TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	11/9/2018
Department:	Core Lab	**Due Date:**	12/1/2018
		Implementation:	**12/1/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Osmolality, Serum and Urine, Advanced 3320 SGAH.C71 v3

Description of change(s):

Note change to QC temperature

Other changes are to match current practice

Section	Reason
6.1	Update product numbers
6.2	Change serum QC range to -50C
6.3	Specify levels by product type
13	Added reference to App B
17	Updated serum QC & PI dates

This revised SOP will be implemented on December 1, 2018

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

Technical SOP

Title	**Osmolality, Serum and Urine, Advanced 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	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Osmolality, Serum Osmolality, Urine	Freezing Point Depression / Advanced 3320	OSMO UOSMO

Synonyms/Abbreviations
Osmo

Department
Chemistry

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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.

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Criteria		
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:	Advanced Instruments
-50 mOsm/kgH20 Calibration Standard	3MA005
-850 mOsm/kgH20 Calibration Standard	3MA085
-2000 mOsm/kgH20 Calibration Standard	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 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. 5. Upon successful calibration, the instrument will briefly display "**Calibration Complete**", then "**Osmometer Ready**". 6. Verify the calibration by running a Clinitrol™ 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 **[EXIT]**. The instrument will display "**Calibration Canceled**", and beep twice. The previous calibration will be retained. The user will be prompted again to insert the appropriate calibration standard.

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
Liquid Assayed Multiqual 1 & 3	Bio-Rad Laboratories Cat. No. 337 & 339
Liquichek Urine Chemistry Control Levels 1 & 2	Bio-Rad Laboratories Cat. No. 195 & 196

6.2 Control Preparation and Storage

Control	**Bio-Rad Liquid Assayed Multiqual Level 1 & 3**
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	**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	**Opened**: stable for 30 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.
If no osmolality test is received during a shift, then no QC is required to be run.
Once a patient specimen is received:

1. 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 for Urine and QC levels 1 & 3 for Serum 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 and Criteria for Acceptable QC

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	**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. • 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. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. • The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.
3	**Corrective Action**: • All rejected runs must be addressed through corrective action. Steps 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 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.

6.6 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 3320

7.2 Equipment

Centrifuge

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.

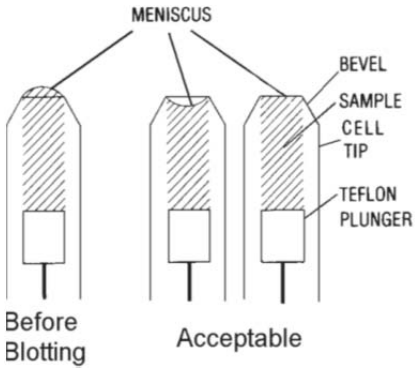
1. Remain at the analyzer throughout the testing process. Do NOT leave the analyzer unattended.

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. 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.

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 H2O

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. (see Appendix B)

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.

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 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 Liquid Assayed Multiqual, revised 5/2017
5. Package insert, Bio-Rad Liquichek™ Urine Chemistry Control, revised 10/2017
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

Version	Date	Section	Reason	Reviser	Approval
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
001	8/16/16	Header	Add WAH	L Barrett	R SanLuis
001	8/16/16	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
001	8/16/16	7.3	Specify name of sampler	L Barrett	R SanLuis
001	8/16/16	10.5	Review data moved from section 6	L Barrett	R SanLuis
001	8/16/16	15	Update to new standard wording	L Barrett	R SanLuis
001	8/16/16	App B	Re-organize sequence, add sampler numbering process, remove plunger wire replacement	L Barrett	R SanLuis
001	8/16/16	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
2	10/17/18	6.1	Update product numbers	D Collier	R SanLuis
2	10/17/18	6.2	Change serum QC range to -50C	D Collier	R SanLuis
2	10/17/18	6.3	Specify levels by product type	D Collier	R SanLuis
2	10/17/18	13	Added reference to App B	D Collier	R SanLuis
2	10/17/18	17	Updated serum QC & PI dates	D Collier	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 fully inserted into sample port	There could be a problem with the internal switch that initiates the test. Try restarting the instrument, or use the keypad to start and cancel the test until service can be performed on the instrument.
Results not repeatable (too scattered)	Often, poor repeatability is a result of poor technique or not following recommended procedures. • Be certain that the sample probe is carefully cleaned between tests. • Possible sample probe problem.
Error message: "**Fan Driver Failure**"	Try restarting the instrument.
Error message: "**No Plateau**"	Instrument was unable to detect a freeze plateau, and was therefore 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: "**Parameter RAM Failed" or "No Parameters in RAM**"	This message indicates that the information stored in parameter RAM has been corrupted. Restore probe bin numbers, date, time, and any other custom settings.
Error message: "**New Software Version**"	This message indicates that a new software version has been installed.
Error message: "**Recalibration Needed**"	This message indicates a need to recalibrate the instrument, and will normally appear after the installation of new software, or when probe bin numbers have changed.
Error message: "**Sample Pre-freeze...**"	A sample pre-freeze message usually appears when the sample freezes prematurely. • Confirm good technique and sampler condition. • Check for particulate matter in the sample. • Check probe bin numbers. • Possible sample probe problem.
Error message: "**Sample Probe Open/ Block Probe Open**"	Check the sample probe by running the A/D Tests
Error message: "**Sample Did Not Freeze**"; Impact does Occur	Sample may be above range of instrument. • Run Controls • Check probe bin numbers. • Confirm good technique and sampler condition.

