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Beaumont

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Single-Sample Micro-Osmometer Osmo1 – Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To provide a procedure to utilize the Advanced Osmometer Osmo1 for diagnostic testing. Advanced Osmometers are devices for the determination of the concentration of solutions by means of freezing point measurement. The osmometer utilizes a high precision thermistor to sense the sample temperature, to control the degree of supercooling and freeze induction and to measure the freezing point of the sample. The sample is supercooled to several degrees below its freezing point and then mechanically is induced to freeze. The heat of fusion suddenly liberated causes the sample temperature to rise toward a plateau wherein an ice/water equilibrium occurs. This equilibrium by definition is the freezing point of the solution.

II. SPECIMEN COLLECTION AND HANDLING:

Acceptable specimen types include serum, plasma, and urine. Specimen must be centrifuged prior to analysis. All specimens utilize 20 microliters for analysis.

III. REAGENTS/SUPPLIES:

A. 290 mOsm/kg Standard - Clinitrol Reference Solution
B. 50 mOsm/kg Standard
C. 850 mOsm/kg Standard
D. Biorad Multiqual unassayed serum controls
E. Biorad Urine Chemistry unassayed urine controls
F. Advanced Linearity Set – To verify or establish reportable ranges

G. Micro-Sample Test Kit (500 tests)

H. Printer Paper

IV. CALIBRATION:

A. Calibration of the Advanced Micro-Osmometer requires no adjustment of the instrument on the user's part. If repeatability of calibration standards is acceptable, the instrument automatically performs an internal calibration. The two necessary calibration standards are 50 mOsm/kg H2O and 850 mOsm/kg H2O. The procedure is as follows.

1. From the Home screen, tap the menu icon  . The Main menu displays.
2. From the Main menu, tap "CALIBRATION". The system prompts you to log in. Log in as "User" with the password "user".
3. After entering the password, the Calibration screen displays.

Our instrument is configured for a 2-point calibration so, the row for the 2000 mOsm/kg calibration will not appear.

4. Follow the on-screen instructions to test samples from each specified standard five times.
    a. After each successful calibration test, a green checkmark appears in the calibration matrix  and the unit prints "DONE" for that calibration test.
    b. If a single calibration test fails or is canceled, the system prompts for a retest using a new sample.
    c. If two failures occur within the same standard group, that calibration fails and the screen displays the message "Two replicate failures".
    d. Upon completion of the last calibration test, the system displays a "Calibration successful" message.
5. Click OK to close the success (or failure) message.
    a. When you close a success message, the instrument saves the calibration and the system returns you to the Home screen.
    b. When you close a failure message, the system clears all checkmarks and returns you to the Calibration screen. From there, you can restart the

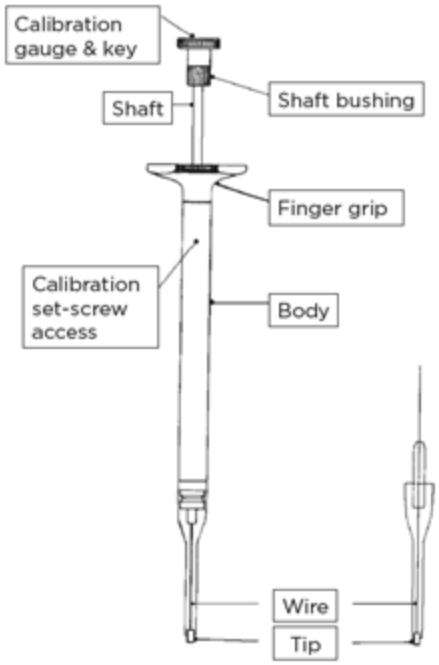
calibration or exit to the Home Screen via the Cancel button  . If a calibration test fails or is canceled, the instrument does not save that data; instead, it maintains the last successful calibration.

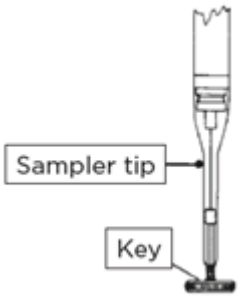
6. Verify the calibration by running a Clinitrol 290 mOsm/kg Reference Solution and all QC (Quality Control) before running samples.

V. SAMPLER PLUNGER REPLACEMENT:

A. To ensure proper instrument operation, the sampler plunger should be replaced for every 500 tests (when opening a box of sample tips).

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.
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 sampler plunger wire into the sampler as far as it will go.
8. Tighten the calibration set-screw with the calibration gauge.
9. Screw the calibration gauge and key back into the top of the sampler.





B. For verification that the wire is calibrated correctly, use the following procedure:
    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 wire 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.

C. Reference Solution:
    1. Run 2 samples of 290 mOsm/kg Reference Solution daily to check instrument operation or to confirm your calibration. Back-to-back readings for this Reference Solution must be +/- 2. In addition to running the 290 standard following a calibration, run levels 1 & 3 of Biorad Multiqual and levels 1 & 2 of Biorad Urine Chemistry QC material. Doing so will allow you to verify proper operation or recognize and diagnose problems promptly.

VI. MAINTENANCE:

A. Monthly - Solenoid Maintenance
    1. Supplies
        a. 70% Isopropanol solution
        b. Wooden applicator sticks
        c. Kim wipes
        d. Phillips head screwdriver
    2. Procedure
        a. Open the section of instrument housing that contains the printer to access the solenoid.

b. Insert a disposable chamber cleaner into the sample probe opening until you feel a positive stop.
c. Unscrew the two solenoid retainer bracket screws and gently remove the bracket.
d. 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.

