

0617-04

Embryo Thawing Pack

Product No.:

1098

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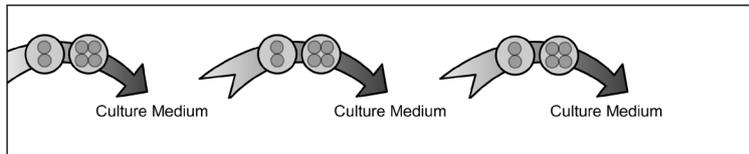
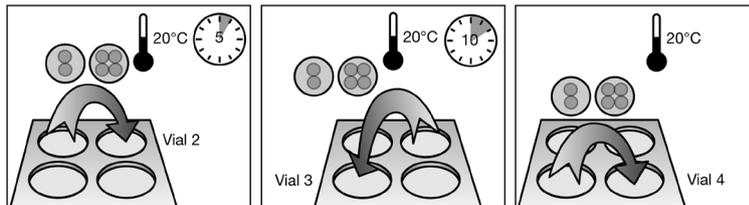
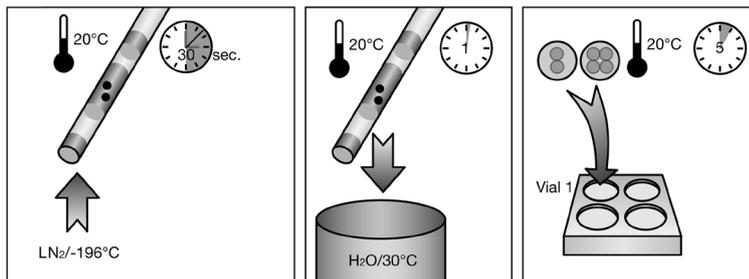
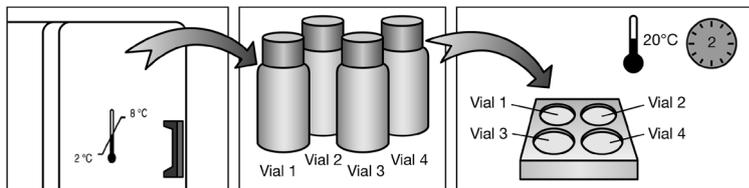
Distributor: ORIGIO AUSTRALASIA Pty Ltd

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MEDIA

Symbol:



Discard excess (unused) media following warming.



Embryo Thawing Pack

Intended use

Embryo Thawing Pack is for thawing of human zygotes and cleavage stage embryos frozen using Embryo Freezing Pack

This product is for IVF treatment of women, whether the cause of infertility is male or female. The product should only be used by professionals trained in IVF treatment.

Composition

Vial 1:

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

*Contains Recombinant Human Insulin
Human serum albumin (HSA)
1,2-propanediol
Sucrose
Physiological salts

Vial 2:

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

*Contains Recombinant Human Insulin
Human serum albumin (HSA)
1,2-propanediol
Sucrose
Physiological salts

Vial 3:

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

*Contains Recombinant Human Insulin
Human serum albumin (HSA)
Sucrose
Physiological salts

Vial 4:

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

*Contains Recombinant Human Insulin
Human serum albumin (HSA)
Physiological salts

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

The products are aseptically processed and supplied sterile.

Store in original container at 2-8°C, protected from light.

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

Do not freeze.

The product does not contain any antimicrobial agents and is provided in vials intended for single use.

Excess (unused) media should be discarded.

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 from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of IVF media has not been determined and is still unknown.

Instructions for use

1. Pre-warm for a minimum of 2 hours at room temperature.
2. Remove straws from liquid nitrogen and keep at room temperature for 30 seconds. Then place straws in water at 30°C for 1 minute.
3. Open the straws or cryo-tubes according to the manufacturer's instructions and expel the contents into a Petri dish.
4. Place zygotes or embryos in medium from Vial 1 at room temperature for 5 minutes.
5. Transfer zygotes or embryos into medium from Vial 2 at room temperature for 5 minutes and then into medium from Vial 3 also at room temperature for 10 minutes.
6. Transfer zygotes or embryos into medium from Vial 4 at room temperature.
7. Remove zygotes or embryos from the Vial 4 medium and wash in an appropriate culture medium, depending on the stage of development at freezing and the day of transfer. Place the zygotes or embryos in culture using the same medium.