



PRIME-XV

COMPLETE CELL CULTURE MEDIA SOLUTIONS FOR PRIMARY MESENCHYMAL CELLS

The PRIME-XV Portfolio

Serum-free media and reagents for mesenchymal stem cells (MSCs)

Expansion Media

Complete, ready-to-use media formulated to deliver maximal expansion of mesenchymal stem cells (MSCs) from a variety of sources while maintaining functionality.

Differentiation Media

Media specially formulated for the robust differentiation of MSCs and amniotic fluid-derived stem cells into chondrogenic or adipogenic cells.

Cryopreservation Solutions

A collection of advanced cryopreservation solutions, including DMSO-free and DMSO-containing options, targeted to preserve cells without compromising functionality.

Attachment Substrate

Extracellular matrix for culturing MSCs and other stem cell types.



Supports Cell Therapy Applications at Any Stage

Developed through a Quality by Design (QbD) approach, the PRIME-XV portfolio is comprised of chemically defined, serum-free formulations aimed to minimize risk from adventitious agents and deliver consistent results. It is ideally suited to support cell therapy applications at any stage—from research to further manufacturing use.

Expansion Media

Maximum expansion. Maintain multipotency.

PRIME-XV MSC expansion media are targeted to support optimal and reliable expansion of human MSCs while retaining morphology, marker expression, immunosuppressive function, and differentiation potential over multiple passages.

- Available in xeno-free, serum-free and serum-free formulas

PRIME-XV MSC EXPANSION XSFM

Xeno-free, serum-free MSC expansion medium

Key benefits:

PRIME-XV MSC Expansion XSFM is formulated to deliver excellent expansion and viability of MSCs over several passages in culture, while maintaining multipotency and functional characteristics.

- Improve expansion and viability in comparison to other commercially-available options and serum-containing media
- Consistently maintain tri-lineage differentiation potential of MSCs derived from bone marrow, adipose tissue, and umbilical cord
- Preserve immunosuppressive potential
- Does not contain antibiotics
- Complete, ready-to-use medium
- Custom formulation available upon request
- Mycoplasma USP <63> testing on all lots

PRIME-XV Media Outperforms Other Commercially-available Options and Serum-containing Media

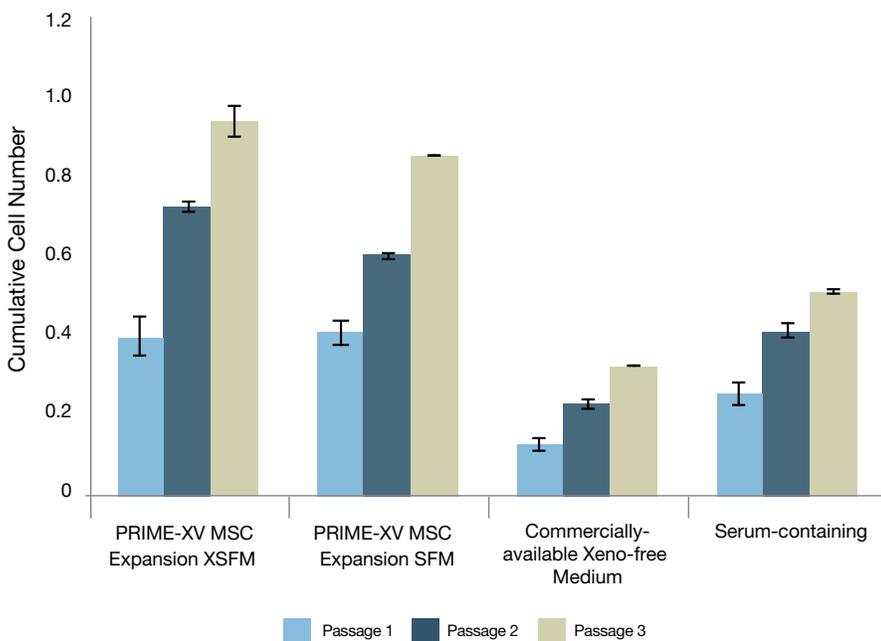


Figure 1. PRIME-XV Expansion media support higher rate of MSC expansion.

Human bone marrow-derived (BM) MSCs were cultured in PRIME-XV MSC Expansion XSFM, PRIME-XV Expansion SFM, commercially-available xeno-free medium, and serum-containing medium. MSCs were plated at 6,000 cells/cm²; cumulative cell number over 3 passages was assessed.



