# 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:** J000007508

**Expiry date:** 19 Aug. 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

Electronically signed by: Elliot Atchison

Peasor: Approval

Peasor: Approval

Reason: Approval Date: Oct 1, 2025 13:28:00 GMT+10

Date: Oct 1, 2025 13:28:00 GMT

Name: Elliot Atchison

Job Title: QA Lead

**Date:** 01 Oct. 2025

QFRM211-11 Page 1 of 1

## Certificate of Analysis - J000007508

Final Audit Report 2025-10-01

Created: 2025-10-01 (Australian Eastern Standard Time)

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

Status: Signed

Transaction ID: CBJCHBCAABAAcEZaaxzLXhaXa5MlEqK-nKBRmGJYQxDn

### "Certificate of Analysis - J000007508" History

Document created by Elliot Atchison (elliot.atchison@geneabiomedx.com)

2025-10-01 - 1:26:31 PM GMT+10- IP address: 202.67.82.173

- Document emailed to Elliot Atchison (elliot.atchison@geneabiomedx.com) for signature 2025-10-01 1:26:51 PM GMT+10
- Email viewed by Elliot Atchison (elliot.atchison@geneabiomedx.com) 2025-10-01 1:26:57 PM GMT+10- IP address: 4.199.143.156
- Elliot Atchison (elliot.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2025-10-01 - 1:27:12 PM GMT+10

Document e-signed by Elliot Atchison (elliot.atchison@geneabiomedx.com)

Signing reason: Approval

Signature Date: 2025-10-01 - 1:28:00 PM GMT+10 - Time Source: server- IP address: 202.67.82.173

Agreement completed.

2025-10-01 - 1:28:00 PM GMT+10

Elliot Atchison (elliot.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2025-10-01 - 1:28:00 PM GMT+10

