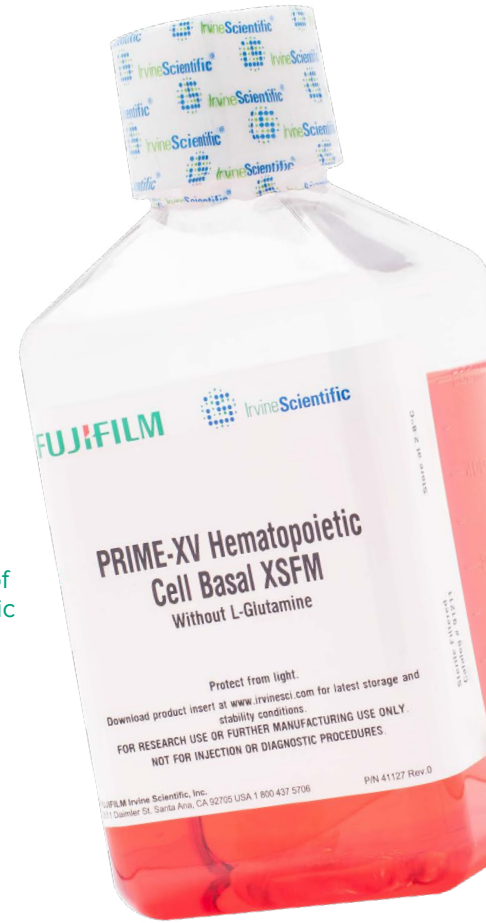


# PRIME-XV Hematopoietic Cell Basal XSFM

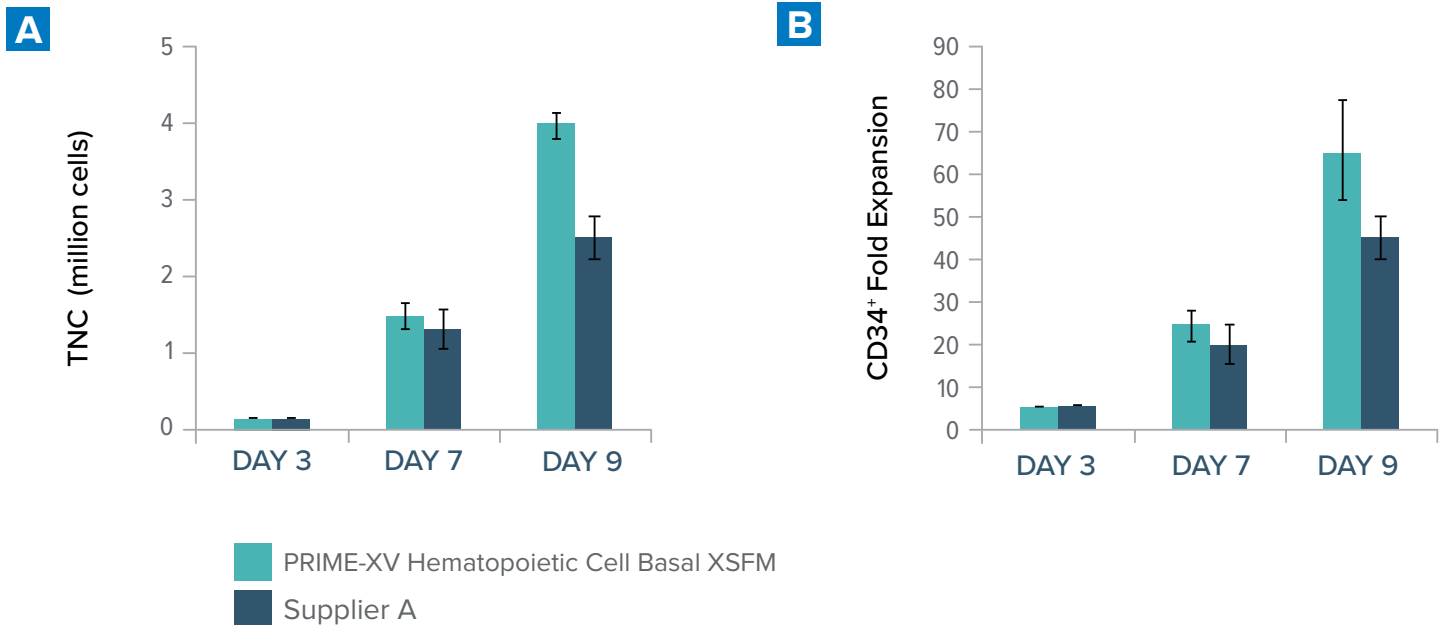
Xeno-free, serum-free basal medium for human hematopoietic progenitor cell culture

