

PRODUCT USP PURIFIED WATER LOT #XXXXXXXXX

CATALOG #9308

MFR DATE: 03/19/13

EXPIRES: 12/31/13

STORAGE: 2-30°C PREPARED BY: JN 03/26/13

## **CERTIFICATE OF ANALYSIS**

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

USP Purified Water is intended for use as an ingredient of official preparations and in tests and assays. Do not use USP Purified Water for sterile dosage forms or preparations intended for parenteral administration. USP Purified Water is not filled in a sterile area and into sterilized containers. It is produced from high purity water that meets USP microbial quality requirements. It contains no added substance.

Assay	Specification	Result
TOC	≤500ppb	92 ppb
Microbial Count	≤100 cfu/mL	1 cfu/mL
Conductivity <sup>1</sup>	$\leq$ 5 $\mu$ S/cm	$0.85 \mu\text{S/cm}$
Oxidizable Substances <sup>2</sup>	Pass	Pass

<sup>&</sup>lt;sup>1</sup>In accordance with current USP Conductivity <645> Stage 2.

<sup>&</sup>lt;sup>2</sup>In accordance with USP Water for Injection Monograph.