

# Biopsy Medium

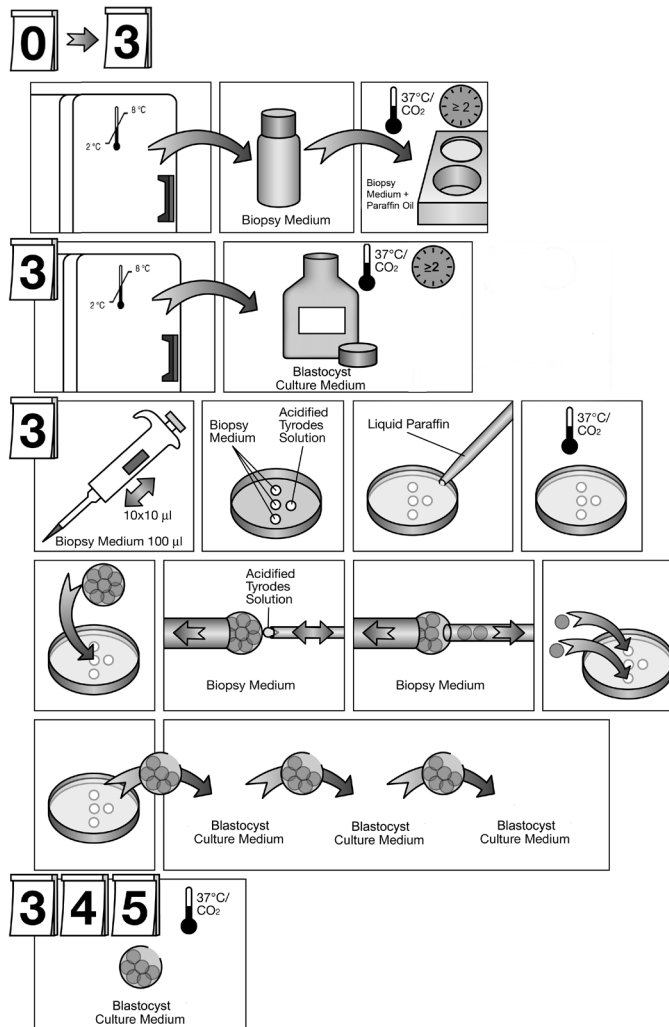
Product No.:

1062

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# Biopsy Medium

## Intended use

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

## 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

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 (MEA) ≥ 80%

Blastocysts by 72h

**Note:** The results of each batch are stated on a Certificate of Analysis, which is available on [www.origio.com](http://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 to be used within 7 days after opening.

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:** Subsequent handling of embryos should be gentle so as to reduce the risk of blastomere loss.

## Instructions for use

Day 2 (2 days after egg collection)

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% CO<sub>2</sub> environment for a minimum of 2 hours.

Day 3 (day of embryo biopsy)

1. Cleavage stage embryo biopsy is carried out early in the morning of Day 3 post-fertilization.
2. Half an hour before the biopsy, prepare a biopsy dish for each embryo. Flush the tip of the pipette with 10x 10 µL Biopsy Medium. Pipette three droplets of Biopsy Medium and one droplet of Acidified Tyrodes Solution as shown in the illustration.
3. 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% CO<sub>2</sub> environment. At the same time prepare microdrops/wells of blastocyst culture media, for wash and final culture of the embryos whilst the diagnosis is carried out.
4. Take the pre-equilibrated biopsy dish and transfer the embryo into the middle droplet of the dish.
5. 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.*
6. 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.

7. Immediately after the biopsy wash the embryo(s) thoroughly by transferring them between several drops/wells of blastocyst culture medium
8. Finally transfer the embryo into a new dish with pre-equilibrated microdrops/wells of blastocyst culture medium overlaid with pre-equilibrated Liquid Paraffin.
9. The biopsy dish with the isolated blastomeres is then ready for sample preparation.