Pariksha Biotech
A game changer in IVD

Uric Acid Estimation Kit

High-Q Uric Acid- ML STAT (AOX/TOOS)

Uricase - PAP Trinder's Method

HIGH®
Command on Quality

Intended Use:

Kit for the quantitative determination of uric acid in human serum, plasma and urine.

Summary & Clinical Significance :

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukaemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. The oxidation of uric acid provides for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid. A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidise uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV masurement of the consumption of uric acid or in combination with other enzyme to provide a colorimetric method. The assay described here is a slight modification of the colorimetric method. The modifications were described by Siedel. In this reaction, the peroxide reacts in the presence of peroxidase, TOOS and aminoantipyrine to form a Blue purple quinoneimine dye. The intensity of the Blue purple color is proportional to the uric acid concentration and is determined photometrically.

Principle:

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

$$H_2O_2 + \text{TOOS} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Blue purple complex} + HCl + 4H_2O$$

Storage and Stability:

All the reagents should be stored at 2-8^{0}C and are stable till the expiry date mentioned on the labels.

Specimen:

Unhemolysed Serum / Heparinised plasma / Urine. Urine should be diluted 1:10 with distilled water before use.

Reagent Preparation:

The Uric Acid Reagent is ready to use and stable up to expiry provided contamination is avoided. A slight blue purple color (up to 0.15 abs units) at 546 nms does not affect performance of the reagent.

Notes:

1. Reagent must be stored at 2-8^{0}C till expiry.
2. If a larger volume of reagent is required for the absorbance reading, requisite volumes can be taken in multiples keeping the same ratio of reagent to specimen/standard.
3. Programmes for specific auto analyzers are available on request.
4. The rate of increase in the reagent blank absorbance can be reduced by ensuring the storage of reagent (highly photosensitive) at 2-8^{0}C.
5. As with all the diagnostics procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

Procedure:

Pipette into test tubes labeled Blank (B), Standard (S) and Test (T) as follows:

Reagent	Blank (B)	Standard (S)	Test (T)
Uric Acid Reagent	1.0 ml	1.0 ml	1.0 ml
Uric Acid Standard (Conc : 8 mg/dl)	-	25 µl	-
Specimen	-	-	25 µl

Mix and incubate for 5 minutes at 37°C or 10 minutes at R.T. Mix and read absorbance of Standard (S) and Test (T) against Reagent Blank (B) at 546 nm (540-578 nm).

Calculations:

$$\text{Serum Uric Acid in mg/dl} = \frac{\text{Abs. of T}}{\text{Abs. of S}} \times 8$$

$$\text{Urine Uric Acid in mg/dl} = \frac{\text{Abs. of T}}{\text{Abs. of S}} \times 8 \times 10 \text{ (Urine Dilution Factor)}$$

System Parameters:

Reaction type	:	End Point
Wave length	:	546 nm (540 - 578)
Flow cell Temp.	:	37°C
Sample volume	:	25µl
Reagent volume	:	1000µl
Standard concentration	:	8
Units	:	mg/dl
Blanking with	:	Reagent
Low normal	:	2.4
High normal	:	7.0
Linearity	:	30

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Quality Control:

To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality Control material checks both, the instrument and the reagent functions.

Normal Range:

Serum Uric Acid

Women	:	2.4– 5.7 mg/dl
Men	:	3.4–7.0 mg/dl
Urine Uric Acid	:	250– 750 mg/24 hours urine

It is recommended that laboratories should establish their own normal range.

Limitation & Interference:

No significant interference was observed from Bilirubin up to 25 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl,Lipemia as Triglycerides up to 2000 mg/dl,Ascorbic acid up to 100 mg/dl.

Imprecision:

Reproducibility was determined using human samples and controls within run (n = 20). The following results were obtained:

Within run

Sample	Mean(mg/dl)	SD(mg/dl)	CV%
Sample1	4.23	0.03	0.74
Sample2	5.96	0.04	0.65
Sample3	11.49	0.06	0.48

Reproducibility was determined using human samples and controls between day (n = 20). The following results were obtained:

Between day	Mean(mg/dl)	SD(mg/dl)	CV%
Sample1	4.70	0.04	0.92
Sample2	6.44	0.08	1.27
Sample3	11.03	0.13	1.20

Method Comparison:

A comparison of the High-Q Uric Acid - ML(AOX/TOOS) (y) with a commercially obtainable assay (x) gave with 44 samples the following result:
y = 0.897 x – 1.149; r = 0.9685

Bibliography:

1. Bablock Wet al A General Regression Procedure for Method Transformation. J Clin Chem ClinBiochem 1988;26:783-790
2. Colombo J-P (ed) Klinisch - chemische Urindiagnostik. Rotkreuz: Labolive-Verlagsgesellschaft. 1994:180Stuttgart/New York: Schattauer Verlag; 1995.

Ordering information:

Cat No:	Pack Size	Presentation
P-URI(2)-25	25 ml	Mono Reagent
P-URI(2)-50	2 x 25 ml	
P-URI(2)-100	4 x 25 ml	
P-URI(2)-250	5 x 50 ml	

Product Features

- Liquid Stable, Ready to use Mono Reagent
- No Ascorbic Acid interference up to 100 mg/dl
- Superior TOOS Chromogen
- 5 Minutes End Point Reaction
- Lipid Clearing Factor (LCF)
- Aqueous Uric Acid standard provided (Standard Conc: 8 mg/dl)
- Linearity: 30 mg/dl)
- Measuring Wavelength 546 nm (540 – 578 nm)
- Serum/ Heparinized Plasma/Diluted Urine are the specimens
- Available as multipurpose reagents and dedicated system packs

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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