



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, MgSO₄7H₂O, NaHCO₃, CaCl₂2H₂O, 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 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/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.
- quest 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:

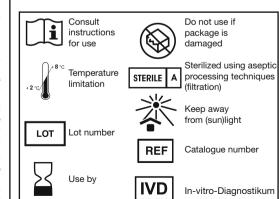
pH (at 37°C) 7.20-7.60
Osmolality (mOsm/kg) 280-320

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 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:



Lübecker Straße 9, 23738 Lensahn - Germany **Phone:** +49 (0) 4363 90 32 90 **- Fax:** +49 (0) 4363 90 32 91-9 **Email:** info@gynemed.de **- http:** //www.gynemed.de

Gebrauchsanweisung:GM501 SpermMobil: Gebrauchsanweisung_GM501_SpermMobil_EN_Rev09_00.indd Stand: 2016-02-01

GYNEMED Medizinprodukte GmbH & Co. KG.

