

GM501 Collagenase

Material included in the packing:

- 3 ml GM501 Collagenase

Material not included in the packing:

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

Product code:

- 4 COLL_AIR

Composition:

- GM501 Collagenase is based on the sperm preparation media GM501 Air with Gentamicin and Phenolred.
- 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.
- It has an activity of 1000 CDUs/ml (Collagenase Digestive Units). The Collagenase is obtained from culture filtrates of clostridium histolyticum.

Intended use/Intended users

- GM501 Collagenase is a ready-to-use medium for the digestion of human testicular tissue obtained by testicular biopsy (TESE). Using Collagenase, it is possible to degrade testicular tissue in single cells to fa-

cilitate the isolation of sperm cells that can be used for the microinjection into oocytes (ICSI).

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

Instructions for use:

1. Extract 1.5 ml GM501 Collagenase out of original bottle and fill into a 5 ml round bottom tube.
2. Never place the GM501 Collagenase in a CO₂-Incubator, just warm up the medium to 37°C. The medium's pH is stable on air. Fill approx. 4,5 ml spermpreparation medium (GM501 Air) into a round bottom tube and also warm up to 37°C.
3. For digestion of testicular tissue carefully pick the chosen tissue pieces with a fine syringe cannula. For easier handling, if necessary, fill the tissue suspension into a 60 mm petri dish. Let adhesive transport or cryo medium drop off as much as possible and transfer into Collagenase tubes.
4. Close the tube complete. Now put the tube for 60 minutes in the incubator or ideally in a heat cabinet for digestion of the tissue.
5. Suspend the digested tissue by carefully pipetting up and down. Under ideal conditions a suspension of single testicular tissue cells and free semen cells has been formed. If coarse tissue pieces are still visible, repeat the process 3 for a further 20 to 30 minutes.
6. Now centrifuge the tissue cell suspension and wash 2 twice times with 1-2 ml spermpreparation medium (GM501 Air). Discard the obtained supernatants.
7. After the last centrifugation re-suspend the pellet in a small volume of 30-80 µl spermpreparation medium (GM501 Air) and add a few µl into the drops provided for it in the ICSI dish(es).
8. Control by microscope whether viable semen cells are present. If not, digest further tissue sample.
9. Pick up the motile Sperms for the ICSI.
10. If no motile sperms can be found Gynemed recommends the application of GM501 SpermMobil.

Product specifications and quality control:

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

pH (at 37°C, 6 % CO ₂)	7.10 - 7.40
Osmolality (mOsm/kg)	270 - 310
Sterility	steril - SAL 10 ⁻³ (Sterility Assurance Level)

NOTE:

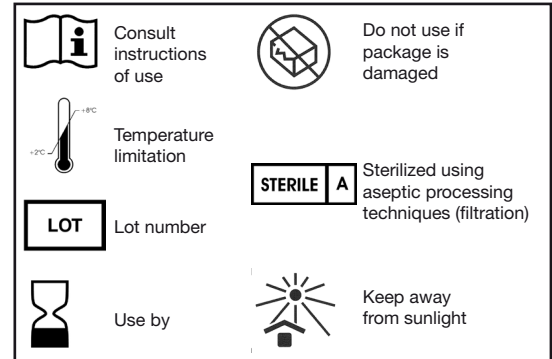
- Performing LAL-endotoxin and MEA-test is not possible with these media as the activity of the Collagenase inactivates the enzymes (LAL) and damages the mouse embryos (MEA), which are used for these assays, respectively. The basic media GM501 Air with Gentamicin and Phenolred is LAL- and MEA-tested.

Precautions and warnings:


- GM501 Collagenase contain 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 from is 9 month 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.



For technical support:


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