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 ($0.2–2\times10^8$)
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

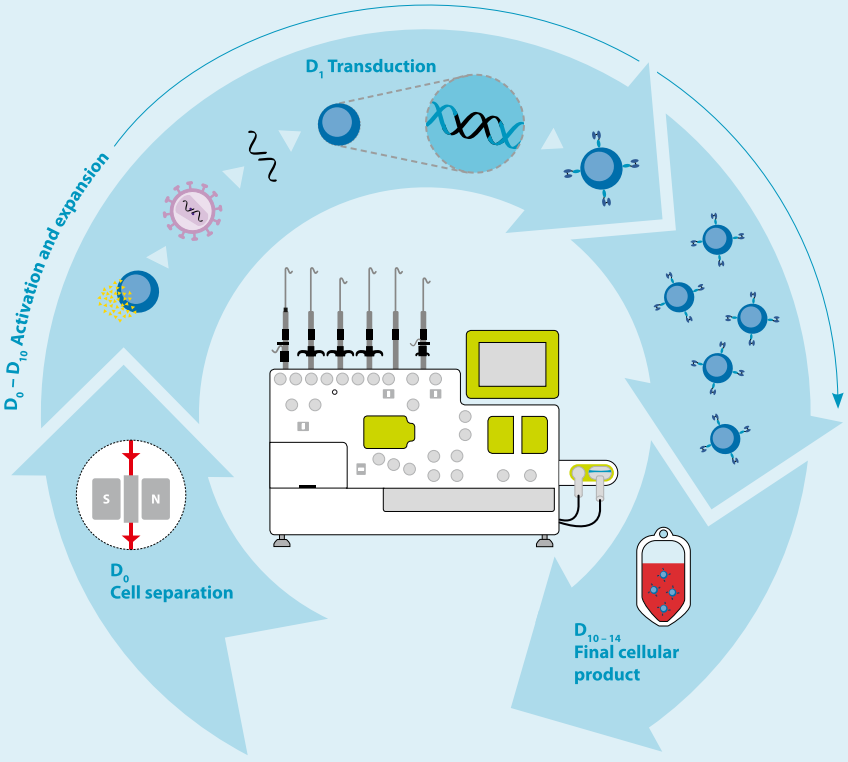
*Please discuss your specific requirements with your Miltenyi Biotec representative.

Process overview

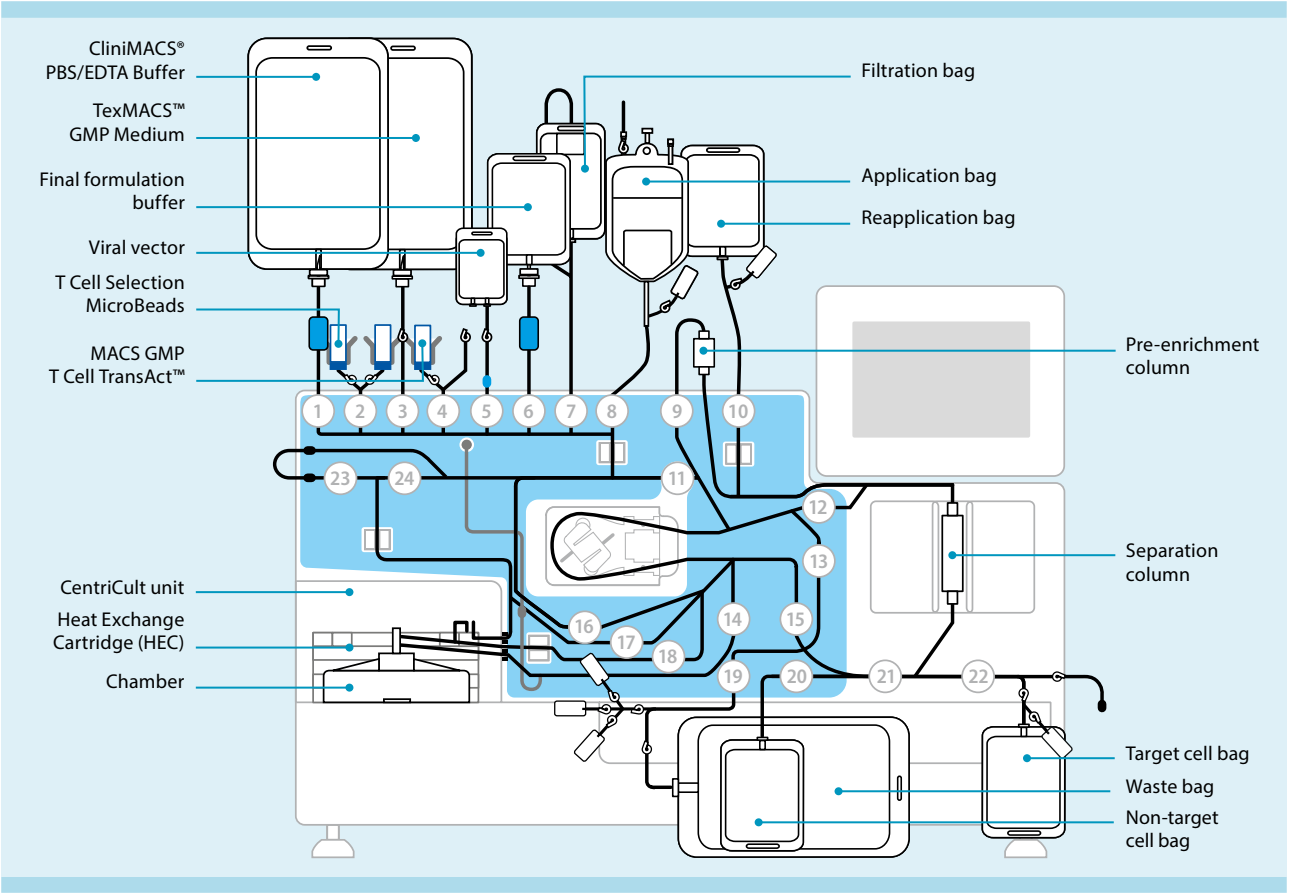
Pre-process	Tubing set installation and priming ▼ Connection of starting material to tubing set
T cell enrichment	Red blood cell reduction ▼ T cell enrichment (CD4/CD8)
Activation	Stimulation of T cells with T Cell TransAct™
Viral transduction	Lentiviral or retroviral (+ Vectofusin-1) transduction
Cell expansion	Expansion in TexMACS™ Medium with IL-7 and IL-15
Cell harvest and final formulation	Cells washed and harvested in 100 mL of buffer
Post-process	Tubing set deinstallation

