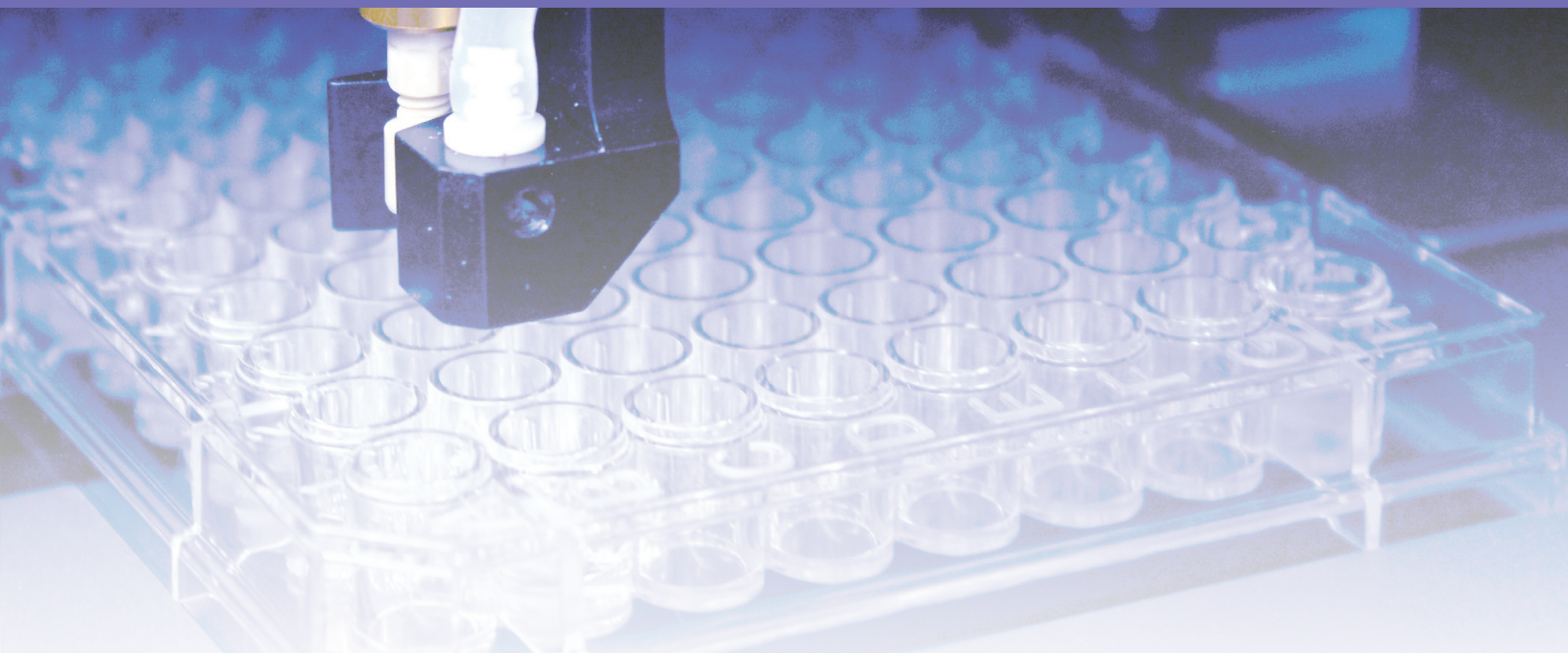


Image a) **Image b)**

Image captured using VIPS instrument at day 14 as an example of enhanced colonies from a) LD seeded plates and b) VIPS seeded plates

To learn more, visit www.aicompanies.com





About Advanced Instruments

Advanced Instruments is a global company offering a novel portfolio of analytical tools including, OsmoTECH®, a robust line of micro-osmometers to support bioprocessing and quality control (QC), and Solentim, a portfolio of best in class imaging and single-cell deposition technologies for cell line development workflows and assurance of clonality for regulatory bodies. Our Solentim portfolio enables the clonal isolation, outgrowth, and characterization of the highest value cells for monoclonal antibody upstream development and cell and gene therapy. This enables our customers to use these clones and have the documentation they were clonally-derived to confidently form their Master Cell Banks.

Delivering speed and confidence in single-cell seeding

Advanced Instruments offers a line of products to enhance your cell line development workflows. Our single-cell seeding products include Solentim VIPS™, which takes single-cell cloning and image-based clonality assurance to a new level.

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