FUJIFILM
Value from Innovation

PRIME-XV T Cell CDM

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

- Supports T cell expansion in static and dynamic automation systems while maintaining functionality
- Eliminates the adverse effects undefined components cause on T cell phenotypes
- Supports polarization to targeted T cell types, such as Th_1, Th_2, cytotoxic T cells, to further possible therapy applications
- Performs transduction and expansion of T cells without requiring spinoculation or transduction enhancers

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 transduction of human T cells. The formulation is optimized to deliver consistently vigorous growth while maintaining T cell functionality and potency.

PRIME-XV T Cell CDM supports viable T cell expansion across different culture vessels

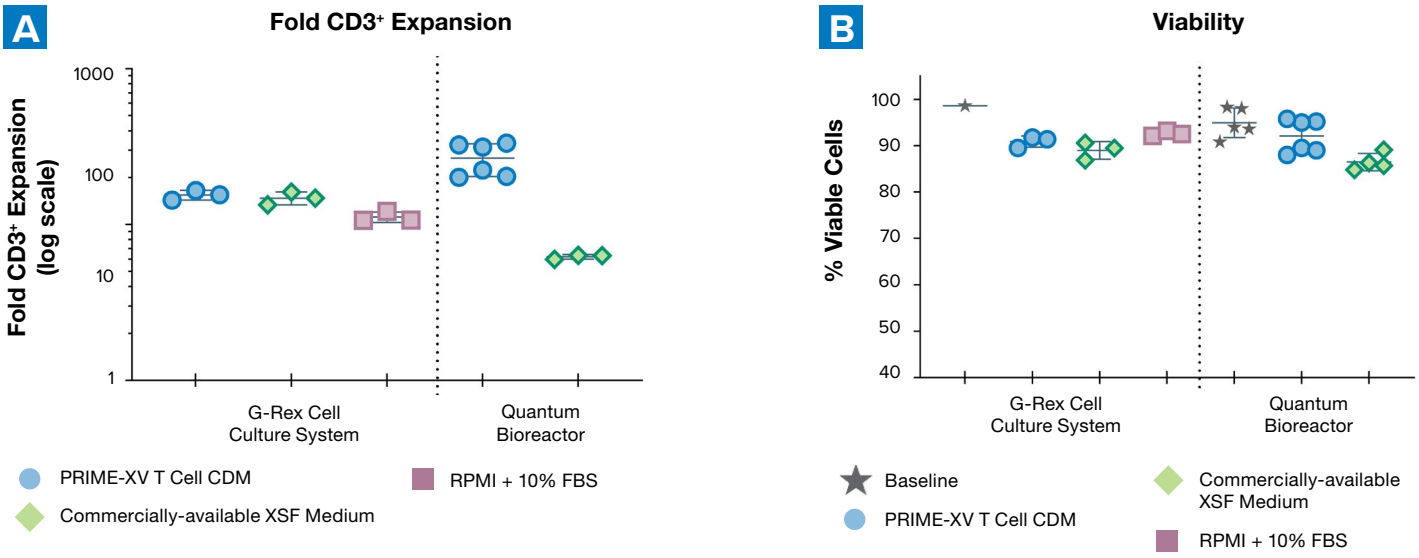

Figure 1. PRIME-XV T Cell CDM supports viable T cell expansion across different culture volumes and vessels. (A) Fold expansion of CD3+ cells in PRIME-XV T Cell CDM is robust across the 2 documented culture systems, performing as well as or better than FBS-supplemented RPMI and commercially-available XSF media. **(B)** Viability is maintained at or above 85% by the end of the culture period in all 2 cell culture systems. Though significant inter-donor variability is observed, these data are representative of 3 donors, analyzed on Day 14 (G-Rex) or Day 9 (Quantum Bioreactors).

Activation and exhaustion cell surface markers for cells cultured in PRIME-XV T Cell CDM are comparable

