

MediCult Vitrification Warming

Product No.:

1229

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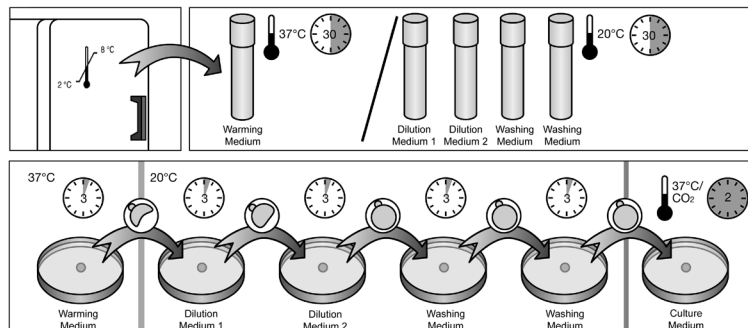
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References

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MediCult Vitrification Warming

MediCult Vitrification Warming is for warming vitrified human day 3 cleavage-stage embryos.

Caution: Federal Law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

Caution: The user should read and understand the Directions for Use, Warnings and Precautions, and be trained in the correct procedure before using MediCult Vitrification Cooling and Warming products for vitrification of human day 3 cleavage-stage embryos.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Precautions and warnings

The long term safety of vitrification for children born following this method of embryo cryopreservation is unknown.

Do not use the product if:

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

Composition

Vials 1, 2, and 3

Human serum albumin (HSA)
Sucrose
Sodium lactate
Physiological salts
L-glutamine
Sodium bicarbonate
Gentamicin sulphate 10 µg/mL

Vial 4

Human serum albumin (HSA)
Sodium lactate
Physiological salts
L-glutamine
Sodium bicarbonate
Gentamicin sulphate 10 µg/mL

Quality control testing

Sterility tested (USP).
pH tested (USP) with limits of 7.1-7.5.
Endotoxin tested ≤ 0.5 EU/mL (USP).
2 cell Mouse Embryo Assay (MEA) $\geq 80\%$ Blastocysts by 72h.
Osmolality tested (USP) with limits of:

- Vial 1: 519-579 mOsm/kg in 1:3 dilution
- Vial 2: 975-1055 mOsm/kg
- Vial 3: 580-620 mOsm/kg
- Vial 4: 272-288 mOsm/kg.

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.
Do not freeze prior to use.

Discard excess (unused) media following warming.

The product is provided in vials intended for single use.

Do not reuse.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Instructions for use

1. Pre-warm the Warming Medium to 37°C, and the Dilution Medium 1, Dilution Medium 2 and Washing media to room temperature for at least 30 minutes.
2. Prepare a reservoir with enough liquid nitrogen to allow complete submersion of a goblet on a cryocane.
3. Collect the cryocane and goblet containing the carrier device with vitrified day 3 cleavage-stage embryos from the storage container and quickly transfer them to the liquid nitrogen reservoir. Make sure the carrier device remains submerged under liquid nitrogen.
4. Mix the content of the individual vials by a few gentle inversions prior to use.
5. In separate dishes, place 2 mL of Dilution Medium 1, 2 mL of Dilution Medium 2, and 2 x 2 mL Washing Medium.
6. Place 2 mL of Warming Medium at 37°C in a pre-warmed dish just before opening the carrier device according to the manufacturer's instructions for use.
7. Quickly transfer the day 3 cleavage-stage embryos into Warming Medium, and leave them there for a maximum of 3 minutes (at this point, the embryos are still shrunken).
8. Using a suitable pipette and minimum

volume of Warming Medium, transfer the day 3 cleavage-stage embryos into Dilution Medium 1 at room temperature.

Leave for 3 minutes (at this point, the embryos will start to re-expand).

9. Using a minimum volume of medium, transfer the day 3 cleavage-stage embryos into Dilution Medium 2 and leave them there for 3 minutes (at this point the embryos will continue re-expanding).
10. Using a minimum volume of medium, transfer the day 3 cleavage-stage embryos into the Washing Medium and leave them there for 3 minutes. Repeat the washing step by transferring the day 3 cleavage-stage embryos to the final well containing Washing Medium (at this point the embryos are fully re-expanded).
11. Transfer the day 3 cleavage-stage embryos into equilibrated culture medium and allow them to rest in the incubator for a minimum of two hours before transfer.