Reactivos GPL

Barcelona, España

CE

- URIC ACID LS -

URIC ACID

Uricase-POD. Liquid Stable

Store at: +2+8ºC.

Presentation:

Cod. SU042 CONT: R 2 x 50 mL. + Cal 1 x 5 mL
SU043 CONT: R 2 x 125 mL . + Cal 1 x 5 mL
SU043-B CONT: R 8 x 125 mL. + Cal 1 x 5 mL.
SU044 CONT: R 4 x 125 mL. + Cal 1 x 5 mL.

Procedure

Quantitative determination of uric acid.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

Uric acid is oxidized by uricase to allantoine and hydrogen peroxide ($2H_2O_2$), which under the influence of POD, 4–aminophenazone (4-AP) and adenosine diphosphate (ADPS) forms a red quinoneimine compound:

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoine} + CO_2 + 2H_2O_2$$

$$2H_2O_2 + \text{4-AP} + \text{ADPS} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4H_2O$$

The intensity of the red color formed is proportional to the uric acid concentration in the sample[1,2].

REAGENTS COMPOSITION

R	PIPES pH 7.5	50 mmol/L
	Adenosine diphosphate (ADPS)	4 mmol/L
	Uricase	160 U/L
	Peroxidase (POD)	6600 U/L
	Ascorbate oxidasa	1200 U/L
	4 – Aminophenazone (4-AP)	1 mmol/L
Uric Acid CAL	Uric acid aqueous primary calibrator	6 mg/dL.

REAGENT PREPARATION AND STABILITY

All the reagents are ready to use.
All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use.
Do not use reagents over the expiration date.
Uric Acid Cal: Proceed carefully with this product because due its nature it can get contaminated easily.
Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 500 nm ≥ 0.20

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC. Do not use reagents over the expiration date.

SPECIMEN

Serum or plasma[1] : Stable 3-5 days at 2-8ºC or 6 month at -20ºC.
Urine (24h)[1] : Stable 4 days at 15-25ºC., pH>8. Dilute sample 1/50 in distilled water. Mix. Multiply results by 50 (dilution factor); If urine is cloudy; warm the specimen to 60ºC for 10 minutes to dissolve precipitated urates and uric acid. Do not refrigerate.

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 500 nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE

1. Assay Conditions
   - Wavelenght : ..... 500 nm.
   - Cuvette: ..... 1 cm light path.
   - Temperature .....37ºC. 15-25ºC.
2. Adjust the instrument to zero with Blank of reagent.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
R (mL.)	1.0	1.0	1.0
Calibrator(note1-2) (µL.)	--	25	--
Sample (µL.)	--	--	25

4. Mix and incubate for 5 minutes at 37º C or 10 minutes at room temperature (15-25º C).
5. Read the absorbance (A) of the samples and calibrator, against the Blank. The colour is stable at least 5 minutes.

CALCULATIONS

Serum or Plasma:

$$\text{Uric Acid (mg/dL.)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 6 \text{ (Calibrator conc.)}$$

Urine 24h:

$$\text{Uric Acid (mg/24h)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 6 \times \text{vol.(dL.) urine 24 h}$$

Conversion Factor. mg/dL. x 59.5 = µmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control H Normal Ref. QC003 and Control H Pathological Ref. QC004. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES

Serum or Plasma

Women	2.5 – 6.8 mg/dL.	149-405 µmol/L.
Men	3.6 – 7.7 mg/dL.	214-458 µmol/L.
Urine	250 – 750 mg/24h.	1.49-4.5 mmol/24h.

(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

Uric acid and its salts are end products of the purine metabolism. With progressive renal insufficiency, there is retention in blood of urea, creatinine and uric acid.
Elevate uric acid level may be indicative of renal insufficiency and is commonly associated with gout[1,5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- *Measuring Range*:
  From *detection limit* 0.2 mg/dL. to *linearity limit* 25 mg/dL.
  If the concentration is greater than linearity limit dilute 1/2 the sample with ClNa 9 g/L and multiply the result by 2.
- *Precision*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (mg/dL)	4.36	10.2	4.41	10.8
SD	0.12	0.18	0.08	0.33
CV (%)	2.89	1.84	1.95	3.08

- *Sensitivity:*
  1 mg/dL. = 0.206 (A).
- *Accuracy:*
  Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

- No interferes were observed to bilirubin up to 170 µmol/L, hemoglobin up to 130 mg/L. and ascorbic acid up to 570 µmol/L[2].
- Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et. al[3,4].

NOTES

1. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

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