



Miltenyi Biotec

Manufacturing of monocyte-derived dendritic cells

CliniMACS Prodigy® LP-14 Mo-DC

Application

This process uses a closed, automated system to perform labeling, enrichment, differentiation, maturation, antigen loading, and rebuffering of CD14⁺ cells from leukapheresis products to produce monocyte-derived dendritic cells (Mo-DCs).

This application sheet provides an overview of the specifications and materials required to perform the indicated process. It also outlines the workflow, configuration of the CliniMACS Prodigy Tubing Set, and relevant performance data.

Specifications

Monocyte enrichment

Process name:	LP-14 Mo-DC Process
Selection capacity:	Up to 4×10 ⁹ CD14 ⁺ labeled cells within 20×10 ⁹ WBCs
Sample volume for selection:	50–300 mL
Process time:	3–3.5 hours

Monocyte cultivation

(differentiation to Mo-DC and maturation)

Starting cell number for cultivation:	Up to 0.8×10 ⁹ cells
Expansion capacity:	Up to 2×10 ⁸ Mo-DCs in a maximum culture volume of 260 mL
Final product harvest volume:	Two harvesting modes available: 55 mL or 100 mL
Process time:	Approx. 8 days (default setting)

Products required

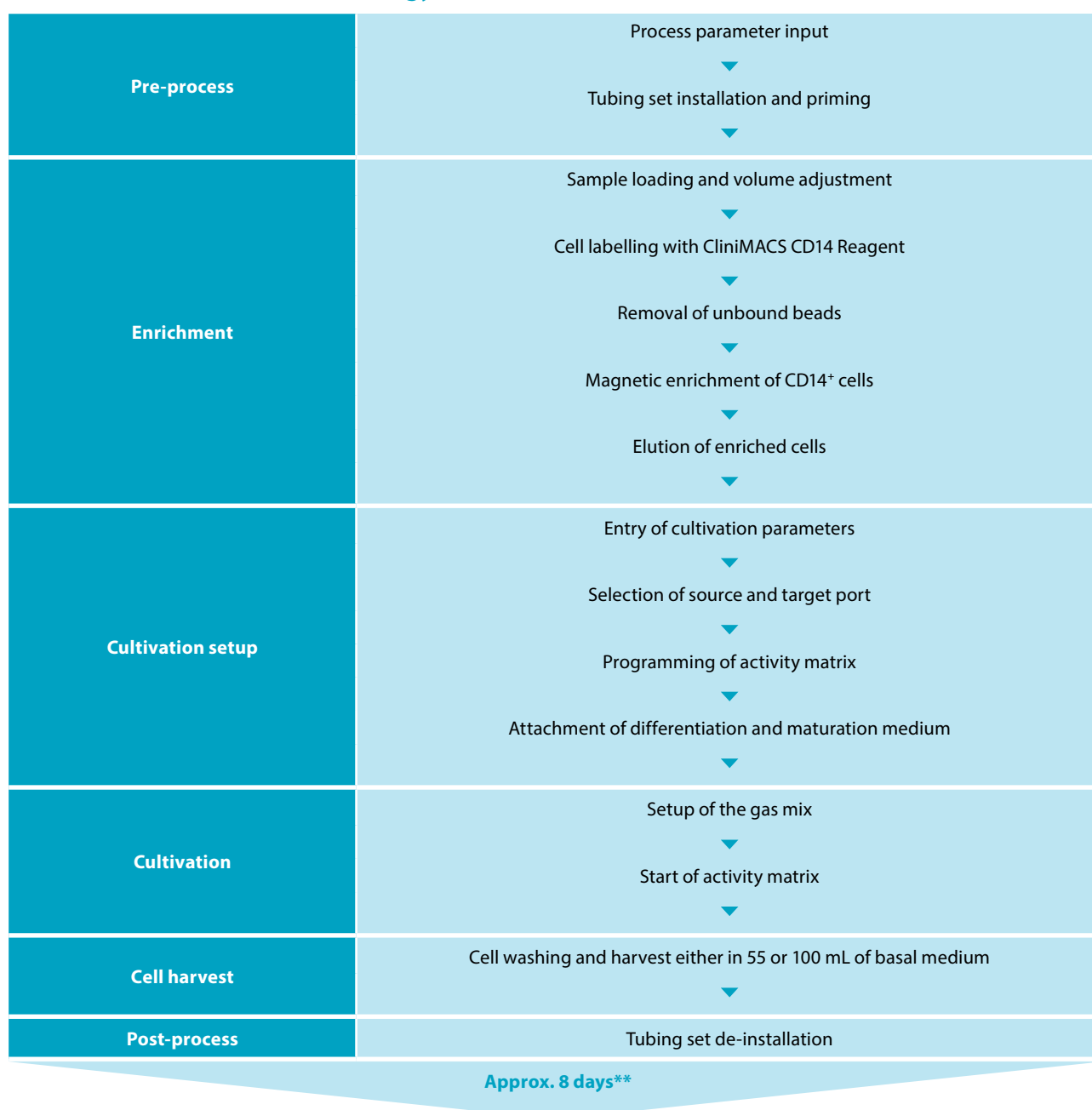
CliniMACS® and MACS® GMP Products	Amount
CliniMACS Prodigy	1
CliniMACS Prodigy TS 510	1 set
CliniMACS CD14 Reagent (different regulatory variants available)	1 vial
CliniMACS PBS/EDTA Buffer (2×3 L)	1×3 L
CliniMACS PBS/EDTA Buffer (3×1 L)	1×1 L
MACS GMP Recombinant Human GM-CSF	1 vial (250 µg/vial)
MACS GMP Recombinant Human IL-1β	1 vial (25 µg/vial)
MACS GMP Recombinant Human IL-4	1 vial (25 µg/vial)
MACS GMP Recombinant Human IL-6	1 vial (25 µg/vial)
MACS GMP Recombinant Human TNF-α	1 vial (25 µg/vial)
MACS GMP PepTivators® Peptide Pools (optional)	1 vial for 1×10 ⁹ cells

