GENESIS

Instructions For Use

Uric Acid (Uricase/PAP Method)

Cat no.	size
1110 101	4*25
1110 102	2*50
1110 103	4*50
1110 104	2*25

INTENDED USE

The Uric Acid Reagent is Intended for in vitro Quantitative diagnostic determination of uric acid in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

In humans, uric acid is the major product of the catabolism of the purine bases which are obtained partly from the diet and partly from in vivo synthesis. Increased uric acid concentration in serum and urine maybe attributable to an overproduction of urate (increased purine synthesis) or to a defective elimination of urate.Hyperuricemia is commonly associated with gout, decreased renal function, dehydration, myeloproliferative disorders, and other conditions not well known

PRINCIPLE OF THE METHOD

Uric acid in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry

$$\text{Uric Acid} + H2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$\text{TBHBA} + \text{4-Aminoantipyrin} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Quinonimine} + 3H2O$$

COMPOSITION

REAGENT(R)	
Phosphate buffer pH 7	100 mmol/L
TBHBA	1 mmol/L
Aminoantipyrine	0.3 mmol/L
K4 [Fe(CN)6]	10 µmol/L
Peroxidase (POD)	≥ 2 kU/L
Uricase	≥ 30 U/L
STANDARD(S)	6.0 mg/dL

STORAGE

Store at 2-8ºC.

Reagent and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 546 nm

SPECIMEN

1.Serum, plasma or urine collected by standard procedures.

2.Dilute urine 1/10 with distilled water before measurement.

3.Uric acid in serum or plasma is stable for 5 days at 2-8ºC and for 3 days at 15-25 ºC.

4.Heparin and EDTA may be used as anticoagulants.

5.Uric acid in urine is stable for 4 days at room temperature if pH is adjusted to > 8 with NaOH. Do not refrigerate.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	20 µL	-
Sample	-	-	20 µL

3. Mix thoroughly and incubate the tubes for **10 minutes** at room temp or **5 minutes** in water path at 37 C.
4. Measure the absorbance (A) of the Standard and Sample at 546 nm against the Blank. The color is stable for at least 1 hour.

CALCULATIONS

The Uric Acid concentration in the sample is calculated using the following general formula:

$$\frac{A\ \text{Sample}}{A\ \text{Standard}} \times \begin{matrix} 6.0 \\ 357 \end{matrix} = \begin{matrix} \text{mg/dL} \\ \text{mmol/l} \end{matrix} \text{ Uric Acid}$$

REFERENCE VALUES

Male	3.0 - 7.0 mg/dL
Female	2.5 - 6.0 mg/dL
Children	2.0 - 5.5 mg/dL
Urine	250 - 750 mg/day

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

− Detection limit: 0.02 mg/dL

− Linearity limit: 20.0 mg/dL

For higher values dilute sample **1/2** with physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	cv	n
5.0 mg/dL	0.4 %	20
8.22 mg/dL	0.5 %	20

− Reproducibility (run to run):

Mean Concentration	cv	n
5.0 mg/dL	2.1 %	25
8.22 mg/dL	1.9 %	25

INTERFERENCES

Hemoglobin (2 g/L), bilirubin (2.5 mg/dL) and lipemia interfere.

Other drugs and substances may interfere.

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.

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