URIC ACID

COD 12521 10 x 50 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

URIC ACID
URICASE/PEROXIDASE

INTENDED USE

Reagent for the measurement of uric acid concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis and monitoring of gout and hyperuricemia secondary.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

In humans, uric acid is the major product of the catabolism of the purine bases which are obtained partly from the diet and partly from *in vivo* synthesis.

Increased uric acid concentration in serum and urine maybe attributable to an overproduction of urate (increased purine synthesis) or to a defective elimination of urate[1].

Hyperuricemia is commonly associated with gout, decreased renal function, dehydratation, myeloproliferative disorders, and other conditions not well known[1,2].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Uric acid in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[3,4].

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$2\ H_2O_2 + 4 - \text{Aminoantipyrine} + \text{DCFS} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\ H_2O$$

CONTENTS AND COMPOSITION

A. Reagent. 10 x 50 mL. Phosphate 100 mmol/L, detergent 1.5 g/L, dichlorophenolsulfonate 4 mmol/L, uricase > 0.12 U/mL, ascorbate oxidase > 5 U/mL, peroxidase > 1 U/mL, 4-aminoantipyrine 0.5 mmol/L, pH 7.8.

STORAGE AND STABILITY

Store at 2-8ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagent is provided ready to use.

SAMPLES

Serum, plasma or urine collected by standard procedures.

Uric acid in serum or plasma is stable for 7 days at 2-8ºC. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

Uric acid in urine is stable for 4 days at room temperature if pH is adjusted to > 8 with NaOH. Do not refrigerate.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, cod. 18009 and cod. 18042), level II (cod. 18007, cod. 18010 and cod. 18043) and and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[1]

Men: 3.5-7.2 mg/dL = 210-420 μmol/L

Women: 2.6-6.0 mg/dL = 150-350 μmol/L

Urine[1]

250-750 mg/24-h = 1.5-4.5 mmol/24-h

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 0.11 mg/dL = 6.5 μmol/L.
- Linearity limit: 25 mg/dL = 1487 μmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
5.30 mg/dL = 315 μmol/L	0.6 %	1.2 %
9.24 mg/dL = 550 μmol/L	0.8 %	1.7 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: Hemolysis (hemoglobin up to 2 g/L), bilirubin (up to 2.5 mg/dL) do not interfere. Lipemia interfere. Ascorbic acid (up to 2.5 mg/dL) does not interfere. Other drugs and substances may interfere[5].

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Barham D, Trinder P. An improved colour reagent for the determination of blood glucose by oxidase system. *Analyst* 1972; 27:142-145.
4. Fossati P, Prencipe L, Berti G. Use of 3,5-dichloro-2-hydroxybenzenesulfonicacid/4-aminophenazone chromogenic system in direct enzymic assay of uric acid in serum and urine. Clin Chem 1980; 26:227-231.
5. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A.

	A25	A15
GENERAL		
Name	**URIC ACID**	**URIC ACID**
Sample type	SER / URI	SER / URI
Analysis mode	endpoint mon.	endpoint mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	no
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	bichrom.	bichrom.
Main filter	505	505
Reference filter	670	670
Sample	7.5	7.5
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	21	14
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	- / 10	- / 10
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.200	0.200
Kinetic blank limit	-	-
Linearity limit	25 / 250	25 / 250
Substrate depletion	-	-

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BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global