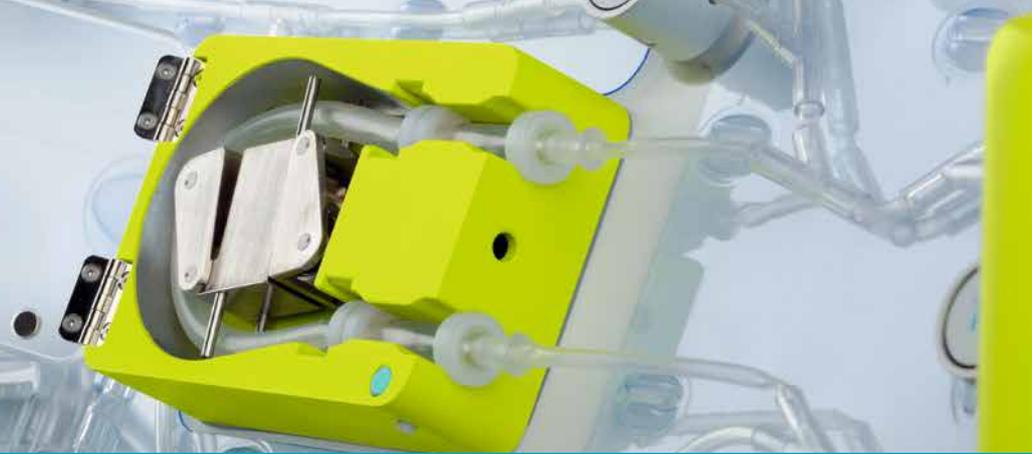




Miltenyi Biotec



Enrichment of human CD4⁺ and CD8⁺ antigen-specific T cells

Cytokine Capture System (IFN-gamma)

Application

Fully automated specific labeling and enrichment procedure for the purification of antigen-specific IFN- γ secreting CD4⁺ and CD8⁺ T cells. The specificity of enriched T cells is determined by the MACS[®] GMP PepTivator[®] Peptide Pools or lysate chosen for the CCS-IFN- γ enrichment. A growing repertoire of MACS GMP PepTivators of various viral antigens like Adv, BKV, EBV and HCMV are available. Additionally, using MACS GMP PepTivator NY-ESO-1 or WT1, cancer antigen specific T cells may also be isolated.

This application sheet provides an overview of the required and additional materials needed to perform the indicated process. It also provides an overview of the process workflow, the setup of the tubing set and literature references.

Specifications

Process name: CCS-IFN Enrichment

Process capacity: 1×10⁹ total white blood cells (WBC)

Sample volume: 50–150 mL

Elution volume: 7–8 mL

Process time: Approx. 12 hours*

*Process can be paused in between, but needs to be completed within 36 hours.

Materials required

CliniMACS [®] Products	Amount required
CliniMACS Prodigy [®]	1 unit
CliniMACS Cytokine Capture System (IFN-gamma)	1 set (2 vials)
CliniMACS Prodigy TS 500	1 set
CliniMACS PBS/EDTA Buffer	3 liters

MACS GMP Products**	Amount required
MACS GMP PepTivator HCMV pp65 or equivalent	1 vial
MACS GMP PepTivator Adv5 Hexon or equivalent	1 vial
MACS GMP PepTivator BKV LT or equivalent	1 vial
MACS GMP PepTivator BKV VP1 or equivalent	1 vial
MACS GMP PepTivator EBV Select or equivalent	1 vial
MACS GMP PepTivator EBV LMP2A or equivalent	1 vial
MACS GMP PepTivator EBV EBNA-1 or equivalent	1 vial
MACS GMP PepTivator EBV BZLF1 or equivalent	1 vial
MACS GMP PepTivator HPV-16-E6 or equivalent	1 vial
MACS GMP PepTivator HPV-16-E7 or equivalent	1 vial
MACS GMP PepTivator NY-ESO-1 or equivalent	1 vial
MACS GMP PepTivator WT-1 or equivalent	1 vial
TexMACS [™] GMP Medium	2 liters

Additional products	Amount required
Elution buffer, e.g., 0.9% sodium chloride solution	1000 mL
Human serum albumin (HSA) <ul style="list-style-type: none"> to be added to the CliniMACS PBS/EDTA Buffer to a final concentration of 0.5% (w/v) to be added to the Reservoir bag to a final concentration of 2.5% (w/v) filled with elution buffer (optional) 	
Appropriate syringes (5 mL, 10 mL, 30 mL) and hypodermic 20 gauge needles	
Sterile water	8 mL
600 mL transfer bag	1 bag
150 mL transfer bag	1 bag
Luer/Spike Interconnector	3 pieces
Equipment (optional)	
Uninterruptable power supply unit	
Sterile docking device	
Cell counter	

