FUJIFILM
Value from Innovation

IrvineScientific

PRIME-XV Hematopoietic Cell Basal XSFM

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

- Supports maintenance of CD34⁺ hematopoietic stem and progenitor cell populations
- Optimized expansion of hematopoietic stem and progenitor cell populations
- Maintains balanced lineage differentiation potential

Optimal expansion of human hematopoietic progenitor cells

Higher expansion rates compared to an alternative supplier

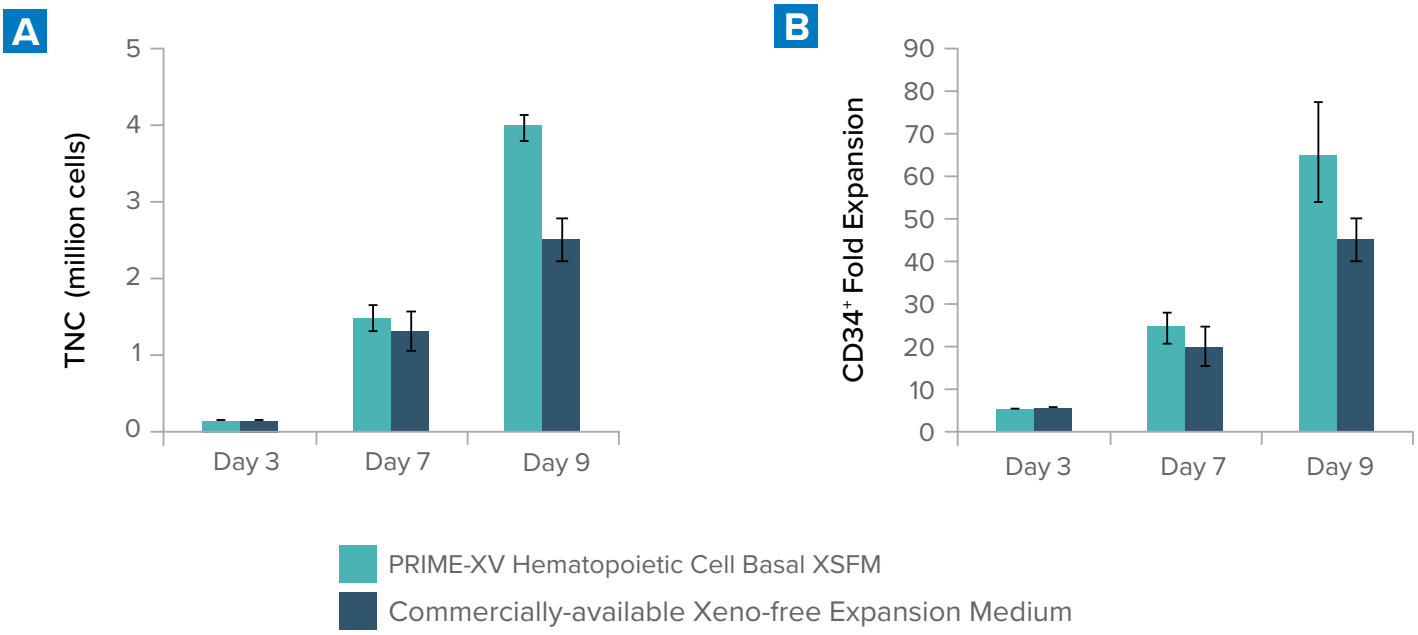


Figure 1. CD34⁺ hematopoietic progenitor cells derived from human cord blood were cultured in PRIME-XV Hematopoietic Cell Basal XSFM or a commercially-available xeno-free expansion medium, both supplemented with a cocktail of cytokines (TPO, SCF, FLT-3L, IL-3, and IL-6). After 3, 7, and 9 days, the TNC (A) and fold expansion (B) of CD34⁺ cells were quantified.

