CHALLENGING THE UNKNOWN



SOLALLIS BIO

About SOLALLIS BIO

"Regenerative medicine holds the potential to help make previously untreatable diseases treatable. However, significant barriers remain to its widespread clinical adoption. Convinced that advances in culture medium technology are key to overcoming these barriers, we founded Solallis Bio in Kyoto in 2023.

We solve challenges in cell manufacturing through consumables such as culture media and cryopreservation solutions. The name “SOLALLIS BIO” reflects our commitment to cultivating fertile ground, represented by “SOLO,” where our customers’ brilliant technologies, symbolized by “SOLIS,” meaning “the sun,” can take root, grow, and reach society. It also expresses our hope that patients, medical professionals, and pharmaceutical companies will thrive together —”All is well.”

To this end, we will continue to take on new challenges.



Philosophy

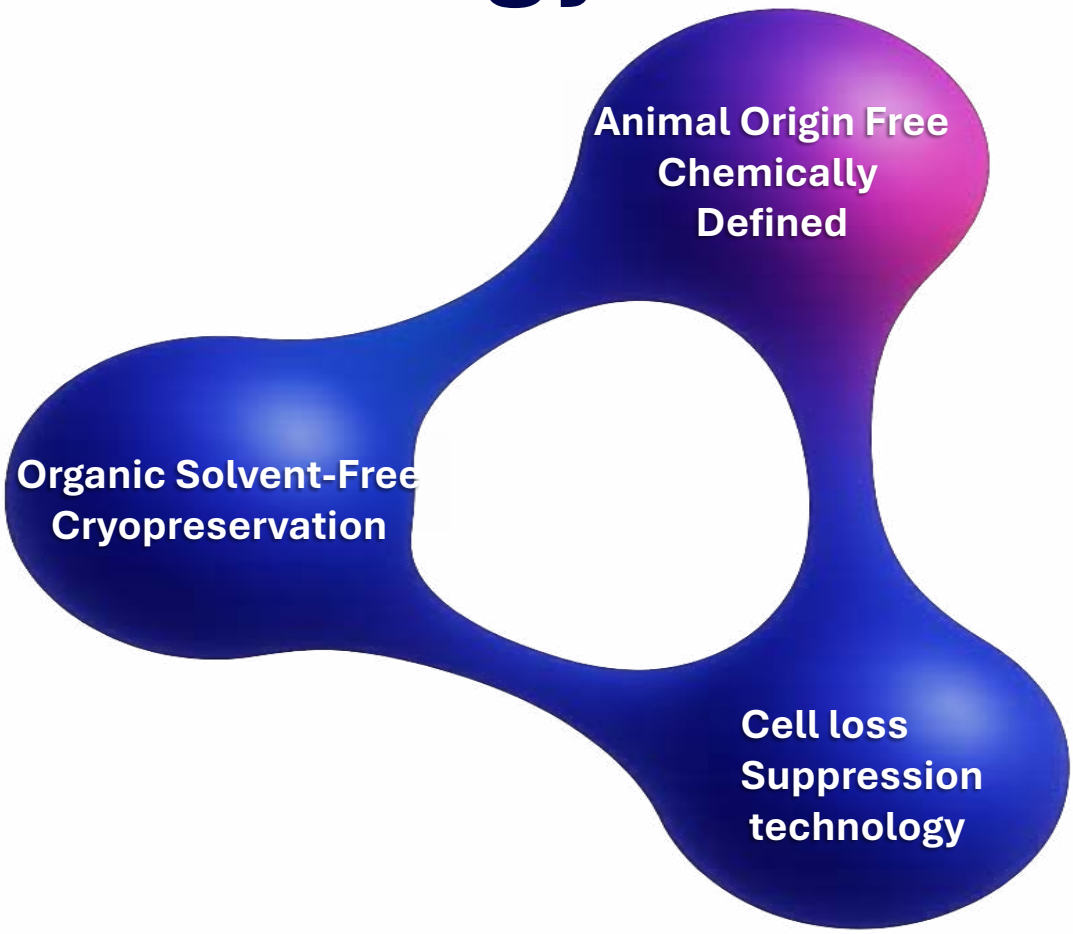
Contributing to cure the world’s "incurable” diseases.

Mission

Providing solutions to the challenges of regenerative medicine.

Making regenerative medicine a core industry in Japan.

Technology



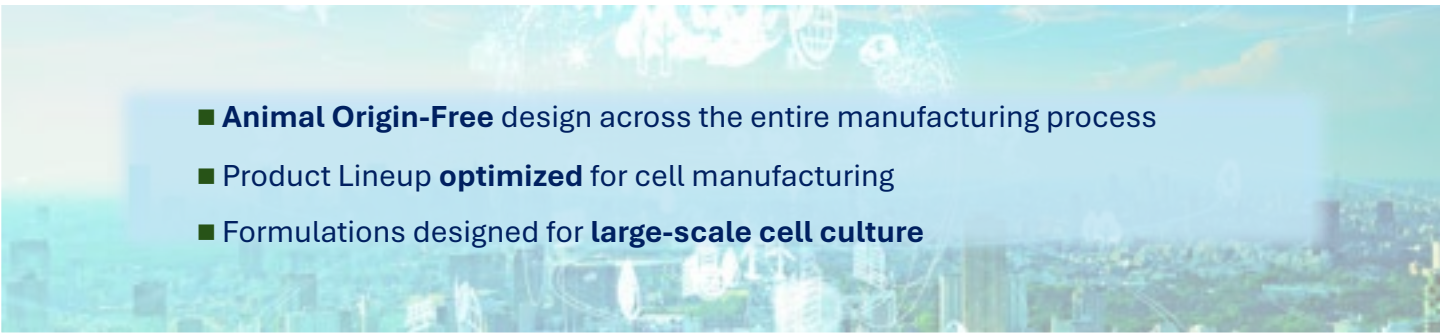
Our Products

SOLALLIS BIO

Stem Design™

Stem Design™ — Designing Cells for an Optimal State

Serum-free culture systems require optimization not only of the culture medium but of the entire culture process. Based on rigorous standards, we select raw materials with low infection risk while maximizing cell production efficiency. We provide an optimal total solution, from culture media to cryopreservation.



- **Animal Origin-Free** design across the entire manufacturing process
- Product Lineup **optimized** for cell manufacturing
- Formulations designed for **large-scale cell culture**

Product code	Product name	Volume	JPY
M101-AF-500GMP	Stem Design MSC Culture Medium AF-GMP	500 mL	49,500
M103-XF-500	Stem Design MSC Culture Medium XF PRIME	500 mL	50,000
M201-500	Stem Design EV Collection Medium	500 mL	45,000
D101-AF-500	Stem Design Cell Dissociation Solution AF for Serum Free Culture	500 mL	20,500
TD101-AF-100	Stem Design Collagenase Solution AF for MSC Isolation	100 mL	55,000
C101-AF-100	Stem Design MSC Banker AF	100 mL	23,000
C201-AF-100	Stem Design ELSSA OSFree	100 mL	30,000

Please contact us for bulk orders.
We also offer development of custom culture media.

