



Instructions for the Use of Sperm Freezing

(Catalogue Numbers: LGSF-005, LGSF-020)

PRECAUTIONS AND WARNINGS

Sperm Freezing contains small amounts of Human Serum Albumin (HSA). The Human Serum Albumin used in the preparation of this product has been heated at 60°C for ten hours.

Caution: 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 totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time that Sperm Freezing is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Always wear protective clothing when handling specimens.

Always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid possible contamination.

Only for the intended use. Do not resterilize.

GENERAL INFORMATION

Medium for freezing human sperm.

Indications for Use

For freezing human sperm including epididymal or testicular sperm.

Storage and Shelf Life

Store at 2-8°C and protected from light. Eighteen (18) months from the date of production when stored unopened at 2-8°C and protected from light. Do not freeze before use. Keep away from light. Discard unused medium within 7 days after opening. Do not use after expiry date.

Disposal Consideration

Treat or dispose of waste material in accordance with all local state/provincial, and national requirements. Dispose with laboratory waste.

Composition

Sperm Freezing 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 mg/ml) to protect sperm from damage due to the freezing procedure.

Pre-Use Checks

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



QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
Physicochemical Tests	
pH	7.2-7.9
Osmolality	280-320 mOsM
Biological Tests	
Endotoxin (LAL)	≤ 0.25 EU/ml
Sterility Test (SAL 10 ⁻³)	PASS
Sperm survival test: ≥ 80% survival after 4 hours exposure of untreated semen to the test medium	≥ 80%

METHOD

Ensure all media are well mixed before use.

Freezing

1. Allow the semen to liquefy at room temperature for 30 minutes.
2. Mix 1 ml of semen or sperm suspension with 0.7 ml of Sperm Freezing. Add the Sperm Freezing in drops while gently swirling.
Caution: to avoid cold shock, make sure that Sperm Freeze is at room temperature.
3. Leave the mixture for 10 minutes at room temperature for equilibration.
4. Suck the sample/medium mixture into the freezing straws, leaving approximately 1.5cm of air at the end of the straw.
5. Seal the straws.
6. Dry off individually with a linen free cloth.
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 straws 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 against the side of the container to allow complete evacuation of the mixture.
4. Dilute the concentrated sperm in a suitable insemination medium (at least 3 ml per 0.5 ml semen) and mix thoroughly.
5. Centrifuge during 15 minutes at 300-350 g.
6. Re-suspend pellet in a suitable insemination medium.

Disclaimer

The procedures described below have been found to be effective for the freezing and thawing of human sperm and are offered only as examples. Every laboratory must define and optimize its own procedures.



EC REP



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Sperm Freezing and Sperm Preparation

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.

After Thawing

If necessary, use sperm preparation techniques after thawing the semen to eliminate dead sperm cells and debris. Dilute the concentrated sperm a suitable insemination medium.

QUALITY ASSURANCE

STERILE A	RX Only	REF	LOT		
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
Keep Away From Sunlight	Temperature Limitation	Use By	GS1 DataMatrix Barcode	Do Not Resterilize	