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 evalution 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 3×	450 mL

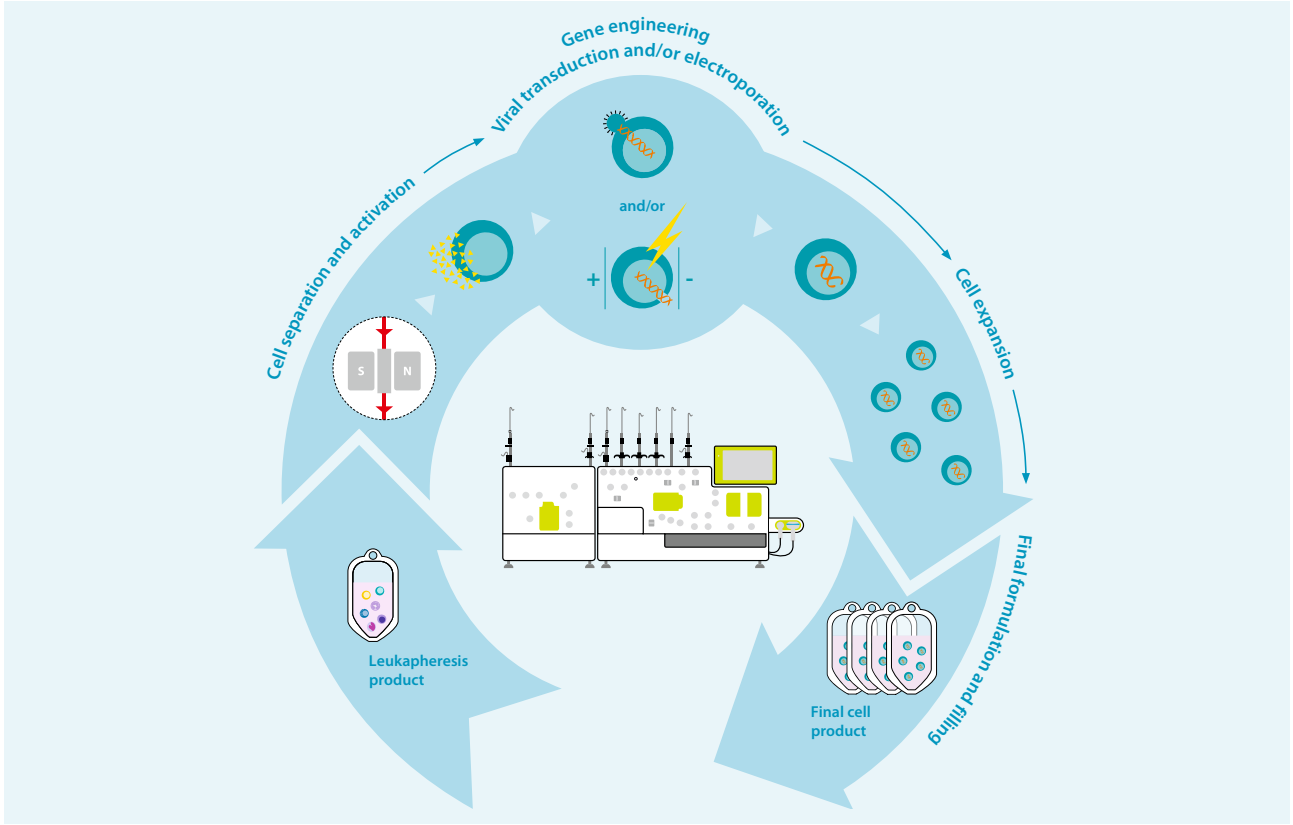
Additional materials	Amount required
Sterile welding device (e.g. Terumo)	1 piece

