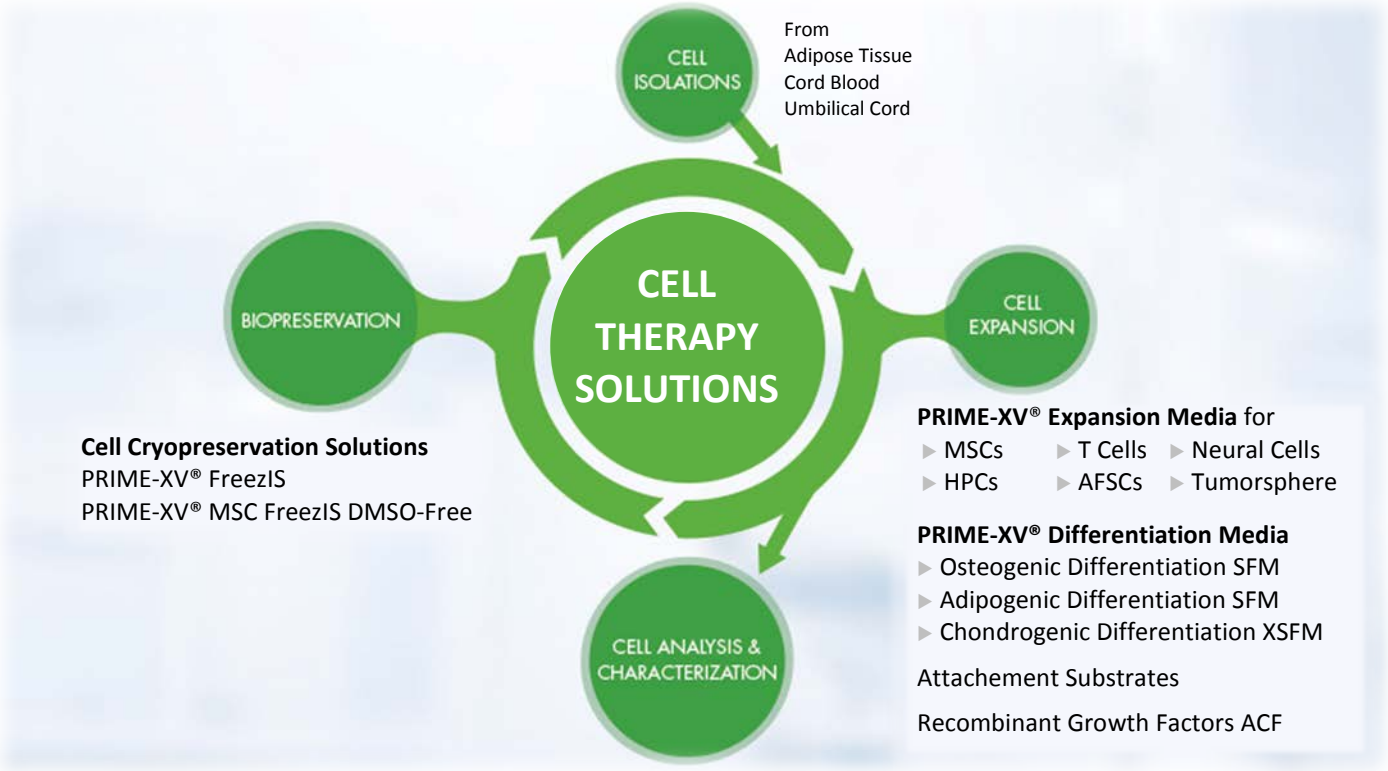
PRIME-XV® Cell Therapy Products by IrvineScientific®

Product List 2017

TRINOVA BIOCHEM now distributes the PRIME-XV® Cell Therapy line by Irvine Scientific® in Germany, Austria and Switzerland.

Irvine Scientific® is a worldwide leader in the design, manufacture and distribution of medical devices, including Cell Therapy, Industrial Cell Culture, Cytogenetic and Assisted Reproductive Technology products. The company's extensive experience in the design of culture media, compliance with ISO and FDA regulations for class II/III medical devices and industrial scale manufacturing capacity provides our customers with unique capabilities and support.

With expertise for more than 25 years as a global supplier of a comprehensive range of high performance cGMP and CE-certified media and ancillary reagents, Irvine Scientific® understands the importance of having an integrated workflow solution and pre-validated products when working with primary cells:



PRIME-XV® products are usually processed under cGMP conditions and for research or further manufacturing use only.

