

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium
Product code: FEM-20
Lot number: J000007689
Expiry date: 01 Dec. 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:

A handwritten signature in black ink, appearing to read 'nconnor'.

Electronically signed by: Nicole Connor
Reason: QA Approval
Date: Jan 6, 2026 11:27:50 GMT+11

Name: Nicole Connor

Job Title: Quality Assurance Associate

Date: 06 Jan. 2026








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Final Audit Report

2026-01-06

Created:	2026-01-06 (Australian Eastern Daylight Time)
By:	Nicole Connor (nicole.connor@geneabiomedx.com)
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Transaction ID:	CBJCHBCAABAAJcWoI19DrGz0fOHBAzuUjkWsgiG-CEBd

"Certificate of Analysis- J000007689" History

-  Document created by Nicole Connor (nicole.connor@geneabiomedx.com)
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