#### TRAINING UPDATE

Lab Location: Department: SGAH & WAH Core Lab Date Distributed:
Due Date:
Implementation:

9/16/2013 9/30/2013 **10/1/2013** 

#### DESCRIPTION OF PROCEDURE REVISION

#### Name of procedure:

Osmolality, Serum and Urine, Advance 3320 SGAH.C71,WAH.C70 v001

**Urine / Serum OSMO Patient Log AG.F134.002** 

#### **Description of change(s):**

Section	Reason
6.3	Specify run size, add consecutive run for reference solution
8	Add instruction to stay with analyzer
16	Add forms
19	Remove forms

**Osmo Patient Log** revised to specify run size of 3 samples and add note to remain at the analyzer during testing.

Changes are shown in blue on attached documents

Note: The Osmo maintenance and calibration logs are NOT changing

This revised SOP and log will be implemented on October 1, 2013

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

#### Approved draft for training all sites (version 001)

#### **Technical SOP**

Title	Osmolality, Serum and Urine, Advance 3320		
Prepared by	Ashkan Chini	Date:	2/17/2012
Owner	Robert SanLuis	Date:	8/15/2013

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

Review		
Print Name	Signature	Date

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#### 1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Osmolality, Serum	Freezing Point Depression /	OSMO
Osmolality, Urine	Advance 3320	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	Serum or Urine		
-Other Acceptable	None		
<b>Collection Container</b>	Serum: SST or Plain red top tube		
	Urine: Sterile container		
Volume - Optimum	1.0 mL or greater		
- Minimum	0.5 mL		
Transport Container and	Serum: Plastic vial or spun barrier tube at room		
Temperature	temperature		
	Urine, random: Collection kit (preferred) or container at		
	room temperature, submitted within 2 hours of collection.		
Stability & Storage	Room Temperature: Serum: 3 hours		
Requirements	Urine: Not recommended		

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Criteria			
	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	
	<u> </u>	<sub>2</sub> O, decomposition, or combination of	
		lysis, specimens must be warmed to	
	-	nd gently mixed to aid the complete	
solution of any precipitated solutes.		ripitated solutes.	
<b>Unacceptable Specimens</b>	Specimens that are unlabeled, improperly labeled, or those		
& Actions to Take	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	Hemolysis does not	interfere with test result.	
Characteristics	Specimens should b	be free from particles. Centrifuge urine,	
	if necessary, to remove gross particulate matter.		
Other Considerations Allow to clot completely prior to centrifugation.		letely prior to centrifugation.	

#### 4. REAGENTS

None

#### 5. CALIBRATORS/STANDARDS

#### 5.1 Calibrators/Standards Used

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

Reference	Supplier and Catalog Number	
Clinitrol <sup>™</sup> 290 Reference Solution	Advanced Instruments 3MA029	

#### 5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation,

# (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

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 <sup>TM</sup> 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 after major maintenance or parts replacement. Calibration is also required if the average of the reference material is not within specifications.
Procedure	1. When the display reads "Osmometer Ready", press the [NEXT] button until [CALIB] appears over the left button. Press it to initiate the calibration procedure. Calibration can be cancelled without changing the existing calibration by pressing the [EXIT] button.
	2. Display will briefly read "50 mOsm Calibration" and then prompt the user to insert a 50 mOsm calibration standard. Follow the prompts on the instrument display. When the instrument completes the test and reports the result, remove the sampler and clean the cooling chamber. Continue testing 50 mOsm calibration standards until this calibration point is complete.
	3. The calibration program will now briefly read "850 mOsm Calibration" and then prompt the user to insert an 850 mOsm calibration standard. Again, follow the prompts on the instrument display. Continue testing 850 mOsm calibration standards until this calibration point is complete.
	4. The calibration program will now briefly read "2000 mOsm Calibration" and then prompt the user to insert a 2000 mOsm calibration standard. Again, follow the prompts on the instrument display. Continue testing 2000 mOsm calibration standards until this calibration point is complete.

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	5.	Upon successful calibration, the instrument will briefly display "Calibration Complete", then "Osmometer Ready".	
	6.	Verify the calibration by running a Clinitrol <sup>TM</sup> 290 Reference Solution, before testing unknown samples.	
Calibration Notes		The Model 3320 will retain its previous calibration data until it completes a new calibration, and the display reads "Calibration Complete".	
		If the instrument has calibration information in memory, the results displayed during the calibration procedure will be close to the nominal value of the standards used. If the instrument has no calibration information in memory, or if a probe has been replaced, the results displayed may be far from the nominal value of the standards used. If the displayed values repeat consistently, the calibration will automatically adjust when the calibration sequence is complete.	
	•	The calibration procedure may be terminated at any time by pressing <b>[EXIT]</b> . The instrument will display " <b>Calibration Canceled</b> ", and beep twice. The previous calibration will be retained. The user will be prompted again to insert the appropriate calibration standard.	

