

# Certificate of Analysis



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## Product Details

**Product description:** Fertilisation Medium  
**Product code:** FEM-50  
**Lot number:** J000007702  
**Expiry date:** 07 Jan. 2027

## 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> | 7.3 – 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: Nicole Connor  
Reason: QA Approval  
Date: Feb 9, 2026 08:58:21 GMT+11

**Name:** Nicole Connor

**Job Title:** Quality Assurance Associate

**Date:** 09 Feb. 2026

# Certificate of Analysis- J000007702

Final Audit Report

2026-02-09

|                 |  |
|-----------------|--|
| Created:        | 2026-02-09 (Australian Eastern Daylight Time)  |
| By:             | Nicole Connor (nicole.connor@geneabiomedx.com) |
| Status:         | Signed   |
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