Solutions for Neural Cell Cultures

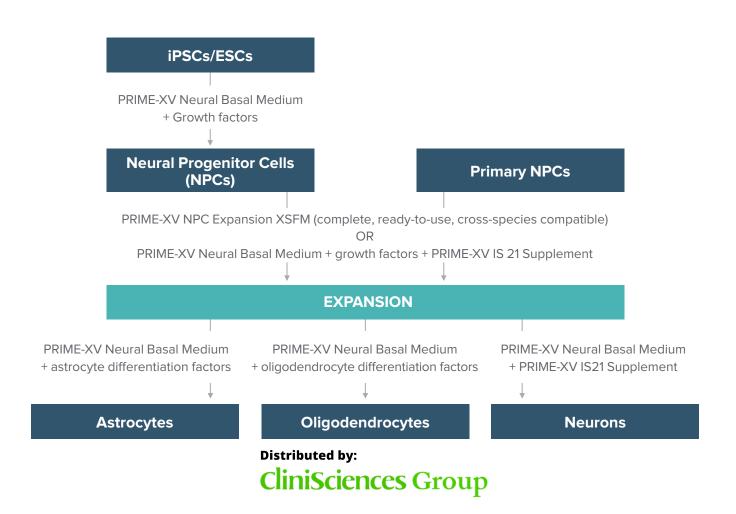
Realize the potential of cell-based therapeutics with PRIME-XV

- Reliable results to fulfill research and industrial standards
- Maintained functionality and viability—even in long-term cultures
- Serum-free workflows to minimize need for lot testing and reduce risk of pathogen transmission
- Stringent raw material qualification to minimize lot-to-lot variation
- Smooth transition from research to the clinic



Working with precious cells that are often expensive, difficult to acquire, difficult to derive and, in the case of neurons, impossible to expand, increases the need for the highest levels of performance, consistency and reliability from a culture medium.

FUJIFILM Irvine Scientific has leveraged over 45 years of experience in delivery of specialized media to develop the PRIME-XV products, providing solutions that consistently equal or outperform leading commercially-available alternatives and serum-based media.

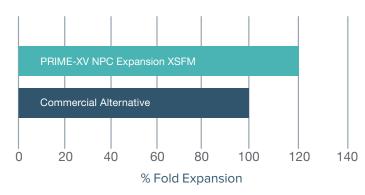




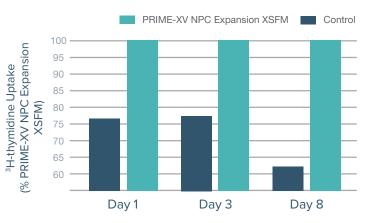
Maximize Expansion, Maintain Multipotency

Optimized for the culture of primary and iPSC/ESC-derived neural progenitor cells (NPCs), PRIME-XV NPC Expansion XSFM offers the convenience of a complete, ready-to-use, medium for expansion in a xeno-free, serum-free environment. Capable of supporting the expansion of rat, mouse, and human NPCs, this cross-species compatible medium facilitates transition from rodent models to human cell cultures studies. PRIME-XV NPC Expansion XSFM also ensures that primary NPCs expand and maintain their multipotency over multiple passages in monolayer and neurosphere cultures.

Acheive greater expansion compared to commercially-available alternatives

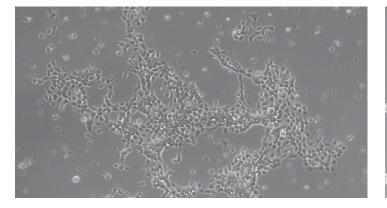


Rat NPCs (fourth passage) cultured for 3 days. Neurospheres were dissociated and processed for viable cell count.

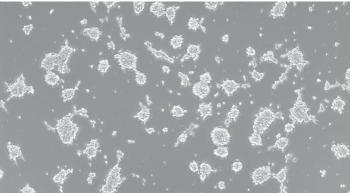


Enhanced ³H-thymidine uptake in mouse NPC cultures indicates increased proliferation. Data courtesy of Dr. Shuxian Hu, Infectious Disease and International Medicine, Medical School, University of Minnesota, U.S.A.

