

# Certificate of Analysis



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

Phone: +61 2 9229 6420  
Email: info@geneabiomedx.com  
Website: geneabiomedx.com

## Product Details

**Product description:** Fertilisation Medium  
**Product code:** FEM-50  
**Lot number:** J000006076  
**Expiry date:** 17 Jul. 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 <sub>2</sub>	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:**

Electronically signed by: Elliot Atchison  
Reason: approval  
Date: Oct 17, 2023 11:45 GMT+11

**Name:** Elliot Atchison

**Job Title:** Manufacturing QA Team Leader

**Date:** 17 Oct. 2023