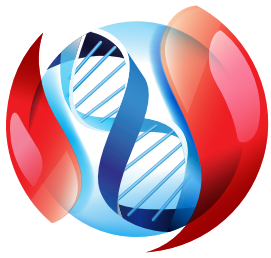
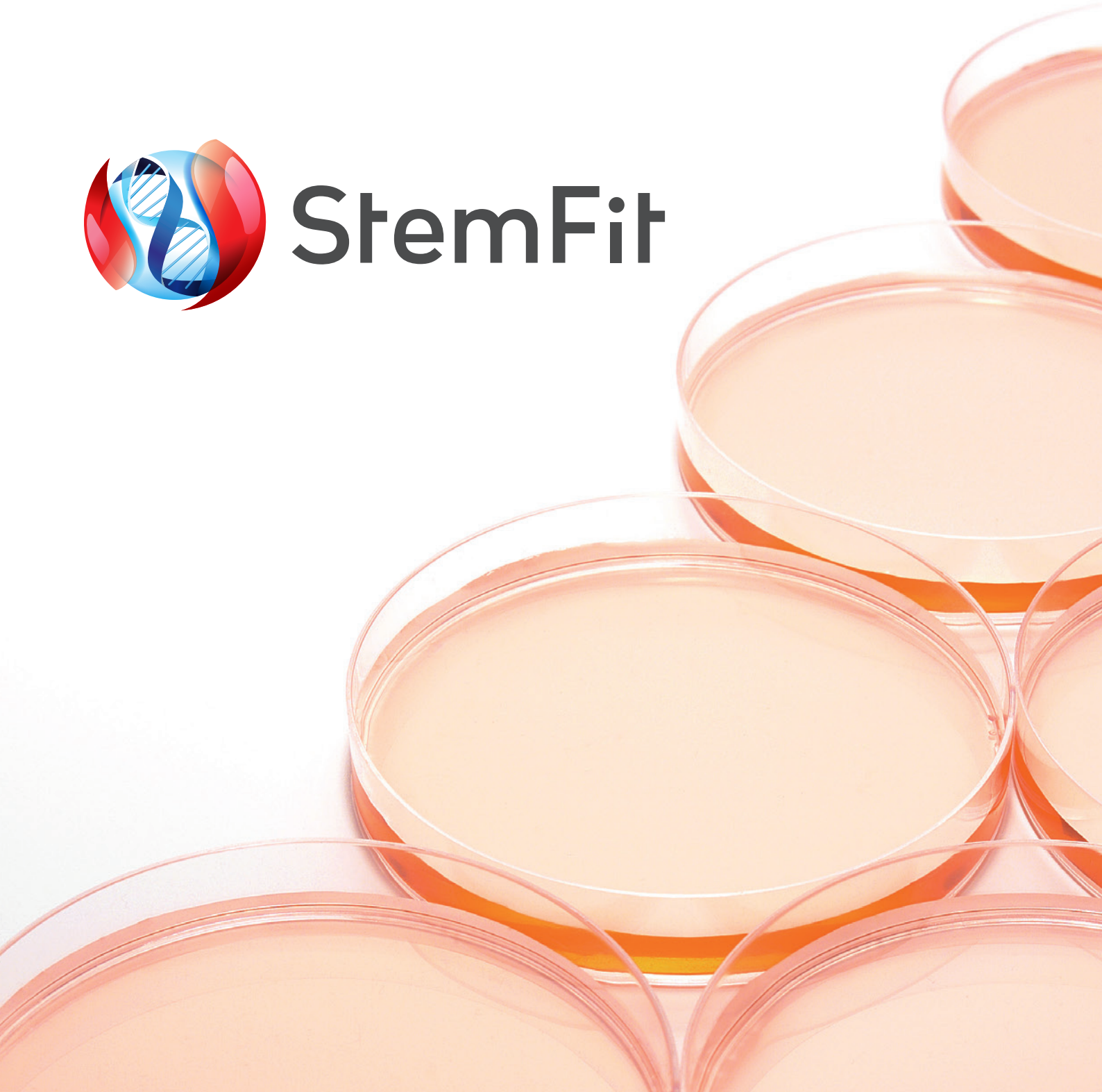


Eat Well, Live Well.