Additional material/equipment*
Leukapheresis product (not older than 24 hours)
Human serum albumin (HSA)
Medium (basal, differentiation and maturation)
Prostaglandin E ₂ (PGE ₂)
Sterile Luer Lock syringes
Hypodermic needles
Transfer bag(s) 600 mL (module-dependent)
Transfer Set Coupler/Coupler (module-dependent)
Luer/Spike Interconnector (module-dependent)
1 m extension line (optional)

Additional material/equipment*
Uninterruptible power supply
CO ₂ and compressed air supply
Sterile tubing welder
Cell counter and flow cytometer

*This protocol requires the use of components and materials that are not part of the CliniMACS Prodigy LP-14 Mo-DC System, such as human serum albumin or prostaglandine E₂. Only pharmaceutical-grade products approved in your country should be used. If these components are not available as registered drugs, the user must evaluate all associated risks before applying the target cell product in humans.

Workflow of the CliniMACS Prodigy LP-14 Mo-DC enrichment and cultivation



** The processing time largely depends on the design and protocol of the individual workflow.

CliniMACS Prodigy TS 510 setup for LP-14 Mo-DC Process

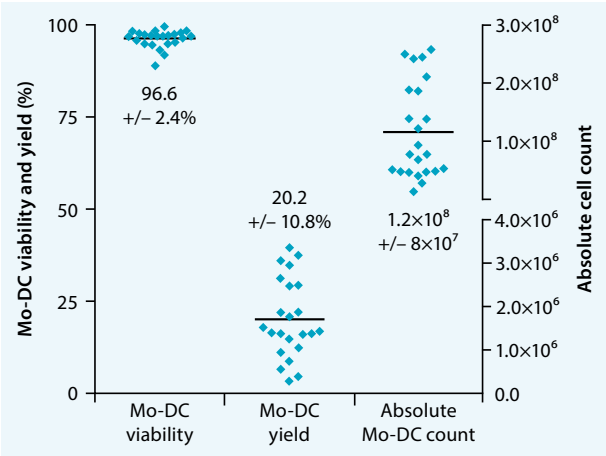
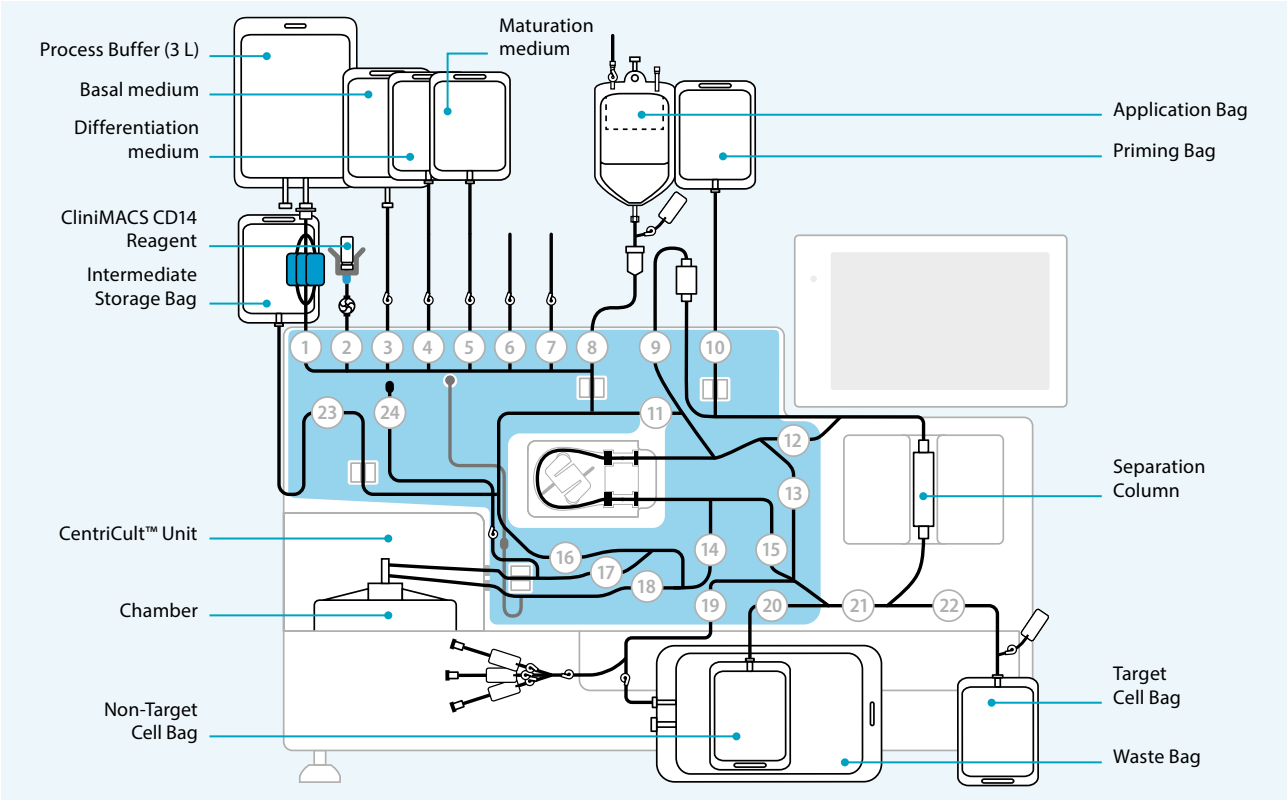


Figure 1: Internal data showing the viability, yield, and absolute count of monocyte-derived dendritic cells generated using the CliniMACS Prodigy LP-14 Mo-DC Process. Mature Mo-DCs (mMo-DCs) were generated with an average recovery of 20%, calculated based on the number of initially seeded monocytes. The viability of mMo-DCs was evaluated by flow cytometry, specifically by excluding PI⁺ dead cells, with an average viability of 97%.

