

Certificate of Analysis



Level 2, 321 Kent Street, Sydney NSW 2000, Australia

Phone:

+61 2 8228 2719

Email:

info@geneabiomedx.com

Website:

geneabiomedx.com

Product Details

Product description: Fertilisation Medium

Product code: FEM-50

Lot number: J000007033

Expiry date: 27 Oct. 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:

A handwritten signature in black ink that reads 'Eila McGregor'.

Name:

Eila McGregor

Job Title:

Quality Assurance Associate

Date:

08 Jan. 2025