Expand successfully in monolayer or neurosphere cultures



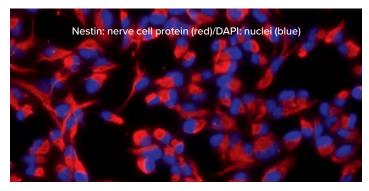
Mouse NPCs expanded as a monolayer in PRIME-XV NPC Expansion XSFM (shown at day 3 after 3 passages).



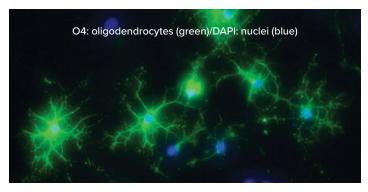
Rat NPCs expanded as neurospheres in PRIME-XV NPC Expansion XSFM (shown at day 3 after 3 passages).

Maintain potential to differentiate

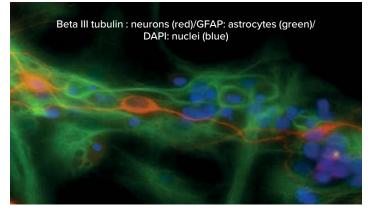
NPCs cultured in PRIME-XV NPC Expansion XSFM maintain their potential to differentiate into neurons, astrocytes, and oligodendrocytes over multiple passages in monolayer and neurosphere cultures.



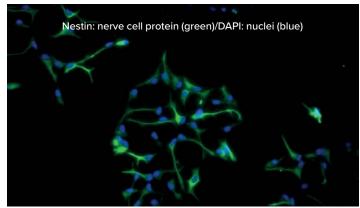
Rat NPCs expanded in PRIME-XV NPC Expansion XSFM and spontaneously differentiated after 3 passages express neural progenitor marker, nestin.



Rat NPCs expanded in PRIME-XV NPC Expansion XSFM and spontaneously differentiated after 3 passages express oligodendrocyte marker O4.



Rat NPCs expanded in PRIME-XV NPC Expansion XSFM and spontaneously differentiated after 3 passages express neuron marker Beta III tubulin and astrocyte marker GFAP.



Human NPCs cultured on PRIME-XV Human Fibronectin-coated plate. Courtesy of Dr. Shuxian Hu, Infectious Disease and International Medicine, Medical School, University of Minnesota, U.S.A.

PRIME-XV NPC Expansion XSFM

- Minimizes wastage and reduces contamination risk
 - No need to mix, filter, or aliquot
 - Complete, ready-to-use medium includes all required supplements and growth factors
- · Minimizes need for lot testing and reduces risk of pathogen transmission
 - Serum-free, xeno-free
- Ready for project transfer from research to clinical studies - Medium supports rat, mouse, and human NPCs
 - cGMP manufacture ensures lot-to-lot consistency

cGMP-compliant manufacture

CliniSciences Gro

Drug Master Files available

> RESEARCH USE OR FUE NOT FOR INJEC

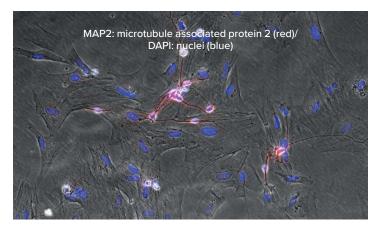
11 Daimler St. Santa Ana, Irvine Scientific PRIME-XV NPC Expansion XSFM Human Neural Progenitor Cell Expansion Xeno-Free, Serum-Free Medium

CA 92705 USA

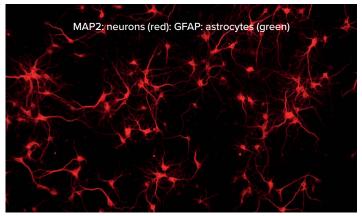
Maintain Functionality and Long-term Viability

PRIME-XV Neural Basal Medium, together with PRIME-XV IS21 Supplement, offers a complete, optimized solution for neuronal cultures. Achieving long-term viability of primary mammalian neurons *in vitro* is a major challenge, often requiring time-consuming tests of neural supplements that are known to exhibit lot variations. PRIME-XV products ensure efficacy and lot-to-lot consistency through stringent control of raw materials, including preselection of the BSA used in PRIME-XV IS21 Supplement.

