ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

URIC ACID

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of Uric Acid in serum, plasma or urine on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
2 X 10 ml	UA 02 10
5 X 10 ml	UA 05 10
2 X 50 ml	UA 02 50
5 X 100 ml	UA 05 100

CLINICAL SIGNIFICANCE : Uric Acid and its salts are end products of the purine metabolism. In gout, the most common complication of hyperuricemia, increased serum levels of uric acid lead to formation of monosodium urate crystals around the joints. Further causes of elevated concentrations of uric acid in blood are renal diseases with decreased excretion of waste products, starvation, drug abuse and increased alcohol consumption as well as use of certain medicaments. High uric acid levels also constitute to indirect risk factor for coronary heart disease. Hypouricemia is seldom observed and associated with rare hereditary metabolic disorders.

METHOD :
Photometric test according to Trinder reaction, Enzymatic, Uricase PAP, End Point.

PRINCIPLE :
Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine and DHPS to quinoneimine.

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

$$\text{DHPS} + \text{4-Aminoantipyrine} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Quinoneimine} + 3\,H_2O$$

REAGENTS :

COMPONENTS AND CONCENTRATIONS:
N.B: Concentrations are those in the final test mixture.

Hepes Buffer	:	100 mmol/l
Uricase	:	>200 U/l
Peroxidase	:	>0.6 U/l
Preservative & Stabilizer		
Standard	:	6 mg/dl (357 µmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents and the standard are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagents!
Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent blank is < 0.4 at 510 nm, against distilled water.

WARNINGS AND PRECAUTIONS :
Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The Reagent and standard is ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum, heparinized plasma or EDTA plasma,
Urine diluted 1:10 in distilled water and multiply the results by 11. If urine is not preserved, add 0.1 ml of 12.5 M NaOH to 10 ml of well-mixed urine.
Stability in serum / heparinized plasma: 3 to 5 days at 2 to 8°C, 6 months at – 20°C
Stability in urine: 3 days at 15 to 25°C.
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 510 nm, 546 nm, 505 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Pre warm the reagent at 37°C for 2 minutes
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	25 µl	—	—
Standard	—	25 µl	—
Sample / Control	—	—	25 µl

Mix and read the absorbance (A) after a 10 minutes incubation but within 30 minutes.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard - Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR :
Uric Acid [mg / dl] x 59.48 = Uric Acid [µmol/l]

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :
The test has been developed to determine Uric Acid concentrations within a measuring range from 0.1 to 20 mg/dl (5.9 to 1190 µmol/L). When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :
No interference was observed by bilirubin up to 20 mg/dl (342 µmol/L) and lipemia up to 700 mg/dl (7.98 mmol/L) triglycerides. Hemoglobin interferes starting with a concentration of 0.05 g/dl (0.50 g/L). Ascorbic acid interferes even in minimal concentrations. A list of drugs and other interfering substances with Uric Acid determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 0.1 mg/dl (5.95 µmol/L).

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	7.27	0.03	0.50
Sample 2	8.46	0.07	0.90
Sample 3	10.14	0.06	0.62

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	9.32	0.12	1.33
Sample 2	9.31	0.15	1.70
Sample 3	7.77	0.08	1.07

METHOD COMPARISON :
A comparison between Robonik Prietest Uric Acid (y) and a commercially available test (x) using 20 samples gave following results:
Linear Regression : y = 1.012x + 0.5097 mg/dl
Correlation Coefficient : r = 0.9349

REFERENCE RANGE :

Serum / Plasma	Female	Male
Adults	2.3 to 6.1 mg/dl (137 to 363 µmol/L)	3.6 to 8.2 mg/dl (214 to 488 µmol/L)
Children		
0 to 5 days	1.9 to 7.9 mg/dl (113 to 470 µmol/L)	1.9 to 7.9 mg/dl (113 to 470 µmol/L)
1 to 4 years	1.7 to 5.1 mg/dl (101 to 303 µmol/L)	2.2 to 5.7 mg/dl (131 to 339 µmol/L)
5 to 17 years	3.0 to 6.4 mg/dl (178 to 381 µmol/L)	3.0 to 6.4 mg/dl (178 to 381 µmol/L)

URINE 250 to 750 mg/24 hrs (1500 to 4500 µmol/24hrs)
It is recommended that each laboratory should assign its own normal range.

LITERATURE :

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.208-14.
2. Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed, (W.B. Saunders eds. Philadelphia USA), (1995), 624.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION
prietest TOUCH

Name : URICACI, Mod : END-P
Pri.: 510 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mg/dl
Lag : 5 , Read : NA
Blk : Y, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 6.0
Normal HI = 8.2
Normal LO = 2.3
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Rgnt. Linearity : 20
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING

TEST NAME	URIC ACID
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	6
Units	mg/dl
Sample Volume	25 µl
Reagent Volume	1000 µl
Incubation Time	10 minutes
Reference Range	2.3 to 8.2
Reagent Linearity	20

ROBONIK®

An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

Manufactured and Marketed by:
ROBONIK (INDIA) PVT. LTD.,
A-374, TTC Industrial Area, Mahape,
Navi Mumbai - 400 710, INDIA.
Tel. No.: + 91 (22) 67829700
Fax. No.: + 91 (22) 67829701
Orders : sales.reagents@robonikindia.com
Queries : feedback@robonikindia.com
Website : www.robonik.in

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