#### **QUALITY CONTROL 6.**

#### 6.1 **Controls Used**

Controls	Supplier and Catalog Number
Liquichek Unassayed Chemistry Control Levels 1 & 2	Bio-Rad Laboratories Cat. No. 691 & 692
Liquichek Urine Chemistry Control Levels 1 & 2	Bio-Rad Laboratories Cat. No. 397 & 398

#### **Control Preparation and Storage 6.2**

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquichek Unassayed Chemistry Control Level 1 & 2		
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)		

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	Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.	
Storage/Stability	Open controls are stable for 6 days at 2-8°C.	
	Unopened controls are stable until the expiration date at -20 to	
	-70°C.	

Control	Liquichek Urine Chemistry Control Levels 1 & 2		
Preparation	Before sampling, allow the control to reach room temperature		
	(18-25°C) and swirl gently to ensure homogeneity.		
Storage/Stability	Open controls are stable for 30 days at 2-8°C.		
	Unopened controls are 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. If no osmolality test is received during a shift, then no QC is required to be run. Once a patient specimen is received:

- Run Clinical 290 Reference Solution in duplicate once per shift. Record each result on the Urine/Serum OSMO Patient Log. The Clinical 290 Reference Solution must have two 2 consecutive runs within limits (290 ± 2) before proceeding to run QC.
- 2. Bracket the patient run between QC levels (1 & 2) each of Urine and Serum QC material as appropriate.
  - Run size is limited to 3 patient samples. If more than 3 samples are to be tested, bracket each group of 3 between QC levels as specified.
  - Record all results and corrective action of all runs and repeats.
  - DO NOT run in duplicate.
- 3. If all results in steps 1 and 2 are within acceptable ranges, then report the patient results.
- 4. For the rest of the shift bracket all patient runs between two levels of appropriate QC material (i.e., run urine QC with a urine sample and serum QC with a serum sample).
- 5. Record all results on the Urine/Serum OSMO Patient Log.

#### **6.4** Tolerance Limits

Step	Action				
1	Acceptable ranges for Bio-Rad Quality Control are programmed into the Laboratory Information System (LIS) and may be posted near the				
	instrument for use during computer downtime.  Acceptable range for Advanced Clinitrol Reference Solution 290 mOsm/kgH20 is: 288 – 292				
2	<ul> <li>Run Rejection Criteria</li> <li>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.</li> </ul>				

Step	Action						
	<ul> <li>If the results of the Clinitrol 290 Reference Solution do not agree within ± 2 of 290, repeat the test using a fresh aliquot from the reference solution ampule. If all tests indicate that the instrument is repeating but out of calibration, re-calibrate according to the instructions in section "Calibration" of the procedure.</li> <li>The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.</li> </ul>						
3	Corrective Action:     All rejected runs must be addressed through corrective action. Step taken in response to QC failures must be documented. Consult and follow corrective action guidelines in Laboratory QC Program.						
	• Corrective action documentation must follow the Laboratory Quality Control Program.						
4	Review of QC						
	QC/CV must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.						
	If the SD is outside established ranges, investigate the cause and document corrective actions.						

#### 6.5 Review Patient Data

Technologist must review for error messages. Resolve any problems noted before issuing patient reports. Check appendix A Troubleshoot Table.

#### **6.6** Documentation

- QC tolerance limits are programmed into the LIS. The LIS calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Document all QC and patient result manually on the Urine/Serum OSMO Patient Log.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead 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.
- Save and document all the instrument print outs.

#### **6.7 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 3320

#### 7.2 Equipment

Centrifuge

#### 7.3 Supplies

- Sample Cells
- 20µL sampler
- Chamber Cleaners
- 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.

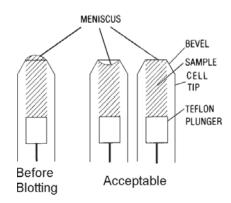
The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

- 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  $\frac{1}{4}$  inch (6 mm) below the surface of the fluid to be tested. Gently release the plunger to load a 20- $\mu$ L 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:

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- 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. Your instrument will run the test for approximately one minute and display the result in the format "Osmolality xxx mOsm". You may also start the test by pressing the left key on the keypad, and then pushing in the cradle.

