

# Certificate of Analysis



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## Product Details

**Product description:** Fertilisation Medium  
**Product code:** FEM-20  
**Lot number:** J000007331  
**Expiry date:** 14 May. 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 <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: Jun 19, 2025 15:40 GMT+10

**Name:** Eila McGregor  
**Job Title:** Quality Assurance Associate  
**Date:** 19 Jun. 2025








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Final Audit Report

2025-06-19

Created:	2025-06-19 (Australian Eastern Standard Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAwP8BQtdkktHTBF83sLLMHznkkDzW07YF

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