Osmolality in Plasma/Serum and Urine
Advanced 2020 Osmometer Operating Procedure

Purpose

This procedure provides instructions for Osmolality In Plasma/Serum And Urine On The Advanced 2020 Osmometer.

Policy Statements

This procedure is intended for all Chemistry personnel responsible for collecting and testing specimens for Osmolality on the Advanced Instruments model 2020 Osmometer.

Principle

The Advanced Instruments Osmometer Model 2020 is a device for the extremely precise determination of the concentration of solutions by means of freezing point measurement. High-precision electronic thermometers are used to sense the sample temperature, to control the degree of super cooling and freeze induction and to measure the freezing point of the sample.

The freezing point of a solution is measured by super cooling it several degrees below its freezing point, and then mechanically inducing the sample to freeze. The heat of fusion liberated causes the sample temperature to rise toward a temporary plateau wherein liquid/solid equilibrium is maintained. The equilibrium temperature is, by definition, the freezing point of the solution.

Clinical Significance

Serum osmolality is used to evaluate electrolyte and water balance, hydration status, antidiuretic hormone function, and hyperosmolar coma. Osmolality can be used to measure the concentrating ability of the kidney tubules. It is most relevant if the serum and urine fluids are measured at the same time and are compared to one another.

High serum osmolality may result from hypernatremia, dehydration, hyperglycemia, mannitol therapy, and ingestion of ethanol, methanol, or ethylene glycol. Ethanol ingestion is the most common cause of increased osmolality.

Low serum osmolality may be secondary to overhydration, hyponatremia, and the syndrome of inappropriate antidiuretic hormone secretion.

Instrument

Advanced Instruments 2020 Osmometer

Sunquest Test Codes

OSMO: Osmolality Plasma/Serum
UOSM: Urine Osmolality

Materials

Equipment
Advanced Instruments Micro-Osmometer, Model 2020 System

Minneapolis	SN 04070624A
St. Paul	SN 05070745A

The use of a narrow-tipped precision pipette is employed to load exactly 20 µl of sample into the bottom of each sample tube.

Reagents
All calibration standards are purchased from Advanced Instruments, Inc. through Cardinal Health.

- **50** mOsm/kg calibration standard (PN 3MA005). Acceptable range: 48 - 52 mOsm/Kg
  Use for calibration/calibration verification
- **850** mOsm/kg calibration standard (3MA085). Acceptable range: 845.75 - 854.25 mOsm/Kg
  Use for calibration/calibration verification
- **290** mOsm/Kg calibration standard (3MA029). Acceptable range: 288 - 292 mOsm/Kg
  Run in duplicate with each run
- **2000** mOsm/Kg calibration standard (3LA201). Acceptable range: 1990 – 2010 mOsm/Kg
  For use with the 2000 mOsm/Kg range calibration

Reagent Preparation: All standards are liquid and are ready to use

Storage Instructions: Store at 20 - 25ºC.

Expiration: Unopened vials are stable until the expiration date stamped on the carton. Once opened the solution is stable at room temperature in a tightly stoppered vial for 24 hours.

Sample

Serum/plasma and urine are acceptable specimens for this assay. Specimens for processing on the Osmometer should be collected according to current laboratory policy. Refer to the Phlebotomy/Specimen Collection Manual for proper collection procedures.

Serum (preferred): Draw 0.6 mL of blood in gold, marble, or red top tube or MICROTAINER to yield 0.2 mL of serum. Specimens collected in serum tubes or microtainers should be allowed to clot for 30 – 60 minutes prior to centrifugation.

Plasma: Draw 2.7 mL of blood in green-top, (lithium heparin) tube or 0.6 mL blood in a MICROTAINER® to yield a minimum of 0.2 mL of lithium-heparinized plasma. Specimens collected in tubes/microtainers containing anticoagulant may be centrifuged immediately.

Urine: Urine specimens are collected according to usual collection procedures. Urine samples should be centrifuged prior to analysis to remove particulate matter.

Sample Volume Requirement: Sample must have enough volume to pipette 20uL in duplicate.

Sample Handling:

1. Check for specimen integrity. Specimens ***must*** be stored tightly capped until analysis to reduce evaporation, since ingestion of volatiles can contribute to elevated osmolality.
2. Samples are stable tightly capped at room temperature for 48 hours.
3. Samples may be stored at 2-8° C for up to 48 hours.
4. Mild to moderate hemolysis, icterus, and lipemia do not have a significant impact on osmo results.
5. Grossly hemolyzed specimens should not be used.
6. The sample should be free of clots, and fibrin strands.
7. Specimens must be centrifuged prior to analysis.
8. Specimens should be at room temperature for analysis.

Criteria for Rejection: Unlabelled specimens, plasma specimens other than lithium heparin.

Maintenance Procedures

Step	Action
1.	Complete and log maintenance on the Maintenance checklist.

