



Miltenyi Biotec

# CliniMACS® CD19 GMP MicroBeads

REF 170-070-129

## Description

### General information

Developed for the magnetic labeling of CD19 positive cells. To be used in combination with suitable products including but not limited to instruments, tubing sets, buffers.

### Content

**QTY** One vial contains 7.5 mL CliniMACS® CD19 GMP MicroBeads in a sterile solution.

### Composition

The vial contains 7.5 mL of a colloidal solution of iron-dextran beads conjugated to murine monoclonal CD19 antibody in PBS/EDTA buffer stabilized with Poloxamer 188 (0.03% w/v).

### Capacity

Up to  $5 \times 10^9$  target cells from up to  $40 \times 10^9$  total cells


### Endotoxins

The product is tested for endotoxins.

### Sterility

**STERILE A** Sterile. Manufactured aseptically, sterile filtered, filled aseptically.

### Storage

 The product is shipped refrigerated and must be stored at +2 °C to +8 °C (+35 °F to +46 °F) immediately after receipt. Do not freeze.

### Animal origin

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

## Precautions



National legislation and regulations must be followed. Any clinical application of the magnetically labeled cells is exclusively within the responsibility of the user. Regulations for the treatment of infectious material must be observed.

## Warnings



The CliniMACS GMP MicroBeads and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients.

The product is not recommended for use with patients known or suspected to have sensitivity against mouse immunoglobulins or iron-dextran.

Patients may develop human anti-mouse antibodies (HAMA).

When the magnetically labeled CD19 positive cells are infused or injected into patients, they may receive traces of murine antibody and iron-dextran.

Iron-dextran beads and/or murine antibodies may cause allergic or anaphylactic reactions in patients. Intensive care equipment and medication should be available.



Do not use after the use-by date indicated on the product label.



Do not use if package is damaged. Use product only if the vial is undamaged and sealed.

## Instructions for use



Use the content of one vial of CliniMACS CD19 GMP MicroBeads for the labeling of up to  $5 \times 10^9$  target cells from up to  $40 \times 10^9$  total cells.

All cell preparation and labeling steps must be performed at controlled room temperature (+19 °C to +25 °C [+67 °F to +77 °F]).

Work under sterile conditions.

Remove the reagent from the vial manually or use an automated process.

If a user manual for a specific application is available, refer to it for detailed information on the magnetic labeling procedure of the cells.








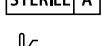





**Optional:** The efficiency of the labeling can be evaluated by flow cytometry or fluorescence microscopy using appropriate staining reagents. Propidium iodide or 7-AAD should be used for flow-cytometric exclusion of dead cells. Contact Miltenyi Biotec Technical Support for recommended flow cytometry analysis protocols and solutions.



Miltenyi Biotec B.V. & Co. KG

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## Glossary of symbols

	Consult instructions for use
	Caution
	Manufacturer
	Catalogue number
	Part number
	Batch code
	Contents of the packaging
	Sterilized using aseptic processing techniques
	Temperature limit
	Use-by date
	Do not use if package is damaged
	Phone
	Website

## Regulatory and legal notes

### Disclaimer

The CliniMACS GMP Products are for research use and *ex vivo* cell culture processing only, and are not intended for human *in vivo* applications. They 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.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use.

### 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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