**NOTE:** To cancel a test in progress, use the same method used to start the test. If the cradle was used, pull back on the cradle. If the keypad was used, use the right "Cancel" key.

- 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.

#### 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<sub>2</sub>O

#### 10.4 Clinically Reportable Range (CRR)

50 - 2000 mOsm/kg H2O

#### 10.5 Repeat Criteria and Resulting

Refer to section 8

#### 11. EXPECTED VALUES

#### 11.1 Reference Ranges

Serum: 280-295 mOsm/kg H<sub>2</sub>O Urine: 500-800 mOsm/kg H<sub>2</sub>O

#### 11.2 Critical Values

None established

#### 11.3 Priority 3 Limit(s)

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.

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#### 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  $\pm 2$  mOsmol/kg.

#### 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<sub>2</sub>O between 0 and 400 mOsm/kg H<sub>2</sub>O
- Plus or minus 0.75% between 400 and 2000 mOsm/kg H<sub>2</sub>O

#### 15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries <u>immediately</u> to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

#### 16. RELATED DOCUMENTS

- 1. Laboratory Quality Control Program
- 2. Laboratory Safety Manual
- 3. Material Safety Data Sheet (MSDS)
- 4. Quest Diagnostics Records Management Procedure.

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- 5. Centrifuge use, maintenance and functions checks (Lab Policy)
- 6. Repeat Testing Requirements (Lab Policy)
- 7. Current Allowable Total Error Specifications at <a href="http://questnet1.qdx.com/Business">http://questnet1.qdx.com/Business</a> Groups/Medical/qc/docs/qc bpt tea.xls
- 8. Current Package Insert Clinitrol 290
- 9. Advanced Micro-Osmometer Model 3320 Analyzer Maintenance Log (AG.F161)
- 10. Urine / Serum OSMO Patient Log (AG.F134)
- 11. OSMO Calibration Log (AG.F110)

#### 17. REFERENCES

- 1. User's Guide The Advanced Micro-Osmometer by Advanced Instruments, Inc. 3325 Rev6 042710
- 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 Liquichek<sup>TM</sup> Unassayed Chemistry Control, revised 10/2010
- 5. Package insert, Bio-Rad Liquichek<sup>TM</sup> Urine Chemistry Control, revised 10/2010
- 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
			Supersedes WAH.C59.000		
000	8/15/13		Update owner	L Barrett	R SanLuis
000	8/15/13	6.3	Specify run size, add consecutive run for reference solution	L Barrett	R SanLuis
000	8/15/13	8	Add instruction to stay with analyzer	L Barrett	R SanLuis
000	8/15/13	16	Add forms	L Barrett	R SanLuis
000	8/15/13	19	Remove forms	L Barrett	R SanLuis

#### 19. ADDENDA

Appendix A: Troubleshooting Appendix B: Maintenance

#### Appendix A

## **Troubleshooting**

Problem/Message	Explanation				
Abrupt loss of power	Check instrument fuse. Confirm that proper voltage is being supplied to the instrument.				
No response when sampler is	There could be a problem with the internal switch that initiates the				
fully inserted into sample	test. Try restarting the instrument, or use the keypad to start and				
port	cancel the test until service can be performed on the instrument.				
Results not repeatable	Often, poor repeatability is a result of poor technique or not				
(too scattered)	following recommended procedures.				
	• Be certain that the sample probe is carefully cleaned between tests.				
	Possible sample probe problem.				
Error message:	Try restarting the instrument.				
"Fan Driver Failure"					
Error message:	Instrument was unable to detect a freeze plateau, and was therefore				
"No Plateau"	unable to give a result.				
	• Retest sample, or run Clinitrol 290 Reference Solution.				
	Confirm good technique and sampler condition.				
	Possible sample probe problem.				
Error message:	This message indicates that the information stored in parameter RAM				
"Parameter RAM	has been corrupted. Restore probe bin numbers, date, time, and any				
Failed" or "No	other custom settings.				
Parameters in RAM"					
Error message:	This message indicates that a new software version has been				
"New Software	installed.				
Version"					
Error message:	This message indicates a need to recalibrate the instrument, and will				
"Recalibration	normally appear after the installation of new software, or when probe				
Needed"	bin numbers have changed.				
Error message:	A sample pre-freeze message usually appears when the sample				
"Sample Pre-freeze"	freezes prematurely.				
	Confirm good technique and sampler condition.      Charle for particulate metter in the sample.				
	<ul><li> Check for particulate matter in the sample.</li><li> Check probe bin numbers.</li></ul>				
	Possible sample probe problem.				
Error message:	Check the sample probe by running the A/D Tests				
"Sample Probe Open/	Check the sample proof by running the A/D Tests				
Block Probe Open"					
Error message:	Sample may be above range of instrument.				
"Sample Did Not	• Run Controls				
Freeze"; Impact does	• Check probe bin numbers.				
Occur	Confirm good technique and sampler condition.				
Error message:	Solenoid impactor may need cleaning. Refer to solenoid cleaning				
"Sample Did Not	instructions. If the error persists, contact Advanced Instruments Hot-				
Freeze"; Impact does	Line Service.				
not occur					

