PARAMCARE LIFE SCIENCES PVT. LTD.
where innovation starts....

PARAMCARE™

Uric Acid

Enzymatic Colorimetric Method

Quantitative determination of Uric Acid in serum / Plasma / Urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
UAC 25	1 X 25 mL
UAC 100	2 X 50 mL
UAC 200	4 X 50 mL
UACMONO 25	25 X 1 mL
UACMONO 50	50 X 1 mL

CLINICAL SIGNIFICANCE

Uric acid and its salts are end products of the purine metabolism. With progressive renal insufficiency, there is retention in blood of urea, creatinine and uric acid. Elevate uric acid level may be indicative of renal insufficiency and is commonly associated with gout. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Colorimetric enzymatic test using Uricase

PRINCIPLE

Uric acid is converted by uricase to allantoin and hydrogen peroxide, which under the catalytic influence of peroxidase, oxidises 3, 5 - dichloro - 2 - hydroxybenzenesulfonic acid and 4- aminophenazone to form a red-violet quinoneimine compound.

REAGENT

Reagent1 : Uric Acid Reagent
Uric acid Standard : 5 mg/dL

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

The Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma
Stability: 7 days at 4 – 8°C
6 Months at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	505 nm (490-550 nm)
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	25µl
Reagent Volume	1000 µl
Incubation	10 minutes
Blank Absorbance Limit	< 0.200
Low Normal	2.4 mg/dL (0.14 mmol/L)
High Normal	7.2 mg/dl (0.43 mmol/L)
Linearity	25.0 mg/dL (1.50 mmol/L)

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Blank	Standard	Test
Reagent 1	1000µL	1000µL	1000µL
Standard	--	25µL	--
Sample	--	--	25µL

- Mix & Incubate for 10 min. at 37 ^{0}C. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 505 nm. The colour is stable for 30 min. at R.T.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 25 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Uric Acid mg/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value (5mg/dL)}$$

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Uric Acid standard** have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
BIORAD 1	4.66	0.02	0.51%
BIORAD 2	9.54	0.03	0.28%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
BIORAD 1	4.65	0.02	0.46%
BIORAD 2	9.54	0.02	0.23%

LINEARITY

The method is linear upto a concentration of 25 mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Uric Acid is 0.5 mg/dL.

METHOD COMPARISON

A comparison of Paramcare Uric Acid with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.9750$

REFERENCE VALUES

Child	0.12 - 0.33 mmol/L	2.0 - 5.5 mg/dL
Adult Male	0.21 - 0.43 mmol/L	3.5 - 7.2 mg/dL
Adult Female	0.15 - 0.36 mmol/L	2.6 - 6.0 mg/dL
Urine	14.9 - 44.6 mmol/day	250 - 750 mg/day

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 10 mg/dl.
- Hemoglobin: No interference found upto 2.5 mg/dL.
- Lipemia: No interference found upto 750 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Caraway , WT Clinchem 4,239(1963).
2. Morin LG Clinchem,20,51(1974).
3. Trivedi RC Rebar L.,Berka E.,Strong L.,Clinchem.,(1978),24,1908.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,
Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
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