

Instructions for Use

NutriStor[®] Cold Storage Solution

An Animal Component-free (ACF), Chemically Defined, Protein-free, Cold Storage Solution for Cells



2976141-000-02



SARTORIUS

Animal component-free (ACF), chemically defined, protein-free,
cold storage solution for cells

REF

05-F3F3001-1A
05-F3F3001-1B
05-F3F-3001-1D
05-F3F3001-1-0.25L
05-F3F3001-1-0.5L



2–8 °C

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1 Product Description

NutriStor® Cold Storage Solution is an optimized serum-free, protein-free, animal component-free (ACF), salt-based, chemically defined formulation.

It is designed for the short-term storage of cells (up to 7 days, recommended 3–4 days), in cold temperatures (2–8 °C) by providing a stable, defined and protective environment. NutriStor® Cold Storage Solution enables the storage and maintenance of cells without the need of repeated freeze-thaw cycles and multiple centrifugation steps. It has been tested on a variety of cells (including peripheral blood mononuclear cells (PBMCs), chimeric antigen receptor T-cells (CAR-Ts) and mesenchymal stem cells (MSCs)) from various sources and ensures high viability, recovery rates and performance after cold storage.

NutriStor® Cold Storage Solution is optimally formulated and does not contain any antibiotics, antimycotics, hormones, growth factors, serum or proteins.

2 Features

- An all-in-one bottle, ready-to-use solution
- Chemically defined, serum-free, protein-free, animal component-free
- Maintains high viability and recovery of cells.
- Maintains the unique features of cells (e. g. multipotency of hMSCs).
- Diminishes temperature-induced cell stress responses that take place during cold storage of cells.
- Does not contain any antibiotics, antimycotics, hormones or growth factors
- Sterile

3 Intended Use and Safety

- For research or further manufacturing use only
- Not intended for human in vivo applications
- Not intended for in vitro diagnostics use or use as medical device
- Do not use the medium if visible particles and | or precipitate are observed.
- Do not use the medium beyond the expiration date indicated on the product label.
- Do not use if there is any package leak or any exposure to environmental conditions. The sterility of the product might be compromised.
- Maintain aseptic work conditions.
- Refer to the Material Safety Data Sheet (MSDS) for hazard information.

4 Cell Type Applications

- Human Mesenchymal Stem Cells (hMSCs), from various sources:
 - Bone Marrow (BM-MSCs)
 - Adipose Tissue (AT-MSCs)
 - Umbilical Cord Tissue (UC-MSCs)
 - Dental Pulp Tissue (DP-MSCs)
- Human Peripheral Blood Mononuclear Cells (PBMCs)
- T Cells (including CAR-Ts)

5 Storage and Stability

- Store at 2–8 °C.
- Protect from direct light.
- Shelf life: Refer to product label for expiration date.

6 Instructions for Use

NOTE Keep NutriStor® Cold Storage Solution at 2–8 °C until use.

Cold Storage Procedure

1. To maintain aseptic work conditions, wipe the outer packaging with a cloth moistened in 70 % Ethanol | 70 % Isopropanol before opening the vial.
2. Centrifuge the cells to obtain a cell pellet, at 300–400 xg for 4–5 minutes, then aseptically decant supernatant without affecting the cell pellet. The centrifugation conditions are according to the cell type used (e. g. hMSCs at 300–400 xg for 4–5 minutes, PBMCs at 150 xg for 8 minutes).
3. Suspend the pellet in cold (2–8 °C) NutriStor® Cold Storage Solution and mix thoroughly.
4. Transfer the cells to the desired storage vials (e. g. cryovials, 1–2 mL/vial).

NOTE The maximal cell concentrations that were tested in the storage vials:

- hMSCs: $\sim 5 \times 10^6$ cells/mL (2 mL/vial)
 - Healthy PBMCs: $\sim 5 \times 10^6$ cells/mL (2 mL/vial)
 - Patient's CAR-Ts: $\sim 25 \times 10^6$ cells/mL (1 mL/vial)
5. Store the vials at 2–8 °C until required. Vials can be stored up to 7 days, 3–4 days are recommended.

NOTE NutriStor® Cold Storage Solution can be used for storage of an adherent culture. In this case the culture medium should be replaced with NutriStor® Cold Storage Solution before storing at 2–8 °C. After completion of the storage at 2–8 °C, remove the NutriStor® Cold Storage Solution and replace it with culture medium (no wash step is required). Incubate cells at 37 °C in a CO₂ incubator for 24 hours prior to additional in-vitro tests.

Post Storage Procedure

The cells in the vials are ready to use and further procedures are application dependent.

- We recommend performing viable cells count to evaluate the cell number, viability, and yield.
- Using PBMCs, 24 hours recovery in culture medium (e. g. 4Cell Nutri-T Medium) is recommended prior to additional in-vitro tests.
- Optional: Centrifuge the cells prior to further cell seeding.
 - The centrifugation conditions are according to the cell type used (e. g. hMSCs at 300–400 xg for 4–5 minutes, PBMCs at 150 xg for 8 minutes).

Culture the cells according to the recommended seeding density and the common practice.

7 Quality Control

Each lot is visually examined and tested for pH, osmolality, sterility, endotoxins and mycoplasma as well as performance (using BM-MSCs). For full specifications see the lot specific Certificate of Analysis (CoA).

8 Quality Assurance

- Manufactured under ISO 13485 QMS and ISO 9001 and in compliance with applicable cGMP guidelines
- Manufactured under controlled environments and processes in accordance with:
 - ISO 13408 – Aseptic Processing of Health Care Products
 - ISO 14644 – Cleanrooms and associated controlled environments



Manufacturer

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Product Label Symbols



Indicates the manufacturer's catalogue number so that the product can be identified.



Indicates the manufacturer's batch code so that the batch or lot can be identified.

NOTE Synonyms for batch code are lot number and batch number.



Indicates the date after which the product is **not** to be used.



Indicates the temperature limits to which the product can be safely exposed.



Indicates a product that has been manufactured using accepted aseptic techniques.



Indicates the need for the user to consult the instructions for use.

9 Related Products

| Product | Cat. No. |
|----------------------------------|-----------------|
| MSC NutriStem® XF Medium | 05-200-1 |
| MSC NutriStem® XF Supplement Mix | 05-201-1 |
| 4Cell® Nutri-T Medium | 05-11F2001-1 |
| 4 Cell® Nutri-T GMP Medium | 05-F3F2111-1 |

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The information and figures contained in these instructions correspond to the version date specified below.

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