Adventist HealthCare

TRAINING UPDATE

Lab Location:	SGMC, WOMC	**Date Distributed:**	3/7/25
Department:	Core Lab	**Due Date:**	3/31/25
		Implementation:	**4/1/25**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.C 1001 Osmolality Serum and Urine, Osmo1 Micro-Osmometer
Description of change(s):
• Implementing new osmometer. • The new osmometer is very similar to the previous osmometer. • Because this instrument is new, we will no longer need to bracket patients with the 290 standard. • Please review the NEW attached SOP and Patient QC log and take the MTS quiz.

Document your compliance with this training update by taking the quiz in the MTS system.

AHC.C 1001 Osmolality Serum and Urine, Osmo1 Micro-Osmometer

Copy of version 1.0 (approved, not yet effective)

Last Approval or Periodic Review Completed	2/18/2025
Next Periodic Review Needed On or Before	2/18/2027
Effective Date	4/1/2025

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	2/18/2025	1.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	Core lab approvals	2/18/2025	1.0	Robert SanLuis Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved, Not Yet Effective	Initial version	2/14/2025	4/1/2025	Indefinite

Technical SOP

Title	**Osmolality Serum and Urine, Osmo1 Micro-Osmometer**
Prepared by	Ashkan Chini Date: 2/12/2025
Owner	Robert SanLuis Date: 2/12/2025

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Osmolality, Serum Osmolality, Urine	Freezing Point Depression / Osmo1	OSMO UOSMO

Synonyms/Abbreviations
Osmo

Department
Chemistry

2. ANALYTICAL PRINCIPLE

When a solute is dissolved in a solvent, four colligative properties of the solution are changed in a roughly linear response to the solute added. One of these properties is the freezing point. The resultant change in the freezing point is proportional only to the molar concentration. In other words, the lowering of the freezing point is a function of the number of particles, molecules or ions in a solution. It is upon this property and response that the osmolality of a serum or urine is measured in this method. The concentration of free particles in the serum or urine is determined by measuring the depression in the freezing point since the osmolality is proportional to the freezing point. This is accomplished using an osmometer, which is an instrument for freezing point depression. The instrument monitors the temperature changes of a liquid sample while the solution is carried through a controlled freezing cycle. Since solvent crystallizes out during the freezing, the concentration of the solution changes. At the freezing point the temperature is held at equilibrium and the temperature measured. Results are read off the instrument in milliosmoles of solute/Kg solvent.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and urine may be used for samples to be analyzed by this method.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Serum or Urine None	
Collection Container	Serum: SST or Plain red top tube Urine: Sterile container	
Volume - Optimum **- Minimum**	1.0 mL or greater 0.5 mL	
Transport Container and Temperature	Serum: Plastic vial or spun barrier tube at room temperature Urine, random: Collection kit (preferred) or container at room temperature, submitted within 2 hours of collection.	
Stability & Storage Requirements	Room Temperature:	Serum: 3 hours Urine: Not recommended
	Refrigerated:	Serum: 3 days Urine: 24 hours
	Frozen:	Serum: 1 week Urine: 1 week
Timing Considerations	If testing is delayed, refrigerate or freeze the capped specimen to avoid a change in the original osmolality due to evaporation of H_2O, decomposition, or combination of solutes. Prior to analysis, specimens must be warmed to room temperature and gently mixed to aid the complete solution of any precipitated solutes.	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Hemolysis does not interfere with test result. Specimens should be free from particles. **Centrifuge urine, if necessary, to remove gross particulate matter.**	
Other Considerations	Allow to clot completely prior to centrifugation.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

None

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Advanced Micro-osmometer Calibration Standards: -50 mOsm/kgH20 Calibration Standard -850 mOsm/kgH20 Calibration Standard -2000 mOsm/kgH20 Calibration Standard	Advanced Instruments 3MA005 3MA085 3LA201

Reference	Supplier and Catalog Number
Clinitrol™ 290 Reference Solution	Advanced Instruments 3MA029

5.2 Calibrator Preparation and Storage

Calibrator	**Advance Calibrators, 50 std, 850 std and 2000 std**
Preparation	None
Storage	2 - 30°C
Stability	Open controls are stable for 24 hours. Unopened controls are stable until the expiration date.

Reference	**Clinitrol™ 290 Reference Solution**
Preparation	None
Storage	2 - 30°C
Stability	Open controls are stable for 24 hours. Unopened controls are stable until the expiration date.

