



Miltenyi Biotec

Ex-vivo T cell depletion in allogeneic hematopoietic stem cell transplantation (HSCT)

CliniMACS Prodigy® LP-TCRα/β-19-45RA System

Application

Automated magnetic depletion of human TCRα/β⁺ T cells, CD19⁺ B cells, and CD45RA⁺ cells from leukapheresis products, e.g., in the context of allogeneic hematopoietic stem cell transplantation. The depletion procedures can be combined flexibly.

This application sheet gives an overview of process specifications and required materials, illustrates the instrument setup, and summarizes the process workflow. It also provides key performance data for the separation process.

Specifications

Process name:	LP-TCRab-19-45RA Depletion
Cell source:	Leukapheresis product
Capacity:	
TCRα/β(-CD19):	
Normal scale:	Up to 24×10 ⁹ TCRα/β ⁺ cells and 10×10 ⁹ CD19 ⁺ cells from 60×10 ⁹ WBC
Large scale:	Up to 48×10 ⁹ TCRα/β ⁺ cells and 15×10 ⁹ CD19 ⁺ cells from 120×10 ⁹ WBC
CD45RA:	Up to 2.4×10 ⁹ CD45RA ⁺ cells from 6×10 ⁹ WBC
Starting volume:	
TCRα/β(-CD19):	50–600 mL
CD45RA:	10–60 mL, if combined with TCRα/β(-CD19) depletion 10–350 mL, for CD45RA depletion only
Process time:	
TCRα/β(-CD19):	5.1–9.0 hours*
CD45RA:	1.5–2.1 hours*
	*approximate; excluding device setup and optional in-process storage
Storage option:	up to 16h

Products

Consumables**

CliniMACS Prodigy Instrument
CliniMACS TCRα/β-Biotin
CliniMACS TCRα/β-Biotin XL
CliniMACS Anti-Biotin Reagent
CliniMACS Anti-Biotin Reagent XL
CliniMACS CD19 Reagent
CliniMACS CD19 Reagent XL
CliniMACS CD45RA Reagent XS
CliniMACS Prodigy TS 320
CliniMACS PBS/EDTA Buffer, 3 L
Transfer Set Coupler/Coupler

**The required material depends on the selected use case.

Additional materials

Human serum albumin (HSA), pharmaceutical grade, to be added to the CliniMACS PBS/EDTA Buffer and to the infusion solution to a final concentration of 0.5% (w/v)
Appropriate Luer Lock syringes (10 mL, 50 mL) and hypodermic 20 gauge needles
Transfer bag(s) 1,000 mL
3-way tube adapter (optional)
Infusion solution (e.g. sodium chloride solution, for infusion), preferably in bags
Rinsing solution (aqua bidest. for injection use), preferably in bags
Uninterruptable power supply unit (optional)
Sterile docking device
Cell counter
Flow cytometer

Process overview

Select your desired depletion strategy based on your specific requirements. The CliniMACS Prodigy TCRα/β-19-45RA Depletion Application provides the option to eliminate either

a single cell subset from your apheresis product or to integrate multiple depletion processes – all within the same closed tubing set and in a single process.

Use case	Depletion
1	Depletion of CD45RA ⁺ cells (LP-45RA Depletion process)
2	Depletion of TCRα/β ⁺ cells (LP-TCRab Depletion process)
3	Depletion of TCRα/β ⁺ and CD19 ⁺ cells (LP-TCRab-19 Depletion process)
4	Depletion of TCRα/β ⁺ and CD45RA ⁺ cells (LP-TCRab-45RA Depletion process)
5	Depletion of TCRα/β ⁺ , CD19 ⁺ , and CD45RA ⁺ cells (LP-TCRab-19-45RA Depletion process)

