

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium
Product code: FEM-50
Lot number: J000007062
Expiry date: 05 Nov. 2025

Intended Use

Fertilisation Medium is used to provide a suitable environment for both oocytes and sperm, to promote optimal fertilisation rates.

USA only: Gems Fertilisation Medium is used to provide a suitable environment for both oocytes and sperm and support *in vitro* fertilisation. This medium can be used for transfer of zygotes into the uterus.

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 37°C with 6 % CO ₂	7.3 – 7.5	Pass
Osmolality	295 – 305 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
HSA Analysis	3.75 - 6.25 mg/mL	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: Mar 3, 2025 14:04 GMT+11

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 03 Mar. 2025








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Final Audit Report

2025-03-03

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