Miltenyi Biotec

MACS® GMP CD8-FITC REAlease Kit

Order no. 170-076-515

Contents

1. **Description**
2. **Applications**
3. **Warnings and precautions**
4. **Instructions for use**
5. **Glossary of symbols**

1. Description

Components	1 vial containing 5 mL MACS GMP CD8-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	REAL100 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 CD8-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 CD8-FITC REAlease consists of monoclonal recombinant releasable antibody against the CD8 antigen conjugated to fluorescein (FITC). The releasable antibody recognizes the CD8 antigen (alternative names: Leu-2, CD8a, MAL, p32, Cd8b1, LY3, Lyt3, P37, Ly-2). CD8 is mainly expressed on T and NK cells.

2. Applications

Fluorescent labeling (and optional release of label) of CD8 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 CD8-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 CD8-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/170-076-515.**

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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