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Problem/Message	Explanation
Error message:	This message will appear during the calibration procedure if the
"Standards Reversed?	instrument detects that the low and high calibration standards have
Please Repeat"	been introduced in the wrong sequence. Retry the calibration, being
	sure to follow the displayed prompts.
Error message:	This message indicates a problem with the thermoelectric cooling
"T E Driver Failure"	module. Restart the instrument.
Error message:	The instrument was unable to complete the test within the allotted
"Test Time-out"	time.
	Confirm good technique and sampler condition.
	Assure that sample probe has been fully inserted.
Error message:	This message indicates that the internal battery needs replacing. This
"Low Battery"	part cannot be serviced by the user. Contact Advanced Instruments
	Hot-Line Service.
Error message:	This error can be produced in two ways:
"Cooling System	1) When the cooling chamber is below 0°C before diagnostics starts;
Error"	2) When the block channel fails to get below 0°C during the
	cooldown portion of diagnostics, but the sample channel does.
	Try restarting the instrument. If the error persists, contact Advanced
	Instruments Hot-Line Service.
"Pull Cradle Out"	This message will appear during instrument startup if the operating
	cradle is not fully retracted away from the cooling chamber. Pull the
	cradle toward the front of the instrument until it contacts the internal
	stop.
Other error messages	Try restarting the instrument. If the error persists, contact Advanced
	Instruments Hot-Line Service.

#### Appendix B

#### Maintenance

#### **Solenoid cleaning**

This cleaning procedure should be used if you suspect that your samples are not freezing properly because the solenoid impactor cannot move freely due to the accumulation of sample residue within the freezing chamber.

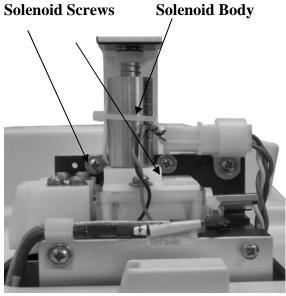
- 1. Remove the power cord from the rear of instrument.
- 2. Loosen the screw (Figure 9) holding the solenoid cover on the instrument and remove the cover.
- 3. Place a dry chamber cleaner in the cooling chamber.
- 4. Locate the solenoid retainer and loosen both screws. Remove the retainer.



5. Withdraw the solenoid plunger while leaving the solenoid body in place. Care must be taken

when removing the solenoid plunger to not lose the spring, spring retainer, or plastic washer.

- 6. Inspect the impactor for excessive wear.
- 7. Clean the smaller diameter tip of the solenoid plunger with a 70% isopropanol solution. Do not use any abrasive for this cleaning procedure.
- 8. Dampen the wooden end of a cotton-tipped applicator with a 70% isopropanol solution, and insert it through the solenoid body into the smaller diameter plunger hole until it reaches the chamber cleaner. Move the applicator in and out to scrub the sides of the hole.

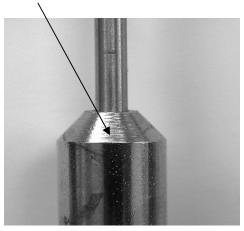


9. Return the cleaned solenoid plunger, including spring, retainer and any washers, to the solenoid body. Secure the retainer and remove the chamber cleaner.

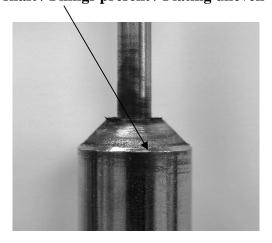
# Spring Spring Retainer Washer

10. Replace the solenoid cover, restore power and recalibrate, if necessary.

### No Black deposits on shaft / No fillings present / Plating even bright and shiny



Black deposits on shaft / Filings present / Plating uneven



#### **Maintaining the Instrument:**

#### 1. Cleaning Air Vents

Examine the air vents on the underside and rear of the instrument to ensure that they are unobstructed by dust or debris.

