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: Cleavage Medium

Product code CLM-50

Lot number: J000007403

Expiry date: 10 Jun. 2026

Intended Use

Cleavage Medium is used to provide necessary nutrients for embryo development *in vitro*. The embryos can remain in this solution for up to 2 days prior to being transferred to the uterus or grown for up to another 3 days in Blastocyst Medium (BLM-20, BLM-50).

USA only: Gems Cleavage Medium is for *in vitro* culture of embryos following fertilisation to the 4-8 cell stage. This medium can be used for transfer of cleavage 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	7.3 – 7.5	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: Elliot Atchison Reason: Approval Date: Jul 7, 2025 11:15 GMT+10

Name: Elliot Atchison

Job Title: QA Lead

Date: 07 Jul. 2025

QFRM206-10 Page 1 of 1

Certificate of Analysis - J000007403

Final Audit Report 2025-07-07

Created: 2025-07-07 (Australian Eastern Standard Time)

By: Elliot Atchison (elliot.atchison@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAB4pFNZ83t5wZrFLz6jNpNbxWtA6w3v5k

"Certificate of Analysis - J000007403" History

Document created by Elliot Atchison (elliot.atchison@geneabiomedx.com) 2025-07-07 - 11:15:01 AM GMT+10- IP address: 202.67.82.173

- Document emailed to Elliot Atchison (elliot.atchison@geneabiomedx.com) for signature 2025-07-07 11:15:15 AM GMT+10
- Email viewed by Elliot Atchison (elliot.atchison@geneabiomedx.com) 2025-07-07 11:15:22 AM GMT+10- IP address: 48.215.3.148
- Elliot Atchison (elliot.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign. Challenge: The user opened the agreement.

2025-07-07 - 11:15:29 AM GMT+10

Elliot Atchison (elliot.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2025-07-07 - 11:15:47 AM GMT+10

Document e-signed by Elliot Atchison (elliot.atchison@geneabiomedx.com)

Signing reason: Approval

Signature Date: 2025-07-07 - 11:15:48 AM GMT+10 - Time Source: server- IP address: 202.67.82.173

Agreement completed.

2025-07-07 - 11:15:48 AM GMT+10

