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IVD CE

en

Osmolality Standards

Calibration and Reference Standards

0 ... 4000 mOsm/kg H_2O

Intended Use

Osmolality standards are designed for an accurately calibration of osmometer. In addition, the standards can be used to evaluate the performance of your osmometer and test methods. Osmolality standards are suitable for laboratories following the European Pharmacopoeia (EP 2.2.35) [1] and/or United States Pharmacopoeia (USP 785) [2] osmolality test methods.

Use Osmolality Standards to:

- Perform routine osmometer calibration
- Verify calibration accuracy and instrument performance
- Test unknown solutions of similar osmolality

The accuracy of reported osmolalities can be no better than the accuracy of the standards solutions used to calibrate your osmometer. Bioanalytic osmolality standards provide uncompromising accuracy to satisfy the most stringent laboratory quality assurance regimens. Calibration integrity is assured because ampoules provide fresh solution with each use. Ideal as reference standards, our ampoules are so economical they can be used for routine osmometer calibration. The osmolality standards are manufactured under strict quality control and sealed in glass to preserve accuracy during the entire storage life.

Bioanalytic osmolality standards are in vitro diagnostic medical devices IVD and marked with CE.

All common calibration values from 0 to 4000 mOsm/kg are available. The calibration values are usually calculated and produced on the basis of round numerical values [2].

The standards are used for all metrological procedures (e.g: freezing point reduction, coloid measurement, membrane osmometry, vapour pressure osmometry etc.).

Osmolality Calibration Standards

Osmolality calibration standards are used for the exact calibration of osmometers. All common calibration values from 0 to 4000 mOsm/kg are available. The calibration values are usually calculated and produced on the basis of round numerical values.

The standards are used for all metrological procedures (e.g: freezing point reduction, coloid measurement, membrane osmometry, vapour pressure osmometry etc.).

Osmolality Reference Standards

Osmolality reference standards are used for ongoing internal quality control, interlaboratory comparisons or internal samples to check the performance of the osmometer.

Various numerical values are available, the most commonly used reference is 290 mOsm/kg. Controls are available in aqueous and protein-based matrix.

Metrological Traceability

This product is traceable to NIST / SRM sodium chloride. The metrological traceability is assured through calibration on quality control freezing point depression osmometer. The calibration is drawn using standard solutions prepared gravimetrically to USP (chapter 785) and European Pharmacopoeia (EP 2.2.35).

This osmolality standard is produced gravimetrically from pure analysis sodium chloride and high-purified 0.055 µS/cm deionized water, filtered through a 0.22 µm filter.

The measurement results are traceable to SI. All analytical balances used for the manufacturing process are calibrated at set intervals under an in-house standard procedure with class E2 analytical weights. All analytical weights are calibrated from an ISO 17025 accredited laboratory and are traceable to OIML / DAkkS* (DKD).

Class A laboratory glassware is used.

The results from temperature measurement are traceable to SI. The thermometers used for solution's calibration are calibrated from an ISO 17025 accredited laboratory and are traceable to DAkkS* (DKD).

** The DAkkS is signatory to the multilateral agreements of the European cooperation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.*

The management system governing the manufacturing of this product is ISO 9001 and ISO 13485 registered.

Method

The result reported in the certificate of analysis was determined by analysis of multiple samples of this lot taken at time of manufacture and tested in accordance with in-house standard procedures using a high performance calibrated osmometer. The certificate of analysis relates solely to the sample as received by the laboratory, bearing the product code and lot number given above.

All contributions in relation to the preparation of standard solutions are considered when evaluating the uncertainty. The uncertainty of measurement has been estimated not to exceed ± 8.2 % 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.

Certificate of Analysis

For all osmolality standards a batch dependend certificates of analysis is available via download.

CoA Download via link: http://www.lotdocs.com/bioanalytic.

Application and Use

The osmolality standard is a highly accurate calibration material and is suitable for all osmometers.

Each ampoule contains 1.0 mL of solution. The osmolality standard can be used directly. Aspirate no more than the volume required for measurement directly from the ampoule. Use a fresh micropipettor tip each time to avoid contamination of the solution. The aim is to leave as much solution as possible in the container so as to maintain a low concentration rate.

Osmolality Calibration Standards

Calibration standards are used for calibration/adjustment of the osmometer to a defined calibration value. As a rule, the instruments are calibrated/adjusted to 0 mosm/kg H_2O and to a calibration value required according to the measuring range.

Osmolality Reference Standards

Reference standards are used for internal quality control and independent testing of the correct calibration/adjustment and analysis procedure (handling) of an osmometer.

Ampoule Handling

For high breakage safety, only colourless OPC (one point cut) glass ampoules are used with a blue marked breaking point. For further protection, each ampoule is carefully packed in a wave cardboard box.

Capillary action will tend to hold a portion of the solution in the top of the ampoule. "Flip" the top or tap the bottom of the ampoule against a hard surface to clear solution from the top before opening. To open an ampoule, place the ampoule body in a holder or hold the body of ampoule firmly in one hand. Note that the blue marked breaking point is facing you. Grasping the top firmly between the thumb and forefinger of the other hand, snap the neck of the ampoule.

