



Osmolality Standards & Controls

0 ... 3000 mosm/kg H₂O

Intended Purpose

CAL Osmolality-Standards

Osmolality standard solutions are used for the exact calibration of osmometers. These are marked with the CAL symbol. Almost all common calibration values from 0 to 3000 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, colloid measurement, membrane osmometry, vapour pressure osmometry etc.).

CTRL Osmolality Controls

Controls for osmometry serve as ongoing internal quality control, inter-laboratory comparisons or internal sample testing as "unknown" samples. Controls are marked with the CTRL symbol. They can be produced for any numerical values ⁽¹⁾.

The osmolalities are usually not mentioned on the labels, so that a neutral and independent test is possible. The nominal value is usually specified on the certificate of analysis for each batch. Controls are possible both in aqueous matrix and protein-based.

OEM Contract Manufacturing

Osmolality standards and controls are usually offered in glass ampoules, other fillings are also possible.

On request, we manufacture all calibration or control values as custom-made products. Target groups for this are equipment manufacturers/distributors and interlaboratory organisations. Please send us your inquiry.

Principle

Standards and Controls

The standard osmolality solutions give the osmolality values per kg H₂O (mOsm/kg H₂O or mOsmol/kg H₂O). The standard solutions are based on sodium chloride (NaCl) in water (Aqua p.a.).

Osmolality standards from Bioanalytic are produced according to precisely calculated formulations and are subject to internal quality control.

Certificates of analysis are available for the osmolality standards.

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

Certificates of analysis for controls are not available for download and are only part of the package.

Specifications

The shelf life in the original sealed condition is indicated on the label. Each ampoule is labelled with a traceable LOT/batch number. The contents must be used immediately after opening. Portioning into smaller containers is not possible. Do not freeze or overheat.

Storage

Store in the package protected from light. See package label for storage temperature.



Risks and Safety

The Standards and Controls 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).



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 Standards & Control Solutions 0 ... 5000 mOsm/kg

Contents/Main Components

Standards: All osmolality standards contain water (Aqua p.a.) and NaCl in the concentration indicated on the label in mOsm/kg.

Controls: All osmolality controls contain water (Aqua p.a.) and NaCl 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.

Application

CAL Osmolality-Standards

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 H₂O and to a calibration value required according to the measuring range.

Please also refer to the instructions for use of your osmometer

CTRL Osmolality Controls

Osmolality controls are used for separate and independent testing of the correct adjustment and analysis procedure (handling) of an osmometer. The nominal value of the osmolality controls can only be seen from the certificate of analysis.

These certificates of analysis are not available for download but are only part of the package.

Instructions for use

1. Remove the required number of ampoules from the package.
2. Make sure that the solution is in the lower part of the ampoule. This can be done by slinging the solution towards the bottom of the ampoule.
3. Do not shake the ampoules but mix them thoroughly!
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°.
4. Opening: Protect hands with gauze, cotton cloth or gloves.
5. Hold the ampoule(s) with the coloured OPC point upwards and break off the neck of the ampoule in the opposite direction.
6. Remove with reciprocating pipette and pipette tip. Hold the ampoule at an angle if necessary.
7. Discard the ampoule with any residue after use.

For the calibration of your osmometer, please refer to the instructions for use of the instrument.

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).

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 be disposed of as household waste or recycled, unless otherwise specified.

Ordering Information

Available Osmolality Calibration Standards can be found on our website www.bioanalytic.de. Other calibration values available on request.

Literature & Footnotes

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

*1) Please do not hesitate to contact us if you have any questions regarding the production of controls or other calibration values.

[1] Documenta Geigy, Wissenschaftliche Tabellen. 6. Auflage, 1960 S. 289ff.