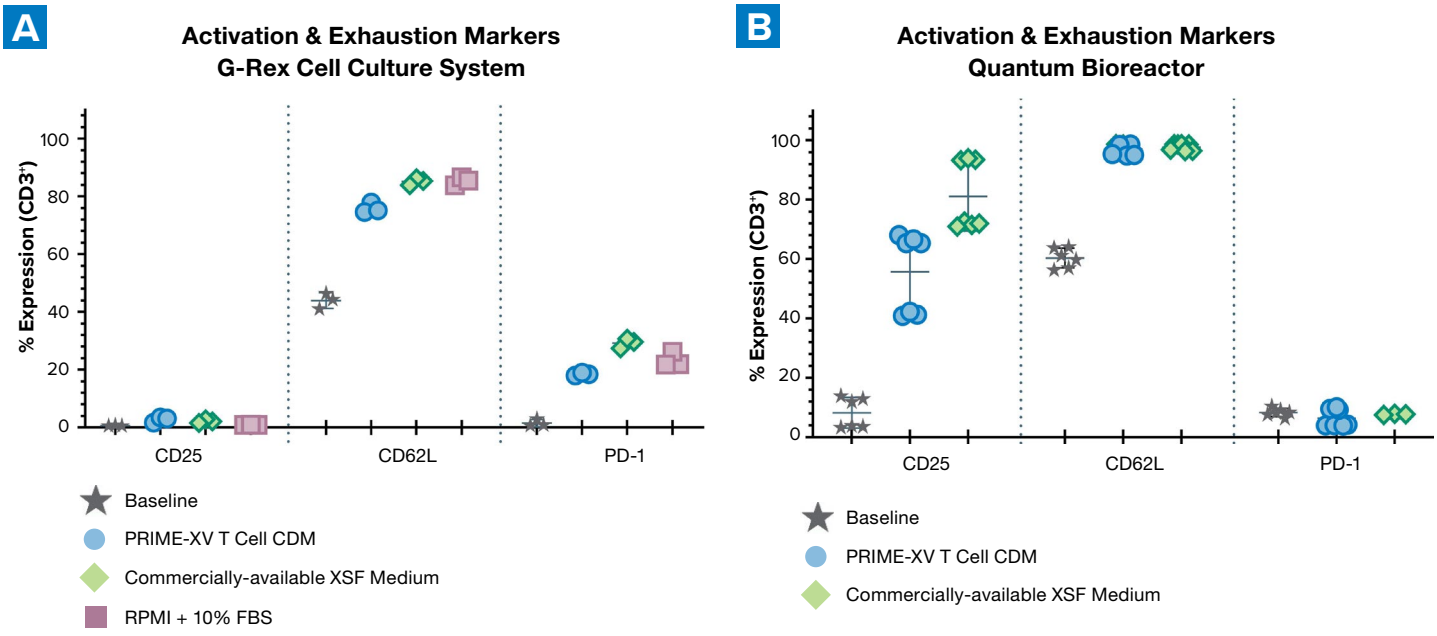

Figure 2. Activation and exhaustion cell surface markers for cells cultured in PRIME-XV T Cell CDM are comparable across platforms. At harvest, G-Rex **(A)** cultures exhibited low CD25 and high CD62L, indicating that the expanded cells reverted to the naive state. The higher PD-1 expression in G-Rex at harvest is a result of high cell density in the static wells at the end of culture. Quantum Bioreactor **(B)** PBMC cultures likewise show high CD62L expression and negligible levels of PD-1. Due to the earlier harvest time point for Quantum cultures, moderate CD25 expression is still observed in PRIME-XV T Cell CDM-cultured cell. Higher levels of CD25 expression in commercially-available XSF medium implies slower cell activation and expansion. Though significant inter-donor variability is observed, these data are representative of 3 donors, analyzed by multiparameter flow cytometry on Day 14 (G-Rex) or Day 9 (Quantum Bioreactors).

PRIME-XV T Cell CDM supports both CD4+ and CD8+ lymphocyte expansion across all systems

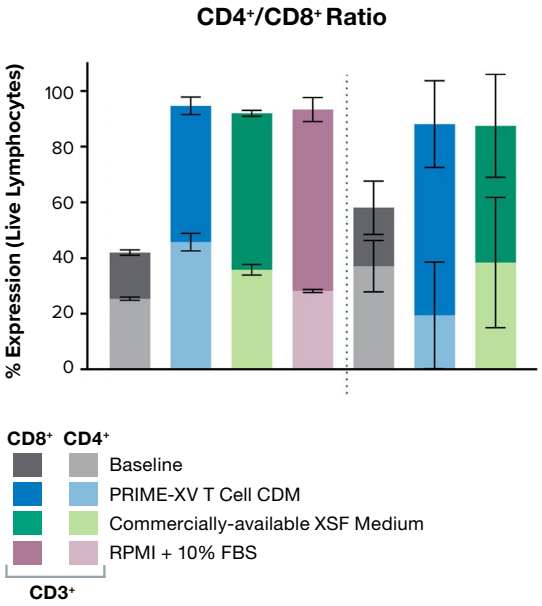

Figure 3. PRIME-XV T Cell CDM supports both CD4+ and CD8+ lymphocyte expansion across all systems. Though the proportion of CD8+ cells increases over the course of the culture in all systems, PRIME-XV T Cell CDM supports robust expansion of both subsets. Though significant inter-donor variability is observed, these data are representative of 3 donors, analyzed by multiparameter flow cytometry on Day 14 (G-Rex) or Day 9 (Quantum Bioreactors).

