Certificate of Analysis



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Product Details

Product description:

Oocyte Retrieval Buffer

Product code

ORB-50

Lot number:

J000006156

Expiry date:

26 Aug. 2024

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	7.30 – 7.50	
Osmolality	280 – 290 mOsm/kg	Pass Pass
MEA	MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours	Pass
Endotoxin	<0.4 EU/mL	Pass
Sterility	No Growth	Pass
Gentamicin	0.0075 – 0.0125 mg/mL	Pass

Product passed and released by Quality

Signature:

Name:

Elliot Atchison

Job Title:

Manufacturing QA Team Leader

Date:

23 Oct. 2023