Certificate of Analysis



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Product Details

Product description:

GAVI Medium Cartridge

Product code

GAVI-MED-20

Lot number:

J000006013

Expiry date:

17 Jun. 2024

Intended Use

Gavi Medium Cartridge is intended for use within the Gavi instrument (GAVI-INS-01) for the vitrification of human embryos for Assisted Reproductive Technology (ART) procedures.

GAVI-MED-20 comprises of Gavi Solution 1 containing 8 % DMSO and Gavi Solution 2 containing 16 % DMSO.

Product Analysis

Assay	Specification		Danilla
	Solution 1	Solution 2	Result
pH at 25 °C in air	7.30 – 7.50		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	12.6 – 21.0 mg/mL	10.1 – 16.9 mg/mL	Pass

Product passed and released by Quality

Signature:

Name:

Elliot Atchison

Job Title:

Manufacturing QA Team Leader

Date:

01 Sep. 2023