

IN VITRO HIGH EXPANSION OF CHIMERIC ANTIGEN RECEPTOR (CAR)-T CELLS IN SERUM-FREE PROCESS CONDITIONS

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Manufacturing process is an important and complex factor for preparing chimeric antigen receptor (CAR) T cells for therapy. Although serum was widely applied in the culture or expansion of T cells, the quality of serum could be varied from batch to batch, leading to the variation of T cell expansion and quality. In addition, the safety of pathogens from serum and Chemistry, Manufacturing, and Control (CMC) were required to be considered. To overcome the disadvantages of serum application in T cell culture, serum-free and xeno-free culture conditions were required. We intended to develop a rapid serum-free culture condition for the expansion of immune T cells *ex vivo*. In our optimized serum-free condition, CAR-T cells could be expanded to about 100-200 times to the initial cell number after 6-day culture and the cell viability of all specimens was above 98%. Of interest, the percentage of CAR+ population in all specimens was increases, and the T cell pollutions could be maintained at averagely about 35-40% of CD8+ T cells and averagely about 50-55% of CD4+ T cells after culture. Taken together, our conditions could be applied in the expansion of CAR-T cells for cell therapy to support the minimum requirement of blood or cell samples from patients and to maintain the T cell population.

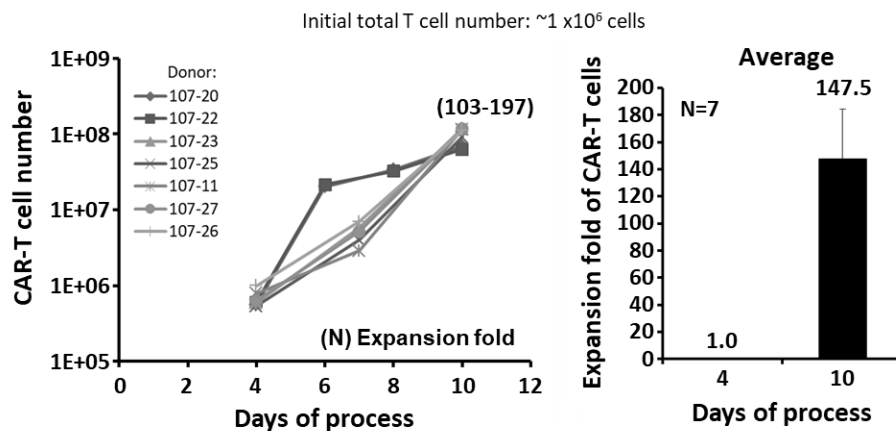


Figure 1 – CAR-T cells prepared from 7 donors' T cells were applied to the serum-free culture condition, and the CAR-T cells grew to averagely 147.5 times to the initial CAR-T cells number.