FUJIFILM
Value from Innovation

IrvineScientific

PRIME-XV T Cell CDM

Chemically defined, animal component-free medium for T cell culture

Chemically defined, animal component-free formula delivers optimal performance.

- Optimized to support vigorous growth while maintaining functionality
- Provides lot-to-lot consistency
- Removes the effects undefined components have on T cell phenotypes
- Supports polarization to targeted T cell types such as Th_1 and T regulatory cells

Scalable formula for static and dynamic automation systems

PRIME-XV T Cell CDM is the first commercially available chemically defined, animal component-free medium for the expansion and cultivation of T cells of human origin. The formulation is optimized to deliver consistently vigorous growth while maintaining T cell functionality and potency.

High viability and expansion rates compared to non-chemically defined alternatives

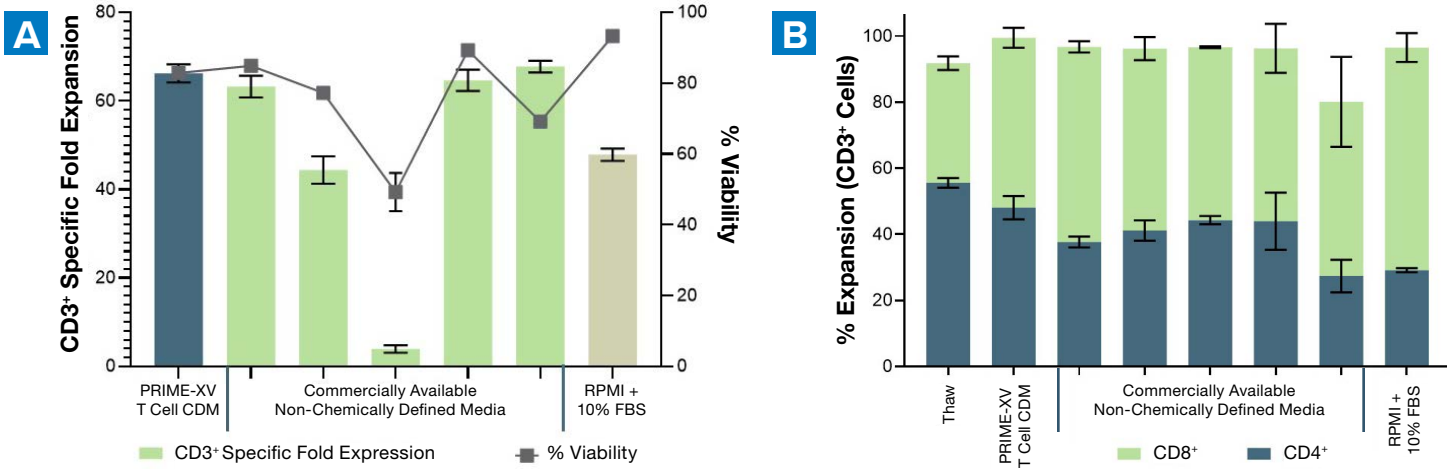
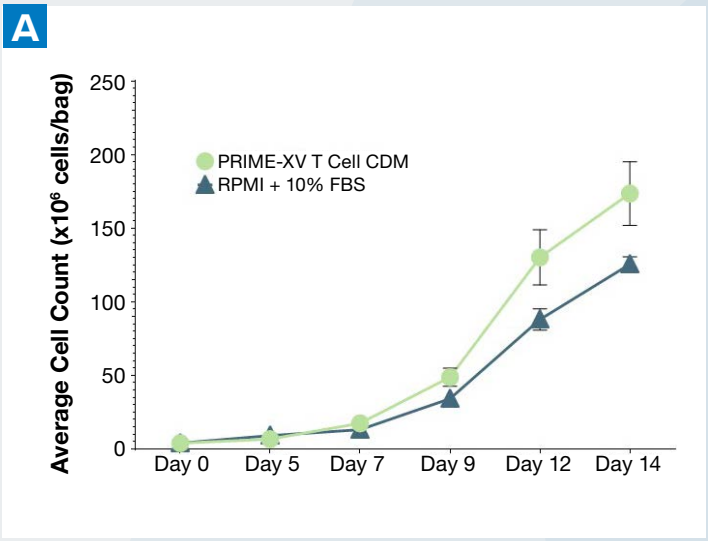
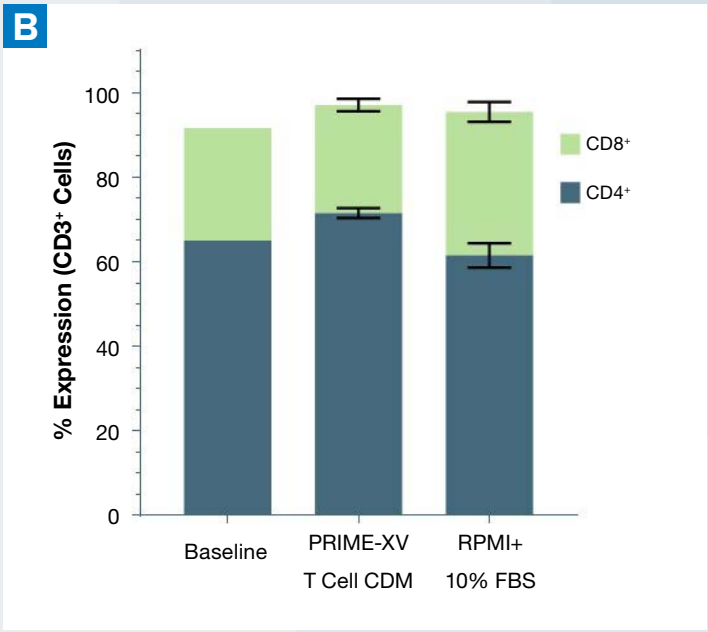


