

BlastFreeze™

Product No.:

1053

Customer Service:

E-mail:

customerservice.medicult@origio.com

Tel: +45 46 79 02 02 • Fax: +45 46 79 03 02

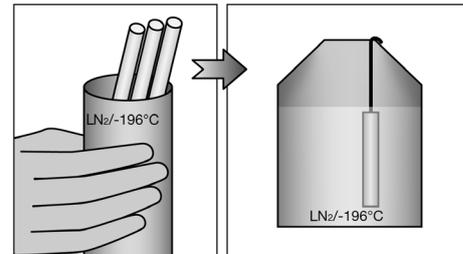
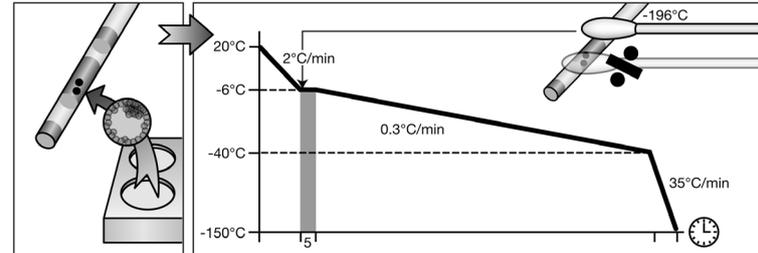
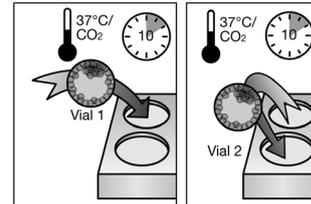
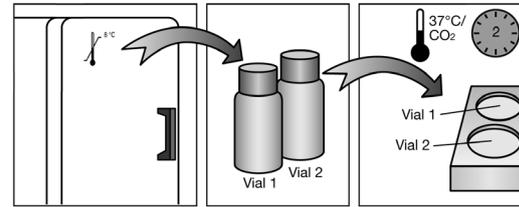
ORIGIO a/s

Knardrupvej 2, DK-2760 Måløv, Denmark

www.origio.com

Tel: +45 46 79 02 00 • Fax: +45 46 79 03 00

origio MEDICULT
MEDIA



BlastFreeze™

Intended use

BlastFreeze™ is for freezing of blastocysts.

Composition

Vial 1

Synthetic Serum Replacement (SSR®)

(USA: ART Supplement)

Contains Recombinant Human Insulin

Human serum albumin (HSA)

Glucose

Glycerol

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

Glycerol

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 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.

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

Caution: Attention must be paid to the handling of straws at low temperature as they may thaw very quickly.

Instructions for use

1. Equilibrate for a minimum of 2 hours in 5-6% CO₂-environment at 37°C.
2. Place the embryos in a 5-6% CO₂ incubator at 37°C in medium from Vial 1 for 10 minutes, and then in medium from Vial 2 for 10 minutes.
While incubating in medium from Vial 2, the inner part of the cryo straw is cleaned with the same medium from another dish.
3. Transfer the embryos into straws (a maximum of 2 embryos per straw) and begin the cooling programme as described below:
4. Cool from room temperature to -6°C at a rate of 2°C per minute.
5. Seed manually at -6°C. Do not seed the straw close to the blastocyst and do not drop or shake it.
When the solution is white, seeding has been initiated.
6. Cool from -6°C to -40°C at a rate of 0.3°C per minute.
7. Cool from -40°C to -150°C at a rate of 35°C per minute.
8. Transfer the straws into liquid nitrogen and store at -196°C.