

Certificate of Analysis



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Product Details

Product description: GAVI Medium Cartridge
Product code GAVI-MED-20
Lot number: J000006341
Expiry date: 21 Nov. 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		Result
	Solution 1	Solution 2	
pH at 25 °C in air	7.3 – 7.5		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	12.60 – 21.00 mg/mL	10.13 – 16.88 mg/mL	Pass

Product passed and released by Quality

Signature:

*Electronically signed by:
Eila McGregor
Reason: QA Approval
Date: May 23, 2024
12:45 GMT+10*

Name: Eila McGregor
Job Title: Quality Assurance Associate
Date: 23 May. 2024