



Miltenyi Biotec



Enrichment of human CD14⁺ monocytes

CliniMACS Prodigy® LP-14 System

Application

Fully automated specific labeling and enrichment procedure for the purification of human CD14⁺ monocytes from unmobilized apheresis products.

This application sheet gives an overview of the specifications and materials needed to perform the indicated process. Furthermore, it provides the application workflow, the configuration of the used ClinMACS Prodigy Tubing Set, and performance data.

Specifications

Program name:	LP-14 Enrichment
Target cells:	4×10 ⁹ CD14 ⁺ cells
Total cells:	2×10 ¹⁰ total white blood cells (WBC)
Sample volume:	50–300 mL
Elution volume:	Approx. 40 mL per stage
Process time:	Approx. 2–3.5 hours

Materials required

CliniMACS® Product	Amount required
CliniMACS Prodigy	1 unit
CliniMACS Prodigy TS 510	1 set
CliniMACS CD14 GMP MicroBeads	1 vial
CliniMACS PBS/EDTA Buffer	3 L

Additional materials

Human serum albumin (HSA) to be added to the ClinMACS PBS/EDTA Buffer to a final concentration of 0.5% (w/v)

Appropriate syringes (10 mL, 30 mL, 50 mL) and hypodermic 20 gauge needles

Additional devices

Uninterruptable power supply unit

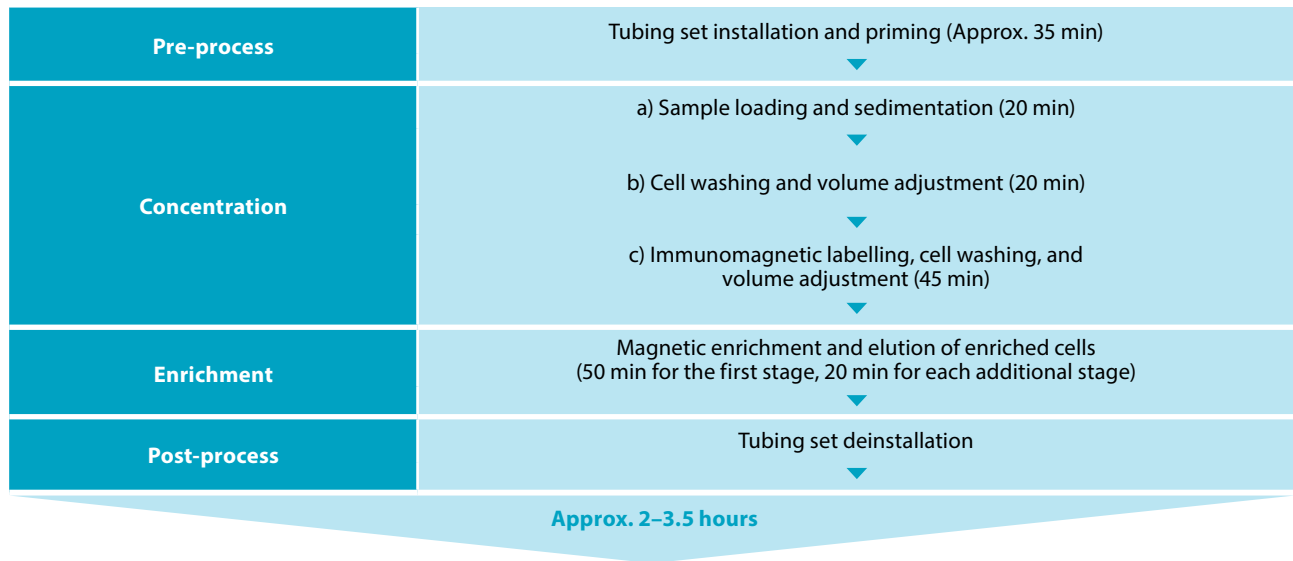
Sterile docking device

Cell counter

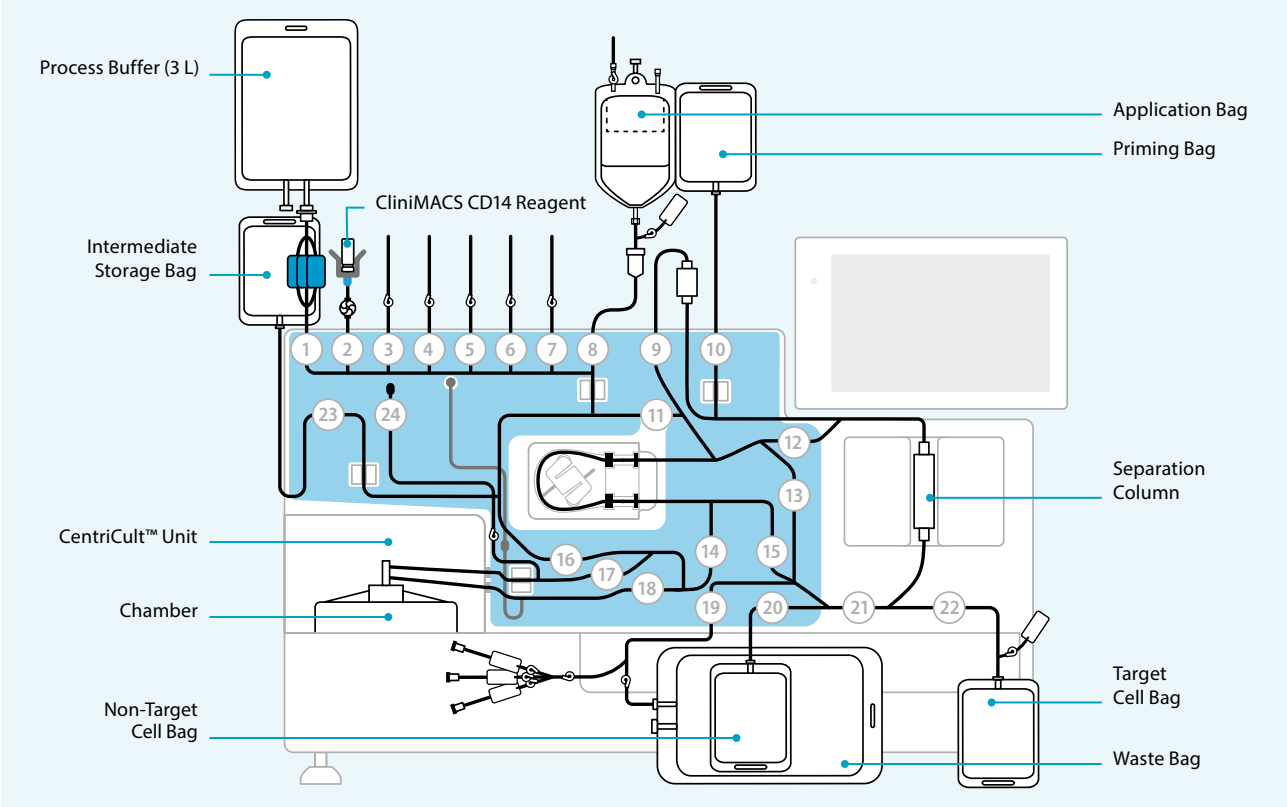
Flow cytometer

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 510 setup for CD14+ monocyte enrichment



Performance data

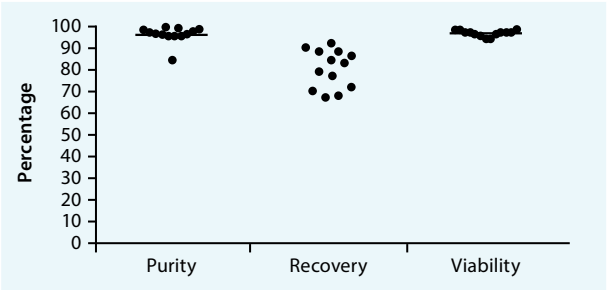


Figure 1: Purity, recovery, and viability of monocytes enriched with the CliniMACS Prodigy LP-14 System measured by flow cytometer. Data shows the results of 13 independent LP-14 enrichment procedures using 13 different apheresis products.



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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. CliniMACS GMP MicroBeads are for research use and *ex vivo* cell processing only. CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use. CliniMACS, CliniMACS Prodigy, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec and/or its affiliates in various countries worldwide. Copyright © 2021 Miltenyi Biotec and/or its affiliates. All rights reserved.