

Weekend-Free Stem Cell Culture



StemFit
Stem cell culture media



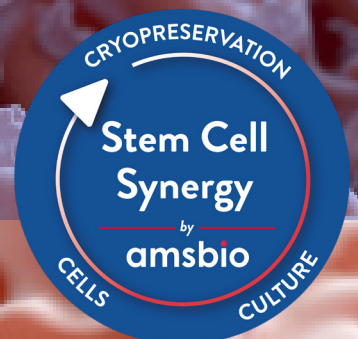
Purotein®
Recombinant Proteins

Animal Origin Free
Culture Media - Recombinant Proteins

LOWER COST
HIGHER EFFICIENCY

StemFit® can support
50% more wells than the
leading competitor

Recommended by Nobel Prize
winner Shinya Yamanaka



WHAT IS STEMFIT®?

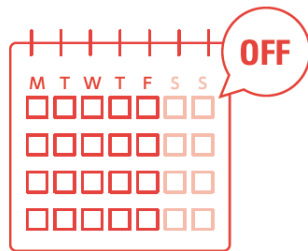
StemFit® is a xeno-free, defined medium proven to effectively maintain Induced Pluripotent Stem (iPS) and Embryonic Stem (ES) cells under feeder-free conditions during the reprogramming, expansion and differentiation phases of stem cell culture.

- Highly stable and reproducible feeder-free culture system
- Easy transition from on-feeder to feeder-free culture
- High affinity to commercially available coating matrices
- Superior colony forming efficiency from a single cell clone enables high quality and cost effective genome-edited clone generation
- High replication capacity when used with iMatrix-511
- Consistent gene expression profile

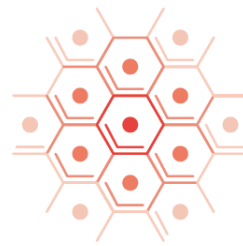
— Product Features —



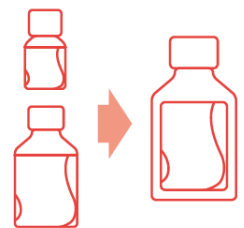
**Animal-Origin
Free (AOF)**



**Weekend-Free
Feeding**



**Single-Cell
Expansion**



**One Bottle
Composition
Basic 04 complete**

StemFit for Mesenchymal stem cells (MSC) is a chemically defined medium optimized for the expansion and maintenance of human bone marrow-derived MSC (BM-MSC), umbilical cord-derived MSC (UC-MSC), and adipose-derived stem cells (ADSC), under serum-free, human platelet lysate free conditions.

StemFit for Differentiation is a chemically defined and animal origin-free supplement for hPSC differentiation. It can be used with a variety of different induction factors or cytokines to support differentiation along ectoderm, mesoderm or endoderm lineages.

StemFit Purotein is a brand of recombinant proteins that includes bFGF, Activin, SCF and KGF. They are highly compatible with StemFit hPSC media; allowing for the establishment of highly efficient differentiation systems.

AMSBIO's StemFit cell culture media, iMatrix laminin as ECM & CELLBANKER series freezing solutions work together to create the perfect Stem Cell Synergy for your ES/iPS cell culture.

iMatrix-511 Recombinant Laminin
E8 Fragments

StemFit® Feeder-Free Stem Cell
Culture Media

STEM-CELLBANKER®
Cryopreservation Media

STEMFIT HPSC EXPANSION MEDIA

Gold-Standard media for clinical research

GMP compliant (Basic03 GMP)

Ancillary material for
CGT manufacturing[†]

[†]Approved by Japanese PMDA - Equivalent to FDA



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, Stem Fit 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.

THE MOST COST EFFECTIVE SOLUTION FOR STEM CELL CULTURE

With less frequent media changes and lower than standard medium volume consumption, one 500ml pack of StemFit® can support over 50% more wells than other leading competitor products. This makes it a highly cost effective solution for stem cell culture.