Optimize transduction in enhancer-free conditions with PRIME-XV T Cell CDM

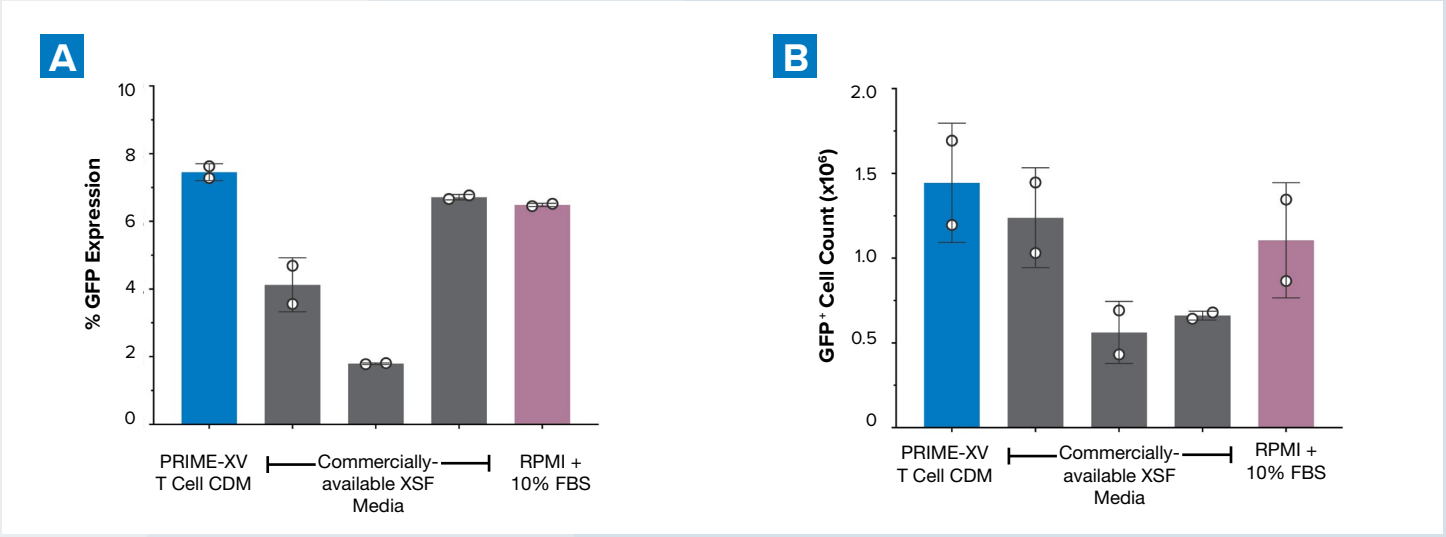

Figure 4. Enhancer-free transduction in PRIME-XV T Cell CDM is better than commercially-available xeno-free media and FBS-supplemented RPMI. (A) Transduction efficiency and **(B)** total cell count of GFP reporter-positive cells at Day 14 of expansion are robust in the chemically defined medium, even in the absence of transduction enhancers.

