Certificate of Analysis



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Product Details

Product description: Oocyte Retrieval Buffer

Product code ORB-50

Lot number: J000007618

Expiry date: 27 Oct. 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:

Electronically signed by: Nicole
Connor
Reason: QA Approval
Date: Dec 2, 2025 11:02:13 GMT+11

Name: Nicole Connor

Job Title: Quality Assurance Associate

Date: 02 Dec. 2025

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Final Audit Report 2025-12-02

Created: 2025-12-02 (Australian Eastern Daylight Time)

By: Nicole Connor (nicole.connor@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAHhiQUrl9LrEr_Z7dxuTnpLrM3xf-RlhQ

"Certificate of Analysis- J000007618" History

Document created by Nicole Connor (nicole.connor@geneabiomedx.com) 2025-12-02 - 11:01:11 AM GMT+11- IP address: 149.167.36.126

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Agreement completed.

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