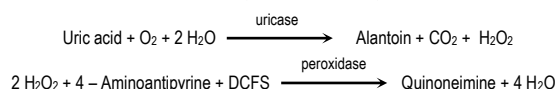




COD 11821 1 x 50 mL	COD 11521 1 x 200 mL	COD 11522 1 x 500 mL	COD 11540 1 x 1 L
STORE AT 2-8°C			
Reagents for measurement of uric acid concentration Only for <i>in vitro</i> use in the clinical laboratory			

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^{1,2}.



CONTENTS

	COD 11821	COD 11521	COD 11522	COD 11540
A. Reagent	1 x 50 mL	1 x 200 mL	1 x 500 mL	1 x 1 L
S. Standard	1 x 5 mL	1 x 5 mL	1 x 5 mL	1 x 5 mL

COMPOSITION

A. Reagent: Phosphate 100 mmol/L, detergent 1.5 g/L, dichlorophenolsulfonate 4 mmol/L, uricase > 0.12 U/mL, ascorbate oxidase > 5 U/mL, peroxidase > 1 U/mL, 4-aminoantipyrine 0.5 mmol/L, pH 7.8.

S. Uric Acid Standard: Uric acid 6 mg/dL (357 µmol/L). Aqueous primary standard.

STORAGE

Store at 2-8°C.

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

Indications of deterioration:

- Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.200 at 520 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C
- Analyzer, spectrophotometer or photometer able to read at 520 ± 20 nm

SAMPLES

Serum, plasma or urine collected by standard procedures. Dilute urine 1/10 with distilled water before measurement

Uric acid in serum or plasma is stable for 7 days at 2-8°C. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

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

PROCEDURE

- Bring the Reagent to room temperature.
- Pipette into labelled test tubes: (Note 1)

	Blank	Standard	Sample
Distilled water	25 µL	—	—
Uric Acid Standard (S)	—	25 µL	—
Sample	—	—	25 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

- Mix thoroughly and incubate the tubes for 10 minutes at room temperature (16-25°C) or for 5 minutes at 37°C.
- Measure the absorbance (A) of the Standard and the Sample at 520 nm against the Blank. The colour is stable for at least 30 minutes.

CALCULATIONS

The uric acid concentration in the sample is calculated using the following general formula:

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} \times \text{Sample dilution factor} = C_{\text{Sample}}$$

If the Uric Acid Standard provided has been used to calibrate (Note 2):

	Serum and plasma	Urine
$\frac{A_{\text{Sample}}}{A_{\text{Standard}}}$	x 6 = mg/dL uric acid x 357 = µmol/L uric acid	x 60 = mg/dL uric acid x 3570 = µmol/L uric acid

REFERENCE VALUES

Serum and plasma³

Men: 3.5-7.2 mg/dL = 210-420 µmol/L

Women: 2.6-6.0 mg/dL = 150-350 µmol/L

Urine³

250-750 mg/24-h = 1.5-4.5 mmol/24-h

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, cod. 18009 and cod. 18042), level II (cod. 18007, cod. 18010 and cod. 18043) and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.02 mg/dL = 1.19 µmol/L
- Linearity limit: 25 mg/dL = 1487 µmol/L. For higher values dilute sample 1/5 with distilled water and repeat measurement.
- Repeatability (within run):

Mean Concentration	CV	n
5.00 mg/dL = 298 µmol/L	0.4 %	20
8.22 mg/dL = 489 µmol/L	0.5 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
5.00 mg/dL = 298 µmol/L	2.1 %	25
8.22 mg/dL = 489 µmol/L	1.9 %	25

- Sensitivity: 33.3 mA·dL/mg = 0.56 mA·L/µmol
- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 2). Details of the comparison experiments are available on request.
- Interferences: Hemolysis (hemoglobin up to 2 g/L), bilirubin (up to 2.5 mg/dL) do not interfere. Lipemia interfere. Ascorbic acid (up to 2.5 mg/dL) does not interfere. Other drugs and substances may interfere⁴.

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

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 may be attributable to an overproduction of urate (increased purine synthesis) or to a defective elimination of urate³.

Hyperuricemia is commonly associated with gout, decreased renal function, dehydration, myeloproliferative disorders, and other conditions not well known^{3,5}.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

- These reagents may be used in several automatic analysers. Specific instructions for application in many of them are available on request.
- Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

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