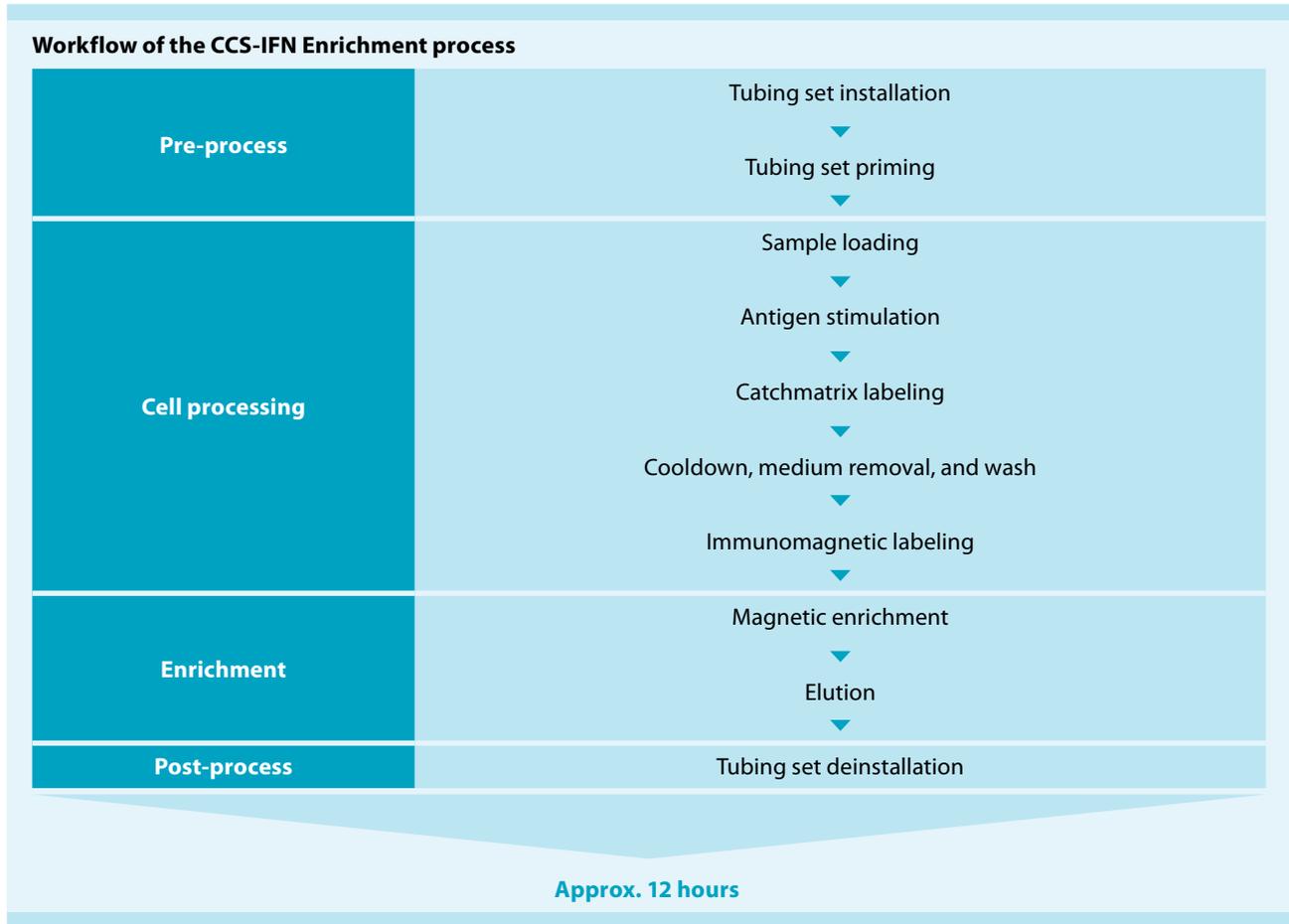
** Note: Up to five antigens can be used for the incubation of the antigen-specific T cells. If more than one antigen is used, the desired peptide pools need to be combined.

U.S. MasterFile available for the CliniMACS Prodigy CCS (IFN-gamma) System.