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 fulfill regulatory demands

As potential therapies move towards commercialization, the need to grow sufficient numbers of cells for effective therapeutic doses using a well-controlled, optimized process becomes paramount. PRIME-XV media follow cGMP-compliant manufacture to ensure a smooth transition to large-scale production. 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.

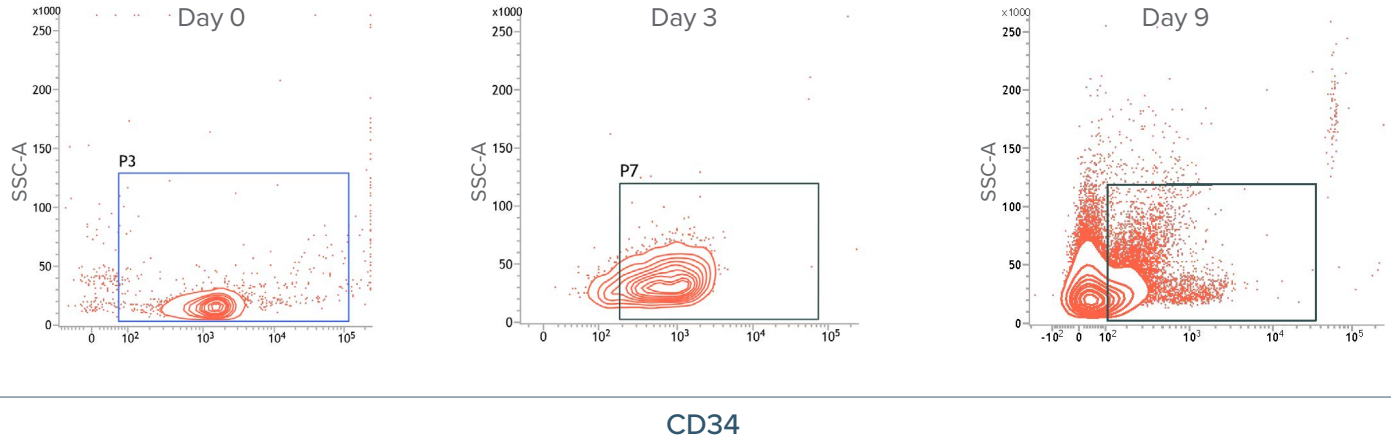
> To discuss your requirements, contact us at **getinfo@irvinesci.com** or visit our website at **www.irvinesci.com/contact-us.**

- 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

Supports maintenance of CD34⁺ hematopoietic progenitor cell population

CD34⁺ cell dose used in transplantation may correlate with engraftment kinetics and long-term peripheral blood counts[1,2]. However, hematopoietic stem and progenitor cells (HSPCs) spontaneously differentiate over time in culture. PRIME-XV Hematopoietic Cell Basal XSFM is formulated to expand and maintain a population of cells in their progenitor state, indicated by expression of CD34⁺ and differentiation potential. The ability to efficiently expand CD34⁺ HSPCs is critical to facilitate the progression of both allogeneic and autologous cell-based therapies towards clinical applications.

