

Generation of gene-engineered T cells

T cell transduction process

Application

Fully automated labelling, enrichment, activation, transduction and expansion of human T cells from patient material for production of gene-engineered T cells.

This application sheet gives an overview of the specifications and material to perform the T cell transduction (TCT) process. Furthermore, it provides an overview of the setup for the tubing set, general workflow and performance data.

Specifications

Process name:	T cell transduction process
Selection capacity:	up to 3×10^9 cells
Sample volume for selection:	50–280 mL
TransAct™ stimulation capacity:	1×10^8 cells (0.2 – 2×10^8)
Expansion capacity:	maximum 2×10^7 cells/mL
Final product elution volume:	100 mL
Process time:	8–14 days

Products

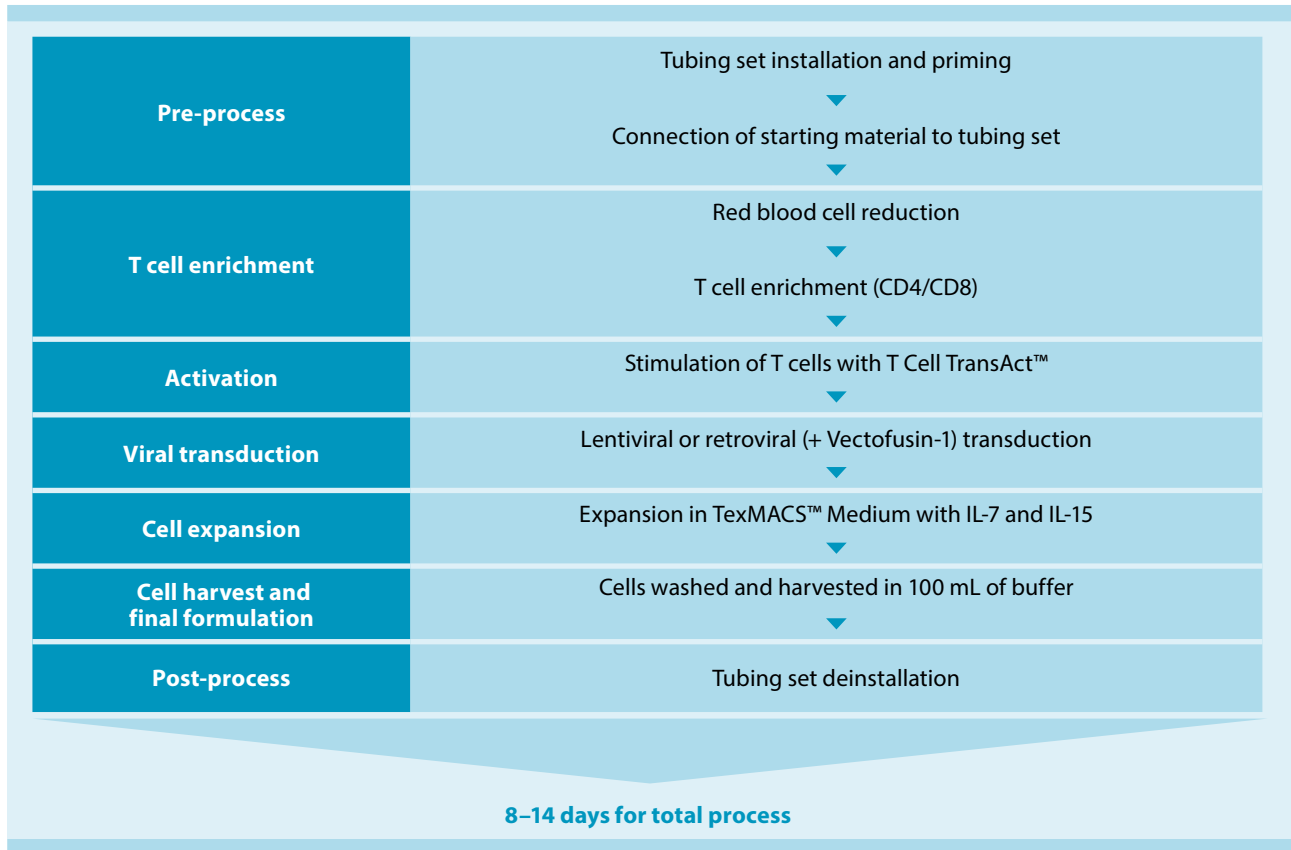
Consumables	Amount required
CliniMACS Prodigy®	1 piece
CliniMACS Prodigy TS 520	1 set
CliniMACS® PBS/EDTA Buffer	1 bag
TexMACS™ GMP Medium	3×2 L bags
CliniMACS CD4 Reagent	1 vial
CliniMACS CD8 Reagent	1 vial
MACS® GMP T Cell TransAct	1 vial
MACS GMP Recombinant Human IL-7	3 vials
MACS GMP Recombinant Human IL-15	3 vials

