SBio URIC ACID KIT

(Uricase / PAP Method)

(For invitro diagnostic use only)

REF	90880075	90882150
Pack Size	75 ml	2 X 150 ml

CE

8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L2 Enzyme Reagent	Uricase / PAP Uricase / PAP Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	S Uric Acid Standard (8 mg/dl)	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Buffer Reagent	This way up	

INTENDED USE

Uric Acid Kit is used for the determination of Uric Acid in serum or plasma.

PRINCIPLE OF THE TEST

Uricase converts uric acid to allantoin and hydrogen peroxide. The hydrogen peroxide formed further reacts with a phenolic compound and 4 aminoantipyrine by the catalytic action of peroxidase to form a red coloured quinoneimine dye complex. Intensity of the colour formed is directly proportional to the amount of uric acid present in the sample.

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

$$H_2O_2 + \text{4 Aminoantipyrine} + \text{Phenolic Compound} \longrightarrow \text{Red Quinoneimine dye} + H_2O$$

CLINICAL SIGNIFICANCE

Uric acid is the end product of the metabolism of exogenous and endogenous purines. In humans, uric acid is excreted as the metabolic end product of purines. Uric acid is mostly eliminated from the circulation by urine (about 75%), and about 25% are secreted to the intestines, where it is degraded by intestinal bacteria. Increased levels are found in Gout, arthritis, impaired renal functions and starvation. Decreased levels are found in Wilson's disease, Fanconis syndrome and yellow atrophy of the liver.

PRESENTATION	75 ml	2 x 150 ml
L1 : Buffer Reagent	60 ml	2 x 120 ml
L2 : Enzyme Reagent	15 ml	2 x 30 ml
S : Uric Acid Standard (8 mg/dl)	5 ml	5 ml

COMPOSITION

Phosphate Buffer 100 mM; pH 7.0; Uricase ≥ 100 U/L; POD ≥ 1000 U/L; 4-AAP 0.6 mM; TBHA 1.0 mM; Non Reactive Stabilizers, Detergents and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

REAGENT PREPARATION

Reagents are ready to use.

Working reagent: Pour the contents of 1 bottle of L2 (Enzyme Reagent) into 1 bottle of L1 (Buffer Reagent). This working reagent is stable for at least 4 weeks when stored at 2-8°C. Upon storage the working reagent may develop a slight pink colour however this does not affect the performance of the reagent.

Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Buffer Reagent) and 1 part of L2 (Enzyme Reagent). Alternatively 0.8ml of L1 and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

SAMPLE MATERIAL

Serum, plasma. Uric Acid is reported to be stable in the sample for 3-5 days when stored at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter	:	520 nm (Hg 546 nm) / Yellow Green
Temperature	:	37°C / R.T.
Light path	:	1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Working Reagent	1.0	1.0	1.0
Distilled Water	0.02	--	--
Uric Acid Standard (S)	--	0.02	--
Sample	--	--	0.02

Mix well and incubate at 37°C for 5 min. or at. R.T (25°C) for 15 minutes. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against the Blank, within 30 minutes.

CALCULATIONS

$$\text{Uric Acid in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 8$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Uric Acid. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 20 mg/dl. If values exceed this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Uric Acid is 0.15 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	4.54	2.07	4.89	2.22	9.43	4.29
Control 2	11.12	1.38	10.16	1.84	21.28	3.22

Method comparison:

Comparative studies were done to compare our reagent with another commercial Uric Acid Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum / Plasma (Males) : 3.4 - 7.0 mg/dl
(Females) : 2.5 - 6.0 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

The reagent may be used in several automated analyzers. Instructions are available on request.

Standard is traceable to standard reference material (SRM) 909b. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Trinder P., (1969) Ann. Clin. Biochem. 6:24.
2. Fossati P., Prencipe L., (1980) Clin. Chem. 26 : 227.
3. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et.al., 5th Edition.

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EC REP

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