

Certificate of Analysis



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Product Details

Product description: Fertilisation Medium
Product code: FEM-50
Lot number: J000006297
Expiry date: 12 Nov. 2024

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	7.30 – 7.50	Pass
Osmolality	295 – 305 mOsm/kg	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
HSA Analysis	3.8 – 6.2 mg/mL	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: 22 Jan. 2024