- Optimized to support vigorous expansion of hematopoietic progenitor cells while maintaining functionality
- Provides lot-to-lot consistency
- Maintains balanced lineage differentiation potential
- Manufactured to be scalable and facilitate transfer from research to clinic

Optimal expansion of human hematopoietic progenitor cells



Higher expansion rates compared to an alternative supplier



**Figure 1.** CD34<sup>+</sup> 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<sup>+</sup> cells were quantified.

# A PRIME-XV Solution 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.

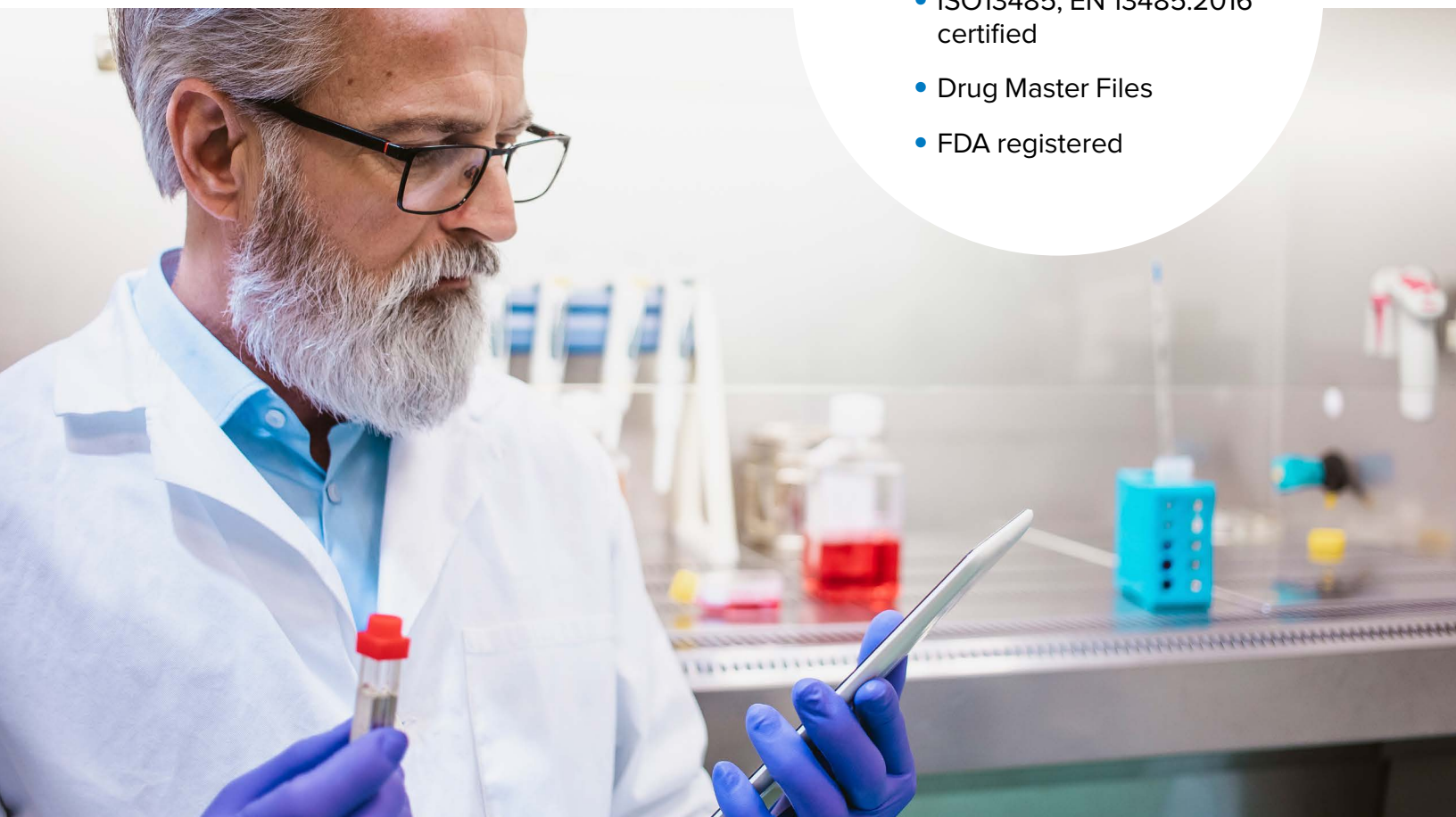
## Cell-specific media development, optimization and manufacture

