

0629-04

Biopsy Medium

Product No.:

1062

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

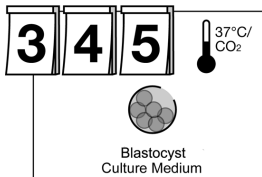
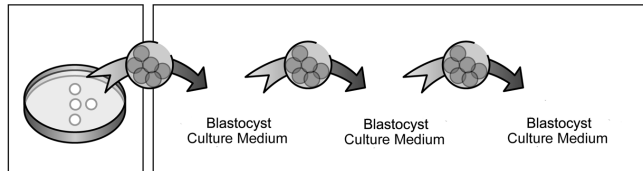
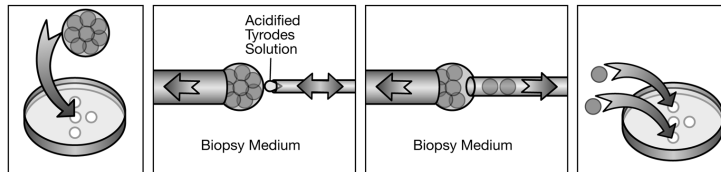
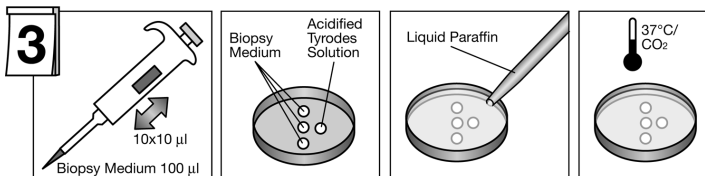
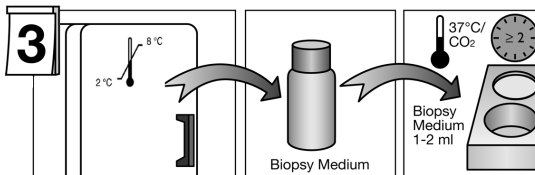
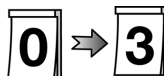
Distributor: ORIGIO AUSTRALASIA Pty Ltd

origio MEDICULT
MEDIA

Symbol:



Discard excess (unused) media following warming.



Biopsy Medium

Intended use

Biopsy Medium is for blastomere biopsy of cleavage stage embryos for Pre-implantation Genetic Diagnosis (PGD)

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

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

*Contains Recombinant Human Insulin
Human serum albumin (HSA)

Glucose

Physiological salts without calcium and magnesium ions

Amino acids

Choline chloride

Sodium bicarbonate

HEPES

Gentamicin sulphate 10µg/ml

Quality control testing

Sterility tested (Ph.Eur.,USP)

Osmolality tested (Ph.Eur.,USP)

pH tested(Ph.Eur., USP)

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

2-Cell Mouse Embryo Assay ≥ 80%
blastocysts by 72h.

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 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

Cleavage stage embryo biopsy is carried out on Day 3 post-fertilization.

1. Place 1-2 ml of Biopsy Medium in a culture dish, overlay with pre-equilibrated Liquid Paraffin and warm to 37°C in a 5-6% CO₂ environment for a minimum of 2 hours.
2. Half an hour before the biopsy, prepare a biopsy dish for each embryo. Flush the tip of the pipette with 10 x 10 µl Biopsy Medium.
3. Pipette three droplets of Biopsy Medium and one droplet of Acidified Tyrodes Solution as shown in the illustration. Immediately cover the dish with 4 ml of pre-equilibrated Liquid Paraffin to avoid evaporation and warm the prepared dishes to 37°C in a 5-6% CO₂ environment.
4. Prepare wells of blastocyst culture media, for wash and final culture of the embryos whilst the diagnosis is carried out.
5. Take the pre-equilibrated biopsy dish and transfer the embryo into the middle droplet of the dish.
6. Perform the drilling of Zona Pellucida. When using Acidified Tyrodes Solution for chemical drilling of the zona, please refer to the specific protocol recommended for the use of this product.
7. Once a small hole in the zona has been obtained, the blastomeres should be readily accessible with the sampling pipette. To minimise the reduction in mass, one or two of the smallest blastomere(s) are biopsied and placed in the corresponding droplets of Biopsy Medium.
8. Immediately after the biopsy wash the embryo(s) thoroughly by transferring them between several wells of blastocyst culture medium.
9. Finally transfer the embryo into a new dish with pre-equilibrated wells of blastocyst culture medium overlaid with pre-equilibrated Liquid Paraffin.
10. The biopsy dish with the isolated blastomeres is then ready for sample preparation.