ANA BIO ISP URIC ACID

(Uricase-POD Method)

For Miura Instruments

Intended Use

Uric acid is a reagent kit used for the determination of Uric acid based on enzymatic reactions using Uricase and Peroxidase enzymes.

Principle

Uricase converts Uric acid into allantoin and hydrogen peroxide (H_2O_2). In presence of Peroxidase, hydrogen peroxide oxidatively couples with phenolic chromogens to form a red coloured compound, The intensity of the colored complex is directly proportional to the concentration of Uric Acid in specimen.

$$\text{Uric acid} + H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + H_2O_2$$

$$\text{Phenolic chromogens} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Red colour compound} + 3\,H_2O$$

Components & Concentration of Reagents

Reagent	Component	Concentration
Enzyme Reagent	Goods Buffer PH 7.8	50 mmol/L
	DHBS	≥ 1 mmol/L
	4-AAP	≥ 0.1 mmol/L
	Uricase	≥ 400 U/L
	AOD	≥ 300 U/L
	POD	≥ 2000 U/L
	Stabilizers, excipients & surface active agents	

Reagent storage and stability

The kit should be stored at 2° - 8°C and is stable till the expiry date indicated on the label. **DO NOT FREEZE THE REAGENT.**

Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light. Do not mix different batches.

Specimen collection and preservation

Blood should be collected in a clean and dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Serum or plasma should be separated from the cells at the earliest possible (with in 30 minutes). For plasma collection, following anticoagulants are used.

- EDTA 2 mg/ml of blood
- CITRATE 6 mg/ml of blood
- HEPARIN 200 IU/ml of blood
- OXALATE 3 mg/ml of blood
- SODIUM FLUORIDE 10 mg/ml of blood

In neatly separated serum/plasma Uric acid is stable for 3 days at room temperature (below 25°C) and for 6 months when stored at -20°C.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Uric Acid	
Method Code	UA	
Type	End-Point	
Unit	mg/dl	
Filter F1	505 nm	
Blank in	Use	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	5	µl
Final Incubation	300	Sec.

Normal range

Male : 3.4 - 7.0 mg/dl
Female : 2.4 - 5.7 mg/dl
Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

Reaction is linear up to 25 mg/dl. If the Uric Acid value exceeds 25 mg/dl, then dilute the specimen suitability with normal saline and repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain correct Uric Acid value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Uric Acid added to a serum matrix containing known amounts of Uric Acid gave an average recovery of 96%.

Interference

Bilirubin below 40 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 500 mg/dl, Ascorbic Acid up to 30 mg/dl does not interfere in the reaction.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	5.95	0.12	2.00	20
High	mg/dl	8.31	0.13	1.59	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	5.86	0.11	1.85	60
High	mg/dl	8.31	0.11	1.26	60

Sensitivity

At 505 nm a concentration of 0.29 mg/dl of Uric Acid can estimate.

References

1. Thefeld Wetal. Dtsch. Med Wechr., 98, 380 (1973).
2. Fossali P. et al, Clin Chem. 26, 227 (1980).

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

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