



Miltenyi Biotec

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

Materials required*:

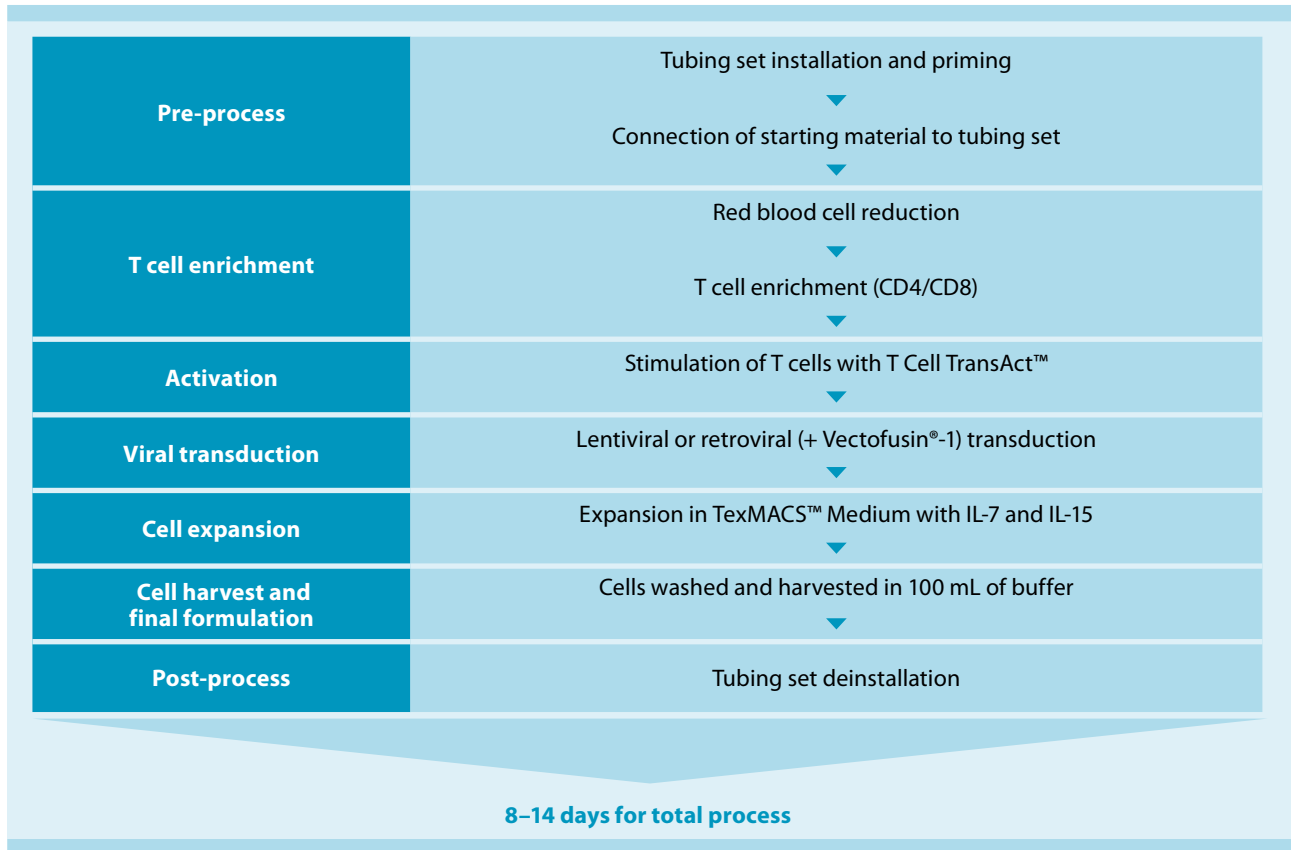
Consumables	Amount required
CliniMACS Prodigy®	1 piece
CliniMACS Prodigy TS 520	1 set
CliniMACS® PBS/EDTA Buffer	1 bag
TexMACS™ GMP Medium	3×2 L bags
CliniMACS CD4 Reagent	1 vial
CliniMACS CD8 Reagent	1 vial
MACS® GMP T Cell TransAct	1 vial
MACS GMP Recombinant Human IL-7	3 vials
MACS GMP Recombinant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

