# 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:** J000007278

Expiry date: 23 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:

Electronically signed by: Elliot Atchison Reason: Approval Date: Jun 18, 2025 11:27 GMT+10

Name: Elliot Atchison

Job Title: QA Lead

**Date:** 18 Jun. 2025

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## Certificate of Analysis - J000007278

Final Audit Report 2025-06-18

Created: 2025-06-18 (Australian Eastern Standard Time)

By: Elliot Atchison (elliot.atchison@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAB2qhlj33PmmoefCn\_2o9Jwh\_dzq9YCmv

### "Certificate of Analysis - J000007278" History

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