

# Certificate of Analysis



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## Product Details

**Product description:** Oocyte Retrieval Buffer  
**Product code** ORB-50  
**Lot number:** J000007057  
**Expiry date:** 10 Nov. 2025

## 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, appearing to read 'Elliot Atchison'.

Electronically signed by: Elliot Atchison  
Reason: Approval  
Date: Jun 11, 2025 11:01 GMT+10

**Name:** Elliot Atchison

**Job Title:** QA Lead

**Date:** 11 Jun. 2025








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Final Audit Report

2025-06-11

|                 |   |
|-----------------|---|
| Created:        | 2025-06-11 (Australian Eastern Standard Time)       |
| By:             | Elliot Atchison (elliott.atchison@geneabiomedx.com) |
| Status:         | Signed  |
| Transaction ID: | CBJCHBCAABAAQ5xpSKibWCCJwBYCFVf7WOmHpVfZpHc         |

## "Certificate of Analysis - J000007057" History

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