Certificate of Analysis



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

Phone:

+61 2 8228 2719

Email:

info@geneabiomedx.com

Website: geneabiomedx.com

Product Details

Product description:

Blastocyst Medium

Product code

BLM-20

Lot number:

J000006550

Expiry date:

02 Apr. 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 % CO₂	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:

Name:

Elliot Atchison

Job Title:

Manufacturing QA Team Leader

Date:

01 May. 2024