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	Calibration is required quarterly or - If the test results for the reference solutions are out of specification. - If the instrument has been serviced. - If the ambient temperature has changed more than 5 °C since the last calibration.
Procedure	The 3-point calibration uses the 50, 850, and 2000 mOsm/kg calibration standards. - From the Home screen, tap the menu icon (the icon has 3 parallel lines). - From the Main menu, tap Calibration. - Log in.

	- Follow the on-screen instructions to test samples from each specified standard five times. After each successful calibration test, a green checkmark appears in the calibration matrix and the unit prints "DONE" for that calibration test. - If a single calibration test fails or is canceled, the system prompts for a retest using a new sample. - If two failures occur within the same standard group, that calibration fails and the screen displays the message "Two replicate failures". - Upon completion of the last calibration test, the system displays a "Calibration successful" message or the reason for failure. Click OK to close the message. Closed success message, returns to the Home screen. Closed failure message, clears all checkmarks and returns to the Calibration screen.
Calibration Notes	When calibration is successful, the instrument calculates a new calibration slope and intercept and saves those values to memory. If a calibration test fails or is canceled for any reason, the instrument does not save the calibration data; instead, it maintains the last successful calibration. The date of the last successful calibration is displayed on the Calibration screen.

6. QUALITY CONTROL

The package insert for new lots must be reviewed for any changes before the product is used. A current Package Insert is included as a Related Document.

6.1 Controls Used

Controls	Supplier and Catalog Number
Assayed Multiqual Control Levels 1 & 3	Bio-Rad Laboratories Cat. No.-12008256 & 12008258
Urine Chemistry Control Levels 1 & 2	Bio-Rad Laboratories Cat. No. 12009995 & 12009996

6.2 Control Preparation and Storage

Control	Assayed Multiqual Control
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	**Opened**: stable for 6 days at 2-8°C. **Unopened**: stable until the expiration date at -20 to -50°C.

Control	Urine Chemistry Control
Preparation	Before sampling, allow the control to reach room temperature (18-25°C) and swirl gently to ensure homogeneity.
Storage/Stability	**Opened**: stable for 10 days at 2-8°C. **Unopened**: stable until the expiration date at 2-8°C.

6.3 Frequency

Quality Control is run upon arrival of any patient samples during a shift.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. • Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. • Consult and follow corrective action guidelines according to the Laboratory Quality Control Program (AHC.QA 40).

Step	Action
	• Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Lead Technologist or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of QC material or new shipment of the same lot must be tested in parallel with current control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEa for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

The Advance Micro-Osmometer, Model Osmo 1

7.2 Equipment

None

7.3 Supplies

- Micro Sample Test Kit (Sample Cells and Chamber Cleaners)
- 20µL Ease-Eject sampler
- Kim-wipes

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

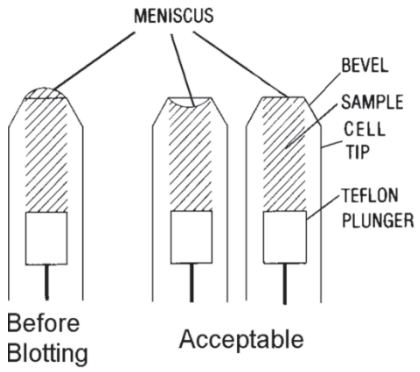
1. Remain at the analyzer throughout the testing process. Do NOT leave the analyzer unattended.

2. Insert a sampler tip into place on the sampler. The sampler tip must be straight and firmly seated.

3. Depress the sampler's plunger and insert the sampler tip at least ¼ inch (6 mm) below the surface of the fluid to be tested. Gently release the plunger to load a 20-µL sample.

4. Visually inspect the sample. If there are any large voids or bubbles in the sample, expel the sample and load a bubble-free sample.

5. Wipe the sides of the loaded sampler tip with a Kim-wipe to remove any clinging droplets. Then quickly wipe the end of the sampler tip to remove any fluid protruding beyond the tip. Be careful not to remove any of the sample. The exposed surface of the sample must be level with the end of the tip or may be slightly concave. See below:



6. Remove the chamber cleaner from the sample port and discard.

7. Holding the sampler by the barrel, insert the tip into the sample port, then rest the sampler in the operating cradle.

8. To start the test, push the operating cradle in until it reaches a positive stop.
   NOTE: To cancel a test in progress pull back on the cradle.

