

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

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

- GM501 Basic must be supplemented with Human Albumin

	Consult instructions for use		Do not use if package is damaged
	Temperature limitation -2°C to +8°C		Sterilized using aseptic processing techniques (filtration)
	Do not re-sterilize		Keep away from sunlight
	Lot number		Use by
			Catalogue number

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.
- The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

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 and the products are stored at 2-8°C.
- Stable after transport (max. 5 days) at elevated temperature (≤ 37°C).
- Content cannot be re-sterilized after opening.
- Do not use after expiry date.

For technical support:

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