Certificate of Analysis

ACCREDITED
CERT #6739.03

Osmolality Standard

Osmolality Standard 600 mOsm/kg H2O

Product No:	RE-OSM-600	Date of Measurement:	16/08/2024
Lot No:	OSM60024H1	Date of Sample Receipt:	16/08/2024
Expiry Date*:	28/08/2027	Date of Manufacture*:	16/08/2024

Specification:

597 - 603 mOsm/Kg H2O

Mean Measured Value:

599 mOsm/kg H2O

Method:
The result reported above was determined by analysis of a sample of this lot taken at time of manufacture. Tested in accordance with In-House Test Method TPOSM. This certificate relates solely to the sample as received by the laboratory, bearing the product code and lot number given above. The uncertainty of measurement has been estimated not to exceed ± 1.2% at 95% confidence level, i.e. coverage factor k =2. The uncertainty reported above was estimated in compliance with the Guide to the Expression of Uncertainty in Measurement (GUM), JCGM 100:2008.

Metrological Traceability:
Standard Osmolality Solutions used to calibrate the freezing point depression Osmometer Advance Instrument Model 3250 have traceability to NIST (SRM) 919b Sodium Chloride via an unbroken chain of comparisons.

Accreditation:
Reagecon Diagnostics Ltd. is accredited to ISO 17025 by the American Association for Laboratory Accreditation, under scope 6739.03, for the test method, TPOSM, used to generate the above result. This accreditation deems Reagecon competent on a quality systems level and a technical level to perform the tests on the scope of accreditation. Reagecon has the Quality Management Systems in place to ensure that each individual test result generated using TPOSM is technically valid and is supported by appropriate uncertainty measurements.

Date of Issue of the Certificate :

16/08/2024

Quality Director

MCGRATH Darren

All raw materials used to prepare this product are of high purity.
*The detail above is based on information supplied in writing by Reagecon Manufacturing.
Tested by Reagecon Quality Control Laboratories for Reagecon Manufacturing

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