

GM501 VitriStore Freeze GM501 VitriStore Thaw

VitriStore Freeze Kit (4 VF_KIT1)

Material included in the package:

- 1 vial of 5 ml VitriStore Pre-vitrification Medium
- 1 vial of 1 ml VitriStore Freeze Medium 1
- 1 vial of 1 ml VitriStore Freeze Medium 2

VitriStore Thaw Kit (4 VT_KIT1)

Material included in the package:

- 1 vial of 5 ml VitriStore Thaw Medium 1
- 1 vial of 1 ml VitriStore Thaw Medium 2
- 1 vial of 1 ml VitriStore Thaw Medium 3
- 1 vial of 1 ml VitriStore Thaw Medium 4

The media should be used in the order displayed above.

Material not included in the package:

- 4-well dishes
- Freezing tank with liquid nitrogen
- Water bath (able to hold 37°C)
- Attenuated pipettes
- Forceps
- Vitrifaction device
- LAF-bench (ISO Class 5)
- Microscope
- Labtimer

Product code:

VitriStore Freeze Kit

- 4 VF_KIT1

VitriStore Thaw Kit

- 4 VT_KIT1

Composition:

- GM501 VitriStore Freeze/VitriStore Thaw are DMSO/ethylene glycol based vitrification media that also contain PBS, sucrose, Ficoll and human serum albumin (10-20 g/liter).

- GM501 VitriStore Freeze/VitriStore Thaw do not contain antibiotics.

Intended use/Intended users:

- GM501 VitriStore Freeze/VitriStore Thaw are a set of ready-to-use media for vitrification and thawing of human embryos.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- Ensure all media are well mixed before use. We strongly advice to read through all the steps of the vitrification/warming procedure before starting the procedure.

Preliminary steps

- In a 4-well dish fill the first well with 300 µl of VitriStore Pre-vitrification Medium, the second with VitriStore Freeze Medium 1 and the third with VitriStore Freeze Medium 2. Next open as many packs of vitrification devices as will be required for the vitrification step. Conveniently place the separate parts of the vitrification device on the workbench for easy access later in the procedure.

Freezing preparation

Transfer the embryos from the blastocyst cell culture medium into each of the VitriStore Freeze solutions using the following scheme:

Stage	VitriStore Pre-vitri-fication	VitriStore Freeze 1	VitriStore Freeze 2	Temperature
Early Blastocyst, Morulae	2 min.	2 min.	30 sec.	Room temperature
Blastocyst-expanded Bl.	2 min.	3 min.	30 sec.	37°C
Blastocyst-expanded Bl + artificial shrinkage*	2 min.	2 min.	30 sec.	Room temperature

**Before starting the vitrification procedure, in order to reduce the negative effect of the blastocoel, expanded blastocysts should be collapsed by reducing artificially with a glass pipette the volume of the blastocoel. (Vanderzwalmen et. al., 2002; Sonet al., 2003; Hiraoka, 2004)*

Vitrification

1. Using an attenuated pipette or an equally suitable device, deposit maximum 2 blastocysts in a volume of approximately 0.3 µl of VitriStore Freeze 2 in the gutter of the tip of the vitrification straw.
2. Place the vitrification straw in the outer sheath and seal it as indicated in the instructions for use of the vitrification device.
3. Plunge the sealed device into the liquid nitrogen.

Thawing

1. Remove the vitrification straw from the outer sheath as indicated in the instructions for use of the vitrification device.
2. Immediately plunge the vitrification straw into pre-heated VitriStore Thaw Medium 1 (37°C) and leave in Thawing 1 Medium for 3 minutes.
3. Transfer into VitriStore Thaw Medium 2 (37°C) and leave in this medium for 2 minutes.
4. Transfer into VitriStore Thaw Medium 3 (37°C) and leave in this medium for 2 minutes.
5. Finally transfer into VitriStore Thaw Medium 4 (37°C) and wash for at least 1 minute.
6. Transfer into blastocyst culture medium for continued cell culture.

GM501 VitriStore Freeze/VitriStore Thaw and Embryoculture:

- GM501 VitriStore Freeze/VitriStore Thaw can be used in combination with GM501 Media (Washing- and IVF-Media) before freezing and after thawing.

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 VitriStore Freeze/VitriStore Thaw are manufactured and tested according to the following specifications:

pH	7.20-7.40
Osmolality (mOsm/kg)	270-290 (VitriStore Freeze PV) 805-850 (VitriStore Thaw 1) 535-565 (VitriStore Thaw 2) 405-435 (VitriStore Thaw 3) 270-290 (VitriStore Thaw 4)
Sterility	sterile - SAL 10^{-3} (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96h in %)	≥ 80

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 (LAF-bench ISO Class 5) to avoid possible contamination.
- Only for the intended use.
- The long term safety of embryo vitrification on children born following this procedure is unknown.

Pre-use checks:

- Do not use the product if seal of the container 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.



Consult instructions for use



Do not use if package is damaged



Temperature limitation



Sterilized using aseptic processing techniques (filtration)



Lot number



Use by



Keep away from sunlight



Catalogue number

Storage instructions and stability:

- The shelf life is 12 month from time of manufacture.
- Store between 2-8°C.
- Keep away from sunlight.
- 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.
- Do not freeze before use.

For technical support:



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