Specific Gravity-Urine, on AUTION 9EB multi-parameter test strip Technical Procedure 3300
ARKRAY USA, Inc., manufacturer

Principle

Intended Use

For the determination of the specific gravity of urine.
Specific gravity of urine determined by the AUTION MAX AX-4280 Urine Analyzer.

Clinical Significance

Specific gravity is a measure of the dissolved substances present in the urine and is one measure of the concentrating and diluting ability of the kidneys and hydration status of the patient.

Specific gravity ranges from 1.002-1.035, but usually remains between 1.010 and 1.025. Specific gravity is highest in the first morning specimen and generally exceeds 1.020. The ability of the kidney to concentrate urine can be measured by testing the first morning specimen after withholding all fluids after the evening meal and discarding urine passed during the night. A specific gravity of 1.026 or higher is expected. Low specific gravity may indicate loss of effective concentration ability as in diabetes insipidus where specific gravity usually ranges from 1.001 to 1.003. Other diseases such as glomerulonephritis, pyelonephritis, or other renal anomalies may also result in loss of concentrating ability.

High specific gravity may occur in diabetes mellitus, adrenal insufficiency, hepatic disease or congestive heart failure. Excessive water loss from sweating, fevers, vomiting, or diarrhea will elevate specific gravity. Increases may also be seen with abnormally high amounts of certain urinary constituents such as glucose or protein. Specific gravity increases 0.004 for every 1% glucose and 0.003 for every 1% protein.

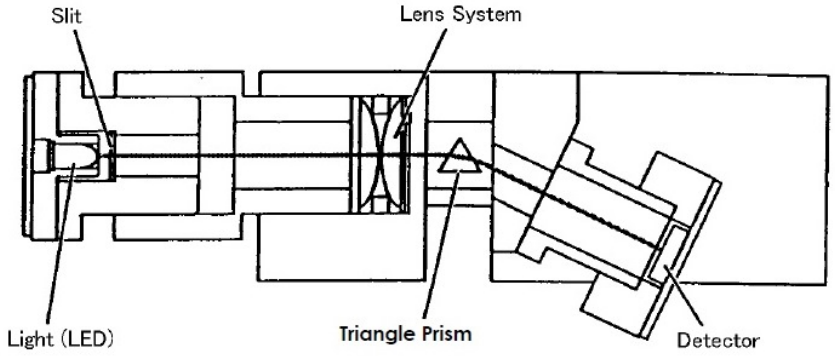
In severe renal damage both concentrating and diluting ability of the kidney may be impaired resulting in fixed low specific gravity of approximately 1.010 which varies little from sample to sample (isosthenuria).

Methodology

Specific gravity is a measure of the dissolved substances present in the urine. The refractive index is a ratio of the velocity of light in air to the velocity of light in a solution. It correlates closely with specific gravity and varies directly with the number of dissolved particles in the specimen.

The specific gravity of urine determined by the AUTION MAX AX-4280 Urine Analyzer is obtained by measuring the refraction angles of light passing through a triangle prism. This is called the Refractive Index Method.

An LED emits a beam of light through a slit and a lens. The refractive index changes according to the specific gravity of the sample, the higher the specific gravity the greater is the angle of measurement. The change in the angle of the light is reported as the specific gravity. The result is automatically corrected for elevated protein or glucose concentrations as measured by the test strip.



Specific gravity is obtained using the following formula:
SGX = (SGH - SGL) ·(KX - KL) / (KH - KL) + SGL (formula 1)
SGH: Specific gravity of High Calibrator
SGL: Specific gravity of Low Calibrator
SGX: Specific gravity of sample
KH: Position Coefficient of High Calibrator*
KL: Position Coefficient of Low Calibrator KX:*
Position Coefficient of sample*
*Position Coefficient: Calculated from the data output by the detector (has a straight-line relationship with the refractive index).

