respons®910

Uric acid FS* TOOS

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

Order Information

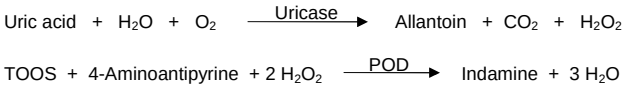
Cat. No. 1 3001 99 10 920
4 twin containers for 200 tests each

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.



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 Instructions and Reagent Stability

The reagents 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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. In very rare cases, samples of patients with gammopathy might give falsified results.
3. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the reference method GC-IDMS gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N and P controls should be assayed. 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

Measuring range up to 20 mg/dL uric acid (in case of higher concentrations re-measure samples after manual dilution or use rerun function).	
Limit of detection**	0.1 mg/dL uric acid
On-board stability	6 weeks
Calibration stability	3 weeks

Interfering substance	Interferences < 10%	Uric acid [mg/dL]
Ascorbate	up to 30 mg/dL	7.95
Hemoglobin	up to 65 mg/dL	3.30
	up to 65 mg/dL	9.22
Bilirubin, conjugated	up to 25 mg/dL	3.55
	up to 25 mg/dL	7.94
Bilirubin, unconjugated	up to 23 mg/dL	3.66
	up to 23 mg/dL	7.95
Lipemia (triglycerides)	up to 2200 mg/dL	3.26
	up to 2200 mg/dL	8.40
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	3.18	6.41	10.6
Coefficient of variation [%]	1.80	1.91	1.25
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	4.35	6.43	11.0
Coefficient of variation [%]	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	1.012
Intercept	0.054 mg/dL
Coefficient of correlation	0.998

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor:

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

Reference Range

	Female mg/dL (µmol/L)	**Male** mg/dL (µmol/L)
Adults [3]	2.6 - 6.0 (155 - 357)	3.5 - 7.2 (208 - 428)
Children [4]		
1 - 30 days	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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 48-9.
2. 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.
3. 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.
4. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals, 6th ed. Washington DC; The American Association for Clinical Chemistry Press, 2007; p. 204-5
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 208-14.
6. Newman DJ, 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.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®910

Uric Acid FS TOOS

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
Name:	UA
Shortcut:	
Reagent barcode reference:	055
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	45
Blanc correction	Yes
Main wavelength:[nm]	546
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(4:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.1
Concentration technical limits-Upper	20
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	Male
Age	
SERUM	>=3.5 <=7.2
URINE	
PLASMA	>=3.5 <=7.2
CSF	
Genre	Female
Age	
SERUM	>=2.6 <=6.0
URINE	
PLASMA	>=2.6 <=6.0
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value