FUJIFILM
Value from Innovation

IrvineScientific

PRIME-XV NK Cell CDM

CHEMICALLY-DEFINED, ANIMAL COMPONENT-FREE MEDIUM FOR NATURAL KILLER (NK) AND NKT CELL EXPANSION

Achieve optimal expansion of NK and NKT cells in chemically defined, animal component-free conditions

PRIME-XV NK Cell CDM is the first commercial chemically defined, animal component-free medium for the *ex vivo* expansion of NK and NKT cells.

Key benefits include:

- Efficient *ex vivo* expansion of NK and NKT cells in a chemically-defined medium (CDM) designed to deliver high lot-to-lot consistency
- Animal component-free (ACF) formulation helps to minimize the risk from adventitious agents

Designed for use in NK and NKT cell-based immunotherapy research and translational applications, this advanced formulation delivers growth while maintaining NK and NKT cell functionality and potency.

Designed to facilitate a seamless transition from preclinical to clinical research

- cGMP manufactured for quality, consistency, and scalability
- Traceability documentation provided including Certificates of Analysis, Certificates of Origin, and a Drug Master File (DMF) filed with the US FDA
- Robust raw material controls and supply chain management
- Extensive QA testing including functionality, sterility, and endotoxin
- Custom sizes and packaging available on request

Improved NK and NKT cell expansion in chemically-defined conditions

PRIME-XV NK Cell CDM maximizes the expansion of NK and NKT cells with the desired phenotype and cytotoxicity.

SUPPORTS EXPANSION OF NK CELLS

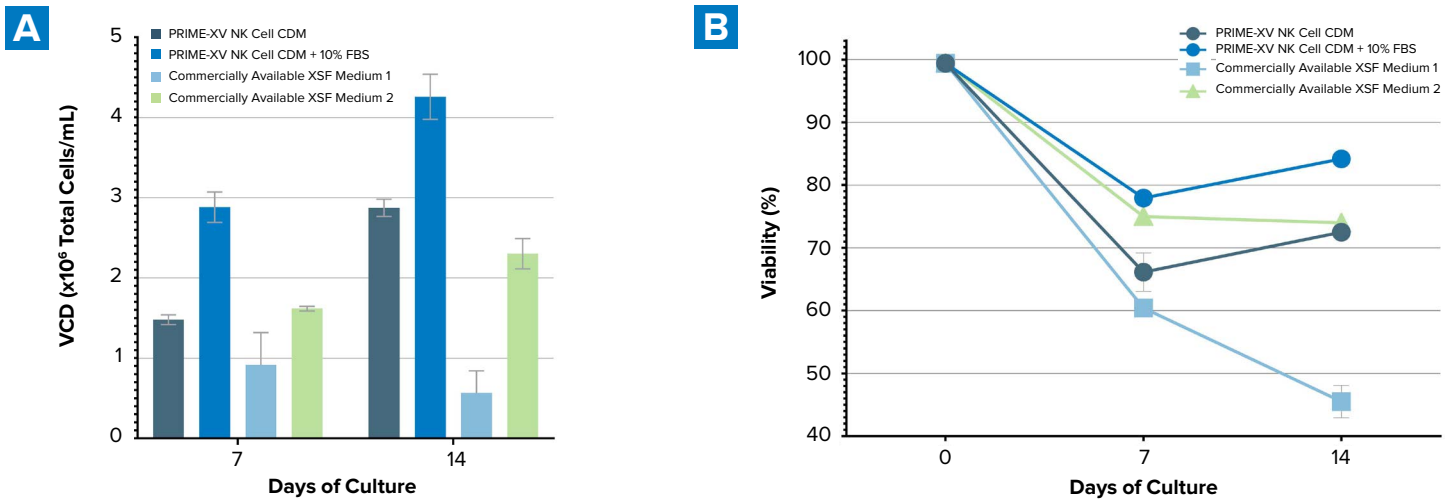

Figure 1. PRIME-XV NK Cell CDM supports robust cell expansion and viability in heterogeneous PBMC culture enriched for CD56⁺ cells. PBMC cells were enriched for CD56⁺ using magnetic cell sorting, activated using commercially available NK activation beads, and cultured for 14 days in PRIME-XV NK Cell CDM supplemented with 500 IU/mL rhIL-2, 10 ng/mL rhIL-12, 10 ng/mL rhIL-18, and 10 ng/mL rhIL-21. **(A)** Total viable cell density on days 7 and 14 of culture. **(B)** Cell viability on days 7 and 14 of culture. Data collected using Vi-CELL XR Cell Viability Analyzer.

