

# Certificate of Analysis



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## Product Details

**Product description:** Oocyte Retrieval Buffer

**Product code** ORB-50

**Lot number:** J000007293

**Expiry date:** 30 Mar. 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, appearing to read 'Elliot Atchison'.

Electronically signed by:  
Elliot Atchison  
Reason: Approval  
Date: Jun 12, 2025 13:38  
GMT+10

**Name:** Elliot Atchison

**Job Title:** QA Lead

**Date:** 12 Jun. 2025








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Final Audit Report

2025-06-12

Created:	2025-06-12 (Australian Eastern Standard Time)
By:	Elliot Atchison (elliott.atchison@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAXZFQITgb3jk8wMcY_LuKRG0aUF00lwZ4

## "Certificate of Analysis - J000007293" History

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