Additional materials	Amount required
Triple sampling adaptor	1 piece
Transfer bag 150 mL	1 bag
Luer/Spike Interconnector	1 piece
MACS GMP Vectofusin-1*	1 vial
Transfer bag 1000 mL	1 bag

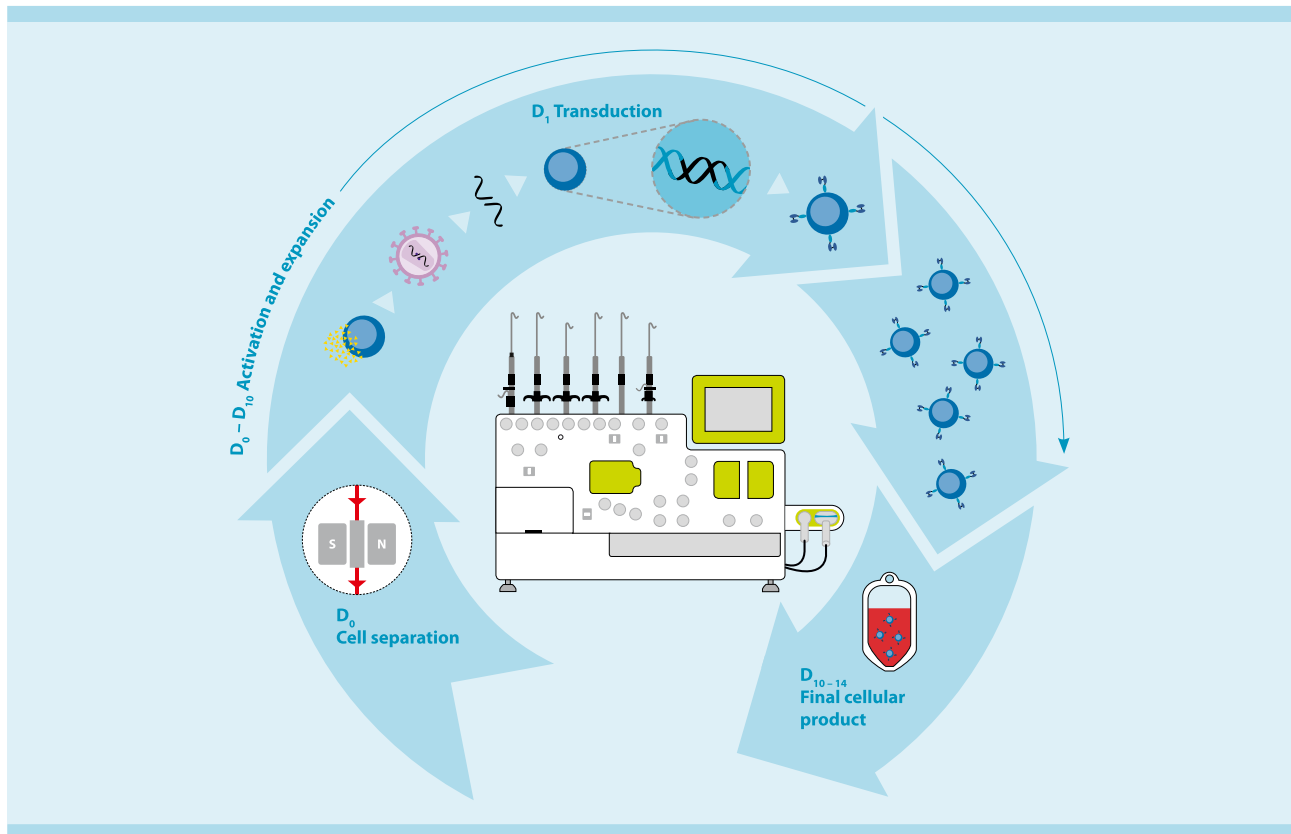
Additional equipment and materials
Sterile docking device
Cell counter
Flow cytometer
Syringes and hypodermic needles
Human serum albumin
Final formulation buffer
Human AB serum

*Please discuss your specific requirements with your Miltenyi Biotec representative.

