

PRODUCT: Continuous Single Culture -NX (CSCM -NX)

LOT #0000031404

CATALOG #90167

MFR DATE: 12/23/2024

STORAGE: 2°- 8°C

EXPIRES: 04/22/2025

## CERTIFICATE OF ANALYSIS

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with the Guideline for Manufacture of In Vitro Diagnostic Products and the Good Manufacturing Practices (GMP's) for Medical Devices. FUJIFILM Irvine Scientific, Inc. is licensed by both Federal and State agencies and is inspected regularly for compliance.

Assay	Specification	Result
Sterility <sup>1</sup>	Pass	Pass
pH <sup>2</sup>	7.3-7.5	7.4
Osmolality	260-270 mOsm/Kg H <sub>2</sub> O	263 mOsm/Kg H <sub>2</sub> O
Endotoxin <sup>3</sup>	≤0.25 EU/ml	<0.05 EU/ml
Mouse Embryo Test (One-cell) <sup>4</sup>		
-Control:		
% of embryos developing	≥ 80%	94% (87/93)
-This lot:		
% of embryos developing	≥ 80%	100% (93/93)
Human Sperm Survival Assay <sup>5</sup>	≥ 70%	98%

<sup>1</sup>In accordance with the Current USP <71>; 21 CFR, Part 610.12.

<sup>2</sup>With CO<sub>2</sub> equilibration at 5.5% CO<sub>2</sub> (+/- 0.2% CO<sub>2</sub>) at 37°C

<sup>3</sup>Utilizes a Chromogenic Assay with a sensitivity of 0.05 EU/ml.

<sup>4</sup>One cell mouse embryo testing is performed using mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture.

<sup>5</sup>Human Sperm Survival Assay (HSSA) test results indicate the percent of original motility at 24 hours.

Released By: Dalia Ramirez

Date: 01/17/2025

Title: QA Product Release Coordinator

Rev 4