SUPPORTS ROBUST EXPANSION OF NKT CELLS

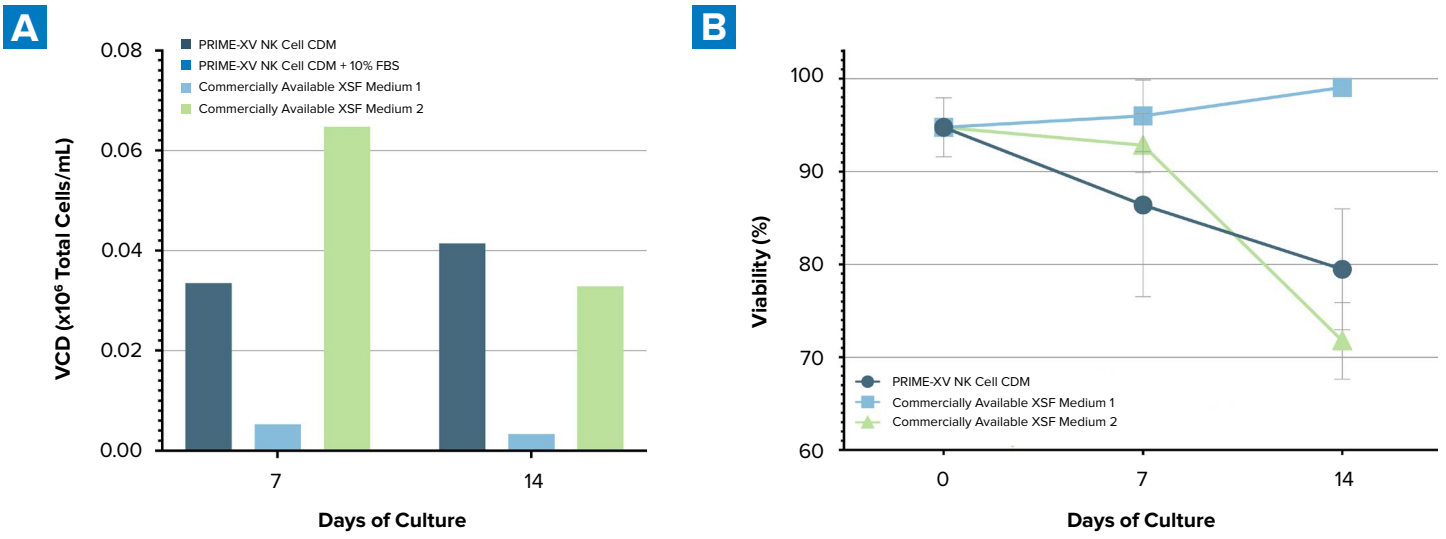

Figure 2. PRIME-XV NK Cell CDM supplemented with IL-2 and no additional cell activation cytokines supports robust NKT cell expansion and viability in PBMC culture enriched for CD56⁺ cells. PBMC cells were enriched for CD56⁺ using magnetic cell sorting and cultured for 14 days in PRIME-XV NK Cell CDM supplemented with 1000 IU/mL rhIL-2. **(A)** Viable cell density of NKT cells on days 7 and 14 of culture. **(B)** Cell viability on days 7 and 14 of culture. Data collected using Vi-CELL XR Cell Viability Analyzer.

