Spermtec® Cryo

PRODUCT INFORMATION
SpermTec® Cryo

Catalogue no.	
STC-5	5 ml
STC-10	10 ml
STC-20	20 ml

Application
SpermTec® Cryo is a four times concentrated ready-to-use HEPES buffered cryopreservation medium for freezing human semen at ultra low temperatures (-196°C) in liquid nitrogen.

Composition
SpermTec® Cryo is a HEPES buffered freezing medium for human sperm. It contains 26,7% glycerol in order to protect the sperm from damage due to the freezing process and it contains 0,4% HSA.

Material not included
- Sperm freezing straws (e.g. CBS high security sperm straws)
- Freezing tank with liquid nitrogen
- LAF Bench (ISO Class 5)
- Sterile pipettes

Quality Control
- pH: 7,20 – 7,90
  (Release criteria: 7,20 – 7,60)
- Endotoxin: < 0,25 EU/ml
- Sterility: sterile, SAL 10^{-3}
- Sperm Survival Test ≥ 80% survival
  (after 4h exposure of untreated sperm to the test medium)
- Chemical composition
- Use of Ph Eur or USP grade products if available
- Not MEA tested
- Certificate of Analysis available upon request

Sterility
SpermTec® Cryo is sterilized by sterile filtration.

STERILE A

Precautions and warnings
Always work under hygienic conditions (LAF-bench, ISO Class 5) to avoid possible contamination.
Always wear protective clothing when working with specimens.
Handle specimens as if capable of transmitting HIV or hepatitis.

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 be completely 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.

The above media do not contain antibiotics.

Pre-use checks
Do not use if the seal on the bottle is broken or open when the product is delivered.
Do not use if the product shows any signs of microbial contamination or becomes cloudy.

Storage Conditions
Store refrigerated (2º - 8ºC).
Do not use after expiry date.
Do not freeze before use.
Keep away from sunlight.
After opening the container, do not use the product longer than 7 days. Sterile conditions must be maintained and product must be stored at 2º - 8º C.
Stable after transport (up to 5 days) at elevated temperatures (≤ 37°C).

Technical Support

Gynotec

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CE
0344

Distributor:

Spermtec® Cryo

Instructions for use

Sperm Preparation
SpermTec® Cryo can be used in combination with SpermTec® ready-to-use gradients.

Before freezing
It is recommended to concentrate the sperm before freezing in case of very low sperm concentrations. This may increase the sperm quality after thawing and will reduce the number of straws to be frozen.

After thawing
In case needed, use sperm preparation techniques after thawing to eliminate dead sperm cells and debris. Dilute the concentrated sperm in a washing medium or any other medium to your use.

Method

Ensure that all media is well mixed before use.

Freezing
- Allow the semen to liquefy at room temperature for 30 minutes.
- Add 1 part SpermTec® Cryo to 3 parts semen.
- Add SpermTec® Cryo dropwise while gently swirling the sample.
- Caution: To avoid cold-shock make sure SpermTec® Cryo is at room temperature.
- Leave the sample for 10 minutes at room temperature for equilibration.
- Suck the mixture into the freezing straws, leaving approximately 1.5 cm of air at the end of the straw. Seal the straws.
- Dry each straw with a linen free cloth and shake in order to move the air bubble to the centre of the straw.
- Freeze the straws vertically just above the liquid nitrogen level for 15 minutes
- Store the straws in liquid nitrogen.

Thawing
- Retrieve the required straws from the liquid nitrogen.
- Place the straws in tap water for 5 minutes.
- Cut off the end of the straw, place open end inside a container (e.g. test tube) and tap straw against the side of the container in order to allow complete evacuation of the mixture into the container.
- Dilute the concentrated sperm in a suitable insemination medium, at least 3 ml per 0.5 ml semen, mix thoroughly.
- Centrifuge at 300-350g for 15 minutes.
- Resuspend the pellet in a suitable insemination medium (e.g. SpermTec® Wash)

SYMBOL	MEANING
REF	Catalogue number
LOT	Batch code
	Use by (expiry date)
2 8	Temperature limitations
STERILE A	Sterile medical device processed using aseptic technique (filtration)
	Consult instructions for use
CE	CE mark

Bibliography
1 Mahadevan M, Trounson AD. Effect of cryoprotective media and dilution methods on the preservation of human spermatozoa. Andrologia, 1983; 15: 355-66.
2 Mahadevan M, Trounson AD, Leeton JF. Succesful use of human semen cryobanking for in vitro fertilization, Fertil Steril, 1983; 15: 355-66.
3 Brotherton J. Cryopreservation of human semen. Archives of Andrology, 1990; 25: 181-95.
4 Kobayashi T, Kaneko S, Hara I, Park YJ, et al. Concentrating human sperm before cryopreservation. Andrologia, 1991; 23: 25-8.
5 Graczykowski JW, Siegel MS. Influence of sperm processing on the fertilizing capacity and recovery of motile sperm from thawed human semen. Archives of Andrology, 1991; 26: 155-61.