

# Certificate of Analysis



Level 2, 321 Kent Street, Sydney NSW 2000, Australia

Phone: +61 2 8228 2719  
Email: [info@geneabiomedx.com](mailto:info@geneabiomedx.com)  
Website: [geneabiomedx.com](http://geneabiomedx.com)

## Product Details

**Product description:** Fertilisation Medium  
**Product code:** FEM-50  
**Lot number:** J000007099  
**Expiry date:** 25 Nov. 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>	7.3 – 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:  
Eila McGregor  
Reason: QA Approval  
Date: Mar 12, 2025 11:42  
GMT+11

**Name:** Eila McGregor  
**Job Title:** Quality Assurance Associate  
**Date:** 12 Mar. 2025








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Final Audit Report

2025-03-12

Created:	2025-03-12 (Australian Eastern Daylight Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUaU0-O4oSB-u7PrsBEvs5q9V_YIPS_8J

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