

Uric acid FS* TOOS

Order Information

Cat. No.

1 3001 99 10 962

Kit size



1890 (R1: 6 x 315, R2: 6 x 315)

Intended Use

Diagnostic reagent for quantitative in vitro determination of uric acid in human serum, heparin plasma or urine on automated BioMajesty® JCA-BM6010/C.

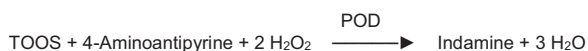
Summary

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. [1,2]

Method

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

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.



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

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Protect from light.

The in-use stability of the reagent is 9 months.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [4]:

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

Only freeze once. Discard contaminated specimens.

Stability in urine [5]:

4 days	at	20 – 25°C
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Dilute urine 1 + 10 with dist. water and multiply results by 11.

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 20 mg/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.24 mg/dL
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences ≤ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	24 mg/dL
Hemoglobin	350 mg/dL
Lipemia (triglycerides)	2000 mg/dL

For further information on interfering substances refer to Young DS [6,7].

Precision (Serum/Plasma)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	3.14	6.20	9.95
CV [%]	0.92	0.47	0.75
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	3.14	5.25	8.64
CV [%]	1.11	1.63	1.36

Method comparison (Serum/Plasma; n=100)	
Test x	Competitor Uric acid
Test y	DiaSys Uric acid FS TOOS
Slope	0.982
Intercept	-0.011 mg/dL
Coefficient of correlation	0.998

Precision (Urine)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	7.36	14.4	22.5
CV [%]	1.19	1.51	1.42
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	7.36	14.4	22.4
CV [%]	2.45	1.44	1.13

Method comparison (Urine; n=100)	
Test x	Competitor Uric acid
Test y	DiaSys Uric acid FS TOOS
Slope	1.01
Intercept	0.488 mg/dL
Coefficient of correlation	0.997

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor

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

Reference Range

Serum/Plasma

	Female		Male	
	[mg/dL]	[µmol/L]	[mg/dL]	[µmol/L]
Adults [8]	2.6 – 6.0	155 – 357	3.5 – 7.2	208 – 428
Children [9]				
1 – 30 day(s)	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

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 208-14.
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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 48-9.
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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.
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9. Soldin SJ, Bruynara C, Wong EC. Pediatric Reference Intervals, 6th ed. Washington DC: The American Association for Clinical Chemistry Press, 2007; p. 204-5.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.



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* Fluid Stable

Uric acid FS TOOS

Chemistry code 10 300

Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.6
Sample vol (U)	1.6
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	UA
Digits	2
M-wave L.	545
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.6	1.6
Diluent method	No dil	With dil
Undil. sample vol.	0	5
Diluent volume	0	50
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999