



Miltenyi Biotec

Final formulation and filling of engineered cells

Basic Formulation TS 520-TCT/TCE

Application

The CliniMACS Prodigy® in combination with the CliniMACS® Formulation Unit allows the final formulation and filling of engineered T cells.

This application sheet provides an overview of the process, the specifications, required materials, and performance data. In addition, it elucidates the setup of the CliniMACS Prodigy Tubing Set (TS) 520 and the connection and setup of the Formulation Set.

The Basic Formulation TS 520-TCT/TCE is executed downstream to the T cell transduction (TCT) or the T cell engineering (TCE) process on the same TS 520 Tubing Set and an additionally connected Formulation Set.

Cells will be formulated in cryopreservation medium containing dimethyl sulfoxide (DMSO) in desired number of product bags at a pre-defined volume. Moreover, QC sample can be taken and delivered in a designated QC Bag. An Excel sheet is available to assist with calculating the process parameter input values for the desired filling requirements*.

The Basic Formulation TS 520-TCT/TCE is a research-use-only process capable of formulating engineered T cells for freezing after cell processing via the generic application TCT/TCE and is for evaluation purpose only.

* Excel sheet is unvalidated

Specifications

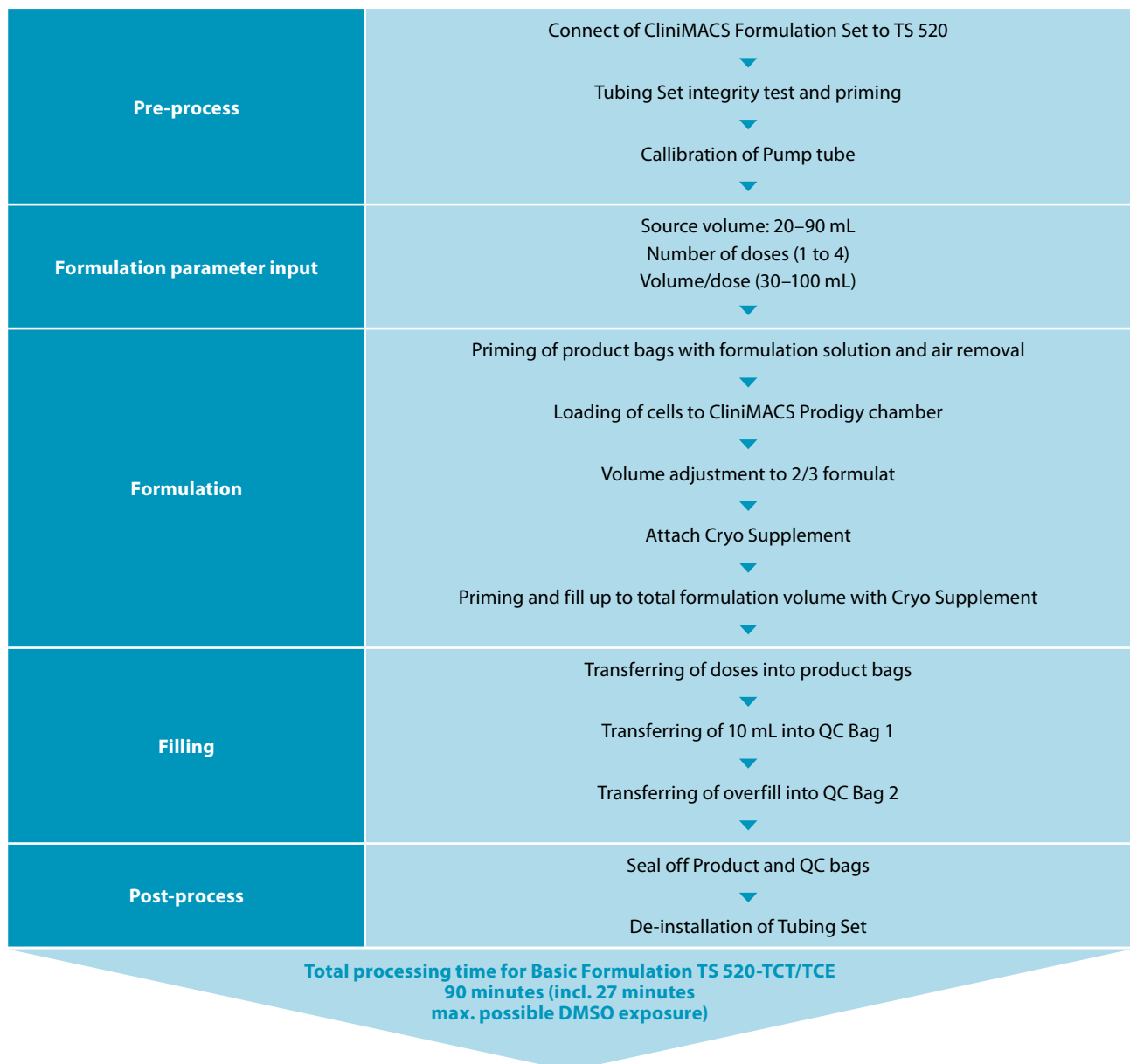
Process name:	Basic Formulation TS 520-TCT/TCE
Software requirement:	CliniMACS Prodigy Software version 1.4.30 or higher
Starting cell volume:	20–90 mL
Final product:	Engineered T cells formulated in cryopreservation solution and filled in Product Bags and one QC Bag
Final product volume:	Up to four filled Product Bags (30–100 mL) and one QC Bag (10 mL)
Process time:	90 minutes average; approx. 27 minutes max. possible DMSO exposure time

