

GM501 Cult

Material included in the package:

- 20 ml GM501 Cult
- 50 ml GM501 Cult

Material not included in the package:

- CO<sub>2</sub>-incubator at 37°C
- Petri-dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501H-20
- 4 GM 501H-50

Composition:

- NaCl, KCl, KH<sub>2</sub>PO<sub>4</sub>, MgSO<sub>4</sub>·7H<sub>2</sub>O, NaHCO<sub>3</sub>, CaCl<sub>2</sub>·2H<sub>2</sub>O, D(+)-Glucose anhydrous, Na-Lactate (50% solution), Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential and essential Amino Acids, human serum albumin (10.00 g/liter).

GM501 Cult with Gentamicin

Material included in the package:

- 20 ml GM501 Cult with Gentamicin
- 50 ml GM501 Cult with Gentamicin

Material not included in the package:

- CO<sub>2</sub>-incubator at 37°C
- Petri-dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501H+G-20
- 4 GM 501H+G-50

Composition:

- NaCl, KCl, KH<sub>2</sub>PO<sub>4</sub>, MgSO<sub>4</sub>·7H<sub>2</sub>O, NaHCO<sub>3</sub>, CaCl<sub>2</sub>·2H<sub>2</sub>O, D(+)-Glucose anhydrous, Na-Lactate (50% solution), Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential and essential Amino Acids, human serum albumin (10.00 g/liter), Gentamicin (10.00 mg/liter).

GM501 Cult with Gentamicin and Phenolred

Material included in the package:

- 20 ml GM501 Cult with Gentamicin and Phenolred
- 50 ml GM501 Cult with Gentamicin and Phenolred

Material not included in the package:

- CO<sub>2</sub>-incubator at 37°C
- Petri-dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501H+PR+G-20
- 4 GM 501H+PR+G-50

Composition:

- NaCl, KCl, KH<sub>2</sub>PO<sub>4</sub>, MgSO<sub>4</sub>·7H<sub>2</sub>O, NaHCO<sub>3</sub>, CaCl<sub>2</sub>·2H<sub>2</sub>O, D(+)-Glucose anhydrous, Na-Lactate (50% solution), Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential and essential Amino Acids, human serum albumin (10.00 g/liter), Gentamicin (10.00 mg/liter), Phenolred.

Intended use/Intended users:

- The media are ready-to-use bicarbonate-buffered culture media, designed for fertilisation and for human embryo culture from day 1 to blastocyst stage. It can also be used for embryo transfer.
- 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 the media are available upon request and can also be downloaded from our website.
- The media are manufactured and tested according to the following specifications:  
pH (at 37°C, 6 % CO<sub>2</sub>) 7.20-7.45

Osmolality (mOsm/kg) 270-290

Sterility sterile - SAL 10<sup>-3</sup> (Sterility Assurance Level)

Endotoxins (EU/ml) < 0.25

MEA (Blastocysts after 96 hours culture in %) ≥ 80  
(96h exposure from zygote state)

**Instructions for use:**

- The medium must be equilibrated over night in a humidified CO<sub>2</sub>-incubator (at 5-7 % CO<sub>2</sub>, 37°C).
- The media are designed for embryo culture under oil as well as in open systems.

**Precautions and warnings:**

- GM501 Cult with Gentamicin and GM501 Cult with Gentamicin and Phenolred contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot totally be excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin, manufactured to European Pharmacopoeia specifications by established processes.
- 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 (ISO 5 environment, e.g. LAF-bench) to avoid possible contamination, even when GM501 Cult medium contains Gentamicin.
- 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 month 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.



Consult instructions for use



Do not use if package is damaged



Temperature limitation



Lot number



Use by



Catalogue number



Sterilized using aseptic processing techniques (filtration)



Keep away from sunlight

**For technical support:**

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