Culture Medium

Animal Origin-Free



Xeno-Free



EV Collection



Dissociation Solution

Optimized for Serum-Free Media



Collagenase Solution

Ready to Use



Cryopreservation Solution

DMSO-Containing



Organic Solvent-Free



Stem Design™ MSC Culture Medium AF-GMP
Stem Design™ MSC Culture Medium XF PRIME

AF: Animal Origin-Free
***GMP grade manufacturing**



XF: Xeno-Free



Complies with Biological Raw Material Standards

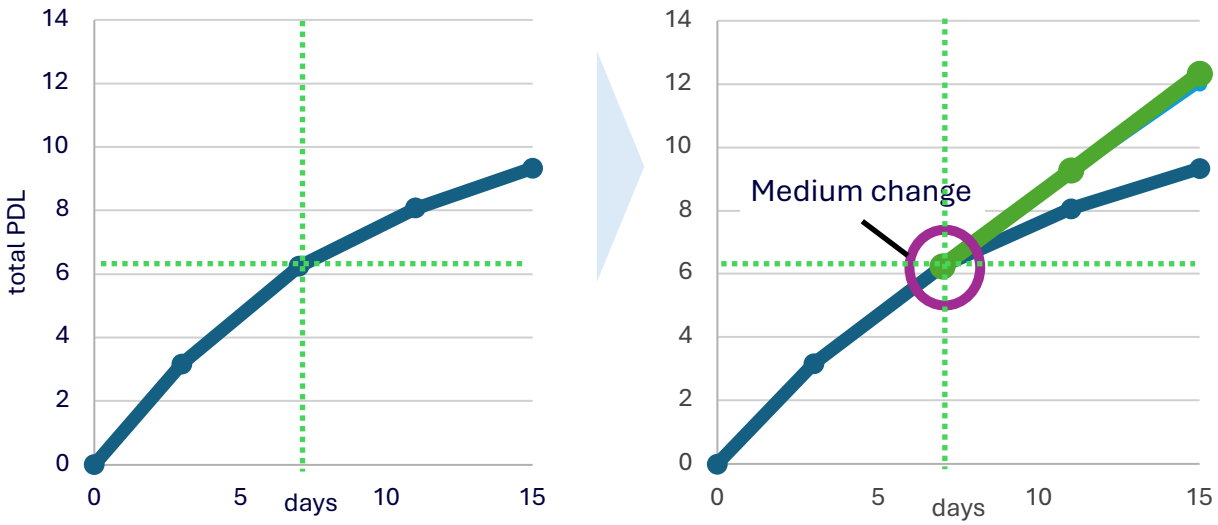
High Growth Performance

High Stability

*Manufactured and quality-controlled in a GMP-compliant facility.
(Referring to our internal GMP standards referencing ISO 13485)

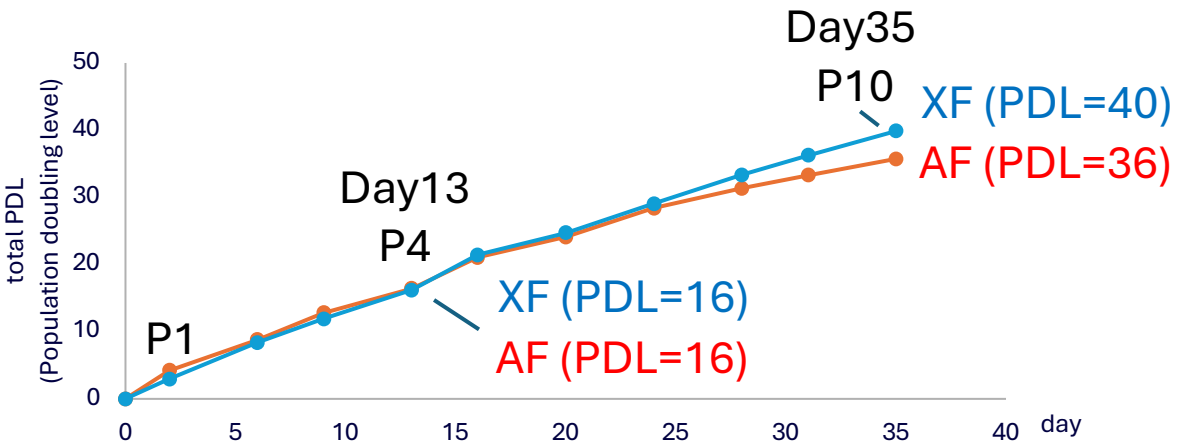
Cell Senescence Suppression Technology

After extensive research into blood components, we developed a formulation that suppresses the decline in proliferative capacity associated with cellular senescence. Even when proliferation inhibition due to replicative senescence was observed, switching to our culture medium helped maintain the previous level of proliferative capacity.



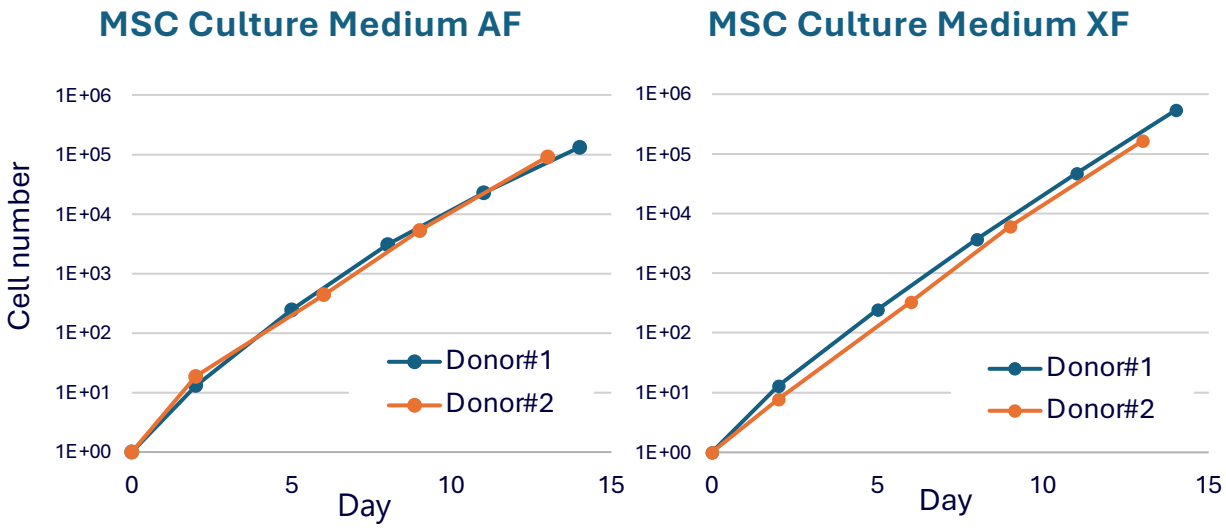
Long-Term Culture Test

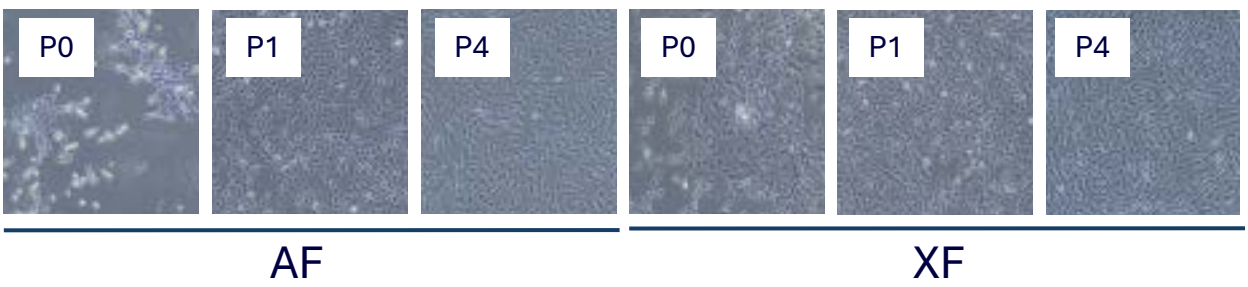
Our proprietary formulation is designed to suppress changes caused by replicative senescence. Based on population doubling level (PDL) analysis, adipose-derived stem cells (ADSCs) maintained more than one population doubling per day over a long-term culture period.