A



B

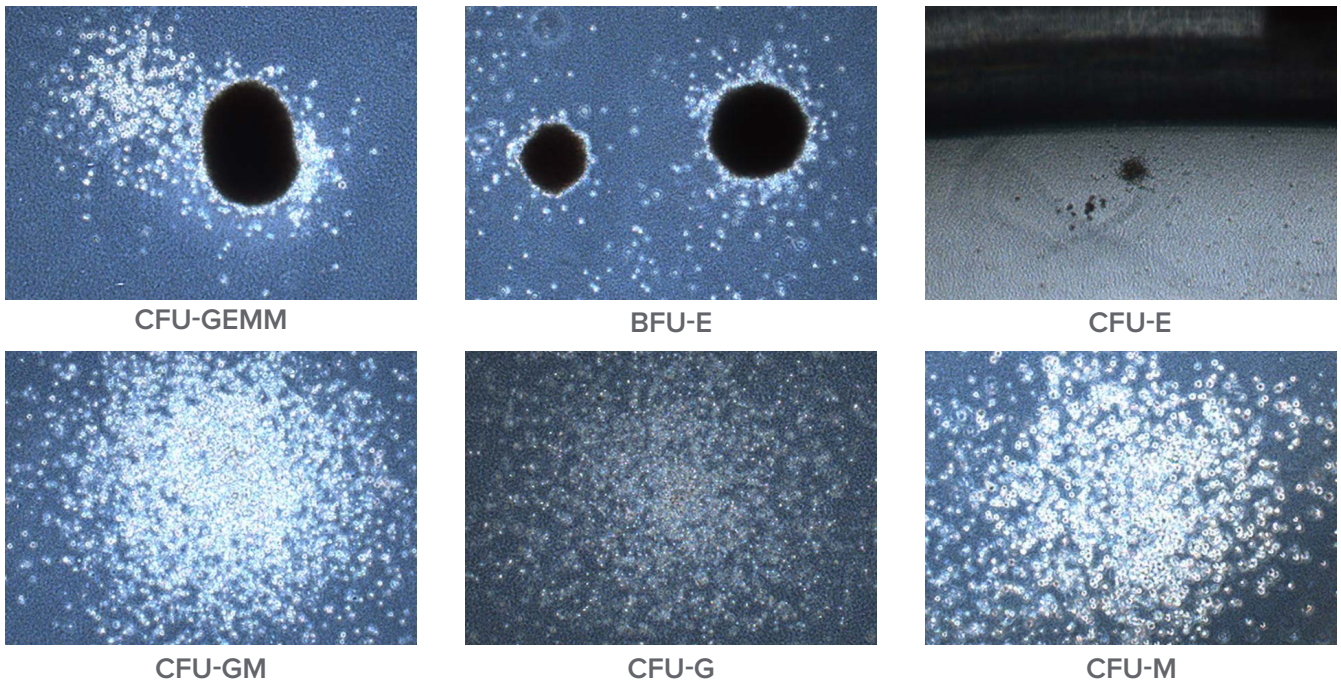
Figure 2. CD34⁺ hematopoietic progenitor cells derived from human cord blood were cultured in PRIME-XV Hematopoietic Cell Basal XSFM or a commercially-available xeno-free expansion medium, both supplemented with a cocktail of cytokines (TPO, SCF, FLT-3L, IL-3, and IL-6). At days 0, 3, and 9 in culture cells were analyzed by flow cytometry for expression of CD34 (A). The percentage of CD34⁺ cells was determined at Day 9 (B).

[1] Perez-Simon et al. (2000) Blood Marrow Transplant 24(12):1279-1283
[2] Pastore (2006) Blood 108 (11):2954

Maintains balanced lineage differentiation potential

The colony-forming unit (CFU) assay (Figure 4) is an *in vivo* functional assay commonly used to assess the differentiation potential of HSPCs. As a strong independent predictor of successful engraftment, CFU dose has become widely used as an important part of graft selection and often correlates with reconstitution of HSPCs following transplantation[3,4]. Analysis by CFU assay demonstrates PRIME-XV Hematopoietic Cell Basal XSFM maintains differentiation potential and supports balanced distribution of lineage subtypes.