Retains Typical MSC Marker Expression Profiles Over Multiple Passages

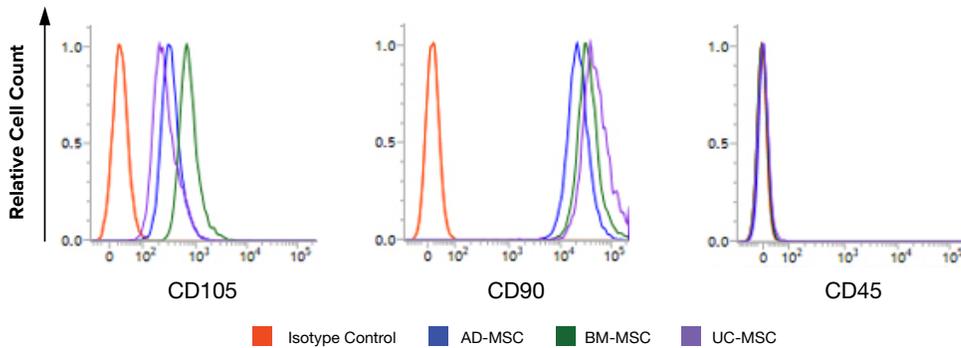


Figure 2. PRIME-XV Expansion XFSM preserves marker expression over multiple passages.

Adipose-derived (AD-MSC), bone marrow-derived (BM-MSC), and umbilical cord-derived MSCs (UC-MSC) were cultured in PRIME-XV MSC Expansion XFSM. MSCs were expanded for 3 passages. Expression of CD105, CD90, and CD45 was assessed by flow cytometry. Cells retained characteristic MSC marker expression profiles after multiple passages: expression of CD105 and CD90, and absence of CD45.

Robust Expansion of MSCs Derived From Multiple Sources

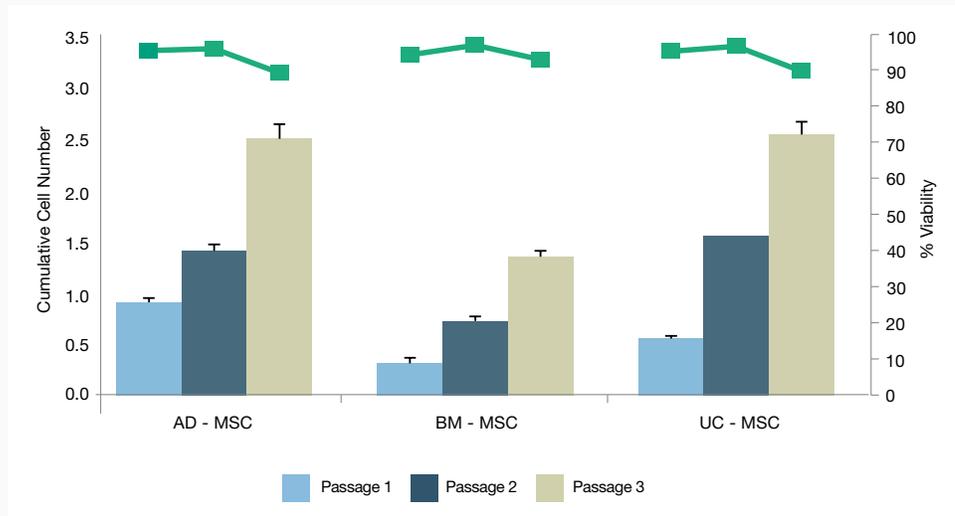


Figure 3. PRIME-XV MSC Expansion XFSM supports robust expansion of MSCs derived from bone marrow, adipose tissue, and the umbilical cord.

AD-MSCs, BM-MSCs, and UC-MSCs were plated at 6,000 cells/cm² and cultured in PRIME-XV MSC Expansion XFSM through 3 passages. Each passage was harvested at 80% confluence and assessed for cell count and viability.