The refractive index changes according to the temperature of the sample. The specific gravity value is corrected using the following formula:
SGt = SGX + (TSAM - TSTD) Ct (formula 2)
SGt: Specific gravity of High Calibrator
SGX: Specific gravity of Low Calibrator
TSAM: Temperature of sample
TSTD: Temperature of Low Calibrator
Ct : Temperature coefficient (SG 0.001/3 C)

If glucose or protein values are high, the specific gravity is affected.
Specific gravity is corrected using the glucose and/or protein concentration obtained by the test strip.
SG = SGt - CGLU - CPRO
SG: Reported Specific gravity value after compensating for protein and glucose
SGt: Specific gravity value obtained by formula 2 above
CGLU: Glucose correction value
CPRO: Protein correction value

Specimen Collection and Preparation

Acceptable Sample Containers

Sterile collection bottles
BD yellow top urinalysis tubes
BD tiger top urinalysis tubes with preservative.

Gray Top culture tubes are not acceptable.

Sample Collection

A clean freshly voided midstream specimen should be collected in a clean container for routine analysis, and a sterile container for UACII requests. Infant bag collections are acceptable for children ≤ 2 years of age. Other acceptable specimens include catheterized specimens, suprapubic and ostomy collections, as well as kidney or bladder collections from the operating room.

BD tiger top urinalysis preservative tubes must be filled to a level between the marked minimum and maximum lines on the tubes (7-9 mL). Under-filled or over-filled tubes are unacceptable.

For best results, BD yellow top urinalysis tubes without preservative require eight (8) mL for UA or UACII. Urine specimens with a volume < 3 mL will be diluted for microscopic analysis, if possible. Urine specimens with a volume < 1 mL may not have enough volume for microscopic analysis.

Specimens exhibiting gross hematuria cannot be tested on the AX-4280. Gross hematuria may cause incorrect results in subsequent samples.

If analysis cannot be performed within one hour after collection, immediately refrigerate (2° and 8° C) the specimen. Bring the specimen to room temperature prior to analysis. Do not centrifuge the specimen prior to analysis.

The specimen volume placed on the iQ System must be at least 3 mL. If testing on the AX-4280 module only, the minimum volume is 2 mls. If testing on the iQSeries module only, the minimum volume is 2 mL.

Sample Stability and Handling

1. Urine collected without preservative at room temperature must be delivered to the lab within 1 hour of collection.
2. Urine collected without preservative and immediately placed on ice must be delivered within 4 hours of collection.
3. Urine collected in BD urinalysis preservative tubes will be accepted up to 48 hours after collection.

All specimens should be handled using the principles of Universal Precautions, and must be capped tightly.

Specimens that leak are unacceptable for analysis.

Reagents

None.

Precautions and Warnings

Gloves: Avoid contact with skin and mucous membranes. Wearing of gloves, when handling blood and body fluids, is included in the Center for Disease Control's recommended universal precautions.

Equipment

This test on the AUTION 9EB strips is used with the AUTION MAX AX-4280 Urine Analyzer. The analyzer is manufactured and supplied by ARKRAY FACTORY, Inc. in Japan and distributed by Iris Diagnostics, A Division of IRIS International, Inc., Chatsworth, California.

For technical assistance, contact IRIS Customer Service Support at (800) 776-4747.

Calibration

Specific gravity is calibrated monthly using deionized water for the Low Calibrator and the IRIS SG High Calibrator. Refer to the *Iris Maintenance Procedure*, AX-4280 module monthly schedule.

Quality Control

At least two levels of control material should be analyzed each shift. Parallel testing between the old shipment or lot number and the new shipment or lot number will be done to assure acceptable strip performance.

The following controls should be prepared and used in accordance with the package inserts. Allow controls to come to room temperature and mix well for several minutes before testing. Quality Control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Strip lot changes are documented on the IRIS reagent log sheet.

Quality Control Material

Control	Storage
MAS Liquid UA Abnormal Control 1	+2°C to +8°C*
MAS Liquid UA Normal Control 3	+2°C to +8°C*

*Urine controls are received and stored at 2°C to 8°C. Bottles of controls in use are stored at +2°C to +8°C and are good for 30 days

Testing Procedure

Follow the correct testing set-up, testing and control procedures, as outlined in the AUTION MAX AX-4280 Urine Analyzer *Operating Manual.*

Standard Reporting Format

Specific Gravity is reported by refractive index quantitatively with a value to 3 decimal places, ranging from 1.000 to 1.050, in 0.001 increments.

Results greater than 1.050 will be reported as > 1.050.

Results can be printed directly from the urine analyzer and/or transferred to the LIS.

