Serum, Plasma & Urine Osmolality

OSMO 1- Advanced Instruments Single-Sample Micro-Osmometer

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Adopted 10/8/20 by Ricky Grisson MD \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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# Principle

The Advanced Instruments Osmo1 osmometer uses the principle of freezing point depression to measure osmolality. Osmolality is the total solute concentration of an aqueous solution. Osmometers measure the number of solute particles irrespective of molecular weight or ionic charge. The Advanced Osmometers utilize high-precision electronic thermometers to sense the sample temperature, to control the degree of supercooling and freeze induction and to measure the freezing point of the sample. The freezing point depression of a solution is a measure of the concentration of solutes dissolved that solution. The sample volume, 20 ul, is presented to the thermistor probe or cooling chamber. The sample begins cooling rapidly to a predetermined temperature below the expected sample freezing point. The rate of cooling is tightly controlled by the osmometer. While the sample is in the super cooled state, a physical shock called the freeze pulse is introduced to the sample. As a result, the sample becomes partially crystalized forming an ice/water mixture surrounding the temperature probe. The heat of fusion resulting from the crystallization process raises the sample temperature to a plateau where the liquid/solid equilibrium is maintained. This temperature plateau represents the true freezing point of the solution. The osmometer precisely measures this temperature at the plateau and calculates the concentration in mOsm/kg of water. This is the osmolality result.

# Clinical Significance

Osmolality determinations have found a widespread use in the diagnosis and prognosis of various diseases and in the follow-up therapy. Osmolality is a valuable clinical tool used in the diagnosis and treatment of patients. It is a quick and effective test to help evaluate the body’s water balance or its ability to produce and concentrate urine, to investigate low sodium levels (hyponatremia), to detect the presence of toxins in the body, and to monitor osmotically active drug therapies such as mannitol, which is used to treat cerebral edema. This test is also ordered to help monitor the effectiveness of a treatment for a condition found to be adversely affecting a person’s osmolality.

The comparison of the measured Osmolality to the calculated Osmolality can indicate the presence/absence of analytes in the specimen that may contribute to the actual Osmolality. For serum or plasma, a calculated Osmolality can he obtained using one of two different formulas. LIS system rules will determine which calculation is appropriate based on ethanol results.

1. **Calculated Osmo =** (2 x serum Na+) + [(BUN in mg/dL)/2.8] + [(glucose in mg/dL)/18]

A difference of greater than 10 mOsm between the measured Osmolality and that which can be calculated, may indicate the presence of an ingested substance, mannitol or another analyte not taken into account by the calculation.

In the case of ethanol ingestion, an additional calculation will be used.

1. **Calculated Osmo =** (2 x serum Na+) + [(BUN in mg/dL)/2.8] + [(glucose in mg/dL)/18] + [(EtOH in mg/dL)/3.7]

**Osmo Gap (OGAP) is a separate** order (calculation) that may be requested by the Pharmacy department and is utilized to determine certain drug toxicities.

**Calculation (OGAP)= serum /plasma OSMO - (calc)COSMO**

# Specimen

**Serum** - 20 ul of non-hemolyzed sample (see procedural note on gross hemolysis). No special patient preparation is required.

**Plasma** - 20 ul of non-hemolyzed sample. (see procedural note on gross hemolysis). Lithium Heparin is the only acceptable anticoagulant.

**Urine** - 20 ul of urine. Specimens should be free of preservatives. If the specimen is a timed sample, it should remain refrigerated during collection to minimize bacterial growth. Samples should be spun prior to measurement if there is evidence of cells or particulate matter in the sample.

**Reagents-NONE**

**Supplies**

Advanced Instruments Standards :50 mOsm/kg, 850 mOsm/kg,

and 2000 mOsmo/kg Calibration

Advanced Instruments Clinitrol 290 Reference Solution

Advanced Instruments Disposable Sampler Tips and Chamber Cleaners

Advanced Instruments Sampler

All supplies may be stored at room temperature and no special handling is necessary. No standard or solution should be used beyond the manufacturer’s stated expiration date.

**Instrument**

Advanced InstrumentsOsmo 1 Single-Sample Micro-Osmometer

**Calibration**

It is recommended to recalibrate the Osmo1 in any of the following cases:

* If the test results for the reference solutions (QC) are repeatedly out of specification
* If the instrument has been serviced (especially if any hardware was replaced)
* Following monthly maintenance or impactor cleaning during troubleshooting
* Following pipette tip replacement when opening a new box of tips.

Calibration of the Advanced Micro-Osmometer is a simple procedure requiring no adjustment of the instrument by the user. The user simply follows a menu driven calibration program requiring the testing of three standards. The necessary calibration standards are 50, 850, and 2000 mOsm/kg. Each standard is run 5 times. If at any time a replicate value fails, the instrument will prompt a rerun. Two failed replicates in a single standard group will result in a Failed Calibration and the user must begin again. If the reproducibility is acceptable, the instrument displays a calibration successful message. For details of calibration, see page 30-32 of the User Guide.

