

Certificate of Analysis



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Product Details

Product description: Oocyte Retrieval Buffer
Product code ORB-50
Lot number: J000007321
Expiry date: 21 Apr. 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 that reads 'Emcgregor'.

Electronically signed by: Eila
McGregor
Reason: QA Approval
Date: Jun 17, 2025 14:25
GMT+10

Name: Eila McGregor

Job Title: Quality Assurance Associate

Date: 17 Jun. 2025








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Final Audit Report

2025-06-17

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