

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: J000008028
Expiry date: 24 Jun. 2027

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: Caitlin De Cruz
Reason: QA Approval
Date: Jul 29, 2026 13:48:21 GMT
+10

Name: Caitlin De Cruz

Job Title: Quality Assurance Associate

Date: 29 Jul. 2026

Certificate of Analysis - J000008028

Final Audit Report

2026-07-29

Created:	2026-07-29 (Australian Eastern Standard Time)
By:	Caitlin De Cruz (caitlin.decruz@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAINEQ0ZC1bjcDn0YxjdxhzBmM5ek2jTVN

"Certificate of Analysis - J000008028" History

-  Document created by Caitlin De Cruz (caitlin.decruz@geneabiomedx.com)
2026-07-29 - 1:46:49 PM GMT+10- IP address: 157.211.44.217
-  Document emailed to Caitlin De Cruz (caitlin.decruz@geneabiomedx.com) for signature
2026-07-29 - 1:47:06 PM GMT+10
-  Email viewed by Caitlin De Cruz (caitlin.decruz@geneabiomedx.com)
2026-07-29 - 1:47:20 PM GMT+10- IP address: 4.199.143.130
-  Caitlin De Cruz (caitlin.decruz@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2026-07-29 - 1:47:34 PM GMT+10
-  Caitlin De Cruz (caitlin.decruz@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2026-07-29 - 1:48:16 PM GMT+10
-  Document e-signed by Caitlin De Cruz (caitlin.decruz@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2026-07-29 - 1:48:21 PM GMT+10 - Time Source: server- IP address: 157.211.44.217 - Signature Appearance Selected: IMAGE
-  Agreement completed.
2026-07-29 - 1:48:21 PM GMT+10