

Certificate of Analysis



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Product Details

Product description: Cleavage Medium
Product code CLM-50
Lot number: J000007382
Expiry date: 01 Jun. 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 ₂	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: Elliot Atchison
Reason: Approval
Date: Jul 2, 2025 08:45 GMT+10

Name: Elliot Atchison

Job Title: QA Lead

Date: 02 Jul. 2025








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Final Audit Report

2025-07-02

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