GM501 Gradient 45% - 90% (EN)

GYNEMED

Material included in the package:
GM501 Gradient 45 %

Product code: 4 GM 501G-45-10
- 1 x 10 ml GM501 Gradient 45 %

Product code: 4 GM 501G-45-50
- 1 x 50 ml GM501 Gradient 45 %

Product code: 4 GM 501G-45-100
- 1 x 100 ml GM501 Gradient 45 %

Product code: 4 GM 501G-45-250
- 1 x 250 ml GM501 Gradient 45 %

Material included in the package:
GM501 Gradient 90 %

Product code: 4 GM 501G-90-10
- 1 x 10 ml GM501 Gradient 90 %

Product code: 4 GM 501G-90-50
- 1 x 50 ml GM501 Gradient 90 %

Product code: 4 GM 501G-90-100
- 1 x 100 ml GM501 Gradient 90 %

Product code: 4 GM 501G-90-250
- 1 x 250 ml GM501 Gradient 90 %

Material not included in the package:
- Incubator or water bath at 37°C (optional)
- LAF bench (ISO 5 environment)
- Test tubes
- 3 cc syringes with 21 G needle
- Centrifuge (must be able to operate for up to 30 minutes at 400 g)
- Sperm washing medium (e.g. GM501 SpermActive)

Composition:
- GM501 Gradient 45 % and 90 % consists of silane-coated colloidal silica particles suspended in HEPES-buffered medium.

Intended use/Intended users:
- GM501 Gradient 45 % and 90 % is a gradient system for semen preparation. GM501 Gradient 45 % and 90 % can be used in combination with IUI, IVF and ICSI.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Calculation of g-forces:
- The g-force of your centrifuge can be calculated using this formula:

$g = 1.118 \times r \times rpm^2$ or rpm = Square root {g/ (1.118 x r)}
r = radius of centrifuge in mm
rpm = rotations per minute/1000

Example 1
r = 150 mm
rpm = 1200 rotations per minute
g = 1.118 x 150 x 1.44 = 242 g
Example 2
r = 150 mm
g = 300 g
rpm = SQR {300/ (1.118 x 150)} = 1.33
rpm = 1330 rotations per minute

Instruction for use with fresh semen samples:
1. Before use warm all components of the system and the samples to 37°C or to room temperature.
2. Mix the density gradient bottles by 5 bottles inversions before use.
3. Pipet 2.5 ml of the lower density gradient (45 %) into a sterile disposable centrifuge tube.
4. Using a 3 cc syringe with a 21 G needle, layer 2.5 ml of the higher density gradient (90 %) under the lower density gradient (45 %) free of air bubbles. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle at the bottom of the centrifuge tube and slowly dispensing the higher density gradient. This two layer gradient is stable for about two hours.
5. Gently place 2.5 ml of liquefied semen onto the upper layer using a transfer pipette or syringe.
6. Centrifuge at 350-400 g for 15-18 minutes. In case, no pellet is visible after this step, centrifuge for another 3 minutes.
7. Aspirate the supernatant.
8. Using a syringe, resuspend the pellet with 2-3 ml of fresh washing medium.
9. Centrifuge at 300 g for 8-10 minutes. In case you want to gain higher sperm concentrations it is advisable to centrifuge for the whole 10 minutes.
10. Aspirate the supernatant and repeat the last two steps.
11. Finally remove the supernatant and resususpend the peltet again in appropriat medium for the use with the subsequent procedure of assisted reproductive medicine (e.g. IVF, ICSI, IUI).

Instruction for use with frozen semen samples:
1. Before use warm all components of the system and the samples to 37°C or to room temperature.
2. Mix the density gradient bottles by 5 bottle inversions before use.
3. Pipet 1 ml of the lower density gradient (45 %) into a sterile disposable centrifuge tube.
4. Using a 3 cc syringe with a 21 G needle, layer 1 ml of the higher density gradient (90 %) under the lower density gradient (45 %) free of air bubbles. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle at the bottom of the centrifuge tube and slowly dispensing the higher density gradient. These two layers of density are stable for about two hours.
5. Gently place maximum 0.5 ml of thawed semen onto the upper layer using a transfer pipette or syringe.
6. Centrifuge for 15-20 minutes at 350 g. In case, no pellet is visible after this step, centrifuge for another 3 minutes.
7. Aspirate the supernatant down to no less than the 0.5 ml mark above the pellet.
8. Using a syringe, resuspend the pellet with 2-3 ml of fresh washing medium.
9. Centrifuge at 300 g for 8-10 minutes. In case you want to gain higher sperm concentrations it is advisable to centrifuge for the whole 10 minutes.
10. Aspirate the supernatant and repeat the last two steps.
11. Finally remove the remaining liquid to have the pellet resuspended again in the desired amount for the use with the subsequent procedure of assisted reproductive medicine (e.g. IVF, ICSI, IUI).

In order to achieve better seperation of the spermatozoa the sample should not be diluted, but rather the centrifugal force should be increased (not higher than 500 g).

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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 Gradient 45 % and 90 % is available upon request and can also be downloaded from our website.
- GM501 Gradient 45 % and 90 % is manufactured according to the following specifications:

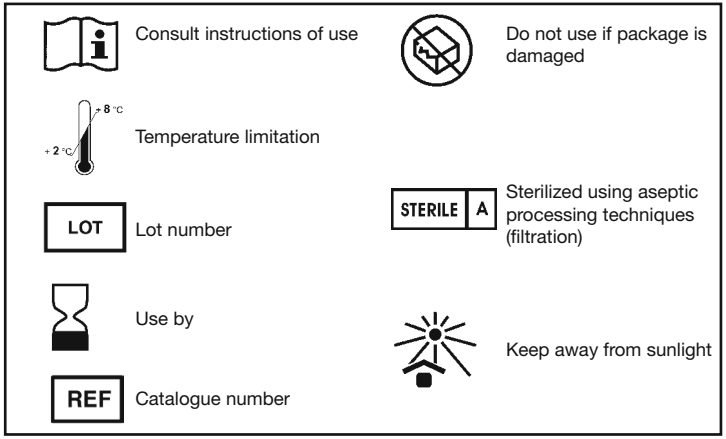
pH	7.20-7.90 (Release criteria: 7.20-7.60)
Osmolality (mOsm/kg)	310-340 (GM501 Gradient 45 %) 320-350 (GM501 Gradient 90 %)
Density (g/ml)	1.1050-1.1150 (GM501 Gradient 90 %)
Viscosity (cP)	< 1.65 (GM501 Gradient 90 %)
Sterility	sterile - SAL10^{-3} (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.5
Sperm Survival test	≥ 80% survival after 4 hours exposure of density selected spermatozoa to the test medium
Mouse Embryo Assay (MEA)	not MEA tested

Precautions and warnings:

- All human organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting HIV or hepatitis.
- Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (e.g. LAF-bench, ISO Class 5) to avoid possible contamination.
- Only for the intended use.

Pre-use checks:

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



Storage instructions and stability:

- The shelf life is 18 months from time of manufacture.
- Store products between 2-8°C.
- 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.
- Do not freeze before use.
- Do not use after expiry date.
- Keep away from (sun)light.
- Content cannot be re-sterilized after opening.
- Stable after transport (max. 5 days) at elevated temperature (≤ 37°C).

For technical support:

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