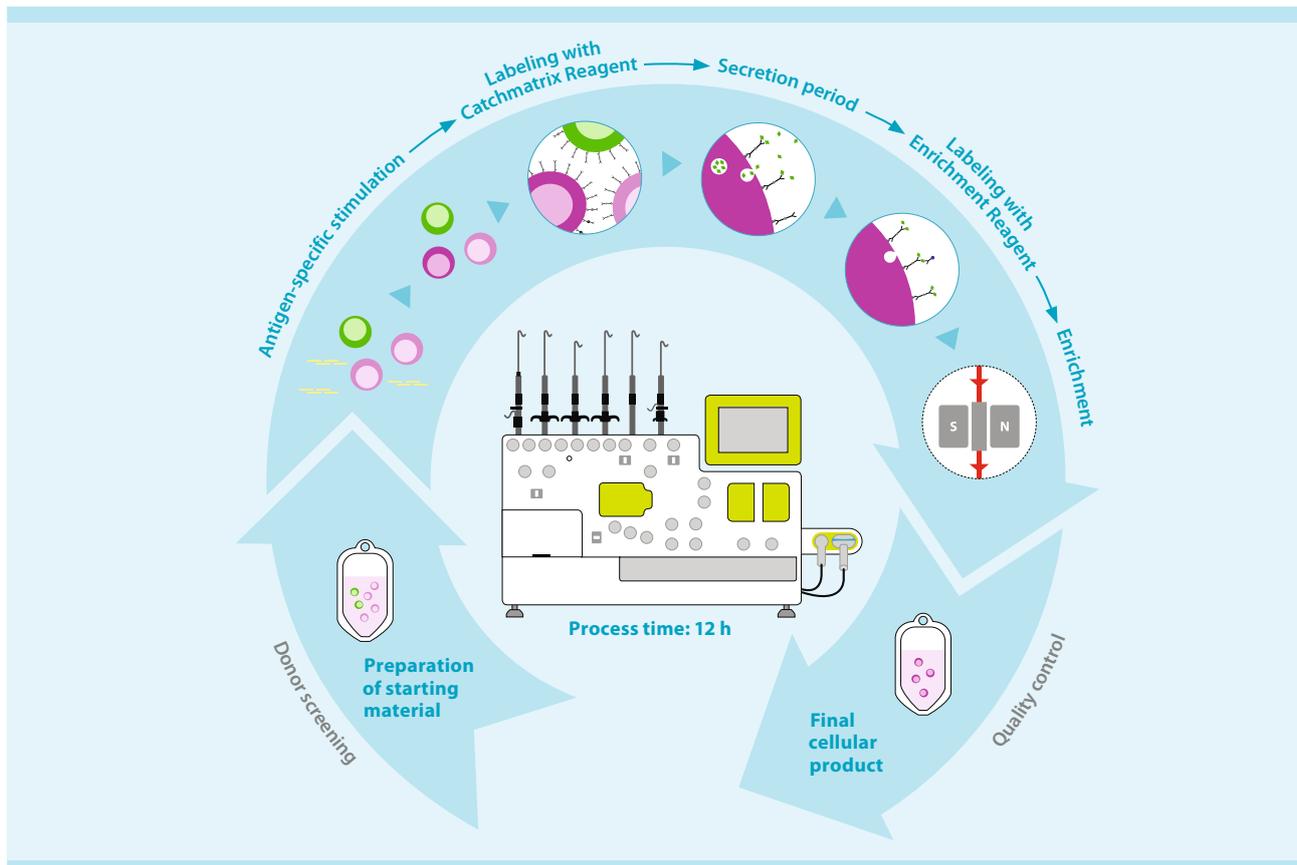
For availability in your country please contact your local representative.

For complete regulatory and legal notices please refer to the last page.