Abbr: ACF = Animal Component-Free CDM = Chemically-Defined Medium SFM = Serum-Free Medium XSFM = Xeno- /Serum-Free Medium
AFSC = Amniotic Fluid Stem Cell MSC = Mesenchymal Stem Cell NPC = Neural Progenitor Cell

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PRIME-XV® Portfolio

* Further Recombinant Human Growth Factors / Cytokines are available. Please inquire!

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Media and Accessory for Mesenchymal Stem/Stroma Cells

Mesenchymal stem/stromal cells (MSCs) are the leading adult stem cells in clinical trials due to their immune modulatory properties and multipotent differentiation potential to form cartilage, bone and other cell types. However, because mesenchymal stem cells and mesenchymal stromal cells exist in small populations, the ability to expand these progenitor cells in vitro is a limiting step in utilizing MSCs for cell therapy applications.

Using the PRIME-XV® brand of validated MSC media and reagents, users are able to maximally expand mesenchymal stem cells and mesenchymal stromal cells derived from human bone marrow, adipose tissue, umbilical cord, and other cell sources in a serum-free cell culture system

PRIME-XV® MSC Expansion SFM [91135]

Human Mesenchymal Stromal/Stem Cell (MSC) Expansion Serum-free Medium

- Outperforms leading competitors and serum-containing media in expansion while maintaining MSC characteristics and multipotency
- Supports MSCs derived from bone marrow, adipose tissue and umbilical cord
- Available as a complete, ready-to-use medium
- Requires little to no adaptation from serum-containing medium

PRIME-XV® MSC Expansion XSFM [91149]

Human Mesenchymal Stromal/Stem Cell (MSC) Expansion Xeno-free / Serum-free Medium

- Maintains MSC quality after extended culture
- Supports MSCs derived from human adipose, human bone marrow, and human umbilical cord
- Xeno-free and serum-free formulation for lot-to-lot consistency
- Drug Master File (DMF) registration

PRIME-XV® Osteogenic Differentiation SFM [91132]

Osteogenic Differentiation Serum-free Medium

- Supports robust induction of osteogenesis from human adipose-derived MSCs and human amniotic fluid stem cells (AFSCs)
- Classical staining method and immunocytochemistry demonstrate the presence of osteoblasts and osteocytes
- Available as a complete, ready-to-use medium

PRIME-XV® Adipogenic Differentiation SFM [91137]

Adipogenic Differentiation Serum-free Medium

- Supports robust induction of adipogenesis from human mesenchymal stem/stromal cells (MSCs)
- Classical staining method and immunocytochemistry demonstrate the presence of adipocytes
- Available as complete, ready-to-use medium

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PRIME-XV® Chondrogenic Differentiation XSFM [91138]

Chondrogenic Differentiation Xeno-Free Serum-free Medium

- Supports robust induction of chondrogenesis from human mesenchymal stem/ stromal cells (MSCs)
- Classical staining method demonstrates the presence of chondrocytes
- Available as complete, ready-to-use medium

PRIME-XV® Media and Accessory for Mesenchymal Stem/Stroma Cells

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
91135	PRIME-XV® MSC Expansion SFM	250 ml	-20°C
91149	PRIME-XV® MSC Expansion XSFM	250 ml/ 1 l	-20°C
91132	PRIME-XV® Osteogenic Differentiation SFM	100 ml	-20°C
91137	PRIME-XV® Adipogenic Differentiation SFM	100 ml	-20°C
91138	PRIME-XV® Chondrogenic Differentiation XSFM	100 ml	-20°C
31001	PRIME-XV® MatrIS F	200 µg	-20°C
31002	PRIME-XV® Human Fibronectin	1 mg	-20°C
31139	PRIME-XV® FreezIS	10 ml / 100 ml	2-8°C
91140	PRIME-XV® MSC FreezIS DMSO-free	10 ml / 100 ml	2-8°C

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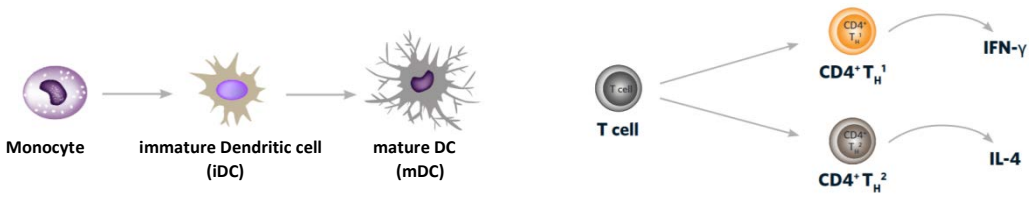
Media and Accessory for Dendritic Cells / T Cells

