URIC ACID

METHOD – URICASE
PRODUCT CODE – LU01

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Uric Acid in serum / plasma using uricase method.

SUMMARY AND PRINCIPLE

Uric Acid concentration is increased in various renal diseases, with increased cell lysis in the presence of tumours, leukaemia, and toxaemia of pregnancy. Prolonged elevation of the concentration leads to gout.
O.R.G. Uric acid is a single ready to use reagent set for determination of Uric acid based on enzymatic method using Uricase and Peroxidase.

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

$$H_2O_2 + \text{Chromogen} \xrightarrow{\text{POD}} \text{Red Dye} + H_2O$$

KIT COMPONENTS

Reagent 1: Uric Acid Reagent
Reagent 2: Uric Acid Standard (6 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Uric acid is a ready to use reagent. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 510 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Uric Acid
Reaction Type	End Point
Wavelength	510 nm
Flow Cell Temp	37 °C
Blank setting	Reagent
Blank abs limit	< 0.300

Reagent Volume	1000 µl
Sample Volume	25 µl
Temperature	37 °C
Incubation Time	5 min.
Standard Conc.	6 mg/dL
Linearity	25 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Uric acid in the serum is stable for 3 days when stored at 2-8 ^{0}C and 6 months when stored at -10 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Buffer , pH 7.8	50 mmol/l
Uricase	>100 IU/L
Ascorbate Oxidase	>100 IU/L
Peroxidase	>100 IU/L
Chromogen	1.0 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	25 µl	NA
Sample	NA	NA	25 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 5 mins at 37 ^{0}C.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 30 minutes if not directly exposed to light.			

CALCULATION

$$\text{Uric Acid (mg/dL)} = \frac{\text{Abs. of sample} \times 6}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Male: 3.4 - 7.0 mg/dL
Female: 2.4 - 5.7 mg/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.3 - 25 mg/dL. If the Uric Acid value exceeds linearity limit (above 25 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct uric acid value of the specimen.

Interference: There is no significant interference in samples containing upto 20 mg/dL of Bilirubin, 8 mg/dL of ascorbic acid and 500 mg/dL of haemoglobin.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	4.67	0.04	0.8	4.86	0.05	1.1
High Value Serum	9.15	0.10	1.1	9.55	0.13	1.3

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Uric Acid. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance exceeds 0.300 at 510 nm against distilled water.

2. If Uric acid value exceeds 25 mg/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct Uric Acid value.

BIBLIOGRAPHY

1. Town MH.Gehm S, Hammer B, Ziegenhorn, J.J. Clin. Chem Clin Biochem 1985; 23:591.

2. Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa: WB Saunders Company, 1995 : 624 - 626.

3. Thefeld W. *et.al*, Dtsch. Med Vschr., 98, 380 (1973).

4. Fossati P., *et al*, Clin Chem 26, 227 (1980).

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE