FUJIFILM
Value from Innovation

PRIME-XV MSC XSFM Dual Component Kit with or without Phenol Red

SIMPLIFIED AND EFFICIENT LARGE-SCALE MSC EXPANSION

Maximize cell expansion and differentiation within a fully closed system

Mesenchymal stromal/stem cells' (MSCs) proliferation, self-renewal, and multipotent differentiation potential make them cornerstones of regenerative medicine and cell therapy development. Because MSCs constitute a small percentage of their source tissues and isolation processes show variable efficiency, the ability to expand these progenitor cells *in vitro* can limit therapeutic efficacy.

Deliver greater numbers of MSCs by moving to an automated closed-system platform

- Maintains lot-to-lot consistency with xeno- and serum-free media
- Enables up to an 8-fold MSC expansion (donor-dependent)
- Yields 200x10^6 cells in 7 days of expansion with viability at or above 90%
- Does not contain antibiotics, with or without phenol red
- Extensive QC testing on all lots including:
  - Mycoplasma (USP <63>), functionality, sterility (USP <71>), and endotoxin (USP <85>)

PRIME-XV MSC XSFM Dual Component Kit with or without Phenol Red

Our closed-system solutions include basal media and supplement in a complete kit for use with Quantum or other compatible hollow fiber bioreactors. A simplified and efficient GMP solution for large-scale MSC expansion.

- Simplifies and expedites the process of MSC expansion for large-scale solutions
- Minimizes risk of contamination and cell stress, and increases efficiency
- Provides a fully closed system solution for Quantum* or other compatible hollow fiber bioreactors

8-fold expansion in xeno- and serum-free conditions

PRIME-XV MSC XFSM Dual Component Kit is comprised of two components; PRIME-XV MSC XSFM Base media and PRIME-XV MSC XSFM Supplement.

*Quantum Bioreactor protocol available in IFU (Product Insert)

Consistent, Reproducible MSC Expansion

PRIME-XV MSC XSFM Dual Component Kit with or without Phenol Red is formulated to deliver expansion and viability of MSCs over several passages in culture, while maintaining multipotency and functional characteristics.

Results from three different donors demonstrate some donor-to-donor variability. This supports a yield of 200x10^6 total MSCs from an initial seed of 25x10^6 cells in 7 days of expansion and helps maintain stemness of ADMSCs post expansion.

Large-scale expansion of MSCs in a closed system format

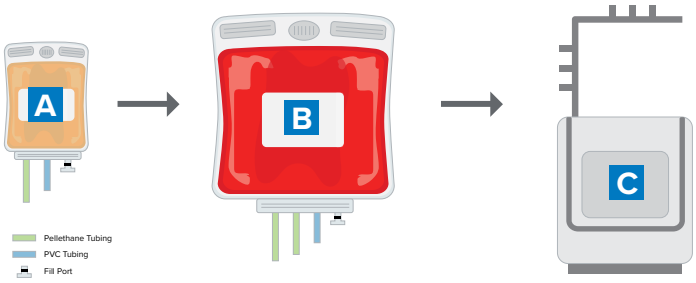

Figure 1. The dual bag format keeps the critical, temperature-sensitive supplement frozen until ready to use. The supplement and basal bag are aseptically welded and mixed to create the complete medium.

A) 10 mL PRIME-XV MSC XSFM Supplement stored at -20˚C

B) 5 L PRIME-XV MSC XSFM Base with Phenol Red or PRIME-XV MSC XSFM Base without Phenol Red in bag stored at 2 – 8˚C

C) Quantum Bioreactor or another compatible bioreactor system

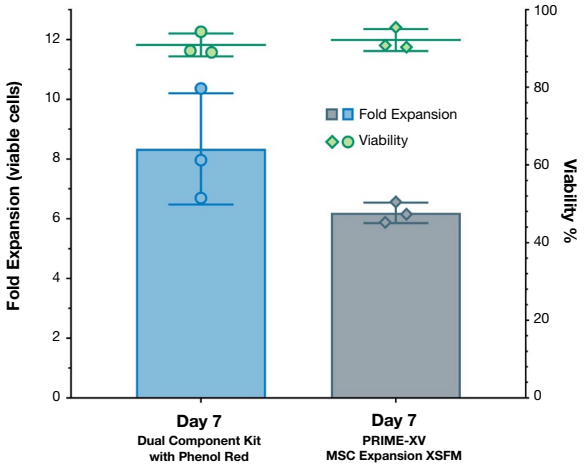

Figure 2. Results from the 7-day expansion PRIME-XV MSC XSFM Dual Component Kit with Phenol Red show that viability is consistently maintained at or above 90%.

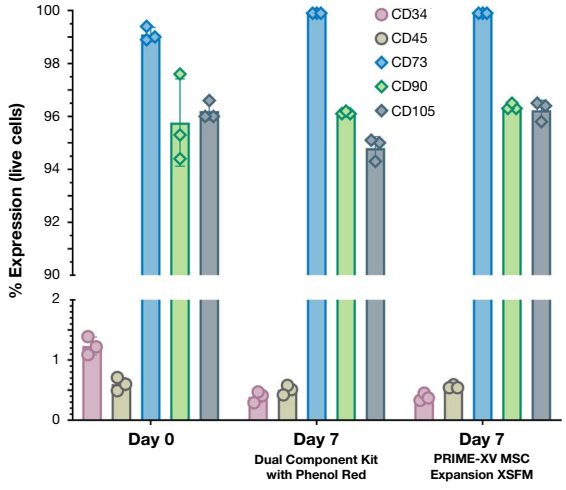

Figure 3. ADMSCs maintain their stem cell phenotype at Day 7 post-expansion in the Terumo Quantum bioreactor with PRIME-XV MSC XSFM Dual Component with Phenol Red and in PRIME-XV MSC Expansion XSFM (Catalog #91149). The expression of negative markers CD34 and CD45 remained well below 2% over the course of the culture.

Ordering Information

Product Description	Catalog #	Size*	Additional Information
PRIME-XV MSC XSFM Dual Component Kit with Phenol Red	91149DC	10 mL Supplement 5 L Basal	Xeno-free, serum-free, medium for MSC expansion.
PRIME-XV MSC XSFM Dual Component Kit without Phenol Red	91214DC	10 mL Supplement 5 L Basal	Xeno-free, serum-free, medium for MSC expansion.

Related Products

Product Description	Catalog #	Size*	Additional Information
PRIME-XV MSC Expansion XSFM	91149	250 mL 1 L	Xeno-free, serum-free, medium for MSC expansion.
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 Adipogenic Differentiation SFM	91137	100 mL	Serum-free adipogenic differentiation medium.
PRIME-XV Chondrogenic Differentiation XSFM	91138	100 mL	Xeno-free, serum-free chondrogenic differentiation medium.
PRIME-XV Human Fibronectin	31002	1 mg	Human plasma-derived fibronectin, carrier-free.

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