

# 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-20  
**Lot number:** J000007318  
**Expiry date:** 16 Apr. 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:**

Electronically signed by: Eila  
McGregor  
Reason: QA Approval  
Date: Jun 16, 2025 08:28  
GMT+10

**Name:** Eila McGregor  
**Job Title:** Quality Assurance Associate  
**Date:** 16 Jun. 2025








# Certificate of Analysis - J000007318

Final Audit Report

2025-06-16

Created:	2025-06-16 (Australian Eastern Standard Time)
By:	Eila McGregor (eila.mcgregor@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAszfUC2xiRe8zXTqk_5ZAoLlubMvjMCdl

## "Certificate of Analysis - J000007318" History

-  Document created by Eila McGregor (eila.mcgregor@geneabiomedx.com)  
2025-06-16 - 8:26:39 AM GMT+10- IP address: 220.245.114.106
-  Document emailed to Eila McGregor (eila.mcgregor@geneabiomedx.com) for signature  
2025-06-16 - 8:27:16 AM GMT+10
-  Email viewed by Eila McGregor (eila.mcgregor@geneabiomedx.com)  
2025-06-16 - 8:27:27 AM GMT+10- IP address: 68.218.165.157
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user opened the agreement.  
2025-06-16 - 8:27:43 AM GMT+10
-  Document e-signed by Eila McGregor (eila.mcgregor@geneabiomedx.com)  
Signing reason: QA Approval  
Signature Date: 2025-06-16 - 8:28:11 AM GMT+10 - Time Source: server- IP address: 220.245.114.106
-  Agreement completed.  
2025-06-16 - 8:28:11 AM GMT+10
-  Eila McGregor (eila.mcgregor@geneabiomedx.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2025-06-16 - 8:28:11 AM GMT+10