



0209-01

OocyteFreeze™

Cat. No.:

10485010 5 x 10 ml
(Vial 1 x 3, Vial 2 and Vial 3)

Symbols:

Catalogue Number

REF

Batch Code

LOT

Sterilized using aseptic processing techniques (filtration)

STERILE A

Storage temperature limitation from 2°C to 8°C



Use by



Consult instructions for use, i.e. the package insert



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MediCult

Innovation with Care

OocyteFreeze™

Intended use

OocyteFreeze™ is for freezing human oocytes.

Background

Cryopreservation of surplus oocytes serves to augment the success of assisted conception treatments for infertile couples. Storage of oocytes has clear advantages, especially for young women undergoing oophorectomy or receiving chemotherapy.

One of the pioneers in this field, Dr. Raffaella Fabbri, has developed and tested formulations containing varying concentrations of sucrose together with a slow freezing procedure. The results of these clinical trials were published by Fabbri et al., 2001 and showed survival rates as high as 82%.

OocyteFreeze™ is supplied as ready-to-use solutions prepared with 1,2-propanediol and sucrose for a 3-step freezing procedure according to Dr. Fabbri.

OocyteFreeze™ and OocyteThaw™ have been tested by Dr. Fabbri at the IVF Centre, University of Bologna, Italy and show survival rates at the same level as reported in the published study (R. Fabbri, 2001).

Composition

Vial 1:

Dulbecco's Phosphate Buffered Saline (PBS)

Human serum albumin (HSA)

Alpha- and betaglobulins.

Vial 2:

Dulbecco's Phosphate Buffered Saline (PBS)

Human serum albumin (HSA)

Alpha- and betaglobulins

1,2-propanediol

Vial 3:

Dulbecco's Phosphate Buffered Saline (PBS)

Human serum albumin (HSA)

Alpha- and betaglobulins

1,2-propanediol

Sucrose

Quality control testing

Sterility tested

Endotoxin tested ≤ 2.0 EU/ml (USP, Ph.Eur.)

Mouse Embryo Assay (MEA) tested

Note: The results of each batch are stated on a Certificate of Analysis, which is available upon request.

Storage instructions and stability

Store at 2-8°C and protected from light.

The product has a minimum shelf life of 12 weeks from the date of shipment if stored according to the manufacturer's suggested guidelines.

We recommend that the product should be used within 7 days of opening.

Do not freeze prior to use.

Whenever the product has been warmed to room temperature, it should not be refrigerated again.

Precautions and warnings

Do not use the product if:

- Product packaging appears damaged or if the seal is broken
- Expiry date has been exceeded.

The product contains small amounts of human serum albumin (HSA), which originates from larger pools of screened healthy donors, tested negative for HbsAg, anti-HCV and anti-HIV1/-HIV2.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Handling

Warm to room temperature prior to use.

Instructions for use

1. A petri dish (Dish 1) is prepared using 3 ml of Vial 1 in which the oocytes are washed.
2. Another 4-well dish (Dish 2) is prepared. Two wells to the left should contain 0.5 ml of Vial 2. The two wells to the right should contain 0.5 ml of Vial 3.
3. The oocytes are transferred from dish 1 to dish 2.
4. 1-2 oocytes per well are placed in the wells to the left and maintained for 10 minutes.
5. Then the oocytes are transferred to the wells on the right side of the dish and rapidly loaded in straws using this medium as transfer medium.
6. The straws are put in the freezer (e.g. Planer Kryo 10/1.7GB) and maintained for 15 minutes at room temperature (20°C) before the cooling program starts.

7. Then the temperature is slowly reduced to -7°C at a rate of 2°C per minute.
8. Seed manually at -7°C.
9. After a hold of 10 minutes at -7°C, the straws are cooled slowly to -30°C at a rate of 0.3°C per minute.
10. Then rapidly to -150°C at a rate of 50°C per minute.
11. After 10-12 minutes of temperature stabilisation, the straws are transferred into liquid nitrogen tanks and stored until thawing.

References

- Fabbri, R., Porcu, E., Marsella, T., Rocchetta, G., Venturoli, S. & Flamigni, C. (2001) Human oocyte cryopreservation: new perspectives regarding oocyte survival. *Human Reproduction*, **3**: 411- 416.
- Fabbri, R. (2001) Private Communication.