StemFit





StemFit

Stem cell culture media



As cell therapy development continues, the demand for clinically applicable ancillary materials, such as cell culture media and growth factors, is rapidly increasing for industrial use. In particular, stem cell culture media that are used in the manufacture of cell therapy products are required to have higher quality standards than conventional research reagents. This includes consistency between lots, and compliance with various laws and regulations.

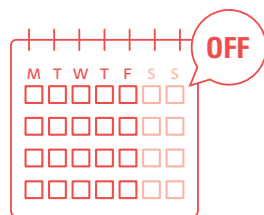
StemFit is a brand of stem cell culture media for use from the laboratory to GMP compliant manufacturing of cell therapy products. StemFit was originally developed in collaboration with Prof. Shinya Yamanaka (CiRA, Kyoto Univ.), a Nobel laureate for the discovery of induced pluripotent stem cell (iPSC), to meet the requirements of a clinically relevant human pluripotent stem cell (hPSC) culture media (Sci.Rep. 2014 Jan 8;4:3594). Now, StemFit media is widely used in clinical projects, as well as basic research, around the world.

Importantly, StemFit media for hPSC is designed and manufactured free from animal or human derived components, which ensures high safety and lot-to-lot consistency. Additionally, its well-optimized formulation enables unmatched cell expansion with a flexible weekend-free feeding schedule. Furthermore, its optional one-bottle form (Basic04CT) is a perfect match for advanced manufacturing because it enables the omission of the time-consuming preparation process.

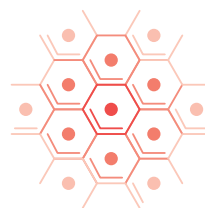
— Product Features —



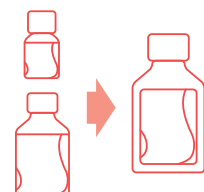
Animal-Origin Free (AOF)



Weekend-Free Feeding



Single-Cell Expansion



One Bottle Composition

» StemFit hPSC expansion media

Gold-Standard media for clinical research

| | |
|-----------------------------|----------------------|
| Animal Origin Free | PMDA consultation |
| Single cell expansion | Weekend-free feeding |
| GMP compliant (Basic03 GMP) | |



StemFit Basic03

StemFit Basic03 GMP

• Animal-Origin Free & regulatory compliance for CGT product manufacturing

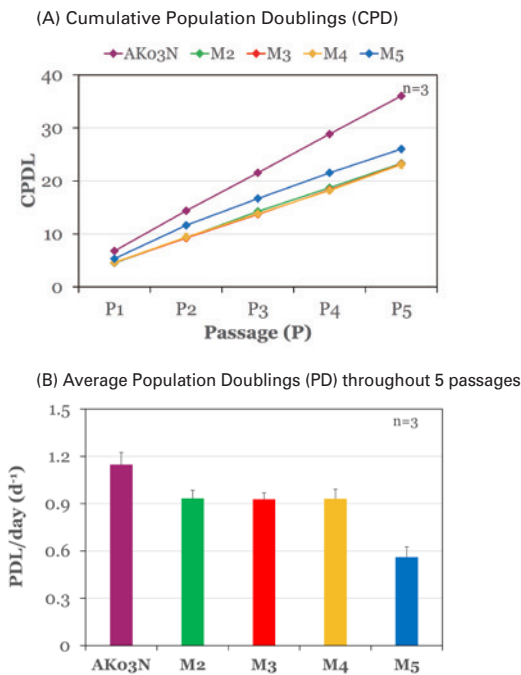
Animal or human derived components, such as serum derived albumin, or animal cell derived recombinant proteins, are known to carry a risk of hazardous viral contamination for cell therapy. Therefore, StemFit is designed and manufactured under a strict animal origin free policy and is free from animal or human derived components, as referred in USP<1043> and ISO20399. This makes StemFit Basic03 a gold-standard hPSC expansion media for clinical research. To this end, the Japanese PMDA was consulted on the formulation and manufacturing process and found that Basic03 satisfies all requirement of ancillary materials for cell and gene therapy (CGT) manufacturing. Additionally, StemFit offers a GMP compliant product, Basic03 GMP, which is manufactured under applicable GMP guidelines and is thus preferable for CGT products.

