

Enrichment of human CD34<sup>+</sup> cells

# LP-34 Enrichment process

## Application

Fully automated magnetic enrichment process for human CD34<sup>+</sup> cells from mobilized leukapheresis products, e.g., in the context of hematopoietic stem cell transplantation.

This application sheet gives an overview on the required and additional materials needed to perform the indicated process. Further it gives an overview of the setup of the tubing set, the process workflow, and the performance data.

## Specifications

**Process name:** LP-34 Enrichment

**Process capacity:** Scalable process

- Normal scale application:  
Target cells:  $0.6 \times 10^9$  CD34<sup>+</sup> cells  
Total cells:  $60 \times 10^9$  total white blood cells (WBC)
- Large scale application:  
Target cells:  $1.2 \times 10^9$  CD34<sup>+</sup> cells  
Total cells:  $120 \times 10^9$  total white blood cells (WBC)

**Sample volume:** 50–660 mL

**Elution volume:** Approx. 80 mL

**Process time:** Approx. 4.5–5.5 hours

## Materials required

CliniMACS® Products	Amount required		Order no.
	normal scale	large scale	
CliniMACS Prodigy®	1 unit	1 unit	200-075-301
CliniMACS CD34 Reagent	1 vial	2 vials	171-01
CliniMACS Prodigy TS 310	1 set	1 set	200-073-602* 130-097-183**
CliniMACS PBS/EDTA Buffer (2×3 L)	6 liters	6 liters	700-29* 130-021-201**

Additional materials	Amount required	Order no.
Transfer Bag 150 mL	1 bag	130-018-301
Transfer Bag 600 mL	1 bag	130-019-001
Luer/Spike Interconnector	1 piece	130-018-701
Transfer Set Coupler/Coupler	1 set	130-018-601
1 m Tube Extension	1 piece	130-017-904
5% IgG solution	10 mL	
Elution buffer (e.g. NaCl + 0.5% HSA (w/v))	500 mL	
Human serum albumin (HSA)		
Appropriate syringes (10 mL, 50 mL)		
Hypodermic 20 gauge needles		

