



0215-03

Biopsy Medium

Cat. No.:

10620010 10 ml

Symbols:

Catalogue Number



Batch Code



Sterilized using aseptic processing techniques (filtration)



Storage temperature limitation from 2°C to 8°C



Use by



Consult instructions for use, i.e. the package insert



Technical Services:

E-mail: customer.service@medicult.com

Internet: www.medicult.com

Customer Service:

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

MediCult a/s

Møllehaven 12, DK-4040 Jyllinge • Denmark

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



MediCult

Innovation with Care

Biopsy Medium

Intended use

Biopsy Medium is for blastomere biopsy of cleavage stage embryos for preimplantation genetic diagnosis.

Background

Biopsy Medium is ready-to-use and has been formulated without calcium and magnesium ions to facilitate the process of blastomere biopsy.

The medium has been tested and used routinely in different clinics around the world over a 3-year period.

Composition

Synthetic Serum Replacement (SSR®)

Human serum albumin (HSA)

Glucose

Sodium pyruvate

Physiological salts without calcium and magnesium ions

Essential amino acids

Non-essential amino acids

Sodium bicarbonate

HEPES

Streptomycin 50 mg/litre

Penicillin 50.000 IU/litre

Quality control testing

Sterility tested

Osmolality tested

pH tested

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

Mouse Embryo Assay (MEA) tested.

Note: The results of each batch are stated on a Certificate of Analysis, which is available upon request.

Storage instructions and stability

Store at 2-8°C and protected from light.

The product has a minimum shelf life of 5 weeks from the date of shipment if stored according to the manufacturer's suggested guidelines.

We recommend that the product should be used within 7 days of opening.

Do not freeze.

Whenever the product has been warmed to 37°C, it should not be refrigerated again.

Precautions and warnings

Do not use the product if:

- Product packaging appears damaged or if the seal is broken
- Expiry date has been exceeded.

The product contains small amounts of potentially hazardous human serum albumin, which has been obtained from an U.S. licensed source. It originates from larger pools of screened healthy donors, tested negative for HBsAg, Anti-HCV, anti-HIV1/-HIV2. Levels of ALT (GPT) in the plasma are determined and donations are rejected if the values found are above the upper limit of the specifications. Donors of the source material have been screened for CJD.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Handling

Equilibrate for a minimum of 2 hours in 5% CO₂ at 37°C prior to use.

Day 0 to 2

1. Follow recommended protocol for fertilisation and cleavage stage culture in either BlastAssist® System (Cat.No.1039/1040) or ISM™ series media (Cat.No.1050/1051)

Day 2 (2 days after egg collection)

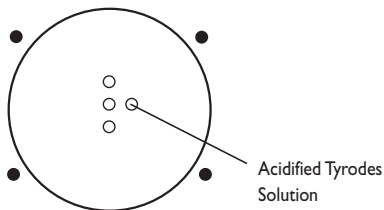
2. In a tissue culture dish place a sufficient volume of Biopsy Medium for the biopsy of the embryos, overlay with pre-equilibrated Liquid Paraffin (Cat.No. 1010) and warm to 37°C in a 5% CO₂ in air environment for a minimum of 2 hours (allow 30 µl per embryo plus 100 µl for flushing the pipette tip as necessary). Remember to pre-equilibrate sufficient Liquid Paraffin for the biopsy procedure (allow 4 mls per embryo).

Day 3 (day of embryo biopsy)

Cleavage stage embryo biopsy is carried out early in the morning of Day 3 post-insemination.

3. Half an hour before the biopsy, set up a biopsy dish for each embryo and label it with the patient's name and embryo number. Take an automatic pipette set at 10 µl with a sterile tip and flush the tip (x10) with Biopsy Medium. Pipette 3 drops of Biopsy Medium and one drop of Acidified Tyrodes Solution (Cat.No.

1060) as shown in the diagram – it is important that the dish is oriented as shown in relation to the "bumps" on the outside of the dish.



Immediately cover the dish with 4 mls of pre-equilibrated Liquid Paraffin to avoid evaporation and warm the prepared dishes to 37°C until required. At the same time prepare additional 4-well dishes and/or microdrops of extended culture media correspondingly labelled, for wash and final culture of the embryos whilst the diagnosis is carried out.

Check list:

1x biopsy dish per embryo

1x 4-well dish per embryo for washing.

Appropriate number of 4-well dishes or microdrops for final culture of the biopsied embryos.

4. Take the appropriately labelled biopsy dish from the holding incubator and aseptically, transfer the embryo into the middle droplet of the dish.
5. Prime pipettes with the appropriate solutions and immobilise the embryo to be biopsied. Decompaction should be completed within a short period and the embryo should be observed throughout the process.
6. Bring the Acidified Tyrodes Solution pipette into contact with the zona of the embryo. Take care only to use the smallest possible volume of Acidified Tyrodes Solution to facilitate the drilling process.
7. Once a small hole in the zona has been obtained, the blastomeres should be readily accessible with the sampling pipette. Choose a small blastomere to minimise the reduction in mass.
8. At the end of the biopsy, the embryo should then be transferred to the 4-well dish and thoroughly washed through 3 wells of the extended culture medium to remove all traces of the Biopsy Medium. The effects of the Biopsy Medium are reversed by placing the embryo in BlastAssist® System or ISM™ series media, provided that the recommended wash process is completed.
9. Once washed, the embryo should be transferred to a new 4-cell well dish or fresh microdrops of extended culture medium overlaid with pre-equilibrated Liquid Paraffin.
10. The biopsy dish with the isolated blastomeres is then ready for sample preparation.

When the PGD is complete, assess the morphology of each of the embryos and count the number of cells as accurately as possible to get an indication of division post biopsy.

In consultation with the other members of the PGD team and finally with the couple themselves, select a maximum of two unaffected embryos with the best morphology for transfer.