

GM501 Wash

Material included in the package:

- 20 ml GM501 Wash
- 50 ml GM501 Wash
- 500 ml GM501 Wash

Material not included in the package:

- CO₂-incubator at 37°C
- Petri-dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

- 4 GM 501W-20
- 4 GM 501W-50
- 4 GM 501W-500

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose anhydrous, Na-Lactate (50 % solution), Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential and essential Amino Acids, 15 mM HEPES, human serum albumin (5.00 g/liter).

Intended use/Intended users:

- The media are ready-to-use media designed for washing procedures of human oocytes and embryos and any short-term handling procedures outside the incubator like washing after Hyaluronidase treatment (denudation), ICSI, polar body or blastomere biopsy and others.
- 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.

GM501 Wash with Phenolred and Gentamicin

Material included in the package:

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

Material not included in the package:

- CO₂-incubator at 37°C
- Petri-dishes
- LAF-bench (ISO 5 environment)
- Microscope
- Test-tubes

Product code:

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

Composition:

- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose anhydrous, Na-Lactate (50 % solution), Na-Pyruvate, EDTA, Alanine-Glutamine, water, non-essential and essential Amino Acids, 15 mM HEPES, human serum albumin (5.00 g/liter), Gentamicin (10 mg/liter), Phenolred.

- 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 ₂)	7.20-7.50
Osmolality (mOsm/kg)	270-290
Sterility	sterile - SAL 10 ⁻³ (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96h in %)	≥ 80 after 60 min exposure (zygote stage)

Instructions for use:

- The medium must be equilibrated over night in a humidified CO₂-incubator (at 5-7 % CO₂, 37°C).

Precautions and warnings:









- GM501 Wash with Phenolred and Gentamicin 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 Wash 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 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 expiry date.

	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

For technical support:



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