Maintain viability, morphology, and marker expression in long term cultures

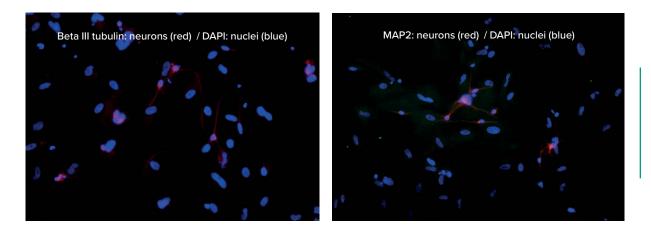


Human iPSC-derived neural progenitors cultured in PRIME-XV Neural Basal Medium/IS21 Supplement for 12 days.



Rat hippocampal neurons cultured in in PRIME-XV Neural Basal Medium/PRIME-XV IS21 Supplement for 14 days. Positive expression of neuron marker MAP2 and negative astrocyte marker GFAP show maintenance of neurons.

Maintain multipotency of iPSC-derived NPCs



iPSC-derived human NPCs differentiated in PRIME-XV Neural Basal Medium/PRIME-XV IS21 Supplement express neuronal markers Beta III and MAP2.

One medium for expansion and differentiation

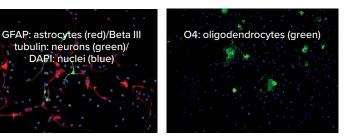
PRIME-XV Neural Basal Medium provides an optimal, serum-free environment for primary cells as well as a reliable, reproducible solution for expansion and differentiation of primary and iPSC/ESC-derived NPCs.

Achieve greater expansion compared to commercially-available alternatives





Maintain multipotency after expansion



Spontaneously differentiated rat NPCs (E14.5) expressing oligodendrocyte marker O4, neuron marker Beta III tubulin and astrocyte marker GFAP after expansion in PRIME-XV Neural Basal Medium with N2 supplement and growth factors.

Maintain marker expression profile and morphology

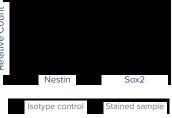
0.35

Supplier B



0.11

Supplier A



0.84

Т

PRIME-XV

Rat NPCs expanded in PRIME-XV Neural Basal Medium for 3 days expressing Nestin and SOX2 and showing desired morphology.

PRIME-XV Neural Basal Medium

- Chemically-defined basal medium—add growth factors or cytokines as required
- Serum-free to minimize need for lot testing and reduce risk of pathogen transmission
- Optimized for use with PRIME-XV IS21 Supplement

PRIME-XV IS21 Supplement

1.0

0.8

0.6

0.4

0.2

0

Rat NPCs

x10⁶ cells/mL)

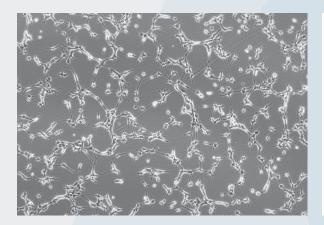
- No more pre-screening—BSA preselected for efficacy
- No astrocyte feeder layer required



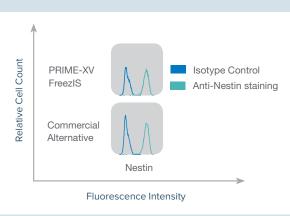
Preserve Cell Viability and Multipotency

PRIME-XV FreezIS is a complete, animal component-free and protein-free, chemically-defined

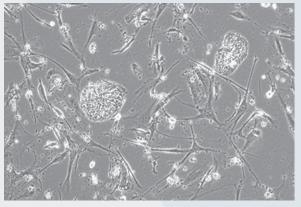
cryopreservation solution. Optimized to preserve a variety of cell and tissue types at -80°C to -196°C, PRIME-XV FreezIS ensures consistently high viability post-thaw to enable efficient expansion and retention of multipotency.

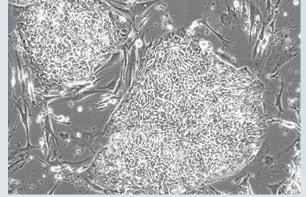


Rat NPCs show high plating efficiency two days postthaw after cryogenic preservation in PRIME-XV FreezIS.



