Miltenyi Biotec

MACS® GMP CD3-FITC REAlease Kit

Order no. 170-076-516

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1. Description

Components	1 vial containing 5 mL MACS GMP CD3-FITC REAlease (A) 1 vial containing 5 mL MACS GMP REAlease Release Reagent (B)
Product format	Both components are supplied in phosphate-buffered saline (PBS), pH 7.4, and stabilizer containing 0.1% recombinant Human Serum Albumin (HSA).
Clone	REAL104 for component (A)
Capacity	For labeling up to 1×10^9 total cells and optional release of label.
Source	Component A and B are recombinantly produced in cell lines
Endotoxin content	≤ 5 EU/mL as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Stain Index	For component (A): >2.5 as defined by $\frac{(\textit{mean positive cells}) - (\textit{mean negative cells})}{2 \times (\textit{standard deviation negative cells})}$
Sterility	Sterile. Manufactured aseptically, sterile filtered, filled aseptically.
Transport	At +2 °C to +8 °C (+36 °F to +46 °F)
Storage	Store MACS GMP CD3-FITC REAlease Kit protected from light at +2 °C to +8 °C (+36 °F to +46 °F) directly upon arrival.
Shelf life	The use-by-date is indicated on the vial label.

Disclaimer

MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative.

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.

The declaration of animal- or human-derived materials is given on the Certificate of Origin.

Background information

MACS GMP CD3-FITC REAlease consists of monoclonal recombinant releasable antibody against the CD3 antigen conjugated to fluorescein (FITC).

The releasable antibody recognizes the CD3 antigen (alternative names: CD3-epsilon, CD3e, Leu4, T-cell surface antigen T3/Leu-4 epsilon chain, T3E, IMD18, TCRE). CD3 is mainly expressed on T, NK and NKT cells.

2. Applications

Labeling and (optionally release of label) of CD3 antigen in human heterogeneous blood products.

3. Warnings and precautions

- The instructions for use must be followed.
- Do not inject or infuse the product directly into humans. Not for human application.
- 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 reuse.
- Use undamaged and sealed vials only.
- Do not use after the use-by date indicated on the vial label.

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4. Instructions for use

- For labeling cells and flow cytometric analysis the recommended antibody dilution for MACS GMP CD3-FITC REAlease is 1:11. Up to 1×10^9 total cells in 50 mL of CliniMACS PBS/EDTA Buffer are labeled with 1 vial of MACS GMP CD3-FITC REAlease.
- For optional release the recommended dilution for MACS GMP REAlease Reagent is 1:20. Up to 1×10^9 total cells can undergo release of label in 95 mL of CliniMACS PBS/EDTA Buffer with 1 vial of MACS GMP REAlease Reagent.
- For detailed instructions, please refer to the Special Protocol for MACS® GMP labeling of cells and preparation for cell sort on MACSQuant® Tyto® on our website.

5. Glossary of symbols

	Manufacturer	+2 °C +8 °C	Temperature limit
REF	Order number		Keep away from sunlight.
P/N	Part number		Do not use if package is damaged.
LOT	Batch code		Phone
	Consult instruction for use		Fax
	Use-by date		E-mail
STERILE A	Sterilized using aseptic processing techniques		Website

This data sheet and corresponding information as well as special protocols can be found under **www.miltenyibiotec.com/170-076-516.**

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.

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