



URIC ACID		
<u>OSR6098</u>	4 x 12 mL 4 x 5 mL	R1 R2
<u>OSR6198</u>	4 x 30 mL 4 x 12.5 mL	R1 R2
<u>OSR6298</u>	4 x 42.3 mL 4 x 17.7 mL	R1 R2
<u>OSR6698*</u>	4 x 109 mL 4 x 45.3 mL	R1 R2

Intended Use

System reagent for the quantitative determination of Uric Acid in human serum, heparinized plasma and urine on Beckman Coulter AU analyzers.
*Uric Acid reagent OSR6698 for use on the AU2700/5400 system only.

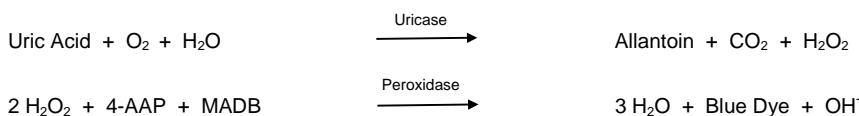
Summary

Measurements of Uric Acid are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Methodology

Uric acid can be determined by direct measurement, by measurement of oxygen consumed or by measurement of hydrogen peroxide produced by the uricase reaction. Several methods utilize coupled enzyme reactions to detect the hydrogen peroxide produced by the uricase reaction. Fossati et al¹ proposed a method which utilized the well established Trinder reaction to measure the hydrogen peroxide produced, and a substituted phenol to enhance sensitivity.

This Uric Acid procedure is a modification of the Fossati method. Uric acid is converted by uricase to allantoin and hydrogen peroxide. Hydrogen peroxide reacts with 4-aminoantipyrine (4-AAP) in the presence of N,N-bis(4-sulfobutyl)-3,5-dimethylaniline, disodium salt (MADB) to produce a chromophore which is read bichromatically at 660/800 nm. The amount of dye formed is proportional to the uric acid concentration in the sample.



System Information

For AU400/400[®]/480, AU600/640/640[®]/680 and AU2700/5400 Beckman Coulter Analyzers.

Reagents

Final concentration of reactive ingredients:

Phosphate buffer (pH 7.5)	42 mmol/L
Peroxidase	≥ 5.9 kU/L
MADB	0.15 mmol/L
4-Aminophenazone	0.30 mmol/L
EDTA	0.44 mmol/L
Uricase	≥ 250 U/L

Also contains preservatives

Precautions

1. For *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.
4. Dispose of all waste material in accordance with local guidelines.

Preparation of Reagents

For OSR6098, OSR6198 and OSR6298, the Uric Acid reagents are ready for use. No preparation is required. For OSR6698, insert the pipe supplied into the 180 mL reagent vial before use on the analyzer. Care must be taken when handling the pipe to avoid contamination. The pipe is for single use only.

Storage and Stability

1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 - 8°C.
2. Opened reagents are stable for 30 days when stored in the refrigerated compartment of the analyzer.

Indications of Deterioration

Visible signs of microbial growth, gross turbidity, precipitate or change in color in the Uric Acid reagent may indicate degradation and warrant discontinuance of use.

Specimen Collection and Preparation

Serum samples or heparinized plasma, free from hemolysis are the recommended specimens. Timed, 24 hour urine specimens are recommended.

Uric Acid

Sample Storage and Stability

Uric Acid in serum is stable for 3 - 5 days at 2 - 8°C, and six months frozen ≤ -20°C. Fluoride, oxalate or EDTA plasma is not recommended for use with uricase methods.²

To prevent urate precipitation in urine specimens, after specimen collection, add a sufficient volume of sodium hydroxide solution to bring the pH between 8 and 9. Uric acid in urine is usually stable for approximately 3 days at room temperature 15 - 25°C, provided that there is no bacterial growth to destroy it.³

Interfering Substances

Results of studies⁴ show that the following substances interfere with this uric acid determination.

The criteria for no significant interference is recovery within 10% of the initial value.

Ascorbic Acid:	No significant interference up to 20 mg/dL Ascorbate
Bilirubin:	No significant interference up to 40 mg/dL Bilirubin
Hemolysis:	No significant interference up to 500 mg/dL Hemolysate
Lipemia:	No significant interference up to 1000 mg/dL Intralipid*

* Intralipid, manufactured by KabiVitrium Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.

