

Certificate of Analysis



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Product Details

Product description: Cleavage Medium
Product code: CLM-20
Lot number: J000006424
Expiry date: 10 Feb. 2025

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 | 7.30 – 7.50 | 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: Elliot Atchison
Reason: Approval
Date: Mar 15, 2024 08:44 GMT+11

Name: Elliot Atchison
Job Title: Manufacturing QA Team Leader
Date: 15 Mar. 2024