

# Certificate of Analysis



Level 2, 321 Kent Street, Sydney NSW 2000, Australia

Phone: +61 2 8228 2719  
Email: [info@geneabiomedx.com](mailto:info@geneabiomedx.com)  
Website: [geneabiomedx.com](http://geneabiomedx.com)

## Product Details

**Product description:** Oocyte Retrieval Buffer  
**Product code** ORB-50  
**Lot number:** J000007498  
**Expiry date:** 14 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

**Signature:**

A handwritten signature in black ink that reads 'ECooper'.

Electronically signed by: Eila Cooper  
Reason: QA Approval  
Date: Sep 25, 2025 11:14:32 GMT+10

**Name:** Eila Cooper  
**Job Title:** Quality Assurance Associate  
**Date:** 25 Sep. 2025








# Certificate of Analysis - J000007498

Final Audit Report

2025-09-25

|                 |                                               |
|-----------------|-----------------------------------------------|
| Created:        | 2025-09-25 (Australian Eastern Standard Time) |
| By:             | Eila Cooper (eila.cooper@geneabiomedx.com)    |
| Status:         | Signed                                        |
| Transaction ID: | CBJCHBCAABAAS6pTIZHN5vcvMLtENrerktUuJjzLwWn9  |

## "Certificate of Analysis - J000007498" History

-  Document created by Eila Cooper (eila.cooper@geneabiomedx.com)  
2025-09-25 - 11:13:27 AM GMT+10- IP address: 163.47.70.120
-  Document emailed to Eila Cooper (eila.cooper@geneabiomedx.com) for signature  
2025-09-25 - 11:13:52 AM GMT+10
-  Email viewed by Eila Cooper (eila.cooper@geneabiomedx.com)  
2025-09-25 - 11:14:00 AM GMT+10- IP address: 68.218.165.147
-  Eila Cooper (eila.cooper@geneabiomedx.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user opened the agreement.  
2025-09-25 - 11:14:12 AM GMT+10
-  Eila Cooper (eila.cooper@geneabiomedx.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2025-09-25 - 11:14:31 AM GMT+10
-  Document e-signed by Eila Cooper (eila.cooper@geneabiomedx.com)  
Signing reason: QA Approval  
Signature Date: 2025-09-25 - 11:14:32 AM GMT+10 - Time Source: server- IP address: 163.47.70.120
-  Agreement completed.  
2025-09-25 - 11:14:32 AM GMT+10