CliniMACS® CD19 Reagent CR/GMP

Order no. 200-070-204

Miltenyi Biotec

CAUTION:
The product as part of the MACS GMP family is for *ex vivo* cell processing only and it is Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval. The product is not intended for human *in vivo* applications.

Contents

QTY One vial contains 7.5 mL of CliniMACS CD19 Reagent CR/GMP in a sterile solution.

Composition

Each 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).

Intended purpose

The CliniMACS CD19 Reagent CR/GMP is intended for the *in vitro* magnetic labeling for pre-separation or other processing of human CD19 positive cells from heterogeneous cell populations in combination with the CliniMACS System only, enabling further cultivation and/or genetic modification of the cells.

Side effects

When the magnetically labeled 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 must be available.

Precautions

⚠ Before use in human applications, the suitability of the target cells must be demonstrated regarding indication, quality, and quantity.

Further processing and use in clinical applications must be in accordance with national legislation and regulations. In the U.S., the FDA investigational use regulations must be observed.

Any clinical application of the separated cells is exclusively within the responsibility of the user.

The separation of cells using this product must be performed by trained operators only.

Operators using the product should have experience in the separation of cells from bone marrow or peripheral blood.

All materials that have come into contact with blood or blood products must be treated as infectious material. Regulations for the treatment of infectious material must be observed.

Warnings

⚠ The product is intended for *in vitro* use only. Not for intravenous infusion. Not for parenteral applications.

The magnetically labeled cells are 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).

See also "Side effects".

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

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

Do not re-use.

Storage

+2 °C +8 °C The product is shipped refrigerated and must be stored at +2 °C to +8 °C (+36 °F to +46 °F) immediately after receipt. Do not freeze.

Further information

The product is tested for endotoxins.

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

Animal Origin

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

Performance

For information regarding the application performance of the product as part of the CliniMACS System, refer to the corresponding CliniMACS user manual.

Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach | Germany

For U.S. distributed by:
Miltenyi Biotec Inc.
2303 Lindbergh Street
Auburn, CA 95602 | USA

Miltenyi Biotec Technical Support
+49 2204 8306-3803
technicalsupport@miltenyi.com
www.miltenyibiotec.com

33213/02 | Issued: 2023-10 | Page 1/2

Instructions for use

Use the complete contents of one vial of CliniMACS CD19 Reagent CR/GMP for cell labeling.

If a user manual is available, additional information on specific applications involving magnetic cell labeling procedures can be found there.

Regulatory and legal notes

Disclaimer & Quality Statement

CR/GMP products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.

CR/GMP products are designed, manufactured and tested under an ISO 13485 quality management system 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 in compliance with EP chapter 5.2.12 for "Raw materials of biological origin for the production of cell-based and gene therapy medicinal products".

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 Specification 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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