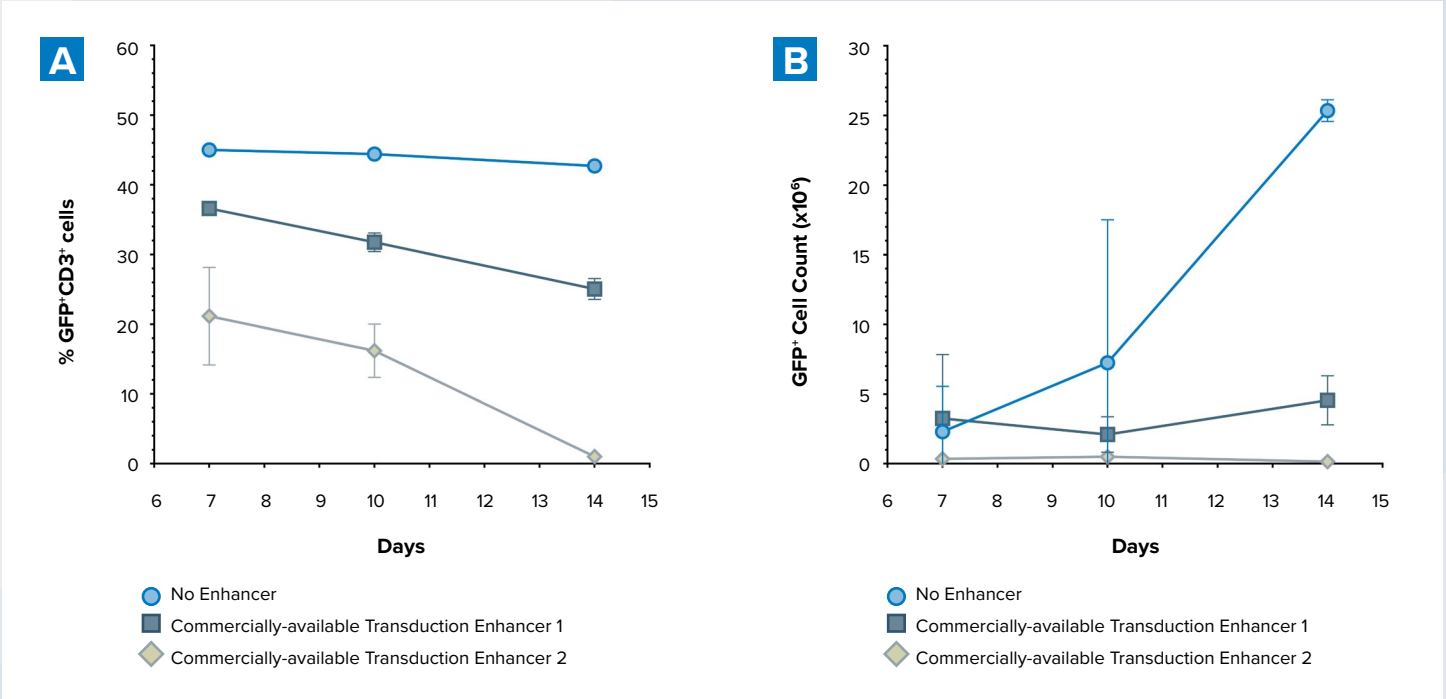

Figure 5. PRIME-XV T Cell CDM supports lentiviral transduction in the absence of commercially-available transduction enhancers. (A) Cells transducted and expanded in PRIME-XV T Cell CDM + 200 IU/mL rh IL-2 without transduction enhancers maintain a high level of GFP reporter expression at Day 14 of culture. **(B)** The addition of commercially-available transduction enhancers inhibited cell expansion in the second week post transduction, yielding a lower total count of transduced GFP⁺.

Achieve consistent cell count and viability with Shenandoah CTGrade GMP Proteins

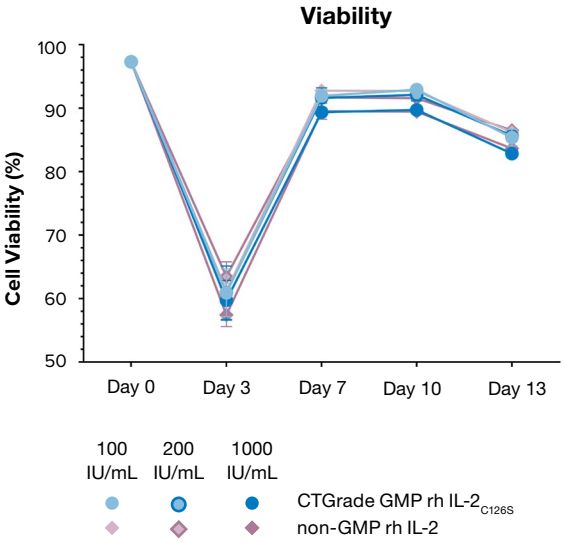

Figure 6. No significant difference seen between PBMC viability in the presence of different GMP lots of CTGrade GMP rh IL-2 across 3 donors (only D2 shown). Throughout expansion, all 3 donors maintained an average cell viability above 83%, indicating healthy cells. All 3 donors showed a sharp dip in viability at the Day 3 checkpoint, which corresponds both to activation-induced cell death and the prevalence of activation beads (Dynabeads) that are read by the cell counter as dead cells. By Day 7, these beads are diluted out of the culture and no longer interfere with viability readings, and the cells have recovered from the initial wave of apoptosis.

