# Certificate of Analysis



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#### **Product Details**

**Product description:** Oocyte Retrieval Buffer

Product code ORB-50

**Lot number:** J000007245

Expiry date: 04 Mar. 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: Emgrefor

Electronically signed by: Eila McGregor Reason: QA Approval Date: May 7, 2025 09:14 GMT+10

Name: Eila McGregor

Job Title: Quality Assurance Associate

**Date:** 07 May. 2025

QFRM211-11 Page 1 of 1

## Certificate of Analysis - J000007245

Final Audit Report 2025-05-07

Created: 2025-05-07 (Australian Eastern Standard Time)

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

Status: Signed

Transaction ID: CBJCHBCAABAAXCUG7RyFxvQjiazfE5622w48u0Q6jGVd

### "Certificate of Analysis - J000007245" History

Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com) 2025-05-07 - 9:13:43 AM GMT+10- IP address: 163.47.70.127

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