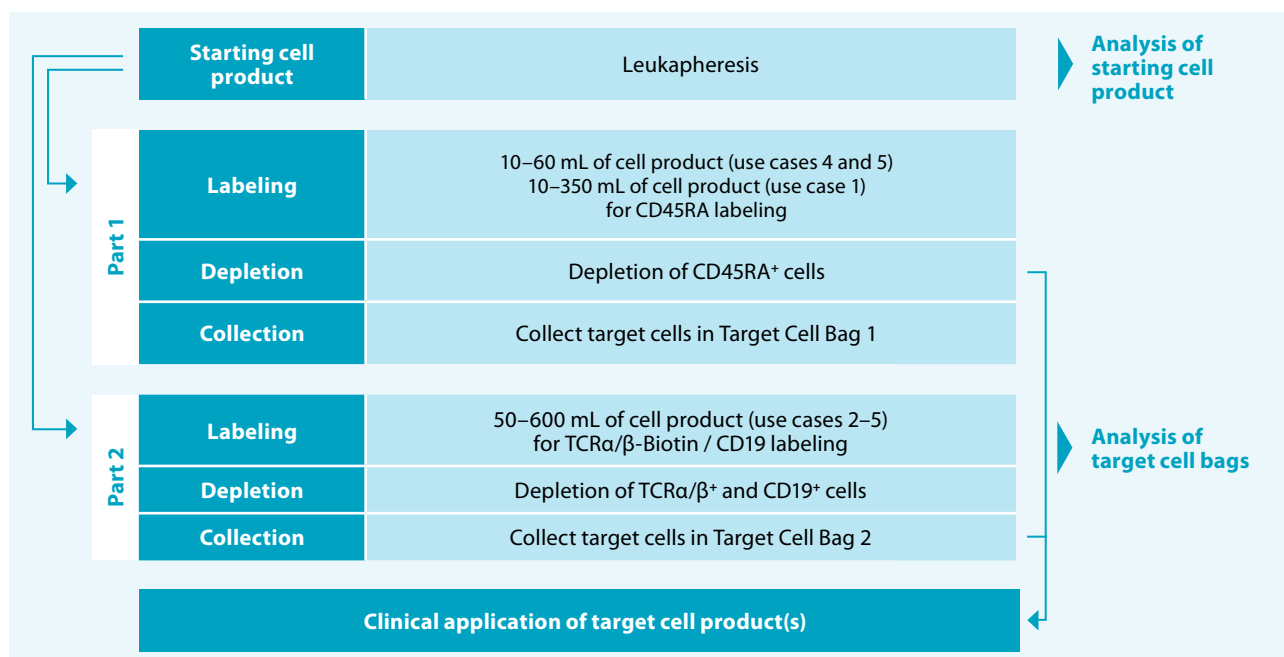
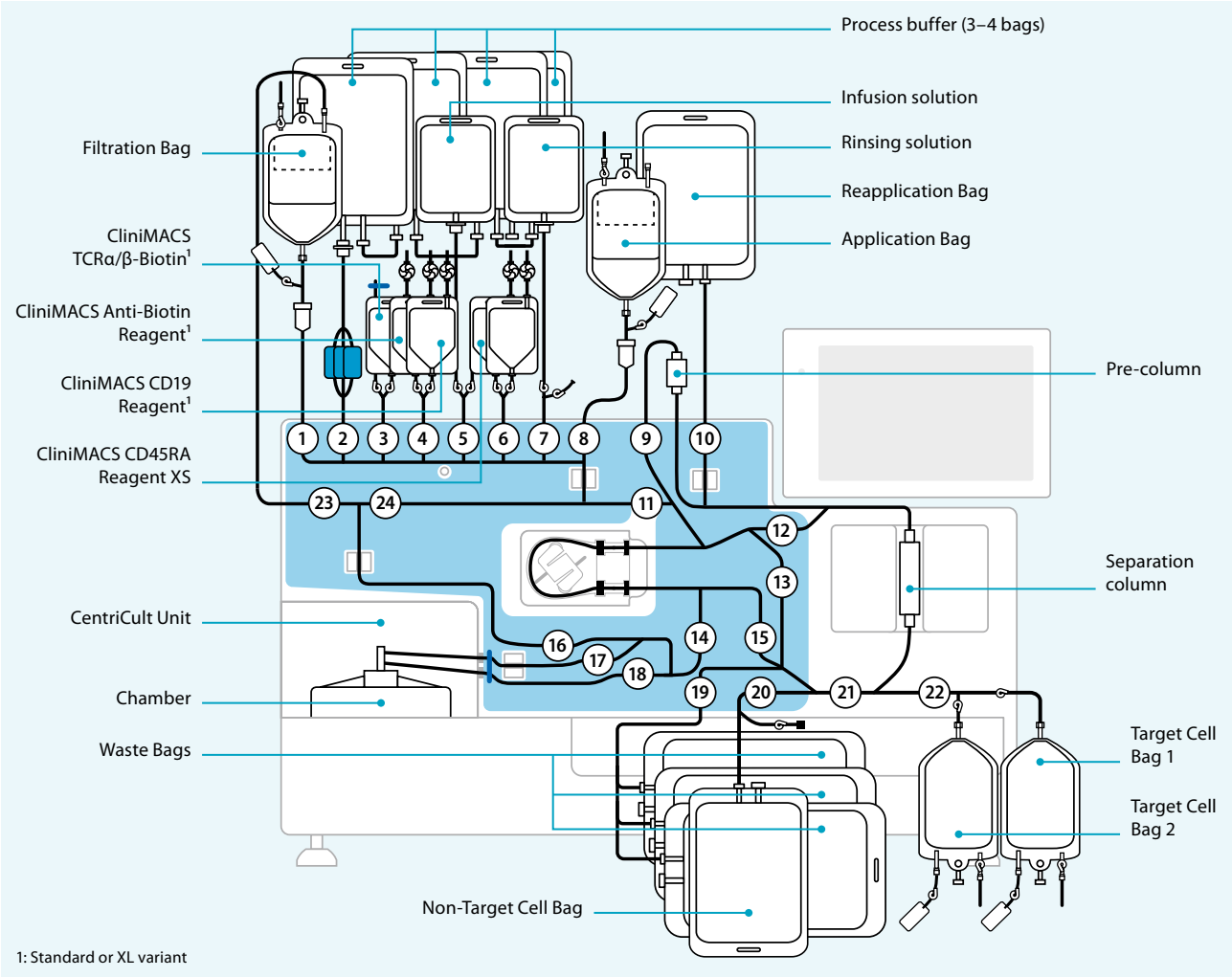


