

Uric Acid MonlabTest®

Uricase-POD. Liquid



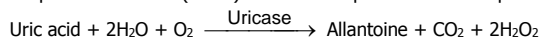
IVD

Quantitative determination of uric acid.

Only for professional *in vitro* diagnostic use. Store at 2-8°C.

PRINCIPLE OF THE METHOD

Uric acid is oxidized by uricase to allantoin and hydrogen peroxide (2H₂O₂), which under the influence of POD, 4-aminophenazone (4-AP) and 2,4-Dichlorophenol sulfonate (DCPS) forms a red quinoneimine compound:



The intensity of the red color formed is proportional to the uric acid concentration in the sample^{1,2}.

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. Elevated 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.

REAGENTS

R1	Phosphate pH 7.4	50 mmol/L
Buffer	2-4 Dichlorophenol sulfonate (DCPS)	4 mmol/L
R2	Uricase	60 U/L
Enzymes	Peroxidase (POD)	660 U/L
	Ascorbate oxidase	200 U/L
	4 - Aminophenazone (4-AP)	1 mmol/L
URIC ACID CAL	Uric acid aqueous primary standard	6 mg/dL

PREPARATION

Working reagent (WR): Mix equal volumes of R1 Buffer and R2 Enzymes. The working reagent is stable 1 week at 2-8°C or 4 days at room temperature (15-25°C).

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 \geq 0.16.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 520 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

- Serum or plasma¹: Stability 3-5 days at 2-8°C or 6 months at -20°C.
- Urine (24 h): Stability 4 days at 15-25°C, pH >8. Dilute sample 1/50 in distilled water. Mix. Multiply results by 50 (dilution factor). If urine is cloudy; warm the specimen to 60°C for 10 minutes to dissolve precipitated urates and uric acid. Do not refrigerate.

PROCEDURE

- Assay conditions:
Wavelength: 520 nm (490-550)
Cuvette: 1 cm light path
Temperature: 37°C / 15-25°C
- Adjust the instrument to zero with distilled water.
- Pipette into a cuvette (Note 3):

	Blank	Standard	Sample
WR (mL)	1.0	1.0	1.0
Standard (Note 1,2) (μL)	--	25	--
Sample (μL)	--	--	25
- Mix and incubate for 5 minutes at 37°C or 10 minutes at 15-25°C.
- Read the absorbance (A) of the samples and Standard, against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS

Serum or plasma

$$\frac{(A) \text{ Sample} - (A) \text{ Blank}}{(A) \text{ Standard} - (A) \text{ Blank}} \times 6 \text{ (Standard conc.)} = \text{mg/dL uric acid in the sample}$$

Urine 24 h

$$\frac{(A) \text{ Sample} - (A) \text{ Blank}}{(A) \text{ Standard} - (A) \text{ Blank}} \times 6 \times \text{vol. (dL) urine 24 h} = \text{mg/24 h uric acid}$$

Conversion factor: mg/dL x 59.5 = μmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: CONTROL Normal and Pathologic (MO-165107 and MO-165108). If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES¹

Serum or plasma:
 Women 2,5 - 6,8 mg/dL \cong 149 - 405 μmol/L
 Men 3,6 - 7,7 mg/dL \cong 214 - 458 μmol/L
 Urine: 250 - 750 mg/24 h \cong 1,49 - 4,5 mmol/24 h
 These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 0.1647 mg/dL to linearity limit of 40 mg/dL.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/L)	4.46	10.37	4.71	11.02
SD	0.02	0.05	0.06	0.15
CV (%)	0.46	0.44	1.20	1.37

Sensitivity: 1 mg/dL = 0.0323 A.

Accuracy: Results obtained using MonlabTest reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 50 samples were the following:

Correlation coefficient (r)²: 0.99734.

Regression equation: y=0.816x + 0.319.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No interferences were observed to bilirubin up to 170 μmol/L, hemoglobin up to 130 mg/dL and ascorbic acid up to 570 μmol/L².

A list of drugs and other interfering substances with uric acid determination has been reported^{3,4}.

NOTES

- URIC ACID CAL: Proceed carefully with this product because due its nature it can get contaminated easily.
- Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.
- MONLAB has instruction sheets for several automatic analyzers.**

BIBLIOGRAPHY

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PACKAGING

MO-165103 R1: 1 x 125 mL R2: 1 x 125 mL CAL: 1 x 5 mL	MO-165104 R1: 1 x 500 mL R2: 1 x 500 mL CAL: 1 x 5 mL	MO-165188 R1: 1 x 50 mL R2: 1 x 50 mL CAL: 1 x 2 mL	MO-165231 R1: 2 x 125 mL R2: 2 x 125 mL CAL: 1 x 5 mL
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SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer		For <i>in vitro</i> diagnostic use only
	Don't re-use		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
	Catalogue Code		Temperature limitation
	Lot Number		Use by