Material required

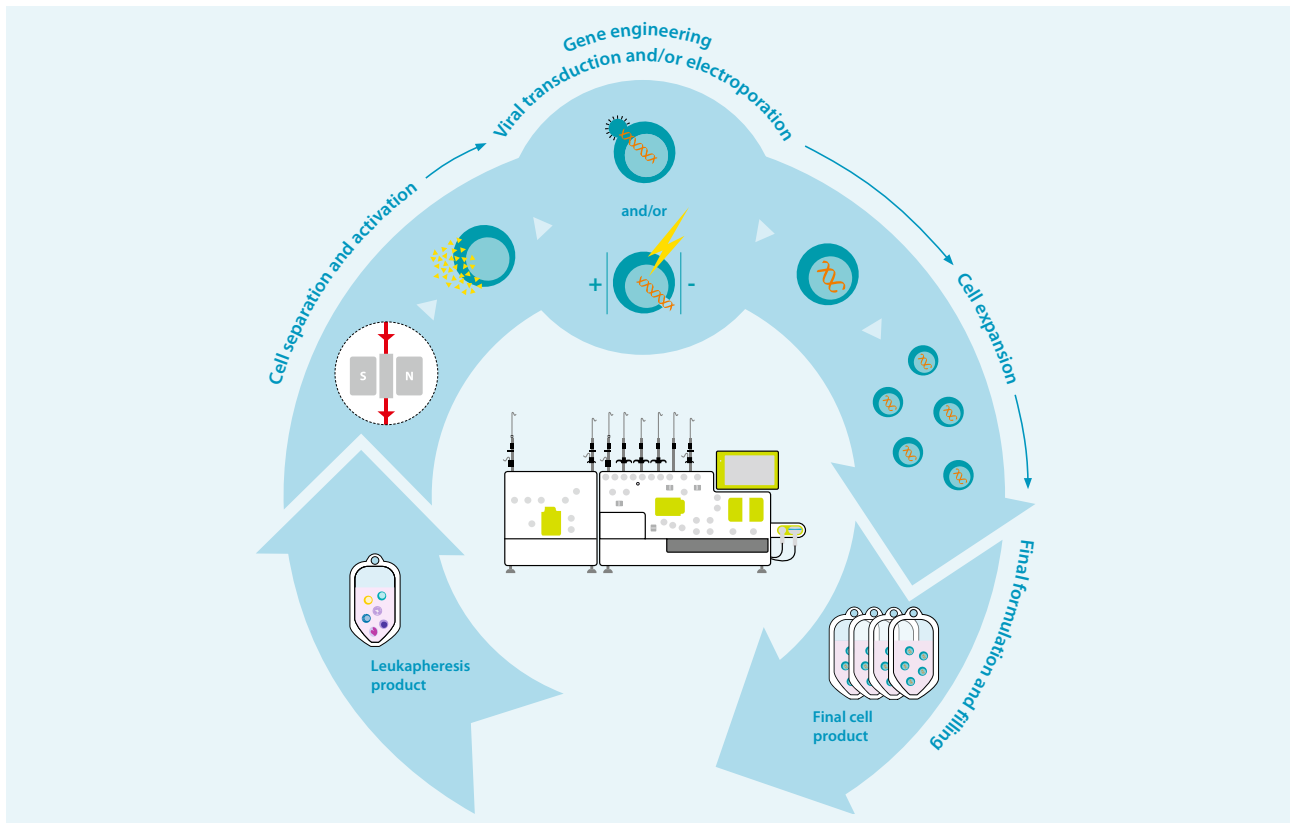
CliniMACS Materials	Amount required
CliniMACS Prodigy	1 unit
CliniMACS Prodigy Software 1.4.30 or higher	1
CliniMACS Formulation Unit	1 piece
CliniMACS Prodigy TS 520	1 piece (from previous process)
CliniMACS Formulation Set	1 set
CliniMACS Formulation Solution	1 L
CliniMACS Cryo Supplement 3x	450 mL

