



PRODUCT: PBS 1X LOT #0000039218

Dulbecco's Phosphate Buffered

Saline solution CATALOG #9235

MFR DATE: 01/08/2025

STORAGE: 15°-30°C EXPIRES: 01/31/2026

## **CERTIFICATE OF ANALYSIS**

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with 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	7.0 - 7.2	7.0
Osmolality	270 - 290 mOsm/Kg H <sub>2</sub> O	281 mOsm/Kg H <sub>2</sub> O
Endotoxin <sup>2</sup>	≤0.5 EU/ml	<0.05 EU/ml
Mouse Embryo Test (One-cell) <sup>3</sup>		
-Control: % of embryos developing	≥ 80%	100% (93/93)
-This lot: % of embryos developing	≥ 80%	99% (92/93)

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

Control was for growth media only.

Released By: \_\_\_\_\_ Date: <u>01/29/2025</u>

Title: **QA Product Release Coordinator** 

<sup>&</sup>lt;sup>2</sup>Utilizes a Chromogenic assay with a sensitivity of 0.05 EU/ml.

<sup>&</sup>lt;sup>3</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 following a 2 hour exposure to PBS 1X.