

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium
Product code: FEM-20
Lot number: J000006111
Expiry date: 06 Aug. 2024

Intended Use

Fertilisation Medium is used to provide a suitable environment for both oocytes and sperm, to promote optimal fertilisation rates.

USA only: Gems Fertilisation Medium is used to provide a suitable environment for both oocytes and sperm and support *in vitro* fertilisation. This medium can be used for transfer of zygotes into the uterus.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician or practitioner trained in its use.

Product Analysis

| Assay | Specification | Result |
|-------------------------------------|--|--------|
| pH at 37°C with 6 % CO ₂ | 7.30 – 7.50 | Pass |
| Osmolality | 295 – 305 mOsm/kg | Pass |
| MEA | MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours | Pass |
| Endotoxin | <0.4 EU/mL | Pass |
| Sterility | No Growth | Pass |
| HSA Analysis | 3.8 – 6.2 mg/mL | Pass |
| Gentamicin | 0.0075 – 0.0125 mg/mL | Pass |

Product passed and released by Quality

Signature:

Name: Elliot Atchison

Job Title: Manufacturing QA Team Leader

Date: 08 Sep. 2023