Miltenyi Biotec

MACS® GMP T Cell TransAct™ - Large Scale, CRR

Order no. 200-076-204

Contents

1. Description

Components	1 Vial containing 4 mL MACS® GMP T Cell TransAct™ – Large Scale, CRR
Capacity	The reagent is sufficient to activate and expand up to 4×10^8 enriched $CD3^+$ T cells in a maximal volume of 210 mL, when used at recommended titer of 1:52.5.
Product format	Polymeric nanomatrix conjugated to humanized CD3 and CD28 agonist supplied in phosphate buffered-saline (PBS), containing 0.03% poloxamer 188 and 5 g/L recombinant human serum albumin, pH 7.3–7.9
Endotoxin content	≤2 EU/vial as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
T cell proliferation assay	≥ 20% CD25/CD69 co-expression on day 2 ≥ 80% proliferating T cells on day 7
Sterility	Sterility is tested according to Ph. Eur.
Transport	At +2 °C to +8 °C (+36 °F to +46 °F)
Storage	Store protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Do not freeze.
Shelf life	The use-by date is indicated on the vial label.

Disclaimer

Caution: Clinical Research Reagent Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval.

Quality statement

MACS GMP Products are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The manufacturing and testing of this product is compliant with the requirements laid down in the Ph.Eur. Chapter 5.2.12.

No animal- or human-derived materials were used for the manufacture of this product, unless otherwise stated in the respective Certificate of Origin.

Background information

The MACS GMP T Cell TransAct – Large Scale, CRR has been designed to activate and expand enriched T cell populations, and is provided in a format directly applicable to the CliniMACS Prodigy. Polyclonal T cell expansion can be used when increased numbers of effector cells are required or when T cells are activated to enable gene modification.

Due to the nanoscale structure of the MACS GMP T Cell TransAct – Large Scale, CRR, it can be sterile filtered and excess reagent can be removed by centrifugation and following conventional supernatant replacement. This reagent is suitable for the use in automated culture Systems, such as the CliniMACS® Prodigy.

2. Applications

- MACS GMP T Cell TransAct – Large Scale, CRR is intended for the *in vitro* stimulation and expansion of human T cells from hematological cell populations (e.g. CD4 and CD8 enriched T cells).
- MACS GMP T Cell TransAct – Large Scale, CRR is intended for *in vitro* use only and is not intended for therapeutic use or direct infusion into humans.

3. Warnings and precautions

- The instructions for use must be followed.
- Do not inject or infuse the product directly into humans. Not for human applications.
- When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- For single use only. Do not re-use.
- Use only if vials are undamaged and sealed.
- Do not use after the use-by date indicated on the vial label.

33909/01 | Issued: 2020-09

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4. Instructions for use

4.1 Reagents and materials required

Product	Order No
CliniMACS® Prodigy TS 620 (CR)	170-076-620
MACS GMP® T Cell TransAct™ – Large Scale, CRR	200-076-204
TexMACS™ GMP Medium – 2000mL	170-076-306
MACS® GMP Recombinant Human IL-2, or equivalent	170-076-148
MACS® GMP Recombinant Human IL-7, or equivalent	170-076-111
MACS® GMP Recombinant Human IL-15, or equivalent	170-076-114

4.2 General notes

- Excess MACS GMP T Cell TransAct – Large Scale, CRR is removed by a washing step, e.g. centrifugation (at least 10-fold reduction) 2-3 days after initial stimulation. Performing a washing step earlier may result in reduced T cell proliferation.
- MACS GMP T Cell TransAct – Large Scale, CRR has been developed in combination with TexMACS™ GMP Medium and IL-7 + IL-15 or IL-2.
- MACS GMP T Cell TransAct – Large Scale, CRR can be used in combination with lentiviral transduction. It is recommended to transduce T cells with lentiviral vector one day after stimulation.
- Presence of residual EDTA (e.g. when using CliniMACS buffer) will hamper T cell stimulation. Ensure removal (i.e. over 200-fold reduction) of EDTA prior to T cell stimulation with MACS GMP T Cell TransAct – Large Scale, CRR e.g. via a washing step.

4.3 Protocol

4.3.1 Fresh or Frozen cell product with CliniMACS Prodigy System

For automated stimulation of fresh CD4 and CD8 enriched T cells with MACS GMP T Cell TransAct- Large Scale, CRR, a final dilution of 1:52.5 is recommended. Cells should be cultured at a concentration of 1.9×10^6 cells/mL. Stimulation of frozen cell product can be performed after thaw and automatic DMSO removal prior to CD4 and CD8 enrichment by the CliniMACS Prodigy T Cell Transduction - Large Scale process. Refer to CliniMACS Prodigy T Cell Transduction - Large Scale User manual for more information.

4.3.2 Manual preparation of fresh or frozen cell product

For stimulation of CD4 and CD8 enriched T cells from fresh or thawed cell product with MACS GMP T Cell TransAct – Large Scale, CRR, a final dilution of 1:52.5 is recommended. Cells should be cultured at a concentration of 1.0×10^6 cells/mL. When working with frozen material, it is recommended (before further downstream activities) to rapidly thaw the cells, wash away the freezing solution containing DMSO, resuspend the cells in culture medium at densities below 5×10^6 cells/mL and rest the cells overnight at +37 °C (+99 °F) and 5% CO_2, in culture medium.

5. Glossary of symbols

	Manufacturer		Use-by date
REF	Order number		Do not re-use
P/N	Part number		Phone
LOT	Batch code		Fax
	Consult instruction for use		E-mail
	Do not use if package is damaged.		Website

This data sheet and corresponding information as well as special protocols can be found under **www.miltenyibiotec.com/200-076-204.**

Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. Miltenyi Biotec B.V. & Co. KG makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the Technical Specifications of the products. Miltenyi Biotec B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

33909/01 | Issued: 2020-09