Certificate of Analysis



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Product Details

Product description: Oocyte Retrieval Buffer

Product code ORB-50

Lot number: J000007469

Expiry date: 31 Jul. 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: EMGPGFO Reason: QA Approval Date: Sep 4, 2025 11:43:37 GMT+10

Name: Eila McGregor

Job Title: Quality Assurance Associate

Date: 04 Sep. 2025

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Final Audit Report 2025-09-04

Created: 2025-09-04 (Australian Eastern Standard Time)

By: Eila McGregor (eila.mcgregor@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAA1txRK446-r4jBwnMpS1P2U_eHKTC7itA

"Certificate of Analysis - J000007469" History

Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com) 2025-09-04 - 11:42:11 AM GMT+10- IP address: 163.47.70.120

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