Process overview of Basic Formulation TS 520-TCT/TCE

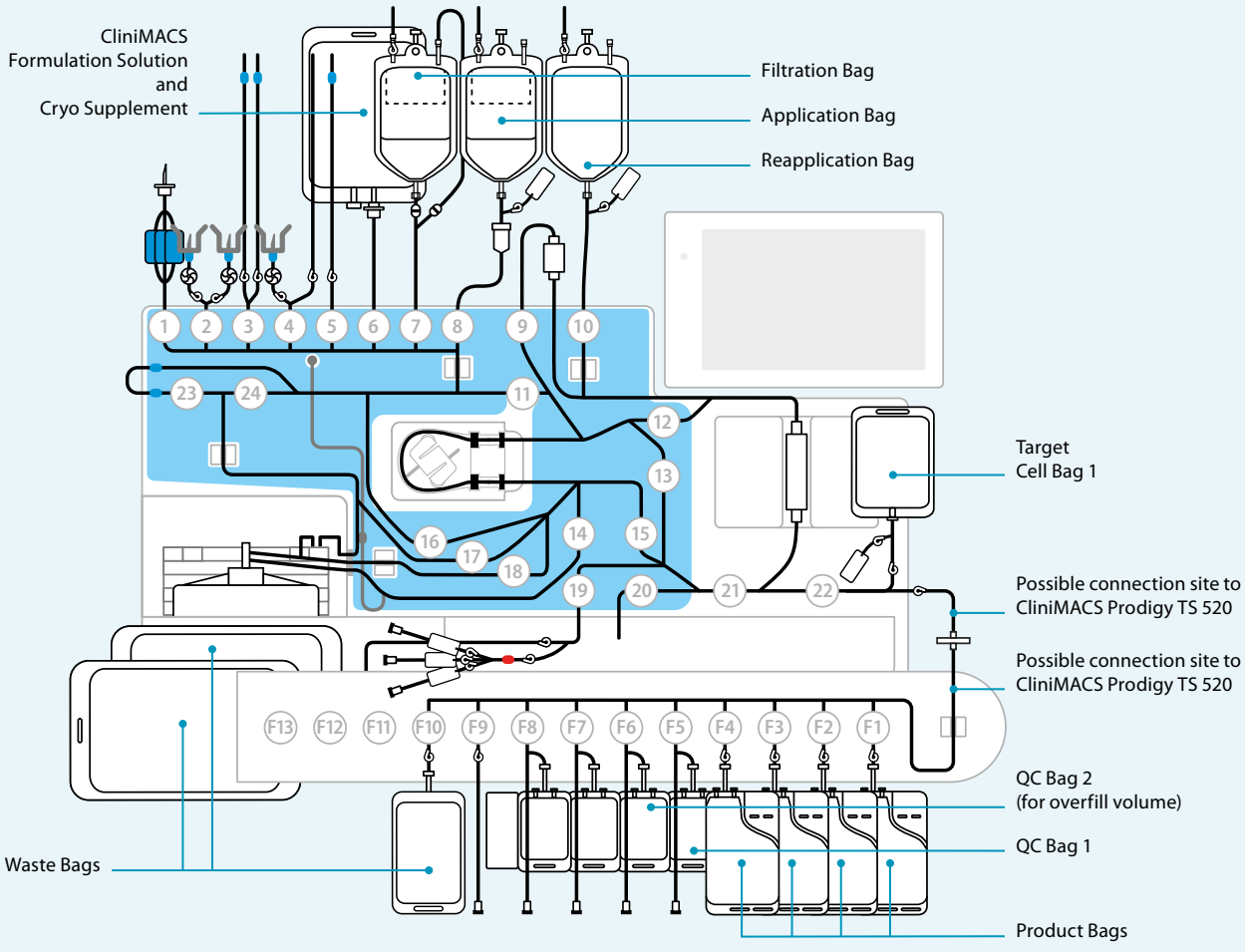
Pre-process	Connect of CliniMACS Formulation Set to TS 520 ▼ Tubing Set integrity test and priming ▼ Callibration of Pump tube ▼
Formulation parameter input	Source volume: 20–90 mL Number of doses (1 to 4) Volume/dose (30–100 mL) ▼
Formulation	Priming of product bags with formulation solution and air removal ▼ Loading of cells to CliniMACS Prodigy chamber ▼ Volume adjustment to 2/3 formulat ▼ Attach Cryo Supplement ▼ Priming and fill up to total formulation volume with Cryo Supplement ▼
Filling	Transferring of doses into product bags ▼ Transferring of 10 mL into QC Bag 1 ▼ Transferring of overfill into QC Bag 2 ▼
Post-process	Seal off Product and QC bags ▼ De-installation of Tubing Set

