

Isolation of Virus-Specific T cells (VST)

The CliniMACS® Cytokine Capture System (IFN-gamma)

- Fast: in as little as 12 hours
- Easy, safe, and robust: cell manufacturing in a completely closed and automated system
- CE approved medical devices
- US MasterFile available

▶ miltenyibiotec.com

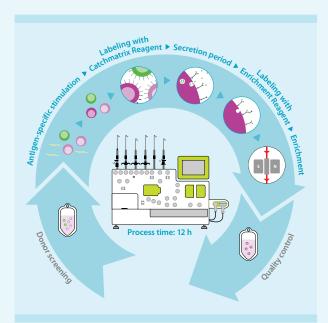


Figure 1: The CliniMACS Prodigy integrates and automates all critical steps of the CliniMACS Cytokine Capture System (IFN-gamma): From antigen-specific T cell stimulation to magnetic isolation and final formulation within 12 h total time.

Isolation of virus-specific T cells

Enjoy all the advantages of an automated manufacturing process with the combination of the CliniMACS Prodigy® and the CliniMACS® Cytokine Capture System (IFN-gamma).

- Highly convenient and standardized process in a closed and sterile system
- Isolation of virus-specific T cells within 12 h total time
- Minimal hands-on time (1 h)
- Simultaneous isolation of CD4+ and CD8+T cells
- No HLA-restriction
- · No in vitro expansion required

Antigen-specific T cell stimulation

During the manufacturing process, the automated antigen-specific stimulation of T cells can be performed with high quality and GMP-compliant reagents.

MACS® GMP PepTivator® Peptide Pools

MACS GMP PepTivator Peptide Pools are overlapping oligopeptides covering the complete sequence of a respective antigen.

- Ensure efficient in vitro stimulation of CD4+ and CD8+T cells
- Enable generation of multivirus-specific T cells
- Available for many virus specificities including CMV, AdV, EBV, BKV and for tumor antigens like WT-1 and NY-ESO-1¹

Check our website for more MACS GMP PepTivators: www.miltenyibiotec.com/MACSGMPPepTivator

TexMACS™ GMP Medium

- Optimized medium, recommended for the use in combination with the CliniMACS Cytokine Capture System (IFN-gamma).
- Serum-free application

Published clinical data

- Protective immunity and the control of established AdV^{2,3}, HCMV^{4,5}, EBV^{6,7} and BKV⁸ infections could be restored after hematopoietic stem cell transplantations (HSCT).
- Small doses (i.e. 150 T cells/kg body weight⁷) of adoptively transferred T cells have been shown to restore antiviral immunity post HSCT²⁻⁷.
- Recent publications report minimal side effects and no acute toxicity (e.g. increased incidence of GvHD) so far.^{2-5,7,9}

Would you like to learn more about the CliniMACS Prodigy and the CliniMACS Cytokine Capture System (IFN-gamma)? Contact your local representative and make an appointment: www.miltenyibiotec.com/local

References

- 1. Kayser, S. et al. (2015) Oncoimmunology 4: e1002723
- 2. Feuchtinger, T. et al. (2006) British Journal of Haematology 134: 64–76
- 3. Feucht, J. *et al.* (2015) Blood 125: 1986–94
- 4. Feuchtinger, T. et al. (2010) Blood 116: 4360-7
- 5. Peggs, K. S. *et al.* (2011) Clinical Infectious Diseases 52: 49–57
- 6. Moosmann, A. et al. (2010) Blood 115: 2960-70
- 7. Icheva, V. et al. (2013) J. clin. Oncol. 31: 39–48
- 8. Pello, O. M. *et al.* (2017) Eur J Haematol. 98: 632–634 9. Bollard, C. M. and Heslop, H. E. (2016) Blood 127: 3331–40

Miltenyi Biotec B.V. & Co. KG | Friedrich-Ebert-Straße 68 | 51429 Bergisch Gladbach | Germany | Phone +49 2204 8306-0 | Fax +49 2204 85197 macsde@miltenyi.com | www.miltenyibiotec.com

 $Miltenyi\ Biotec\ provides\ products\ and\ services\ worldwide.\ Visit\ \textbf{www.miltenyibiotec.com/local}\ to\ find\ your\ nearest\ Miltenyi\ Biotec\ contact.$

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. MACS® GMP Products are for research use and ex vivo cell culture 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 manufactured and tested under a quality system certified to ISO 13485 and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The CliniMACS® System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485.

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, CliniMACS, Prodigy, MACS, the Miltenyi Biotec logo, PepTivator, and TexMACS are registered trademarks or trademarks of Miltenyi Biotec and/or its affiliates in various countries worldwide. Copyright © 2020 Miltenyi Biotec and/or its affiliates. All rights reserved.