SYNBIOS® MEDIA
Safety. Performance. Innovation

SYNBIOS® SPERMFREEZE

GENERAL INFORMATION ON USE

SYNBIOS® SpermFreeze is a medium for freezing human sperm including epididymal or testicular sperm.

MATERIALS SUPPLIED

Two types of SpermFreeze media available, with added proteins and without proteins. The latter is completely chemically defined and synthetic. Both comes ready-to-use. Clients may order either one or both.

50 mL of **SYNBIOS® SpermFreeze medium** (Ref: SF10050) Medium with Phenol Red, Gentamicin and HSA

50 mL **SYNBIOS® SpermFreeze Synthetic Medium** with Phenol Red, Gentamicin and without HSA but with macromolecules (Ref: SM10050.SYN)

MATERIALS REQUIRED BUT NOT SUPPLIED

Sperm freezing straws, test tubes & culture dishes; oocyte and embryo handling pipettes; Laminar flow/Biological hoods, Stereo & Inverted Microscopes; Incubators, and other ART Lab equipment. Others include: SYNBIOS® culture, sperm; Gamete, Flush, PVP, and Hyaluronidase media for cIVF / ICSI and HSA Solution

SPECIFICATIONS AND QUALITY CONTROL

pH between 7,20 – 7,90 (Release criteria: 7,20 – 7,60)
Sterility: sterile (SAL 10^{-3})
Endotoxins < 0,25 EU/ml
Sperm survival test ≥ 80% survival after 4 hours exposure of untreated semen to the test medium
Not MEA tested
Use of Ph Eur or USP grade products if applicable
Certificate of analysis and MSDS are available upon request

STORAGE AND CONSERVATION

Store SYNBIOS® SpermFreeze between 2-8°C. Do not freeze before use. Keep the product in original packaging and shield from light/ sun. The product can be used for 7 days after opening when sterile conditions are maintained and stored at between 2-8°C. Do not use after expiry date. Do not use the product if it becomes 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.

CAUTION

SpermFreeze Medium exposed to the elements or above 8ºC for >8 hours may be unfit for use for human ART treatment due to possible formation of toxic free radicals and products of putrefaction.

DISCLAIMER:

This product is manufactured in compliance with GMP quality standards. Every effort has been taken to ensure quality of the product. We have no control over the products during transport. Shippers are aware of cold-chain protocol. Product could be damaged for any reason during transport. End users must ensure products received are in good condition by internal QC/QA procedures prior to use.

WARNINGS AND PRECAUTIONS

Standard measures to prevent infections 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 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 (e.g. LAF-bench ISO Class 5) to avoid possible contamination. Only for the intended use.

INSTRUCTIONS FOR USE

Ensure all media are well mixed before use.

Freezing

1. Adhere to aseptic technique. Allow the semen to liquefy at room temperature for 30 minutes.
2. Commence equilibration. 1 part of cryoprotectant is mixed gradually with 3 parts of semen, (the cryoprotectant is divided into 5 equal volumes; each part added with gentle mixing) with a pause of 1 min between each addition of cryoprotectant solution.
3. Perform this at room temperature. After all the cryoprotectant solution has been added allow to stand for 5 mins.
4. Using a syringe suck the sample/medium mixture into the freezing straws, leaving approximately 1.5cm of air

approximately 1.5cm of air at the end of the straw. Dry off individually with sterile lint-free cloth or tissue.

5. Heat-seal the straws at both ends.

[Cryo vials may also be used instead of straws].

6. Then freeze according to standard protocol or hold over liquid nitrogen (LN2) vapour (initially 14cm above LN2 surface for 20mins then at 7cm above LN2 surface for 20mins.

7. Then drop into LN2. The specimen can then be stored in LN2.

Thawing

[Warming and rehydration can be as per standard established protocol.]

1. Remove as many straws as required from the liquid nitrogen.

2. Warm the straws in water held at room temperature for 5 minutes.

3. Cut off one-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. Alternatively cut-off one end of straw. Fit snugly it into a sterile pipet tip fitted to a pipettor. Then cut-off the other end. Using the pipettor push out the semen specimen into the container using air pressure.

4. Harvest sperm by density gradient centrifugat -ion as per manufacturer's protocol.

Alternatively motile spermatozoa may be harvested by the standard swim-up technique.

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Good Laboratory Practices

ART Lab personnel are urged to adhere to Good Laboratory Practices (GLP) for optimizing the treatment outcome. Dishes must not be out of incubator for more than 3 mins at any one time.

Note: This product is classified as a medical device. US Federal Law restricts its sale by or on order of a physician (Rx only).

GMP-manufactured for ANDROCRYOGENICS, Malaysia

www.synbiosmedia.com

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786

SYNBIOS® SPERMFREEZE MEDIUM

20 Years of Research

Ensures Optimal Performance

SYNBIOS® MEDIA

Safety. Performance. Innovation

GMP-Manufactured

SYNBIOS® SpermFreeze for the freezing of ejaculatory, epididymal or testicular sperm.

Ref: 50 mL SF10050 (contains HSA: Ready-to-use)

Ref: 50 mL SF10050.SYN (synthetic Medium without HSA; Ready-to-use)

SYNBIOS® SPERMFREEZE is sterilized by sterile filtration.