

DIAGNOSTIC KIT FOR DETERMINATION OF URIC ACID CONCENTRATION



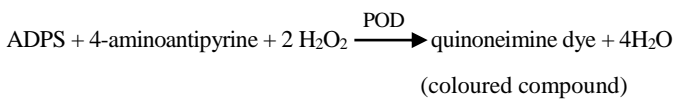
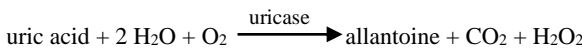
OS – UA

INTRODUCTION

Uric acid is a product of purine catabolism. It is produced in the liver and excreted in the urine. Both, the amount of uric acid production and the efficiency of renal excretion, affect serum urate level. Elevated serum uric acid level is caused usually by gout, leukemia, diabetes mellitus, hyperfunction of parathyroid and thyroid, renal failure, renal calculus. Urate concentration in serum and in urine depends on glomerular filtration, thus is useful for renal function monitoring.

METHOD PRINCIPLE

Enzymatic, colorimetric method with uricase and peroxidase.



The colour intensity is proportional to the uric acid concentration.

REAGENTS

Package	
1-Reagent	2 x 56 ml
2-Reagent	2 x 18.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

buffer PIPES (pH 7.0)	100 mmol/l
4-aminoantipyrine	0.78 mmol/l
ADPS	0.67 mmol/l
ferricyanide potassium	3.8 µmol/l
peroxidase (POD)	> 38.34 µkat/l
uricase	> 1.65 µkat/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- 1-Reagent meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Warning.



H315 Causes skin irritation.
H319 Causes serious eye irritation.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SPECIMEN

Serum, heparinized plasma free from hemolysis.
Do not use EDTA and fluoride as anticoagulants.
Specimen can be stored 3-5 days at 2-8°C or 6 months at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
Olympus OS – UA page 1

For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: 098

Specific Test Parameters									
General		LIH	ISE	Range					
Test name:		UA				Type:	Serum	Operation:	Yes
Sample: Volume	2	µL	Dilution	10	µL	Pre-Dilution Rate:	1		
Reagents: R1 Volume	100	µL	Dilution	50	µL	Min OD		Max OD	
R2 Volume	25	µL	Dilution	10	µL	L	-2.0000	H	2.5000
						Reagent OD Limit:			
Wavelength: Pri.	540		Sec.	700		First L	-2.0000	First H	2.5000
Method:	END					Last L	-2.0000	Last H	2.5000
Reaction Slope:	+					Dynamic Range:			
Measuring Point 1: First	0		Last	27		L	0.42	H	28
Measuring Point 2: First	0		Last	9		Correlation Factor:			
Linearity:		%				A	1.000	B	0.000
No-Lag-Time:						On-board Stability Period:	84		

Specific Test Parameters									
General		LIH	ISE	Range					
Test name:		UA				Type:	Serum		
Value/Flag:		#	Level L:		#	Level H:		#	
Normal Ranges:									
	Sex	Age L	Month	Age H	Month	L	H		
1.	#	#	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#	#	#
7. None Selected						#	#	#	#
8. Out of Range						#	#	#	#
Panic Value:						L	H	Unit:	mg/dl
						#	#	Decimal Places:	1

Calibration Specific									
General		ISE							
Test name:		UA				Type:	Serum		
Calibration Type:		2AB	Formula:	Polygonal	Counts:	3	Process:	CONC	
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H				
Point 1:	#		*	-2.0000	2.5000				
Point 2:	#		*	-2.0000	2.5000				
Point 3:									
Point 4:									
Point 5:									
Point 6:									
Point 7:									
1-Point Cal.Point:			with CONC=0	Slope Check:	None	Advanced Calibration:	#		
MB Type Factor:			Calibration Stability Period:		84				

User defined
* Calibrator value

REFERENCE VALUES ⁵

serum / plasma	mg/dl	µmol/l
females	2.5 – 6.8	149 – 405
males	3.6 – 7.7	214 – 458

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Olympus AU400. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.42mg/dl (24.98 µmol/l).
- **Linearity:** up to 28 mg/dl (1665.44 µmol/l).
- **Specificity / Interferences**
Haemoglobin up to 1.25 g/dl, ascorbate up to 31 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.76	0.05	0.97
level 2	9.38	0.10	1.05

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.38	0.12	2.67
level 2	9.00	0.20	2.21

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 37 samples gave following results:

$$y = 0.9645 x - 7.9916 \mu\text{mol/l};$$

$$R = 0.9724 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Thefeld C. et al.: Dtsch. Med. Wschr. 98, 380-384 (1973).
2. Barham D., Trinder P.: Analyst 97, 142-145 (1972).
3. Fossati P., Prencipe L., Berti G.: Clin. Chem. 26/2, 227-231 (1980).
4. Henry R.J.: Clinical Chemistry, Harper & Row Publishers Inc., New York (1974).
5. Kaplan L.A., Pesce A.J., ed. Chemistry Theory, Analysis, and Correlation, 3rd ed. St Louis, MO: Mosby, 501-2 (1996).
6. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 624, (1995).

Date of issue: 05. 2015.

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05/15/05/15