Uric Acid (Uricase-POD Enzymatic colorimetric method)

In-Vitro Diagnostic reagent for the quantitative determination of Uric Acid present in human serum, plasma or urine samples on photometric system.

Labgene biotech

ORDER INFORMATION

Cat no.	Kit Configuration
LG113-100	Reagent - 2 x 50mL Standard – 1 x 2mL
LG113-1000	Reagent - 2 x 500mL Standard – 1 x 4mL

REAGENT

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

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.

PRINCIPLE

Uric acid is oxidized by uricase to allantoine and hydrogen peroxide (2H2O2), which under the influence of POD, 4–aminophenazone (4-AP) and 2-4 Dichlorophenol sulfonate (DCPS) forms a red quinoneimine compound:

$$\text{Uric Acid} + 2H_2O + O_2 \longrightarrow \text{Allantoine} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{4-AP} + \text{DCPS} \longrightarrow \text{Chromogen} + 4H_2O$$

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

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 legal requirements.

REAGENT PREPARATION & STORAGE

Mix 4 parts of Reagent 1 and 1 part of Reagent 2 to make Working Reagent.
Allow the working reagent stand for 5 minutes before use.
The working reagent is stable for upto 5 days at 15°C – 22°C, upto 4 weeks at 2°C – 8°C and avoid contamination.
The mono reagent must be protected from light.
Do not freeze the reagents!

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 or Standard
Working Reagent	1000 µL	1000 µL
Sample or Standard	–	20 µL

Mix and incubate at 37°C for 5 minutes and read the absorbance against reagent blank.

CALCULATION

With Standard or Calibrator

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

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

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

PERFORMANCE CHARACTERISTICS AND 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

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

Intra 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:
$y = 0.993x + 0.132$; $r^2 = 0.996$

ASSAY PARAMETERS

Mode	Endpoint
Wavelength	505 nm
Path length	10 mm
Standard conc.	6 mg/dL
Reagent volume	1000 µL
Sample volume	20 µL
Temperature	37°C
Blanking	Reagent blank
Linearity	30 mg/dL
Sensitivity	0.5 mg/dL

REFERENCE RANGE

Gender	Male		Female	
	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.

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.

INDEX OF SYMBOLS

ISO 13485	International Organization or Standardization		Keep out of Sunlight
	Manufacturer	IVD	For invitro diagnostic use only
	Expiry date		Read product insert before use.
LOT	Lot (batch) number		Do not use if package is damaged
2°C 8°C	Store between 2-8°c		Keep Away From Moisture

ART/IFU/PRC-113-01

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