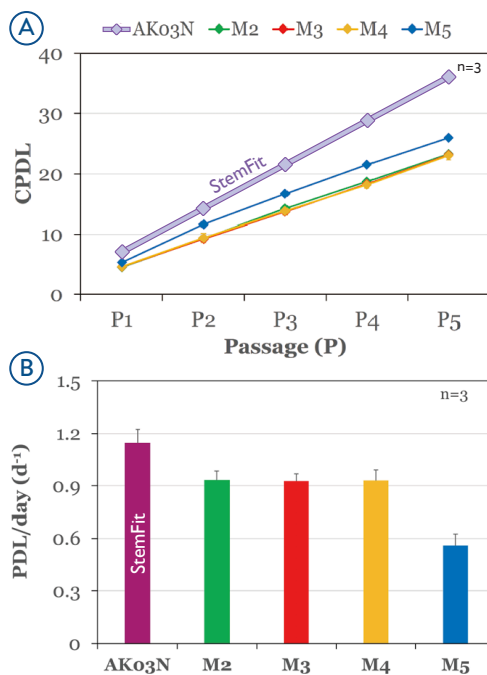
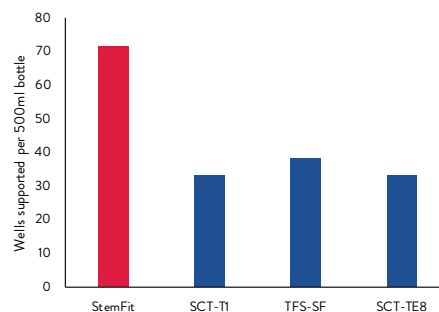
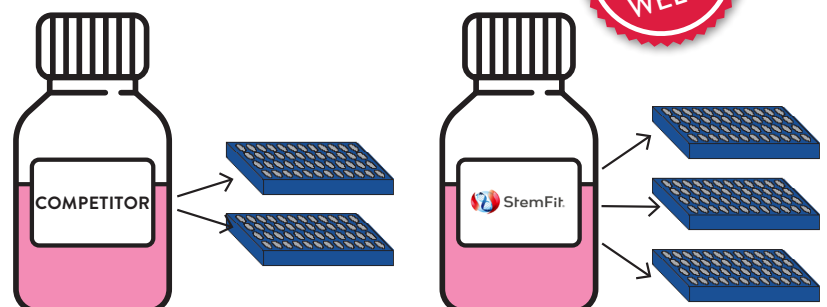


FIGURE 1. EASY EXPANSION

(A) Cumulative Population Doublings (CPD).
(B) Average Population Doublings (PD) throughout 5 passages



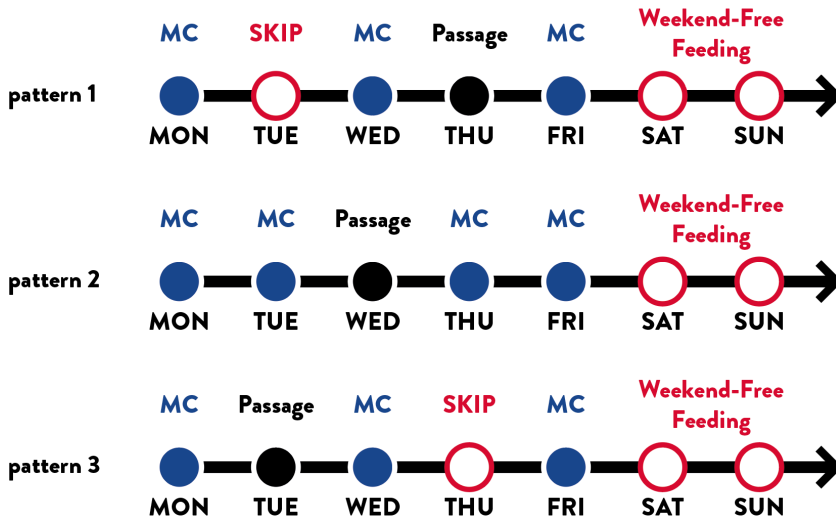
50%
MORE
WELLS



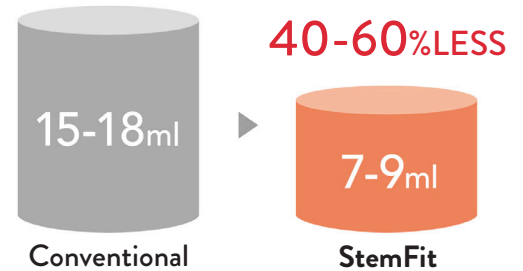
WEEKEND-FREE FEEDING

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 (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