Total processing time for Basic Formulation TS 520-TCT/TCE
90 minutes (incl. 27 minutes
max. possible DMSO exposure)

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

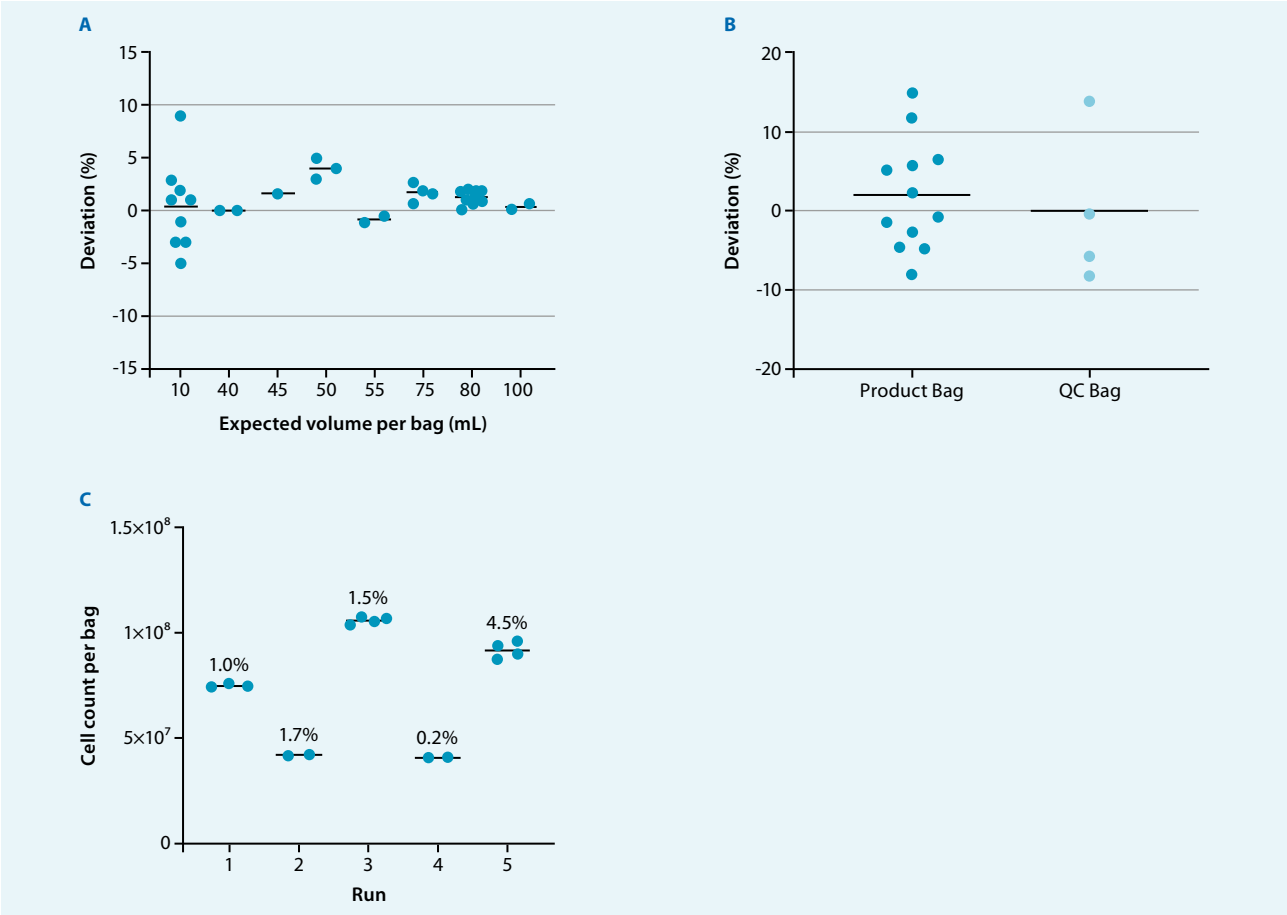


Figure 1: (A) Deviation of expected volume to measured volume per filled bag (PBS/EDTA buffer). (B) Deviation of expected cell number to measured cell number per filled bag (human T cells). (C) Final filled cell number per bag from five separate runs (human T cells after processing in CliniMACS Prodigy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

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