respons®910

Uric acid FS* TOOS

Order Information

Cat. No.	Kit size
1 3001 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of uric acid in human serum or heparin plasma on automated DiaSys respons®910.

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. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

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

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

Stability [4]:

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

Only freeze once. 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 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

Performance Characteristics

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

Measuring range up to 25 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**	0.08 mg/dL
Onboard stability	6 weeks
Calibration stability	3 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	7.95
Bilirubin (conjugated)	25 mg/dL	3.55
	25 mg/dL	7.94
Bilirubin (unconjugated)	23 mg/dL	3.66
	23 mg/dL	7.95
Hemoglobin	650 mg/dL	3.30
	650 mg/dL	9.22
Lipemia (triglycerides)	2200 mg/dL	3.26
	2200 mg/dL	8.40
For further information on interfering substances refer to Young DS [6,7].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	3.18	6.41	10.6
CV [%]	1.80	1.91	1.25
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	4.35	6.43	11.0
CV [%]	2.07	2.51	2.04

Method comparison (n=99)	
Test x	DiaSys Uric acid FS (Hitachi 911)
Test y	DiaSys Uric acid FS (respons®910)
Slope	1.01
Intercept	0.054 mg/dL
Coefficient of correlation	0.998

** according to CLSI document EP17-A, Vol. 24, No. 34

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

Reference Range

	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

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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3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.
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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8. 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.
9. Soldin SJ, Brugnara 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.

IVD CE

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* Fluid Stable

respons®910

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Application for serum and plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	UA
Shortcut:	
Reagent barcode reference:	055
Host reference:	055

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(4:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.1000
Concentration technical limits-Upper	20.0000
SERUM	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	6.0
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	6.0
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	6.0
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	6.0
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	6.0
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>=3.50 <=7.20
URINE	
PLASMA	>=3.50 <=7.20
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>=2.60 <=6.00
URINE	
PLASMA	>=2.60 <=6.00
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.004
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value