Reference interval: 1.002 - 1.030

Procedural Notes

Limitations

None.

Interferences

1. No substances currently can cause false negative results.
2. No substances currently can cause false positive results.

Carryover

Studies were performed to assess the amount of analyte carried over by the AUTION MAX AX-4280 Urine Analyzer from one specimen reaction into subsequent specimen reactions. The studies consisted of the measurement of four identical high control samples immediately followed by four identical low control samples. Results of the testing demonstrated zero carryover for bilirubin as measured by the AUTION MAX AX-4280.

Gross hematuria may cause incorrect results in subsequent samples. Do not test specimens exhibiting gross hematuria. If carryover is suspected, sample a few tubes of saline and rerun samples that followed a sample that may have caused carryover.

Performance Characteristics

Sensitivity and Range

1. Analytical Sensitivity: 0.001 increments within the SG range of 1.000 to 1.050
2. Analytical Measurement Range: 1.000 to 1.050

Method Comparison

The performance of the AUTION MAX AX-4280 was evaluated in comparison with a commercially available automated urinalysis system. Both urinalysis systems provide semi-quantitative results. Results for the individual urine samples were referred to the respective cut-off values for each system to discriminate between negative (normal) and positive (abnormal) findings. Overall agreement, sensitivity (positive agreement), and specificity (negative agreement) between the AUTION MAX AX-4280 and the comparative system are shown in the following table.

Analyte	No. of Samples	Overall Agreement (%)	Sensitivity (%)	Specificity (%)
Specific Gravity	227	98.7	N\A	N\A

N\A = Not applicable

Note: The AUTION MAX AX-4280 reports results for specific gravity as continuous values. Therefore, in order to compare these results with those from the reference system, the AX-4280 results shown in the table above were categorized as follows:

1.005 includes	≤ 1.005 to	1.0
1.010 includes	1.008 to	1.0
1.015 includes	1.013 to	1.0
1.020 includes	1.018 to	1.0
1.025 includes	1.023 to	1.0
1.030 includes	1.028 to	≥ 1.030

Precision

Analyte	Number of Replicates	Mean	Standard Deviation	Correlation of Variation (%)
Specific Gravity Control A	21	1.005	0.0002	0.02
Specific Gravity Control B	21	1.0074	0.0005	0.05

Precision Studies performed at UCDMC

See attached AUTION MAX AX-4280 Precision Reflectance Report sheet.

Additional Information

For more detailed information on the X AX-4280 Urine Analyzer, refer to the AUTION MAX AX-4280 Urine Analyzer *Operating Manual*.

References

1. Free, A.H.,et. al. *Clincal Chemistry*, 1957; 3:716.
2. Free, H.N.,et. al. *Clincal Chemistry*, 1960; 6:352
3. Free, A.H. and Free, H.M.: Urinalysis, Critical Discipline of Clinical Science. CRC Crit Rev Clin Lab Sci 3(4):48- 1531, 1972.
4. Graff, Sr. L., *A Handbookof Routine Urinalysis*, J.B. Lippincott Co., Philadelphia; 1983; 7-67.
5. Hayashi, Y., *Modern Medical Technology, Basic Clinical Technology and Analytical Toxicology*, Igaku-shoin, 1973.
6. Hayashi, A., et. al., *Journal of Japan Diabetes Society*, 1992; 35:819.
7. Henry, J.B., et. al., *Clinical Diagnosis and Management by Laboratory Methods*, 17th ed. Saunders, Philadelphia; 1984; 394:1441.
8. Kark, R.M. et al: A Primer of Urinalysis, 2nd Ed., New York, Harper and Row, 1963.
9. Ringsrud, K.M, and Linné, J.J. *Urinalysis and Body Fluids, A Color Text and Atlas*, Mosby-Year Book, St. Louis; 1995; 34-73.
10. Iris Diagnostics, a Division of International Remote Imaging Systems, Inc. AUTION MAX™ AX-4280 – Operators Manual –300-3500 - Rev D – 7/2003

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	07/09/2008	Atlas 3462.T

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			07/09/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
			11/16/2011	G. Kost
09/25/2012	Added acceptable sample containers	M.Inn	11/20/2013	G. Kost
03/21/2015	Change to MAS UA Controls	kdagang	03/22/2015	J. Gregg