

Certificate of Analysis

Test Date: 1 August 2013
 Product: Osmolality Linearity Set
 Part Number: 3LA028
 Lot Number: 24057
 Expiration Date: 2016-01

Product Data

Test Method	Analytical Result	Specification
100 Osmolality (Freezing Point Depression)	101 mOsm/kg	100 ± 2.0 mOsm/kg
500 Osmolality (Freezing Point Depression)	501 mOsm/kg	500 ± 2.5 mOsm/kg
900 Osmolality (Freezing Point Depression)	902 mOsm/kg	900 ± 4.5 mOsm/kg
1500 Osmolality (Freezing Point Depression)	1498 mOsm/kg	1500 ± 7.5 mOsm/kg
2000 Osmolality (Freezing Point Depression)	2002 mOsm/kg	2000 ± 10.0 mOsm/kg

The Quality Management System of Advanced Instruments, Inc. and its subsidiaries is certified according to the requirements of ISO 9001 and ISO 13485. The product defined herein has been manufactured in accordance with Quality System requirements and conforms to all specifications.

Analyst Printed Name: MEREDITH PESTA Approver Printed Name: Julie Rosenman
 Signature: Meredith Pesta Signature: Julie Rosenman

Traceability

This product is traceable to NIST (SRM) 919b Sodium Chloride via an unbroken chain of comparisons. The NIST standards were formulated gravimetrically following USP Chapter 785 and tested on a Quality Control Freezing Point Depression Osmometer.

NIST Traceable Standard Used	Standard Lot Number	Standard Expiration
100 mOsm/kg	1002032	2014-07
500 mOsm/kg	0101083	2014-10
900 mOsm/kg	0801072	2014-05
1500 mOsm/kg	0101093	2014-10
2000 mOsm/kg	0102093	2014-10

Balances used to prepare these NIST standards have been calibrated with American Society for Testing and Materials (ASTM) class weights traceable to NIST.

Note: NIST standard formulation and balance calibration records are on file.

Hazardous Information: Refer to the Material Safety Data Sheet (MSDS).

Statement of Uncertainty: Refer to document DCN11-1283.

Storage and Handling: The information on this Certificate is only valid when the manufacturer's instructions are followed. Please see the product insert for more information.