

GM501 SpermFluid

Material included in the packing:

- 10 ml GM501 SpermFluid

Material not included in the packing:

- CO₂-incubator
- Petri-dishes
- LAF-bench (ISO5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501FLUID10

Composition:

- Bromelaine solved in GM501 Air with Gentamicin and Phenolred.
- GM501 Air: NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, 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 SpermFluid is a ready-to-use medium designed to dilute viscous semen samples for better assessment of motility and concentration.
- If an ICSI has to be done, the sperm has to be washed again through a swim-up (for example with GM501 SpermActive or GM501 Air).
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- Warm GM501 SpermFluid up to 37°C. The medium's pH is stable on air and has not to be preincubated in CO₂-at-

mosphere. Gynemed recommends a pH-value of 7.20-7.50.

- Dilute semen sample with GM501 SpermFluid in proportion 1:1 (for highly viscous, cuttable ejaculate we recommend a coarse grinding of the ejaculate first!).
- Incubate the ejaculate for approx. 10 minutes at 37°C.
- After 10 minutes you can use the liquefied semen sample for diagnostic evaluation. Attention: To calculate the sperm concentration the dilution 1+1 (1:2) of semen with Bromelaine must be accounted.








Product specifications and quality control:

- GM501 SpermFluid 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 SpermFluid is manufactured and tested according to the following specifications:

pH (at 37°C, 6 % CO₂) 7.20 - 7.50

Osmolality (mOsm/kg) 270 - 290

Sterility steril - SAL 10⁻³ (Sterility Assurance Level)

	Consult instructions of use		Do not use if package is damaged
	Temperature limitation		Sterilized using aseptic processing techniques (filtration)
	Lot number		Keep away from sunlight
	Use by		

Precautions and warnings:

- GM501 SpermFluid 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 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 6 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.

Reference:

- WHO laboratory manual for the examination and processing of human semen - Fifth Edition

For technical support:

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