Primary Culture Results

Serum-free culture media are generally considered difficult to use for primary culture. However, through our proprietary formulation technology, we have confirmed that MSCs can be efficiently cultured from adipose tissue-derived stromal vascular fraction (SVF).

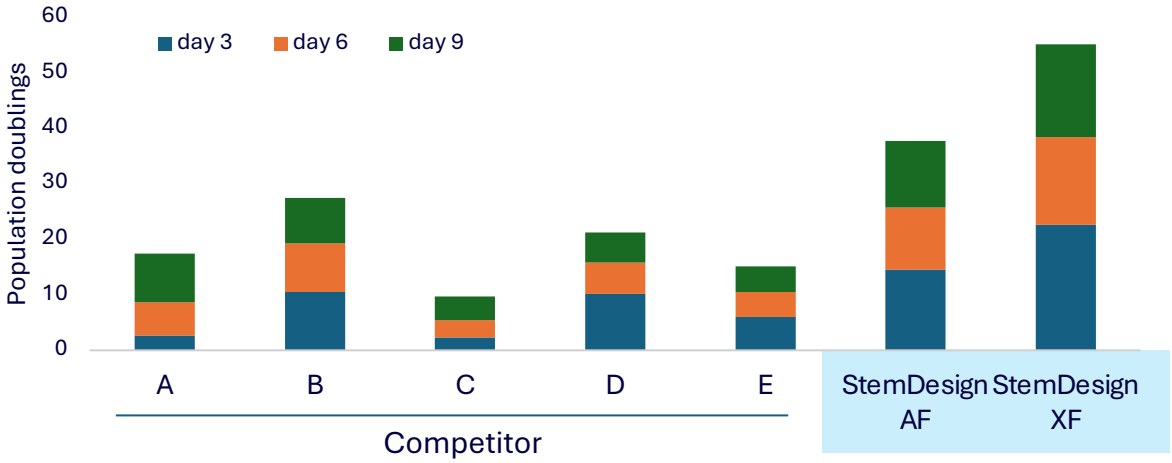




Culture Medium

Proliferation Comparison with Competing Media

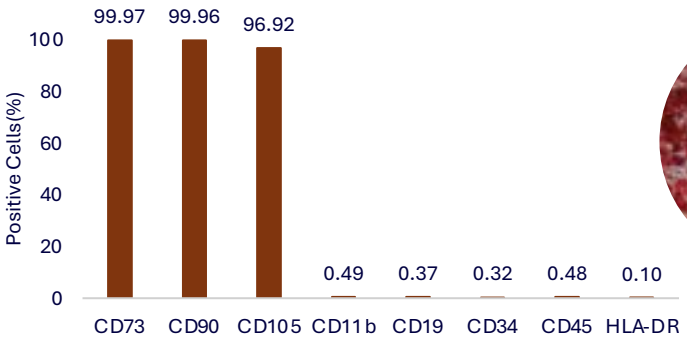
Our culture media demonstrated superior proliferative performance compared to competing products when evaluated using adipose-derived MSCs.
It showed top-class culture performance among media available in Japan. (SF: Serum-free medium)



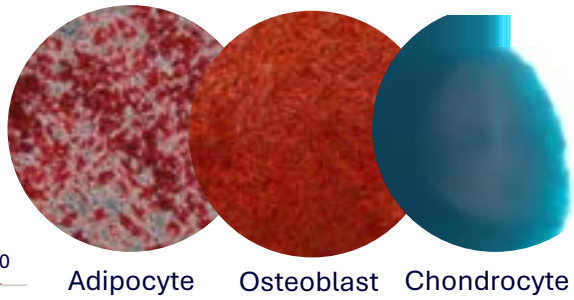
MSC Quality Characteristics

We have confirmed that MSCs cultured in our media meet MSC criteria for cellsurface antigen markers and differentiation potential.

