

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium

Product code: FEM-20

Lot number: J000007655

Expiry date: 16 Nov. 2026

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 | 7.3 – 7.5 | Pass |
| Osmolality | 295 – 305 mOsm/kg | Pass |
| MEA | MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours | Pass |
| Endotoxin | <0.40 EU/mL | Pass |
| Sterility | No Growth | Pass |
| HSA Analysis | 3.75 - 6.25 mg/mL | Pass |
| Gentamicin | 0.0075 – 0.0125 mg/mL | Pass |

Product passed and released by Quality

Electronically signed by: Nicole

Connor

Signature:

Reason: QA Approval

Date: Dec 17, 2025 11:12:33 GMT+11

Name: Nicole Connor

Job Title: Quality Assurance Associate

Date: 17 Dec. 2025

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Final Audit Report

2025-12-17

| | |
|-----------------|---|
| Created: | 2025-12-17 (Australian Eastern Daylight Time) |
| By: | Nicole Connor (nicole.connor@geneabimex.com) |
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