Formulated to support generation of desired NK and NKT cell populations

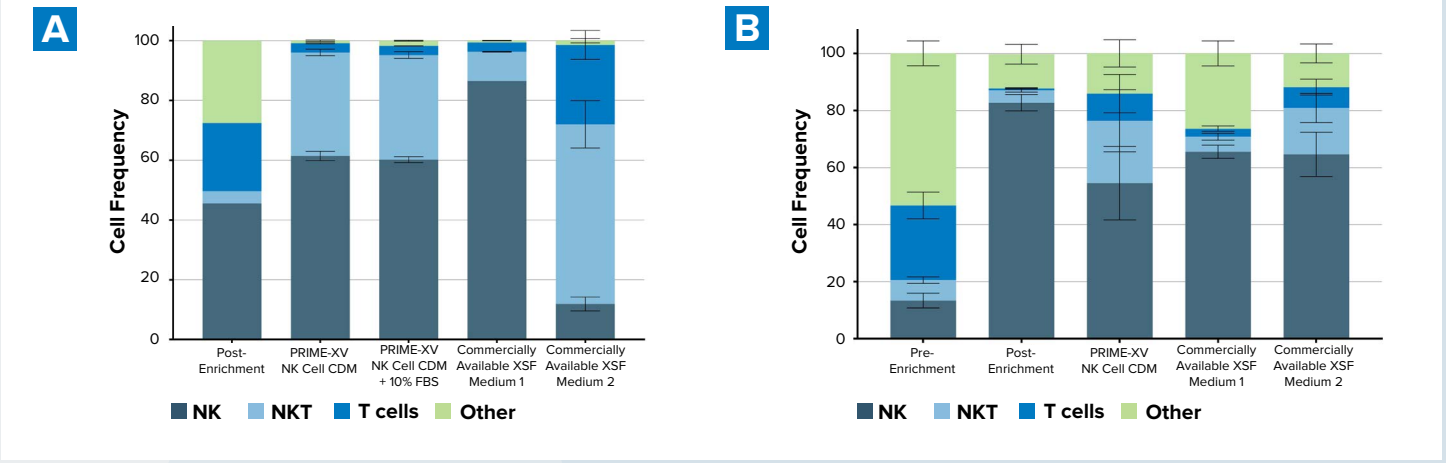

Figure 3. PRIME-XV NK Cell CDM preferentially expands NK and NKT cells in heterogeneous PBMC culture enriched for CD56⁺ cells. PBMC cells were enriched for CD56⁺ using magnetic cell sorting and cultured for 14 days, after which the cells were stained for surface phenotype markers and analyzed using FACSymphony A3 flow cytometer. Day 14 cell type composition of cells cultured in PRIME-XV NK Cell CDM supplemented with **(A)** 500 IU/mL rhIL-2, 10 ng/mL rhIL-12, 10 ng/mL rhIL-18, and 10 ng/mL rhIL-21 or **(B)** 1000 IU/mL rhIL-2.

