

# Certificate of Analysis



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## Product Details

**Product description:** Oocyte Retrieval Buffer  
**Product code** ORB-50  
**Lot number:** J000007949  
**Expiry date:** 24 May. 2027

## 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: Caitlin De Cruz  
Reason: QA Approval  
Date: Jul 1, 2026 13:47:04 GMT  
+10

**Name:** Caitlin De Cruz

**Job Title:** Quality Assurance Associate

**Date:** 01 Jul. 2026

# Certificate of Analysis - J000007949

Final Audit Report

2026-07-01

|                 |                                                    |
|-----------------|----------------------------------------------------|
| Created:        | 2026-07-01 (Australian Eastern Standard Time)      |
| By:             | Caitlin De Cruz (caitlin.deacruz@geneabiomedx.com) |
| Status:         | Signed                                             |
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