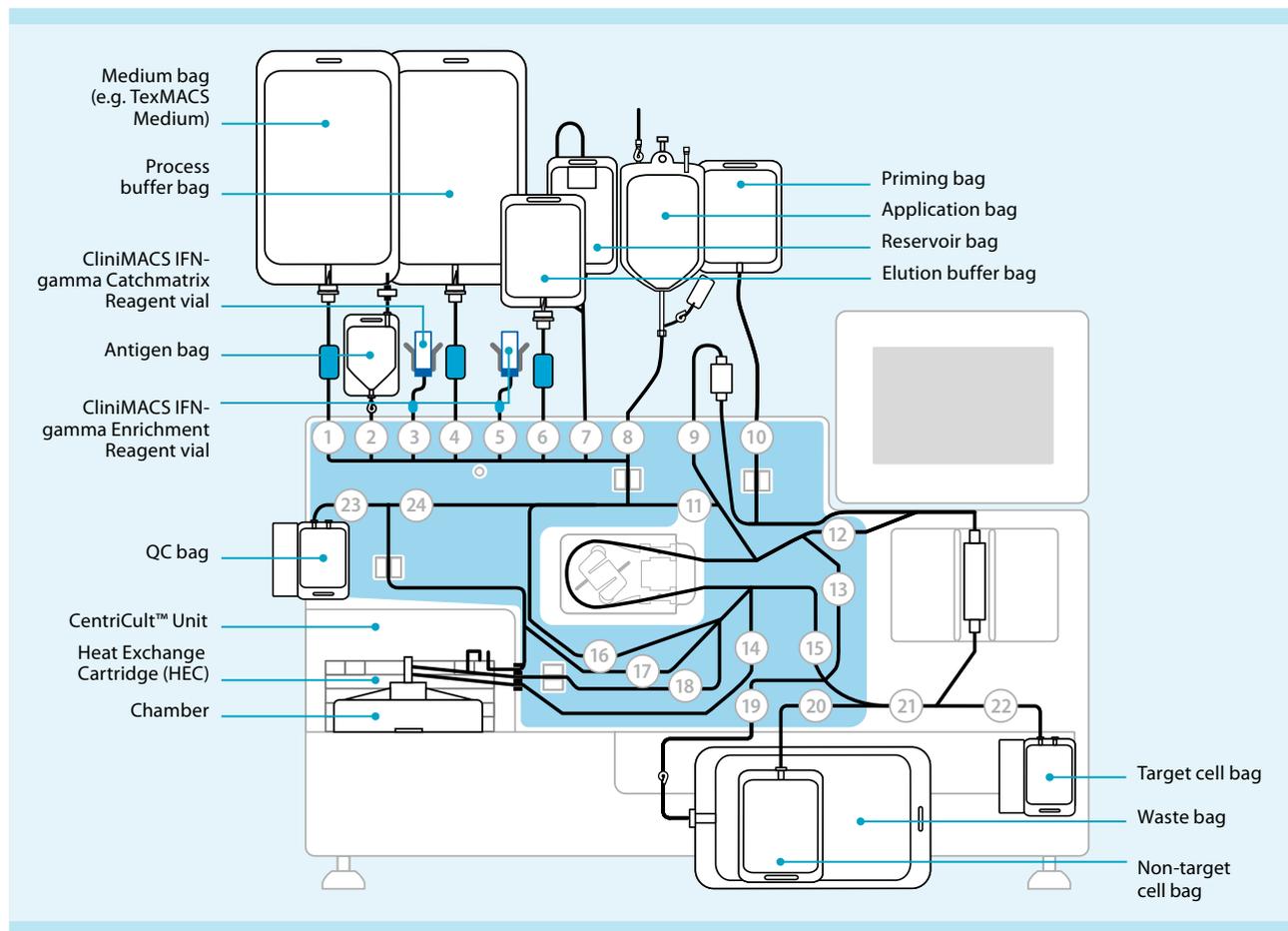
Process overview



Principle of the Cytokine Capture System



CliniMACS Prodigy® TS 500 setup



References

Performance data of the Cytokine Capture System (IFN-gamma) in combination with the CliniMACS Prodigy are shown in the following publications:

Automated isolation of primary antigen-specific T cells from donor lymphocyte concentrates: results of a feasibility exercise.

Bunos, M. *et al.* (2015) *Vox Sanguinis*, 109(4), 387–393.

Automated Cell Enrichment of Cytomegalovirus-specific T cells for Clinical Applications using the Cytokine-capture System.

Kumaresan, P. *et al.* (2015) *Journal of Visualized Experiments*, (104), e52808

Comparative Analysis of Clinical-Scale IFN-γ-Positive T-Cell Enrichment Using Partially and Fully Integrated Platforms.

Priesner, C. *et al.* (2016) *Frontiers in Immunology*, 7: 393.

Robust Production of Cytomegalovirus pp65-Specific T Cells Using a Fully Automated IFN-γ Cytokine Capture System.

Kim, N. *et al.* (2016) *Blood*, 128(22), 5739.

BKV-specific T cells in the treatment of severe refractory haemorrhagic cystitis after HLA-haploidentical haematopoietic cell transplantation.

Pello, O. *et al.* (2017) *European Journal Of Haematology*, 98(6), 632–634.

Early Experience With CliniMACS Prodigy CCS (IFN-gamma) System in Selection of Virus-specific T Cells From Third-party Donors for Pediatric Patients With Severe Viral Infections After Hematopoietic Stem Cell Transplantation.

Kállay, K. *et al.* (2017) *J Immunotherapy 1*: Epub ahead of print, Dec. 12.



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