The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc. makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young⁵ for a compilation of reported interferences with this test.

Procedure

A complete list of test parameters and operational procedure can be found in the User's Guide appropriate to the analyzer.

Materials Provided

Uric Acid Reagent
Pipe (one per each 180 mL vial)

Materials Required But Not Provided

Chemistry Calibrator (Cat # DR0070)
Urine Calibrator (Cat # DR0090)

Stability of Final Reaction Mixture

The Beckman Coulter AU analyzer automatically computes every determination at the same time interval.

Calibration/Blanking

The frequency of calibration is every 30 days. Calibration of the Uric Acid reagent is accomplished by use of the Chemistry Calibrator (Cat # DR0070), which is traceable to the National Institute of Standard and Technology (NIST) Standard Reference Material (SRM) 909b for serum and plasma specimens. For urine specimens use Urine Calibrator (Cat # DR0090).

Recalibration of this test is required when any of these conditions exist:

1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

If QC values drift during the calibration stability period, perform reagent blanking when necessary.

Quality Control

During operation of the Beckman Coulter AU analyzer at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

Appropriate qualified urine controls, should be established and utilized during urine analysis.

Results

Automatically printed out for each sample in mg/dL at 37°C. For SI units (mmol/L) the result must be multiplied by 0.059.

Dynamic Range

The Uric Acid procedure is linear from 1.5 to 30.0 mg/dL for serum determinations and 1.0 to 100 mg/dL for urine determinations. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically by utilizing the AUTO REPEAT RUN.

Expected Values

Serum: ²	Adults:
Female:	2.3 - 6.6 mg/dL
Male:	4.4 - 7.6 mg/dL

Urine: ⁶	
Female:	250 - 750 mg/24 hours
Male:	250 - 800 mg/24 hours

Excretion may decrease by 20 to 25% on a purine-free diet to less than 400 mg/24 hours.

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific Performance Characteristics

The following data was obtained using the Uric Acid Reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision⁸

Estimates of precision, based on CLSI recommendations⁷, are consistent with typical performance. The within run precision for serum samples is less than 2% CV and total precision is less than 3% CV. The within run precision for urine samples is less than 3% and total precision is less than 5%. Assays of serum pools were performed and data reduced following CLSI guidelines above.

Serum

N = 80	Within run		Total	
	Mean, mg/dL	SD	CV%	SD
3.8	0.01	0.38	0.03	0.80
7.2	0.03	0.43	0.06	0.89
9.7	0.05	0.53	0.08	0.85

Urine

N = 100	Within run		Total	
	Mean, mg/dL	SD	CV%	SD
21.8	0.24	1.12	0.35	1.61
58.4	0.95	1.63	1.33	2.28
89.3	1.78	2.00	2.01	2.25

Method Comparison⁸

Serum

Patient samples were used to compare this Uric Acid. The table below demonstrates representative performance on AU analyzers.

Y Method	AU600/640/640 ^e
X Method	Method 2
Slope	1.014
Intercept	-0.226
Correlation Coeff. (r)	1.000
No. of Samples (n)	122
Range (mg/dL)	1.9 – 29.4

Urine

Urine samples were used to compare this Uric Acid. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	Method 2
Slope	0.981
Intercept	0.496
Correlation Coeff. (r)	0.998
No. of Samples (n)	159
Range (mg/dL)	0.9 – 98.6

Plasma

Matched serum and heparinized plasma samples were run on the AU640 Beckman Coulter analyzer to demonstrate that no matrix effect exists for this Uric acid reagent, between serum and heparinized plasma samples.

Slope	1.018
Intercept	-0.241
Correlation Coeff. (r)	1.000
No. of Samples (n)	47
Range (mg/dL)	1.51 – 29.1

Analytical Sensitivity (Lower Detection Limit)

The lowest detectable level using serum settings on an AU analyzer was calculated as 0.02 mg/dL.

The lowest detectable level represents the lowest measurable level of uric acid that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

Limit of Quantitation

The Limit of Quantitation (LOQ) using serum settings for the Uric Acid reagent was determined to be 0.8 mg/dL and using urine settings was determined to be 1.0mg/dL. This was determined according to CLSI protocol EP17-A⁹ and represents the lowest concentration of uric acid that can be measured with a total imprecision of 20%.

References

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