Spectrum For Diagnostic Industries

Uric acid
Uricase-POD

IVD

REF.	Pack size
155 01 050	(1 x 50 ml) 50 tests
155 02 030	(2 x 30 ml) 60 tests
155 05 030	(5 x 30 ml) 150 tests

Intended Use

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

Introduction

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.

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.

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

Reagents

Reagent

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

Standard uric acid

6 mg/dL	0.357 mmol/L

Reagents preparation, storage and stability

Uric acid reagent is supplied ready-to-use and stable till the expiration date labeled on the bottles when properly stored refrigerated at 2 – 8 °C.Once opened, the reagent and the standard are stable for 3 months at the specified temperature.

Deterioration

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

Precautions and Warnings

Do not ingest or inhale. 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.

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°C and for 6 months at -20°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 percipitation. Upon receipt, urine sample pH should be checked and kept over 8.0.

Procedure

Wavelength	546 nm (500 – 550 nm)
Optical path	1 cm
Assay type	Endpoint
Direction	Increase
Sample : Reagent Ratio	1 : 50
Temperature	37 °C or 15 – 25 °C
Reaction Time	5 minutes at 37 °C 10 minutes 15 – 25 °C
Zero adjustment	Reagent blank
Reagent Blank Limits	Low 0.00 AU High 0.15 AU

	Reagent 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 °C or 10 minutes at 15 –25 °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 control serum of known concentration should be analyzed with each run.

Interference

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

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

Expected 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)

Performance characteristics

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

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.46	11.42
SD	0.15	0.21
CV%	3.38	1.88

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.51	11.59
SD	0.23	1.32
CV%	3.46	1.97

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.

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. Tietz NW, ED. Clinical guide to laboratory tests. 2nd ED. philadelphia: WB Sauners; 1990: 566.
2. 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.
3. Richterich R, colombo JP. Klinische Chemie. 4th ed.basel:karger .

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