Additional materials	Amount required
Sterile welding device (e.g. Terumo)	1 piece

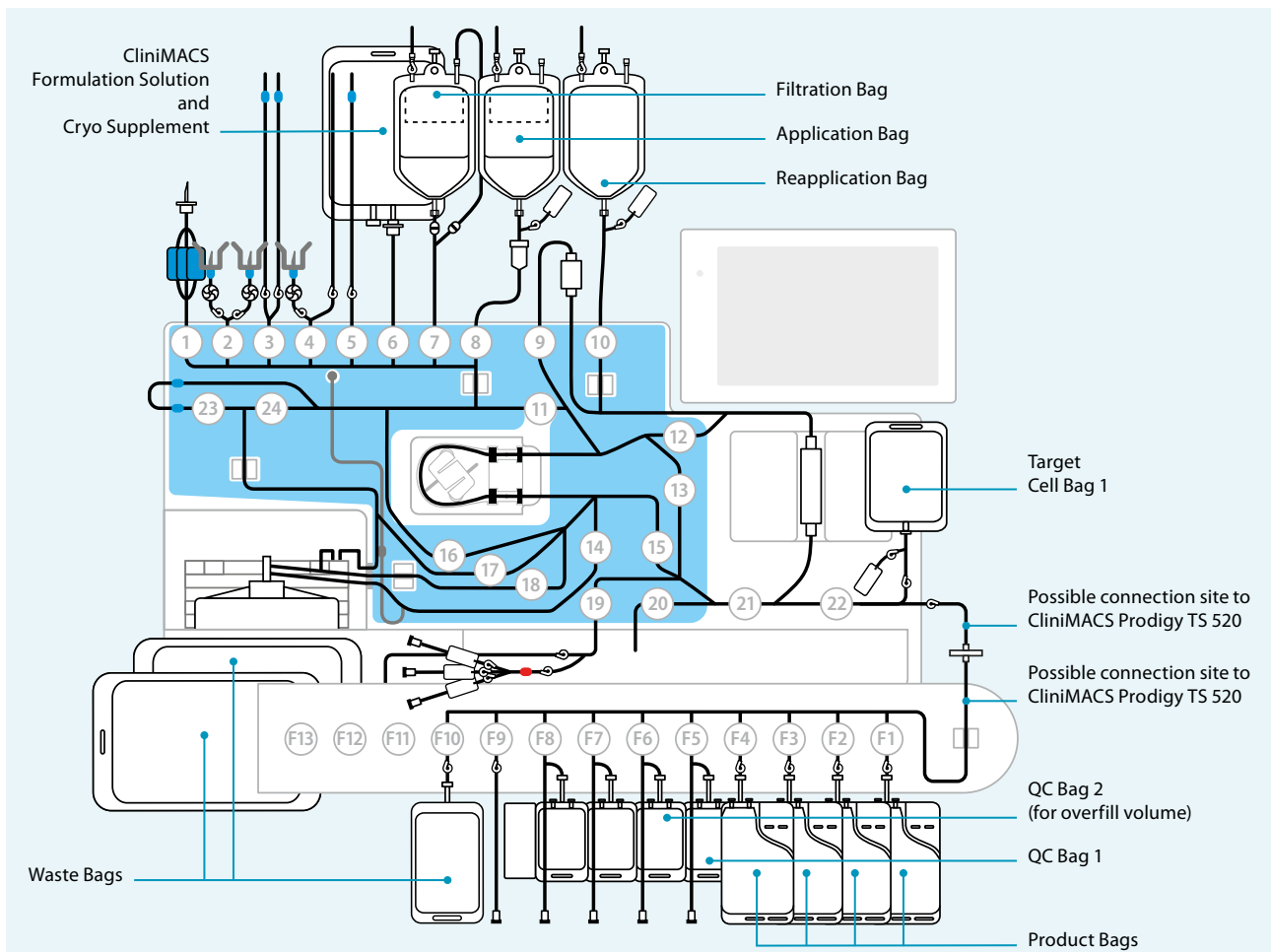
Process overview of Basic Formulation TS 520-TCT/TCE