• Superior performance in single-cell expansion

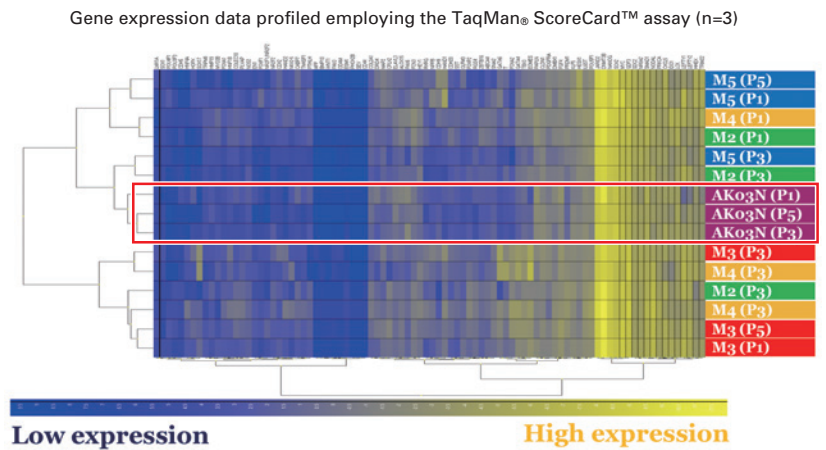
Single-cell expansion is an ideal method for CGT product manufacturing since it allows well-controlled, reproducible, and efficient cell expansion. StemFit is optimized for the single-cell expansion method and shows higher cell survival rate in single-cell conditions, which enables efficient and genetically stable cell growth without karyotypic abnormalities.

CGT Catapult, an independent center of excellence to advance the growth of the UK CGT industry, performed a comprehensive comparison program for hPSC culture media and found that StemFit Basic03 to have the highest performance in clinical hPSC expansion.

» Figure 1. Easy expansion



» Figure 2. Consistent gene expression profile



» Table 2. Result of karyotyping (CGH array) analysis after expansion

| | AK03N | M2 | M3 | M4 | M5 |
|---------|--------|--------|----------|--------|--------|
| Bank | Normal | Normal | Normal | Normal | Normal |
| +P9/P10 | Normal | Normal | Abnormal | Normal | Normal |

Full data is available on the webpage

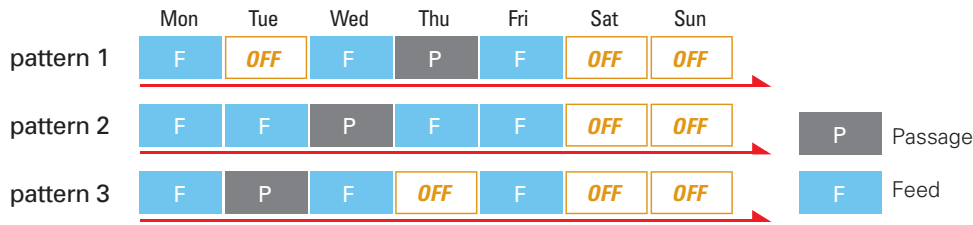
Web site »

*Basic03 is described as AK03N in some publications since AK03N is the Japanese brand name of Basic03.
 **bFGF is sold separately. 80 ng/ml should be added for best performance.

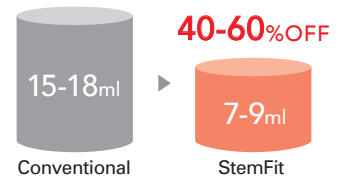
• Weekend-Free Feeding

Traditional culture medium requires daily medium changes to maintain hPSCs, which increases the labor cost and risk of human error or contamination in CGT product manufacturing. StemFit allows flexible weekend-free feeding in which hPSC can be expanded healthily without medium change during the weekends. This feature enables researchers to simplify their culture protocol and minimize the labor and culture media costs.

» **Skip feeding on weekends for flexible scheduling**



» **Medium volume for a well**



• One-bottle formulation (Only Basic04CT)

Aseptic process in the clean bench or isolator should be simplified to avoid bacterial contamination. StemFit Basic04 Complete Type (Basic04CT) is our next generation hPSC expansion media which has the same features as Basic03 but is delivered in 1 ready-to-use bottle. This feature allows the omission of the mixing process in media preparation which minimizes the risk of bacterial contamination.



