Miltenyi Biotec

Automated enrichment of human CD34$^+$ cells

CliniMACS Prodigy® HSC Enrichment System

Application

Automated magnetic enrichment process for human CD34$^+$ cells from mobilized leukapheresis products, e.g., as starting material for subsequent engineering of hematopoietic stem cells (HSCs).

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

Specifications

Process name:	HSC Enrichment
Process capacity:	Scalable process
Normal scale application:	
Target cells:	Up to 0.6×10^9 CD34$^+$ cells
Total cells:	Up to 60×10^9 total white blood cells (WBC)
Large scale application:	
Target cells:	Up to 1.2×10^9 CD34$^+$ cells
Total cells:	Up to 120×10^9 total white blood cells (WBC)
Sample volume:	50–600 mL
Elution volume:	Approx. 80 mL
Process time:	Approx. 3–5.5 hours*

*Excludes device setup and optional in-process storage

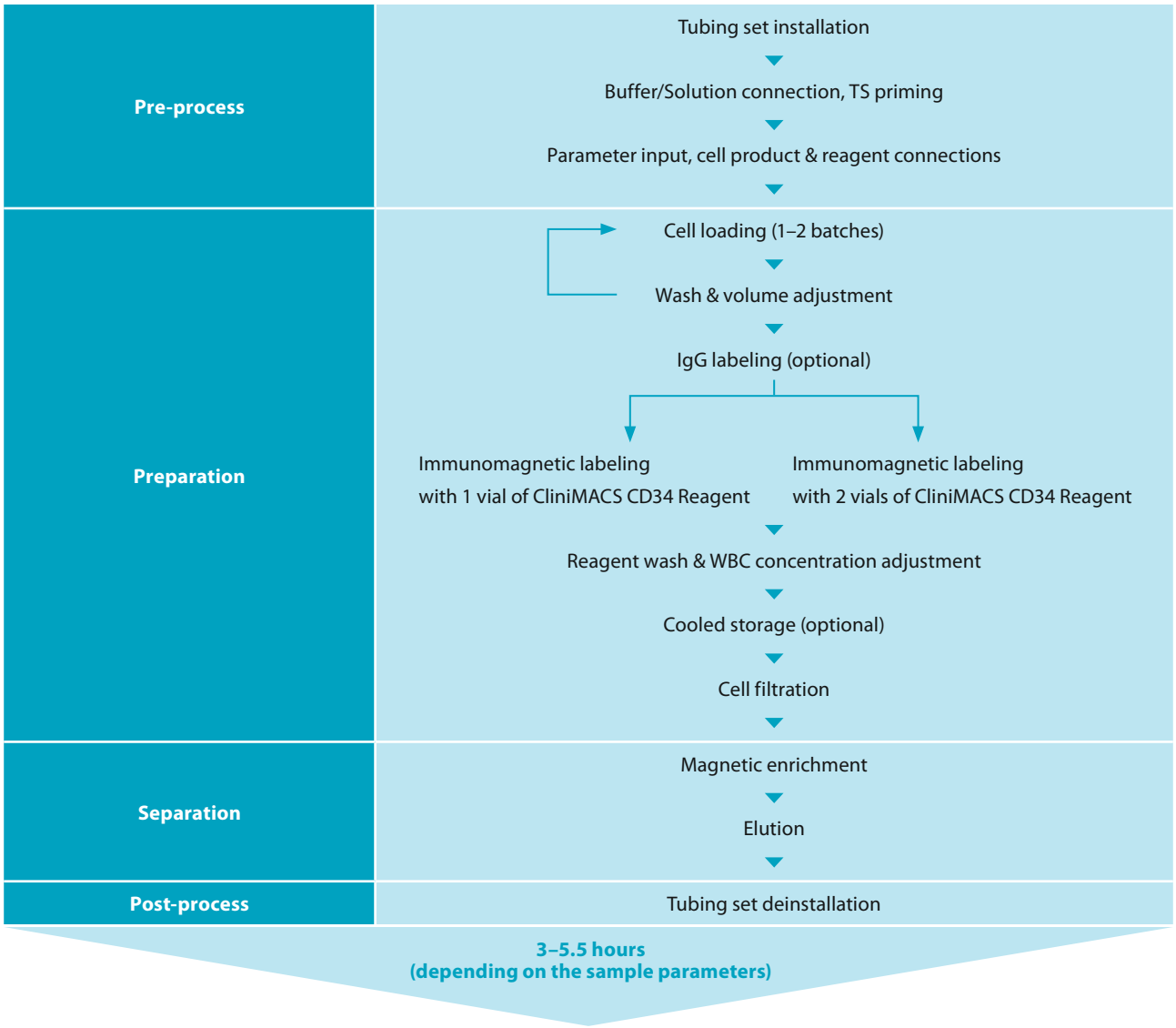
Materials required

CliniMACS® Materials	Amount required	
	normal scale	large scale
CliniMACS Prodigy® Instrument	1 piece	1 piece
CliniMACS CD34 Reagent	1 vial	2 vials
CliniMACS Prodigy TS 320	1 set	1 set
CliniMACS PBS/EDTA Buffer (2×3 L)	6 L	9 L