9. Record the results and pull back the operating cradle to a positive stop.

10. Remove the sampler from the operating cradle.

11. Insert a clean, dry chamber cleaner into the sample port and rotate it four or five times in both a clockwise and counterclockwise direction. Withdraw the chamber cleaner and insert the opposite end. Rotate the chamber cleaner in the same manner and leave it in the sample port until your next test.

12. Remove the used sampler tip from the sampler by pressing firmly enough on the sampler plunger to dislodge the tip, or apply a slight bending force using the thumbs and forefingers where the tip is pressed onto the sampler. Discard the used sampler tip.

13. Wipe the Teflon plunger tip with a Kim-wipe. Be careful not to dislodge the tip.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None

10.2 Rounding

None

10.3 Units of Measure

mOsm/kg H_2O

10.4 Clinically Reportable Range (CRR)

50 – 2000 mOsm/kg H_2O

10.5 Review Patient Data

Technologist must review for error messages. Resolve any problems noted before issuing patient reports. Refer to appendix A Troubleshooting table.

10.6 Repeat Criteria and Resulting

Refer to section 8

11. EXPECTED VALUES

11.1 Reference Ranges

Serum: 280-295 mOsm/kg H_2O
Urine: 500-800 mOsm/kg H_2O

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Osmolality determinations are helpful in the clinical management of water and electrolyte disturbances. Serum osmolality studies are useful in the evaluation of hypernatremia and hyponatremia, renal solute retention in acute renal failure and hydration status. Osmolality studies are also used in detecting undetermined solute in poisoning and in estimating the requirements for and effectiveness of dialysis.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved
- **Validated Test Modifications:** None

1. Microsamples are more susceptible to contamination and evaporation than larger samples. Avoid leaving sample containers open.
2. Cold samples are susceptible to condensation; warmer samples are susceptible to evaporation.
3. If an occasional sample produces irregular results, discard obviously discrepant readings as long as the instrument has been producing accurate readings repeatedly. Repeat the sample in question.
4. Replace Ease-Eject sampler (pipet) after every 500 tests or whenever a new Micro Sampler Test Kit is opened.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

50 – 2000 mOsm/kg H_2O

14.2 Precision

Precision of freezing point depression method is ± 2 mOsmol/kg H_2O.

14.3 Interfering Substances

In vivo substances such as ethanol, isopropanol, methanol, acetone, and ethylene glycol will increase osmolality readings.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Specifications – Repeatability

- Plus or minus 3 mOsm/kg H_2O between 0 and 400 mOsm/kg H_2O
- Plus or minus 0.75% between 400 and 2000 mOsm/kg H_2O

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheet (SDS)
4. Quest Diagnostics Records Management Procedure.
5. Centrifuge Use, Maintenance and Functions Checks (Lab Policy)
6. Repeat Testing Requirements (Lab Policy)
7. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
8. Current Package Insert Clinitrol 290
9. Advanced Micro-Osmometer Model Osmo 1 Analyzer Maintenance Log.
10. Urine / Serum OSMO Patient Log.
11. OSMO Calibration Log.

17. REFERENCES

1. User's Guide – The Advanced Micro-Osmometer, Rev 5, 12/2021
2. Package insert, Clinitrol 290 Reference Solution, Advanced Instruments, Inc. REF 3MA029.
3. Package insert, Osmometer Standards, Advanced Instruments, Inc. REF 3MA005, 3MA085 & 3LA201.
4. Package insert, Bio-Rad Assayed Multiqual Control, revised 01/2025.
5. Package insert, Bio-Rad Urine Chemistry Control, revised 11/2024.
6. Osmolality SOP by Cristina Lapus, document SC.547 Version 009. Quest Diagnostics Nichols Institute, Chantilly, VA 09/28/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

Appendix A: Troubleshooting
Appendix B: Maintenance

Appendix A

Troubleshooting

Problem/Message	Explanation
AI consumable box not detected	Place a Micro-Sample Test Kit on the instrument.
Sample did not freeze	Cause: The sample might be above the range of the instrument. Action: Confirm sample is present in the sampler. Test the solenoid. Clean the sample probe.
Sample pre-freeze	Cause: The sample froze prematurely. Action: Check for particulate matter in the sample. Clean the sample probe with a chamber cleaner dampened with water.
Test timeout	Cause: The instrument was unable to complete the test within the allotted time. Action: Check for particulate matter in the sample. If the issue persists, the sample might be outside the range of the instrument.