StemFit Basic04 Complete Type

• Large scale production

Large scale cell production for CGT requires a stable supply of large-volume, high-quality ancillary materials. StemFit products are manufactured on a large enough scale to accommodate industrial cell production and have sufficient supply capacity. This feature minimizes the risk of an unstable supply chain or undesirable frequent lot changes. Additionally, other features such as efficient single-cell expansion, ready-to-use one bottle formulation, and weekend-free feeding, are perfect matches for large scale cell production, as well as process scale-up.

• Multiple product lineups for different research applications

StemFit provides 3 types of media for hPSC expansion, which allows researchers to choose the best solution based on the purpose of their research. For basic or early clinical research, Basic04CT can be the best option since it provides ready-to-use formulation. For clinical projects, Basic03 or Basic03 GMP may be the best option thanks to their unrivaled performance, in addition to GMP regulatory compliance.

» **Product comparison table**

| | Basic03 | Basic03 GMP | Basic04 Complete Type |
|--------------------|-------------------|-----------------------|------------------------------------|
| Animal origin-free | ✓ | ✓ | ✓ |
| GMP manufacturing | | ✓ | In preparation |
| bFGF | Sold separately | Sold separately | Included |
| Use | Clinical research | Further manufacturing | Basic research & Clinical research |
| Number of Bottle | 2 | 2 | 1 |

» Differentiation supplement

Standard media for clinical research

Animal Origin Free, Chemically defined

Efficient EB formation

Lineage-specific differentiation

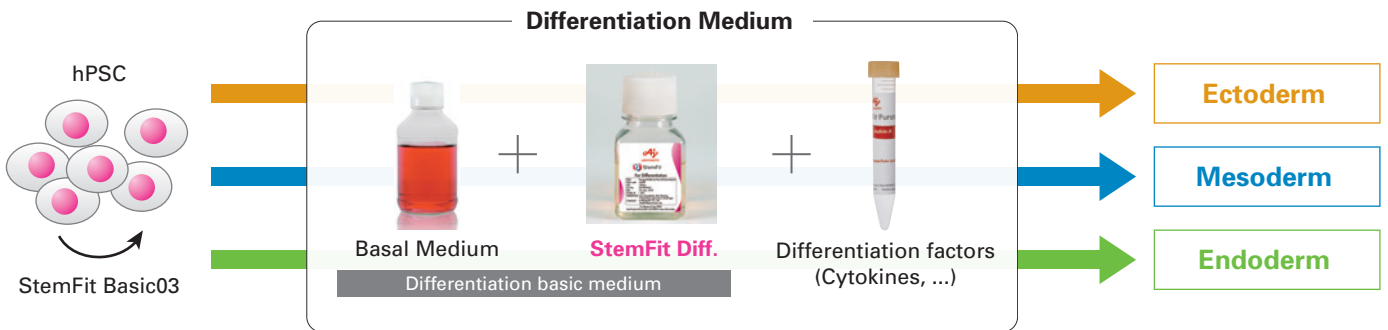


StemFit For Differentiation

• Animal-Origin Free supplement

In the process of hPSC differentiation, BSA or other serum replacements containing animal derived ingredients have been traditionally used, which are known to carry a risk of hazardous viral contamination for cell therapy. Also, animal derived ingredients can cause the lot-to-lot variation which results in the manufacturing instability.