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](mailto:getinfo@irvinesci.com) or visit our website at [www.irvinesci.com/contact-us](http://www.irvinesci.com/contact-us)

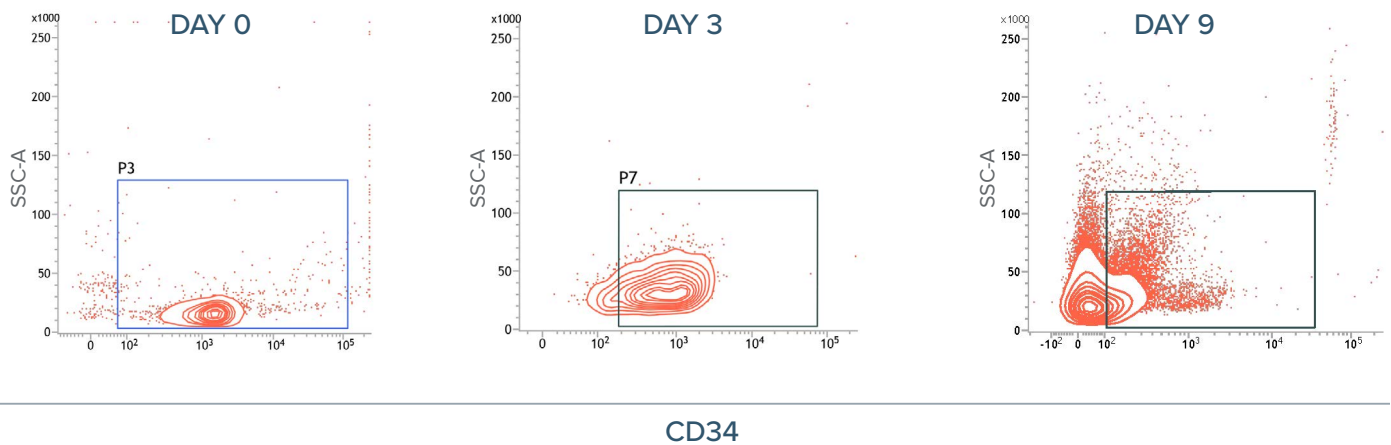
- FDA-regulated
- cGMP compliant manufacture
- ISO13485, EN 13485:2016 certified
- Drug Master Files
- FDA registered



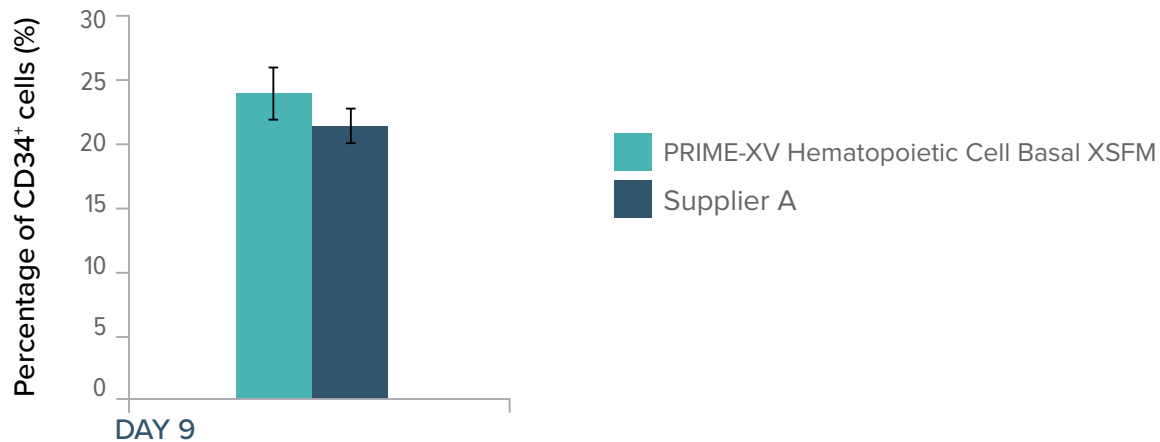
# Supports maintenance of CD34<sup>+</sup> hematopoietic progenitor cell population

