SPECTRUM

The Creative Approach to Bioscience

Uric acid - Liquizyme Uricase-PAP (Single Reagent)

REF: 323 000 (4 x 25 ml) 100 test
REF: 323 001 (4 x 30 ml) 120 test
REF: 323 002 (4 x 50 ml) 200 test
REF: 323 003 (4 x100 ml) 400 test
REF: 323 004 (4 x 60 ml) 240 test
REF: 323 005 (2 x500 ml) 1000 test
REF: 323 006 (4 x250 ml) 1000 test
REF: 323 007 (5 x100 ml) 500 test
REF: 323 008 (2 x 30 ml) 60 test
REF: 323 009 (2 x 50 ml) 100 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics liquizyme uric acid reagent is intended for the in-vitro quantitative, diagnostic determination of uric acid in human serum or urine on both manual and automated systems.

Background

Uric acid is the end product of purine metabolism. Nearly half of the uric acid is eliminated and replaced daily by way of urinary excretion and through microbial degradation in the intestinal tract.
Hyperuricaemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes,hypothyroidism or in some genetic diseases. Decreased levels are present in patients with Wilson's disease, bronchogenic carcinoma, severe hepatocellular disease and Hodgkin's disease.

Method

Uricase-POD enzymatic colorimetric method with 4-amino-antipyrine.

Assay Principle

The assay is based upon the methods of modified trinder peroxidase assay using 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHB). The series of the reactions involved in the assay system is as follows:

1. Uric acid is oxidized to allantoin by uricase with production of hydrogen peroxide.

$$\text{Uric acid} + O_2 + H_2O \xrightarrow{\textit{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

2. The peroxide react with 4-amino-antipyrine and (DCHB) in the presence of peroxidase to yield a quinoneimine dye. The subchange in absorbance at 546 nm (500-550 nm) is proportional to uric acid concentration in the sample.

$$H_2O_2 + \text{4-AAP} + \text{DCHB} \xrightarrow{\textit{POD}} \text{Quinoneimine} + H_2O$$

Reagents

Standard uric acid (ST)
6 mg/dL 0.357 mmol/L

Reagent (R)

Phosphate Buffer	100 mmol/L
(DCHB)	5.0 mmol/IL
Potassium hexacyanoferrate	80 µmol/L
4-amino-antipyrine	0.6 mmol/IL
Peroxidase	>3000 U/L
Uricase	> 500 U/L

For further information, refer to the Uric acid reagent material safety data sheet.

Reagent Preparation,Storage and Stability

Spectrum Uric acid liquizyme Single reagent is supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 ^{O}C. Once opened, the reagent and the standard are stable for 3 months at the specified temperature if contamination is avoided.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Deterioration

Uric Acid Single reagent is normally clear or pale pink. Do not use liquizyme uric acid reagent if it is turbid or if the absorbance is greater than 0.15 AU at 546 nm.

Specimen Collection and Preservation

The only acceptable anticoagulants are heparin and EDTA. Uric acid in serum and plasma samples remains stable for 3 days at room temperature; 3 to 5 days if kept at 4^{O}C and for 6 months at -20^{O}C. Urine samples should be diluted 1:10 before assay with physiological saline. It is recommended that 15 ml of sodium hydroxide 2 mol/l, be added to the urine samples to keep urine alkaline and prevent ureate precipitation. Upon receipt, urine sample pH should be checked and kept over 8.0.

System Parameters

Wavelength	Hg 546 nm (500 – 550 nm)
Optical path	1 cm
Assay type	Endpoint
Direction	Increase
Sample : Reagent Ratio	1 : 50
Temperature	37 ^{O}C or 15 – 25 ^{O}C
Reaction Time	5 minutes at 37 ^{O}C 10 minutes 15 – 25 ^{O}C
Zero adjustment	Reagent blank
Reagent Blank Limits	Low 0.00 AU High 0.15 AU
Sensitivity	1.0 mg/dL (0.06 mmol/L)
Linearity	20 mg/dl (1.19 mmol/L)

Procedure

	Blank	Standard	Specimen
Reagent (R)	1.0 ml	1.0 ml	1.0 ml
Standard	------	20 µl	------
Specimen	------	------	20 µl

Mix and incubate for 5 minutes at 37^{O}C or 10 minutes at 15 - 25 ^{O}C. Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank within 30 minutes.

Calculation

$$\text{Serum uric acid concentration (mg/dL)} = \frac{A_{specimen}}{A_{standard}} \times 6$$

$$\text{Concentration of uric acid in urine} = \frac{A_{specimen}}{A_{standard}} \times 6 \times 10$$

NOTE

Serum blank: Extremely lipemic samples may give falsely elevated results and a serum blank must be run. Add 20 µl serum to 1 ml water.Measure Absorbance of specimen against water at the specified wavelength.Read and record absorbance and subtract reading from test absorbance.

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.46	11.42
SD	0.15	0.21
CV%	3.36	1.84

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.51	11.59
SD	0.13	0.32
CV%	2.88	2.76

Methods Comparison

A comparison between Spectrum Diagnostics Uric Acid reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 1 mg/dL (0.06 mmol/L).

Linearity

The reaction is linear up to a uric acid concentration of 20 mg/dl. Specimens showing higher concentration should be diluted 1+1 using physiological saline, reassayed and the result multiplied by two.

Interfering Substance

Haemoglobin
No interference up to a haemoglobin level of 200 mg/dl.

Icterus
No significant interference from free bilirubin up to a level of 8mg/dl and from conjugated bilirubin up to a level of 12mg/dl.

Lipemia
No significant interference with mild to moderate lipemia.

Drugs
Of the drugs tested in vitro,methyldopa and noramidopyrine cause artificially Low uric acid values at the tested drug Level.

Others
Physiological ascorbic acid concentration does not interfere with the test. Ascorbic Acid levels higher than 170 mmol/l (3.0 mg/dl) decreases the apparent uric acid concentration significantly.

Expectd Values

Child	2.0 - 5.5 mg/dL	(0.119 - 0.327 mmol/L)
Adult female	2.6 - 6.0 mg/dL	(0.155 - 0.357 mmol/L)
Adult male	3.5 - 7.2 mg/dL	(0.208 - 0.428 mmol/L)
Urine	250 -750 mg/day	(14.8 - 44.6 mmol/day)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

1.0 – 20 mg / dL (0.06 – 1.19 mmol/l).

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Barham D.and Trinder P., Analyst 97,142-145 (1972).
2. Fossati P.,Prencipe L.,and Berti G., Clin. Chem . 26/2,227-273 (1980).
3. Richterich R, colombo JP. Klinische Chemie. 4th ed.basel:karger s;1978 :319-324 .
4. Tiffany to, jansen JM, Burtis CA,Overton JB, scott cd.Enzymatic kinetic rate and end point analyses of substrate, by use of a GEMSAEC fast analyzer. Clin Chem. 1972; 18 : 829-840.
5. Tietz NW, ED. Clinical guide to laboratory tests. 2nd ED. philadelphia: WB Sauners; 1990: 566.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
323 000	4 x 25 ml
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323 002	4 x 50 ml
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323 009	2 x 50 ml

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