URIC ACID LYOPHILISED (2-8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRUAL2	4x50ml / 4x50ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of Uric acid in serum, plasma and urine.

Clinical Significance:
Uric acid and its salts are end products of the purine metabolism. With progressive renal disfunction, there is retention of urea, creatinine and uric acid in the blood. Elevated uric acid levels may be indicative of renal deterioration and is commonly associated with gout.

Test Principle:
Uric acid is oxidised by uricase to allantoin and hydrogen peroxide. The latter reacts with 4-aminophenazone and 2-4 dichlorophenol sulfonate (DCPS) via catalysis by Peroxidase to form a red quinoneimine compound. The intensity of the red colour formed can be measured spectrophotometrically and is proportional to the uric acid concentration in the sample.

$$\text{Uric Acid} + 2H_2O + O2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO2 + 2\,H_2O_2$$
$$2H_2O_2 + \text{4-AP} + \text{DCPS} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4H_2O$$

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 Buffer	Phosphate Buffer (pH 7.4)	50 mmol/l
	2-4 Dichlorophenol sulfonate (DCPS)	4 mmol/l
R2 Enzyme Reagent	Uricase	60 U/l
	Peroxidase	660 U/l
	Ascorbate oxidase	200 U/l
	4-Aminophenazone (4-AP)	1 mmol/l
Uric Acid Standard	Uric Acid	6 mg/dl

Reagent Preparation and Stability:
R1: Liquid, ready to use.
R2: Lyophilised.
Reagents are stable up to the expiry date when stored tightly capped at 2 - 8°C.
Working Reagent: Dissolve the contents of one vial of R2 Enzyme Reagent in 1 bottle of R1 Buffer. Mix gently and ensure that all the lyophilised material has gone into solution before use. The reconstituted Working Reagent is stable up to 1 month at 2 - 8°C or 10 days at 15 - 25°C.
Signs of reagent deterioration include: Presence of particles and turbidity, Blank absorbance at 520nm ≥ 0.16
Dispose of reagents carefully in line with local guidelines.

Sample Collection, Preparation and Stability:
Collect serum and heparin or EDTA plasma by standard venepuncture technique. Stable for 3 - 5 days at 2 - 8°C or 6 months at -20°C.
Collect 24 hour urine samples. Stable for 4 days at 15 - 25°C, pH > 8. Dilute sample 1/50 in distilled water. Mix. Multiply results by 50 (dilution factor).
If urine is cloudy, warm the specimen to 60°C for 10 mins to dissolve precipitated urates and uric acid. Do not refrigerate.

Assay Procedure:

WAVELENGTH	520nm (490 – 550)
TEMPERATURE	15 - 25/37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	25 µl
Standard	-	25 µl	-
Working Reagent	1000 µl	1000 µl	1000 µl

Mix and incubate for 5 minutes at 37°C or 10 minutes at 15 - 25°C. Read the absorbance of samples and standard against the reagent blank. The colour is stable for 30 minutes. ΔAbs = Absorbance of sample or Standard – Absorbance of Reagent Blank.

Calculation:
Serum Plasma:

$$\text{Concentration (µmol/l / mg/dl)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$$

Urine 24 hours:

$$\text{Concentration mg/24 h in urine} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Conc of Standard x vol (dl)}$$

Conversion factor: mg/dl x 59.5 = µmol/l.

Performance Characteristics:
Measuring range:
0.0 mg/dl to 40 mg/dl
Dilute samples with higher concentrations using Normal saline 1+1 and rerun the assay. Multiply the result by the dilution factor (for 1+1 dilution, the dilution factor is 2)

Imprecision
Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	4.74	0.02	0.50
Pool 2	10.55	0.03	0.30

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	4.73	0.13	2.67
Pool 2	10.50	0.29	2.77

Method Comparison:
Prestige Diagnostics Uric Acid reagent (y) was compared with another commercially available reagent (x) and gave the following results:
y = 1.162 x + 0.1415, r = 0.9714

Interferences:
No Interference was observed by bilirubin up to 170 µmol/l, Haemoglobin up to 130 mg/dl and ascorbic acid up to 570 µmol/l.

Reference Range:

Serum / Plasma		
Male	3.6 – 7.7 mg/dl	214 – 458 umol/l
Female	2.5 – 6.8 mg/dl	149 – 405 umol/l
Urine: 250 – 750 mg/24h or 1.49 – 4.50 mmol/l 24 h		

Each laboratory should establish its own mean reference range according to the population.

Limitations:
The uric acid result from this test should not be used as the sole criteria for the diagnosis of renal disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Schultz A. Uric acid. Kaplan A et al. clin chem The CV Mosby Co. St. Louis Toronto. Princeton 1984; 1261 – 1266 and 418.
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3. Young DS. Effects of drugs on Clinical Lab Tests. 4th ed AACC 2001.
4. Young DS. Effects of disease on Clinical Lab Tests. 4th ed AACC 1999.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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V2: rev Dec 2018