Supports Tri-Lineage Differentiation Potential

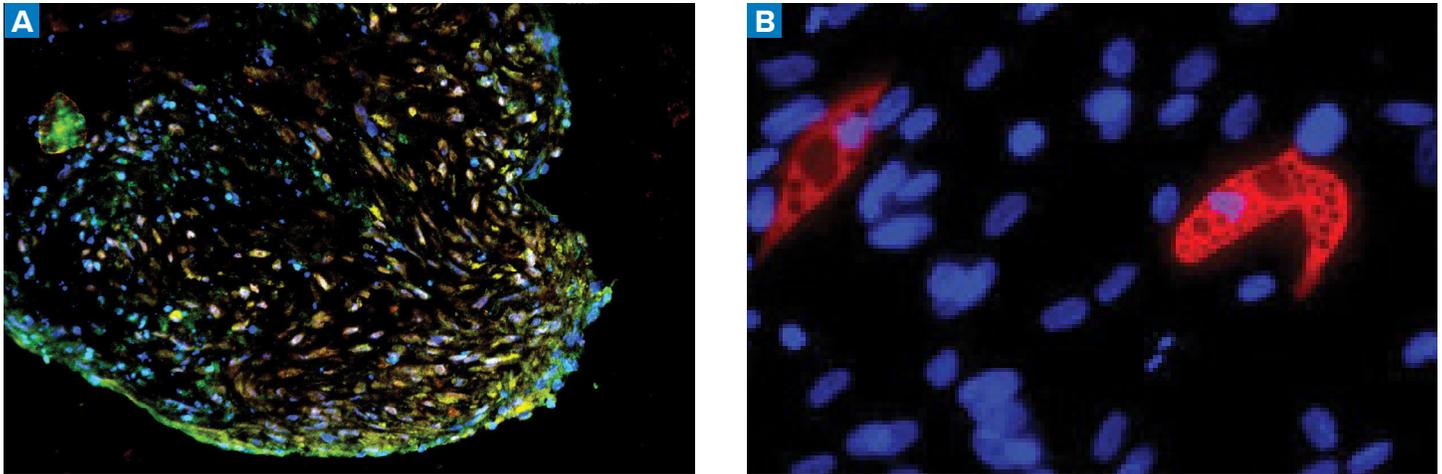


Figure 4. PRIME-XV MSC Expansion XSFM maintains multipotency of human MSCs.

Human BM-MSCs were cultured in PRIME-XV MSC Expansion XSFM then differentiated for 2 weeks using PRIME-XV differentiation media. Staining for aggrecan (red) and collagen type II (green) demonstrates PRIME-XV Chondrogenic Differentiation XSFM induces robust differentiation into chondrocytes (A). Staining for FABP-4 (red) demonstrates PRIME-XV Adipogenic Differentiation SFM induces robust differentiation into adipocytes (B). Nuclei were counterstained with DAPI (A,B).

Maintains Immunosuppressive Potential of MSCs

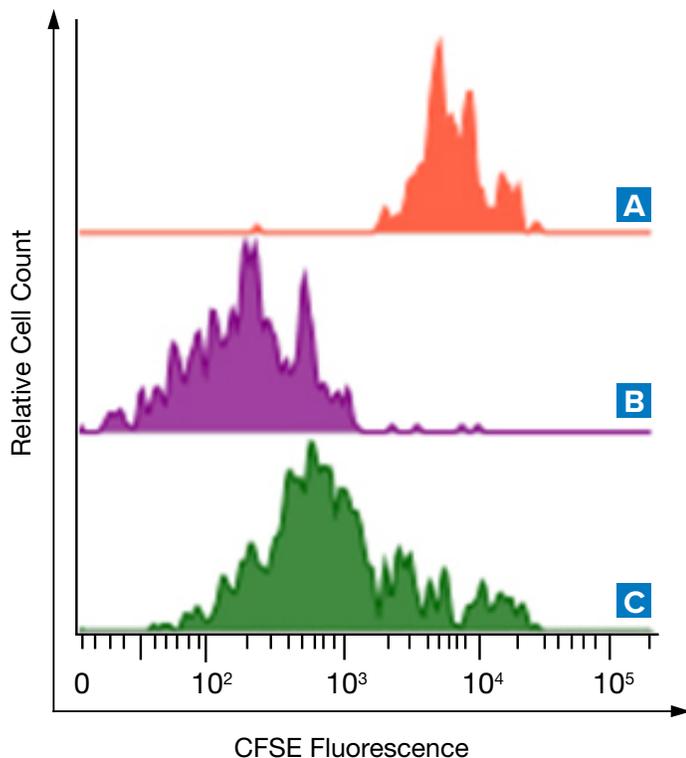


Figure 5. MSC cells expanded in PRIME-XV MSC Expansion XSFM maintain their immunomodulation ability.

