Certificate of Analysis



Level 2, 321 Kent Street, Sydney NSW 2000, Australia

Phone:

+61 2 9229 6420

Email:

info@geneabiomedx.com

Website:

geneabiomedx.com

Product Details

Product description:

Cleavage Medium

Product code

CLM-50

Lot number:

J000006164

Expiry date:

28 Aug. 2024

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:

tmegregor

Name:

Eila McGregor

Job Title:

Quality Assurance Co-ordinator

Date:

18 Oct. 2023