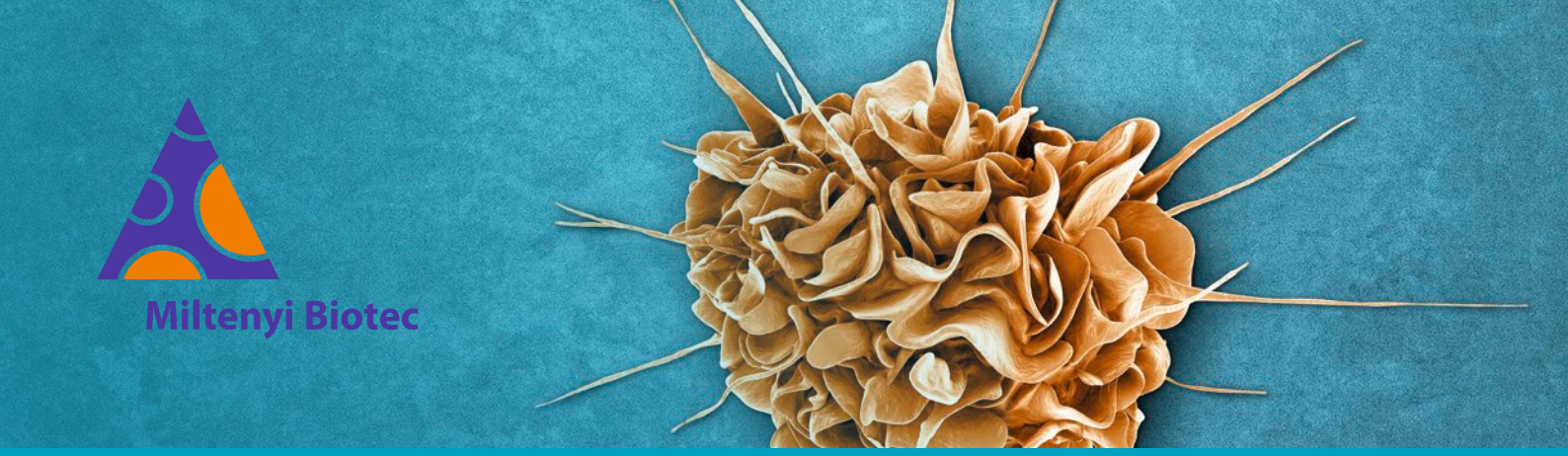


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Clinical trials using CliniMACS Systems for manufacturing of dendritic cells or macrophages

