

Material included in the package:

- 1 ml GM508 CultActive

Material not included in the package:

- CO₂-incubator at 37°C
- Petri dishes
- LAF-bench (ISO Class 5)
- Microscope
- Test tubes
- Embryo culture medium

Product code:

- 4 GM 508CULT-active1

Composition:

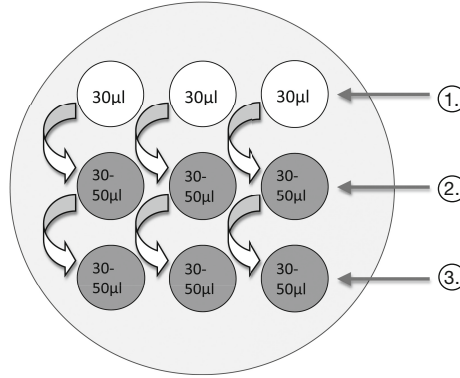
- NaCl, KCl, KH₂PO₄, MgSO₄·7H₂O, NaHCO₃, CaCl₂·2H₂O, D(+)-Glucose anhydrous, Na-Lactate, Na-Pyruvate, EDTA, Alaninyl-Glutamine, water, non-essential and essential Amino Acids, DMSO, Ca²⁺-Ionophore A23187.

Intended use/Intended users

- GM508 CultActive is a bicarbonate-buffered reagent designed to investigate oocytes of patients with failed fertilization after previous Intracytoplasmic Sperm Injection cycles.
- GM508 CultActive is designed to investigate if fertilization failure after previous ICSI-cycles is due to a deficient oocyte activation.
- The intended users are IVF professionals (biologists, lab technicians, embryologists or medical doctors).

Instructions for use:

- GM508 CultActive must be shaken directly before use for approximately 30 sec.
- GM508 CultActive must be equilibrated 4 hours in a vial not firmly closed at 5-7 % CO₂ and 37°C prior to use.
- Equilibrate culture medium for washing (e.g. GM501 Cult) for 4 hours in a vial not firmly closed at 5-7 % CO₂ and 37°C prior to use.
- Prepare for each oocyte 1 drop (30 µl) GM508 CultActive and 2 drops (30-50 µl) MOPS- and HEPES-free culture medium, (e.g. GM501 Cult). An oil overlay is not necessary due to the short exposure time.



1. Activation - GM508 CultActive - 30 µl
2. Washing Step 1 - e.g. GM501 Cult - 30-50 µl
3. Washing Step 2 - e.g. GM501 Cult - 30-50 µl

- Immediately after the ICSI procedure incubate the oocytes for 15 minutes in the pre-equilibrated Ca²⁺-Ionophore GM508 CultActive drops. -Step 1
- Remove the oocytes from the GM508 CultActive drop and wash them twice in culture media. This has to be done in a HEPES- or MOPS-free medium, e.g. GM501 Cult. -Step 2 and 3
- Put the oocytes in your culture media for further culture.
- Assess the development on specific time points.

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 GM508 CultActive is available upon request and can be downloaded from our website.
- GM508 CultActive is manufactured and tested according to the following specifications:

pH (at 37 °C, 6 % CO ₂)	7.00-7.60
Osmolality (mOsm/kg)	400-450
Sterility	sterile - SAL 10 ⁻³ (Sterility Assurance Level)
Endotoxins (EU/ml)	< 0.25
MEA (Blastocysts after 96 h in %)	≥ 80

Precautions and warnings:

- Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Product does not contain any antibiotics. 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 bottle, seal of the container or package is opened or defective 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:

- 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.
- 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 (sun)light
	Use by		In-vitro-diagnostic device
	Catalogue number		

For technical support:

GYNEMED Medizinprodukte GmbH & Co. KG,
Lübecker Straße 9, 23738 Lensahn - Germany
Phone: +49 (0) 4363 90 32 90 - **Fax:** +49 (0) 4363 90 32 9-19
Email: info@gynemed.de - **http:** //www.gynemed.de