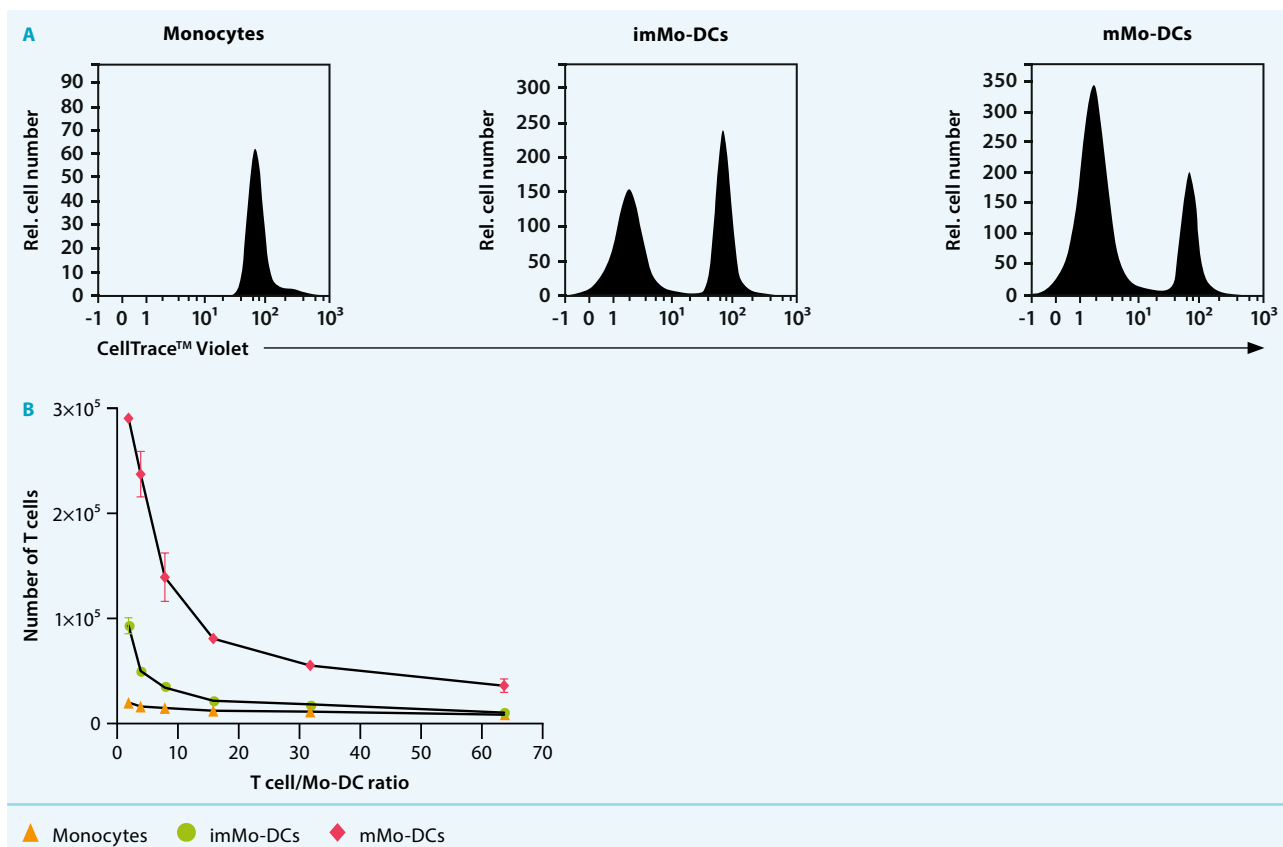


Figure 2: Internal data on the T cell priming capacity of monocytes and Mo-DCs isolated and cultured using the CliniMACS Prodigy. CellTrace Violet-labeled, allogeneic, naive CD45RA⁺CD45RO⁻ T cells were co-cultured with either monocytes or Mo-DCs. After 7 days, T cell numbers and CellTrace Violet staining intensity were analyzed (A). Unlike monocytes, both immature Mo-DCs (imMo-DCs) and mature Mo-DCs (mMo-DCs) induced T cell proliferation, as indicated by increased cell counts and reduced CellTrace Violet staining. Proliferation was highest when mMo-DCs served as antigen-presenting cells (B). In (B), the data represent the mean \pm standard deviation (SD) from duplicate experiments, with error bars indicating the variability between replicates.



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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. MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative. MACS GMP Products are designed, manufactured and tested under an ISO 13485 quality management system and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The manufacturing and testing of MACS GMP Products of biological origin are in compliance with EP chapter 5.2.12 for “Raw materials of biological origin for the production of cell-based and gene therapy medicinal products”.

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