

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: J000007454
Expiry date: 13 Jul. 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: Daire Dowling
Reason: QA Approval
Date: Aug 25, 2025 12:59:27 GMT+1

Name: Daire Dowling
Job Title: Quality Assurance Associate
Date: 25 Aug. 2025








Certificate of Analysis - J000007454

Final Audit Report

2025-08-25

Created:	2025-08-25 (Australian Eastern Standard Time)
By:	Daire Dowling (daire.dowling@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAKvfbNrEz5fPgYMAr48FXraWv4euyMHZ8

"Certificate of Analysis - J000007454" History

-  Document created by Daire Dowling (daire.dowling@geneabiomedx.com)
2025-08-25 - 9:52:35 PM GMT+10- IP address: 89.19.79.124
-  Document emailed to Daire Dowling (daire.dowling@geneabiomedx.com) for signature
2025-08-25 - 9:58:12 PM GMT+10
-  Email viewed by Daire Dowling (daire.dowling@geneabiomedx.com)
2025-08-25 - 9:58:21 PM GMT+10- IP address: 4.199.143.156
-  Daire Dowling (daire.dowling@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-08-25 - 9:58:44 PM GMT+10
-  Daire Dowling (daire.dowling@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-08-25 - 9:59:25 PM GMT+10
-  Document e-signed by Daire Dowling (daire.dowling@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2025-08-25 - 9:59:27 PM GMT+10 - Time Source: server- IP address: 89.19.79.124
-  Agreement completed.
2025-08-25 - 9:59:27 PM GMT+10