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: J000007180

Expiry date: 13 Jan. 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: Eila McGregor Reason: QA Approval Date: Apr 9, 2025 09:47 GMT+10

Name: Eila McGregor

Job Title: Quality Assurance Associate

Date: 09 Apr. 2025

QFRM208-12 Page 1 of 1

Certificate of Analysis - J000007180

Final Audit Report 2025-04-09

Created: 2025-04-09 (Australian Eastern Standard Time)

By: Eila McGregor (eila.mcgregor@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAkyeUKJySLNmu-tTnb1tAxoWi1b38RrvV

"Certificate of Analysis - J000007180" History

Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com) 2025-04-09 - 9:43:33 AM GMT+10- IP address: 163.47.70.127

- Document emailed to Eila McGregor (eila.mcgregor@geneabiomedx.com) for signature 2025-04-09 9:45:26 AM GMT+10
- Email viewed by Eila McGregor (eila.mcgregor@geneabiomedx.com) 2025-04-09 9:45:37 AM GMT+10- IP address: 20.28.16.4
- Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign. Challenge: The user opened the agreement.

2025-04-09 - 9:46:28 AM GMT+10

☑ Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2025-04-09 - 9:47:30 AM GMT+10

Document e-signed by Eila McGregor (eila.mcgregor@geneabiomedx.com)

Signing reason: QA Approval

Signature Date: 2025-04-09 - 9:47:31 AM GMT+10 - Time Source: server- IP address: 163.47.70.127

Agreement completed.

2025-04-09 - 9:47:31 AM GMT+10

