

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium
Product code: FEM-50
Lot number: J000007516
Expiry date: 24 Aug. 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

Signature:

Electronically signed by: Elliot Atchison
Reason: Approval
Date: Oct 1, 2025 13:56:26 GMT+10

Name: Elliot Atchison

Job Title: QA Lead

Date: 01 Oct. 2025







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Final Audit Report

2025-10-01

| | |
|-----------------|---|
| Created: | 2025-10-01 (Australian Eastern Standard Time) |
| By: | Elliot Atchison (elliott.atchison@geneabiomedx.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAQ5PFc3RtebQdYBYforwhp9fSPDKiNjD5 |

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