

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.

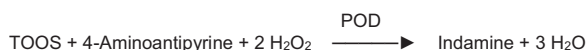
Summary

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 [1,2]. Furthermore, increased concentrations of serum uric acid are associated with the development of hypertension, coronary heart diseases, cerebrovascular accidents, and cardiovascular diseases. Additionally, uric acid levels strongly correlate with an increased risk of cardiovascular disease mortality [3]. On the other hand, a lowered uric acid concentration during hospitalization can be utilized as a prognostic indicator and marker of disease severity in severe COVID-19 patients [4].

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. Do not freeze and protect from light.

The open-vial stability of the reagent is 9 months until expiry date.

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 [5].
- 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 [6]:

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 [6]:

4 days	at	20 – 25°C
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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. All target values of the controls are traceable to DiaSys reagent / calibrator system. 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

Serum/Plasma

Measuring range up to 20 mg/dL, linearity is given within ± 5%. 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

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	5.17
Bilirubin (conjugated)	24 mg/dL	5.17
Bilirubin (unconjugated)	24 mg/dL	5.21
Hemolysis	350 mg/dL	5.77
Lipemia (triglycerides)	2000 mg/dL	5.19

For further information on interfering substances, refer to the literature [7,8].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	3.14	6.20	9.95
CV [%]	0.916	0.471	0.749
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 (n=100)	
Test x	Competitor Uric acid (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Uric acid FS TOOS (BioMajesty® JCA-BM6010/C)
Slope	0.982
Intercept	-0.011 mg/dL
Coefficient of correlation	0.998

Urine

Precision			
Repeatability (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 (n=100)	
Test x	Competitor Uric acid (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Uric acid FS TOOS (BioMajesty® JCA-BM6010/C)
Slope	1.01
Intercept	0.491 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 [2]	2.3 – 6.1	137 – 363	3.6 – 8.2	214 – 488
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 [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 04 09]. Available from: <https://www.clinical-laboratory-diagnostics.com>
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5. 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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7. 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.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in July 2021. Published by AACC Press and John Wiley and Sons, Inc.
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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 / Urine control
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

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.l.	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

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