8–14 days for total process

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 (×10⁹)
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.

Miltenyi Biotec

Miltenyi Biotec GmbH
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany
Phone +49 2204 8306-0
Fax +49 2204 85197
macs@miltenyibiotec.de

Miltenyi Biotec Inc.
2303 Lindbergh Street
Auburn, CA 95602-9562, USA
Phone 800 FOR MACS
Phone +1 530 888 8871
Fax +1 877 591 1060
macs@miltenyibiotec.com

Miltenyi Biotec Australia Pty. Ltd.
Phone +61 2 8877 7400
macs@miltenyibiotec.com.au

Miltenyi Biotec B.V. (Benelux)
macs@miltenyibiotec.nl
Customer service The Netherlands
Phone 0800 4020120
Customer service Belgium
Phone 0800 94016
Customer service Luxembourg
Phone 800 24971

Miltenyi Biotec Technology & Trading (Shanghai) Co., Ltd. (P.R. China)
Phone +86 21 62351005
macs@miltenyibiotec.com.cn

Miltenyi Biotec SAS (France)
Phone +33 1 56 98 16 16
macs@miltenyibiotec.fr

Miltenyi Biotec S.r.l. (Italy)
Phone +39 051 646 0411
macs@miltenyibiotec.it

Miltenyi Biotec K.K. (Japan)
Phone +81 3 5646 8910
macs@miltenyibiotec.jp

Miltenyi Biotec Norden AB (Nordics and Baltics)
macs@miltenyibiotec.se
Customer service Sweden
Phone 0200-111 800
Customer service Denmark
Phone 80 20 30 10
Customer service Norway, Finland, Iceland, and Baltic countries
Phone +46 46 280 72 80

Miltenyi Biotec Asia Pacific Pte. Ltd. (Singapore)
Phone +65 6238 8183
macs@miltenyibiotec.com.sg

Miltenyi Biotec Korea Co., Ltd (South Korea)
Phone +82 2 555 1988
macs@miltenyibiotec.co.kr

Miltenyi Biotec S.L. (Spain)
Phone +34 91 512 12 90
macs@miltenyibiotec.es

Miltenyi Biotec Ltd. (UK)
Phone +44 1483 799 800
macs@miltenyibiotec.co.uk

www.miltenyibiotec.com

Miltenyi Biotec provides products and services worldwide. Visit **www.miltenyibiotec.com/local** to find your nearest Miltenyi Biotec contact.

130-120-858