

## GM501 SpermMobil

### Material included in the packing:

- 5 ml GM501 SpermMobil

### Material not included in the packing:

- CO<sub>2</sub>-incubator
- Petri-dishes
- LAF-bench (ISO5 environment)
- Microscope
- Test-tubes

### Product code:

- 4 GM 501SMOBIL5

### Composition:

- Theophylline solved in GM501 Air with Gentamicin and Phenolred
- GM501 Air: NaCl, KCl, KH<sub>2</sub>PO<sub>4</sub>, MgSO<sub>4</sub>·7H<sub>2</sub>O, NaHCO<sub>3</sub>, CaCl<sub>2</sub>·2H<sub>2</sub>O, Dextrose-Anhydrous, Na-Lactate, Na-Pyruvate, EDTA, Na-Alanyl-Glutamine, water, non-essential and essential amino acids, 0.5% HSA, Gentamicin, Phenolred, 21mmol HEPES.

### Intended use/Intended users

- GM501 SpermMobil is a ready-to-use HEPES-buffered medium containing low bicarbonate. It is used for activating the sperms of necrozoospermic ejaculates as well as of immotile sperms isolated from testicular tissue (TESE).
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

### Instructions for use:

- Warm up GM501 SpermMobil to 37°C.
- The medium's pH is stable on air and must not be preincubated in a CO<sub>2</sub>-atmosphere.
- To facilitate sperm-activation add 1.5 µl - 2.0 µl GM501 SpermMobil to the sperm-containing drop (ca. 5.0 µl) in


sperm preparation-medium inside the ICSI-dish.

- GM501 SpermMobil should be added to the opposing side from where the sperms are to be aspirated.
- Wait for 10 minutes. The activating effect initiates after a few minutes and lasts for one hour.
- The dish should be placed on a heating plate at 37°C.
- Aspirate the vital sperms.
- After accurate washing in culture medium, the selected sperms can be injected into the oocyte.


### Product specifications and quality control:

- GM501 SpermMobil is manufactured according to ISO 9001 and ISO 13485 standards.
- 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.
- GM501 SpermMobil is manufactured and tested according to the following specifications:


pH (at 37°C, 6 % CO <sub>2</sub> )	7.20 - 7.60
Osmolality (mOsm/kg)	280 - 320
Sterility	steril - SAL 10 <sup>-3</sup> (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.50



Consult instructions of use



Do not use if package is damaged



Temperature limitation


STERILE

A


Sterilized using aseptic processing techniques (filtration)

LOT

Lot number



Use by



Keep away from sunlight

### Precautions and warnings:

- GM501 SpermMobil contains the antibiotic: Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- The media contains human albumin solution (HAS), which is produced from blood of donors of certified US blood banks according to the guidelines of FDA. Source materials from which this product was delivered was found negative when tested for antibodies to HIV, Hbc, HCV and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test method can offer assurance that products delivered from human blood will not transmit infectious agents. 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 (ISO5 environment) to avoid possible contamination.
- Do not use the product if bottle, seal of the container or package is opened or defect when the product is delivered.
- Do not use the product if it becomes cloudy or shows any evidence of microbial contamination.
- Only for the intended use.

### Storage instructions and stability:

- Shelf life is 9 months from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun) light.
- After opening the container do not use the product longer than 7 days.
- Do not use after expiration date.

### For technical support:

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