Figure 1. PRIME-XV T Cell CDM performs better than or as well as commercially available xeno-free media in G-Rex culture systems. Human PBMCs were activated with soluble anti-human CD3 and anti-human CD28 antibodies. These results are representative of three healthy donors, run in triplicate. Day 10 data is featured in this figure because it represents the peak of exponential expansion. **(A)** After 10 days of culture in various media supplemented with 200 IU/mL IL-2, cells were harvested and analyzed for viability and fold expansion. **(B)** Flow cytometry analysis compared the ratios of $CD3^+CD4^+$ and $CD3^+CD8^+$ T cells on day 10 to the initial PBMC ratios at thaw.

PRIME-XV T Cell CDM performs better than serum-containing medium





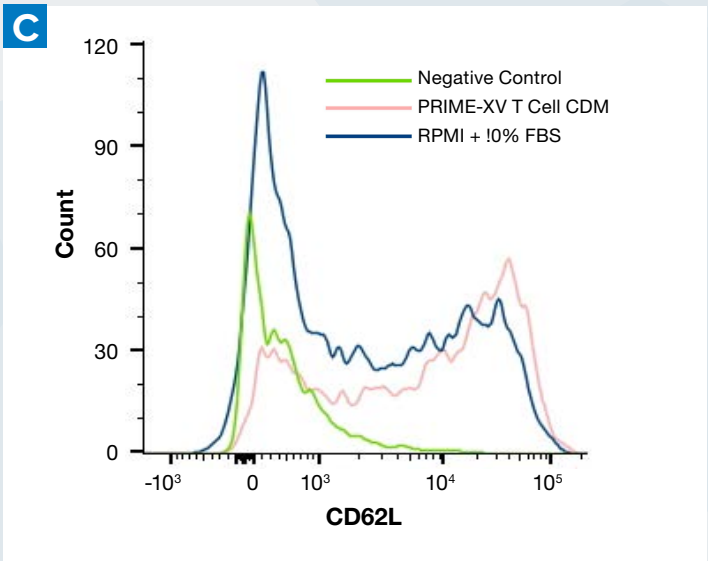


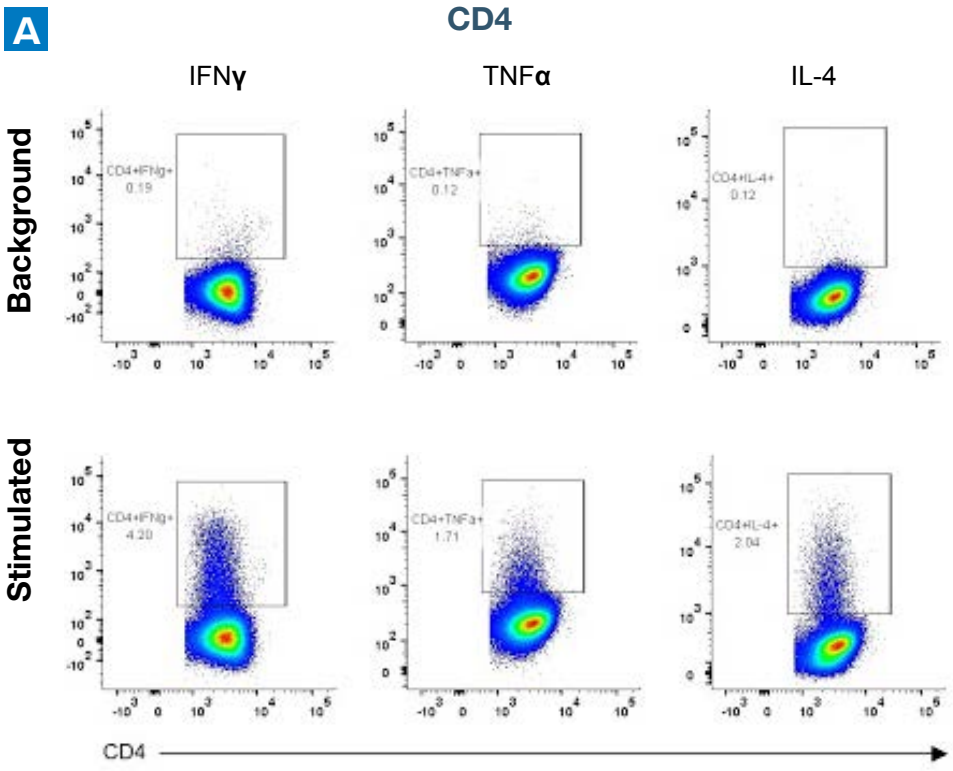
Figure 2. PRIME-XV T Cell CDM performs better than RPMI + 10% FBS in gas-permeable cell culture bags. Human PBMCs were activated with soluble anti-human CD3 and anti-human CD28 antibodies and cultured in PRIME-XV T Cell CDM or RPMI + 10% FBS, both supplemented with 200IU/mL IL-2. These results are representative of two healthy donors, run in duplicate.

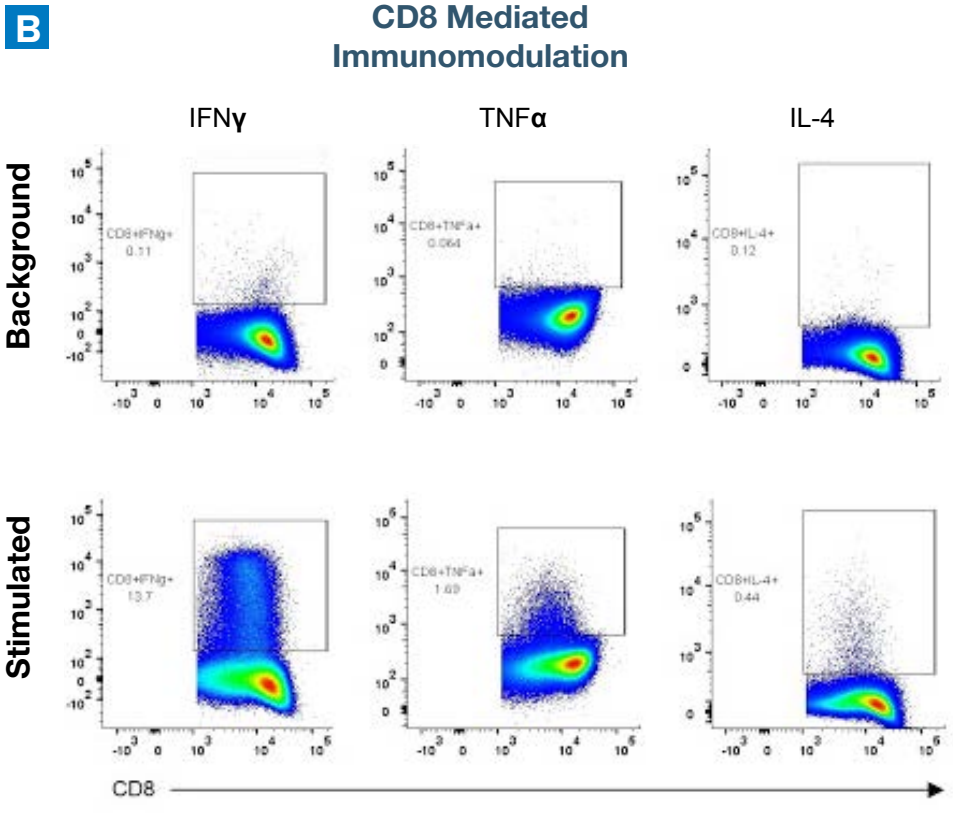
(A) Every two to three days, cells were sampled and counted, and IL-2-containing media was added to the compartmented bag to dilute the cells down to a concentration of $0.5x10^6$ cells/mL.

