0204–02

Embryo Freezing Pack

Cat. No.:

10264010 4 x 10 ml
(Vial 1, Vial 2 and Vial 3 x 2)

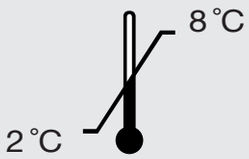
Symbols:

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

Embryo Freezing Pack

Intended use

Embryo Freezing Pack is for freezing and thawing human zygotes and cleavage stage embryos.

Background

Cryopreservation of surplus embryos serves to augment the success of assisted conception treatments for infertile couples.
Embryo Freezing Pack is supplied as ready-to-use solutions prepared with 1,2-propanediol and sucrose for the 3-step freezing procedure according to *(Testart et al., 1986)*.

Composition

Dulbecco's Phosphate Buffered Saline (PBS)
Synthetic Serum Replacement (SSR®) (USA: ART Supplement)
Human serum albumin (HSA)

Vial 1: Embryo Freezing Medium
Vial 2: Embryo Freezing Medium and 1,2-propanediol
Vial 3: Embryo Freezing Medium, 1,2-propanediol and sucrose

Quality control testing

Sterility tested
Endotoxin tested ≤ 0.1 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 potentially hazardous human serum albumin, which has been obtained from a U.S. licensed source. It origins from larger pools of screened healthy donors, tested negative for HBsAg, Anti-HCV, Anti-HIV1/-HIV2. Levels of ALT (GPT) in the plasma are determined and donations are rejected if the values found are above the upper limit of the specifications. Donors of the source material have been screened for CJD.

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. Zygotes or embryos at the 2-4 cell development stage are placed in medium from Vial 1 for 5 minutes at room temperature.
2. Zygotes or embryos are placed in medium from Vial 2 for 10 minutes and then in medium from Vial 3 for 15 minutes, still at room temperature.
3. Medium from vial 3 is used to load the zygotes or embryos in the straws. Freezing is carried out according to the cooling programme below.
4. Cool from room temperature to –7°C in steps of 2°C per minute.
5. Hold for 5 minutes. Manual seeding.
6. Cool from –7°C to –30°C in steps of 0.3°C per minute.
7. Cool from –30°C to –190°C in steps of 50°C per minute.
8. Transfer the straws into liquid nitrogen and store at –196°C.

Reference

Ziebe, S. et al., (1998) Resumption of mitosis during post thaw culture: a key parameter in selecting the right embryos for transfer. *Human Reproduction* **13(1):** 178-181.

Horne, G. et al., (1997) A prospective evaluation of cryopreservation strategies in a two-embryo transfer programme. *Human Reproduction* **12 (3):** 542-547.

Testart, J. et al., (1986) High pregnancy rate after early human embryo freezing. *Fertility and Sterility* **2:** 268-272.