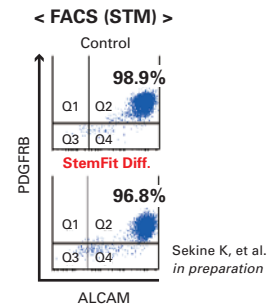
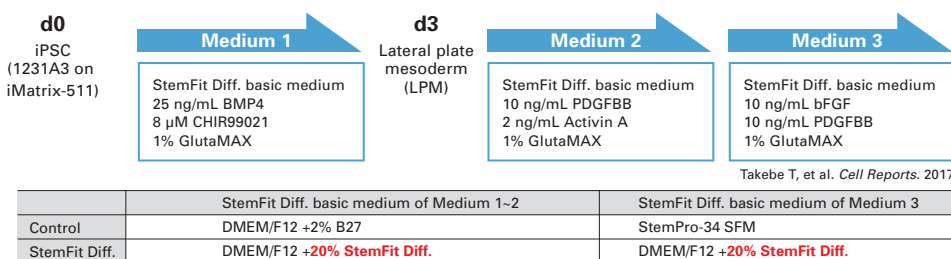
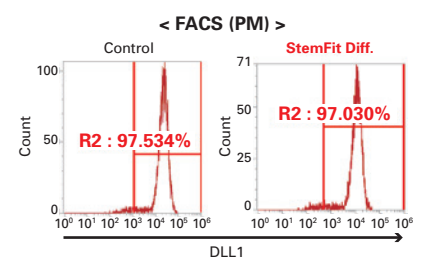
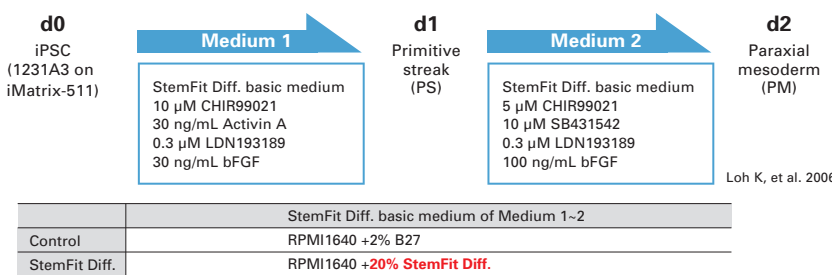
StemFit For Differentiation (StemFit For Diff.) is chemically defined and animal origin-free supplement for hPSC differentiation. StemFit For Diff is designed and manufactured under a strict animal origin free policy and is free from animal or human derived components. StemFit For Diff. is desirable for CGT product manufacturing since its risk of viral contamination and lot-to-lot variation is minimized.



• Lineage-specific differentiation under chemically-defined and AOF condition

StemFit For Diff. allows efficient directed differentiation for specific lineages (endoderm, mesoderm and ectoderm) under chemically defined and animal-origin free condition, which enables stable and clinically applicable differentiation for CGT products.

Mesoderm (Paraxial mesoderm, Septum transversum mesenchyme)



Further information is available on the webpage

Web site




StemFit Purotein®

Recombinant Proteins

StemFit Purotein®, whose name comes from Pure & Protein, is a brand of recombinant proteins applicable for use from the laboratory to GMP compliant manufacturing of cell therapy products.

All StemFit Purotein® products are manufactured free from animal or human derived components, which ensures high safety and lot-to-lot consistency. Additionally, our highly efficient protein expression system and purification flow enables high purity and quality while maintaining affordable prices. Furthermore, its frozen liquid form is a perfect match for advanced manufacturing because it enables the omission of the time-consuming reconstitution process.


StemFit Purotein® is also highly compatible with StemFit hPSC media. The combination of StemFit hPSC media and StemFit Purotein® allows for the establishment of highly efficient differentiation systems in the laboratory while ensuring an easy transition to GMP-compliant production for future cell therapy manufacturing.



