

Embryo Freezing Pack

Product No.:

1026

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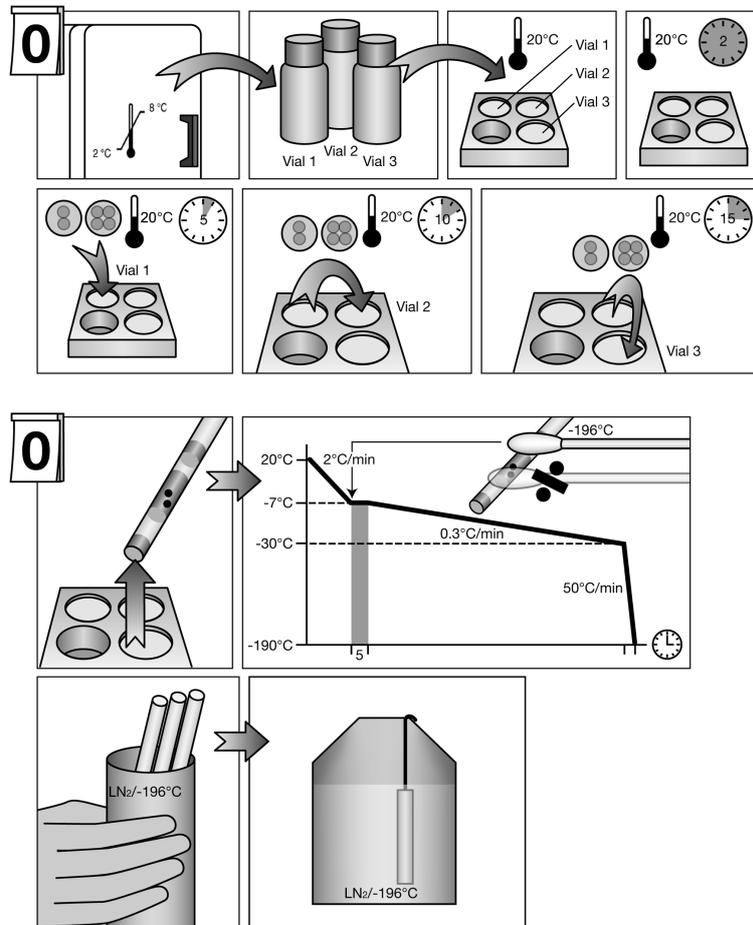
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Embryo Freezing Pack

Intended use

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

Composition

Embryo Freezing Medium:

Physiological salts

Synthetic Serum Replacement (SSR®)*
(USA: ART Supplement)

* Contains Recombinant Human Insulin
Human serum albumin (HSA)

Vial 1: Embryo Freezing Medium

Vial 2: Embryo Freezing Medium
1,2-propanediol

Vial 3: Embryo Freezing Medium
1,2-propanediol
Sucrose

Quality control testing

Sterility tested (Ph.Eur., USP)

pH tested (Ph.Eur., USP)

Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP)

1 cell Mouse Embryo Assay (MEA) $\geq 80\%$

Blastocysts by 96h

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.

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

Precautions and warnings

Do not use the product if:

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

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.

Do not re-use.

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Notes:

Do not seed the straw close to the zygote/embryo and do not drop or shake it. Attention must be paid to the handling of straws at low temperature as they may thaw very quickly.

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. Transfer zygotes or embryos to medium from Vial 2, incubate for 10 minutes at room temperature.
Just before the zygotes or embryos are transferred to medium from Vial 3 the inside of the cryo straws are cleaned with the same solution but from another dish.
3. Transfer the zygotes or embryos to medium from Vial 3 for 15 minutes, still at room temperature.
4. 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.
5. Cool from room temperature to -7°C at a rate of 2°C per minute.
6. Hold for 5 minutes. Manual seeding.
When the solution is white, seeding has been initiated.
7. Cool from -7°C to -30°C at a rate of 0.3°C per minute.
8. Cool from -30°C to -190°C at a rate of 50°C per minute.
9. Transfer the straws into liquid nitrogen and store at -196°C .