Uric acid FS* TOOS

Order Information

Cat. No.	Kit size				
1 3001 99 10 021	R1	5 x 20 mL	+	R2	1 x 25 mL
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

Intended Use

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

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 a 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.

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

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

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

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

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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.

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

Dilute urine 1 + 10 with dist. water and multiply results by 11.

Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	545/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.6 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With calibrator

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

Conversion Factor

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

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). Uric acid Standard FS may be used alternatively for calibration. 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
Uric acid Standard FS	1 3000 99 10 030	6	x	3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

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

Measuring range up to 20 mg/dL. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	0.24 mg/dL

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.

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

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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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