by Ken Micciche

Utilization of controls, materials and osmometry in a clinical setting offers quality benefits

Freezing point osmometry measures the total solute concentration in a liquid. It is most convenient to describe freezing point as the concentration of particles in solution. Freezing point won't tell you how big these particles are, or what shape they have, or if they are charged. It will tell you how many you have. At low concentrations, freezing point is linear with the number of dissolved particles.

Clinical relevance

It is generally accepted that osmotic effects have a major place in the maintenance of equilibrium in the living body with respect to various functions and to the chemical composition of the fluids and tissues. Examples are: temperature, heart rate, blood pressure, water content or blood sugar. These effects occur within or between cells and tissues where they cannot be measured. One troublesome problem in clinical medicine is the maintenance of adequate body fluids and proper balance between extracellular and intracellular fluid volumes in seriously ill patients. Fluid and electrolyte abnormalities are not disease, but the manifestations of disease.

Physiological mechanisms, which control water intake and output, appear to respond primarily to serum osmolality. Renal regulation of output is influenced by variations in rate of release of pituitary antidiuretic hormone (ADH) and other factors in response to changes in serum osmolality. These changes also serve as a stimulus to moderate thirst and are sensitive in order to limit variations in osmolality in normal patients to about 1 percent.

An increase in plasma osmolality of 1 percent will stimulate ADH release, which results in the reduction of urine flow and stimulates thirst causing water intake to occur. This transfer of water through cell membranes occurs so rapidly that any lack of osmotic equilibrium between the two fluid compartments in any given tissue usually is corrected quickly.

The rapid transfer of water does not mean that complete equilibration occurs between the extracellular and intracellular compartments throughout the entire body within this same short period of time. Fluid usually enters the body through the gut and then must be transported by the circulatory system to all tissues before complete equilibration can occur. In the normal person it may require 30 to 60 minutes to achieve reasonably good equilibrium throughout the body after drinking water.

Osmolality determines the physiologic acceptability of a variety of solutions used for therapeutic and nutritional purposes.

Benefits of osmolality use to the clinical laboratory

Osmolality can be used for routine analysis and on patient samples requiring STAT measurements. If screening for toxin ingestion is done, STAT osmolality should be included as a rapid screen for low molecular weight toxins. Treatment of neurosurgical patients often requires calculation of osmotic gap to monitor mannitol therapy, to assure adequate dosage and to prevent toxicity. Evaluation of patients with alteration in serum sodium or abnormal urine output is facilitated by measurement of osmolality. Because freezing point osmolality delivers a more accurate measurement of urine solute concentration, it is preferred over methods based on ionic strength or specific gravity. When STAT results are required, results are available within a short time of specimen collection, which serves to minimize errors caused by loss of volatile substances or production of osmotically active compounds through *in vitro* metabolism.

Osmolality is a simple, rapid and relatively inexpensive procedure that is important in the diagnosis of many physiological conditions. The measurement of osmolality often provides information that cannot be obtained by any other method.

Control solutions and materials

Control solutions and materials can be defined as a solution or patient specimen used solely for quality control purposes. Control products are available commercially in liquid, lyophilized form, packaged in small amounts suitable for daily use. Control materials are widely available and can be purchased from the same companies that sell reagents and instrumentation or from third party manufacturers.

By purchasing from a sole source, differences in products and effects on method or instrument performance can be minimized. Good control materials should have the same matrix as the specimens being tested so that they behave the same as the patient specimen. By developing materials to minimize alterations, a manufacturer can help to eliminate interferences in the testing process.

Controls and materials such as Protinol® serum control, Renol™ urine control, Clinitrol™ 290 reference solution, and Osmolality Linearity Set are designed to perform optimally. These liquid stable controls and materials reduce waste, eliminate vial-to-vial variability, and reduce operator errors frequently associated with the reconstitution process, all while enhancing laboratory quality and confidence in testing.

Advanced Instruments ControLine™ Products for osmometers

Advanced Instruments offers a comprehensive set of control solutions and materials designed specifically for osmometers.

These products can help laboratories avoid workflow disruptions and ensure the reliability of patients' results. With a tighter tolerance than multi-analyte controls, it is easier for users to identify when action needs to be taken due to results found outside satisfactory control limits.

Protinol Protein-based Serum Controls are designed specifically for clinical laboratories testing blood samples and are formulated to produce consistent, reliable results in the human serum range. It is formulated at three levels to allow users to comply with CLIA '88 quality control requirements. The product is premixed and ready to use in three, 3 mL vials per kit. (See Table 1.)

Renol Urine Controls are osmometer specific control solutions for laboratories testing urine samples. The aqueous-based control material is manufactured to extremely tight tolerances for repeatability and precise control over patient results. Renol comes premixed and ready to use in four, 3 mL vials of each value per kit. Formulation values include 300 and 800 mOsm/kg H2O. These concentrations are close to medical decision levels where performance is critical for the use and interpretation of the test.

In order to comply with CLIA 493.1218, laboratories should perform and document control procedures using at least two levels of control materials daily. (See Table 2.)

By utilizing products designed specifically for osmometers and strengthening quality programs, users will be enabled to track control results, identify shifts, trends, and random errors, apply control rules and implement corrective actions.

Clinitrol 290 Reference Solution and Calibration standards are premixed and ready to use reference solutions and calibration standards that meet CLIA 493.1217 regulations.

Laboratories will use Clinitrol 290 to monitor operator technique, which is of particular importance with several shifts. Additionally, when following a calibration routine, Clinitrol 290 is a valuable tool for calibration verification. The calibration standards are manufactured to stringent NIST and ISO9000 quality systems standards

The Osmolality Linearity Set was designed to help clinical laboratories easily monitor instrument performance, which fulfills CLIA 493.1213 requirement for establishment and verification of method performance specifications and reportable range of a laboratory method. CLP

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Table 1. Protinol Control Levels

Low	240 mOsm/kg H2O	233-247 mOsm/kg H2O
Normal	280 mOsm/kg H2O	273-287 mOsm/kg H2O
High	320 mOsm/kg H2O	313-327 mOsm/kg H2O

Table 2. Levy Jennings Control Chart

n	16
Mean	282.6
S.D.	0.7
%CV	0.2
Min	281.2
Max	284.2