Miltenyi Biotec

MACS® GMP Tyto® Cartridge

Order no. 170-076-011

Contents

1. **Description**
2. **Applications**
3. **Warnings and precautions**
4. **Reagent and instrument requirements**
5. **Instructions for use**
6 **Glossary of symbols**

1. Description

Components	One box contains 1 MACS® GMP Tyto® Cartridge
Capacity	Minimum and maximum sample volume: 500 µL – 10 mL Maximum cell concentration: 5×10^7 cells/mL Chamber capacities: • Input chamber: 10 mL • Negative collection chamber: 10 mL • Positive collection chamber: 2 mL
Sterility	Sterile (Ethylene Oxide)
Transport	Room temperature (RT)
Storage	Store the MACS GMP Tyto Cartridge dry and protected from light at room temperature (RT).
Shelf life	The use-by date is indicated on the MACS GMP Tyto Cartridge carton-label and the MACS GMP Tyto Cartridge blister-label.

Disclaimer

MACS GMP Products are for research use and *ex vivo* cell culture 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.

Regulatory notes

The product is compliant with European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

The product is in scope of European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Important note for WEEE: Any product sent back for recycling must be free from contamination. If the product is suspected to be contaminated, a complete decontamination of the product has to be performed before sending back for recycling. In case of biological contamination where the product is expected to be infective, the product is not to be recycled but treatment and disposal of the product as biohazardous waste must be conducted according local regulations.

2. Applications

The sterile, closed, and disposable MACS GMP Tyto Cartridge has been developed for the use with the MACSQuant Tyto Cell Sorter. Its proprietary design enables cells to be aseptically administered and removed. Once a cartridge is loaded into the MACSQuant Tyto Cell Sorter, cell samples are driven with low, positive pressure through a sorting microchip. There, cells are optically analyzed/interrogated by passing three laser spots and sorted by a mechanical sort valve. After sorting, positive and negative cell populations can be removed from the cartridge for further downstream applications.

3. Warnings and precautions

- ▲ The instructions for use must be followed
- ▲ 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.
- ▲ Use undamaged and sealed MACS GMP Tyto Cartridges only.
- ▲ Do not use if any leakages of the MACS GMP Tyto Cartridge is observed during priming or loading cartridge.
- ▲ Do not overfill the MACS GMP Tyto Cartridge.
- ▲ Do not invert the MACS GMP Tyto Cartridge before sorting.
- ▲ Aseptic working procedures must be applied for the unpacking and loading of the MACS GMP Tyto Cartridge before inserting the cartridge into the MACSQuant Tyto Cell Sorter.
- ▲ All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious materials must be observed.
- ▲ Do not store blood, blood fractions or cell fractions in the MACS GMP Tyto Cartridge.
- ▲ For single use only. Do not reuse.

33895/04 | Issued: 2022-06

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

- ▲ Do not use after the use-by date indicated on the MACS GMP Tyto Cartridge carton-label and the MACS GMP Tyto Cartridge blister-label.
- ▲ Apply cell suspension onto a 20 µm nylon mesh filter after sort.

4. Reagent and instrument requirements

- MACSQuant Tyto Cell Sorter (# 130-103-931)
- MACS GMP Tyto Cartridge (#170-076-011)
- MACS GMP PBS/$MgCl_2$ Buffer (# 170-076-155)
- MACS GMP Tytonase (20× Stock solution) (# 170-076-210)
- Human serum albumin (HSA) as supplement to MACS GMP PBS/$MgCl_2$ Buffer, final concentration 0.5%
- 20 µm filter, e.g. Pre-Seperation Filter 20 µm (# 130-101-812)
- 10 mL syringe with Luer-Lock tip
- Extra long pipet tips

5. Instructions for use

For detailed instructions on MACS GMP labeling of cells, preparation of MACS GMP Tyto Running Buffer, loading and retrieval of cells into and from the MACS GMP Tyto Cartridge as well as evaluation and analysis of labeling and sorting performance, please refer to the special protocol "Protocol for MACS® GMP labeling of cells and preparation for cell sort on MACSQuant® Tyto® Cell Sorter" located on the Miltenyi Biotec website.

6. Glossary of symbols

	Manufacturer	UK CA	UKCA mark
REF	Order number	CE	CE mark (RoHS)
P/N	Part number		Waste electrical and electronic equipment
LOT	Batch code		Phone
	Consult instruction for use		Fax
	Do not use if package is damaged.		E-mail
	Use-by date		Website
	Do not re-use		

This data sheet and corresponding information can be found under **www.miltenyibiotec.com/170-076-011**.

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.

MACS and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec B.V. & Co. KG and/or its affiliates in various countries worldwide.

Copyright © 2022 Miltenyi Biotec and/or its affiliates. All rights reserved.

33895/04 | Issued: 2022-06

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