

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: J000006888
Expiry date: 28 Aug. 2025

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: Lalitha Kalyanaraman
Reason: QA Approval
Date: Oct 16, 2024 11:21 GMT+11

Name: Lalitha Kalyanaraman

Job Title: QA Associate

Date: 16 Oct. 2024







Certificate of Analysis - J000006888

Final Audit Report

2024-10-16

Created:	2024-10-16 (Australian Eastern Daylight Time)
By:	Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAngcCx_WPzxjJtTb02KDOXoiUXPWABunC

"Certificate of Analysis - J000006888" History

-  Document created by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
2024-10-16 - 11:20:43 AM GMT+11- IP address: 58.111.90.210
-  Document emailed to Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) for signature
2024-10-16 - 11:21:04 AM GMT+11
-  Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-10-16 - 11:21:23 AM GMT+11
-  Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-10-16 - 11:21:52 AM GMT+11
-  Document e-signed by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2024-10-16 - 11:21:53 AM GMT+11 - Time Source: server- IP address: 58.111.90.210
-  Agreement completed.
2024-10-16 - 11:21:53 AM GMT+11