### Additional equipment (optional)

Uninterruptable power supply unit  
Sterile docking device  
Cell counter

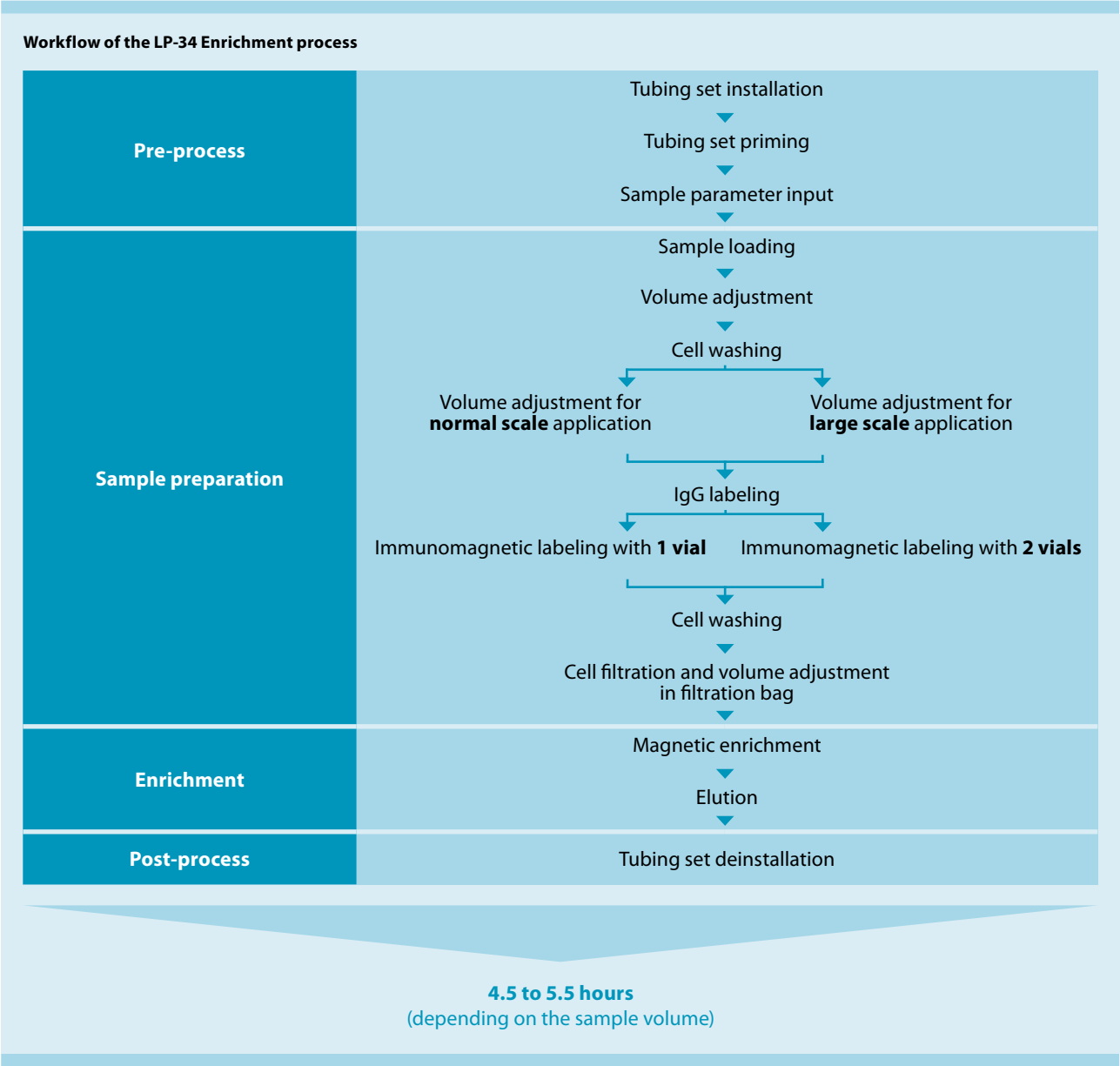
\* CE \*\* For research only

In the U.S. the components of the CliniMACS Prodigy CD34 System are for research use only.

For availability in your country please contact your local representative.

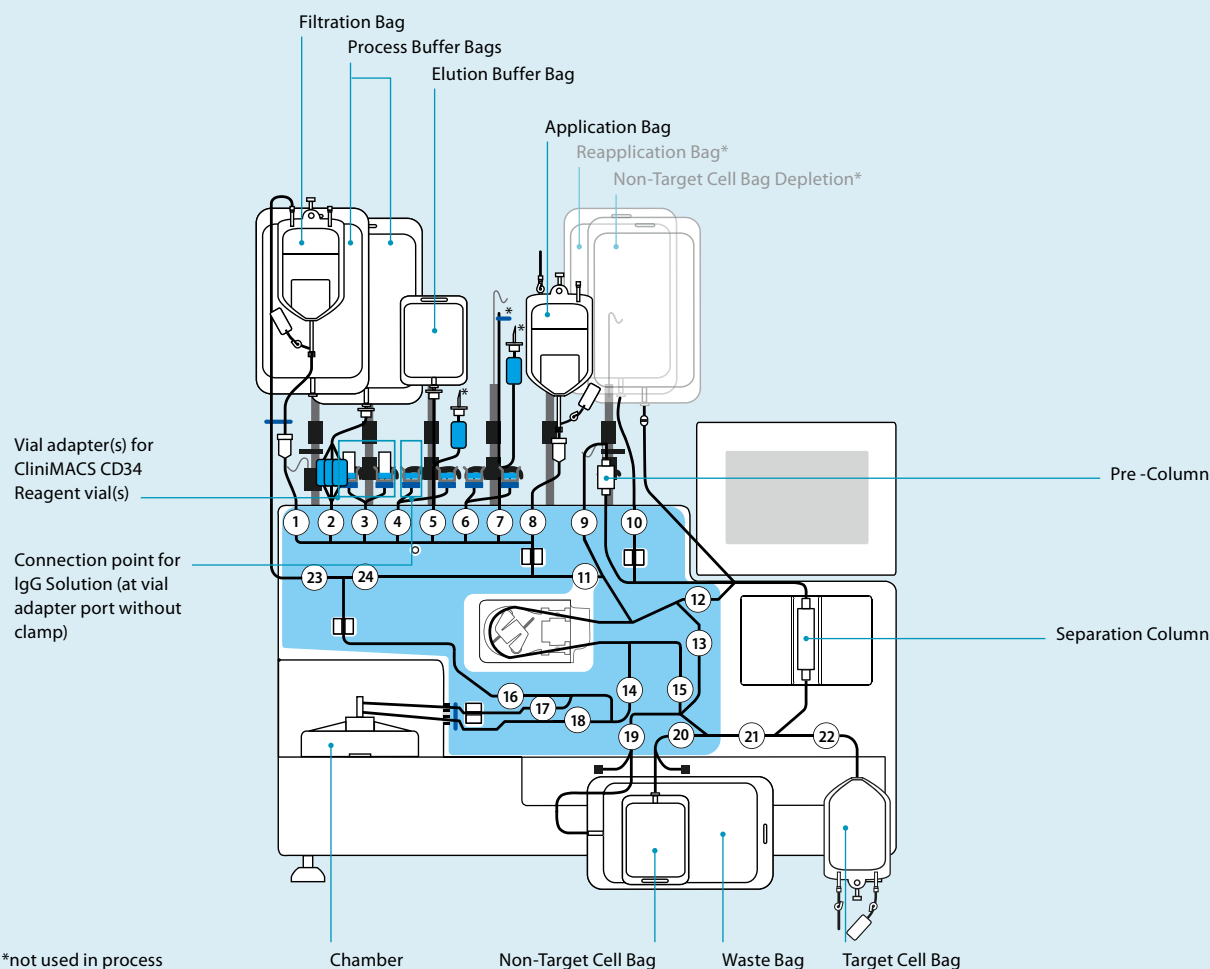
For complete regulatory and legal notices please refer to the last page.