MSC marker level

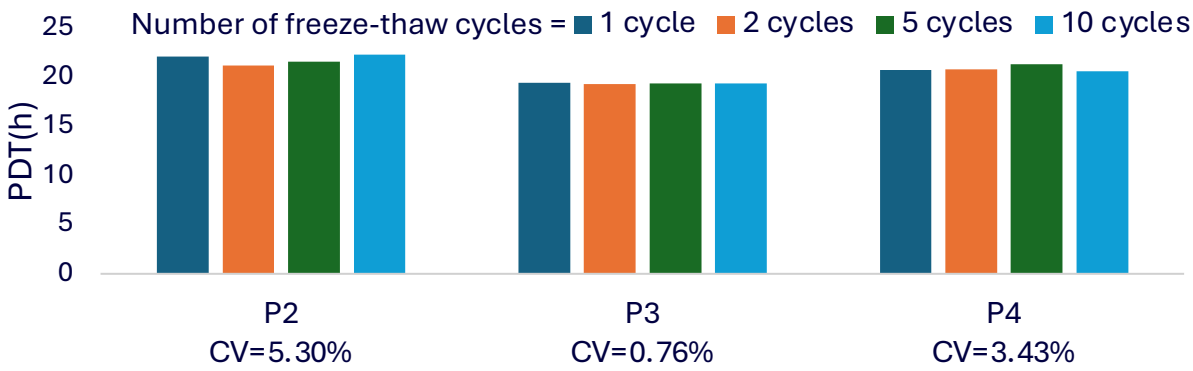


Differentiation potential



Stability Test

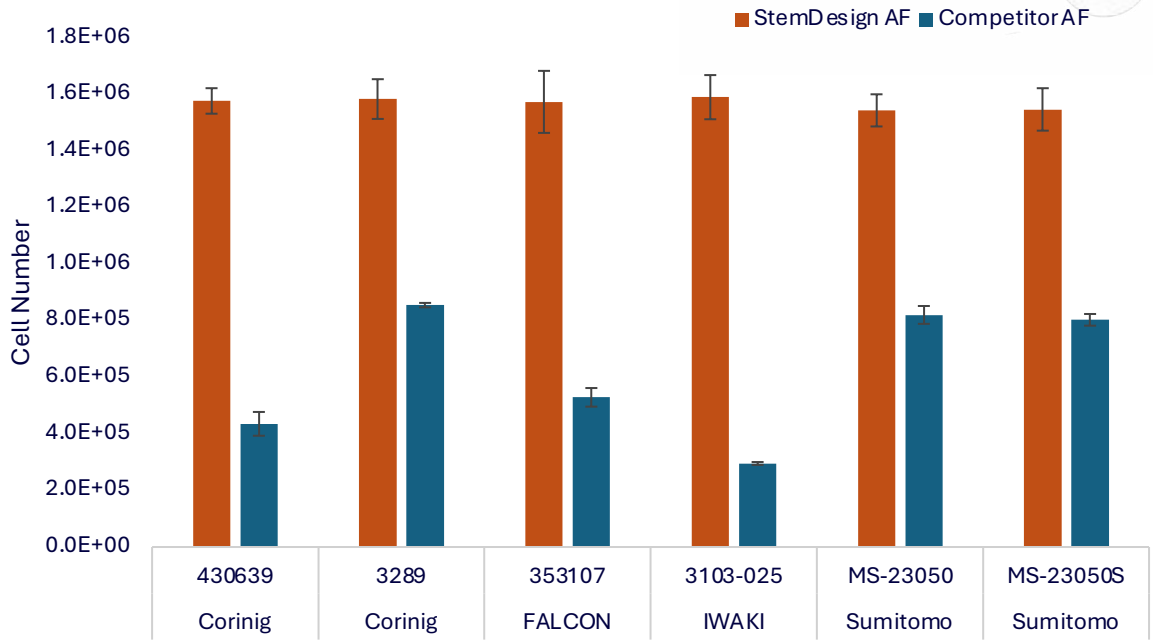
Stem Design MSC Culture Medium AF showed no negative impact on culture performance even after 10 freeze-thaw cycles, demonstrating its exceptionally high stability.



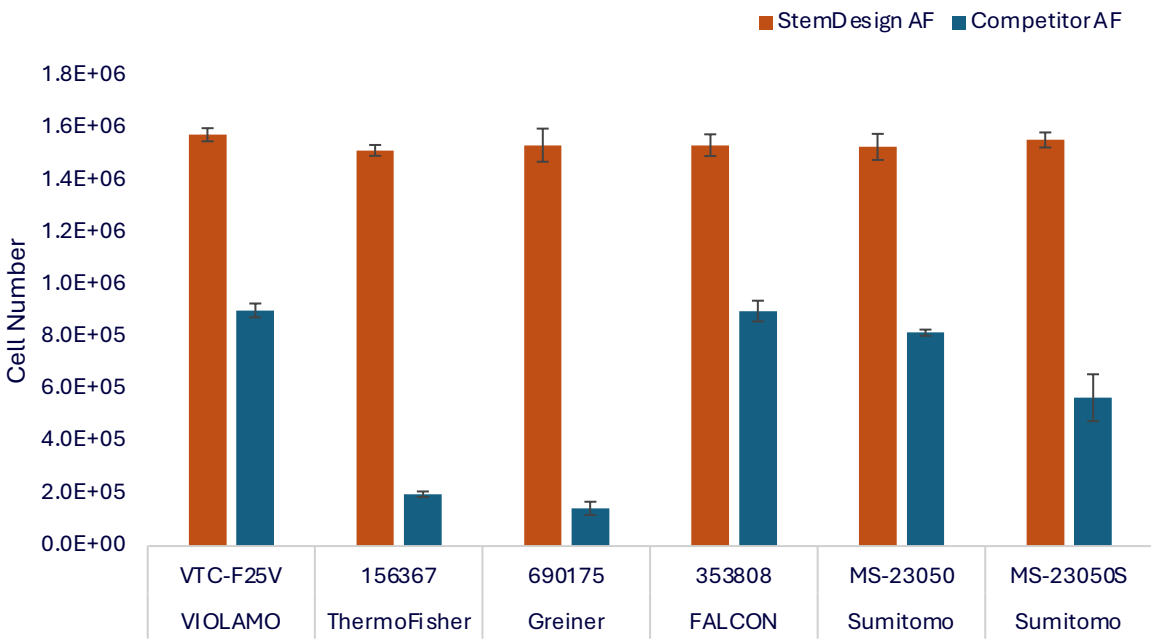
Evaluation of Scaffold Compatibility

Adipose-derived MSCs were seeded at 75,000 cells per flask in commercially available adherent-cell culture flasks from multiple manufacturers. After 3 days of culture, expanded cell numbers were compared.
Our medium demonstrated broad compatibility with various culture flasks and higher proliferative performance compared with a competing animal origin-free medium (n = 3).

Comparison of Cell Yield
- Test 1 -



- Test 2 -



Stem Design™ EV Collection Medium

EV Collection



In combination with our culture medium, it enables seamless AOF culture.



Rigorous Raw Material Selection

Safety Consideration of Culture Medium-Derived Residues in Exosome Formulations.



Animal Origin-Free

Help Reduce Infection Risk



Steroid-, Insulin-Albumin-Free

Facilitate EV Purification



Yeast-and Rice-Derived Free

Consider Allergy Risk

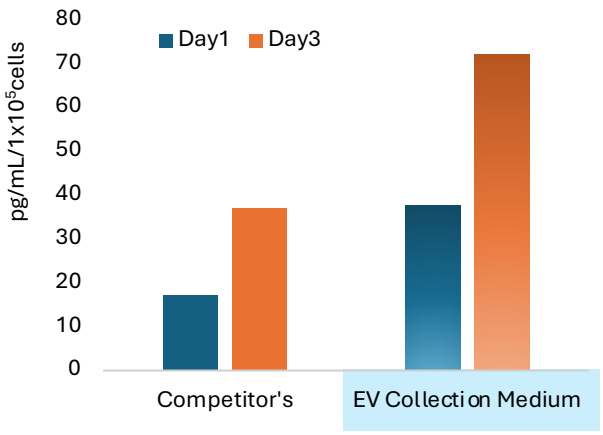
EV Yield

When used in combination with our culture medium, cells can be expanded at large scale and extracellular vesicles (EVs) can then be efficiently collected by switching to our EV Collection Medium.

It is expected to support high purification efficiency because it is free of highly bioactive substances and albumin.

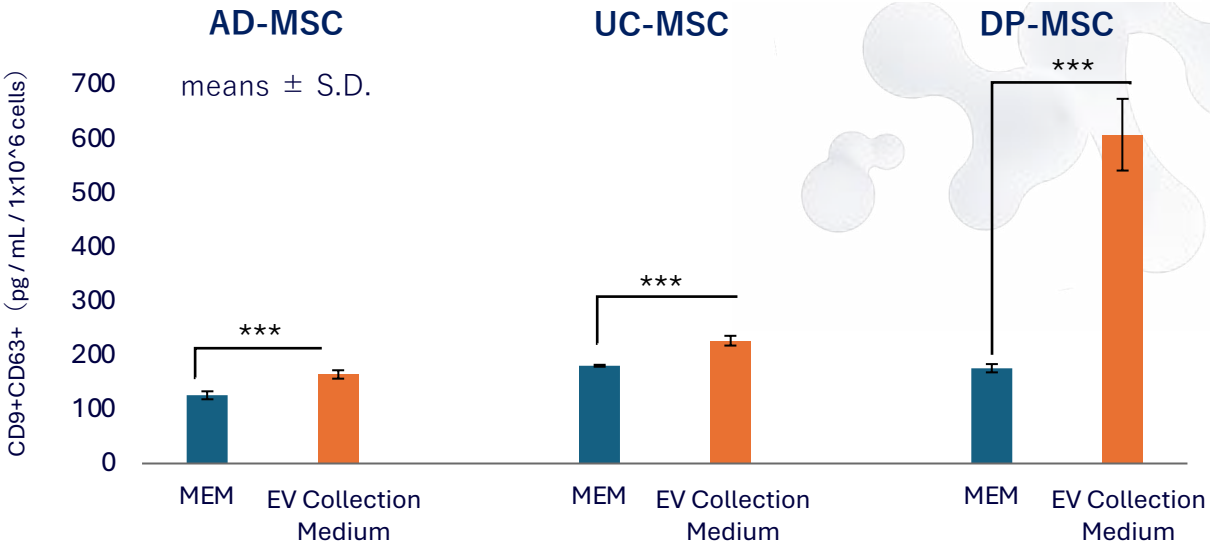
Furthermore, in response to feedback from the field, it does not use recombinant proteins derived from yeast and rice.