Also consider the instructions for use of the osmometer. The sample volume and the calibration process can be learned from the corresponding user's guide of the device.

Bioanalytic GmbH
● biomedical & analytical chemical reagents • medical laboratory diagnostics
● in vitro diagnostics (IVD) • biomedical science & analysis technology
● Waldmatten 10-13 • 79224 Umkirch/Freiburg i. Br. • Germany

Phone: +49 7665 5951
Fax: +49 7665 5683
E-Mail: office@bioanalytic.de
Internet: www.bioanalytic.de

Instructions for use

1. Remove the required number of ampoules from the package.
2. Mix the ampoule gently (do not shake) and make sure that the solution is in the lower part of the ampoule.
   Note: Temperature fluctuations can cause condensate in the air section of the ampoule. Condensate means water with no or lower osmolality. A mixture of the contents of the ampoule is therefore highly recommended. This is possible by rolling the ampoule several times between the palms of the hands at an angle of about 45°.
3. Carefully snap off the top of the ampoule.
4. Obtain samples with calibrated pipette with clean tip.
5. Refer to the instruction for use of the instrument for more information about sample size and testing procedures.
6. Discard the ampoule with any residue after use.

Storage and Stability

The shelf life in the original sealed condition is indicated on the package label. Store ampoules at room temperature and protected from light. While they generally are able to withstand freezing without breaking, we nevertheless recommend that freezing temperatures must be avoided. Do not freeze or overheat.

The solution must be used immediately after opening within one hour. Discard any solution that remains after you have finished your calibration procedures. Do not store the solution after opening the ampoule.

Risks and Safety

The Osmolality calibration and reference standards contain no material of biological origin other than protein-based controls. These are identified as such on the label and additionally have the biohazard symbol.

Please observe the necessary precautions for use of laboratory reagents and body fluids. Applications should be performed by expert personnel only. Follow the national and laboratory internal guidelines for work safety and infection control. Wear suitable protective clothing and disposable gloves while handling.

It is important to ensure effective protection against infection according to laboratory guidelines.

Ampoules can break uncontrollably when opened. Injuries due to glass breakage are possible. Protect yourself with suitable padding (e. g. by using a cotton tissue).

SDS ID International
www.sds-id.com

For additional safety information please refer to the information on the label and the corresponding Safety Data Sheet (SDS).

The safety settings were made according to legal guidelines. If there are differences in the labeling or the safety information between the label and SDS, the details of the SDS are valid.

Download by QR-Code or link:
www.sds-id.com/100174-3
Osmolality Calibration & Reference Standards 0 … 4000 mOsm/kg

Contents / Main Components

Calibration Standard:	All calibration standards contain Aqua p.a. and NaCl p.a. in the concentration indicated on the label in mOsm/kg.
Reference Standard:	All reference standards contain Aqua p.a. and NaCl p.a. at the concentration indicated in the CoA in mOsm/kg.
Controls (+ Protein):	Protein-based controls additionally contain protein in a physiological concentration of 60 g/L = 6.0 g/dL.

Notes

This product information exclusively relates to the product described in this leaflet. In particular, this product information cannot be applied to similar reagents from other manufacturers.

Periodically check for updates of this product information on our website.

Instruction for Use

For professional use only.

To avoid errors, the use of qualified personnel is carried out. National guidelines for work safety and quality assurance must be followed.

The used equipment must comply with the state of technology and the laboratory requirements.

All samples and used tubes/vials must be marked clearly identifiable to exclude any confusion.

Protection against Infection

It is important to ensure effective protection against infection according to laboratory guidelines.

Laboratory personnel working with human samples should be vaccinated against Hepatitis B (HBV).

Classifications

EU:	*EDMA: 14 50 01 00 00; IVD Class A (in vitro diagnostic medical device). Basis UDI: 4061609-0007-P7*
AU:	*Class 1; IVD.*
CA:	*HC: Class I; exempt; for in-vitro diagnostic use.*
US:	*FDA: JCG; Class I; exempt; for in-vitro diagnostic use.*

Support / Information service

For methodological and technical support, please contact us by E-Mail at support@bioanalytic.de.

Periodically check for updates of this product information on our website.

Feedback

Information from users can be reported to support@bioanalytic.de. Suggestions for further developments will be considered.

If a serious incident has occurred during or as a result of use, please report it to the manufacturer and/or its authorized representative and to your national authority.

Waste Management

Please observe your national laws and regulations.

Used and expired solutions must be disposed of in accordance with your local regulations.

Inside the EU, national regulations apply that are based on the current, amended version of Council Directive 67/548/EEG on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Decontaminated packaging can disposed of as household waste or recycled, unless otherwise specified.

Ordering Information

All available osmolality calibration and reference standards can be found on our website www.bioanalytic.de. Other calibration values available on request.

Contract Manufacturing

On request, we manufacture all calibration and reference standards as custom-made OEM products. Target groups of OEM products are equipment manufacturers, distributors and interlaboratory organisations.Please send us your inquiry.

Literature & Footnotes

Legends for the graphic symbols and tags used follow relevant norms or are available on our internet pages.

[1] European Pharmacopoeia, EP 11.0, Chapter 2.2.35.
[2] United States Pharmacopeia, USP 47, Chapter 785.