

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-20
Lot number: J000007358
Expiry date: 19 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 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 'Elliot Atchison'.

Electronically signed by:
Elliot Atchison
Reason: Approval
Date: Jun 19, 2025 13:27
GMT+10

Name: Elliot Atchison

Job Title: QA Lead

Date: 19 Jun. 2025








Certificate of Analysis - J000007358

Final Audit Report

2025-06-19

Created:	2025-06-19 (Australian Eastern Standard Time)
By:	Elliot Atchison (elliott.atchison@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAvsJIGDo_TOXQ28ZHS1untHHHrH4BI

"Certificate of Analysis - J000007358" History

-  Document created by Elliot Atchison (elliott.atchison@geneabiomedx.com)
2025-06-19 - 1:23:40 PM GMT+10- IP address: 202.67.82.173
-  Document emailed to Elliot Atchison (elliott.atchison@geneabiomedx.com) for signature
2025-06-19 - 1:23:55 PM GMT+10
-  Email viewed by Elliot Atchison (elliott.atchison@geneabiomedx.com)
2025-06-19 - 1:24:00 PM GMT+10- IP address: 68.218.165.131
-  Elliot Atchison (elliott.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-06-19 - 1:24:14 PM GMT+10
-  Document e-signed by Elliot Atchison (elliott.atchison@geneabiomedx.com)
Signing reason: Approval
Signature Date: 2025-06-19 - 1:27:20 PM GMT+10 - Time Source: server- IP address: 202.67.82.173
-  Agreement completed.
2025-06-19 - 1:27:20 PM GMT+10
-  Elliot Atchison (elliott.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-06-19 - 1:27:20 PM GMT+10