(B) Flow cytometry analysis compared the ratios of $CD3^+CD4^+$ and $CD3^+CD8^+$ T cells on day 14 to the initial PBMC ratios at thaw.

(C) By day 14 of culture, PRIME-XV T Cell CDM supported a higher proportion of naïve-phenotype cells compared to RPMI, as reflected by CD62L expression.

Optimized to support vigorous growth while maintaining functionality





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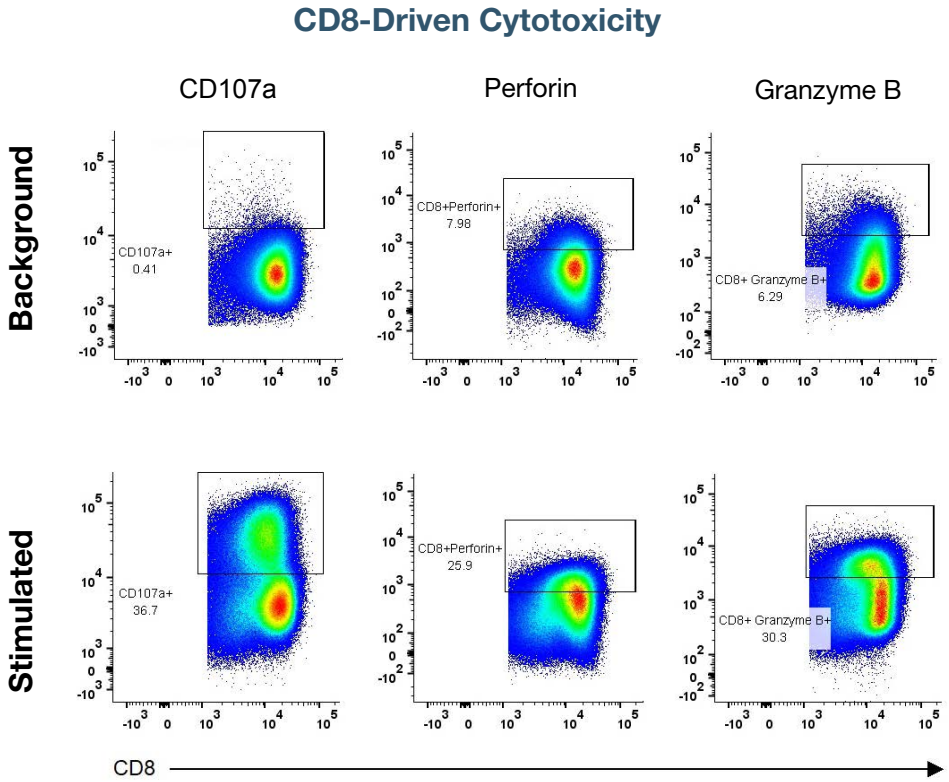

Figure 3. T cells cultured in PRIME-XV T Cell CDM remain functionally active following 14 days in culture. Human PBMCs were activated with soluble anti-human CD3 and anti-human CD28 antibodies and cultured in PRIME-XV T Cell CDM supplemented with 200IU/mL IL-2. Following 14 days of expansion, cells were re-stimulated with Staphylococcus enterotoxin B for two hours, and incubated with a protein transport inhibitor cocktail for an additional four hours. Subset-specific cytokine secretion was quantified using flow cytometry following fixation and intracellular staining. These results are representative of two healthy donors, run in triplicate with unstimulated controls. At day 14, $CD3^+$ T cells demonstrate the capacity for **(A)** CD4- and **(B)** CD8-mediated immunomodulation, as well as **(C)** CD8-driven cytotoxicity.

PRIME-XV T Cell CDM - Manufactured to facilitate transfer from research to clinic

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

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.**

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

Ordering Information

Media	Catalog #	Size*	Additional Information
PRIME-XV T Cell CDM	91154	1 L	Chemically defined, animal component-free formula Does not contain antibiotics or phenol red.

Ancillary Products

Item	Catalog #	Size*	Additional Information
Recombinant IL-2 ACF	95118	10 µg	Animal component-free. Accession Number: P60568.
Recombinant IL-3 ACF	95113	10 µg	Animal component-free. Accession Number: P08700.
Recombinant IL-4 ACF	95114	20 µg	Animal component-free. Accession Number: P05112.
PRIME-XV FreezIS	91139	100 mL 10 mL	Chemically defined, free from animal components and proteins. Contains 10% DMSO.

*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.