A



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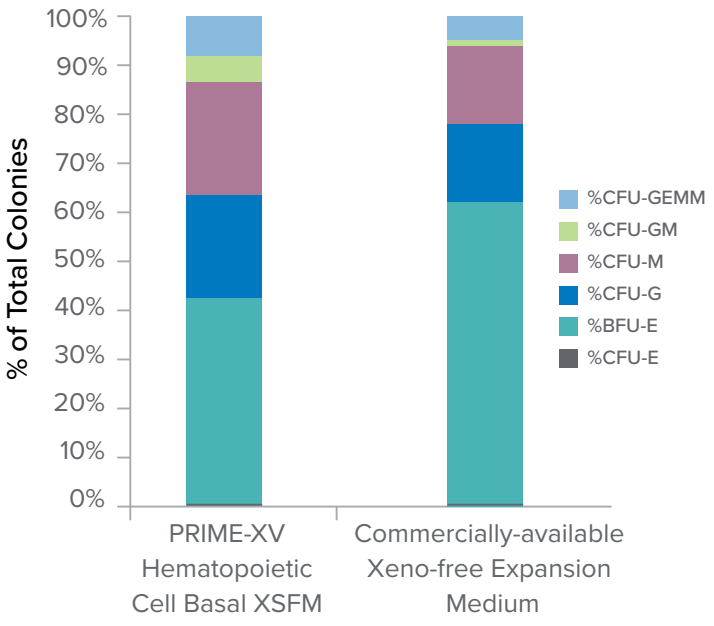

Figure 3. CD34⁺ cells derived from human umbilical cord blood were cultured for 5 days in PRIME-XV Hematopoietic Cell Basal XSFM and a commercially-available medium, both supplemented with a cocktail of cytokines (TPO, FLT-3, SCF, IL-3, and IL-6). On day 6 cells were plated in a semi-solid medium for 14 days. After the 14 days, bright field images were taken (A) and distribution profiles of lineage differentiation by CFU assay (refer to Figure 4) were determined (B).

[3] Page et al. (2011) Blood Marrow Transplant 17(9):1362-1374
[4] Yoo et al. (2007) Bone Marrow Transplant 39(9):515-521

