

Certificate of Analysis

Product: ARTSMedia In Vitro Culture Medium (AM-IVC Medium), 10 ml

Catalog No. 501010

Lot No.:	A23IVCB01
Production date:	2023-06-13
Expiry date:	2024-12-13
HSA Lot No.:	M306B86875

Quality Control	Test Method	Specification	Results
pH (37°C - 6% CO ₂)	Ph Eur. 2.2.3, USP <791>	7.20 - 7.45	7,38
Osmolality	Ph Eur. 2.2.35, USP <785>	257-275 mOsm/kg	262 mOsm/kg
Sterility	Ph Eur. 2.6.1, USP<71>	No growth	No growth
Mouse Embryo Assay	FDA guidance "Mouse Embryo Assay for Assisted Reproduction Technology Devices, January" 2021	1-Cell Mouse Embryo Assay (MEA) ≥80% of embryos developed to expanded blastocyst at 96 hours.	81%
Endotoxin	USP <85>	< 0.05 EU/ml	< 0.05 EU/ml
HSA Concentration	HPLC	2-3 mg / ml	3,0 mg/ml
Appearance	Visual inspection	Clear and particulate-free	Passed

Release date and signature:

2024JAN08



QA Manager

Version 5.0, 2023.01.30

Rx only

Company address:

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