Figure 83: Solenoid plunger assembly

e. Dampen the dampen the end of a wooden applicator stick with a 70% isopropanol solution; then inset it down through the solenoid body into the smaller diameter plunger hole until it reached the chamber cleaner you inserted in step 2.
f. Move the applicator in and out to scrub the sides of the hole.
g. Clean the smaller diameter plunger of the solenoid assembly with a 70% isopropanol solution on a soft cloth.
h. **Do not use any abrasive for this cleaning procedure.**
i. Inspect the solenoid plunger for excessive wear and deposits.
    i. If the plunger shows signs of fouling clean it with a lint-free cloth dampened with isopropyl alcohol or a cleaning solution for protein removal.

ii. If the plunger does not show signs of wear, continue to the next step.

j. Return the solenoid plunger, including spring, retainer, and any washers, to the solenoid body. Screw in the retainer bracket screws. Replace the instrument cover, and remove the chamber cleaner.

k. Perform 2 sample runs with DI water.

l. Run daily QC.

m. If necessary, recalibrate the Osmo-1.

VII. QUALITY CONTROL (QC):

A. Dayshift is to run 2 samples of 290 Reference Solution.

B. PM shift is to run Multiqual (serum) levels 1 and 3.

C. MN shift runs Urine Chemistry (urine) levels 1 and 2.

D. Document QC results in Unity Realtime. Refer to the Method Quality Control Section.

VIII. SPECIAL SAFETY PRECAUTIONS:

A. When placing sample tip on pipette, make sure it is securely fastened completely to ensure proper analysis. Be careful not to crack the sample tip. Also never inject anything into the cooling chamber of the osmometer.

IX. PROCEDURE:

A. If the Home screen is not currently displayed: Tap the Home button  to display the Home screen.

B. Enter the Sample ID. Tap the SAMPLE ID button. A keyboard displays and the barcode scanner on the front of the instrument activates. Either scan or type the sample ID and tap Enter. The SAMPLE ID button should turn from orange to blue after you enter the Sample ID.

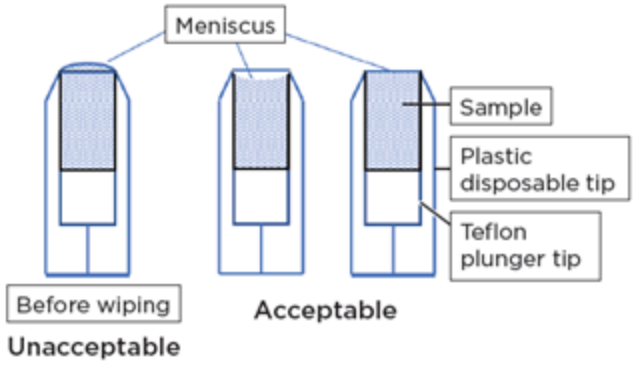
C. Place a new sampling tip on the sampler with the plunger wire inserted carefully into the middle of the tip. Verify that the tip is straight and firmly seated.

D. 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.

E. Look at the sample you have just drawn. If there are voids or bubbles in the sample, discard it and load another sample that does not contain voids.

F. Remove any sample on the outside of the tip using a clean Kimwipe. Quickly swipe the end of the sampler tip to remove any excess sample protruding beyond the tip. Be careful not to remove any of the sample below the acceptable meniscus line.



G. Holding the sampler by the barrel, carefully insert the tip into the sample port; then rest the sampler body in the operating cradle.

H. 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. When the test begins, the progress bar on the screen begins to fill. The status bar at the top of the display is yellow, and the status is TESTING.

I. Wait while the Osmo1 performs the test. When the test completes, the resulting osmolality displays in the middle of the screen. The software provides the instructions to remove the sampler and clean the chamber. Test results are stored in the Results database. If you want to cancel a test, you can withdraw the sample operating cradle at any time.

J. Withdraw the operating cradle and remove the sampler from the cradle.

K. Grasp the sampler tip and depress the plunger to help remove it. Discard the sampler tip.

L. Wipe the plunger tip with a Kimwipe, being careful not to dislodge the Teflon tip.

M. Insert a clean, dry chamber cleaner into the sample port until you feel a positive stop. Rotate four or five times in one direction while applying forward pressure.

N. Withdraw the chamber cleaner and then use the other end to clean the probe again in the same manner. Leave the cleaner in the sample port until the next test.

X. MAXIMUM REPORTABLE RANGE:

0 – 2000 mOsm/kg

XI. REFERENCE RANGE:

A. Serum 275 – 295 mOsm/kg

B. Urine 300 – 1200 mOsm/kg

XII. INTERPRETATION:

Result for osmolality is the displayed number.

XIII. REFERENCES:

1. Osmo1 Single-Sample Micro-Osmometer User Guide, Advanced Instrument, Inc., Needham Massachusetts.

Attachments

Osmo 1 Maintenance Sheet.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Directors	Ann Marie Blenc: System Med Dir, Hematopath	2/16/2024
System Medical Director	Caitlin Schein: Staff Physician	1/23/2024
Medical Director	Subhashree Mallika Krishnan: Staff Physician	1/22/2024
Technical Director	Qian Sun: Tech Dir, Clin Chemistry, Path	1/22/2024
Policy and Forms Steering Committee Approval (if needed)	Kelly Walewski: Supv, Laboratory	1/22/2024
Lab Manager	Leah Korodan: Mgr, Division Laboratory	1/22/2024
	Kelly Walewski: Supv, Laboratory	1/22/2024

Applicability

Royal Oak