





Why Osmolality Determination Matters

Osmolality is a fundamental measurement of the total solute concentration of body fluids including serum, plasma, and urine, and it is directly related to osmotic pressure. Osmotic pressure is of vital importance in biology as it relates to fluid balance, nutrient transfer, and waste removal processes in cellular organisms.

The Value of Osmolality Testing in Clinical Laboratories

Osmolality is a valuable clinical tool used in the diagnosis and treatment of patients. It is a quick and effective test to help evaluate the body's water balance or its ability to produce and concentrate urine, investigate low sodium levels (hyponatremia), detect the presence of toxins in the body, and monitor osmotically active drug therapies such as mannitol, used to treat cerebral edema. It can also help monitor the effectiveness of a treatment for a condition found to be adversely affecting a person's osmolality.

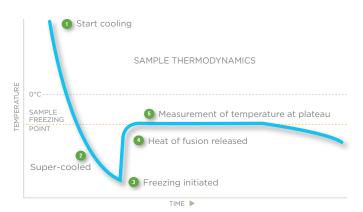




There are many methods for measuring concentration of solutions including: specific gravity, refractive index, and conductivity. Freezing point osmolality, however, is the only method which is truly independent from the size, shape, and other physical characteristics of the liquid solution. This is why freezing point depression is the industrypreferred solution and the gold standard in clinical laboratories around the world.

Theory of Freezing Point Depression for Osmolality **Determination**

Advanced Instruments' osmometers utilize the industry preferred freezing point depression method to determine the osmolality of body fluids. When solutes (particles) are dissolved in a solvent (water), the freezing point of



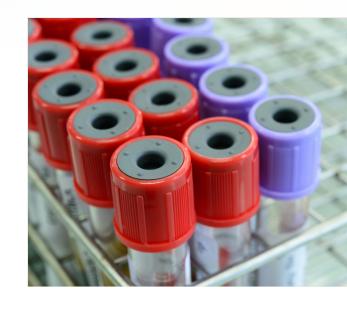
the solution is lowered compared to that of the solvent alone. As more solute is added, the freezing point decreases further. Therefore, by precisely measuring the freezing point of the solution, the osmolality (i.e. concentration) can be determined. Freezing point osmometry can ascertain volatiles in solutions such as CO₂, ammonia, and alcohol unlike vapor pressure osmometry.



The Osmo1 Value

Your laboratory deserves best-in-class technology.

Introducing the Osmo1 Single-Sample Micro-Osmometer. Osmo1 is ideally suited for clinical laboratories that prefer to directly draw and test small sample volumes and are looking for an osmometer that offers ease of use, accurate and precise results, and the security and efficiency of electronic data management.





Easy to Use

- Factory calibrated and ready to test
- Calibration only required if quality control is out of specification, or after maintenance
- One-step direct sampling, simply aspirate sample and load sampler into the instrument
- Fast, 90-second test time
- Color-coding, in combination with on-screen messages, provides clear indication of instrument status

Flexible and Convenient Workflow

- Only requires 20 µL of sample
- Selectable 2- or 3-point calibration to satisfy CLIA calibration verification requirement
- Operating range up to 2,000 mOsm/kg H₂O to cover all of the samples your laboratory may encounter
- Replacement sampler plunger wire included with every Micro-Sample Test
 Kit to optimize instrument performance

Easy to use with one-step direct sampling



Integrated barcode scanner

Built-in barcode scanner allows for traceable sample identification and reduces transcription errors

Touchscreen

Intuitive, color-coded menudriven operating system, with multi-language capability, displays test results and enables enhanced data management

Ethernet and USB ports (located on the back of the instrument)

Allows for easy LIS connectivity and export of data

Consumable box

Micro-Sample Test Kit fits in accessory compartment to maximize available bench space and make sampler tips and cleaners easily accessible Includes replacement plunger wire for optimal performance

On-board printer

For easy printing and archiving of test results

Freezing chamber (located inside)

Hinged cover provides easy access to solenoid for maintenance

Ease-Eject™ Sampler

Convenient sample introduction, eliminates loss of sample

On-board sampler holder

Convenient place to store sampler when not in use

Operating cradle

Guides sampler into freezing chamber

Secure and Efficient Electronic Data Management

Intelligent User Interface

- Interactive and intuitive touchscreen with a menu-driven operating system displaying test results, user ID, sample ID, date, time, test progress bar, instrument status, and errors
- Multi-language capability
- Sampler tip countdown for inventory management



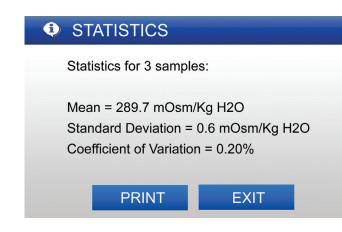
Built-in Quality Control

- Can issue warnings when quality control is out of range so users can react in real-time
- Allows tracking of quality control data over time with exportable Levey-Jennings chart
- Able to set custom range limits for QC samples
- Audit control ensured with events database
- Stores the last 1,000 test records and 10,000 events

Controls >Levey-Jennings Chart 872 864 875 885 885 10/15 10/16 10/17 10/18 10/19 10/20 10/22 10/23 10/24 EXIT

