



0210-01

OocyteThaw™

Cat. No.:

10494010 4 x 10 ml
(Vial 1, Vial 2, Vial 3, Vial 4)

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



Technical Services:

E-mail: customer.service@medi-cult.dk

Internet: www.medicult.com

Customer Service:

Tel: +45 46 79 02 02, Fax: +45 46 79 03 02

Medi-Cult a/s

Møllehaven 12, DK-4040 Jyllinge • Denmark

Tel: +45 46 79 02 00 • Fax: +45 46 79 03 00



MediCult

Innovation with Care

OocyteThaw™

Intended use

OocyteThaw™ is for thawing human oocytes frozen using OocyteFreeze™ (Cat.No. 10485010).

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%.

OocyteThaw™ is supplied as ready-to-use solutions prepared with 1,2-propanediol and sucrose, designed for thawing human oocytes frozen using OocyteFreeze™. The procedure follows the 4-step thawing protocol 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
1,2-propanediol
Sucrose

Vial 2:

Dulbecco's Phosphate Buffered Saline (PBS)
Human serum albumin (HSA)
Alpha- and betaglobulins
1,2-propanediol
Sucrose

Vial 3:

Dulbecco's Phosphate Buffered Saline (PBS)
Human serum albumin (HSA)
Alpha- and betaglobulins
Sucrose

Vial 4:

Dulbecco's Phosphate Buffered Saline (PBS)
Human serum albumin (HSA)
Alpha- and betaglobulins

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.

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, 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 4-well petri dish is prepared:
 - well A: 0.5 ml of Vial 1
 - well B: 0.5 ml of Vial 2
 - well C: 0.5 ml of Vial 3
 - well D: 0.5 ml of Vial 4.
2. To thaw, the straws are air-warmed for 30 seconds and then immersed in a 30°C water bath for 40 seconds until all traces of ice have disappeared.
3. The oocytes contained in coat straw are unloaded into the solution in well A and maintained for 5 minutes at room temperature.
4. The oocytes are transferred to well B and maintained for an additional 5 minutes at room temperature.
5. The oocytes are transferred to well C and maintained for 10 minutes at room temperature.
6. The oocytes are transferred to well D and maintained for 10 minutes at room temperature and for an additional 10 minutes at 37°C.
7. Finally the oocytes are placed in Universal IVF Medium (Cat. No. 1030 or 1031) at 37°C in 5% CO₂ until insemination.

Reference

- 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.

