

# Certificate of Analysis



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## Product Details

**Product description:** Cleavage Medium

**Product code** CLM-50

**Lot number:** J000007448

**Expiry date:** 08 Jul. 2026

## Intended Use

Cleavage Medium is used to provide necessary nutrients for embryo development *in vitro*. The embryos can remain in this solution for up to 2 days prior to being transferred to the uterus or grown for up to another 3 days in Blastocyst Medium (BLM-20, BLM-50).

**USA only:** Gems Cleavage Medium is for *in vitro* culture of embryos following fertilisation to the 4-8 cell stage. This medium can be used for transfer of cleavage 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>	7.3 – 7.5	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: Daire Dowling  
Reason: QA Approval  
Date: Aug 12, 2025 14:37:40 GMT+10

**Name:** Dáire Dowling

**Job Title:** Quality Assurance Associate

**Date:** 12 Aug. 2025








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Final Audit Report

2025-08-12

Created:	2025-08-12 (Australian Eastern Standard Time)
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Transaction ID:	CBJCHBCAABAAOw95E65Z0yU18gLoN_M8ljdW4Y_vKA2Q

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