Certificate of Analysis



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Product Details

Product description: Blastocyst Medium

Product code BLM-50

Lot number: J000006386

Expiry date: 22 Jan. 2025

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 | <0.4 EU/mL | Pass |
| Sterility | No Growth | Pass |
| HSA Analysis | 3.8 – 6.2 mg/mL | Pass |
| Gentamicin | 0.0075 – 0.0125 mg/mL | Pass |

Product passed and released by Quality

Signature:

Electronically signed by: Revathy Veera Raghavalu Reason: QA Approved Date: Feb 29, 2024 15:43 GMT+11

Name: Revathy Veera Raghavalu

Job Title: QA & RA Associate

29 Feb. 2024 Date:

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