



# Material included in the package:

- 5 ml GM501 SpermMobil
- 1 ml GM501 SpermMobil

# Material not included in the package:

- Incubator (no CO<sub>2</sub>)
- Petri dishes
- LAF-bench (ISO5 environment)
- Microscope
- Test-tubes

#### Product code:

- 4 GM 501SMOBIL-5
- 4 GM 501SMOBIL-1

# Composition:

 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, D(+)-Glucose Anhydrous, Na-Lactate, Na-Pyruvate, EDTA, Alanyl-Glutamine, water, nonessential and essential Amino Acids, HEPES, Theophylline, Phenol Red.

### Intended use/Intended users

- GM501 SpermMobil is a HEPES-buffered reagent containing low bicarbonate. It is used for in-vitro examination of sperms of necrozoospermic ejaculates as well as of immotile sperms isolated from testicular tissue (TESE).
- The intended users are IVF professionals (biologists, lab technicians, embryologists or medical doctors).

#### Instructions for use:

- Do not equilibrate GM501 Sperm-Mobil in a CO<sub>2</sub>-incubator, just warm it up to 37°C. GM501 SpermMobil is HEPES-buffered. Incubation in a CO<sub>2</sub>-incubator will lower the pH.
- To facilitate sperm-activation add 1.5-2.0 µl GM501 SpermMobil to the sperm-containing drop (approx. 30-40µl/ditution 1:20) in sperm preparation-medium inside the Petri-dishes.
- 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 up to one hour.

 The dish should be placed on a heating plate (37°C) during the diagnostic evaluation.

## 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.
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   The MSDS for GM501 SpermMobil is available upon request and can be downloaded from our website.
- GM501 SpermMobil is manufactured and tested according to the following specifications:

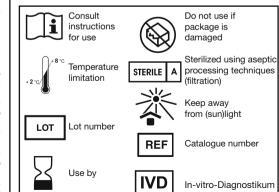
pH (at 37°C) 7.20-7.60
Osmolality (mOsm/kg) 280-320

Sterility sterile - SAL 10<sup>-3</sup> (Sterility Assurance Level)

Endotoxins (EU/ml) < 0.50

Sperm Survival test ≥ 80% survival after 45 minutes exposure of density selected sperma-

tozoa to the test medium



# Precautions and warnings:

- 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.
- 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.
- The concentration of the xanthine derivative Theophylline leads to the occasional formation of precipitate at 2-8°C storage temperature. It is dissolved completely when warmed at 37°C (within 24 h) and does not compromise function and safety of the product.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

# Storage instructions and stability:

- Shelf life is 6 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, when sterile conditions are mentioned.
- Do not use after expiry date.

# For technical support:



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