Figure 1: Process overview for use case 5 (CliniMACS Prodigy LP-TCRαβ-19-45RA Depletion). The starting cell product is split into two parts. Part 1: CD45RA⁺ cell depletion, part 2: TCRα/β(-CD19) depletion. Depending on the preferred scale, TCRα/β(-CD19) depletion can be performed using standard reagents for normal-scale procedures or XL reagent variants for large-scale cell depletion. CD45RA depletion always requires the use of CD45RA Reagent XS (see list of products).

CliniMACS Prodigy TS 320 setup for CliniMACS Prodigy LP-TCRab-19-45RA Depletion, use case 5



Performance data

27 mobilized apheresis products were automatically depleted of human TCRα/β⁺ T cells. In 19 of these products, CD19⁺ B cells were also removed (table 2). In addition, a small volume of the starting material was used for CD45RA⁺ cell depletion in 22 of

the total procedures (table 1). The starting cell products were processed approximately 24 hours after harvest. The target cells were collected in two different target cell bags (TCB1 and TCB2).

CD45RA ⁺ cell depletion						
	Starting material		Viability (%)	Yield (%)	Log depletion	
	WBC	CD45RA ⁺	WBC	CD3 ⁺ /CD45RO ⁺	CD3 ⁺ /CD45RA ⁺	TCRα/β ⁺ /CD45RA ⁺
Median	2.53E+09	1.33E+09	96.05%	13.48%	4.18	4.20
SD	5.67E+08	2.23E+08	4.83%	4.65%	0.47	0.60

Table 1: Viability, yield, and log depletion after CD45RA⁺ cell depletion (TCB1).

TCRα/β(-CD19) cell depletion								
	Starting material	Viability (%)	Yield (%)			Log depletion		
	WBC	WBC	CD34 ⁺	TCRγ/δ ⁺	CD56 ⁺	TCRα/β ⁺ /CD45RA ⁺	TCRα/β ⁺	CD20 ⁺
Median	1.96E+10	94.87%	74.93%	57.83%	57.73%	4.59	4.19	3.69
SD	1.82E+10	4.55%	13.68%	17.10%	14.00%	0.37	0.35	0.34

Table 2: Viability, yield, and log depletion after TCRα/β(-CD19) cell depletion (TCB2).



Miltenyi Biotec B.V. & Co. KG | Phone +49 2204 8306-0 | Fax +49 2204 85197 | macsde@miltenyi.com | www.miltenyibiotec.com
Miltenyi Biotec provides products and services worldwide. Visit www.miltenyibiotec.com/local to find your nearest Miltenyi Biotec contact.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. The CliniMACS System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured, and tested under a quality system certified to ISO 13485.

In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. The CliniMACS Reagents and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients. The CliniMACS Reagents in combination with the CliniMACS System are intended to separate human cells. Miltenyi Biotec as the manufacturer of the CliniMACS System does not give any recommendations regarding the use of separated cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of target cells in humans, the national legislation and regulations – e.g. for the EU the Directive 2004/23/EC ("human tissues and cells"), or the Directive 2002/98/EC ("human blood and blood components") – must be followed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS System.

In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Sets TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. Other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application, Investigational Device Exemption (IDE) or FDA approval.

This publication is for general informational purposes only. While all reasonable care has been taken in the preparation of this publication, Miltenyi Biotec assumes no responsibility for damages or other liabilities due to the accuracy, completeness, or currency of the information herein provided. Changes are periodically made to the information herein; these changes will be incorporated in new editions of the publication. Miltenyi Biotec may make improvements and/or changes in the product(s) and/or the process(es) described in this publication at any time without notice.

CliniMACS, CliniMACS Prodigy, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec B.V. & Co. KG and/or its affiliates in various countries worldwide. Copyright © 2025 Miltenyi Biotec and/or its affiliates. All rights reserved.