

Solupore® Integrated

- Consumable led
- Automated
- Digitalised
- Scale out capability

Introduction

As integrated cell therapy manufacturing platforms advance toward broader adoption, their performance must be evaluated against established manufacturing processes using clinically relevant quality attributes. The Solupore® Integrated platform is a consumable-based, digitally automated system that integrates cell activation, transduction, and expansion within a single closed workflow, enabled by a core bioreactor consumable. In this study, we benchmark the performance of the Solupore Integrated using a CD19 CAR-T model against an industry standard bioreactor process (G-Rex® 100M) conducted at Kincell Bio, a US based CDMO. A 7-day manufacturing workflow was evaluated to assess process performance and resulting product characteristics.

CAR-T Process



Solupore Integrated: Automated CAR-T platform achieves superior transduction efficiency & CAR-T cell yield

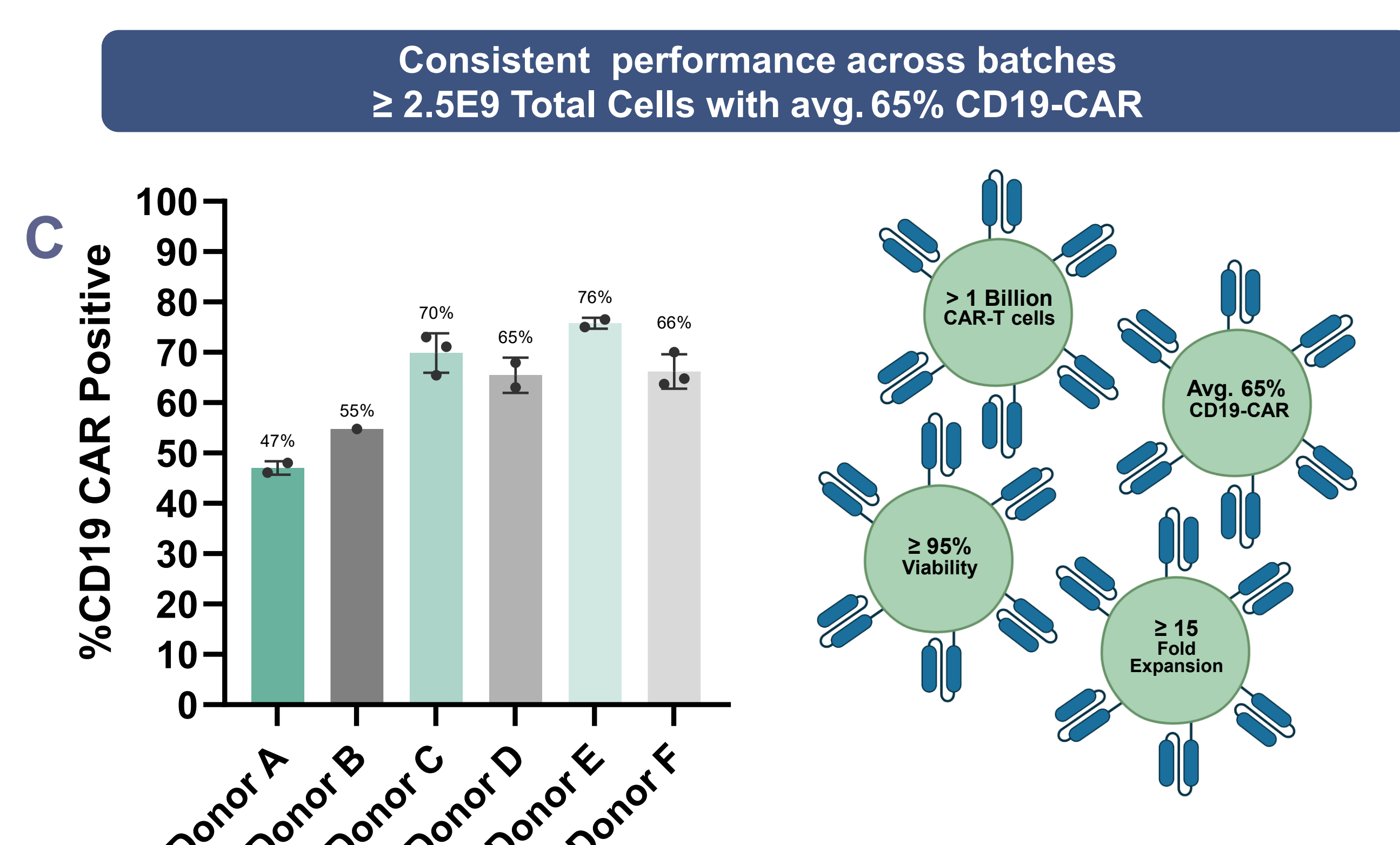
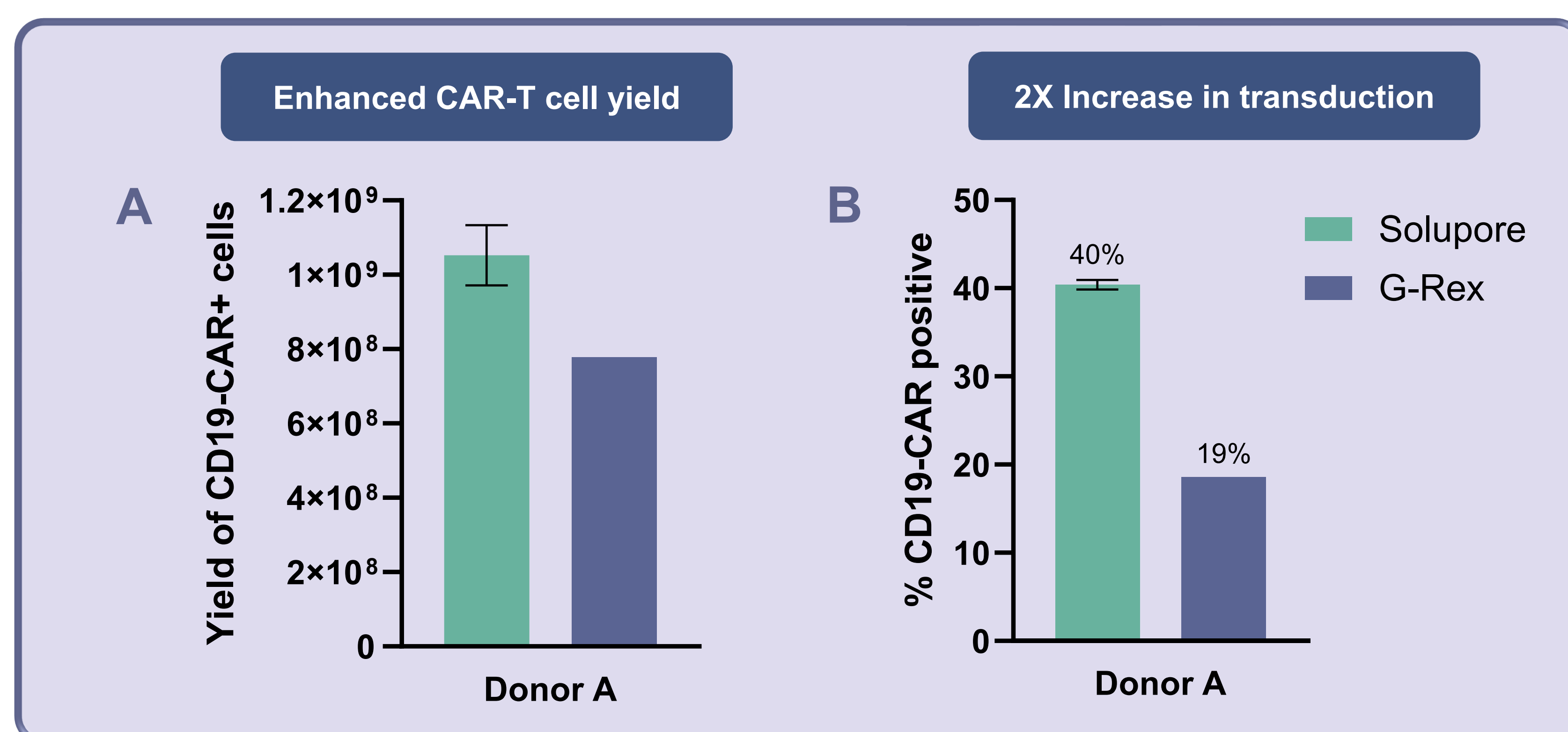