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Problem/Message	Explanation
Error message: "**Sample Did Not Freeze**"; Impact does ***not*** occur	Solenoid impactor may need cleaning. Refer to solenoid cleaning instructions. If the error persists, contact Advanced Instruments Hot-Line Service.
Error message: "**Standards Reversed? Please Repeat...**"	This message will appear during the calibration procedure if the instrument detects that the low and high calibration standards have been introduced in the wrong sequence. Retry the calibration, being sure to follow the displayed prompts.
Error message: "**T E Driver Failure**"	This message indicates a problem with the thermoelectric cooling module. Restart the instrument.
Error message: "**Test Time-out**"	The instrument was unable to complete the test within the allotted time. • Confirm good technique and sampler condition. • Assure that sample probe has been fully inserted.
Error message: "**Low Battery**"	This message indicates that the internal battery needs replacing. This part cannot be serviced by the user. Contact Advanced Instruments Hot-Line Service.
Error message: "**Cooling System Error**"	This error can be produced in two ways: 1) When the cooling chamber is below 0ºC before diagnostics starts; 2) When the block channel fails to get below 0ºC 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

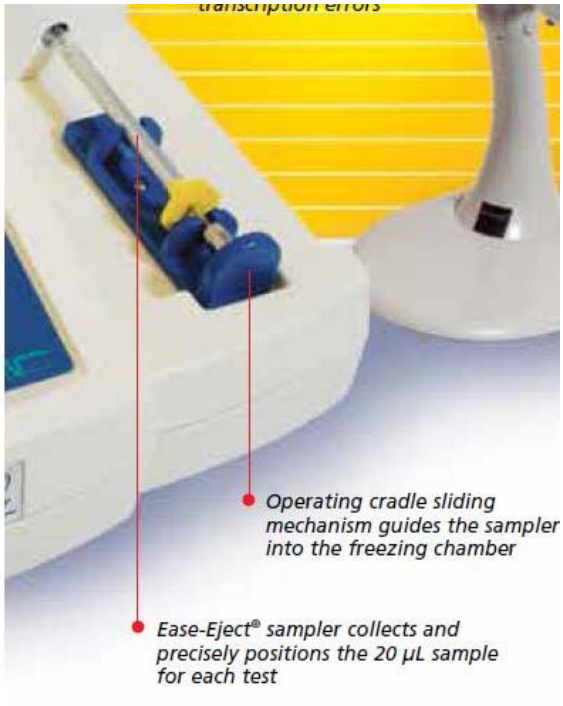
Maintaining the Instrument:

1. **Chamber cleaning (daily)**
   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:
     a. 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.
     b. Dampen (do not saturate) the end of a chamber cleaner with reagent grade water.
     c. 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.
     d. 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.
     e. If the unit was placed in the Utilities Menu, use the keypad to exit and return to the "**Osmometer Ready**" prompt.

2. **Cleaning the Instrument Exterior (daily)**
   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. **Ease-Eject Sampler Replacement**
   To ensure proper instrument operation, you should replace the Ease-Eject sampler every 500 tests (or with every new package of Micro Sample Test Kit). The following process is used to ensure the sampler tip is replaced at the appropriate frequency:
   a. Each box of Disposable Chamber Cleaner and Sampler Tip Kit (500 tests) and sampler (pipette) are numbered from 1 - 4. A spare sampler (pipette) is numbered 5.
   b. When a new box is opened, a new sampler (pipette) that corresponds to the box number must be placed into use.
   c. Log the date and sampler number on the maintenance log each time it is changed.
   d. In the event that a sampler (pipette) malfunctions before the kit is done, sampler (pipette) # 5 is used as a backup; ensure you document on the log when sampler #5 was put into use.
   e. Samplers (pipettes) are scheduled to be calibrated quarterly and thereafter Osmometer must be calibrated.

f. Ensure Osmometer calibration date is documented on the log.