Daily

2.	Each day of use, open and run a fresh 290 mOsm/Kg standard to verify calibration.
3.	Run 2 levels of matrix appropriate Quality control each shift that patients are tested.
4.	Check for availability of printer paper. To load new paper, refer to User's Guide p. 4 – 8.

Monthly

1.	Examine the air vents on the underside, sides and rear of the instrument to ensure that they are unobstructed by dust or debris. Wipe with a lint-free tissue if needed.
2.	Clean the sample well. Remove the turntable
3.	Dampen the foam tip of one swab cleaner (PN 202850)
4.	Grasp the swab just behind the foam tip with one hand, and hold the end of the swab with the other hand.
5.	Bend the swab handle and guide the foam tip into the center of the sample cooling well
6.	Insert the swab until it stops at the bottom of the sample well
7.	Gently and slowly rotate swab back and forth
8.	Do not spin the swab quickly, to prevent tearing the swab tip
9.	Remove and discard the used cleaning swab
10.	More detailed maintenance and troubleshooting information is available in the Advanced Instruments Model 2020 Osmometer User's Guide (pg. 39-48).

Calibration Procedure

Step	Action
1.	Calibration requirements: • After major component repair or replacement • The 290 standard and QC consistently fails acceptability

Calibration Verification and AMR

2.	The instrument automatically adjusts the calibration during the calibration process.	
3.	Start the calibration by pressing the “Next” button under “Osmometer Ready” until the “Calib” prompt appears over the left button.	
4.	Press the “Calib” button. The current calibration status is displayed. Verify the instrument is set to 2000 mOsm Calibration. If not, configure in Diagnostics, Setup Menu, Option # 8.	
5.	At the prompt “50/850 mOsm/Kg calib?” press “Yes”	
6.	At the prompt “Samples loaded?” press “No” to begin loading.	
7.	Load 20 uL of each standard as prompted by the display. The 50 standard loads in positions 1-5, and the 850 standard in positions 6-10.	
8.	Press “ Start” when all samples are loaded to begin the calibration process. When complete, the display shows “Calibration Complete”.	
9.	Press “Yes” to the prompt “2000 mOsm/Kg Calib?”	
10.	Press “No” to the prompt “Samples Loaded?” and load 20 uL of the 2000 mOsm/Kg standard at each prompt. The 2000 standard loads in positions 11-15.	
11.	When the display shows “Calibration Complete”, press “Exit” to return to “Osmometer Ready”. A successful calibration will display “Calibration OK”. An unsuccessful calibration will display the prior calibration status.	
12.	Verify the accuracy of the calibration procedure by running 2 levels of Quality Control prior to running patient samples.	
13.	Analyze each of the standards (50, 290, 850 and 2000 mOsm/Kg) in triplicate in the Osmometer Ready mode to verify calibration and Analytical Measuring range once every 4 months. Enter results in EP Evaluator.	
14.	If:	Then:
	All standards pass EP Evaluator criteria	Give printouts to Technical Specialist for approval
	Any 2 of the standards fail the criteria	Repeat the study
	Study fails after repeat	Recalibrate

Quality Control (Serum/Plasma)

Biorad Liquichek™ Unassayed **Chemistry** Control (Human) Levels 1 & 2

Frequency: Run two levels of quality control each shift that patient samples are tested.

Stability: Refer to the current lot product insert

Sunquest Control names: Level 1 = C-X1, Level 2 = C-X2

Acceptability Ranges: Ranges are current in Sunquest. Refer to the Quality Control Procedure for QC exception codes.

Quality Control (Urine)

Biorad Liquichek® **Urine Chemistry** Control Levels 1 & 2 in Vista ® vials

Frequency: Two levels each day of use

Stability: Unopened at 2-8 C/ date on vial, opened / 30 days.

Preparation: Gently swirl contents prior to use

Sunquest Control names: Urine Level 1 = C-UR1, Level 2 = C-UR2

Procedures:

Running Samples

Step	Action
1.	Loosen the turntable locking screw by turning it counter-clockwise. Lift the turntable up from the mounting spindle and out of the instrument. Place it on a flat surface.
2.	Lift up the turntable cover and remove it from the turntable.
3.	Place a new probe wiper ring over the center knob of the turntable. Make sure the felt side is facing up. Align the wiper ring so that the tab is in the depression near position 1 and the turntable numbers are centered in the holes.
4.	Orient the turntable cover, logo up, over the center knob of the turntable. Center the square notch opening on position 1, facing the instrument.
5.	Position the turntable by grasping the center knob and sliding onto the spindle. Push the turntable forward until it drops onto the drive.
6.	Tighten the locking screw.
7.	Use a 20 μL pipette.
8.	Locate 290 mOsm/Kg standard and two levels of the appropriate quality control.
9.	Using the Soft keys under the display, press “LOAD” to begin loading the turntable in position 1.
10.	Scan the appropriate barcode for standard, control, or patient when prompted by the position number.
11.	Draw each sample into pipette. Wipe tip with lint-free tissue. Use a new pipette tip for each sample.
12.	While holding a clean, dry sample tube and the pipette in a vertical position, insert the pipette tip fully to the bottom of the sample tube. Smoothly eject the sample without splashing or spraying it. Avoid depositing any sample on the sides of the sample tubes.
13.	Withdraw the pipette vertically without touching the sides. Leave no air bubbles!