CD34<sup>+</sup> cell dose used in transplantation may correlate with engraftment kinetics and long-term peripheral blood counts<sup>1,2</sup>. 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<sup>+</sup> HSPCs is critical to facilitate the progression of both allogeneic and autologous cell-based therapies towards clinical applications.

**A**



**B**



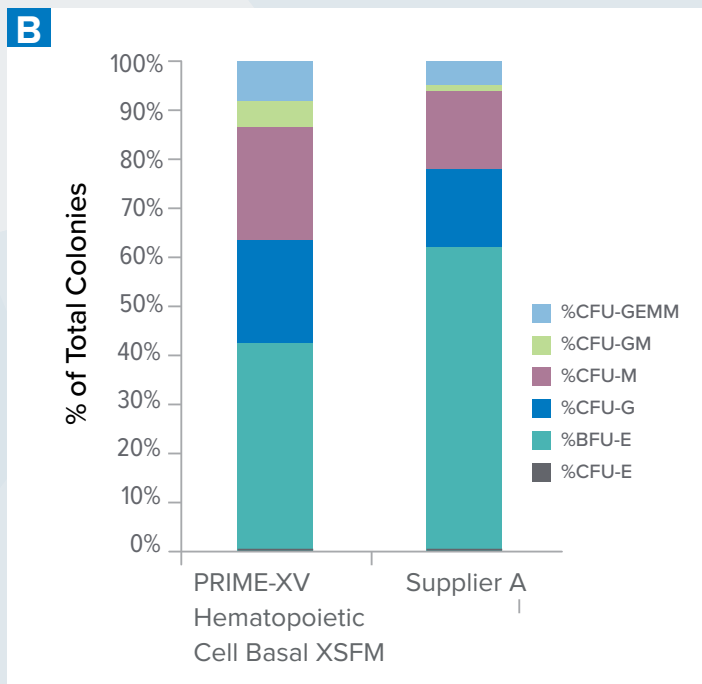
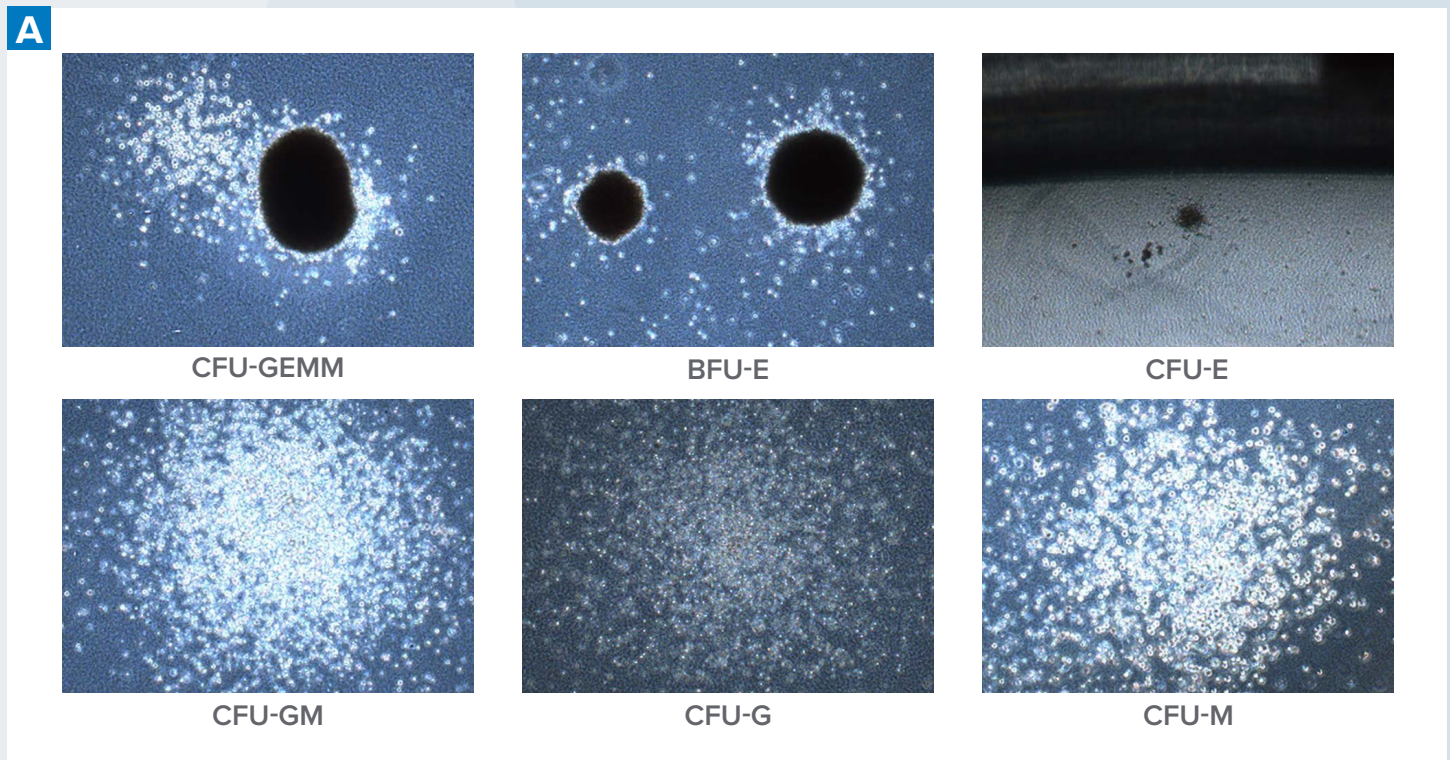
**Figure 2.** CD34<sup>+</sup> hematopoietic progenitor cells derived from human cord blood were cultured in PRIME-XV Hematopoietic Cell Basal XSFM or a commercially-available xeno-free expansion medium, both supplemented with a cocktail of cytokines (TPO, SCF, FLT-3L, IL-3 and IL-6). At days 0, 3 and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