PRIME-XV Dendritic Cell Maturation CDM is the ideal complement to PRIME-XV T Cell CDM, the first commercially available chemically-defined medium for T cell culture. Together they provide a complete workflow free from the variability and risk of contamination that the use of animal-derived components presents. All products are manufactured using stringent raw material qualification and under current Good Manufacturing Practices (cGMP) for consistency and reliability.

PRIME-XV® solutions for T cell cultures offer serum-free, xeno-free, chemically defined and animal component-free media solutions to fulfill the potential of T cell applications from research to the clinic. Manufactured to provide an optimal environment during ex-vivo manipulations, PRIME-XV® T cell media products have been formulated to deliver improved performance over serum-containing media while maintaining functionality and potency.



NEW: PRIME-XV® Dendritic Cell Maturation CDM [91146]

Chemically-defined, Animal Component-free Medium for Dendritic Cell Culture Intended for Differentiation of Monocytes into Immature Dendritic Cells (iDCs) and Maturation of mDCs

Dendritic cells (DCs) are the most potent antigen-presenting cells capable of priming naïve T cells and are therefore essential tools in the activation of immune responses to tumors. They can be generated in vitro from CD14+ peripheral blood or cord blood monocytes through a maturation process. It is essential for these monocyte-derived DCs (Mo-DCs) to maintain their functional capacity of the launching antigen-specific immunity, leading to T cell activation into therapeutic T cells.

- High yields of DCs with the desired characteristics and morphology
- Maintenance potency of dendritic cells for T cell stimulation
- Ready-to-use, just supplement with desired cytokine cocktails
- Fully cGMP and chemically defined (CDM) - designed to facilitate transfer from research to clinic

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NEW: PRIME-XV® T Cell CDM [91154]

Chemically-defined, Animal Component-free Medium for T cell Culture Optimized to Deliver Consistent Growth while Maintaining T cell Functionality and Potency

- Supports vigorous T cell growth in plates, cell culture bags, and in the G-Rex® while maintaining functionality
- Provides lot-to-lot consistency
- Removes the effects of undefined components on T cell phenotypes
- Supports polarization to targeted T cell types such as Th1 and T regulatory cells
- Traceability documentation provided including Certificates of Analysis, Certificates of Origin, and a Drug Master File (DMF) filed with the US FDA
- Extensive QA testing including functionality, sterility, and endotoxin

PRIME-XV® T Cell Expansion XSFM [91141]

T Cell Expansion Xeno-Free, Serum-Free Medium

- Optimized for the activation and expansion of human T lymphocytes
- Maintains T cell potency
- Supports expansion of memory T cells
- Serum-free and xeno-free formulation reduces risk of contamination and provides better lot-to-lot consistency
- Drug Master File (DMF) registration
- Contains gentamicin

PRIME-XV® Media and Accessory for Dendritic Cells / T Cells

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
91146	PRIME-XV® Dendritic Cell Maturation CDM	500 ml	2-8°C
91154	PRIME-XV® T Cell CDM	1 l	2-8°C
91141	PRIME-XV® T Cell Expansion XSFM	1 l	2-8°C
95118*	Recombinant Human IL-2 ACF*	10 µg	-20°C
95113*	Recombinant Human IL-3 ACF*	10 µg	-20°C
95114*	Recombinant Human IL-4 ACF*	20 µg	-20°C
95121*	Recombinant Human IL-6 ACF*	20 µg	-20°C
95112*	Recombinant GM-CSF ACF*	20 µg	-20°C
95117*	Recombinant TNF-α*	10 µg	-20°C

*Produced entirely animal-component-free (ACF) in an E. coli expression system.
Please inquire for the entire range of recombinant growth factors!

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Media and Accessory for Neural Cells

The ability to expand **neural stem / progenitor cells (NPCs)** in vitro offers significant potential for their utilization as a cell source for cell therapy applications, as well as a model system for understanding neural development and pathology. Irvine Scientific provides comprehensive solutions for supporting NPC culture, including cell attachment substrates, media, biopreservation solutions, and growth factors.