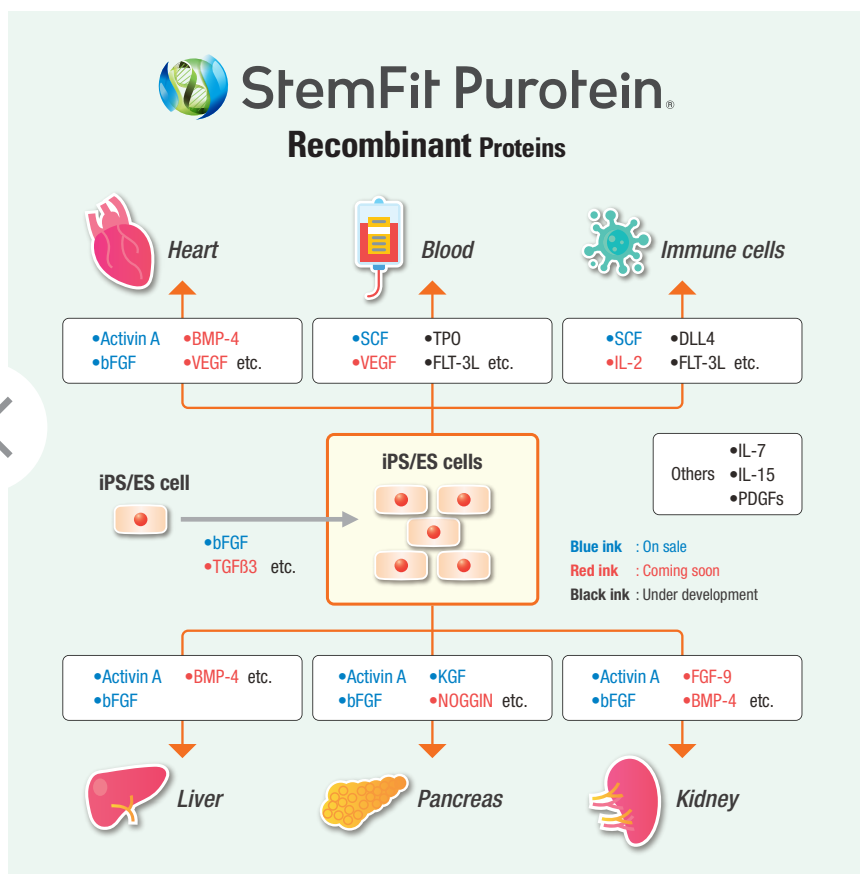
StemFit
Stem cell culture media

StemFit Basic03
[Web site](#)

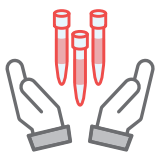
StemFit Basic03 GMP
[Web site](#)



StemFit For Differentiation
[Web site](#)



Product Features



Affordable price

We are committed to technological innovation, production at the optimal scale, and cost reduction, so that we can always supply products at an affordable price.



Animal origin free

Minimize risk of virus contamination and lot-to-lot variation with animal-origin free formula.



Regulatory compliance for cell therapy products

The PMDA has officially confirmed our product's eligibility for use in clinical cell therapy production (in Japan)



Frozen form that is "ready-to-use"

Can eliminate the time-consuming process of reconstitution, while ensuring consistent results.

» Mesenchymal Stem cell media

Clinically applicable MSC media

| | |
|------------------------------|-----------------------------------|
| Chemically defined* | PMDA consultation |
| Excellent cell growth | MSC isolation from tissues |



• Chemically defined & Regulatory compliance for CGT

Undefined extracts, such as FBS or human plate lysate, are known to carry a risk of hazardous viral contamination or lot-to-lot variation, which are not desirable for cell therapy. Even commercially available xeno-free media, whose formulation is not usually disclosed, could still contain such undefined extracts from human or animal sources.

StemFit For MSC media is engineered to be chemically defined, in which no undefined extracts are included, and all protein components are replaced with bacteria-derived recombinant proteins. With this chemically defined formulation, the risk of vial infection and lot-to-lot variation is minimized. Additionally, the Japanese PMDA has been consulted on the formulation and manufacturing process and found that StemFit For MSC satisfies all requirement of ancillary materials for cell and gene therapy (CGT).

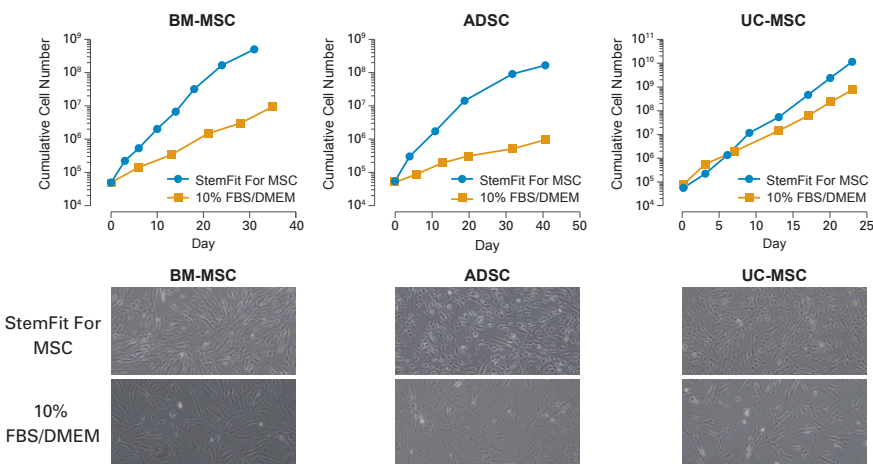
• Excellent cell growth and MSC isolation