Figure 1: A 7-day CAR-T manufacturing workflow incorporating T cell activation, lentiviral transduction, expansion, and harvest was executed using the Solupore Integrated platform and compared with G-Rex 100M industry standard process. Day 0: CD3+ T cells were seeded in the Solupore bioreactor (150×10⁶ cell input) or G-Rex 100M (50×10⁶ cell input) in TCM media + IL-7/15 and activated with TransAct™. On Day 1, cells were transduced with a second generation CD19-CAR lentiviral vector (MOI 1), followed by a media feed on Day 3 (Solupore) or Day 2/Day 5 (G-Rex) and harvest on Day 7. (A) Solupore yielded >1E9 CAR-T cells (n=2 runs, Donor A, green bars), compared to ~7E8 CAR-T yield for the G-Rex process (projected cell yield based on equivalent input of 150E6 cells to the G-Rex, purple bars). (B) Solupore achieved a higher level of CD19-CAR% transduction efficiency, 40% compared to 19% CAR expression using G-Rex. (C) The Solupore Integrated CAR-T automated platform consistently achieves a high level of CD19-CAR transduction efficiency across manufacturing runs. (n=13 runs, 6 donors), yielding ≥ 1E9 CAR-T cells across multiple donors and batches.

Solupore Integrated: Superior retention of naïve T cells to generate functional CAR-T product