Principle of the final formulation and filling of engineered T cells



CliniMACS Prodigy TS 520 and Formulation Set setup for final formulation and filling of engineered T cells



Performance data

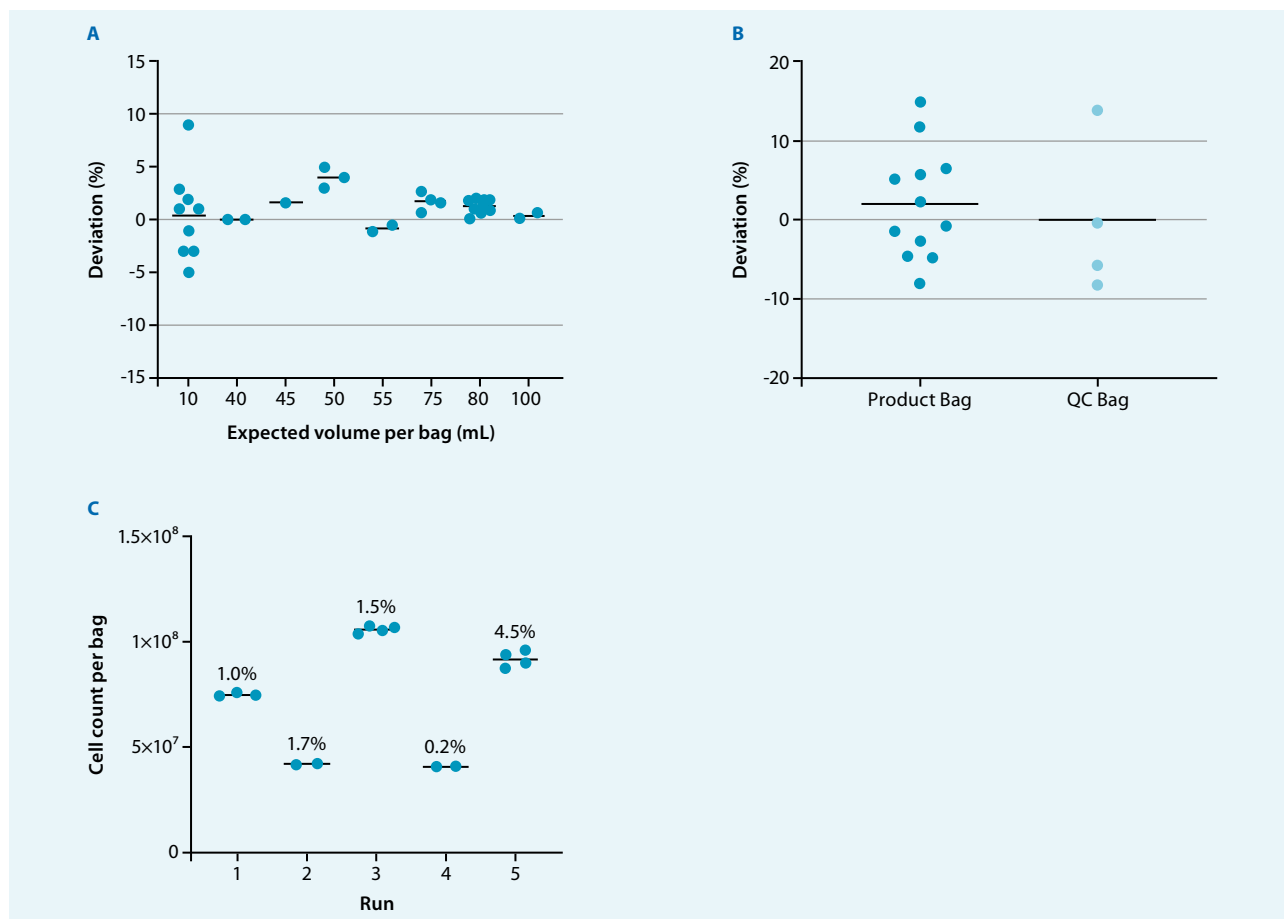


Figure 1: (A) Deviation of expected volume to measured volume per filled bag (PBS/EDTA buffer). (B) Deviation of expected cell number to measured cell number per filled bag (human T cells). (C) Final filled cell number per bag from five separate runs (human T cells after processing in CliniMACS Prodigy TCT process without cultivation). Shown values = % deviation from bag to bag in one run.



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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 Prodigy, MACS, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec and/or its affiliates in various countries worldwide. Excel is a trademark of the Microsoft group of companies. Copyright © 2022 Miltenyi Biotec and/or its affiliates. All rights reserved.