

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: Oocyte Retrieval Buffer
Product code ORB-50
Lot number: J000007398
Expiry date: 09 Jun. 2026

Intended Use

Gems Oocyte Retrieval Buffer is used in the removal of oocytes from ovarian follicles.

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 25 °C in air	7.3 – 7.5	Pass
Osmolality	280 – 290 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
Gentamicin	0.0075 – 0.0125 mg/mL	Pass

Product passed and released by Quality

Signature:

A handwritten signature in black ink, appearing to read 'Emcgregor'.

Electronically signed by: Eila McGregor
Reason: QA Approval
Date: Sep 11, 2025 08:40:03 GMT+10

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 11 Sep. 2025

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Final Audit Report

2025-09-11

Created:	2025-09-11 (Australian Eastern Standard Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
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