

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: Blastocyst Medium
Product code BLM-50
Lot number: J000007376
Expiry date: 27 May. 2026

Intended Use

Blastocyst Medium is used to provide necessary nutrients for embryo development *in vitro* from the cleavage stage to the blastocyst stage. The embryos may remain in this solution for up to 3 days prior to being transferred to the uterus.

USA only: Gems Blastocyst Medium is for *in vitro* culture of embryos from the cleavage stage to the blastocyst stage of development. This medium can be used for transfer of blastocyst stage embryos 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	7.25 – 7.45	Pass
Osmolality	285 – 295 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: Jun 26, 2025 13:30 GMT+10

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 26 Jun. 2025








Certificate of Analysis - J000007376

Final Audit Report

2025-06-26

Created:	2025-06-26 (Australian Eastern Standard Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAACKCTSRa_mDAT_Ojmlb7o7Qklvu7gFVEG

"Certificate of Analysis - J000007376" History

-  Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com)
2025-06-26 - 1:29:00 PM GMT+10- IP address: 163.47.70.127
-  Document emailed to Eila McGregor (eila.mcgregor@geneabiomedx.com) for signature
2025-06-26 - 1:29:18 PM GMT+10
-  Email viewed by Eila McGregor (eila.mcgregor@geneabiomedx.com)
2025-06-26 - 1:29:24 PM GMT+10- IP address: 48.215.3.155
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-06-26 - 1:29:53 PM GMT+10
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-06-26 - 1:30:16 PM GMT+10
-  Document e-signed by Eila McGregor (eila.mcgregor@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2025-06-26 - 1:30:17 PM GMT+10 - Time Source: server- IP address: 163.47.70.127
-  Agreement completed.
2025-06-26 - 1:30:17 PM GMT+10