ELISA CD9/CD63+



Comparison by Cell Source

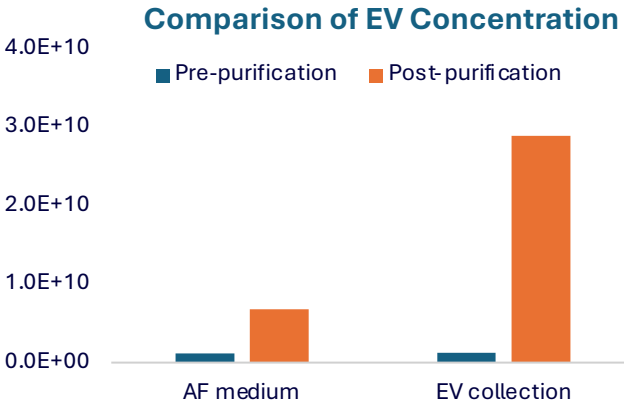
This product is designed to enhance exosome production per cell across MSCs derived from adipose tissue (AD), umbilical cord (UC), and dental pulp (DP). The effect was particularly pronounced in dental pulp-derived MSCs (n = 3).

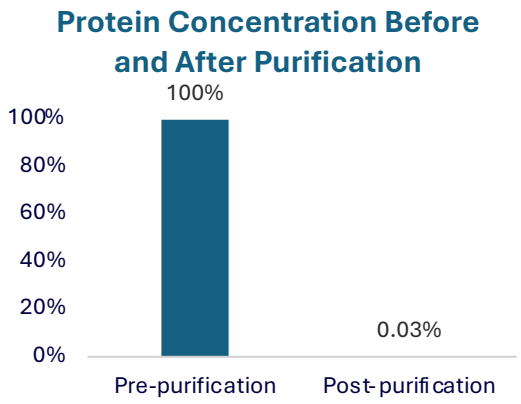


Evaluation of Purified EVs

Purified using the Huixin Lifetech EXODUS H-600

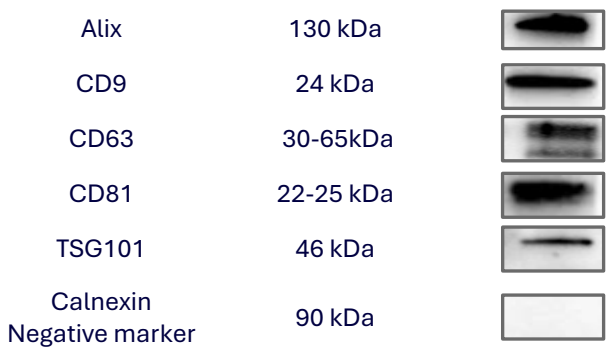
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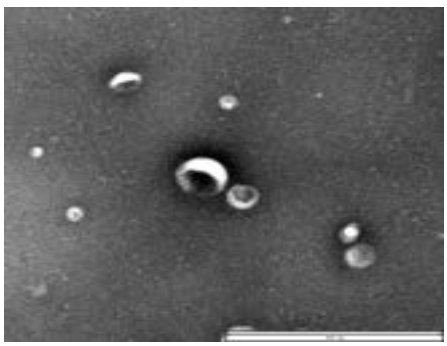


EVs Purified Using the EXODUS H-600

Western Blotting



TEM Image



Stem Design™ Cell Dissociation Solution AF for Serum Free Culture





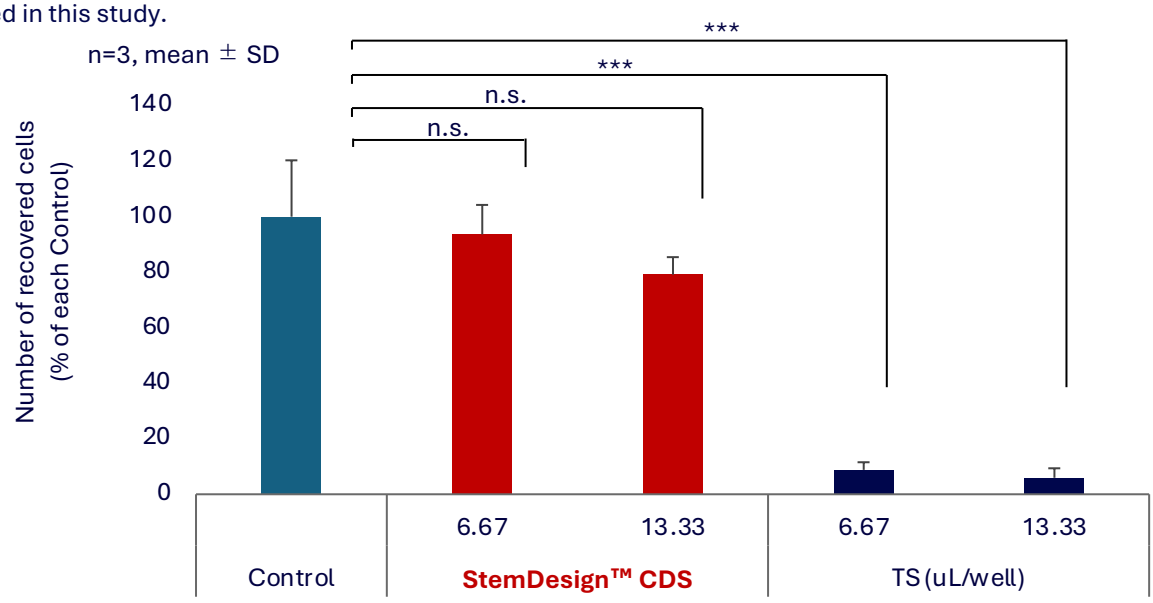
Obtained a "Materials Conformity Certificate for Regenerative Medical Products" from the Pharmaceuticals and Medical Devices Agency (PMDA).

The effect of trypsin varies depending on the culture medium.

Residual trypsin activity can cause cytotoxicity if not properly neutralized during cell harvesting. Since commercially available trypsin solutions are typically designed for **serum-containing media**, we developed a trypsin/EDTA dissociation solution for serum-free culture systems.

Growth inhibition test due to residual dissociation solution

Our dissociation solution (**StemDesign™ CDS**) is designed to minimize the impact of residual trypsin on cell growth, even when washing is insufficient in large-scale culture systems. The evaluation below compares cell growth in 6-well plates containing 2 mL of serum-free medium after addition of our dissociation solution, SBD, or a competitor's dissociation solution, TS. Adipose-derived MSCs were used in this study.



