

# 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-20

**Lot number:** J000006887

**Expiry date:** 28 Aug. 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 <sub>2</sub>	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, appearing to read 'E. McGregor'.

**Name:**

Eila McGregor

**Job Title:**

Quality Assurance Associate

**Date:**

12 Nov. 2024