



Miltenyi Biotec

NK MACS GMP Medium (Phenol Red)

Order no. 170-076-356

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1. Description

Components	NK MACS GMP Basal Medium, 2,000 mL bag (Phenol Red) (# 170-076-354) NK MACS GMP Supplement 200×, 10 mL vial (# 170-100-058)
Main components	Salts, amino acids, vitamins, buffers
Human proteins	NK MACS GMP Basal Medium (Phenol Red) and NK MACS GMP Supplement do not contain human proteins. Human AB Serum has to be added to the final product prior to use. All risks arising from this component must be evaluated by the user before application of the target cell product to humans.
Specifications	For detailed specifications of the NK MACS GMP Basal Medium (Phenol Red) and the NK MACS GMP Supplement please refer to the respective Product Quality Certificate (PQC). Functionality assay: Expansion of NK cells from PBMC.
Total viable aerobic count	No microbial growth detectable.
Transport	NK MACS GMP Basal Medium (Phenol Red) at +2 °C to +8 °C (+36 °F to +46 °F), NK MACS GMP Supplement on dry ice.
Storage	NK MACS GMP Basal Medium (Phenol Red) protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Store NK MACS GMP Supplement at -20 °C (-4 °F).
Shelf life	The use-by date is indicated on the bag and vial label, respectively.

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, if applicable.

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

2. Applications

- NK MACS GMP Medium (Phenol Red) has been developed for NK cell culture and expansion from PBMCs or isolated NK cells. Expanded NK cells are fully functional and can be used in any downstream assay, e.g., killing assays.

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 bags only.
- ▲ Use undamaged and sealed vials only.
- ▲ Do not use after the use-by date indicated on the bag and vial label.

4. Instructions for use

Medium preparation:

1. For the preparation of the NK MACS GMP Medium (Phenol Red) thaw one vial of the NK MACS GMP Supplement 200×, 10 mL at +37 °C (+99 °F). Please shake the vial gently 2–3 times during thawing procedure.
2. Add the thawed NK MACS GMP Supplement 200×, 10 mL aseptically to one bag of NK MACS GMP Basal Medium (2,000 mL).













Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68, 51429 Bergisch Gladbach, Germany
☎ +49 2204 8306-0, ☎ +49 2204 85197
✉ macs@miltenyibiotec.de
🌐 www.miltenyibiotec.com

Miltenyi Biotec Inc.
2303 Lindbergh Street, Auburn, CA 95602, USA
☎ 800 FOR MACS, +1 530 888 8871, ☎ +1 877 591 1060
✉ macs@miltenyibiotec.com

3. Add 5% (v/v) AB serum aseptically to the medium before use. Mix well.

Note: Only prepare the amount of complete medium which is used within 3 weeks.
4. Store complete NK MACS GMP Medium (Phenol Red) protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Complete medium can be used up to 3 weeks when stored at +2 °C to +8 °C (+36 °F to +46 °F).
5. Prior to use, add 500 IU/mL Interleukin-2 (e.g., #170-076-148).

5. Glossary of symbols

	Manufacturer		Use-by date
	Order number		Protect from sunlight
	Part number		Phone
	Batch code		Fax
	Consult instruction for use		E-mail
	Do not use if package is damaged.		Website

This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/170-076-356.

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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