BM-MSCs were cultured in PRIME-XV MSC Expansion XSFM. A cell proliferation assay was performed using CFSE-labeled human CD3⁺ T cells stimulated with anti-human CD3 and anti-human CD28. Non-activated CD3⁺ T cells without MSC co-culture were arrested at the parent generation (A). Activated CD3⁺ T cells proliferated for 6 days without MSC co-culture show low fluorescent intensity indicating cell division (B). Proliferation of CD3⁺ T cells stimulated with anti-CD3 and anti-CD28 show higher fluorescent intensity when co-cultured with MSCs (C)—an indication of immune modulation.

Differentiation Media

Robust differentiation. Serum-free conditions.

PRIME-XV MSC differentiation media offer the convenience of complete, ready-to-use, and serum-free media formulated for optimal differentiation into cartilage and adipose cells.

Key benefits:

- Robust differentiation of a variety of stem cell types
- Verification of MSC multipotency
- Does not contain antibiotics
- Complete, ready-to-use medium
- Custom formulation available upon request



PRIME-XV ADIPOGENIC DIFFERENTIATION SFM

Serum-free adipogenic differentiation medium

Achieves Optimal Adipogenesis

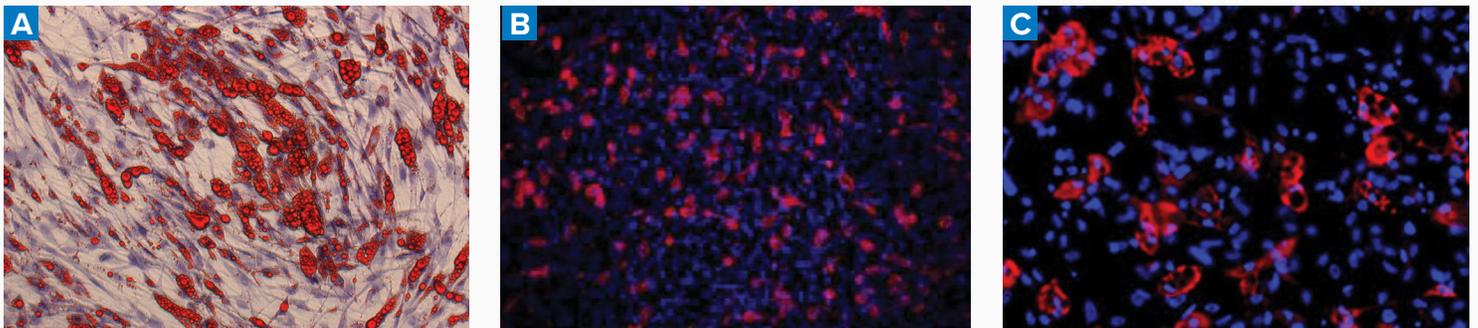


Figure 6. PRIME-XV Adipogenic Differentiation SFM supports adipogenesis.

Human adipose-derived MSCs were differentiated in PRIME-XV Adipogenic Differentiation SFM for 20 days and stained with Oil Red O (A) demonstrating presence of lipid vacuoles (red). Cultured cells were also stained for FABP-4 (red) (B, C). Nuclei were counterstained with DAPI.