StemFit For MSC shows excellent and stable cell growth performance compared to FBS or hPL containing media. Also, StemFit For MSC allows the isolation of MSCs from tissues under chemically defined condition. These features enable efficient and clinically applicable MSC isolation and expansion.

High performance

StemFit For MSC enables superior cell expansion compared to serum-containing media. This medium can maintain MSCs with high level of marker expression and differentiation potential.

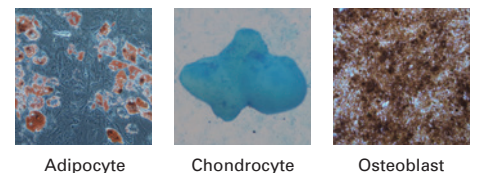
» Expansion



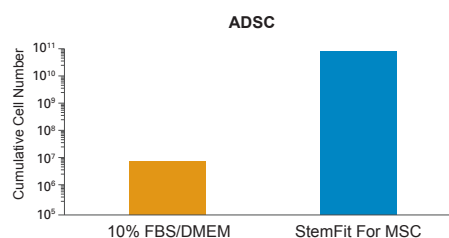
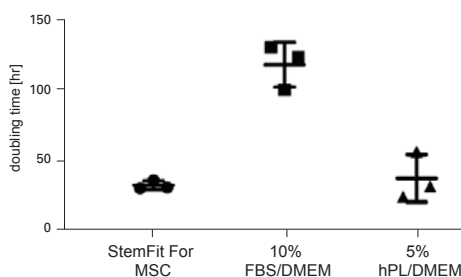
» MSC marker expression

| | positive marker | | | negative marker | |
|--------|-----------------|-------|-------|-----------------|------|
| | CD73 | CD90 | CD105 | CD34 | CD45 |
| BM-MSC | 99.8 | 99.8 | 98.1 | 1.1 | 0.8 |
| ADSC | 100.0 | 100.0 | 98.3 | 2.6 | 0.1 |
| UC-MSC | 99.5 | 99.9 | 99.4 | 0.4 | 0.2 |

» Differentiation potential



Superior isolation performance



2.4×10⁵ cells from human adipose tissue were seeded and cultured in 10% FBS/DMEM or StemFit For MSC. Total isolated ADSCs were counted at day 18.

*We define "Chemically Defined Medium" as

1. A medium in which all of the components and concentrations are known.
2. A medium which does not contain serum, lysates, or other ingredients with unknown composition

» Product list



Please request pricing! ▶



| Product | Information |
|--|--|
| StemFit Basic03 | hPSC expansion medium for clinical research Web site ▶ |
| StemFit Basic03 GMP | hPSC expansion medium for clinical research and further manufacturing Web site ▶ |
| StemFit Basic04 Complete Type | hPSC expansion medium for basic research and clinical research one bottle composition Web site ▶ |
| StemFit For Differentiation | Differentiation supplement for hPSC Web site ▶ |
| StemFit For Mesenchymal Stem cell | hMSC expansion medium Web site ▶ |



Please request pricing! ▶



| Product | Information |
|--|--|
| Activin A | <Non-GMP> 10µg, 50µg, 1mg(0.1mg/ml) <GMP compliant> 1mg(0.1mg/ml) Web site ▶ |
| SCF | <Non-GMP> 10µg, 50µg, 1mg(0.1mg/ml) Web site ▶ |
| bFGF | <GMP compliant> 1mg(0.3mg/ml) Web site ▶ |
| KGF | <Non-GMP> 10µg, 50µg, 1mg(0.1mg/ml) Web site ▶ |
| IL-2 To be released in 2022 | <Non-GMP> 3mg(0.5mg/ml) |

» Publications and references

• KOL interviews



• News and publications

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