# 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:** J000007456

Expiry date: 15 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:

Electronically signed by: Daire Dowling Reason: QA Approval Date: Sep 8, 2025 14:48:51 GMT+1

Name: Dáire Dowling

Job Title: Quality Assurance Associate

**Date:** 08 Sep. 2025

QFRM211-11 Page 1 of 1

## Certificate of Analysis - J000007456

Final Audit Report 2025-09-08

Created: 2025-09-08 (Australian Eastern Standard Time)

By: Daire Dowling (daire.dowling@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAppu3ISAKflQQbuFXiSXIhvj7977OA487

### "Certificate of Analysis - J000007456" History

Document created by Daire Dowling (daire.dowling@geneabiomedx.com) 2025-09-08 - 11:45:45 PM GMT+10- IP address: 89.19.79.66

- Document emailed to Daire Dowling (daire.dowling@geneabiomedx.com) for signature 2025-09-08 11:46:08 PM GMT+10
- Email viewed by Daire Dowling (daire.dowling@geneabiomedx.com)
  2025-09-08 11:46:14 PM GMT+10- IP address: 4.199.143.130
- Daire Dowling (daire.dowling@geneabiomedx.com) authenticated with Adobe Acrobat Sign. Challenge: The user opened the agreement.

2025-09-08 - 11:48:09 PM GMT+10

Daire Dowling (daire.dowling@geneabiomedx.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2025-09-08 - 11:48:49 PM GMT+10

Document e-signed by Daire Dowling (daire.dowling@geneabiomedx.com)

Signing reason: QA Approval

Signature Date: 2025-09-08 - 11:48:51 PM GMT+10 - Time Source: server- IP address: 89.19.79.66

Agreement completed.

2025-09-08 - 11:48:51 PM GMT+10

