

Certificate of Analysis



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Product Details

Product description: Oocyte Retrieval Buffer
Product code: ORB-50
Lot number: J000006975
Expiry date: 07 Oct. 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:  Electronically signed by:
Eila McGregor
Reason: QA Approval
Date: Nov 26, 2024 07:26
GMT+11

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 26 Nov. 2024

Certificate of Analysis - J000006975

Final Audit Report

2024-11-26

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