Human hematopoietic cell differentiation in colony forming assays

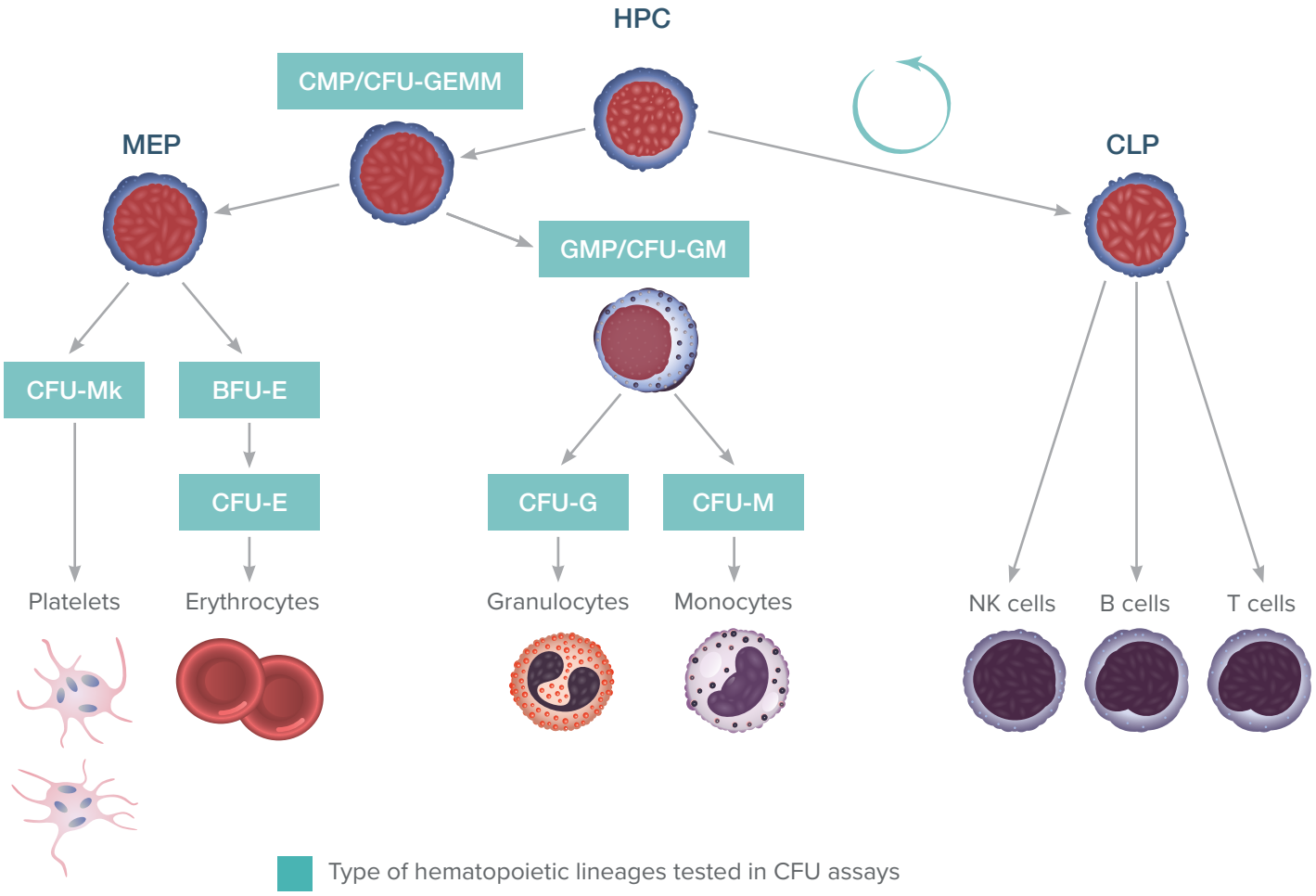

Figure 4. Hematopoietic progenitors replicate by self-renewal (curved arrow), while maintaining the ability to differentiate into all the sub-lineages for replenishing mature blood cells as needed. A hematopoietic progenitor cell (HPC) can differentiate to two different types of precursors, Common Myeloid Progenitors (CMP) and Common Lymphoid Progenitors (CLP). Colony forming unit (CFU) assays identify lineage-restricted progenitor cells, including **CFU-GEMM:** CFU-granulocyte, erythrocyte, monocyte, megakaryocyte; **BFU-E:** burst-forming unit-erythrocyte; **CFU-E:** CFU-erythrocyte; **CFU-GM:** CFU-granulocyte, monocyte; **CFU-G:** CFU-granulocyte; **CFU-M:** CFU-monocyte; **CFU-Mk:** CFU-megakaryocyte.

Ordering Information

Media	Catalog #	Size*	Additional Information
PRIME-XV Hematopoietic Cell Basal XSFM	91211	500 mL	Xeno-free, serum-free HSC basal medium

Related Products

Item	Catalog #	Size*	Additional Information
PRIME-XV FreezIS DMSO-Free	91140	100 mL 10 mL	Protein-free, chemically defined, animal component-free cryopreservation medium. Does not contain DMSO.
CTGrade rh IL-3	500-01	50 ug 100 ug 1 mg	Manufactured following cGMP practices in a facility that does not use or process beta-lactam containing materials, no histidine tags, and 0.2 micron filtered. No animal- or human-derived materials were used during manufacturing or as ingredients.
CTGrade rh IL-6	500-07	50 ug 100 ug 1 mg	Manufactured following cGMP practices in a facility that does not use or process beta-lactam containing materials, no histidine tags, and 0.2 micron filtered. No animal- or human-derived materials were used during manufacturing or as ingredients.
CTGrade rh IL-10	500-16	50 ug 100 ug 1 mg	Manufactured following cGMP practices in a facility that does not use or process beta-lactam containing materials, no histidine tags, and 0.2 micron filtered. No animal- or human-derived materials were used during manufacturing or as ingredients.
CTGrade rh FLT-3 Ligand	500-08	50 ug 100 ug 1 mg	Manufactured following cGMP practices in a facility that does not use or process beta-lactam containing materials, no histidine tags, and 0.2 micron filtered. No animal- or human-derived materials were used during manufacturing or as ingredients.

*Custom sizes and packaging available upon request.

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PRIME-XV and ancillary products are for research use or further manufacturing use only.
Not for injection or diagnostic procedures.

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