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

Stem Fit 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
Animal origin-free	✓	✓	✓
GMP manufacturing		✓	In preparation
bFGF	Sold Separately (AMS-FGF-100)	Sold Separately (AMS-FGF-100)	Included (80ng/ml)
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

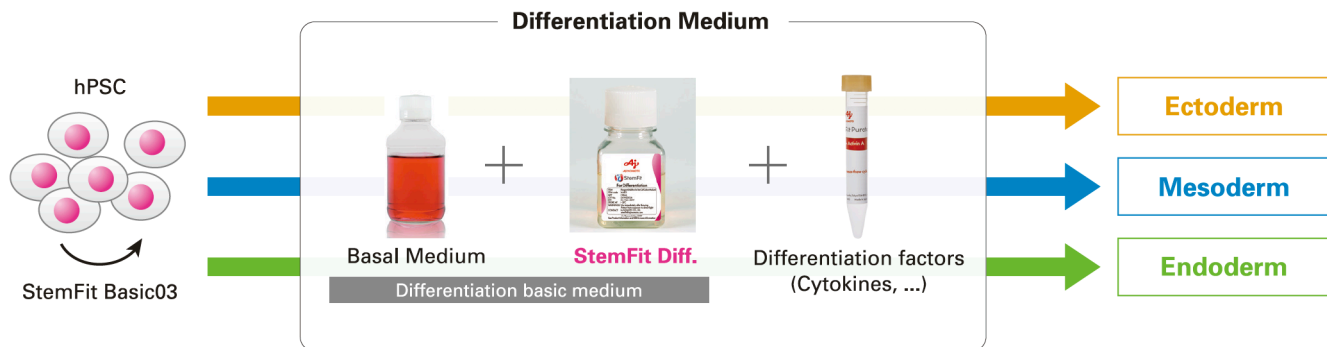


StemFit For Differentiation

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.

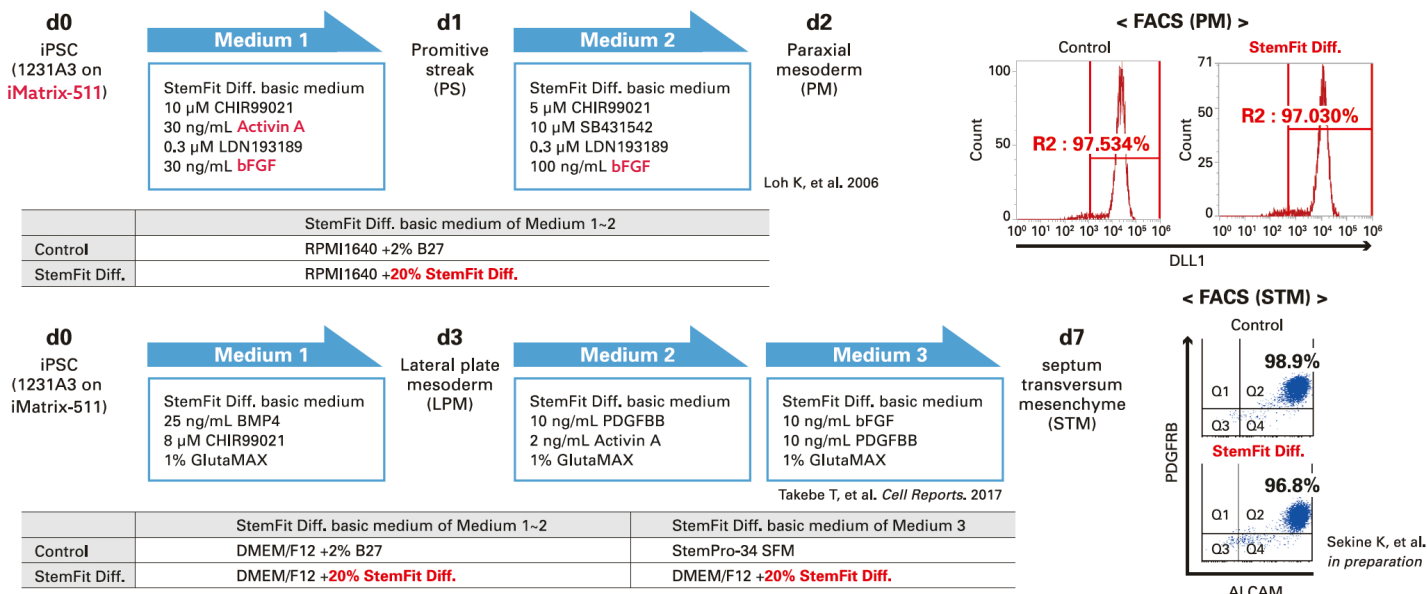
StemFit For Differentiation (StemFit For Diff.) is chemically defined and animal origin-free supplement for hPSC differentiation. StemFit For Diff is designed and manufactured under a strict animal origin free policy and is free from animal or human derived components. StemFit For Diff. is desirable 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)