PRIME-XV CHONDROGENIC DIFFERENTIATION XSFM

Xeno-free, serum-free chondrogenic differentiation medium

Demonstrates Robust Chondrogenesis

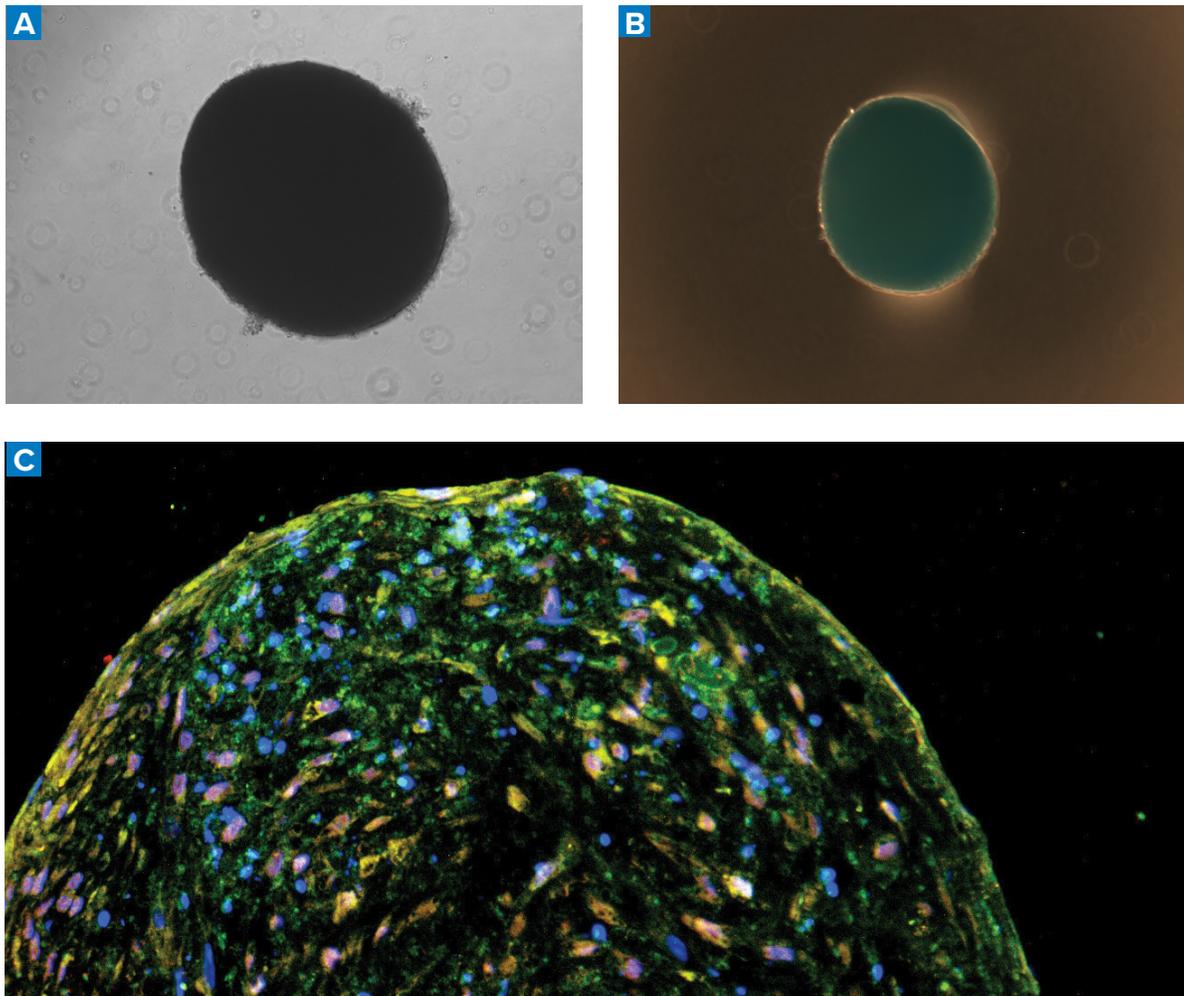


Figure 7. PRIME-XV Chondrogenic Differentiation SFM supports chondrogenesis.

Human adipose-derived MSCs were differentiated in PRIME-XV Chondrogenic Differentiation XSFM. Phase image of a differentiated cell cluster 5 days after differentiation (A). Alcian blue staining of a chondrogenic pellet at day 20 (B). The expression of cartilaginous extracellular matrix was verified by immunocytochemistry. Aggrecan (red) and collagen type II (green) can be detected in cryosectioned spheroid at day 20 (C). Nuclei were counterstained with DAPI (blue).

Cryopreservation Solutions

Ensure viability. Preserve function.

The PRIME-XV portfolio of advanced cryopreservation formulas is optimized to protect and preserve cells during cryopreservation without compromising functionality.

- Available in DMSO-free and DMSO-containing formulas

PRIME-XV FreezIS DMSO-Free

DMSO-free, protein-free, animal component-free, chemically defined cryopreservation solution

- Eliminate the risk of DMSO toxicity and maintain potency of human mesenchymal stem cells (MSCs), T cells, and hematopoietic stem cells (HSCs) throughout cryopreservation
- Comparable post-thaw cell viability to solutions containing DMSO
- Nontoxic when injected in animal models
- Enables cell preservation for short-term storage at -80°C^* and long-term storage in liquid nitrogen to -196°C
- Complete, ready-to-use medium
- Custom formulation available upon request
- Mycoplasma USP <63> testing on all lots



*Human MSC and PBMC (T cell) data available for short-term storage. Human HSC data is not available.