#### 2. Cleaning the Instrument Exterior

Use a mixture of warm water and soap. Isopropyl Alcohol may also be used to further decontaminate the exterior. Do not use abrasive cleansers or scouring pads, as they may mar the surface. Do not allow liquid to enter the cooling chamber or other portions of the instrument.

#### 3. Cleaning the Solenoid Impactor

Freezing the sample depends on the solenoid impactor striking the sample tip when the preset impact point of 3200 is shown on the display. Depending on the instrument test usage, the solenoid impactor should be periodically cleaned to remove any sample residue and chamber cleaner fibers. Instruments used daily should be cleaned monthly, while instruments that are used only occasionally should be cleaned every three months. See the solenoid cleaning instructions, later in this section.

#### **Chamber cleaning**

The cooling chamber and probe are easy to keep clean and dry by faithfully following the operating instructions for cleaning the freezing chamber after each test. If traces of calibrators, controls or biological samples are left in the sample chamber, however, the task will be more difficult and damp cleaning will probably be required. Two indicators that damp cleaning may be required are:

- The instrument has been in use but no clean, dry chamber cleaner is found in the sample port, and successive results on aliquots of the same sample indicate chamber contamination (the first aliquot reading is very high, and subsequent readings are progressively lower).
- "Sample Pre-freeze" errors begin to occur quite frequently. When indicated, the cooling chamber may be damp cleaned as follows:
  - 1. Using the keypad, enter the Utilities Menu or allow the instrument to go into Stand-by Mode. This allows the cooling chamber to warm to room temperature.
  - 2. Dampen (do not saturate) the end of a chamber cleaner with reagent grade water.
  - 3. Firmly insert the dampened chamber cleaner all the way into the sample port, rotate it four or five times (clockwise and counter-clockwise) and withdraw. If the end is stained or has debris stuck to it, repeat with another dampened chamber cleaner.
  - 4. Repeat with a dry chamber cleaner. Insert and leave a clean, dry chamber cleaner in the sample port until the next sample is to be tested.
  - 5. If the unit was placed in the Utilities Menu, use the keypad to exit and return to the "Osmometer Ready" prompt.

#### Sampler plunger wire replacement and verification

To ensure proper instrument operation, you should replace the plunger wire tip of the sampler every 500 tests (or with every new package of Micro Sample Test Kit). To replace the Plunger Wire:

- 1. Unscrew the calibration gauge and key.
- 2. Rotate the sampler shaft until the calibration setscrew appears beneath the access hole in the side of the sampler body.

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- 3. Place the key end of the calibration gauge in the access hole and turn counter clockwise to loosen the setscrew.
- 4. Carefully remove the old sampler plunger wire.
- 5. Place a sampler tip on the sampler to help you place new wire correctly.
- 6. Slip the sampler plunger wire into the sampler tip so the Teflon plunger tip protrudes about 1/16" or 1.6 mm from the end of the sampler tip.
- 7. Using the key end of the calibration gauge, push the plunger wire into the sampler as far as it will go.
- 8. Tighten the calibration setscrew with the calibration gauge.
- 9. Screw the calibration gauge and key back into the top of the sampler.

Your 20-µL sampler is now calibrated and ready to use. For verification that the sampler is calibrated correctly, use the following steps:

- 1. Place a new sampler tip on the sampler
- 2. Unscrew the calibration gauge and key.
- 3. Insert the key end of the calibration gauge into the sampler tip.
- 4. Visually inspect the position of the end of the sampler plunger tip and the end of the calibration key. There should be no gap between the two.
- 5. If necessary, reset the sampler plunger wire as described above.



Germantown Emergency Center
Shady Grove Adventist Hospital
Washington Adventist Hospital

# **Urine / Serum OSMO Patient Log**

**Note**: Remain at the analyzer throughout the testing process.

Tech	Date		Reco	ord Results			
290 Standard (290 +/-2) Perform in duplicate once per shift							
Must be run in this order*		Ser	Serum		Urine		
Control Level 1	Bracket with ea	ach patient run					
Patient Name / MR#							
Patient Name / MR#							
Patient Name / MR#							
Control Level 2	Bracket with ea	ch patient run					
* Run size is limit between QC level		s. If more than 3 s	amples are to	be tested	l, bracket each grou	p of 3	
Tech	ech Date			Record Results			
	Standard (290 +						
Perform in duplicate once per shift  Must be run in this order			Serum		Urine	Urine	
Control Level 1 Bracket with each patient run							
Patient Name / MR#							
Patient Name / MR#							
Patient Name / MR#							
Control Level 2	Bracket with ea	ch patient run					
Weekly review:		Weekly review:		W	eekly review:		
Weekly review:		Weekly review:			onthly review:		

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