

GM501 Flush

Material included in the package:

- 20 ml GM501 Flush
- 50 ml GM501 Flush
- 100 ml GM501 Flush
- 250 ml GM501 Flush
- 500 ml GM501 Flush

Material not included in the package:

- Incubator (no CO₂)
- Petri dishes
- LAF bench (ISO 5 environment)
- Microscope
- Test tubes
- Rubber free syringe

Product code:

- 4 GM 501F-20
- 4 GM 501F-50
- 4 GM 501F-100
- 4 GM 501F-250
- 4 GM 501F-500

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose anhydrous, Na-Lactate (50 % solution), Na-Pyruvate, EDTA, Alanyl-Glutamine, water, non-essential and essential, Amino Acids, HEPEs, 2.5 IU/ml Heparin.
- Gentamicin sulfate can be added by the user (10 mg/liter).

Intended use/Intended users:

- Cell culture medium for human oocyte pick-up.
- GM501 Flush is a ready-to-use medium for flushing the ovarian follicles during aspiration and/or oocyte pick-up intended for extracorporeal fertilization procedures.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- GM501 Flush needs to be warmed at 37°C over night before use (no CO₂, with closed lid). GM501 Flush is HEPEs-buffered. Incubation in a CO₂-incubator will lower the pH.

Oocyte collection:

- Keep GM501 Flush medium at 37°C or as close to this as possible.
- Take about 20-50 ml medium at a time, using a rubber free syringe. Assemble needle and tubing set according to the manufacturer's instructions.
- Attach syringe containing GM501 Flush medium to the appropriate Luer, allowing connection to the lumen of the needle.
- The person holding the syringe should try to apply warmth to it by holding it in the palm of the hand covering as much of the syringe's surface as possible.
- During aspiration of follicles, if an ovum is not extracted after a follicle has been emptied, flushing is indicated. The collapsed follicle may be refilled with GM501 Flush, after which it may be aspirated once again. This may be done repeatedly, after refilling the syringe with fresh aspiration medium each time, until an ovum is recovered or the surgeon decides to abandon the follicle (after three attempts at flushing it may be sensible to move on, but the ultimate decision remains with the surgeon).

Product specifications and quality control:

- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- The MSDS for GM501 Flush is available upon request and can also be downloaded from our website.
- GM501 Flush is manufactured according to the following specifications:

pH (at 37°C)	7.20-7.60
Osmolality (mOsm/kg)	270-290
Sterility	sterile - SAL 10 ⁻³ (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96h in %) after 60min of exposure (zygote stage)	≥ 90

Precautions and warnings:

- All human organic material should be considered potentially infectious. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.
- Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (ISO 5 environment, e.g. LAF-bench) to avoid possible contamination.
- GM501 Flush contains heparin which is derived from porcine intestinal mucosa.
- Only for the intended use.

Pre-use checks:

- Do not use the product if bottle, seal of the container or package is opened or defective when the product is delivered.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

Storage instructions and stability:

- Shelf life is 18 months from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun)light.
- The product can be used safely up to 7 days after opening, if sterile conditions are maintained and the products are stored at 2-8°C.
- Do not use after expiry date.
- Content cannot be re-sterilized after opening.



Consult instructions for use



Do not use if package is damaged



Temperature limitation



Sterilized using aseptic processing techniques (filtration)



Lot number



Keep away from (sun)light



Use by



Catalogue number

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