Flow cytometry analysis of rat NPCs performed one day post-thaw after cryopreservation showed positive staining for Nestin expression.



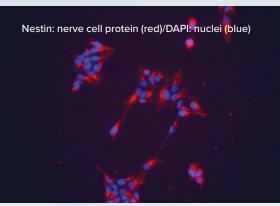


Human induced pluripotent stem cells show desired morphology and growth after cryogenic preservation in PRIME-XV FreezIS (shown at day 3 and day 6).

Day 3

Use human-derived, carrierfree fibronectin for optimal attachment and growth

Fibronectin plays important roles in processes such as cell adhesion, gene expression, and neural stem cell survival. PRIME-XV Human Fibronectin is derived from human plasma to provide optimal attachment and growth in a serum-free workflow.



Human NPCs plated on PRIME-XV Human Fibronectin substrate retained Nestin expression.

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Day 6

Custom Media for Any Cell Type at Any Scale

Routine production of homogeneous cells with the desired functionality and in sufficient quantity is key for high quality research and a smooth transition from development to commercial-scale manufacture.

PRIME-XV media consistently equal or outperform leading commercially-available alternatives and serum-based media. Each PRIME-XV medium is developed and verified using functional assays most relevant to the specific cell type, thereby providing an optimal *ex-vivo* environment during manipulations such as expansion and differentiation.

Transfer smoothly to larger-scale production and fulfill regulatory demands

As potential therapies move toward clinical trials, the need to grow sufficient numbers of cells for effective therapeutic doses using a safe, well-controlled, optimized process becomes paramount. PRIME-XV media are verified beyond the laboratory, often in bioreactor culture systems, to assist in a smooth transfer to clinical production while adhering to global and regional regulatory standards.

Cell-specific media development, optimization, and manufacture

Since 1970, FUJIFILM Irvine Scientific has been meeting the demand for proprietary and customized media solutions for an increasing diversity of cell types. Clients benefit from well-established, proven services, supported by years of knowledge and experience.

Our specialists will be happy to discuss the development of a new customized medium for your specific cell type or to assist with the optimization of your current PRIME-XV medium for scale-up and manufacture.

To discuss your requirements, contact us at getinfo@irvinesci.com or visit our website at www.irvinesci.com/contact-us

- FDA-regulated
- cGMP compliant manufacture
- ISO13485, EN 13485:2016 certified
- Drug Master Files
- FDA registered

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PRIME-XV Ordering Information

Media and Supplement	Catalog #	Size	Additional Information
PRIME-XV NPC Expansion XSFM	91131	250 mL	Xeno-free, serum-free, complete, ready-to-use medium. Does not contain antibiotics.
PRIME-XV Neural Basal Medium	91201	500 mL	Chemically-defined basal medium for neural cultures. Optimized for use with PRIME-XV IS21. Does not contain antibiotics.
PRIME-XV IS21 Supplement (50X)	91142	10 mL	Neural supplement for use with PRIME-XV Neural Basal Medium and conventional media such as Ham's DMEM/F12 with L-glutamine. Does not contain antibiotics.
Cryopreservation Media	Catalog #	Size	Additional Information
Cryopreservation Media PRIME-XV FreezIS	Catalog # 91139	Size 100 mL 10 mL	Additional Information Chemically-defined, free from animal components and proteins. Contains 10% DMSO.
		100 mL	Chemically-defined, free from animal components and proteins.

Ancillary Products

Item	Catalog #	Size*	Additional Information
HBSS 1X-Hank's Balanced Salt Solution (without calcium or magnesium)	9228	100 mL 500 mL	Recommended for dissociation
Recombinant EGF ACF*	95108	100 µg	Animal component-free. Accession Number: P01133
Recombinant FGF-basic 154 ACF*	95109	10 µg	Animal component-free. Accession Number: P09038
Recombinant Human Activin A ACF*	95106	10 µg	Animal component-free. Accession Number: P08476

*Produced in *E. coli*, free from animal components, validated by a relevant bioactivity assay and delivered with a purity \geq 95%.





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