14.	a. Press “NEXT” to expose each new sample position. b. Continue loading samples in order: 1. **three 290 standards** to check repeatability and accuracy, 2. **two levels of QC in duplicate** (first run each day), and 3. patient samples in duplicate. c. Subsequent runs by the same tech, same shift require three 290 standards only.
15.	When all samples are loaded, press “EXIT”.
16.	Press “TEST”. The Osmometer will run all samples loaded on the turntable. Results will be displayed and printed at the same time. When all samples have been run, the Osmometer will beep and display “Tray Complete”

If	**Then**
If the “Cancel” button is pressed while a test is in progress	That test will be cancelled and the instrument will proceed to the next test.
If the “Cancel” button is pressed before the next sample is sampled	The instrument will cancel the remaining tests, rotate the turntable to position 1, display and print “Test Cancelled” and abort the run

17.	When the run is complete, remove the turntable and dispose of the wiper ring and sample cups in a biohazard container. Wipe the turntable clean and reseat it in the Osmometer.
18.	To begin another run using the same partially used wiper ring, remove used cups from tray and discard.
19.	Reinsert turntable.
20.	Press “NEXT” until the turntable arrives at the first unused position, and begin loading samples.
21.	Press “EXIT” and “TEST” when finished loading samples. The instrument will “sense” the first sample position.

STAT Test Procedure

Step	Action
1.	Load the stat sample into a sample tube and press ”STAT” button. At the conclusion of the test in progress, the turntable will rotate position 20 to the front of the instrument.
2.	The message “Load Sample in Pos. 20” indicates the sample may be loaded into Position 20 through the front stat loading hole.
3.	Press “START”. After testing the stat sample the instrument will display “STAT:XXXmOsm” and will automatically resume testing where it left off.

Calculations

Serum osmolality may be calculated using the following formula as a result check:

$$\text{Osmolality (mOsm/Kg)} = 1.86 \times \{Na^{+} \text{ in mEq/L}\} + \{\frac{\text{glucose in mg/dL}}{18}\} + \{\frac{\text{BUN in mg/dL}}{2.8}\} + 9$$

Interpretation/ Results/Alert Values

Results are printed on the instrument printer in mOsm/Kg. Attach a patient label to the instrument tape.

Assay Range: Serum and Urine: 0-2000 mOsm/Kg

Reportable Range: 40-2000 mOsm/Kg, do not dilute

Reference Intervals

Serum/Plasma:
275 – 295 mOsm/Kg
Urine:
0-1 month = 50-600 mOsm/Kg
> 1 month = 50-1400 mOsm/Kg

Limitations

Known Interfering Substances: Oxalate anticoagulant.

For controls and patients:

- 50 to 400 mOsm/kg concentrations have an expected repeatability of **+/- 3 mOsm/kg**
- 400 to 1000 mOsm/kg concentrations have an expected repeatability of **+/- 5 mOsm/kg**
- Standards and controls must be within their stated limits before patient specimens can be reported.

Result Reporting

MEM (manual result entry)

1. In Sunquest, use function MEM.
2. For serum/plasma/urine use worksheet MISC (Mpls) or MISC2 (STP).
3. Enter controls as C-(Control name for Sunquest.) Refer to Quality Control section.
4. Enter patient's accession # and result.
5. Accept or modify result.

References

1. Advanced Instruments Osmometer Model 2020 User's Guide, 2025 Rev16, 081508, Two Technology Way, Norwood, Mass. 02062
2. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Elsevier Saunders Company, 2006, pp. 991 - 994.
3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001, p. 236-237
4. Refrigerated and Room Temperature Storage Stability of Serum Osmolality Measurements, Advanced Instruments Scientific Poster, Two technology Way, Norwood MA, 2009
5. Effects of Hemolysis, Icterus, and Lipemia on Serum Osmolality Results using the Advanced Model 3250 Osmometer, Advanced Instruments, Inc. Norwood, MA, 2010

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1.	Author Unknown	11/02/92	Initial Version
2.	L. Lichty	9/11/2003	Reformatted and revised
3.	L. Lichty	6/14/04	Revised calibration steps
4.	T. Zoerb	10/29/04	Revised for AI 2020
5.	L. Lichty	12/08/05	Revised for STP AI 2020
6.	L. Lichty	11/1/2006	Revised to increase reportable range, new QC material
7.	D. Helfinstine /L. Lichty	April 1, 2011	New format. Renumbered from CH 6.14. Revised AMR requirements. Defined QC frequency.
8.	L. Lichty	2/ 28/ 2013	Revised sample stability, interferents
9.	L. Lichty	09/19/2016	Revised clinical significance, sample handling, calibration, QC