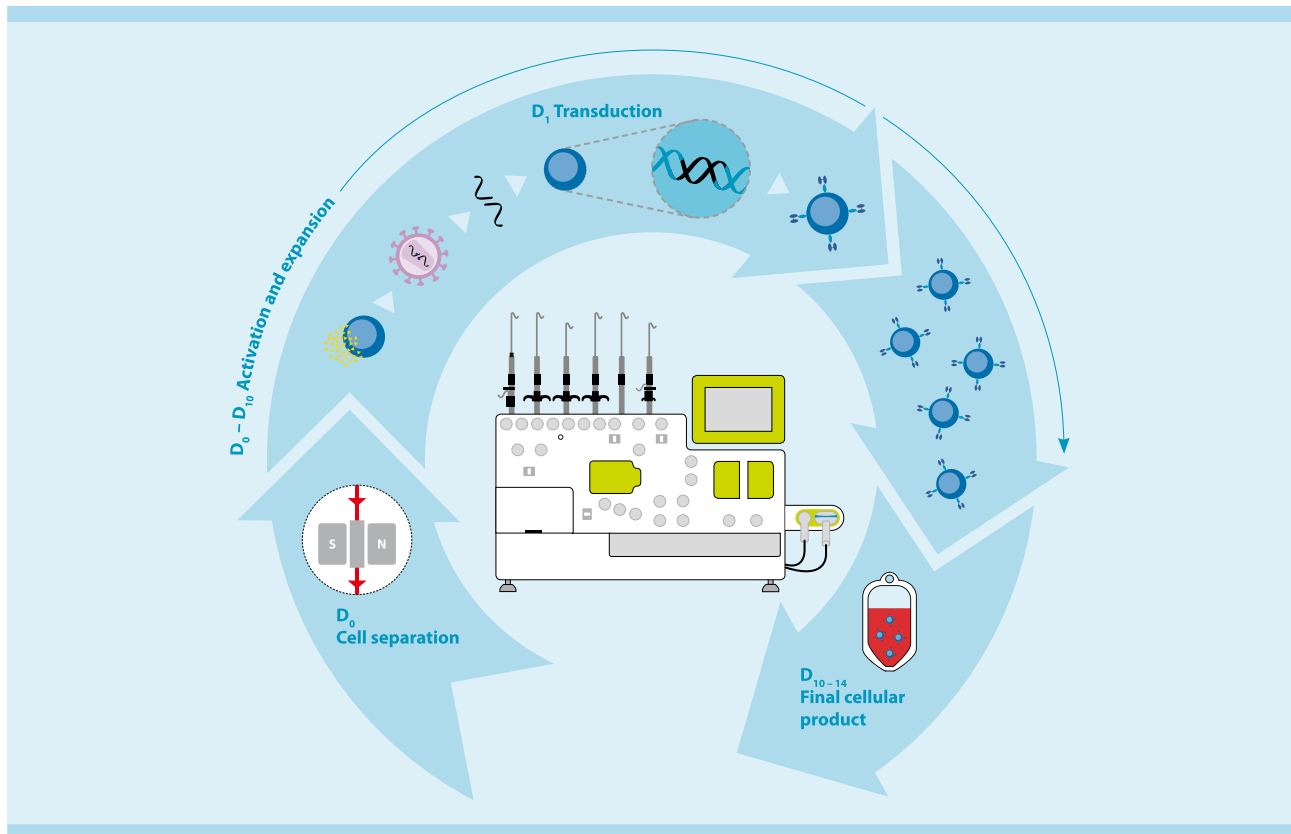
Additional equipment and materials
Sterile docking device
Cell counter
Flow cytometer
Syringes and hypodermic needles
Human serum albumin
Final formulation buffer
Human AB serum