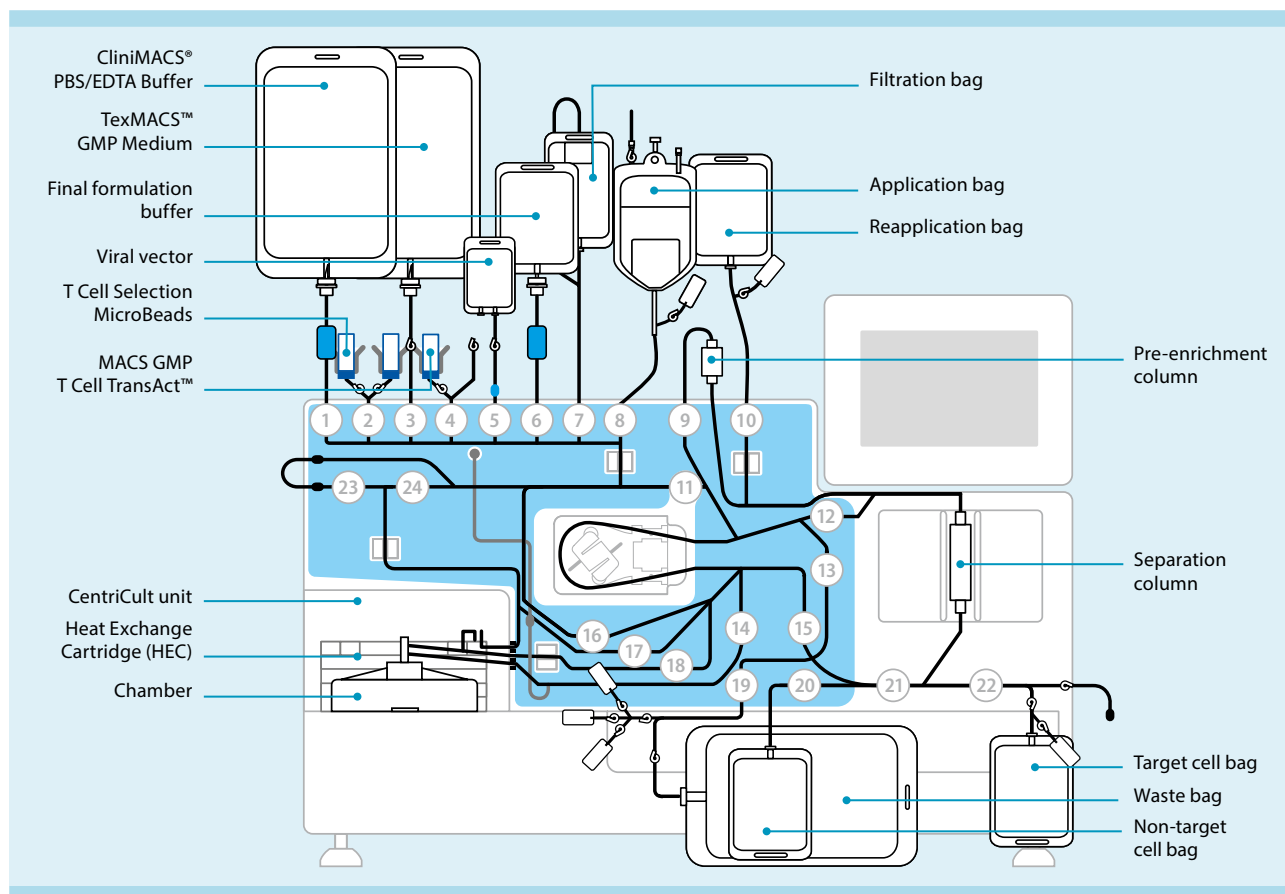
Process overview



Principle of the T cell transduction process on the CliniMACS Prodigy®



CliniMACS Prodigy® TS 520 setup



Performance data

	Starting product CD4 ⁺ and CD8 ⁺ T cells (%)	Isolated CD4 ⁺ and CD8 ⁺ T cells (%)	Final product			
			CD4 ⁺ and CD8 ⁺ T cells (%)	CAR ⁺ T cells (%)	Viability (%)	CAR ⁺ T cell number ($\times 10^9$)
Performance data of healthy donor or patient derived material						
Healthy (n=9)	72% \pm 11%	83% \pm 9%	91% \pm 5%	34% \pm 12%	90% \pm 4%	1.4 \pm 0.7
Patient (n=5)	23% \pm 21%	55% \pm 9%	88% \pm 7%	36% \pm 18%	88% \pm 7%	1.0 \pm 0.4
Performance data of healthy donor with or without human AB serum (3%) for culture						
With (n=8)	58% \pm 17%	82% \pm 14%	92% \pm 3%	36% \pm 9%	93% \pm 3%	1.6 \pm 0.3
Without (n=8)	60% \pm 15%	87% \pm 7%	94% \pm 6%	43% \pm 12%	93% \pm 3%	2.9 \pm 1.3

References

1. Lock, D. and Mockel-Tenbrinck, T. *et al.* (2017) Human Gene Therapy 28(10): 914–925.
2. Mock, U. *et al.* (2016) Cytotherapy 18(8): 1002–11.



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