

# Certificate of Analysis



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## Product Details

**Product description:** Fertilisation Medium  
**Product code:** FEM-50  
**Lot number:** J000006505  
**Expiry date:** 11 Mar. 2025

## 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 <sub>2</sub> | 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:**

Electronically signed by: Lalitha Kalyanaraman  
Reason: QA Approval  
Date: Apr 16, 2024 10:22 GMT+10

**Name:** Lalitha Kalyanaraman

**Job Title:** QA Associate

**Date:** 16 Apr. 2024