

GM501 EmbryoStore**Material included in the package:**

- 1 vial of 10 ml EmbryoStore Freeze
- 1 vial of 10 ml EmbryoStore Thaw 1
- 1 vial of 10 ml EmbryoStore Thaw 2
- 1 vial of 10 ml EmbryoStore Thaw 3

Material not included in the package:

- Sterile pipettes
- Centre Well dishes/4-Well dishes
- Freezing straws
- Automatic freezer
- Freezing tank with liquid nitrogen (LN₂)
- Water bath (able to hold 37°C)
- LAF-bench (ISO Class 5)
- Microscope
- Labtimer

Product code:*EmbryoStore Kit*

- 4 EMF01_P_KIT1

EmbryoStore Freeze

- 4 EMF01_P_F

EmbryoStore Thaw 1

- 4 EMF01_P_T1

EmbryoStore Thaw 2

- 4 EMF01_P_T2

EmbryoStore Thaw 3

- 4 EMF01_P_T3

Composition:

- GM501 EmbryoStore are propanediol based cryopreservation media which also contain PBS, sucrose and human serum albumin (14-15 g/Liter).
- GM501 EmbryoStore do not contain antibiotics.

Intended use/Intended users:

- GM501 EmbryoStore is a set of ready-to-use media for freezing and thawing human embryos between 2PN and 4 cell stage.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- Ensure all media are well mixed before use.

Freezing

1. Using a sterile pipette place 1 ml of EmbryoStore Freeze freezing medium in a centre well dish (at room temperature).
2. Add the embryos (2PN stage) to the freezing medium and allow them to settle for about 30 seconds. Caution: because of density differences the embryos tend to float upwards and shrink like raisins.
3. Load the embryos in straws leaving about 1/5 air in the straws.
4. Seal the straws and label with name, date and number of embryos.
5. Start freezing programme within 5-10 minutes. Below is an example of a freezing protocol.

	Temperature range	Freezing rate	Time
Phase 1	RT to +4°C	-10°C/min.	2 min.
Phase 2	+4°C to -6°C	-2°C/min.	5 min.
Phase 3	-6°C (autoseeding)	0°C/min.	10 min.
Phase 4	-6°C to -30°C	-0,3°C/min.	80 min.
Phase 5	-30°C to -196°C	-199°C/min.	1 min.

Thawing

6. Place in a 4-well culture dish 1 ml of each EmbryoStore Thaw thawing solution (1, 2 & 3). This leaves 1 well empty to retrieve the frozen/thawed embryos.
7. Prepare a water bath at 37°C to thaw the straws. Prepare a 1 ml tuberculin-syringe by filling it with 0.8 ml of air first followed by 0.2 ml of EmbryoStore Thaw 1 medium.
8. Remove the straws from liquid nitrogen and leave at room temperature for about 5 seconds.
9. Submerge the straw in the water bath at 37°C for another 5 seconds (ensure no frozen part remains in the straw).
10. Empty the straw by opening both sides of the straw (above the empty well) and blowing the contents of the syringe through the straw.
11. Retrieve the embryos using a microscope and place them in EmbryoStore Thaw 1 thawing solution.
12. Transfer the embryos to EmbryoStore Thaw 2 thawing solution after 3-5 minutes.
13. After another 3-5 minutes the embryos are transferred to EmbryoStore Thaw 3 thawing solution. Leave for a further 3-5 minutes before proceeding.
14. At the final stage the embryos are transferred in IVF culture medium for washing and further culture.

Product specifications and quality control:

- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- The MSDS for the media are available upon request and can also be downloaded from our website.
- GM501 EmbryoStore is manufactured and tested according to the following specifications:

pH 7.20 - 7.40

Sterility sterile - SAL 10⁻³ (Sterility Assurance Level)

Endotoxins (EU/ml) < 0.25

MEA (Blastocysts after 96h in %) ≥ 80

Osmolality EmbryoStore Thaw 3 (mOsm/kg) 530-560

Precautions and warnings:









- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot totally be excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin, manufactured to European Pharmacopoeia specifications by established processes.
- Therefore, handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (ISO 5 environment, e.g. LAF-bench) to avoid possible contamination.
- Only for the intended use.

Pre-use checks:

- Do not use the product if bottle, seal of the container or package is opened or defect when the product is delivered.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

Storage instructions and stability:

- The shelf life is 18 month from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun) light.
- The product can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C
- Do not use after expiry date.

	Consult instructions for use		Do not use if package is damaged
	Temperature limitation		Sterilized using aseptic processing techniques (filtration)
	Lot number		Use by
	Catalogue number		Keep away from sunlight

For technical support:

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