<sup>1</sup> Perez-Simon et al. (2000) Blood Marrow Transplant 24(12):1279-1283

<sup>2</sup> 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<sup>3,4</sup>. Analysis by CFU assay demonstrates PRIME-XV Hematopoietic Cell Basal XFSM maintains differentiation potential and supports balanced distribution of lineage subtypes.

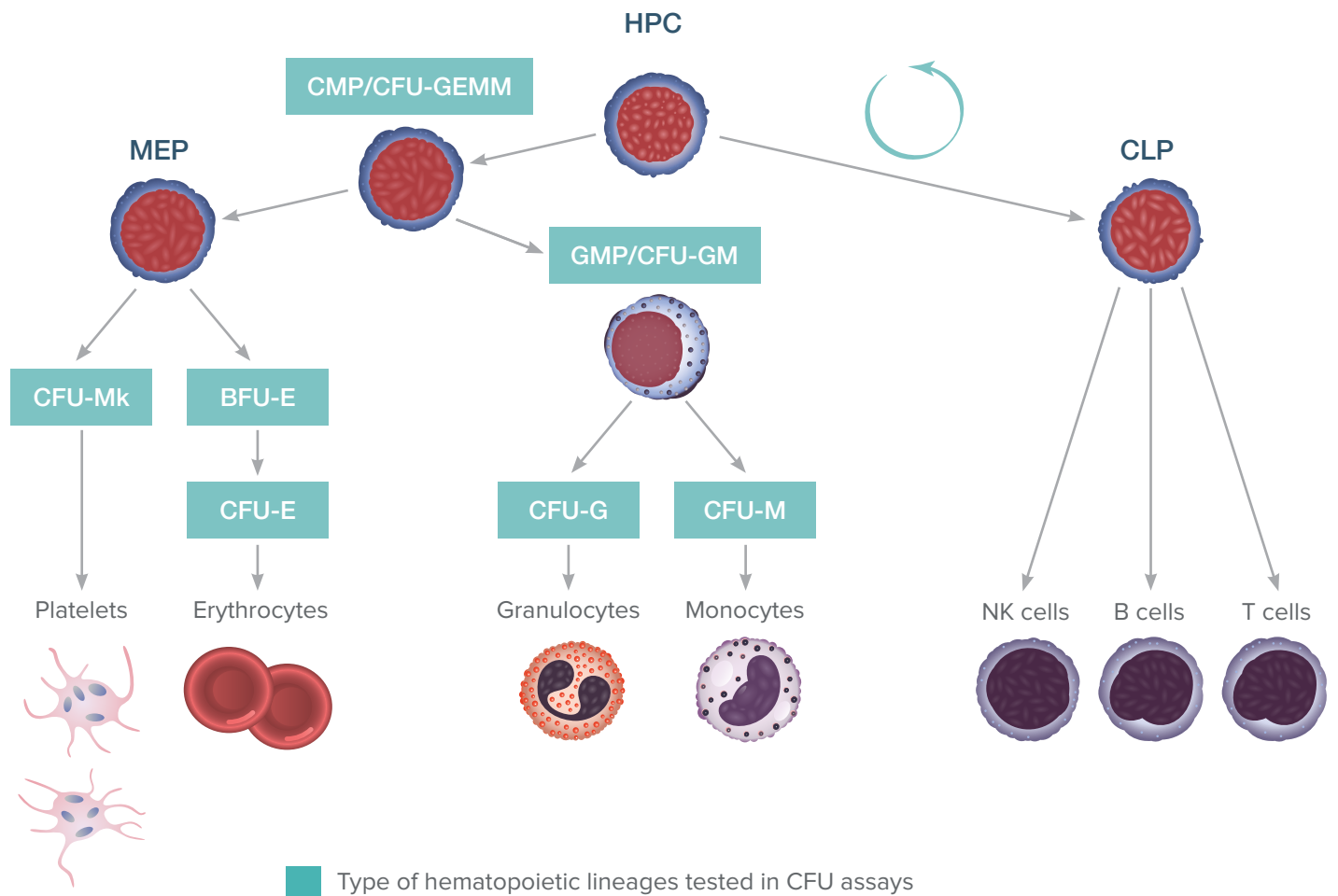


**Figure 3.** CD34<sup>+</sup> cells derived from human umbilical cord blood were cultured for 5 days in PRIME-XV Hematopoietic Cell Basal XFSM and a commercially available medium, both supplemented with a cocktail of cytokines (TPO, FLT-3, SCF, IL-3 and IL-6). On day 6 cells were plated in a semi-solid 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).

<sup>3</sup> Page et al. (2011) Blood Marrow Transplant 17(9):1362-1374

<sup>4</sup> 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.

## PRIME-XV Hematopoietic Cell Basal XFSM - Manufactured to facilitate transfer from research to clinic

- Serum-free, xeno-free formula minimizes risks from adventitious agents
- Extensive QA testing including functionality, sterility, and endotoxin
- Traceability documentation provided including Certificates of Analysis, Certificates of Origin, and a Drug Master File (DMF) filed with the US FDA\*
- Custom sizes and packaging available on request
- Manufactured in compliance with cGMP regulations

\*DMF filing in process

## Ordering Information

Media	Catalog #	Size*	Additional Information
PRIME-XV Hematopoietic Cell Basal XSBM	91211	500 mL	Serum-free and xeno-free basal medium

## Ancillary Products

Item	Catalog #	Size*	Additional Information
Recombinant Human IL-6 ACF	95121	20 µg	Animal component-free. Accession Number: P05231
Recombinant Human FLT-3 Ligand ACF	95120	10 µg	Animal component-free. Accession Number: P49771
Recombinant Human SCF ACF	95115	10 µg	Animal component-free. Accession Number: P21583
Recombinant Human IL-3 ACF	95113	10 µg	Animal component-free. Accession Number: P08700
Recombinant Human TPO ACF	95110	10 µg	Animal component-free. Accession Number: P40225
PRIME-XV Stem FreezIS DMSO-Free	91140	100 mL 10 mL	DMSO-free, protein-free, chemically-defined, animal component-free cryopreservation medium

\*Custom sizes and packaging available on request.

We recommend cryopreservation of hematopoietic stem/progenitor cells using our PRIME-XV Stem FreezIS DMSO Free (PN 91140)



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

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