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| **Osmolality in Plasma/Serum and Urine** |
| **Purpose** | This procedure provides instructions for Osmolality In Plasma/Serum And Urine on the Osmo1 Single-Sample Micro-Osmometer |
| **Policy Statements** | This procedure is intended for all Chemistry personnel responsible for collecting and testing specimens for Osmolality on the Osmo1 Single-Sample Micro-Osmometer |
| **Principle** | Advanced Osmometers are devices for the determination of the concentration of solutions in terms of osmolality by means of freezing-point measurement. Advanced Osmometers utilize high precision thermistors to sense the sample temperature, to monitor the degree of supercooling and freeze induction, and to measure the freezing point of the sample. They can measure osmolality down to a resolution of 1 mOsm/kg H2O.When a solute is dissolved in a pure solvent, the following changes in the solution's properties occur:• The freezing point is depressed.• Boiling point is raised.• Osmotic pressure is increased.• Vapor pressure is lowered.These are the so-called "colligative" or concentrative properties of the solution which, within reasonable limits, change in direct proportion to the solute concentration; in other words, the number of particles in solution. Of the colligative properties, measurement of the freezing point allows the concentration of an aqueous solution to be easily determined with great precision.Refer to the Osmo1 Single-Sample Micro-Osmometer User Guide for more detailed information on principles of freezing point osmometry.  |
| **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 over-hydration, hyponatremia, and the syndrome of inappropriate antidiuretic hormone secretion. |
| **Instrument** | Advanced Instruments- Osmo 1 Single-Sample Micro-Osmometer |
| **Sunquest Test Codes** | **OSMO**: Osmolality Plasma/Serum**UOSM**:Urine Osmolality |
| **Materials** | **Equipment:**Advanced Instruments Micro-Osmometer, Model Osmo1

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| Minneapolis  |  |
| St. Paul | SN 18060815B |

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|  | **Reagents**All calibration standards are purchased from Advanced Instruments, Inc. through Cardinal Health.* **50** mOsm/kg calibration standard (3MA005). Acceptable range: 48 - 52 mOsm/kg
* **850** mOsm/kg calibration standard (3MA085). Acceptable range: 845.75 - 854.25 mOsm/kg
* **290** mOsm/kg calibration standard (3MA029). Stable for 7 days once opened when stored tightly capped in a 6mL Aliquot Tube (CHC# 21538) at 2-8°C. Acceptable range: 286 - 294 mOsm/kg. Run once per shift of patient testing and with each new operator.
* **2000** mOsm/kg calibration standard (3MA200). Acceptable range: 1960 – 2040 mOsm/Kg

For use with the 2000 mOsm/Kg range calibration* **Protinol™ 240, 280, and 320** mOsm/kg H2O (3MA028). Stable for 7 days once opened when stored tightly capped in a 6mL Aliquot Tube (CHC# 21538) at 2-8°C.

240 Expected range: 233-247 mOsm/kg 280 Expected range: 273-287 mOsm/kg 320 Expected Range 313-327 mOsm/kg* **Renol™ 300 and 800** mOsm/kg H2) (3LA085). Stable for 10 days once opened when stored tightly capped in a 6mL Aliquot Tube (CHC# 21538) at 2-8°C.

300 Expected Range: 290-310 mOsm/kg800 Expected Range: 790-810 mOsm/kg**Reagent Preparation:** All standards are liquid and are ready to use**Storage Instructions**: Store at 20 - 25ºC unless noted above.**Expiration**: Unopened vials are stable until the expiration date stamped on the carton.  |
| **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):** SST/No Gel**Plasma:** Li Hep**Urine:** 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.**Stability**:* Serum/Plasma: Room temp or 2-8° C for up to 48 hours. Recommended to test within 24 hours.
* Urine: Room temp or 2-8° C for up to 24 hours

**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 osmolality 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** |
| **Daily** |  | Complete and log maintenance on the Maintenance checklist.Chamber cleaning – after every test, clean the chamber with both ends of a dry chamber cleaner.* If you experience multiple “Sample Pre-freeze” errors, or if you suspect contamination of the sample probe, clean the cooling chamber with a chamber cleaner that has been dampened with DI water, and then dry with both ends of an un-used chamber cleaner.