Verify a successful calibration by running the 290 Reference Solution, Protinol 240 QC, Protinol 320 QC and Level 2 Biorad Urine QC.

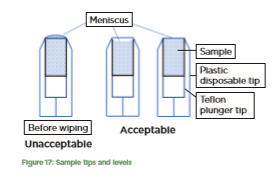
**NOTE**: To reduce the chance of cross contamination, it may be suitable to perform a DH2O blank run after a calibration and before QC to avoid an outlier on the first level of QC run after the 2000 calibrator. The DH2O blank was chosen as opposed to repeating QC to avoid QC outliers in monthly statistics.

# Quality Control

**The Clinitrol 290** is run on each shift prior to performing any patient testing. The obtained result must be 290 ± 2 mOsm. If a result outside this limit is obtained, the 290 solution may be repeated with the same or freshly opened vial. If the repeat is still unacceptable, routine troubleshooting should be performed and the system should be recalibrated.

**Protinol 240, Protinol 320 and Biorad Level 2 Urine QC** are run on each shift prior to performing any patient testing on that shift. If the obtained results are unacceptable, the unacceptable sample may be repeated with the same or freshly opened vial. If the result is still unacceptable, routine troubleshooting should be performed and the system should be recalibrated. If problems persist, notify either a technical specialist or the manager.

**Instrument Operation**

1. For additional in-depth information, refer to the OSMO 1 User Guide.
2. Using the provided 20 ul sampler and disposable tips, place a tip on the sampler verifying that it is straight and firmly seated.
3. Firmly depress the sampler plunger and insert the tip about 1/4 inch below the surface of the sample. Release the plunger to load 20 ul of sample. Check that the sample is free of bubbles.
4. Remove any sample on the outside of the tip using a clean, lint-free, non-ionic paper. Quickly swipe the end of the sampler tip to remove any excess sample protruding beyond the tip (Figure 17). **NOTE: Be careful not to remove any of the sample below the acceptable meniscus line. See Figure below for the proper sample level** 
5. Remove the previous chamber cleaner from the sample port and discard.
6. Holding the sampler by its barrel, insert the filled tip of the sample cell into the sample port and rest the sampler within the operating cradle beneath the cradle top.

## Do not push it in by the plunger handle

**Do not attempt to inject the sample into the chamber**

**Do not remove the sampler until the test has been completed**

1. Push the entire operating cradle forward until it reaches a positive stop. The instrument will automatically complete the test and lock the reading onto the display.
2. The following information will automatically print on a printer enabled unit:
   1. date
   2. time
   3. serial number
   4. user ID (if enabled)
   5. sample ID
   6. osmolality result
3. Withdraw the cradle and remove the sampler from the sample port. Discard the sample tip. Gently blot the plunger tip with a lint free tissue.
4. Firmly insert a clean chamber cleaner into the sample port and rotate five to six times. Reverse the chamber cleaner to insert the opposite end and repeat. Leave the chamber cleaner in place until the next sample is run.
5. Patient samples may be performed in duplicate at the operator’s discretion. Acceptable reproducibility is as follows;

Up to 400 mOsm/kg H2O ± 2 mOsm

401 - 1000 mOsm/kg H2O ±2%

1001 – 2000 mOsm/kg H2O ±4%

**NOTE**: To reduce the chance of cross contamination, it may be suitable to perform a DH2O blank run after a sample with a measured concentration of 1200 mOsm/kg or higher.

1. Continue testing samples in the same manner or log out by tapping the log in button. Automatic user logout occurs after 10 minutes with no further testing.

(For defined user setup only).

**Recommended Daily Procedure & Workflow**

Diagram

Description automatically generated

**Procedural Notes**

1. Grossly hemolyzed samples should not be performed in any instance where all other analytes are not reported due to gross hemolysis.
2. If several specimens are to be analyzed, it is suggested that serums and urines be batched separately.
3. An improperly cleaned and dried sample chamber may cause “pre-freeze” errors and poor reproducibility. Cleaning and drying with a sample chamber cleaner moistened with isopropyl alcohol can improve performance.
4. Cross contamination from previous samples can affect the result obtained from a subsequent test. To minimize this effect when testing samples whose expected range is appreciably different from that for previous tests, it is acceptable to run two or more replicates of the new sample and disregard the first result. Also be sure to clean the cooling chamber and sampler properly after each test.  Alternately, a DH2O blank can be run following any osmolality result greater than 1200 mOsm/kg H2O.

**Reporting Results**

Osmolality results will be manually entered in LIS via task list or resulting worklist. Manually resulted values are checked daily for entry accuracy by a technologist specialist or designee.

# Normal Values

Serum: 290 - 300 mOsm/kg H2O

Urine: None established due to extreme variability

**Reportable Range**

10 - 2000 mOsm/kg H2O

**References**

OSMO 1 Single Sample Micro-Osmometer User Guide ©2018 Advanced Instruments