Electronic Data Management for Security and Efficiency

- Enables laboratories to comply with HIPAA regulations
- Password protected user accounts, with ability to link sample ID and user ID to test results, for improved traceability
- Supervisor login with ability to set restrictions and password expiry
- Bidirectional LIS via Ethernet connectivity
- Provides statistical analysis (mean, standard deviation, and coefficient of variation)
- USB for easy data export



Parts and supplies

| Part number | Product description | |
|---|---|--|
| Instrument | | |
| OSMO1 | Osmo1 Single-Sample Micro-Osmometer | |
| Osmometer Calibration Standards and Reference Solutions | | |
| 3MA005 | 50 mOsm/kg calibration standard, 10x2 mL | |
| 3MA085 | 850 mOsm/kg calibration standard, 10x2 mL | |
| 3MA200 | 2000 mOsm/kg calibration standard, 10x2 mL | |
| 3MA029 | Clinitrol™ 290 reference solution, 10x2 mL | |
| 3LA028 | Osmolality linearity set, 5x2x5 mL | |
| Osmometer Control Solutions | | |
| 3MA028 | Protinol™ Protein-Based Controls (3 levels, 3 mL vials) | |
| 3LA085 | Renol™ Urine Osmolality Controls (2 levels, 3 mL vials) | |
| Osmometer Supplies and Accessories | | |
| 133800 | Micro-Sample Test Kit: 500 tips, 500 cleaners, plunger wire | |
| 3M0825 | 20 μL Ease-Eject Sampler | |
| FLA835 | Thermal printer paper, 5/pkg | |





Optimal performance requires quality test supplies.

Advanced Instruments offers Protinol™ Protein-Based Controls (3 levels, 3 mL vials) and Renol™ Urine Osmolality Controls (2 levels, 3 mL vials) Controls which mimic serum and urine to ensure optimal system performance and accurate test results. Renol™ Urine Osmolality Controls (2 levels, 3 mL vials) and Protinol™ Protein-Based Controls (3 levels, 3 mL vials) satisfy CAP requirement that laboratories run two controls at two different concentrations daily or with each batch of samples and reagent.

Advanced Instruments products are available from a worldwide distributor network. For more information on our products and services or to find your nearest distributor, visit us at aicompanies.com or e-mail us at info@aicompanies.com.

Hot-Line™ Technical Service Advanced Instruments provides 24/7 comprehensive customer service and technical support.

Specifications

| Sample Type | Body fluids |
|----------------------------------|--|
| Sample Volume | 20 ± 1 μL |
| Test Time | 90 seconds |
| Sample Capacity | Single sample |
| Units | mOsm/kg H ₂ O |
| Resolution | $1\mathrm{mOsm/kgH_2O}$ |
| Range | 0 to 2000 mOsm/kg $\rm H_2O$ |
| Accuracy ² | 0 to 400 mOsm/kg H_2O : \leq 2 mOsm/kg H_2O from nominal value (1 SD) > 400 to < 1500 mOsm/kg H_2O : \leq 0.5% mOsm/kg H_2O from nominal value (1 SD) \geq 1500 to 2000 mOsm/kg H_2O : \leq 1% mOsm/kg H_2O from nominal value (1 SD) |
| Precision ² | (within run) 0 to 400 mOsm/kg H 2 O: Standard deviation \leq 2 mOsm/kg H $_2$ O $>$ 400 to $<$ 1500 mOsm/kg H $_2$ O: Coefficient of variation \leq 0.5% mOsm/kg H $_2$ O \geq 1500 to 2000 mOsm/kg H $_2$ O: Coefficient of variation \leq 1% mOsm/kg H $_2$ O |
| Temperature Effects ³ | Less than 1 mOsm/kg H ₂ O per 5°C (9°F) ambient temperature change |
| Communications | On-board printer, USB 2.0 Type A ports (2), USB 2.0 Type B ports (1), Ethernet 10/100, RJ45 connector port (1) |
| Supported Languages | Simplified Chinese, Czech, Danish, English, French, German, Greek, Italian, Japanese, Korean, Portuguese, Russian, Slovak, Spanish, Swedish, Turkish |
| Storage Temperature | -20°C to +45°C (-4°F to +113°F) |
| Electrical Voltage | 100 to 240 VAC (50/60 Hz) |
| Power Consumption | 60 Watts |
| Dimensions (D x W x H) | 38 cm x 36 cm x 38 cm (15" x 14" x 15") ⁴ |
| Net Weight | 6.0 kg (13.3 lbs.) |
| Shipping Weight | 11.4 kg (25 lbs.) |
| Warranty | One-year limited warranty on workmanship and parts |
| | |

¹Subject to change



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

²Accuracy and precision (within run) specifications apply to Advanced Instruments standards and reference solutions. Performance at Reference Conditions: 20°C to 25°C (68°F to 77°F); 40 to 60% relative humidity

³Operating Conditions: Temperature 18°C to 35°C (64°F to 95°F); 30 to 80% relative humidity (non-condensing)

⁴Dimensions when Micro-Sample Test Kit is on the instrument