

**Material included in the package:**

- 1 vial of 20 ml SpermStore

**Material not included in the package:**

- Sperm freezing straws
- Sterile pipettes
- Freezing tank with liquid nitrogen
- LAF-bench (ISO Class 5)

**Product code:**

- 4 SCP-20

**Composition:**

- GM501 SpermStore is a ready-to-use HEPES buffered cryopreservation medium which also contains physiologic salts, glycine, dextrose monohydrate, lactate, glycerol, sucrose and human serum albumin (3.95 g/Liter) to protect sperm from damage due to the freezing procedure.

**Intended use/Intended users:**

- GM501 SpermStore is a medium for freezing human sperm including epididymal or testicular sperm.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

**GM501 SpermStore and Sperm preparation:**

- GM501 SpermStore can be used in combination with GM501 Gradient.

**Instructions for use:**

- Ensure all media are well mixed before use.

**Before freezing:**

- In case of very low sperm concentrations it is advisable to concentrate the sperm before freezing. This may increase sperm quality after thawing and will reduce the number of straws to be frozen.
- GM501 SpermStore needs to be warmed to room temperature before use to avoid cold-shock.

**Freezing:**

1. Allow the semen to liquefy at room temperature for 30 minutes.
2. Mix 1 ml of sperm with 0.7 ml of GM501 SpermStore. Add the medium in drops while gently swirling.
3. Leave the mixture for 10 minutes at room temperature for equilibration.
4. Aspirate the sample/medium mixture into the freezing straws, leaving approximately 1.5 cm of air at the end of the straws.
5. Seal the straws.
6. Dry off individually with a lint-free wipe.
7. Shake to move the air-bubble to the centre of the straw.
8. Freeze vertically for 15 minutes, just above the level of the liquid nitrogen.
9. Store in liquid nitrogen.

**Thawing:**

1. Remove as many straws as required from the liquid nitrogen.
2. Place the samples in tap water for 5 minutes.
3. Cut off the end of the straw, place the open end inside a container (e.g. a test tube) and tap the straw lightly against the side of the container to allow complete evacuation of the mixture.

4. Dilute the thawed sperm in a suitable insemination medium (at least 3 ml per 0.5 ml semen) and mix thoroughly.
5. Centrifuge for 15 minutes at 300-350 x g.
6. Resuspend pellet in a suitable insemination medium.

**After thawing:**

- If necessary, use sperm preparation techniques after thawing the semen to eliminate dead sperm cells and debris.

**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 SpermStore is manufactured and tested according to the following specifications:

pH	7.20-7.90 (Release criteria: 7.20-7.60)
----	---

Sterility	sterile - SAL 10 <sup>-3</sup> (Sterility Assurance Level)
-----------	--

Endotoxins (EU/ml)	< 0.25
--------------------	--------

Sperm survival test (%)	≥ 80
	survival after 4 hours exposure of untreated semen to the test medium

**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.
- Product does not contain any antibiotics. Always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) 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 sunlight.
- After opening the container do not use the product longer than 7 days.
- Do not use after expiry date.
- Stable after transport (max. 5 days) at elevated temperature ( $\leq 37^{\circ}\text{C}$ )

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

**For technical support:**

GYNEMED Medizinprodukte GmbH & Co. KG,  
 Lübecker Straße 9, 23738 Lensahn - Germany  
**Phone:** +49 (0) 4363 90 32 90 - **Fax:** +49 (0) 4363 90 32 91-9  
**E-mail:** info@gynemed.de - **http:** //www.gynemed.de

