

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: Sperm Medium
Product code SPM-50
Lot number: J000007040
Expiry date: 28 Oct. 2025


Intended Use

Sperm Medium is used to wash and resuspend sperm for the insemination step in IUI, IVF or in diagnostic washing, optimised for storage in a 6% CO₂ incubator.

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
Sperm Toxicity Test	Sperm Survival Tested	Pass
Endotoxin	<0.40 EU/mL	Pass
Sterility	No Growth	Pass
HSA Analysis	7.50 – 12.50 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: Nov 26, 2024 08:30
GMT+11

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 26 Nov. 2024







Certificate of Analysis - J000007040

Final Audit Report

2024-11-26

Created:	2024-11-26 (Australian Eastern Daylight Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAACKzbeDOEbfaYhhIqRtuRJkfO1NEp8MAf

"Certificate of Analysis - J000007040" History

-  Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com)
2024-11-26 - 8:29:26 AM GMT+11- IP address: 125.7.7.82
-  Document emailed to Eila McGregor (eila.mcgregor@geneabiomedx.com) for signature
2024-11-26 - 8:30:02 AM GMT+11
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-11-26 - 8:30:21 AM GMT+11
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-11-26 - 8:30:44 AM GMT+11
-  Document e-signed by Eila McGregor (eila.mcgregor@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2024-11-26 - 8:30:45 AM GMT+11 - Time Source: server- IP address: 125.7.7.82
-  Agreement completed.
2024-11-26 - 8:30:45 AM GMT+11