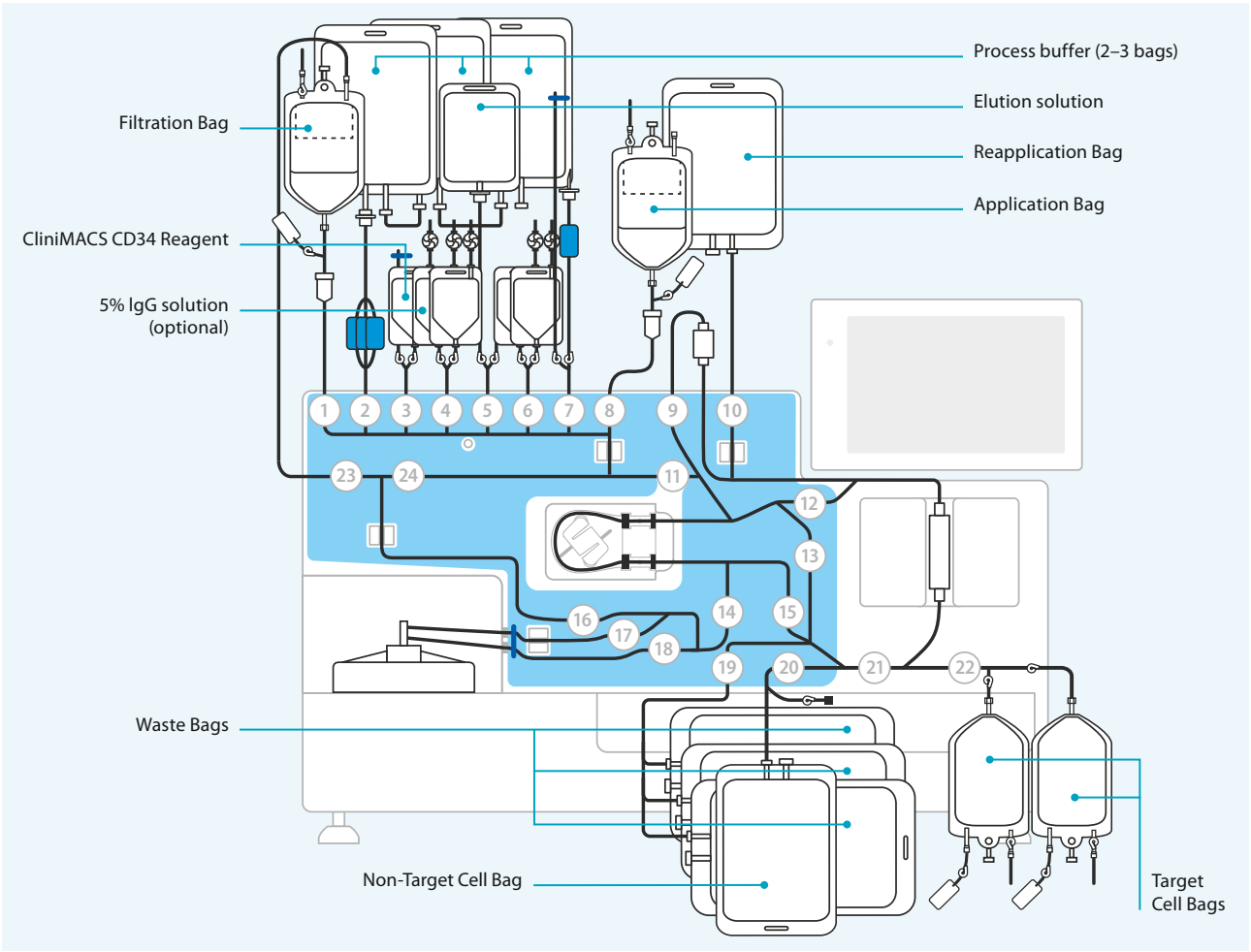
Additional material
Transfer Set Coupler/Coupler

Material & equipment
Human serum albumin (HSA), pharmaceutical grade, to be added to the CliniMACS PBS/EDTA Buffer and to the elution solution to a final concentration of 1.0% (w/v)
Elution solution (500 mL, e.g., sodium chloride solution, for infusion), preferably in bag
Transfer Bag(s) 600 mL (optional)
5% IgG solution (10 mL)
Appropriate Luer Lock syringes (10 mL, 30 mL, and 50 mL) and hypodermic 20 gauge needles
Uninterruptable power supply unit (optional)
Sterile docking device
Cell counter
Flow cytometer

Process overview for HSC Enrichment workflow



CliniMACS Prodigy® TS 320 setup



Performance data

Data from 27 mobilized apheresis products are shown in Table 1. The starting cell products were approximately 24 hours old at the start of the enrichment process. Twelve of these products were processed immediately, while fifteen underwent additional in-process storage for up to 16 hours.

This additional storage time did not affect any of the performance criteria, except for CD34⁺ cell yield. The mean yield of CD34⁺ cells was 65.83% without the additional storage time and 52.22% with the additional storage time.

N=27	Starting material			Final cell product				
	Total WBC	CD34⁺ cells		CD34⁺ cells				CD3⁺ cells
	(%)	(%)	Total	Purity (%)	Total	Viability (%)	Yield (%)	Depletion (log)
Mean	4.26×10^{10}	1.09	4.46×10^{8}	90.66	2.63×10^{8}	99.80	65.83	4.71
SD	2.14×10^{10}	0.32	2.29×10^{8}	4.14	1.53×10^{8}	0.20	6.26	0.26

Table 1: Internal data on the efficiency of CD34⁺ cell enrichment using the HSC Enrichment System.

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Miltenyi Biotec B.V. & Co. KG | Phone +49 2204 8306-0 | Fax +49 2204 85197 | macsde@miltenyi.com | **www.miltenyibiotec.com**
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130-136-880