Selected references

CliniMACS Prodigy®

Scientific publications

**CAR T cells**

Partly automated GMP-generation of CAR T cells from critically small blood samples was feasible with a new stimulation protocol that leads to high functionality and expansion potential, balanced CD4/CD8 ratios and a conversion to a Tcm/Tscm phenotype.


The CliniMACS Prodigy device, tubing set TS520 and TCT software allow CAR T cells to be manufactured in a closed system at the treatment site without need for clean-room facilities and related infrastructure.


Automated cGMP-compliant process on the CliniMACS Prodigy reliably produces a therapeutic dose of anti-CD20 specific CAR T cells, starting from healthy or patient material and independent of operator or device.


Proof of principle in clinical-scale selection, stimulation, transduction and expansion of T cells using the automated closed CliniMACS Prodigy system.

**Virus- / Antigen-specific T cells**

Virus-specific T cell therapy implemented by the CliniMACS Prodigy CCS (IFN-gamma) System is an automated, fast, safe, and probably effective way to control resistant viral diseases after pediatric hematopoietic stem cell transplantation.


The findings reported here suggest that the IFN-γ CCS by the CliniMACS Prodigy is a simple and robust approach to produce CMV-CTLs, which may be applicable for the treatment of clinically urgent CMV-related diseases.


Use of products enriched with BKV-specific T cells generated using CliniMACS Prodigy and the Cytokine Capture System is safe and efficient in HLA-haploidentical HCT where BKV cystitis can be a serious complication.

The manufacturing process on the CliniMACS Prodigy® saved development and hands-on time due to its higher process integration and ability for unattended operation.

https://doi.org/10.3791/52808

The goal of this protocol is to manufacture pathogen-specific clinical-grade T cells using a bench-top, automated, second generation cell enrichment device that incorporates a closed cytokine capture system and does not require dedicated staff or use of a GMP facility.

https://doi.org/10.1111/vox.12291

The CCS protocol on CliniMACS Prodigy is unrestrictedly functional. It runs fully automatically beyond set-up and thus markedly reduces labor. The quality of the products generated is similar to products generated with CliniMACS Plus. The automatic system is thus suitable for routine clinical application.

CD34+ and CD45RA+ cells
https://doi.org/10.1016/j.jcyt.2018.01.006

The novel, closed, fully GMP-compatible process on CliniMACS Prodigy generates highly CD45RA-depleted cellular products predicted to be clinically meaningfully depleted of GVH reactivity.

http://www.bloodjournal.org/content/130/Suppl_1/3201

Results suggest that the CliniMACS Prodigy can be used for the routine clinical application of CD34 selection to HCT products.

https://doi.org/10.1084/jem.20151493

The CliniMACS Prodigy, an all-in-one cell-processing instrument, efficiently harvested viable mononuclear cells (MNCs) after protocol optimization, and viable CD34+ cells as well from frozen UCB cells.

https://doi.org/10.1186/s12967-016-0826-8

The CliniMACS Prodigy is shown to be suitable to perform CD34 selection to validation products met a pre-defined specification.

Stroncek, D. F. et al. (2016) Preliminary evaluation of a highly automated instrument for the selection of CD34+ cells from mobilized peripheral blood stem cell concentrates. Transfusion. 56: 511.
https://doi.org/10.1111/trf.13394

CD34+ cells can be effectively selected from mobilized PBSC concentrates with the CliniMACS Prodigy.

NK cells
https://doi.org/10.1089/hum.2017.157

Fully automated one-step separation of NK CD56+CD3- cells using the CliniMACS Prodigy is shown, starting with approximately 1.2 x 10⁶ leukocytes collected by small-scale lymphapheresis or from buffy coats.

https://doi.org/10.1016/j.jcyt.2015.03.611

The automation of the entire NK cell expansion process presented in the present report represents a novel procedure with the use of a single instrument that allows for the efficient production of clinical-grade NK effector cells.

Miscellaneous
https://doi.org/10.1016/j.jcyt.2017.05.009

Large-scale, GMP-compliant, autologous macrophage cell therapy product for the potential treatment of cirrhosis.

https://doi.org/10.1186/s13287-016-0467-0

Automatic manufacturing of a CD133+ cell product within few hours in compliance with EU guidelines for Good Manufacturing Practice.
Reviews


E-Journals


GMP – Stem cell isolation according to “Good Manufacturing Practice” and “Codes of Good Practice” (GFP) for material procurement. (2017) Reference and Translation Center for Cardiac Stem Cell Therapy (RTC). http://www.cardiac-stemcell-therapy.com/herstellung_en.php


Press releases


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 | www.miltenyibiotec.com

Miltenyi Biotec provides products and services worldwide. Visit 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.

The CliniMACS Product Line is 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.

In the US, the CliniMACS Prodigy™ T Cell Transduction Process is available for research use only.

CliniMACS Plus, CliniMACS Prodigy, and the MACS logo are registered trademarks or trademarks of Miltenyi Biotec GmbH and/or its affiliates in various countries worldwide. Copyright © 2018 Miltenyi Biotec GmbH and/or its affiliates. All rights reserved.