Maintain high NK and NKT cytotoxic capability

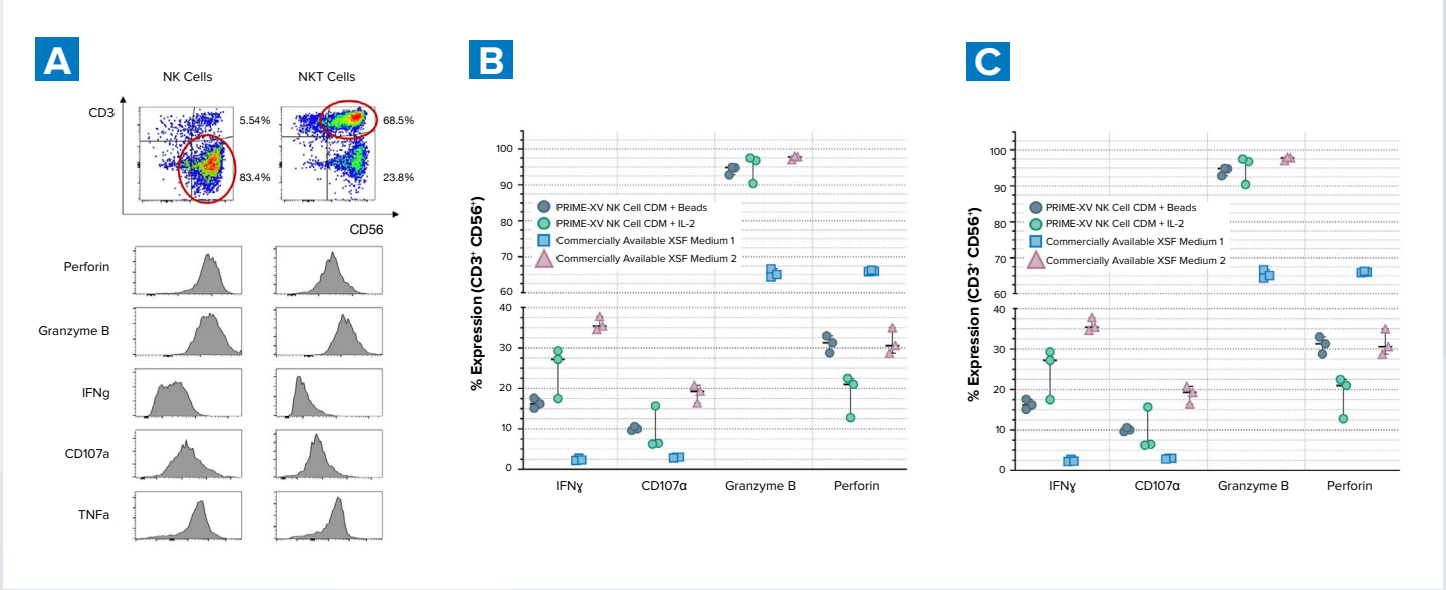

Fig. 4 NK and NKT cells cultured in PRIME-XV NK Cell CDM maintain cytotoxic and immunomodulatory capabilities two weeks post-activation. PBMC cells were enriched for CD56⁺ using magnetic cell sorting and cultured in different cell culture media and activation conditons. Following 14 days of expansion, cells were re-stimulated with Staphylococcus enterotoxin B for two hours, and incubated with a protein transport inhibitor cocktail for an additional four hours. Function-related cytokine secretion was quantified using flow cytometry following fixation and intracellular staining. **(A)** At day 14, CD3- CD56⁺ NK cells cultured in PRIME-XV NK Cell CDM and activated with commercially available NK activation beads (left column) and CD3⁺ CD56⁺ NKT cells cultured in PRIME-XV NK Cell CDM supplemented only with 1000 IU/mL rhIL-2 (right column) demonstrate the expression of immunomodulatory and cytotoxic cytokines. NK cells **(B)** and NKT cells **(C)** cultured in PRIME-XV NK Cell CDM are functionally comparable to those cultured in commercially available NK XSF media.

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** or visit our website at **www.irvinesci.com/contact-us**

- Manufactured under cGMP processes
- EN ISO 13485:2016 certified
- Drug Master Files
- FDA registered facility

Ordering Information

Media	Catalog #	Size*	Additional Information
PRIME-XV NK Cell CDM	91215	1 L	Chemically defined, animal component-free

Ancillary Products

Item	Catalog #	Size*	Additional Information
PRIME-XV T Cell XSFM	91141	1 L	Xeno-free, serum-free
PRIME-XV T Cell CDM	91154	1 L	Chemically defined, animal component-free
PRIME-XV Dendritic Cell Maturation CDM	91146	500 mL	Chemically defined, animal component-free
PRIME-XV Hematopoietic Cell Basal XSFM	91211	500 mL	Xeno-free, serum-free
PRIME-XV Recombinant Human IL- 2 ACF	95118	10 µg	Animal component-free. Accession Number: P60568
PRIME-XV FreezIS	91139	10 mL	Chemically defined, free from animal components and proteins; contains 10% DMSO
HBSS 1x Hank's Balanced Salt Solution	9228	100 mL	Recommended for dissociation; without salt and magnesium

*Custom sizes and packaging available on 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.