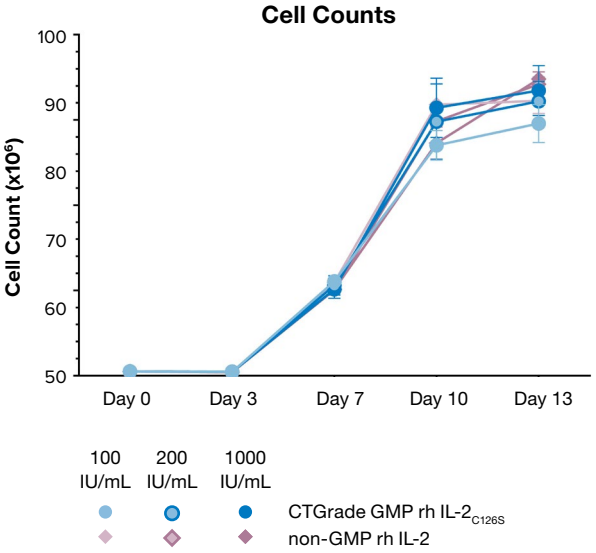

Figure 7. No significant difference seen between PBMC expansion supported by different GMP lots of CTGrade GMP rh IL-2 across 3 donors (only D2 shown). The lowest concentration of rh IL-2 (open circles) led to lowest cell numbers by Day 13 of expansion across all 3 donors. On average, there was no significant difference between the cell expansion supported by the 2 higher concentrations of rh IL-2. The maximum expansion of cells varies donor to donor, but the shape of the growth curve and the performance of the rh IL-2 are consistent.

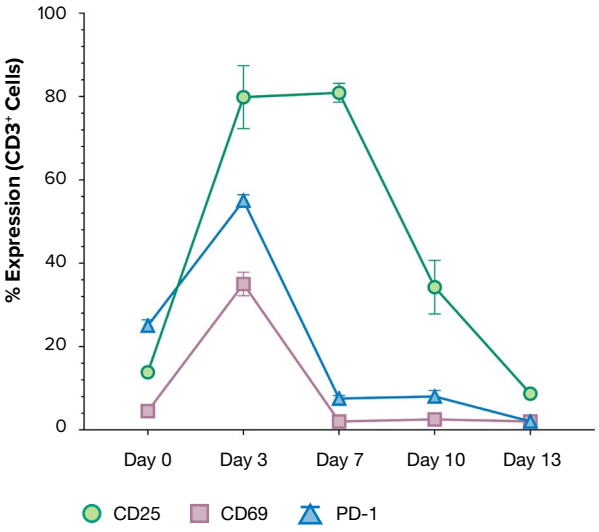

Figure 8. Activation and exhaustion markers illustrate healthy cell growth kinetics over 2 weeks of culture in 24-well G-Rex plate. The high early expression of CD69 peaking by Day 3 post-activation corresponds with the increase in PD-1, which indicates activation-induced apoptosis in the early days of culture. Both markers fall off around Day 7, during the exponential growth phase of the cells. CD25, the late-stage activation marker, peaks as expected between Day 3 and 7. The expression of all 3 markers returns to the resting state by the end of the second week of expansion.

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 is manufactured following GMP 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 GMP manufacture
- EN ISO 13485:2016 certified
- MDSAP certified
- Extensive QC testing including functionality, sterility (USP <71>), endotoxin (USP <85>), and mycoplasma (USP <63>)
- Drug Master Files (DMFs) filed with the FDA — available upon request

Ordering Information

Product Description	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.

Related Products

Product Description	Catalog #	Size*	Additional Information
PRIME-XV FreezIS	91139	100 mL 10 mL	Protein-free, chemically defined, animal component-free cryopreservation medium. Contains DMSO.
PRIME-XV FreezIS DMSO-Free	91140	100 mL 10 mL	Protein-free, chemically defined, animal component-free cryopreservation medium. Does not contain DMSO.
PRIME-XV T Cell Expansion XSFM	91141	1 L	Xeno-free, serum-free T cell medium. Contains Gentamicin.
Click's Medium (EHAA)	9195	500 mL	Contains 1,350 mg/L sodium bicarbonate. Does not contain L-glutamine or 2-mercaptoethanol.
CTGrade GMP rh IL-2_{C126S}	500-01	50 µg 100 µg 1 mg	Manufactured following GMP 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 GMP rh IL-7	500-07	50 µg 100 µg 1 mg	Manufactured following GMP 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 GMP rh IL-10	500-16	50 µg 100 µg 1 mg	Manufactured following GMP 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 GMP rh IL-15	500-08	50 µg 100 µg 1 mg	Manufactured following GMP 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 GMP rh IL-21	500-09	50 µg 100 µg 1 mg	Manufactured following GMP 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.
PBS + EDTA 1mM + 0.5% HSA**	99942	1 L	Does not contain calcium, magnesium, or sodium bicarbonate. Does not contain antibiotics or phenol red. Contains animal-derived components.

*Custom sizes and packaging available upon request.

**This item is made-to-order only.

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