



Instructions for the Use of LG PGD Biopsy Medium

(Catalogue Numbers: LPPG-020, LPPG-050)

PRECAUTIONS AND WARNINGS

1. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
2. **Caution:** The user should read and understand the Instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using LG PGD Biopsy Medium which is designed to facilitate the biopsy of cells from human cleavage-stage embryos for preimplantation genetic diagnosis.
3. Not to be used for injection.
4. Do not resterilize.
5. Do not use the product if:
 - the product packaging appears damaged or if the seal is broken
 - the expiry date has been exceeded
 - the product becomes discolored, cloudy, or shows evidence of particulate matter
6. This product contains human serum albumin, a derivative of human blood. The human serum albumin used in the preparation of this product has been heated at 60°C for ten hours.

Caution: Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time that LG PGD Biopsy Medium is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

7. LG PGD Biopsy Medium contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
8. LG PGD Biopsy Medium contains only a low concentration of sodium bicarbonate and should not be gassed with CO₂.
9. To avoid problems with contamination, practice aseptic techniques.
10. Discard unused medium within 7 days of opening.

GENERAL INFORMATION

Indications for Use

To facilitate the biopsy of cells from human cleavage-stage embryos for PGD.

Storage and Shelf Life

Store at 2-8°C and protected from light. Ten (10) weeks from the date of manufacture.

Disposal Consideration

Treat or dispose of waste material in accordance with all local state/provincial, and national requirements. Dispose with laboratory waste.

Composition

Sodium Chloride	Potassium Chloride	Potassium Phosphate	Sodium Bicarbonate	Glucose
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Lactate Na Salt	Sodium Pyruvate	Glycine	L-Alanine	L-Arginine HCl
L-Asparagine	L-Aspartic Acid	L-Cystine	L-Glutamic Acid	Glycyl-Glutamine
L-Histidine	L-Isoleucine	L-Leucine	L-Lysine HCl	L-Methionine
L-Phenylalanine	L-Proline	L-Serine	L-Threonine	L-Tryptophan
L-Tyrosine	L-Valine	EDTA	Phenol Red	Sucrose
Human Serum Albumin* (5 mg/ml)		Gentamicin Sulfate* (10 µg/ml)		

*from therapeutic-grade source material

QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
Physicochemical Tests	
pH	7.2-7.4
Osmolality	310-320 mOsM
Biological Tests	
Endotoxin (LAL)	≤ 0.5 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 ⁻³)	PASS
Biological Assays	
2-cell Mouse Embryo Assay (% expanded blastocysts at 72 h of culture after 30 minute exposure)	≥ 80%

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the biopsy of human cleavage-stage embryos and are offered only as examples. Every laboratory must define and optimize its own procedures.

1. Warm overnight, 5 ml of HTF-equilibrated oil for each biopsy dish. One dish should be prepared for every 2 embryos that are going to be biopsied. Make no more than 2 biopsy drops per dish.
2. In a Falcon 1006 dish or other appropriate dish, make one 10 µl droplet of Acidific Tyrodes Solution and two 20 µl droplets of LG PGD Biopsy Medium. The droplets of LG PGD Biopsy Medium should be close together, and the droplet containing the Acidific Tyrodes Solution should be circled to distinguish it from the other 2 droplets.
3. Cover droplets with the warmed HTF-equilibrated oil.
4. Tightly place the lid on dish and return to incubator.
5. Allow the dish with droplets to warm for at least one hour prior to use.
6. Place one embryo into one of the droplets and number the droplet accordingly.
7. Perform the biopsy procedure.









NOTE: Do not allow the embryo to remain in LG PGD Biopsy Medium for more than 5 minutes. The effects of the calcium/magnesium free medium are noticed in less than 30 seconds after placing the embryo in the droplet.

8. Remove the embryo from the biopsy dish. Note the position of the removed cell.
9. Wash the biopsied embryo through 5 droplets of global[®] and place it into a fresh droplet of global[®] for culture. Follow the protocols for preparing global[®] for embryo culture.
10. In the second drop of LG PGD Biopsy Medium, place another embryo and perform the biopsy procedure.
11. Remove the embryo, wash as described above and place into culture.



12. Replace the lid on the dish containing the biopsied cells and place on a surface that is a room temperature. The cells can remain there until the biopsy case is complete or until the processing of the cell for either FISH or PCR.

SYMBOLS

STERILE A	RX Only	REF	LOT		
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
		EC REP			
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	GS1 DataMatrix Barcode	Do Not Resterilize
CE 2797					
European Conformance (notified body)	Do Not Use if Package is Damaged				