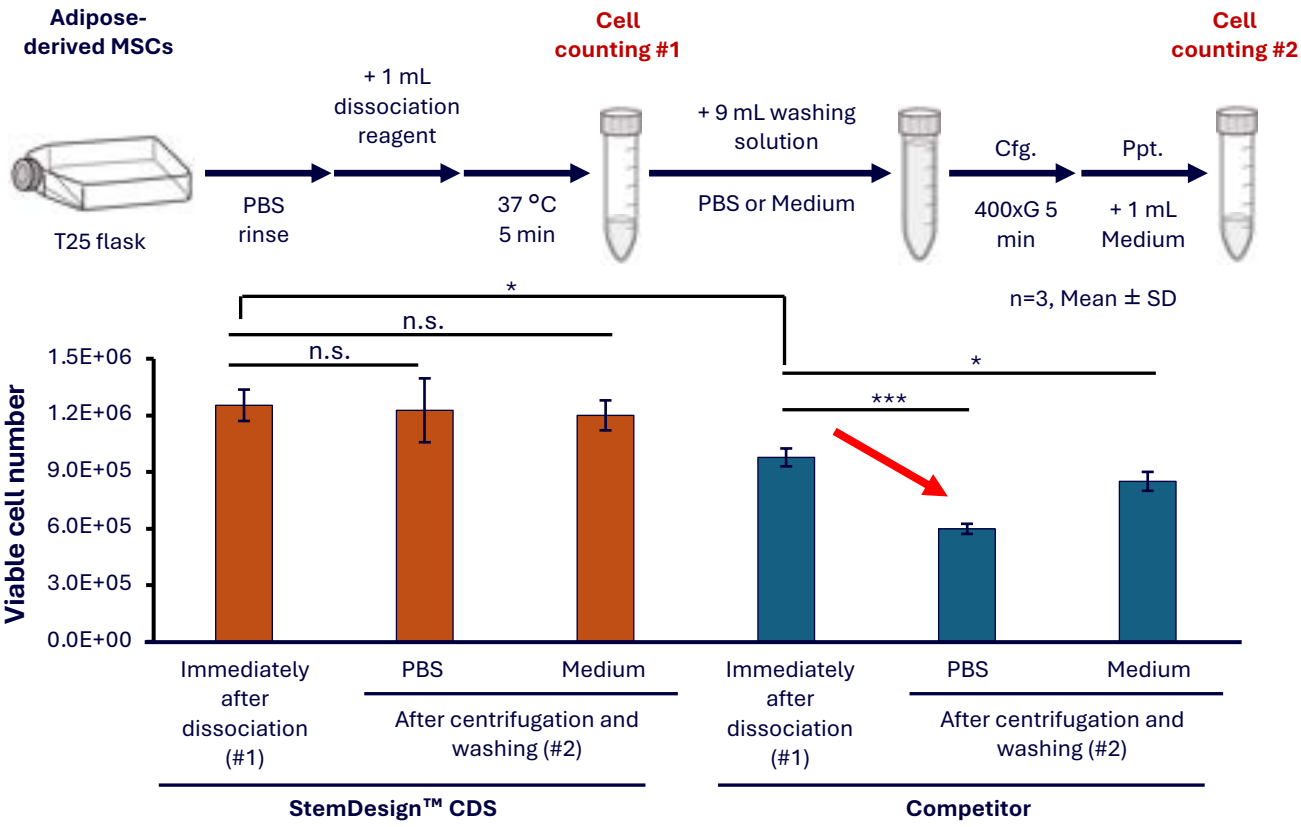
Reducing Cell Loss After Cell Dissociation

Do cell numbers decrease during centrifugation or other handling steps?

To address cell loss during post-dissociation handling, such as centrifugation, we developed a proprietary formulation designed for cell manufacturing workflows.
Patent pending.

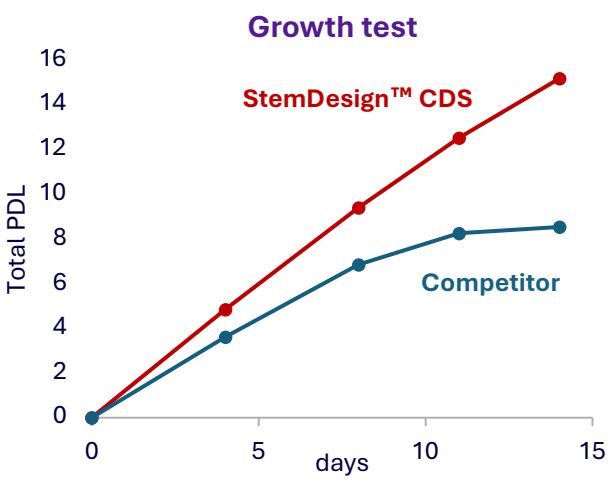
Evaluation of Cell Loss After Dissociation

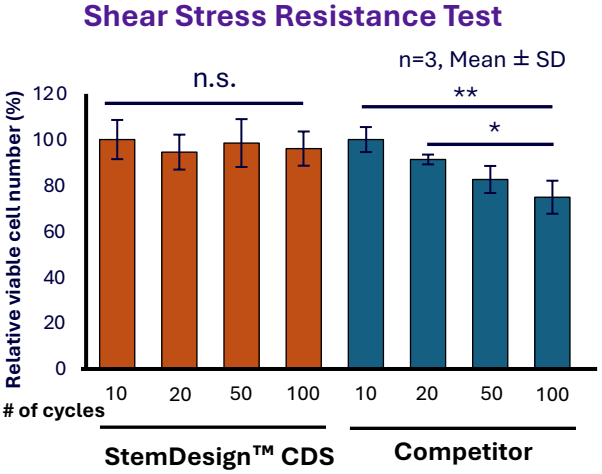
Our dissociation solution reduced cell loss during post-dissociation handling, including washing steps such as centrifugation.



Contribution to Cell Manufacturing

Our solution helps improve production efficiency by reducing cytotoxicity, cell loss, and pipetting-induced cell death during large-scale cell manufacturing.





