Uric acid FS*

TOOS

Diagnostic reagent for quantitative in vitro determination of uric acid in serum, plasma or urine on photometric systems

Order Information

Cat. No.	Kit size					
1 3001 99 10 021	R1	4 x	20 mL	+ R2	1 x	20 mL
	+	1 x	3 mL	Standard		
1 3001 99 10 026	R1	5 x	80 mL	+ R2	1 x	100 mL
1 3001 99 10 023	R1	1 x	800 mL	+ R2	1 x	200 mL
1 3001 99 10 704	R1	8 x	50 mL	+ R2	8 x	12.5 mL
1 3001 99 10 917	R1	8 x	60 mL	+ R2	8 x	15 mL
1 3000 99 10 030		6 x	3 mL	Standard		

Summary [1,2]

Uric acid and its salts are end products of the purine metabolism. In gout, the most common complication of hyperuricemia, increased serum levels of uric acid lead to formation of monosodium urate crystals around the joints. Further causes of elevated blood concentrations of uric acid are renal diseases with decreased excretion of waste products, starvation, drug abuse and increased alcohol consume as well as use of certain medicaments. High uric acid levels also constitute an indirect risk factor for coronary heart disease. Hypouricemia is seldom observed and associated with rare hereditary metabolic disorders.

Method

Enzymatic photometric test using TOOS (N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidin)

Principle

Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine and N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidin (TOOS) to a blue violet dye. Ascorbate oxidase avoids interference by ascorbic acid and other reducing substances.

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

$$\text{TOOS} + \text{4-Aminoantipyrine} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Indamine} + 3\,H_2O$$

Reagents

Components and Concentrations

R1:	Phosphate buffer	pH 7.0	100 mmol/L
	TOOS		1.25 mmol/L
	Ascorbate oxidase		≥ 1.2 kU/L
R2:	Phosphate buffer	pH 7.0	100 mmol/L
	4-Aminoantipyrine		1.5 mmol/L
	$K_4[Fe(CN)_6]$		50 µmol/L
	Peroxidase (POD)		≥ 5 kU/L
	Uricase		≥ 250 U/L
Standard:			6 mg/dL (357 µmol/L)

Storage Instructions and Reagent Stability

The reagents and the standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!
Note: It has to be mentioned, that the measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the working reagent is < 0.3 at 546 nm.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Standard and reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma, urine

Stability [3]
in serum/plasma:

6 months	at	–20°C
7 days	at	4 – 8°C
3 days	at	20 – 25°C

Freeze only once!
Discard contaminated specimens.

in urine:

4 days	at	20 – 25°C

Dilute urine 1 + 10 with dist. water and multiply the results by 11.
Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	550 nm, Hg 546 nm
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample or standard
Sample or standard	-	20 µL
Reagent 1	1000 µL	1000 µL
Mix, incubate 5 min., read the absorbance 1 and then add:		
Reagent 2	250 µL	250 µL
Mix, incubate 5 min. at 37°C or 10 min. at 20– 25°C.		
Read the absorbance 2 within 30 min. Pay attention to apply exactly the same incubation time for standard/calibrator, blank and sample.		

ΔA = (A2 – A1) sample or standard

* fluid stable

Calculation

With standard or calibrator

$$\text{Uric acid [mg/dL]} = \frac{\Delta A \ \text{Sample}}{\Delta A \ \text{Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]}$$

Conversion factor

Uric acid [mg/dL] x 59.48 = Uric acid [µmol/L]

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N and P controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range

The test has been developed to determine uric acid concentrations within a measuring range from 0.3 – 20 mg/dL (18 – 1190 µmol/L). When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences

No interference was observed by bilirubin up to 20 mg/dL, hemoglobin up to 400 mg/dL, ascorbic acid up to 30 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection

The lower limit of detection is 0.3 mg/dL (18 µmol/L).

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	3.09	0.05	1.74
Sample 2	6.39	0.03	0.52
Sample 3	10.9	0.04	0.41

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	3.26	0.04	1.31
Sample 2	6.44	0.04	0.56
Sample 3	10.7	0.04	0.39

Method Comparison

A comparison of DiaSys Uric acid FS TOOS (y) with a commercially available test (x) using 107 samples gave following results:
y = 1.04 x + 0.09 mg/dL; r = 0.999

Reference Range

Serum/Plasma

	Female mg/dL (µmol/L)	Male mg/dL (µmol/L)
Adults [4]	2.6 – 6.0 (155 – 357)	3.5 – 7.2 (208 – 428)
Children [5]		
1 – 30 days	1.0 – 4.6 (59 – 271)	1.2 – 3.9 (71 – 230)
31 – 365 days	1.1 – 5.4 (65 – 319)	1.2 – 5.6 (71 – 330)
1 – 3 year(s)	1.8 – 5.0 (106 – 295)	2.1 – 5.6 (124 – 330)
4 – 6 years	2.0 – 5.1 (118 – 301)	1.8 – 5.5 (106 – 325)
7 – 9 years	1.8 – 5.5 (106 – 325)	1.8 – 5.4 (106 – 319)
10 – 12 years	2.5 – 5.9 (148 – 348)	2.2 – 5.8 (130 – 342)
13 – 15 years	2.2 – 6.4 (130 – 378)	3.1 – 7.0 (183 – 413)
16 – 18 years	2.4 – 6.6 (142 – 389)	2.1 – 7.6 (124 – 448)

Urine [1]

≤ 800 mg/24h (4.76 mmol/24h) assuming normal diet
≤ 600 mg/24h (3.57 mmol/24h) assuming low purine diet

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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Manufacturer

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