Reference	Cellular product	CliniMACS System	Indication	Type of antigen
Schwarze, J. K. *et al.* (2020)	CD1c$^+$ DC	CliniMACS CD1c System	Various solid tumors	–
Sarivalasis, A. *et al.* (2019)	Infl. Mo-DC	CliniMACS Prodigy LP-14 System	Ovarian cancer	Personalized peptide pools or tumor lysate
Westdorp, H. *et al.* (2019)	CD1c$^+$ DC and CD304$^+$ DC	CliniMACS LP-BDC System	Prostate cancer	NY-ESO-1, MAGE-C2, and MUC1 (PepTivator Peptide Pools)
Fraser, A.R. *et al.* (2017)	Regulatory macrophages	CliniMACS Prodigy® LP-14 System	Liver cirrhosis	–
Curbishley, S. (2017)	Infl. Mo-DC	CliniMACS Prodigy LP-14 System	Liver cancer	Tumor lysate
Anguille, S. *et al.* (2017)	Infl. Mo-DC	CliniMACS CD14 System	Acute myeloid leukemia (AML)	WT-1 mRNA electroporation
Inogés, S. Tejada, S. (2017)	Infl. Mo-DC	CliniMACS CD14 System	Glioblastoma	Tumor lysate
De Haar, C. *et al.* (2017)	CBDC	CliniMACS CD34 System	AML	WT-1 mRNA electroporation and WT1 peptides
Bell, G.M. *et al.* (2017)	Tol Mo-DC	CliniMACS CD14 System	Rheumatoid and inflammatory arthritis	Autologous synovial fluid
Schreibelt, G. *et al.* (2015)	CD1c$^+$ DC	CliniMACS CD1c System	Melanoma	gp100 peptides
Prue, R. L. *et al.* (2015)	CD1c$^+$ DC	CliniMACS CD1c System	Prostate cancer	Prostate cancer associated peptides (PSA, PAP)
Zabaleta, A. *et al.* (2015)	Infl. Mo-DC	CliniMACS CD14 System	Chronic hepatitis C virus (HCV) infection	Recombinant adenovirus encoding HCV NS3 protein (AdNS3) fuse to CD40L ectodomain
Van Craenenbroeck, A. H. *et al.* (2015)	Infl. Mo-DC	CliniMACS CD14 System	Cytomegalovirus (CMV) infection	pp65 mRNA electroporation
Coosemans, A. *et al.* (2013)	Infl. Mo-DC	CliniMACS CD14 System	Uterine tumor	WT-1 mRNA electroporation
Nava, S. *et al.* (2012)	Infl. Mo-DC	CliniMACS CD14 System	Glioblastoma	Tumor lysate
Iwami, K. *et al.* (2012)	Infl. Mo-DC	CliniMACS CD14 System	Malignant glioma	IL-13Rα2-derived peptides
Diez Valle, R. *et al.* (2012)	Infl. Mo-DC	CliniMACS CD14 System	Glioblastoma	Tumor lysate
Palma, M. *et al.* (2011)	Infl. Mo-DC	CliniMACS CD14 System	Chronic lymphocytic leukemia (CLL)	Apoptotic B cells
Alfaro, C. *et al.* (2011)	Infl. Mo-DC	CliniMACS CD14 System	Various metastatic solid tumors	Tumor lysate
Bornhäuser, M. *et al.* (2011)	Infl. Mo-DC for T cells	CliniMACS CD14 System	Chronic myeloid leukemia (CML)	Human leukocyte Ag-restricted peptides (from PR1, WT1, and/or B cell receptor–ABL)
Muthuswamy, R. *et al.* (2010)	Infl. Mo-DC	CliniMACS CD14 System	Melanoma	–
Van Tendeloo, V. *et al.* (2010)	Infl. Mo-DC	CliniMACS CD14 System	AML	WT-1 mRNA electroporation
Van Driessche, A. *et al.* (2009)	Infl. Mo-DC	CliniMACS CD14 System	AML	WT-1 mRNA electroporation
Di Nicola, M. *et al.* (2009)	Infl. Mo-DC	CliniMACS CD14 System	B cell lymphoma	Tumor specific IgH sequences
Adamson, L. *et al.* (2009)	Infl. Mo-DC	CliniMACS CD14 System	CLL	Apoptotic B cells
Schwaab, T. *et al.* (2009)	Infl. Mo-DC	CliniMACS CD14 System	Metastatic renal cell carcinoma (RCC)	Tumor lysate
Palma, M. *et al.* (2008)	Infl. Mo-DC	CliniMACS CD14 System	CLL	Apoptotic B cells
Curti, A. *et al.* (2007)	Infl. Mo-DC	CliniMACS CD14 System	Multiple myeloma	Tumor specific IgH sequences
Fuessel, S. *et al.* (2006)	Infl. Mo-DC	CliniMACS CD14 System	Prostate cancer	Prostate cancer associated peptides (prostein, survivin, PSMA, PSA, trp-p8)
Babatz, J. *et al.* (2006)	Infl. Mo-DC	CliniMACS CD14 System	Colorectal cancer, lung cancer	Carcinoembryonic antigen derived altered peptide
Mazzolini, G. *et al.* (2005)	Infl. Mo-DC	CliniMACS CD14 System	Metastatic gastrointestinal carcinoma	–
Höltl, L. *et al.* (2005)	Infl. Mo-DC	CliniMACS CD14 System	RCC	Tumor lysate

Infl. Mo-DC = inflammatory dendritic cells derived from peripheral blood monocytes;
Tol Mo-DC = tolerogenic dendritic cells derived from peripheral blood monocytes;
CBDC = dendritic cells derived from cord blood CD34$^+$ hematopoietic progenitors.



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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.
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