High Cell Viability and Recovery Post-thaw

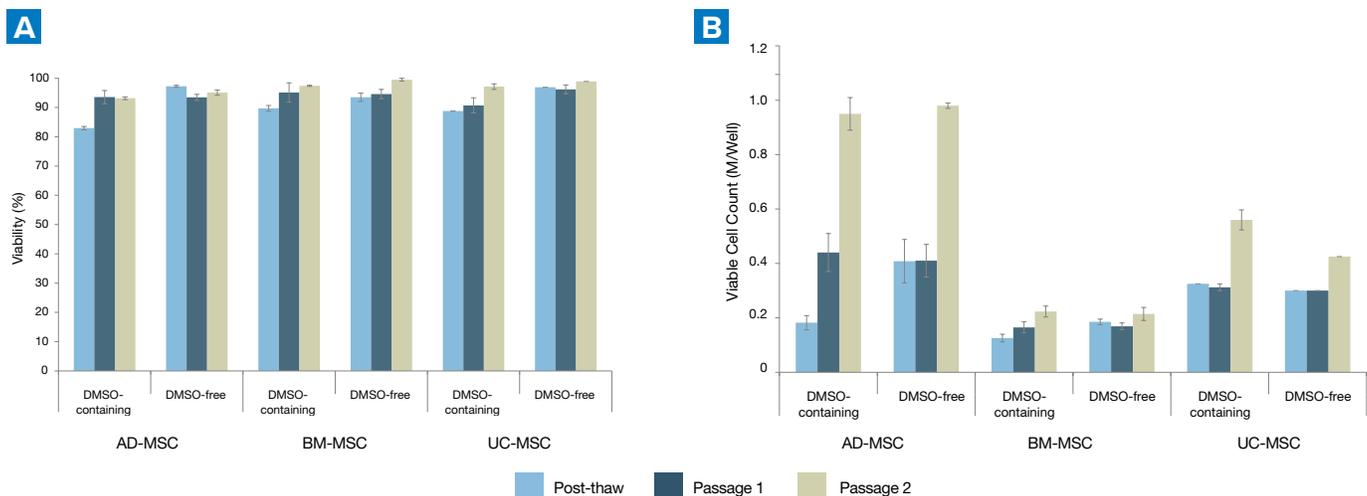


Figure 8. PRIME-XV FreezIS DMSO-Free retains comparable viability and cell expansion profiles of MSCs when compared to a DMSO-containing solution.

MSCs derived from adipose tissue (AD-MSC), bone marrow (BM-MSC) and the umbilical cord (UC-MSC) were frozen in PRIME-XV FreezIS DMSO-Free and in PRIME-XV FreezIS, a DMSO-containing freezing solution. The cells were stored in liquid nitrogen for 2 days before they were thawed and cultured through 2 passages until 80% confluent. The percent viability (A) and cell density (B) were assessed with trypan blue staining. Long-term cryopreservation data is available on request.

