Uric Acid Test Kit

REF	Pack Size	Reagent
URCLMB01	2 x 70	1 x 70ml

INTENDED USE
Uric acid reagent is use to quantitative estimation of uric acid concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
Uric Acid is the end product of Purine metabolism. Uric acid is excreted to a large degree by the kidneys and to a smaller degree in the intestinal tract by microbial degradation.
Uricase converts to hydrogen peroxide and allantoin. The hydrogen peroxide formed further reacts with a phenolic compound and 4 amino antipyrine by the catalytic action of peroxide to form a red colored quinonimine dye complex.

METHOD: Uricase-POD

TEST PRINCIPLE
Conversion of Uric acid into allantoin and hydrogen peroxide, further reaction with chromogens in presence peroxidase leads to red dye.

$$\text{Uric Acid} + H_2O \xrightarrow[\text{Peroxidase}]{\text{Uricase}} \text{Allantoin} + H_2O_2$$

H_2O_2 + Phenolic Chromogens → Red Dye

KIT CONTENTS/COMPONENTS
Reagent : Buffered Enzymes

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

REAGENT STORAGE, STABILITY AND HANDLING
The reagent and standard are ready to use and are stable up to the expiry date mentioned on the label. If stored at 2 to 8°C. Stability since first opening of vials: within 60 days at 2-8°C.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

SPECIMEN
Avoid use of EDTA and fluoride as anticoagulants. Serum/plasma is stable for 7 days at 2-8°C. and 1 month at -20°C.

APPLICATION For LM1016-400 TPH

Method	End Point
Blank	Reagent Blank
Primary filter	505
Secondary filter	No
R1 Volume	300µl
R1 Position	*
Incubation time (Sec)	522
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	7 µl
Read Time	27sec
Calibrator Concentration	As on vial label
Mix speed set	Middle
Unit	mg/dL
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Uric Acid concentration of each sample.

NORMAL VALUES
Male: 3.5 – 7.2 mg / dL
Female: 2.6 – 6.0 mg / dL

LIMITATIONS
If the value exceeds 25mg/dl dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

SAFETY PRECAUTIONS AND WARNINGS
1. For in-vitro diagnostics use only.
2. Do not use the reagent after the expiration date printed on the kit.
3. Avoid reagents contamination.
4. These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result. Using the recommended multi calibrator, calibrate the assay.
1. When using a new reagent or lot
2. When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dl)	4.08	9.22	4.06	9.11
SD	0.12	0.30	0.04	0.23
CV (%)	3.1%	3.3%	1.1%	2.5%

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

IFU/URC/03 Rev.: 00; Rev Date.: 22/07/2024

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