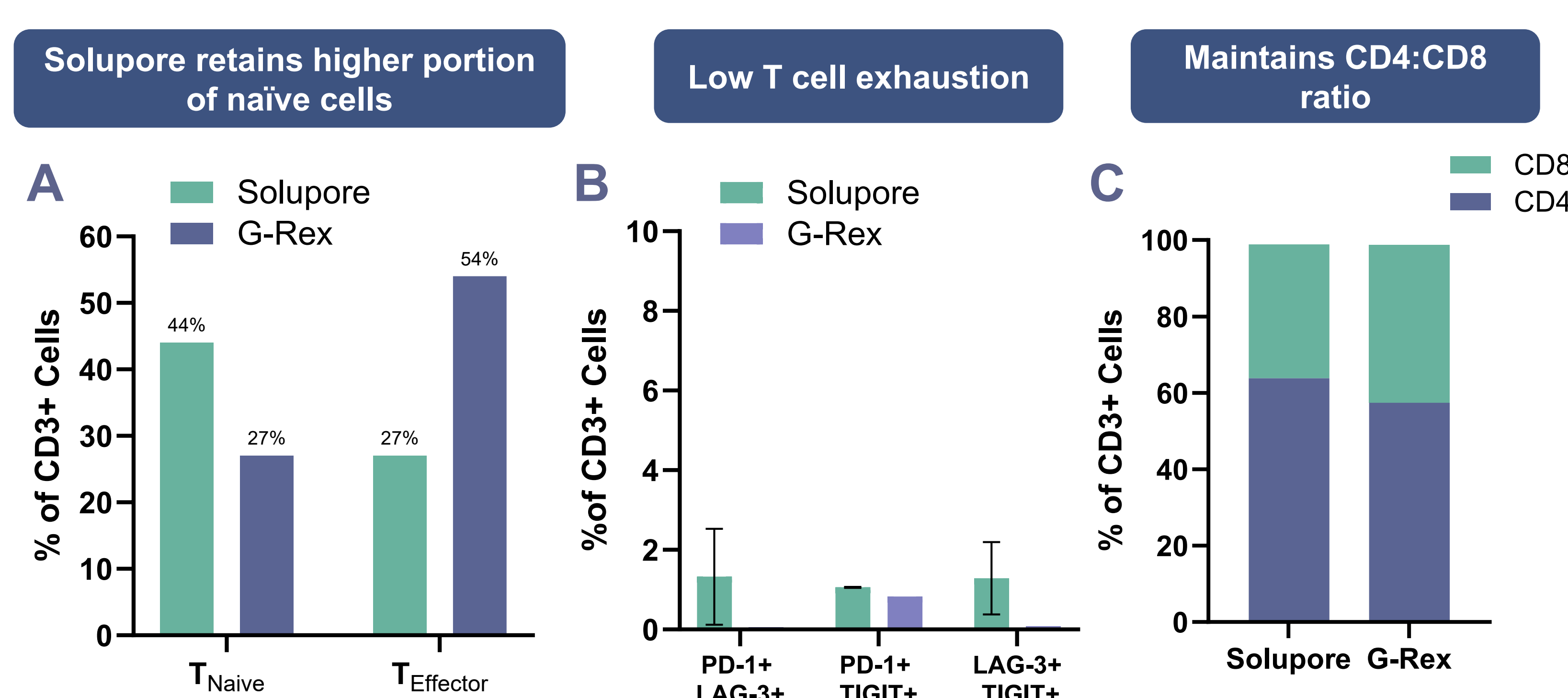


Figure 2: (A) T cell memory phenotype of Day 7 cryopreserved CAR-T product was assessed by flow cytometry CD3>CD8>CD45RA/CCR7. Solupore retained a higher percentage of naïve T cells (44%, green bars) compared to the G-Rex industry standard process (27%, purple bars). The Solupore product had a lower proportion of effector T cells (27%) compared to G-Rex (54%). (B) PD-1, LAG-3 and TIGIT exhaustion marker levels were maintained at <5% for Solupore and G-Rex 7-day CAR-T products. (C) CD4:CD8 phenotype for Solupore and G-Rex CAR-T process products on Day 7.

