

Certificate of Analysis



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

Phone: +61 2 8228 2719
Email: info@geneabiomedx.com
Website: geneabiomedx.com

Product Details

Product description: Fertilisation Medium
Product code: FEM-50
Lot number: J000007629
Expiry date: 02 Nov. 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: Nicole Connor
Reason: QA Approval
Date: Dec 11, 2025 14:53:59 GMT+11

Name: Nicole Connor
Job Title: Quality Assurance Associate
Date: 11 Dec. 2025








Certificate of Analysis- J000007629

Final Audit Report

2025-12-11

Created:	2025-12-11 (Australian Eastern Daylight Time)
By:	Nicole Connor (nicole.connor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAADZaNoDFTWa-DmdulpEaNJnnG4i0fPU-Q

"Certificate of Analysis- J000007629" History

-  Document created by Nicole Connor (nicole.connor@geneabiomedx.com)
2025-12-11 - 2:52:59 PM GMT+11- IP address: 149.167.36.126
-  Document emailed to Nicole Connor (nicole.connor@geneabiomedx.com) for signature
2025-12-11 - 2:53:20 PM GMT+11
-  Email viewed by Nicole Connor (nicole.connor@geneabiomedx.com)
2025-12-11 - 2:53:26 PM GMT+11- IP address: 48.215.3.140
-  Nicole Connor (nicole.connor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-12-11 - 2:53:38 PM GMT+11
-  Document e-signed by Nicole Connor (nicole.connor@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2025-12-11 - 2:53:59 PM GMT+11 - Time Source: server- IP address: 149.167.36.126
-  Agreement completed.
2025-12-11 - 2:53:59 PM GMT+11
-  Nicole Connor (nicole.connor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-12-11 - 2:53:59 PM GMT+11