Uric Acid Single (Uricase-POD Enzymatic colorimetric method)

Invitro Diagnostic reagent kit for quantitative determination of Uric Acid in serum/plasma and Urine samples on Photometric System.

Reagent
Reagent : Uric Acid Reagent
Standard: Uric Acid (Conc. 6 mg/dL)

Principle
Uric acid is oxidized by uricase to allantoine and hydrogen peroxide ($2H_2O_2$), which under the influence of POD, 4–aminophenazone (4-AP) and 2-4 Dichlorophenol sulfonate (DCPS) forms a red quinoneimine compound:

Uric acid + $2H_2O$ + O_2 ⟶ Allantoine + CO_2 + $2H_2O_2$

$2H_2O_2$ + 4-AP + DCPS ⟶ Quinoneimine + $4H_2O$

The intensity of the red color formed is proportional to the uric acid concentration in the sample.

Summary
Uric Acid is waste product excreted by kidneys. The increased concentration of Uric Acid is found in Gout disease, arthritis or impaired renal functions.

Storage Instructions and Reagent Stability
Reagent and standard are stable up to the end of the indicated month of expiry, if stored at 2° – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Components and Concentrations
Reagent: Phosphate buffer, Uricase > 50 U/L, Peroxidase >1 kU/L, 4-Aminoantipyrine 60 mg/dL.
Standard: Uric acid - 6 mg/dL

Waste Management
Please refer to local regulatory requirements.

Reagent Preparation
All reagents are ready to use and are stable till the expiry date mentioned on the label, when stored at 2-8° C

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum, heparin plasma or EDTA plasma Stability:
1 month at 2° – 8 °C,
3 months at -20°C.
The stability in urine is 4 days at 20° - 25°C.
Dilute urine 1:9 with distilled water and multiply the result by 10.
Only freeze once!
Discard contaminated specimens.

Assay Procedure
Wavelength	505 nm
Light path	10 mm
Temperature	37°C
Measurement	Against reagent Blank

	Blank	Sample/Standard
Sample/Standard	-	20 µL
Distilled water	-	-
Reagent	1000 µL	1000 µL
Mix, incubate for 5 min. at 37°C. Read absorbance against the reagent blank		

Calculation:
With Standard or Calibrator

$$\text{Uric Acid (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std. /Cal}} \times \text{Conc. of Std. /Cal (mg/dL)}$$

Quality Control
For internal quality normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions
1. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Always use safety pipettes to pull the reagents into a pipette.
3. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
4. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
5. For professional use only!

Performance Characteristics
Measuring range
The test has been developed to determine uric acid within a measuring range from 0.5 – 30 mg/dL. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result to be multiplied by 2.

Linearity/Limit of Maximum Detection
The maximum limit of detection is 30 mg/dL.

Sensitivity/Limit of Detection
The lower limit of detection is 0.5 mg/dL.

Specificity/Interferences
No interference was observed by, Bilirubin up to 40 mg/dL, and triglycerides up to 2000 mg/dL.

Precision
Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	2.57	0.04	1.74
Sample 2	6.31	0.06	0.98
Sample 3	10.44	0.10	0.96

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	2.40	0.04	1.60
Sample 2	6.33	0.03	0.54
Sample 3	10.89	0.11	1.01

Method Comparison
A comparison of Precision Biomed Uric Acid (y) with a commercially available test (x) using 15 samples gave following results:
$y = 0.993x + 0.132$; $r^2 = 0.996$

Reference Range

Gender	Female	Male
Unit	mg/dL (µmol/L)	mg/dL (µmol/L)
Adults	2.6 – 6.0 (155 – 357)	3.5 – 7.2 (208 – 428)
Children		
0 - 5 days	1.9 – 7.9 (113 – 470)	1.9 – 7.9 (113 – 470)
1 - 4 yr.	1.7 – 5.1 (101 – 303)	2.2 – 5.7 (131 – 340)
5 - 11 yr.	3.0 – 6.4 (178 – 381)	3.0 – 6.4 (178 -381)
12 - 14 yr.	3.2 – 6.1 (190 -363)	3.2 – 7.4 (190 – 440)
15 - 17 yr.	3.2 – 6.4 (190 – 381)	4.5 – 8.1 (268 – 482)
Urine		
≤ 800 mg/24h (4.76 mmol/24h) assuming normal diet.		
≤ 600 mg/24h (3.57 mmol/24h) assuming low urine diet.		

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Uric Acid
Mode	End Point
Wavelength	505 nm
Path length	10 mm
Standard conc.	6 mg/dL
Reagent volume	1000 µL
Sample volume	20 µL
Incubation time	5min
Temperature	37°C
Blanking	Reagent blank
Linearity	30 mg/dL
Sensitivity	0.5 mg/dL

Pack Size

Cat No.	Configuration	Pack
UAS00100	Reagent - 2 x 50mL Standard – 1 x 2mL	100ML
UAS01000	Reagent - 2 x 500mL Standard – 1 x 4mL	1000ML

Literature

1. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH- Books Verlagsgesellschaft; 1998.p.208-14.
2. Tietz Textbook of Clinical Chemistry. 3rd ed, Phihadelphia: WB Saunders Company; 1999.p.1204-70.
3. Disch Med Wschr 1973; 98: 380-384.

Version : UAS/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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