Each day of use, run a 290 mOsm/Kg standard to verify calibration.290 Stability: 7 days at room temperature when stored tightly capped in a 6 mL aliquot tube.Run all levels of matrix-appropriate Quality Control material (Protinol for Serum, 3 levels, and Renol for Urine, 2 levels) each calendar day (from midnight to 23:59 pm) of patient testing. Check off on the maintenance log when you run QC so that other shifts know when it was last run to avoid duplication of work and waste of materials.Check for availability of printer paper. To load new paper, refer to User’s Guide pages 17-18.  |
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| **Monthly** |  | Cleaning air vents – Make sure the fan on the back of the instrument has no accumulated dust and debris that could impede air flow. Dirty air vents can cause instrument overheating and reboots. More detailed maintenance and troubleshooting information is available in the Advanced Instruments Model 2020 Osmometer User’s Guide pages 54-59. |
|  | 2. | Cleaning the Solenoid – A dirty solenoid can cause “Sample Did Not Freeze” errors and can affect instrument accuracy and repeatability.  |
| **As Needed Maintenance** |  | 20 µL Ease-Eject™ SamplerTo ensure proper instrument operation: you should **replace the plunger wire tip of the sampler every 500 tests** (or every time you open a new Micro-Sample Test Kit). Failure to replace the plunger wire may affect instrument accuracy and repeatability. *Note: A sampler plunger wire is included with each Micro-Sample Test Kit* |
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| **Calibration Procedure** |  | Calibration requirements:* 1. From the Home screen, tap the menu icon.
	2. The main menu displays.
	3. From the Main menu, tap **Calibration**. The system prompts you to log in.
	4. Login and follow the on-screen instructions to test samples from each specified standard five times. You will test samples of known standards
		1. 50 and 850 mOsm/kg H2O for a 2-point calibration;
		2. 50, 850, or 2000 mOsm/kg H2O for a 3-point calibration.
	5. Upon completion of the last calibration test, the system displays a “Calibration successful” message or the reason for failure. Click OK to close the success (or failure) message.
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| **Calibration Verification/ AMR** | 1. |  Analyze Advanced Instruments Calibration Verification materials in triplicate in the Osmometer Ready mode to verify calibration and Analytical Measuring range once every 6 months. Enter results in EP Evaluator. |
| 2. | 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 |
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| **Quality Control** | Renol™ **Urine** Osmolality Controls (Part # 3LA085)**Frequency:** Run both levels (300 and 800 mOsm/kg) once per calendar day (from 00:00 am to 23:59 pm) of patient testing**Stability:** 10 days once opened when stored tightly capped in a 6 mL aliquot tube at 2-8°C.**Sunquest Control names:** Renol 300 = C-RENL Renol 800 = C-RENH **Acceptability Ranges:** Ranges are current in Sunquest if the TS is notified upon receipt of new lot numbers. Refer to the Quality Control Procedure for QC exception codes. Expected Ranges are as follows:* Renol 300 mOsm/kg H2O: 290-310
* Renol 800 mOsm/kg H2O: 790-810

**Preparation**: Gently swirl contents prior to useProtinol Protein-Based **(SERUM)** Osmolality Controls (Part # 3MA028)**Frequency:** Run all (3) levels of QC once per calendar day (from 00:00 am to 23:59pm) of patient testing.**Stability:** 7 days once opened when stored tightly capped in a 6 mL aliquot tube at 2-8°C. **Sunquest Control names:** Protinol 240 = C-PROTL  Protinol 280 = C-PROTM  Protinol 320 = C-PROTH**Acceptability Ranges:** Ranges are current in Sunquest if the TS is notified upon receipt of new lot numbers. Refer to the Quality Control Procedure for QC exception codes.Protinol Protein-Based Controls* Protinol 240 mOsm/kg H2O: 233-247 mOsm/kg H2O (per product insert)
* Protinol 280 mOsm/kg H2O: 273-287 mOsm/kg H2O (per product insert)
* Protinol 320 mOsm/kg H2O: 313-327 mOsm/kg H2O (per product insert)

