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Uric Acid – PAP

Diagnostics single reagent for the in-vitro quantitative determination of uric acidin human serum, plasma or urine on both manual and automated systems.

REF: BS.1/UA02.025.0050	50 test	REF: BS.1/UA04.025.0100	100 test
REF: BS.1/UA02.050.0100	50 test	REF: BS.1/UA02.100.0200	200 test

CLINICAL SIGNIFICANCE

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. Increased uric acid level may be observed in renal dysfunction, gout, leukemia, polycythemia, atherosclerosis, diabetes, hypothyroidism, or in some genetic diseases. Decreased levels are present in patients with severe hepatocellular disease, Wilson's disease, bronchogenic carcinoma and Hodgkin's disease.

METHOD PRINCIPLE

Uric acid is determined after enzymatic oxidation in the presence of Uricase (based on modified Trinder peroxidase method). The formed hydrogen peroxide reacts under catalysis of peroxidase (PAP) with 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHB) 4- aminoantipyrine to form a red violet quinonimine dye. Where its absorbance is proportional to the concentration of uric acid in sample.

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

$$H_2O_2 + 4AAP + DCHB \xrightarrow{\text{POD}} \text{Quinonimine Dye} + 2H_2O$$

REAGENT COMPOSITION

R1: Standard	6 mg/dl (0.357mmol/L)
R2: Reagent	
Phosphate Buffer	100 mmol/L
DCHB	5.0 mmol/L
Potassium hexacyanoferrate	80 mmol/L
4-amino-antipyrine	0.6 mmol/L
Peroxidase	>3000 U/L
Uricase	>500 U/L
Sodium Azide	8 mmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

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

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien Uric acid reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2–8°C. Once opened, the opened vial is stable for 3 months at the specified temperature.

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

SPECIMEN COLLECTION AND PRESERVATION

Serum or plasma
Uric acid in serum and EDTA or heparinized plasma samples are stable for 3 days at 25°C or up to 5 days at 4°C, and for 6 months if stored at -20°C.

Urine
Urine samples once received should be tested for pH value. In order to prevent urate precipitation, it is recommended to adjusted the urine pH to over 8.0 (alkaline) by adding 15 ml of sodium hydroxide 2mol/l. Urine samples should be diluted 1:10 before assay with physiological saline.

SYSTEM PARAMETERS

Wavelength	546 nm (500-550 nm)
Optical path	1 cm
Assay type	End point
Direction	Increase
Sample Reagent Ratio e.g.: Reagent volume Sample volume	1:50 1 ml 20 µl
Test reading time First read time delay time last read time	90 seconds 30 seconds 60 seconds 90 seconds
Temperature	37°C or 15-25°C
Incubation time	5 min. at 37°C or 10 min. at 15-25°C
Zero adjustment	Reagent blank
Reagent Blank Limits	Low 0.00 AU High 0.15 AU
Sensitivity	1 mg/dL (0.6 mmol/L)
Linearity	20 mg/dL (1.19 mmol/L)

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	Standard	Specimen
Working Solution	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" and standard "A" against reagent blank within 30 minutes.

CALCULATION

Serum or Plasma:

Uric acid concentration (mg/dl) = (A specimen) x 6
(A standard)

Urine:

Uric acid concentration (mg/dl) = (A specimen) x 6 x 10
(A standard)

N.B.: Extremely lipemic samples may give falsely elevated results and a serum blank must be run. Add 20 µl serum to 1 ml water. Zero the spectrophotometer with water. Read and record absorbance and subtract reading from test absorbance.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean mg/dl	4.46	11.42	4.51	11.59
SD.	0.15	0.21	0.23	1.32
CV. %	3.38	1.88	3.46	1.97

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)

Result obtained from ***BioScien*** Uric acid reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.979.

Sensitivity

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

Linearity

The reaction is linear up to uric acid concentration of 20 mg/dl; specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Haemolysis

No significant interference from haemoglobin up to 200 mg/dl.

Icterus

No significant interference from free and conjugated bilirubin up to levels 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

Serum and plasma	***mg/dl***	***[mmol/L]***
Children	2.0-5.5	[0.119-0.327]
Adults Male	3.5-7.2	[0.208- 0.428]
Adults Female	2.6-6.0	[0.155-0.357]
Urine	***g/24hrs***	***[mmol/day]***
24hrs	250-750	[14.8-44.6]

DYNAMIC RANGE

1.0 - 20 mg/dl (0.6 – 1.19 mmol/L).

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. Young D.S., Effects of drugs on clinical laboratory tests. 4th Ed. (1995), p.3-274 to 3-294.
4. Richterich R, colombo JP. Klinische Chemie. 4th ed.basel:kargers;1978 :319-324 .
5. 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.
6. Tietz NW, ED. Clinical guide to laboratory tests. 2nd ED. philadelphia: WB Sauners; 1990: 566.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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CE