Stem Design™ ELSSA OSFree™

Organic Solvent-Free Cryopreservation



World's First Commercialized Organic Solvent-Free Cryopreservation Solution

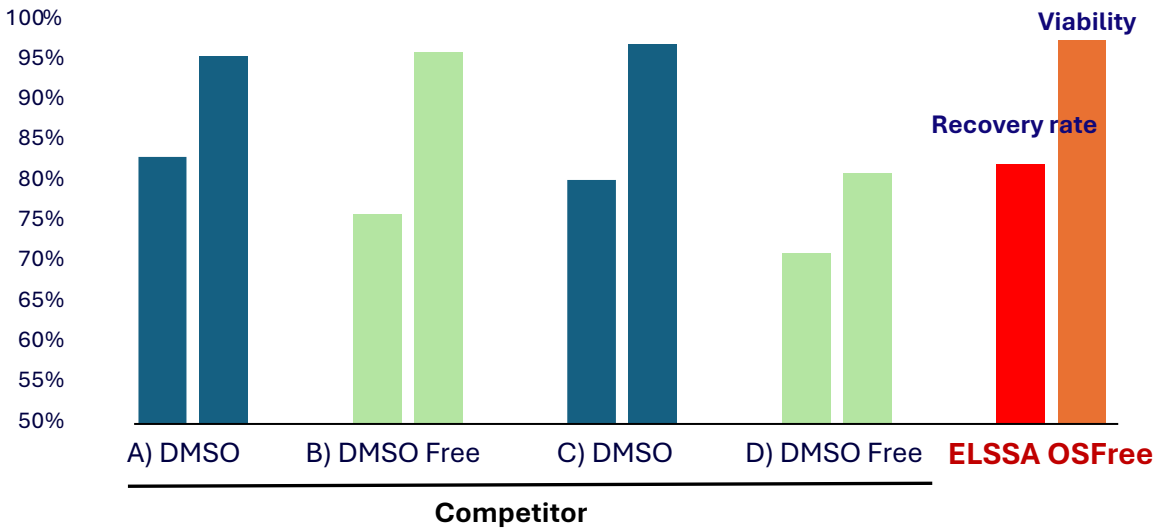
OSFree™ - A New Option for Cell Cryopreservation

NEW

*Based on our internal research

Organic Solvent-Free	**Protein-Free**	**Animal Origin-Free**
Chemically Defined	**Obtained a Materials Conformity Certificate for Regenerative Medical Products**	**Composed of Components with a History of Intravenous Use**

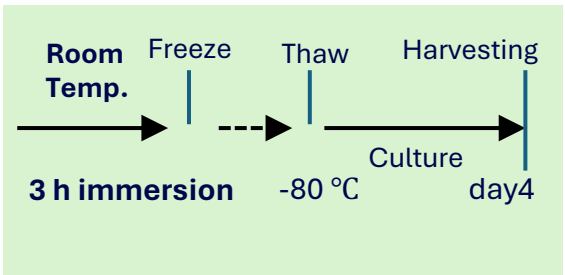
Cryopreservation Performance Comparison

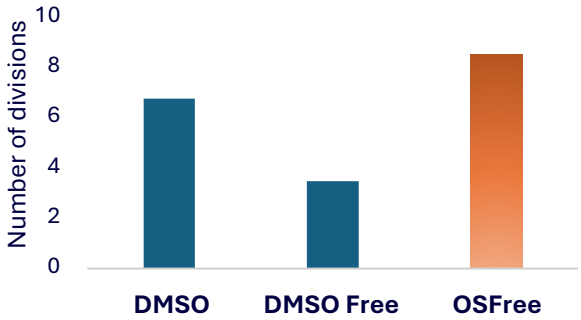


Long-term Immersion Test

Common Test Conditions
Cell Type: ADSC, Media: our AF culture medium

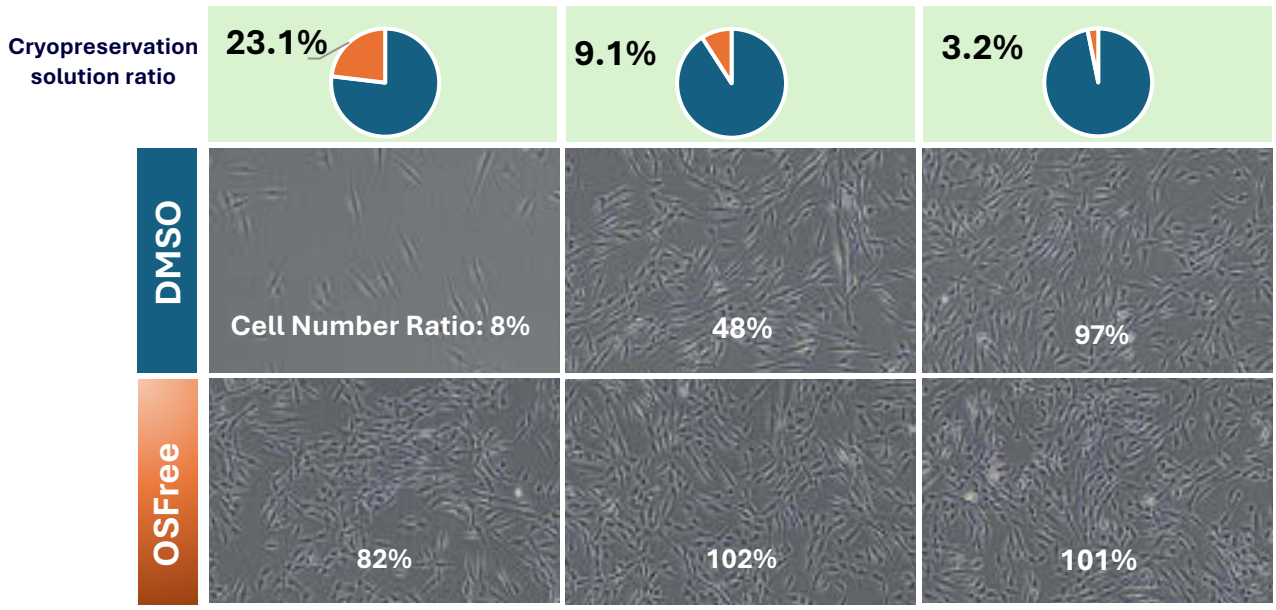
Proliferating cells were suspended in various cryopreservation solutions and incubated at room temperature for 3 hours. They were then frozen at -80℃. After thawing, the number of viable cells was evaluated by trypan blue staining after 4 days of culture .
ELSSA OSFree™ showed an 8.5-fold higher proliferation.





Evaluation of Cytotoxicity

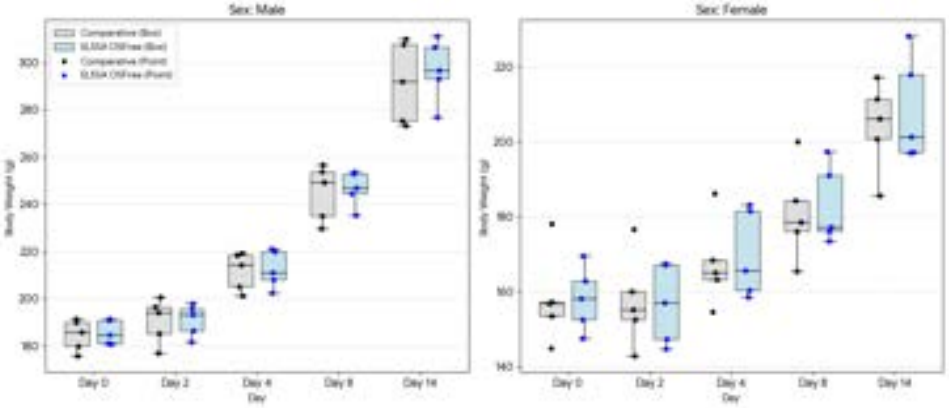
Various cryopreservation solutions were added to the culture medium at the indicated ratios, and proliferating cells were seeded in the resulting media.
After 3 days of culture, cell numbers were compared with those cultured in the medium alone as the control.