Appendix B

Maintenance

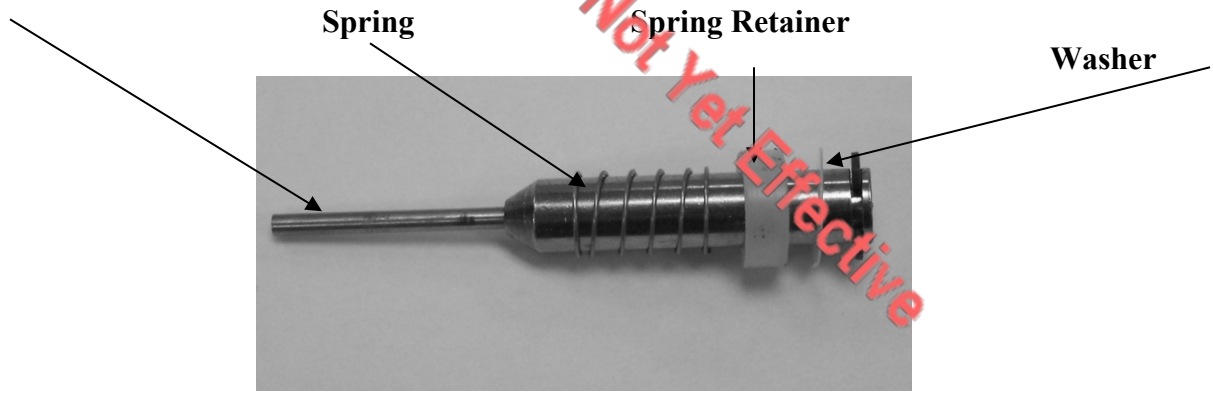
Maintaining the Instrument:

Chamber cleaning:
If multiple Sample Pre-freeze errors are experienced, or if the sample probe is contaminated, clean the cooling chamber with a chamber cleaner that has been dampened with water.

Solenoid maintenance:
A dirty solenoid can cause "Sample Did Not Freeze" errors and can affect instrument accuracy and repeatability. To clean the solenoid:

1. Open the section of instrument housing that contains the printer to access the solenoid in the Osmo1.
2. Insert a disposable chamber cleaner into the sample probe opening until you feel a positive stop.
3. Unscrew the two solenoid retainer bracket screws and gently remove the bracket.
4. Being careful not to lose any small parts, grasp the enclosed solenoid plunger assembly, lift it up, and then withdraw it from the body cylinder.

Impactor



5. Dampen the wooden end of a cotton-tipped applicator with an alcohol pad; then insert it down through the solenoid body into the smaller diameter plunger hole until it reaches the chamber cleaner.
6. Clean the smaller diameter plunger of the solenoid assembly with an alcohol pad.
7. Inspect the solenoid plunger for excessive wear and deposits. If the plunger shows signs of fouling, clean it with a lint-free cloth dampened with an alcohol pad.

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☐ White Oak Medical Center

Urine / Serum OSMO Patient Log

Tech Code _____ Date _____	Record Results	
290 Standard Lot #:	Exp. Date:	
	Serum	**Urine**
1st replicate 290 Standard (290 +/- 2)		
2nd replicate 290 Standard (290 +/- 2)		
Control Level 1 *Lot # & exp. are recorded in Unity*		
Patient Name / MR#		
1.		
2.		
3.		
Control Level 2 *Lot # & exp. are recorded in Unity*		

Tech Code _____ Date _____	Record Results	
290 Standard Lot #:	Exp. Date:	
	Serum	**Urine**
1st replicate 290 Standard (290 +/- 2)		
2nd replicate 290 Standard (290 +/- 2)		
Control Level 1 *Lot # & exp. are recorded in Unity*		
Patient Name / MR#		
1.		
2.		
3.		
Control Level 2 *Lot # & exp. are recorded in Unity*		

Comment:

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

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Advanced Micro-Osmometer Model Osmo 1 Analyzer Maintenance Log

Month: _____ Year: _____ Ease-Eject Sampler #: _____ Date put in use: _____

Instrument Serial Number: _____ Ease-Eject Sampler #: _____ Date put in use: _____ (use if sampler is changed)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily																															
Clean the chamber																															
Wipe the Teflon Plunger tip with a kim-wipe																															
Clean the Instrument Exterior																															
Check Printer Paper																															
Tech Code																															

Quarterly	
Calibration	
Tech Code	
Date	

As Needed	
Clean the Air Vents	
Clean the Solenoid Impactor	
Tech Code	
Date	

Comments:

_____

_____

_____

_____

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: