

Material included in the package:

- 20 ml GM501 Basic
- 50 ml GM501 Basic
- 100 ml GM501 Basic
- 250 ml GM501 Basic
- 500 ml GM501 Basic

Material not included in the package:

- 10 % Human Albumin Solution (e.g. Gynemed product code: 4 HSA-0005 (5 ml)) - or other pharmaceutical grade Human Albumin Solution with registered Plasma Master File
- CO₂-incubator at 37°C
- Petri dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501-20
- 4 GM 501-50
- 4 GM 501-100
- 4 GM 501-250
- 4 GM501-500

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose anhydrous, Na-Lactate (50 % solution), Na-Pyruvate, EDTA, Na-Alanyl-Glutamine, water, non-essential and essential Amino Acids.

Intended use/Intended users:

- GM501 Basic is a bicarbonate buffered cell culture medium, designed for fertilisation and for all embryo culture from day 1 to blastocyst stage. It can also be used for embryo transfer.


Addition of human albumin solution (1 %) by the customer is required for optimal culture conditions.


- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).


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 Basic is available upon request and can also be downloaded from our website.
- GM501 Basic is manufactured and tested according to the following specifications:


pH (at 37°C, 6 % CO ₂)	7.20-7.40
Osmolality (mOsm/kg)	270-290
Sterility	sterile - SAL 10 ⁻³ (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96h in %) after 30 min of exposure (zygote stage)	≥ 80


 Consult instructions for use


 Do not use if package is damaged


 Temperature limitation

 Sterilized using aseptic processing techniques (filtration)

 Lot number

 Keep away from sunlight

 Use by

 Catalogue number

Instructions for use:**Addition of human albumin solution before use (preparation of work solution).**

- GM501 Basic must be supplemented with Human Albumin Solution to a protein end concentration of 1 % (w/v). The use of 4 HSA-0005 (Gynemed) is strongly recommended. To supplement the 50 ml unit, keep 45 ml medium in the bottle and add 5 ml of 4 HSA-0005. Mix well.
- Embryo culture media must be equilibrated over night in a humidified CO₂-incubator (at 5-7 % CO₂, 37°C).
- GM501 Basic is designed for embryo culture under oil as well as in open systems.

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 defect when the product is delivered.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

Storage instructions and stability:

- The 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 maintained.
- Do not use after expiry date.

For technical support:

GYNEMED Medizinprodukte GmbH & Co. KG,
Lübecker Straße 9, 23738 Lensahn - Germany
Phone: +49 (0) 4363 9 03 29-0 - **Fax:** +49 (0) 4363 9 03 29-19
Email: info@gynemed.de - **http:** www.gynemed.de

Gebrauchsanweisung:GM501_Basic:
Gebrauchsanweisung_GM501_Basic_EN_Rev07_00.indd
Stand: 2017-07-31