

BlastThaw™

Product No.:

1054

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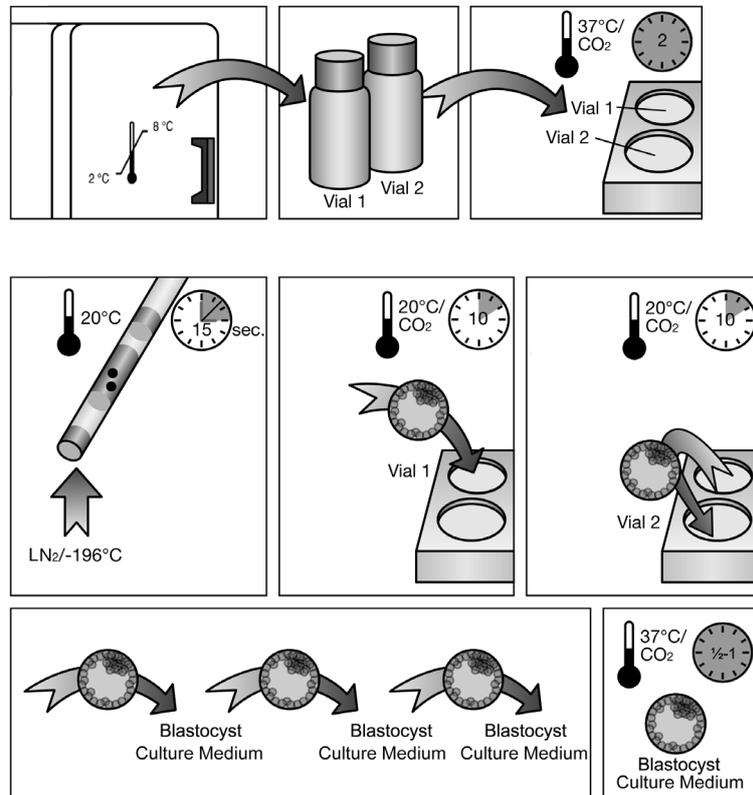
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Intended use

BlastThaw™ is for thawing of blastocysts frozen using BlastFreeze™.

Composition

Vial 1

Synthetic Serum Replacement (SSR®)*

(USA: ART Supplement)

* Contains Recombinant Human Insulin

Human serum albumin (HSA)

Sucrose

Glucose

Sodium pyruvate

Physiological salts

Sodium bicarbonate

Gentamicin sulphate 10µg/mL

Phenol Red

Vial 2

Synthetic Serum Replacement (SSR®)*

(USA: ART Supplement)

* Contains Recombinant Human Insulin

Human serum albumin (HSA)

Glucose

Sucrose

Sodium pyruvate

Physiological salts

Sodium bicarbonate

Gentamicin sulphate 10µg/mL

Phenol Red

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) ≥ 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.

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.

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

Note:

The thawing procedure is intended to be performed under a stream of CO₂ in air and the intensity of the stream is regulated according to the colour of the media to maintain pH stability.

Instructions for use

1. Equilibrate for a minimum of 2 hours at 37°C in a 5-6% CO₂ environment.
2. Warm straws at room temperature by leaving them on the table for 10-15 seconds.
3. Open the straws or cryo-tubes according to the manufacturer's instructions and expel the contents into a Petri dish.
4. Place the blastocysts in medium from Vial 1 for 10 minutes at room temperature, store in the dark.
5. Transfer the blastocysts into medium from Vial 2 for 10 minutes at room temperature, store in the dark.
6. After thawing, place the blastocysts in pre-equilibrated culture medium and aspirate the embryos up and down in the pipette 5 times to ensure thorough washing (this should take only a few seconds).
7. Transfer to fresh pre-equilibrated culture medium and allow blastocysts to recover for a minimum of 30 minutes in a 5-6% CO₂ incubator before embryo transfer.