# Process overview



## CliniMACS Prodigy® TS 310 setup

Scheme of the CliniMACS Prodigy® TS 310 setup



## Performance data

Data from three mobilized apheresis products using the normal scale application are shown below<sup>1</sup>.

N=3	Starting material			Final cell product				
	Total WBC	CD34 <sup>+</sup> cells		CD34 <sup>+</sup> cells			CD3 <sup>+</sup> cells	
		(%)	Total	(%)	Total	Viability (%)	Recovery (%)	Depletion (log)
<b>Mean</b>	2.26×10 <sup>10</sup>	2.13	4.75×10 <sup>8</sup>	97.43	2.81×10 <sup>8</sup>	99.71	58.20	4.25
<b>SD</b>	4.41×10 <sup>9</sup>	0.06	9.08×10 <sup>7</sup>	1.08	9.47×10 <sup>7</sup>	0.21	8.99	0.11

Data from seven unmobilized apheresis products using the normal scale application are shown below (internal data).

N=7	Starting material			Final cell product				
	CD34 <sup>+</sup> cells			CD34 <sup>+</sup> cells			CD3 <sup>+</sup> cells	
	(%)	Total		(%)	Total	Viability (%)	Recovery (%)	Depletion (log)
<b>Mean</b>	0.06	6.58×10 <sup>6</sup>		64.98	3.41×10 <sup>6</sup>	99.44	52.20	4.62
<b>SD</b>	0.02	3.98×10 <sup>6</sup>		9.14	2.28×10 <sup>6</sup>	0.63	11.47	0.22

Data from nine mobilized apheresis products using the large scale application are shown below.<sup>2</sup>

N=9	Starting material			Final cell product				
	CD34 <sup>+</sup> cells		CD3 <sup>+</sup> cells	CD34 <sup>+</sup> cells			CD3 <sup>+</sup> cells	
	(%)	Total	Total	(%)	Total	Viability (%)	Recovery (%)	Depletion (log)
<b>Mean</b>	1.21	4.78×10 <sup>8</sup>	9.58×10 <sup>9</sup>	93.87	3.42×10 <sup>8</sup>	99.85	73.60	4.01
<b>SD</b>	0.26	6×10 <sup>7</sup>	8×10 <sup>8</sup>	0.84	5×10 <sup>7</sup>	0.05	13.2	0.11

The performance data discussed in this publication is presented as derived under specific operating conditions. Actual results may vary due to the properties of the biological materials used and/or other factors. Please consult with Miltenyi Biotec Technical Support on your particular circumstances.

## References

<sup>1</sup> External cooperation with Prof. Bönig, German Red Cross Blood Service Baden-Württemberg-Hesse, Institute Frankfurt, Department of Cellular Therapeutics

<sup>2</sup> Spohn, G. *et al.* (2015) *Cytotherapy* 17: 1465–1471.



### 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](http://www.miltenyibiotec.com/local) to find your nearest Miltenyi Biotec contact.

This print material is not for use in the USA. 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.

The CliniMACS® System components including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer are manufactured and controlled under an ISO 13485 certified quality system. In the EU, the CliniMACS System components are available as CE-marked medical devices. In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Set TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved; all other products of the CliniMACS product line are available for use only under an approved Investigational New Drug (IND) application or Investigational Device Exemption (IDE). CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use. Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. CliniMACS, CliniMACS Prodigy, MACS, and the MACS logo are registered trademarks or trademarks of Miltenyi Biotec GmbH. Copyright © 2018 Miltenyi Biotec. All rights reserved.