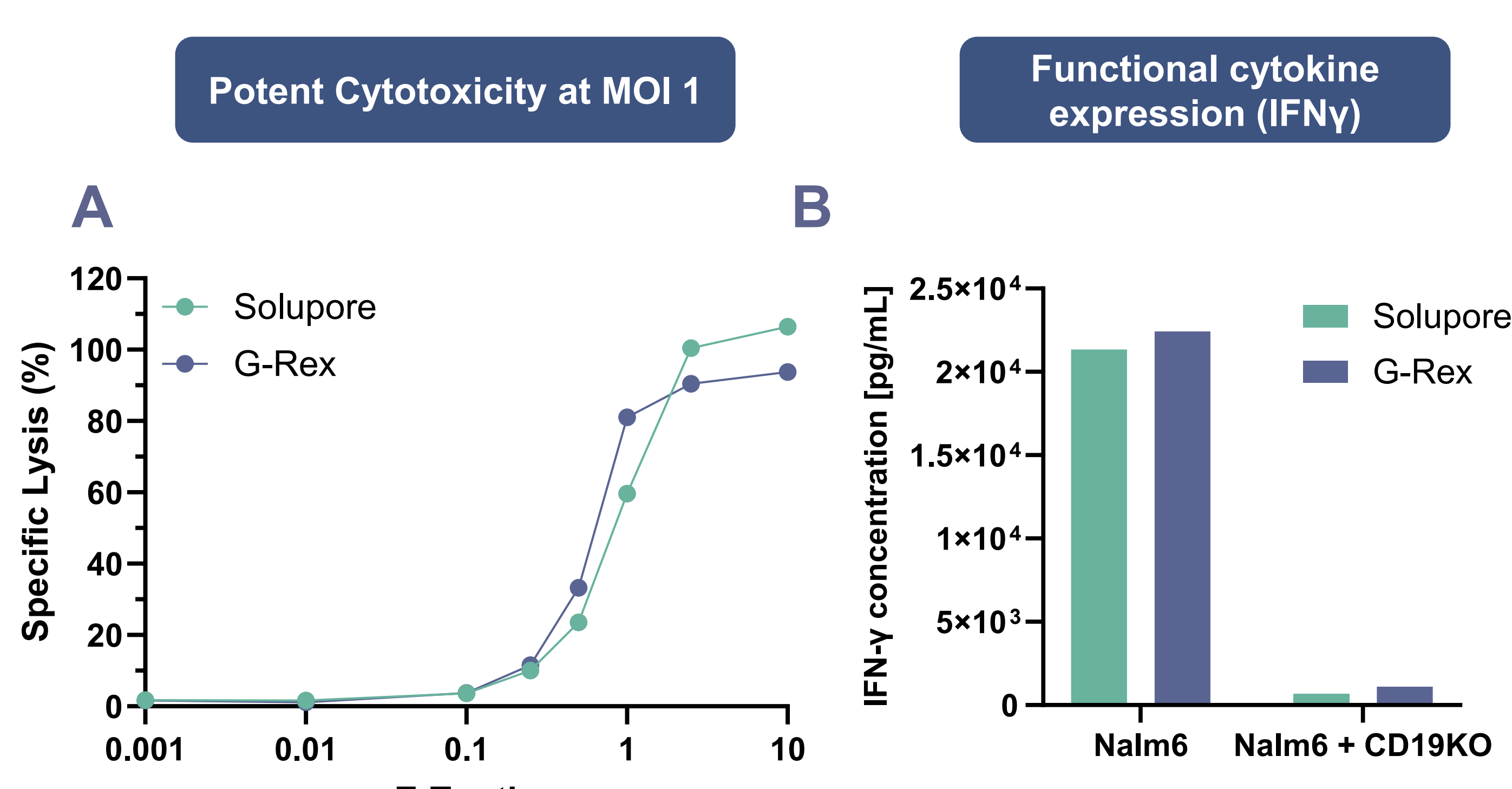


Figure 3: Functional capacity of cryopreserved CAR-T product was assessed via co-culture with CD19+ Ramos cells (A) or CD19+/CD19KO Nalm6 target cells (B). Equivalent levels of cytotoxicity (A) and IFNγ production (B) were achieved for both the Solupore (green) and G-Rex (purple) CAR-T products. Cytotoxicity was measured using a Ramos HiBIT Target cell killing (TCK) reporter assay across a range of E:T ratios.

Results and Discussion

- This study compared the Solupore Integrated platform 7-day manufacturing workflow with an industry standard bioreactor process (G-Rex 100M) at Kincell Bio. Product quality attributes were assessed at harvest, including viability, CAR expression, T cell phenotype, cytokine release, and cytotoxic potency.
- Despite differences in starting cell inputs and culture configurations, the Solupore platform consistently achieved higher CAR expression at harvest (~41%) compared with G-Rex industry standard (19%, Figure 1B). This translated into a substantially greater total yield of viable CAR-T cells (~9.9×10⁸) relative to the G-Rex platform (~2.5×10⁸, Figure 1A).
- Across multiple manufacturing runs (n=13 runs, 6 donors), the Solupore Integrated platform demonstrated consistent CD19 CAR-T production achieving ≥ 1×10⁹ CAR-T cells for multiple donors and batches (Figure 1C).
- Phenotypic analysis showed that Solupore preserved a higher proportion of less-differentiated, naïve-like T cells compared with G-Rex (Figure 2A). The CD4:CD8 ratio was maintained throughout the process (Figure 2C), with low levels of exhaustion marker expression observed in the final product (<5%, Figure 2B).
- Functional assessment demonstrated comparable IFN-γ release and cytotoxic activity for Solupore, and G-Rex manufactured CAR-T cells (Figure 3).
- Collectively, these results indicate that the Solupore Integrated platform enables the generation of CAR-T products with increased CAR+ cell yield and favourable phenotypic and functional characteristics, while maintaining functional activity comparable to an industry-standard manufacturing approach. Supporting its application as an integrated and scalable solution for CAR-T production.

- Commercial
- Consistent, scaled process
- Cost-effective

- Solupore Integrated provides a scalable, automated, and GMP-aligned manufacturing solution that can accelerate clinical translation, enhance product consistency, and improve the economic feasibility of advanced cell therapies.
- Ongoing development efforts are focused on the integration of additional unit operations to further streamline and enhance the manufacturing workflow.