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URIC ACID

Quantitative Determination of Uric Acid
Enzymatic Colorimetric Uricase POD Monoreagent

For professional in vitro diagnostic use only.

INTENDED USE

Quantitative determination of Uric Acid in Serum, Plasma or Urine. Enzymatic Colorimetric method (Uricase-POD)

GENERALITIES

Uric acid is the major product of the catabolism of purine nucleosides (adenosine and guanosine) from the purine metabolism pathway. Purines may be synthesized endogenously from the breakdown of nucleic acids or may be obtained from sources as diets in which nucleic acids are present. An abnormal increase in the level of uric acid in circulation above 7.0 mg/dL (0.42 mmol/L) is referred to as hyperuricemia, being the gout the major form of the ailment resulting in the deposition of urates in the soft tissues, especially in the joint areas. Increased levels may be also found associated with leukemia, toxemia of pregnancy and severe renal impairment. Less common are the cases of hypouricemia where the concentration of uric acid is below 2.0 mg/dL (0.12 mmol/L). These cases are usually secondary to cases of hepatocellular disease, renal reabsorption defect, or overtreatment with uricosuric drugs used in the treatment of hyperuricemia.

TEST PRINCIPLE

Uricase oxidizes Uric Acid to Allantoin with the formation of Hydrogen Peroxide which, in the presence of Peroxidase (POD), reacts with a chromogen (DHBS) and 4-Amino-Antipyrin, forming a red colored compound whose intensity, measured photometrically at 505 nm, is proportional to the concentration of Uric Acid in the sample.

REAGENT COMPOSITION

Reagent	
Good's buffer, pH 7.8	100 mmol/L
Uricase	> 0.5 KU/L
Peroxidase (POD)	> 0.5 KU/L
4-aminoantipyrine	0.5 mmol/L
DCPS	2 mmol/L
Standard	
Uric Acid	value on label

STORAGE, PREPARATION AND SHELFLIFE

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents. Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera. After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge to avoid contamination, degradation from direct light and evaporation. The measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.1 at 505 nm.

SAMPLE COLLECTION AND PREPARATION

Serum, Heparin or EDTA plasma,
Urine 24h diluted 1:10 with H2O (1+9).

Stability in serum/plasma: 7 days at 4°- 8° C. 3 months at - 20°C Only freeze once. Discard contaminated specimens.

Stability in urine: 4 days at 15° - 25°C, Discard contaminated specimens

TEST PROCEDURE

Wavelength	: 505 nm
Light path	: 1 cm
Temperature	: 37 °C
Measurement:	: Against Reagent Blank
Assay type	: ENDPOINT

Assay:

	Blank	Assay
Reagent	**1000 µL**	**1000 µL**
Sample/ Standard/ Cal	**/**	**20 µL**

-Mix and incubate for 5 min at 37 °C or for 10 min at room temperature (16-25 °C).
- Read the absorbance (A) of the samples and the standard against the reagent blank.

CALCULATION

Serum/ Plasma:

$$\text{Uric Acid Concentration} = \frac{\text{Abs Sample - Abs blank}}{\text{Abs Std/Cal - Abs blank}} \times \text{Std/ Cal.}$$

Urine:

Calculate as for the serum and multiply the result by 10 (initial sample dilution).
Uric Acid (mg/24 h) = Uric Acid (mg/dL) x Urine Vol. 24 h (dL).
Uric Acid (µmol /24 h) = Uric Acid (µmol /L) x Urine Vol. 24 h (L).
Conversion Factor: [mg/dL] x 59.48 = [µmol/L]

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analyzed routinely with each group of unknown samples.

EXPECTED VALUES

Serum/plasma:
Male:

- 3.5 -7.2 mg/dL.

Female:

- 2.6 - 6.0 mg/dL.

Urine(24h):

- ≤ 800 mg/24h (4.76 mmol/24h) assuming normal diet
- ≤ 600 mg/24h (3.57 mmol/24h) assuming low purine diet.

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:

Low Level: Samples= 20; Average = 5.6; S.D. = 0.04; CV = 0.70%.
High Level: Samples = 20; Average = 9.14; S.D. = 0.04; CV = 0.41%.

ACCURACY:

A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y=1.03x r =0.978

SENSITIVITY: 0.03 mg/dL.
LINEARITY: 30 mg/dL.

PRECAUTIONS

R contains PHENOL, 4-AMINOANTIPYRINE.
in case of contact of reagents with the operator, you must apply the following first aid:
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing, gloves and eye/face protection.

INTERFERENCES

No interference was observed by Ascorbic Acid up to 20 mg/dL, Hemoglobin up to 200 mg/dL, Bilirubin up to 10 mg/dL and lipemia up to 2000 mg/dL Triglycerides.

LITERATURE

- Barham, D. and Trinder, P. Analyst. 97 : 142 (1972)
- Tietz. N.W. Clinical Guide to Laboratory Tests, 3rd Edition. W.B. Saunders Co. Philadelphia, PA. (1995).
- Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
- Fossati, P., Prencipe, L. and Berti, Q. Clin. Chem. 26 : 227 (1980).

USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
Σ	Contains Sufficient for <N> Tests