Maintains MSC Morphology and Marker Expression

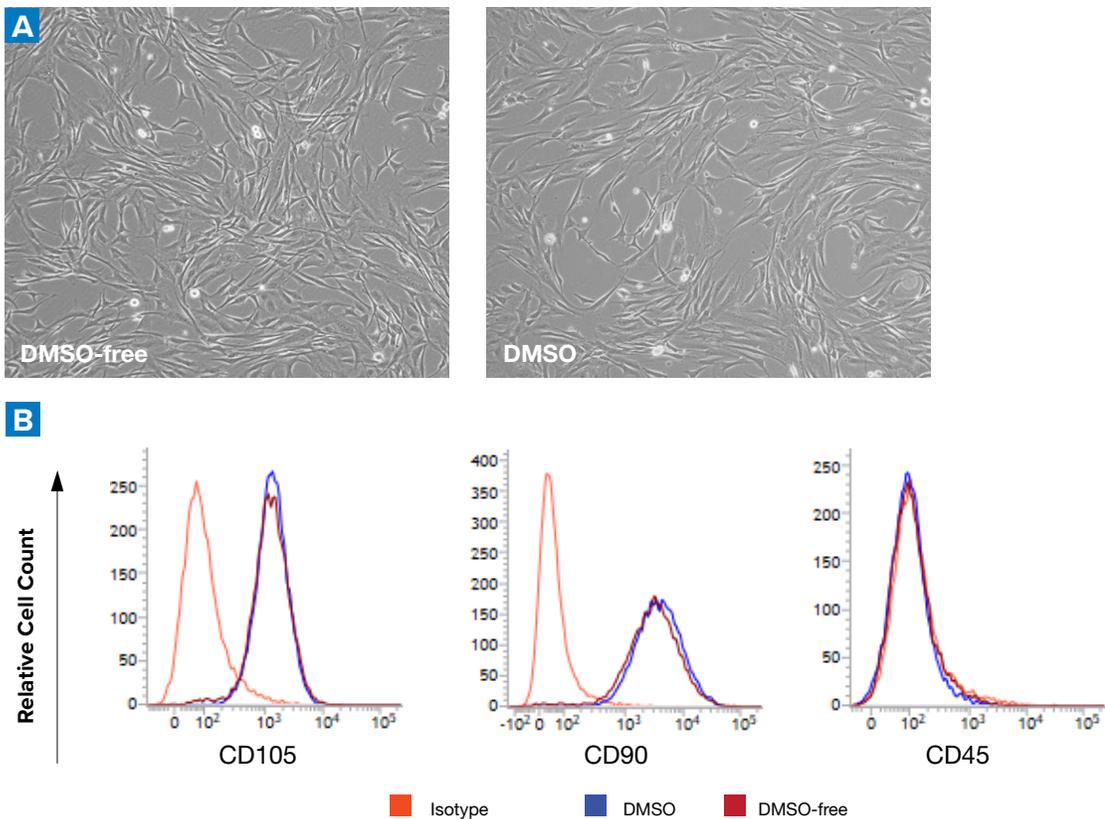


Figure 9. PRIME-XV Freezis DMSO-Free retains MSC morphology and marker expression after thaw and over multiple passages.

Bright field images demonstrate typical MSC morphology after thaw (A). Human AD-MSCs were cultured for 3 passages post-thaw and analyzed by flow cytometry. Expanded cells retained the characteristic MSC marker expression: positive for CD105 and CD90, and absence of CD45 (B).

Preserves Tri-lineage Differentiation Potential

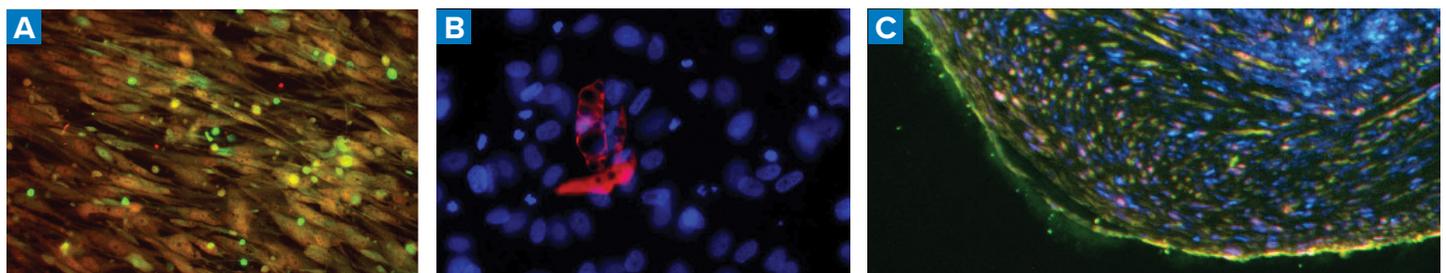


Figure 10. Cells cryopreserved in PRIME-XV Freezis DMSO-Free retain differentiation potential.