Cell number ratio: vs. control

Acute toxicity assessment (GLP)

Organization: External organization
Animals: Rats
Sex: 5 males and 5 females
Dose: 5 mL/kg
Evaluations:
Body weight, clinical observations,
22 hematological parameters
27 biochemical parameters
necropsy
Result: Comparable to physiological saline



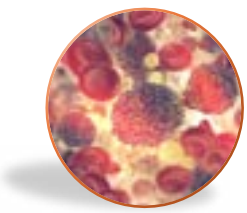
Customization

SOLALLIS BIO

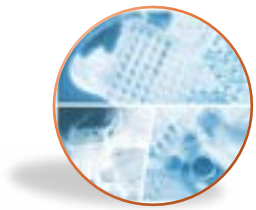
Stem Design™ Custom

Custom Development of Culture Media

Culture medium library with over 500 formulations
We also offer contract development of OSFree cryopreservation solution.



Improve performance



Differentiate From Competitors



Switch to Serum-Free Media



Optimize for Specialized Culture Systems

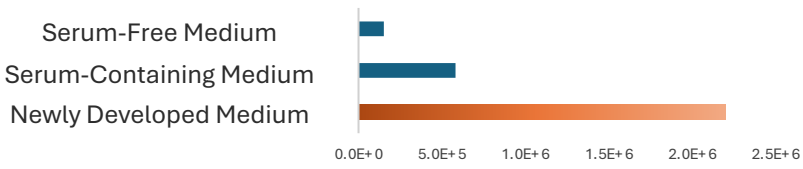
Contract Process

01 Interview → 02 Prototype development → 03 Contract Agreement → 04 Refinement → 05 Sales Contract

- ✓ If you are satisfied at the end of step 02, you can proceed to step 05.
- ✓ At step 05, manufacturing site, product specifications, and related terms will be finalized.
- ✓ Contract development models are available: milestone-based, period-based, or single-project engagement.
- ✓ Custom arrangements are also welcome.

Case

Difficulty culturing cells with commercially available serum-free media



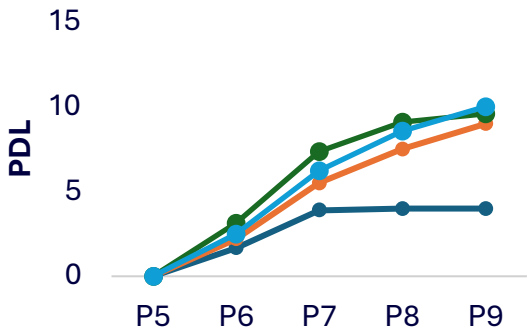
Development costs vary depending on the project.
Costs From JPY 5 million
Leadtime From 2 months

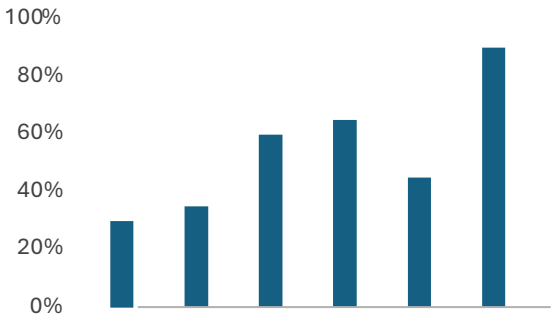
Options
- Formula Disclosure
- Exclusive Use
- GMP Compliance

Custom Development Examples

"We have a proven track record with pharmaceutical companies, universities, research institutions, government agencies, and various other organizations."

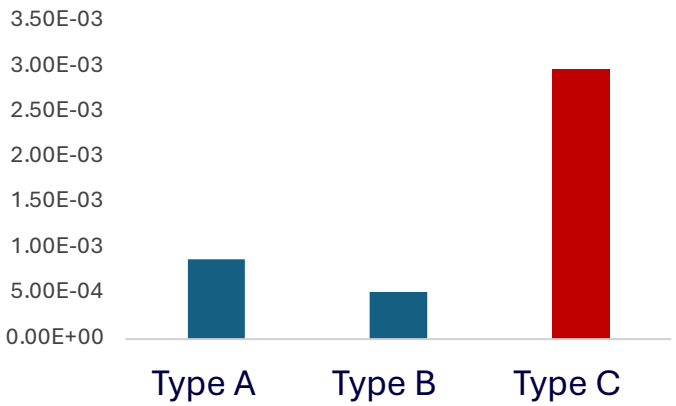
Development of customer-specific culture media

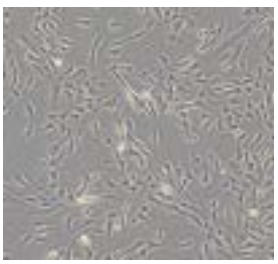




Optimization of dissociation solutions

Development of media designed to induce specified cell characteristics







External evaluation of customer-owned technology seeds

SOLALLIS BIO

Comprehensive Solution Proposals



Cell manufacturing workflows often involve a wide range of challenges.

- **Improving productivity**
  - Need to expand cells in a shorter period of time
  - Difficulty reaching the target cell number with certain donors
- **Switching to serum-free media**
  - Insufficient proliferation performance
  - Poor cell attachment to flasks
- **Improving cost efficiency**
  - Unsatisfactory cost-effectiveness
- **Quality control**
  - Difficulty reaching the target cell number after thawing
- **Changing cryopreservation solutions**
  - Concerns about the toxicity of cryopreservation solutions
  - Washing steps place a burden on clinical sites
- **Exosome research**
  - Influence of medium-derived EVs
  - Low purification efficiency
  - Need to increase EV production

These challenges may not be fully resolved by changing a single product, such as the culture medium alone.
Solallis Bio offers a broad lineup of liquid formulations used in cell manufacturing.
We propose **comprehensive solutions** for optimizing cell manufacturing workflow.
Please feel free to contact us if you are facing any challenges.



Noriyasu, ISHIKAWA Ph.D.

Founder & CEO, Solallis Bio

Studied synthetic biology and served as a JSPS Research Fellow (DC) before graduating as valedictorian with a Ph.D. from the University of Shizuoka.

Recipient of Outstanding Presentation Awards from the Pharmaceutical Society of Japan and the Japan Society for Bioscience, Biotechnology, and Agrochemistry (JSBBA).

Developed culture media, managed manufacturing, and conducted pharmacological evaluations for regenerative medicine at a Kansai-based pharmaceutical company.

Led the development of new regenerative medicine businesses and the launch of an internal venture focused on infertility treatment.

Founded Solaris Bio in 2023 with the vision that advancements in culture media technology are key to solving challenges in regenerative medicine.

Kendo practitioner since the age of nine.

Company Name	Solallis Bio, Inc.
Established	January 26, 2023
Head Office	Keihanna Plaza Lab Bldg., 1-7 Hikaridai, Seika-cho, Soraku-gun, Kyoto, Japan
Nakanoshima Office	Mitsui Link Lab Nakanoshima, NakanoshimaQross 3F, 4-3-51 Nakanoshima, Kita-ku, Osaka, Japan
Representative	Noriyasu Ishikawa, President & CEO
Capital	JPY 51 Million
Business Activities	Manufacturing, sales, R&D, and contract development (CDMO) of culture media and liquid formulations for regenerative medicine.
Board of Directors & Auditor	President & CEO: Noriyasu Ishikawa Director: Daiki Okamoto Director: Yuito Nihei Outside Director: Hironori Nagura Auditor: Shigeru Yoneda

SOLALLIS BIO

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solallis.info@inabata.com