Miltenyi Biotec

MACS® GMP CD137-PE

Order no. 170-076-514

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1. Description

Components	1 vial containing 5 mL MACS® GMP CD137-PE
Product format	MACS GMP CD137-PE is supplied in phosphate-buffered saline (PBS), pH 7.4, and stabilizer containing 0.1% recombinant Human Serum Albumin (HSA).
Clone	4B4-1, mouse IgG1κ
Capacity	For labeling up to 1×10^9 total cells.
Source	Mouse hybridoma cells
Endotoxin content	≤5 EU/mL as determined by kinetic Limulus Amebocyte Lysate (LAL) assay (Pharmacopoeia Europaea (Ph. Eur.)).
Stain Index	>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 CD137-PE 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 CD137-PE consists of a mouse monoclonal antibody against the CD137 antigen conjugated to Phycoerythrin (PE).

This antibody recognizes the CD137 (4-1BB) antigen, a 30 kDa glycoprotein of the tumor necrosis factor (TNF) receptor superfamily. CD137 is mainly expressed on activated CD4 and CD8 T cells, activated B cells, and natural killer cells, but can also be found on resting monocytes and dendritic cells. As a costimulatory molecule it is involved in the activation and survival of CD4 or CD8 T cells, and NK cells. CD137 has been described to be a suitable marker for antigen-specific activation of human CD8 T cells, as it is not expressed on resting CD8 T cells and its expression is reliably induced after 24 hours of stimulation.

2. Applications

Fluorescent labeling of CD137 antigen on human cells.

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.

4. Instructions for use

- For labeling cells and flow cytometric analysis the recommended antibody dilution for MACS GMP CD137-PE 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 CD137-PE.
- 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.

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5. Glossary of symbols

	Manufacturer		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/170-076-514.**

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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Enrichment of $CD137^+$ cells:
The use of this product for isolating and culturing a population of $CD137^+$ tumor-reactive T cells from a sample of solid tumor tissue may be covered by one or more method claims in U.S. Patent Nos. 10,233,425, 10,900,019, controlled by the University of Pennsylvania and licensed to Miltenyi Biotec (Penn Patent Rights). The purchase of this product conveys to the buyer the limited, non-transferable, non-exclusive right under Penn Patent Rights to use the purchased amount of product in research and pre-clinical development conducted by the buyer (whether the buyer is an academic or for-profit entity). Within the scope of these Penn Patent Rights, the buyer may not use (a) this product, (b) its components, or (c) materials made using this product or its components, for any Clinical Use, and buyer may further not sell or transfer any materials made using this product or its components to a third party for Clinical Use. Clinical Use means any activity by a party directed to: (1) use of the product or its components for therapeutic, diagnostic or prophylactic purposes; or (2) use of the product or its components in connection with any clinical trials or similar clinical research programs. For information on obtaining a license to Penn Patent Rights for purposes other than research and pre-clinical development, contact Penn Center for Innovation, University of Pennsylvania, Email: pciinfo@pci.upenn.edu. Neither the name of the University of Pennsylvania nor the names of its contributors may be used to endorse or promote products derived from the use of this product without specific prior written permission from the University of Pennsylvania.

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