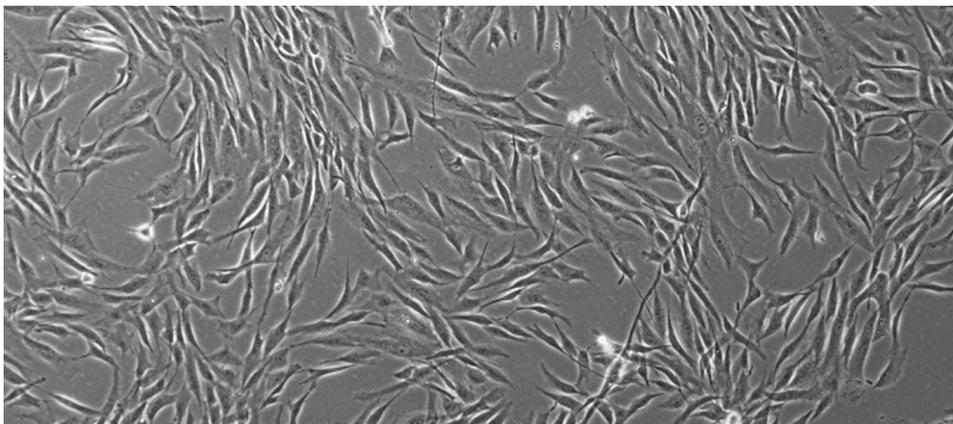
Post-thawed cells were cultured for 3 passages and subsequently differentiated into osteoblasts (A), adipocytes (B) and chondrocytes (C) with PRIME-XV differentiation media. Staining for osteocalcin (green) and RUNX2 (red) shows presence of osteocytes (A). Immunocytochemistry with anti-FABP-4 antibody (red) shows differentiation into the adipogenic lineage (B). Aggrecan (red) and collagen type II (green) can be detected in a cryosectioned spheroid at day 20, demonstrating the expression of cartilaginous extracellular matrix.

PRIME-XV Fibronectin

Human plasma-derived fibronectin, carrier-free

PRIME-XV Human Fibronectin is a purified attachment substrate used to sustain human primary stem and progenitor cells for cell attachment, growth, and spreading.

- Supports cell adhesion of human stem and progenitor cells under serum-free conditions
- Validated for use in a variety of primary cell attachment and spreading applications
- Carrier-free formula



Delivers Optimal Growth and Spread of MSCs.

Human bone marrow-derived MSCs were cultured for 5 days in tissue-culture grade plates coated with PRIME-XV Human Fibronectin. Cells were cultured in PRIME-XV MSC Expansion XSFM. Cells were plated at 6,000 cells/cm². Images were taken at 10X magnification.

A PRIME-XV Solution for Any Cell Type at Any Scale

Routine production of homogeneous cell populations with the desired functionality is key for high-quality research and the smooth transition from development to commercial-scale manufacture. PRIME-XV media consistently equal or outperform leading commercially-available alternatives and serum-containing 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 easily fulfill regulatory demands

As potential therapies move towards further manufacturing use, 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 manufactured following cGMP guidelines and designed to smoothly transition to further manufacturing use. When you are ready for that transition, our regulatory experts are available to discuss how to meet proper global and regional regulatory standards.

Cell-specific media development, optimization, and manufacture

For more than 50 years, FUJIFILM Irvine Scientific has delivered proprietary and customized media solutions for an increasing diversity of cell types. Customers benefit from well-established, proven services, supported by years of knowledge and experience.

Our specialists are available 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.

- FDA, Federal, and State registered - cGMP-compliant manufacture
- EN ISO 13485:2016 certified
- MDSAP certified
- Extensive QC testing including functionality, sterility (USP <71>), and endotoxin (USP <85>)
- Drug Master Files (DMFs) filed with the FDA – available upon request

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



Ordering Information

| Product Description | Catalog # | Size* | Additional Info |
|--|-----------|-----------------|---|
| PRIME-XV MSC Expansion XSFM | 91149 | 250 mL 1 L | Xeno-free, serum-free medium MSC expansion |
| PRIME-XV MSC Expansion SFM | 91135 | 250 mL 1 L | Serum-free medium MSC expansion |
| PRIME-XV Chondrogenic Differentiation XSFM | 91138 | 100 mL | Xeno-free, serum-free chondrogenic differentiation medium |
| PRIME-XV Adipogenic Differentiation SFM | 91137 | 100 mL | Serum-free adipogenic differentiation medium |
| PRIME-XV FreezIS DMSO-Free | 91140 | 10 mL 100 mL | Protein-free, chemically defined, animal component-free cryopreservation medium. Does not contain DMSO. |
| PRIME-XV FreezIS | 91139 | 10 mL 100 mL | Protein-free, chemically defined, animal component-free cryopreservation medium. Contains DMSO. |
| PRIME-XV Human Fibronectin | 31002 | 1 mg | Human plasma-derived fibronectin, carrier-free |

Related Products

| Product Description | Catalog # | Size* | Additional Info |
|--|-----------|---------------|--|
| PBS 1X Dulbecco's Phosphate Buffered Saline Solution | 9236 | 500 mL 1 L | Without phenol red or sodium bicarbonate |

*Custom sizes and packaging available upon request.