MESENCHYMAL STEM CELL MEDIA

Clinically applicable MSC media

Chemically defined*

Excellent cell growth

MSC isolation from tissues

Ancillary material for
CGT manufacturing†

†Approved by Japanese PMDA - Equivalent to FDA



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 viral 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

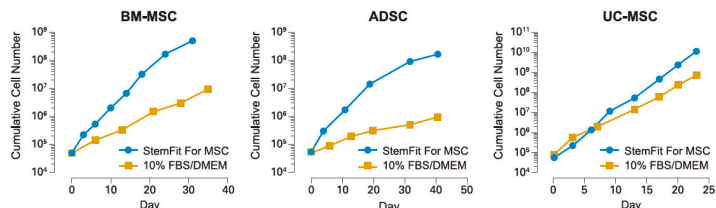
StemFit For MSC enables superior cell expansion compared to serum-containing media. This medium can maintain MSCs with high level of marker expression and differentiation potential.

MSC MARKER EXPRESSION

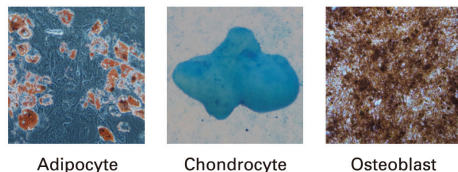
Expression (%)

	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

EXPANSION



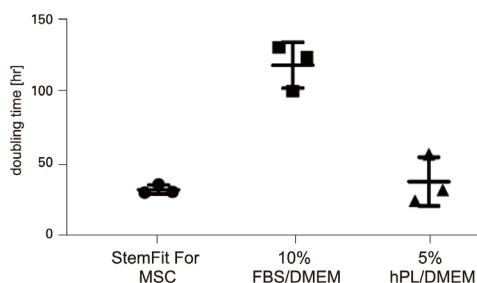
DIFFERENTIATION POTENTIAL



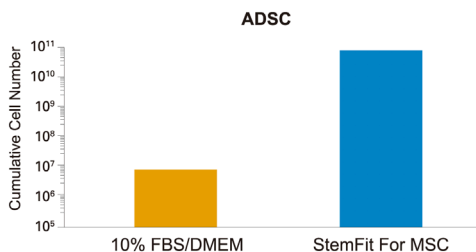
Adipocyte

Chondrocyte

Osteoblast



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



StemFit Purotein®

Recombinant Proteins

Stem Fit 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.

Stem Fit 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.