PRIME-XV® Neural Basal Medium [91201]

Chemically-defined medium that maintains functionality with optimal expansion and long term viability of neural and neuronal cultures

- Generation and expansion of iPSC-derived NPCs:
  Generate and expand neural progenitors from iPSCs or ESCs while maintaining their multipotency
- Long-term neuronal culture:
  PRIME-XV® Neural Basal Medium used with PRIME-XV® IS21 neural supplement provides a complete optimized solution for neuronal culture maintaining viability and morphology, while minimizing glial contamination. PRIME-XV® products are optimized for efficacy and consistency in neural culture whereas eliminating the time-consuming tests of neural supplement
- Achieve greater expansion of NPCs:
  Achieve higher cell density and confluency while maintaining multipotency, marker expression profiles and morphology

PRIME-XV® NPC Expansion XSFM [91131]

Neural Progenitor Cell Expansion Xeno-Free, Serum-Free Medium

- Supports the expansion of human, rat and mouse neural progenitor cells
- Maintains neural progenitor cell potential to differentiate into neurons, oligodendrocytes and astrocytes
- Available as a ready-to-use complete medium in convenient 250ml packaging

PRIME-XV® IS21 Supplement [91142]

Neural supplement for long-term neuronal cultures

- Optimized for long-term neuronal cultures
- Serum-free formulation for lot-to-lot consistency
- Drug Master File (DMF) registration

PRIME-XV® Media and Accessory for Neural Cells

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
91201	PRIME-XV® Neural Basal Medium	500 ml	2-8°C
91131	PRIME-XV® NPC Expansion XSFM	250 ml	-20°C
31001	PRIME-XV® MatrIS F	200 µg	-20°C
31002	PRIME-XV® Human Fibronectin	1 mg	-20°C
91142	PRIME-XV® IS21 Supplement (50X)	10 ml	-20°C

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Media and Accessory for Various Cell Types

NEW: PRIME-XV® Hematopoietic Cell Basal XSFM [91211]

Xeno-free, serum -free basal medium for human hematopoietic progenitor cell culture (hHPCs)

Hematopoietic cells are often obtained from bone marrow, peripheral blood and umbilical cord blood, albeit in very limited numbers. The ability to expand hematopoietic progenitor populations can be difficult to achieve. A successful expansion must provide sufficient numbers of fully functional hematopoietic progenitor cells that are able to self-renew and differentiate into all functional blood cells.

PRIME-XV® Hematopoietic Cell Basal XSFM is an optimized xeno- and serum-free medium recommended for use in the expansion of human hematopoietic cells, including hematopoietic progenitor cells. The performance of this medium was assessed on hematopoietic stem/progenitor cells derived from cord blood. It is intended to be used with cytokine supplements* for the ex vivo culture of hematopoietic progenitor cells. The cytokine cocktail used depends on the experimental requirements of each user.

- Optimized to support vigorous expansion of hematopoietic progenitor cells while maintaining high Total Nucleated Cell (TNC) count and percentages of CD34+
- Provides lot-to-lot consistency
- Manufactured to be scalable and to facilitate transfer from research to clinic
- Drug Master File (DMF) registration

PRIME-XV® Mouse Hematopoietic Cell Basal Medium [91206]

Serum -free medium that supports self-renewal of murine hematopoietic cells (mHPCs) while maintaining multipotency

PRIME-XV® Mouse Hematopoietic Cell Basal Medium was developed in a collaboration program with a leading stem-cell research facility in the USA to fulfill the need for a serum-free, cost-effective medium for *in vitro* culture and expansion and self-renewal of murine hematopoietic progenitor cells (mHPCs).

- Ready-to-use to reduce preparation time and contamination risk from mixing and filtering
- Serum-free to provide lot-to-lot consistency
- Optimized for murine hematopoietic progenitor cells (mHPCs) to deliver improved expansion over other available media
- Capable of maintaining cells in their undifferentiated state

* Recombinant Growth Factors / Cytokines produced entirely animal-component-free (ACF) in an E.coli expression system are available. Please inquire for the entire range!

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PRIME-XV® AFSC Expansion Medium [91133]

Human Amniotic Fluid Stem Cell Expansion Medium

Stem cells obtained from the amniotic fluid have recently become an interesting alternate source of pluripotent stem cells for therapeutic applications. Similar to embryonic stem cells, amniotic fluid stem cells are clonogenic and have the capacity to differentiate into cells of the endoderm, mesoderm and ectoderm lineages.
These cells are characterized by their positive expression of Oct4-A, SOX2 and NANOG.
PRIME-XV® AFSC Expansion Medium is the first commercially available medium specifically designed to expand this small subset of cells in the amniotic fluid.