**Preparation**: Gently swirl contents prior to use |
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|  | **Action** |
| **Procedure for Sample Testing** | 1. Log in with your User ID and enter the Sample ID.
2. Place a new sampling tip on the sampler with the plunger wire carefully inserted into the middle of the tip. Verify that the tip is straight and firmly seated. Do not bend the plunger wire.
3. With your thumb on the plunger top and fingers grasping the barrel, depress the plunger; then insert the tip into the liquid sample at least ¼” (6 mm) below the surface. Gently release the plunger to load a 20 µL sample. Remove the pipette from the liquid.
4. Look at the sample you have just drawn. If there are voids or bubbles in the sample, discard it back into the sample by depressing the plunger, then load another sample, rechecking for air bubbles or voids.
5. Remove any sample on the outside of the tip using a clean, lint-free, non-ionic paper by wiping straight down on the sides of the pipette tip. Then, quickly swipe the end of the sampler tip to remove any excess sample protruding beyond the tip by holding the lint-free paper horizontally and wicking the tip of the pipette across it in one smooth motion. Be careful not to remove any of the sample from inside the tip. Check that the meniscus is either straight or concave.
6. Holding the sampler by the barrel, carefully insert the tip into the sample port; then rest the sampler body in the operating cradle.
7. Grasp the operating cradle and push it slowly forward until you feel a positive stop. The test starts when the cradle reaches the forward position and the operator and sample IDs have been entered.
8. Wait while the Osmo1 performs the tests. When the test completes, the resulting Osmolality displays in the middle of the screen. Record this result on your worksheet.
9. Withdraw the operating cradle and remove the sampler from the cradle.
10. Grasp the sampler tip and depress the plunger down firmly to eject the tip from the end of the pipette. Discard the sampler tip.
11. Wipe the Teflon plunger tip with a clean, lint-free, non-ionic paper, being careful not to dislodge the Teflon tip.
12. Insert a clean, dry clamber cleaner into the sample port until you feel a positive stop. Rotate the chamber cleaner four or five times in one direction while applying forward pressure.
13. Withdraw the chamber cleaner, and then use its other end to clean the internal probe again in the same manner. (If you have no more specimens to test, leave the cleaner in the sample port until the next test if it is your last test.)
14. To test additional samples, repeat this procedure starting with step 2.
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|  | . **Sample order:** * 1. **290 Standard** one time per shift of patient testing and with each new operator per shift. The instrument will alert if the result is not within 1SD. Repeat any flagged result. If out more than 3 times, calibrate.
	2. **All levels of matrix-appropriate QC, one replicate, once per calendar day**
* Run each level of appropriate matrix QC one time. The Osmo1 will flag results that fall outside of 1SD. Repeat the QC one time if outside 1 SD, then, if necessary, perform chamber cleaning and/or calibrate before repeating QC.
* If you have a patient urine specimen, run both levels (300 and 800 mOsm/kg) of Renol.
* If your specimen is serum, run all (3) levels of Protinol QC.

If you are running both sample types in the same run, complete QC for both matrices. * 1. **Patient samples in duplicate.**

 Controls and patients must meet expected repeatability of +/-4 mOsm/kg. * Subsequent runs by the same tech do not require standards or QC. Run new QC on each new calendar day of patient testing.
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| **Calculations** | Serum osmolality may be calculated using the following formula as a result check: |
| **Interpretation/****Results/Alert Values** | Results are printed on the instrument printer in mOsm/kg and may also be found by navigating to the stored results within the Osmo1 software. **For 290 Standard:*** Results must be within 286-294. Osmo1 will flag out of control results.

**For Quality Controls:*** Results must match within 1 SD of stated range. The Osmo1 will flag out of control results. Troubleshoot and repeat no more than 1 time before taking alternative actions.

**For Patient Specimens:*** Results must meet expected repeatability of
	+ **+/- 4 mOsm/kg**
* **To interpret and calculate reported results**: use the **first 2** results that match within 4 mOsm/kg and average them to arrive at the reported value.

*For example, the first two replicates of a patient yield results of 312 and 315. Because they are within 4 mOsm/kg, these results should be added, divided by 2 and rounded up to arrive at a reported value of 314.** Standards and controls must be within their stated limits before patient specimens can be reported.

**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.In a simple solution (i.e., glucose or sodium chloride in water), the freezing point can be measured and the unit concentration easily determined from an equation or a reference table. However, the equation is unique for each solute. In a more complex solution, all ionized and non-dissociated species contribute to the freezing point depression. The concentration of each solute cannot be easily determined. |
| **Result Reporting** | **Print a Worksheet (MISC2 for St. Paul, MISC for Minneapolis) to record your results.****In MEM: (manual result entry)**1. Type function MEM in Sunquest.
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.
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| **References** | 1. Osmo1 Single-Sample Micro-Osmometer User Guide. Norwood, MA. Advanced

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2. NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline.* NCCLS document EP7-A (ISBN 1-56238-480-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2002.
3. Rosenman J, et. al. 2010. Effects of Hemolysis, Icterus, and Lipemia on Serum Osmolality Results using the Advanced® Model 3250 Single-Sample Osmometer. Advanced Instruments Technical Literature.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Stephen Gripentrog/Erin Bartos | 8/17/2018 | New Procedure for Osmo1 Analyzer |
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