

SAFETY PRECAUTIONS AND WARNINGS :

This reagent is for *In vitro* diagnostic use only.

INTENDED USE :

This reagent kit is intended for "*in vitro*" quantitative determination of Uric Acid concentration in serum & urine. Enzymatic colorimetric method.

CLINICAL SIGNIFICANCE :

In the human body uric acid is the end-product of purine metabolism. It is excreted by the kidney. Increases of uric acid in the serum plasma or urine can be due to the overproduction of purine containing molecules or to insufficient excretion. The concentration is increased in various renal diseases, with increased cell lysis in the presence of tumors, leukemia, toxemia of pregnancy. Prolonged elevation of the concentration leads to gout.

PRINCIPLE :

Uricase transforms Uric acid in the sample into Allantoin, Carbon dioxide (CO₂) and Hydrogen peroxide (H₂O₂). By the action of Peroxidase (POD) and in the presence of phenol-derivative, DHBS and 4-Aminoantipyrine, Hydrogenperoxide gives a coloured indicator reaction which can be measured at 520 nm. The increasing in absorbance correlates with (is proportional to) the uric acid concentration of the sample.



REAGENT COMPOSITION :

Reagent 1: Enzyme reagent
 Uric Acid standard: 6 mg/dl

MATERIALS REQUIRED BUT NOT PROVIDED :

- Clean & Dry Glassware.
- Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

SAMPLES :

Serum free of hemolysis,
 Urine diluted in ratio of 1:10 with distilled water. Multiply the result by 10.
 If the urine sample is opalic then incubate at 60°C for ten minutes. The ascorbic acid in the urine sample interferes with the test, so use diluted sample.

STABILITY OF REAGENT :

When Stored tightly closed at 2 to 8°C temperature protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

WORKING REAGENT :

The Reagent is ready for use.

GENERAL SYSTEM PARAMETERS :

Reaction type	End Point (Increasing)
Wave length	520 nm (490 - 550) nm
Light Path	1 Cm
Reaction Temperature	37°C
Blank / Zero Setting	Reagent
Reagent Volume	1ml
Sample Volume	25 µl
Incubation Time	5 Minutes
Standard Concentration	6 mg/dl
Low Normal	2.5 mg/dl
High Normal	7.0 mg/dl
Linearity	20 mg/dl

ASSAY PROCEDURE :

	Blank	Standard	Sample
Reagent	1ml	1ml	1ml
Standard		25 µl	
Sample			25 µl

Mix and read the optical density (A) after a 5 - minute incubation.

CALCULATION :

$$\text{Uric Acid Conc. (mg/dl)} = \frac{\text{OD of Sample}}{\text{OD of Standard}} \times \text{X Conc. of Standard}$$

LINEARITY :

Reagent is Linear up to 20 mg/dl.
 Dilute the sample appropriately and re-assay if Uric Acid concentration exceeds 20 mg/dl. Multiply result with dilution factor.

REFERENCE NORMAL VALUE :

Female: 2.5-6.0 mg/dl (25-60 mg/l)
 Male : 3.4-7.0 mg/dl (34-70 mg/l)
 Urine : 250-750 mg/24 h

QUALITY CONTROL :

For accuracy it is necessary to run known controls with every assay.

LIMITATION & PRECAUTIONS :

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the reagents to room temperature.
4. Avoid contamination of the reagent during assay process.
5. Use clean glassware free from dust or debris.
6. Do not use the reagent if it is hazy or cloudy.
7. No interfere with bilirubin up to 20 mg/dl, Hb up to 50 mg/dl, Ascorbic Acid up to 30 mg/dl and Triglycerides up to 2000 mg/dl.

BIBLIOGRAPHY :

Tietz N.W Fundamentals of clin. Chem, Young D.S, Naito, HK.et.al. (1973), 10.79.

Mfg. By: BIOGENIX INC. PVT. LTD.

Factory: B - 19/A, S.I.L Ancillary Estate, Amausi Industrial Area, Nadarganj, Kanpur Road, Lucknow - 226008 (U.P.), India

Email: biogenix2007@yahoo.com, info@biogenixinc.com

Website: www.biogenixinc.com

Customer care no: +919140971443

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