- Supports robust expansion of human amniotic fluid stem cells (AFSCs)
- Maintains pluripotent characteristic of human AFSCs in extended culture
- Available in 250ml complete component and ready-to-use
- Drug Master File (DMF) registration

PRIME-XV® Tumorsphere SFM [91130]

Tumorsphere Serum-Free Formation Medium

Cancer initiating / stem cells (CSCs) represent a minority of the tumor cell population and are difficult to eradicate through conventional cancer therapeutic treatments. The ability to destroy CSCs by priming immune intervention represents a novel approach in personalized medicine. Similar to other stem cells, these cells possess self-renewing and differentiation potential. They are characterized by their ability to form tumorspheres in suspension cultures. As part of the PRIME-XV® brand of validated cell therapy media, Irvine Scientific provides a serum-free medium designed for maximal enrichment of CSCs from solid tumors.

- Enrich populations of cancer initiating cells
- Validated for tumorsphere formations from a variety of human tumor origins, including, but not limited to, breast adenocarcinoma (MCF-7), cervical carcinoma (HeLa) and alveolar adenocarcinoma (A549)

PRIME-XV® Media and Accessory for Various Cell Types

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
91211	PRIME-XV® Human Hematopoietic Cell Basal XSFM	500 ml	2-8°C
91206	PRIME-XV® Mouse Hematopoietic Cell Basal Medium	500 ml	2-8°C
91133	PRIME-XV® AFSC Expansion Medium	250 ml	-20°C
91130	PRIME-XV® Tumorsphere SFM	100 ml	-20°C

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Attachement Substrates

Extracellular matrices support cell adhesion and spreading.

PRIME-XV® MatrIS F [31001]

Recombinant Human Matrix Protein

- Proprietary attachment substrate for the culture of human stem/progenitor cells under serum-free conditions
- Recombinant human matrix protein to ensure lot-to-lot consistency

PRIME-XV® Human Fibronectin [31002]

Human Plasma-derived Fibronectin, Carrier-free
Validated use in a variety of primary cell attachment and spreading applications

PRIME-XV® Attachement Substrates

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
31001	PRIME-XV® MatrIS F	200 µg	-20°C
31002	PRIME-XV® Human Fibronectin	1 mg	-20°C

Recombinant Growth Factors

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Cell Cryopreservation Solutions

The ability to preserve and thaw primary and stem cells has tremendous potential in allogenec and autologous transplants for clinical therapeutic applications. Irvine Scientific's cryopreservation products are formulated as chemically-defined, protein-free solutions that are manufactured under GMP.

PRIME-XV® FreezIS [91139]

Protein-Free, Chemically-defined Cryogenic Preservation Solution for Cells and Tissues

PRIME-XV® FreezIS enables cell freezing of a variety of cell types, ranging from human mesenchymal stem cells and induced pluripotent stem cells to rat neural progenitor cells. After cryogenic preservation, cells were validated for cell markers, viability, and fold expansion over multiple passages. PRIME-XV® FreezIS follows a slow freezing cryopreservation process that minimizes damage from cold shock.

- Enables preservation of a variety of cell types at -80°C to -196°C environments
- Maintains cell surface marker expression of cells post-thaw
- No additional components are needed
- Drug Master File (DMF) registration
- Available in 10ml and 100ml packaging

NEW: PRIME-XV® MSC FreezIS DMSO-Free [91140]

DMSO-Free, Chemically-defined Cryogenic Preservation Solution for Human Mesenchymal Stem/Stromal Cells

- Comparable post-thaw cell viability as solutions containing dimethyl sulfoxide (DMSO)
- Maintain potency of mesenchymal stem/stromal cells (MSCs) throughout cryopreservation
- Eliminate risk of DMSO in MSC applications
- Animal component-free, chemically-defined solution
- Enables cell preservation at -80°C to -196°C environments
- Drug Master File (DMF) registration

PRIME-XV® Cell Cryopreservation Solutions

CATALOG NO.	DESCRIPTION	SIZE	STORAGE
91139	PRIME-XV® FreezIS	10 ml / 100 ml	2-8°C
91140	PRIME-XV® MSC FreezIS DMSO-Free	10 ml / 100 ml	2-8°C

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IrvineScientific

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