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

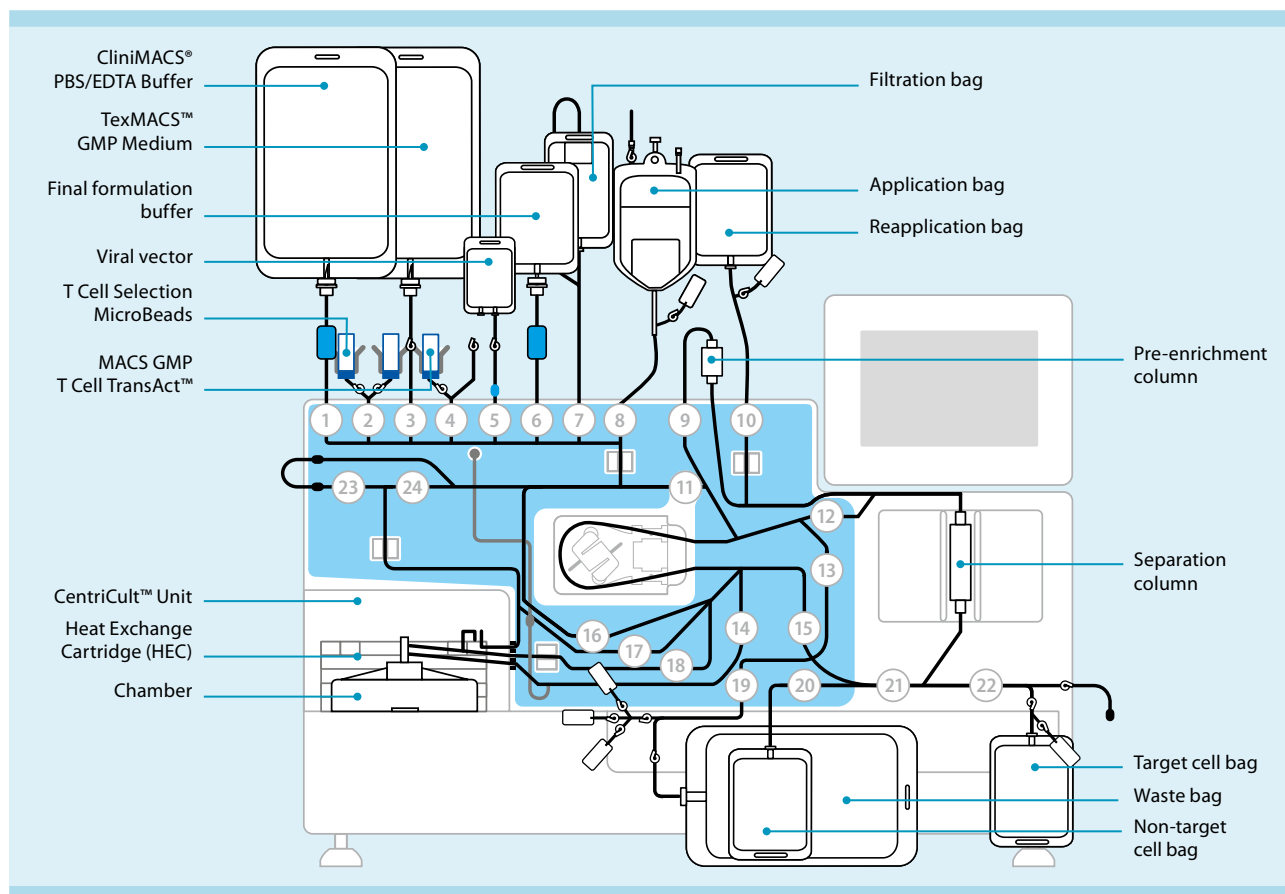
Process overview



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