

Certificate of Analysis



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Product Details

Product description:	Blastocyst Medium
Product code	BLM-20
Lot number:	J000007650
Expiry date:	11 Nov. 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 ₂	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: Nicole Connor
Reason: QA Approval
Date: Dec 3, 2025 14:33:29 GMT+11

Name: Nicole Connor

Job Title: Quality Assurance Associate

Date: 03 Dec. 2025








Certificate of Analysis- J000007650

Final Audit Report

2025-12-03

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