

Material included in the package:

- 5 ml GM501 SpermMobil
- 1 ml GM501 SpermMobil

Material not included in the package:

- Incubator (no CO₂)
- Petri dishes
- LAF-bench (ISO5 environment)
- Microscope
- Test-tubes

Product code:

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

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose Anhydrous, Na-Lactate, Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential 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 SpermMobil in a CO₂-incubator, just warm it up to 37°C. GM501 SpermMobil is HEPES-buffered. Incubation in a CO₂-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/dilution 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.
- 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 10⁻³ (Sterility Assurance Level)



Endotoxins (EU/ml) < 0.50


Sperm Survival test ≥ 80%
survival after 45 minutes exposure of density selected spermatozoa to the test medium



 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

 Catalogue number

 In-vitro-Diagnostikum
  Use by

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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 Gebrauchsanweisung_GM501_SpermMobil_EN_Rev09_00.indd
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