Stem cell culture media



StemFit Basic03
StemFit Basic03 GMP

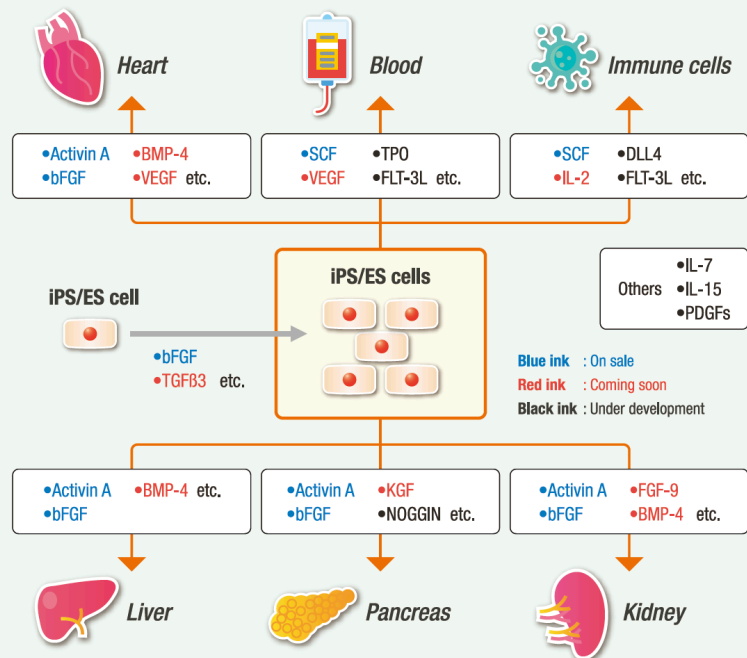


StemFit For Differentiation

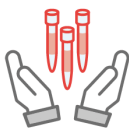


StemFit Purotein®

Recombinant Proteins



— 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.

PRODUCT LIST



Product	Information	Packsize	Product code
StemFit Basic03	hPSC expansion medium for clinical research	Liquid A:400 ml Liquid B:100 ml	SFB-503
StemFit Basic03 GMP	hPSC expansion medium for clinical research and further manufacturing	Liquid A:400 ml Liquid B:100 ml	SFB-503-GMP
StemFit Basic04 Complete	hPSC expansion medium for basic and clinical research one bottle composition	500 ml	SFB-504-CT
StemFit for Differentiation	Differentiation supplement for hPSC	100 ml	SFD-401
StemFit for Mesenchymal Stem cell	hMSC expansion medium	500 ml	SFMSC-A3



Product	Information	Packsize	Product code
Activin A	< Non-GMP > < GMP compliant >	10 ug (0.1 mg/ml)* 1 mg (0.1 mg/ml)	AMS-ACTA – 10 AMS-ACTA-1MG-GMP
SCF	< Non-GMP >	10 ug (0.1 mg/ml)*	AMS.SP-SCF-R-010UG
bFGF	< GMP compliant >	1 mg (0.3 mg/ml)	AMS-FGF-100
KGF	< Non-GMP >	10 ug (0.1 mg/ml)*	AMS.SP-KGF-R- 010UG
IL-2 (to be released 2022)	< Non-GMP >	3 mg (0.5 mg/ml)	TBC

*Larger packsizes available

AMSBIO | www.amsbio.com | info@amsbio.com

04/22

AMSBIO LLC
USA & Canada 
1035 Cambridge Street,
Cambridge, MA 02141
T: +1 (617) 945-5033 or
T: +1 (800) 987-0985
F: +1 (617) 945-8218

AMSBIO Europe BV
EU 
Berenkoog 41,
1822 BH Alkmaar,
Netherlands
T: +31 (0) 72 8080244
F: +31 (0) 72 8080142

AMS Biotechnology (Europe) Ltd
UK & Rest of the World 
184 Park Drive, Milton Park
Abingdon OX14 4SE
T: +44 (0) 1235 828 200
F: +44 (0) 1235 820 482

AMS Biotechnology (Europe) Ltd
Switzerland 
Via Lisano 3,
(CP.683)
CH-6900 Massagno
T: +41 (0) 91 604 55 22
F: +41 (0) 91 605 17 85

AMSBIO Europe BV
Deutschland 
T: +49 (0) 69 779099
F: +49 (0) 69 13376880

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