4. Cleaning Air Vents (as needed)

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

5. Cleaning the Solenoid Impactor (as needed)

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.

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.

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

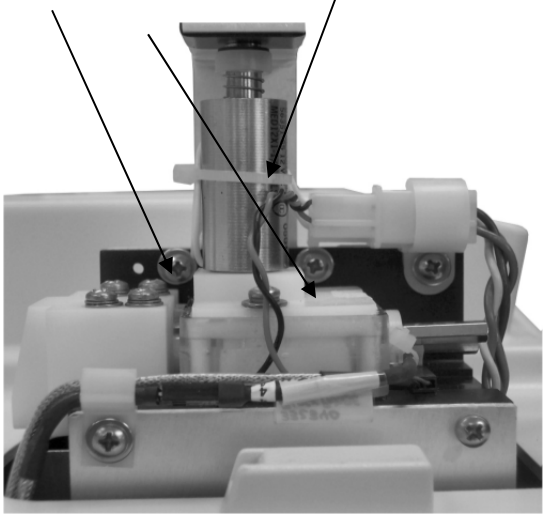
Loosen screw

e. 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.
f. Inspect the impactor for excessive wear.

8. Clean the smaller diameter tip of the solenoid plunger with a 70% isopropanol solution. Do not use any abrasive for this cleaning procedure.

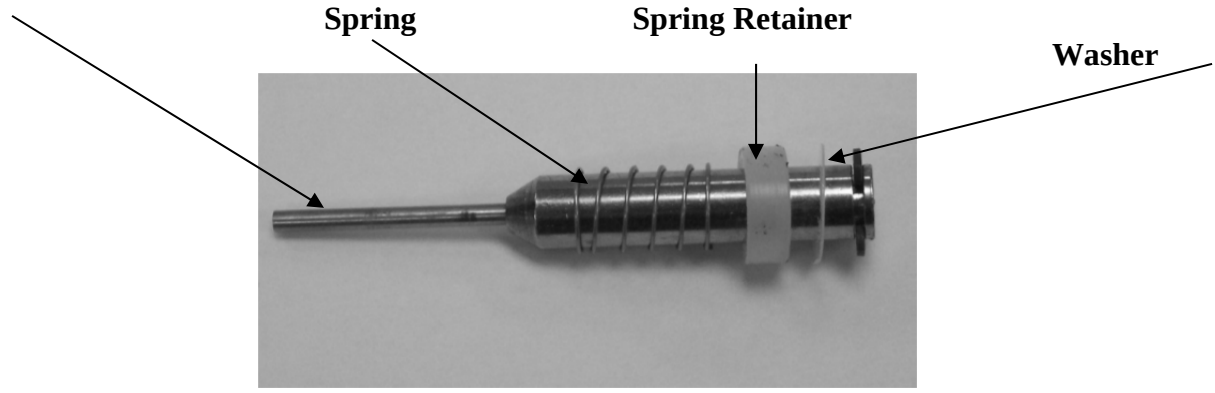
h. Dampen the wooden end of a cotton-tipped applicator with a 70% isopropanol solution, and insert it through the solenoid body into the smaller diameter plunger hole until it reaches the chamber cleaner. Move the applicator in and out to scrub the sides of the hole.

Solenoid Screws **Solenoid Body**



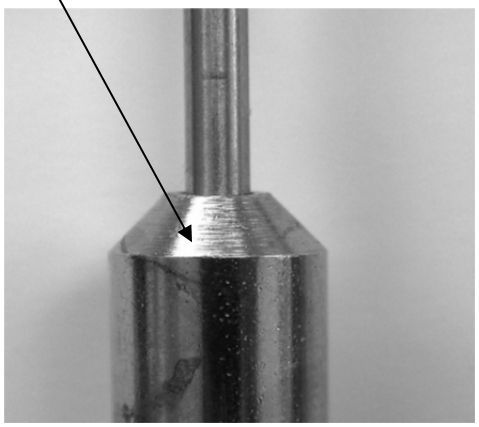
i. Return the cleaned solenoid plunger, including spring, retainer and any washers, to the solenoid body. Secure the retainer and remove the chamber cleaner.

Impactor



j. 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