Uric Acid (TOOS)

DiaSystem Scandinavia AB

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

Order Information

Cat. No.	Kit size						
01 00047 70 04 0100	R1	4 x	20 mL	+	R1	1 x	20 mL
01 00047 70 04 0500	R1	5 x	80 mL	+	R2	1 x	100 mL
CDT-UA	R1	4 x	20 mL	+	R2	2 x	10 mL

06 00118 70 04 0018	Uric Acid Standard 6x3 mL

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. The reagents contain 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., 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 against the reagent blank within 30 min. Pay attention to apply exactly the same incubation time for standard/calibrator, blank and sample.		

ΔA = (A2 – A1) sample or standard

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Calculation

With standard or calibrator

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

Conversion factor

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

Calibrators and Controls

For the calibration of automated photometric systems, DiaSystem UniCal 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 DiaSystem UniLab 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
UniCal CC	06 00122 70 04 0018	6 x 3 mL
UniLab N	07 00123 70 05 0030	6 x 5 mL
UniLab P	07 00124 70 05 0030	6 x 5 mL
UniLab Urine Level 1	07 00125 70 04 0030	6 x 5 mL
UniLab Urine Level 2	07 00126 70 04 0030	6 x 5 mL

Performance Characteristics

Measuring range

The test has been developed to determine uric acid concentrations within a measuring range from 3 – 200 mg/L (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 3 mg/L (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 DiaSystem Uric Acid (TOOS) (y) with a commercially available test (x) using 88 samples gave following results: y = 1.04 x + 0.09 mg/dL; r= 0.999

Reference Range [1,4]

Serum/Plasma

	Female mg/dL (µmol/L)	Male mg/dL (µmol/L)
Adults	2.6–6.0 (155–357)	3.5-7.2 (208-428)
Children		
0 - 30 days	1.0 – 4.6 (59 – 271)	1.2 – 3.9 (71 – 230)
31 - 365days	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

≤ 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

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 208-14.
2. Newman JD, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-70.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001.p. 48-9, 52-3.
4. Newman JD, Price PC. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1250.
5. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals, 6th ed. Washington DC; The American Association for Clinical Chemistry Press, 2007; p. 204-5
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240–1243.

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