Clarity-Urine, on AUTION 9EB multi-parameter test strip
ARKRAY USA, Inc., manufacturer

Technical Procedure 3302

Principle

Intended Use

For the determination of clarity in urine.
AUTION 9EB Strips are manufactured for use only in the AUTION MAX AX-4280 Urine Analyzer.

Clinical Significance

Normal freshly voided urine is usually clear or transparent, but may also be turbid due to the presence of urates or phosphates. Turbidity may also occur due to contamination through improper collection, or due to the abnormal presence of bacteria or cellular elements.

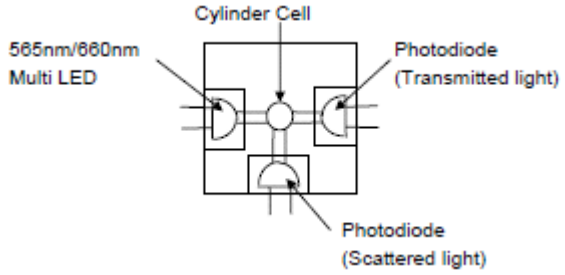
Clarity of urine may be associated with the presence of various constituents:

1. Turbid to opaque with pink sediment may indicate amorphous urates.
2. Turbid to opaque with white sediment may indicate amorphous phosphates.
3. Turbid to opaque with white to yellow sediment may indicate white cells and/or bacteria.
4. Turbid with red color may indicate large numbers of red cells.

Description of clarity of urine should bear some correlation with microscopic findings.

Methodology

The clarity or turbidity of a urine specimen is measured by passing a beam of light through the sample and measuring how the light is scattered. The amount of scattered light increases as the specimen becomes more turbid.



Turbidity is obtained using the following formula:

T = (Ss / Ts - Sw / Tw) / K

T : Turbidity level
Ss : Scattered light level of sample
Ts : Transmitted light level of sample
Sw : Scattered light level of wash solution
Tw : Transmitted light level of wash solution
K : Coefficient factor (Factory settings)

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

For In Vitro Diagnostic Use: Utilize standard precautions required for the handling of all laboratory reagents.

Warnings: Toxic. AUTION strips contain one or more of the following chemicals: Diazonium salt and phenol

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

None.

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

Clarity is reported quantitatively as Clear, Slightly Turbid, Turbid, or Opaque.

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

Reference interval: Clear, Slightly Turbid

Procedural Notes

Limitations

None.

Interferences

Certain drugs may cause incorrect turbidity results. Results from such samples may be flagged with an exclamation point (!) on the printout.

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

T range	Turbidity	Printout	Equivalent To
T < (Level 1)	Clear	---	Clear
(Level 1) = < T < (Level 2)	Turbid	+1	Hazy
(Level 2) = < T	Ex. Turbid	+2	Cloudy

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.

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Analyte	No. of Samples	Overall Agreement (%)	Sensitivity (%)	Specificity (%)
Clarity	227	76.2	76.4	76.1

Precision

Analyte	Number of Replicates	Mean	Standard Deviation	Correlation of Variation (%)
Turbidity	21	0.000	0.00	---

Additional Information

For more detailed information on the AUTION Strips 9EB multi-parameter test strips with glucose and the AUTION MAX AX-4280 Urine Analyzer, refer to the *AUTION Strips 9EB for Urine Chemistry* package insert and the AUTION MAX AX-4280 Urine Analyzer *Operating Manual*.

References

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4. Hayashi, Y., *Modern Medical Technology, Basic Clinical Technology and Analytical Toxicology*, Igaku-shoin, 1973.
5. Hayashi, A., et. al., *Journal of Japan Diabetes Society*, 1992; 35:819.
6. Henry, J.B., et. al., *Clinical Diagnosis and Management by Laboratory Methods*, 17th ed. Saunders, Philadelphia; 1984; 394:1441.
7. Ringsrud, K.M, and Linné, J.J. *Urinalysis and Body Fluids, A Color Text and Atlas*, Mosby-Year Book, St. Louis; 1995; 34-73.
8. Schersten, B. and Fritz, H. Subnormal Levels of Glucose in Urine. JAMA 1967. 201; 129-132.
9. *AUTION Strips 9EB For Urine Chemistry*, package insert, issued: Dec. 2001, Rev.: Dec. 2011; supplied by ARKRAY, Inc., Kyoto, Japan.

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	07/09/2008	Atlas 3457.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 Controld	kdagang	03/22/2015	J. Gregg