# Certificate of Analysis



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#### **Product Details**

Product description: Blastocyst Medium

Product code BLM-50

**Lot number:** J000007178

Expiry date: 12 Jan. 2026

#### **Intended Use**

Blastocyst Medium is used to provide necessary nutrients for embryo development *in vitro* from the cleavage stage to the blastocyst stage. The embryos may remain in this solution for up to 3 days prior to being transferred to the uterus.

**USA only:** Gems Blastocyst Medium is for *in vitro* culture of embryos from the cleavage stage to the blastocyst stage of development. This medium can be used for transfer of blastocyst stage embryos 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>	7.25 – 7.45	Pass
Osmolality	285 – 295 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: Apr 9, 2025 10:33 GMT+10

Name: Eila McGregor

Job Title: Quality Assurance Associate

**Date:** 09 Apr. 2025

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Final Audit Report 2025-04-09

Created: 2025-04-09 (Australian Eastern Standard Time)

By: Eila McGregor (eila.mcgregor@geneabiomedx.com)

Status: Signed

Transaction ID: CBJCHBCAABAAgZsLQ78xbli2s1xTJFQMzzwm-d6bkWkj

### "Certificate of Analysis - J000007178" History

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