

GMP Collectra™ Human CD4 NanoSort Microbeads

Cat. No. GMP-MB004

● Product Information

Product	Size	Capacity
GMP Collectra™ Human CD4 NanoSort Microbeads	7.5 mL	Up to 1.2×10 ¹⁰ target cells from up to 4×10 ¹⁰ total cells

● Product Description

GMP Collectra™ Human CD4 NanoSort Microbeads are dextran-coated superparamagnetic iron oxide nanoparticles of which the surface is conjugated with recombinant monoclonal antibodies specific to human CD4. They are especially designed for positive selection or depletion of CD4⁺ cells.

ACROBiosystems performs rigorous quality control tests on our GMP-grade products (using fully validated equipment, processes, and test methods) to ensure that they meet stringent standards in terms of safety, activity, and inter-batch stability.

● Intended Purpose

GMP Collectra™ Human CD4 NanoSort Microbeads are designed for the positive selection or depletion of CD4⁺ T cells from fresh or cryopreserved peripheral blood mononuclear cells (PBMCs), leukapheresis products, or single-cell suspensions. CD4, also known as T4 and Leu3, is a member of the immunoglobulin superfamily expressed on the majority of thymocytes and on a subset of peripheral blood T lymphocytes (helper/inducer T cells). The magnetic Microbeads are conjugated with monoclonal antibodies targeting human CD4 protein, enabling CD4⁺ cells to be labeled with the specific antibodies and magnetic particles, and separated using separation equipment.

● Formulation

Supplied in PBS containing EDTA, rHSA (0.1% w/v) and Poloxamer 188(0.03% w/v).

● Storage

This product is supplied as a sterile liquid solution and shipped frozen on dry ice.

Stability upon receipt:

- **Long-term storage:** Upon receipt, store the product at -20 °C or below. When stored under the recommended conditions and maintained under sterile conditions, the product is stable for up to 3 years at -20°C under sterile conditions, not exceeding the labeled expiration date.
- **After thawing:** The product may be stored at 2–8 °C for up to 6 months after the first thaw. Do not use beyond the labeled expiration date.

Please protect from light and avoid repeated freeze-thaw cycles.

● Instructions for Use

- Label cells at room temperature for 30 minutes.
- Work under sterile conditions.
- The capacity given is for reference. Optimizing the process according to actual requirements is recommended.

● Warnings & Precautions

- **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).
- **Do not use after the expiry date** printed on the product label.
- **Do not use if package is damaged.** Use reagent only if the vial is undamaged and sealed.
- **Do not reuse.** Single-use only.
- When magnetically labeled cells are infused or injected into patients, they may receive traces of murine antibody and iron-dextran. These components may cause allergic or anaphylactic reactions. Intensive care equipment and medication must be available.
- 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.

● Contact Information

If you have any questions, please contact our technical support team at: TechSupport@acrobiosystems.com

● MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP-grade products are manufactured under a quality management system and in compliance with the following relevant guidelines: Ph. Eur. General Chapter 5.2.12 *Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products*; USP <92> *Growth Factors and Cytokines Used in Cell Therapy Manufacturing*; USP <1043> *Ancillary Materials for Cell, Gene, and Tissue-Engineered Products*; and ISO/TS 20399-1:2018, *Biotechnology — Ancillary Materials Present During the Production of Cellular Therapeutic Products*.

ACROBiosystems Quality Management System includes:

1. Designed in an ISO 9001:2015– and ISO 13485:2016-certified facility; manufactured and QC-tested under a GMP-compliant factory.
2. Animal-free materials.
3. Materials purchased from QA-approved suppliers.
4. Qualified personnel.
5. Quality-related documents reviewed and approved by QA.
6. Complete batch production and quality control records.
7. Equipment maintenance and calibration.
8. Validation of analytical procedures.
9. Stability studies conducted.
10. Comprehensive regulatory support files.

Request For Regulatory Support Files (RSF)

- **Disclaimer**

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