

URIC ACID ENZYMATIC COLORIMETRIC METHOD

IVD For *in-vitro* diagnostic use only


Store at 2-8° C.
CE

INTENDED USE

For the determination of uric acid concentration in human serum, plasma or urine.

INTRODUCTION

Uric acid is a chemical created when the body breaks down substances called purines. Purines are normally produced in the body and are also found in some foods and drinks. Foods with high content of purines include liver, anchovies, mackerel, dried beans and peas, and beer.

Most uric acid dissolves in blood and travels to the kidneys. From there, it passes out in urine. If your body produces too much uric acid or does not remove enough of it, you can get sick.

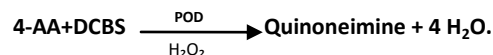
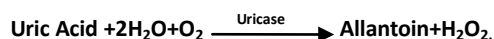
An abnormal increase in the level of uric acid in the circulation above 7.0 mg/dL (0.42 mmol/L) is referred to as hyperuricemia, being the gout the major form of the ailment resulting in the deposition of urates in the soft tissues, especially in the joint areas.

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.

PRINCIPLE

Uric acid is oxidized by uricase to allantoin with the formation of hydrogen peroxide. In the presence of peroxidase (POD), a mixture of dichlorophenol sulphonate (DCBS) and 4-aminoantipyrine (4-AA) is oxidized by hydrogen peroxide to form a quinoneimine dye proportional to the concentration of uric acid in the sample.



MATERIALS

REAGENTS SUPPLIED

R1	Phosphate buffer	100 mmol/L pH 7.8
	Uricase	> 0.5 KU/L
	Peroxidase	> 0.5 KU/L
	Ascorbate oxidase	> 1 KU/L
	4-aminoantipyrine	0.5 mmol/L
	DCBS	2 mmol/L
	non-ionic tensioactives	2 g/L (w/v).
Uric Acid Standard	Uric acid	6 mg/dL (357 μmol/L)

MATERIALS REQUIRED BUT NOT PROVIDED

- Photometer or colorimeter capable of measuring absorbance at 520 ± 10 nm.
- Constant temperature incubator set at 37 ° C.
- Pipettes to measure reagent and samples.

REAGENT PREPARATION

- All the reagents are ready to use.

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C protected from light and contaminations prevented during their use.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
 - Presence of particles and turbidity.
 - Blank absorbance (A) at 520 nm > 0.100 in 1 cm cuvette.

SAMPLE

- Hemolysis-free serum, EDTA or heparinized plasma and urine (See Notes).
- Uric acid in serum or plasma is stable up to 5 days at 2-8 ° C and for 6 months at -20 ° C.
- Whenever possible medication should be suspended 12 hours before sample collection.

PROCEDURE

Allow the test, specimen, and/or controls to reach room

temperature prior to testing.

1. Pipette into labeled tubes:

	Blank	Sample	Standard
Reagent	1.0 mL	1.0 mL	1.0 mL
Sample	---	20 μL	---
Standard	---	---	20 μL

2. Mix and let the tubes stand 10 minutes at room temperature or 5 minutes at 37 ° C.
3. Read the absorbance (A) of the samples and the standard at 520 nm against the reagent blank.
The color is stable for at least 30 minutes protected from light.

CALCULATION

Serum or plasma:

Uric acid (mg/dl) = $\frac{A \text{ Sample} \times C \text{ STD}}{A \text{ STD}}$ = mg/dL uric acid

Urine:

Uric acid (mg/24h) = $\frac{A \text{ Sample} \times 600 \times L/24 \times 10}{A \text{ STD}}$ = mg/dL uric acid

- Samples with concentrations higher than 30 mg/dL should be diluted 1:5 with saline and assayed again. Multiply the results by 5.
- If results are to be expressed as SI units apply:
mg/dL x 59.5 = μmol/L

INTERFERENCES

Lipemia (< 20 g/L), Bilirubin (< 10 mg/dL), Hemoglobin (< 20 g/L), Ascorbic acid (< 20 μM) do not interfere. Other drugs and substances may interfere.

REFERENCE VALUES

Serum, Plasma:	
Men	3.5 - 7.2 mg/dL (208 - 428 μmol/L)
Women	2.6 - 6.0 mg/dL (155 - 357 μmol/L)
Urine: 0.5-2.0g/24h.	

It is recommended that each laboratory establishes its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Detection Limit:** 0.03 mg/dL.

2. **Linearity:** Up to 30 mg/dL.

3. **Precision:**

	Within-run		Between-run	
Mean (mg/dL)	5.6	9.14	5.6	9.14
SD	0.04	0.04	0.06	0.07
CV (%)	0.70	0.41	1.06	0.74
N	10	10	10	10

4. **Sensitivity :** 0.028 A / mg/dL uric acid.

5. **Correlation:**

This assay (y) was compared with a similar commercial method (x). The results were:

N = 120 r = 0.978 y = 1.03x

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

NOTES

- Uric acid in urine may be assayed on fresh random or timed (24-h) samples. To prevent urate precipitation specimens are brought to pH > 8 with 0.01N NaOH. Dilute urine 1:20 with distilled water before the analysis.
- Men and women on normal diets present values <400-800 mg/ 24-h.
- This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

QUALITY CONTROL

- If controls values are found outside the defined range, check the instrument, reagents and procedure for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCES

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














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 REF	Catalogue Number		Temperature limit
 IVD	<i>In Vitro</i> diagnostic medical device		Caution
 Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
 LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry