

PRESTIGE 24i LQ UA

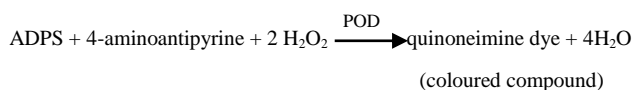
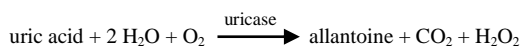
DIAGNOSTIC KIT FOR DETERMINATION OF URIC ACID CONCENTRATION

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

	Cat. No 4-208 (24-TRAY)	Cat. No 4-408 (36-TRAY)
1-Reagent	6 x 40 ml	8 x 23 ml
2-Reagent	6 x 12.5 ml	8 x 7.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Stability on board of the analyser at 2-10°C: Prestige 24i – 12 weeks, Biolis 24i Premium – 12 weeks. 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 Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.
1-Reagent and 2-Reagent are ready to use.
1-Reagent put on basic position in reagent tray.
2-Reagent put on start position in reagent tray.
For reagent blank deionized water is recommended.
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REFERENCE VALUES ⁵

serum / plasma	mg/dl	µmol/l
female	2.5 – 6.8	149 – 405
male	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 (Prestige 24i, Biolis 24i Premium), 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 analysers Prestige 24i and Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity (Prestige 24i):** 0.2 mg/dl (11.9 µmol/l).
Sensitivity (Biolis 24i Premium): 0.31 mg/dl (18.4 µmol/l).
- Linearity (Prestige 24i):** up to 23 mg/dl (1368 µmol/l).
Linearity (Biolis 24i Premium): up to 23 mg/dl (1368 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 (Prestige 24i)**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	2.90	0.09	2.98
level 2	7.39	0.12	1.56

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	3.14	0.05	1.60
level 2	7.83	0.11	1.42

Precision (Biolis 24i Premium)

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.85	0.05	1.03
level 2	8.99	0.09	1.01

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.83	0.07	1.39
level 2	9.03	0.16	1.78

Method comparison

A comparison between uric acid values determined at Prestige 24i (y) and at COBAS INTEGRA 400 (x) using 74 samples gave following results:
y = 0.9579 x + 0.0457 mg/dl;
R = 0.9960 (R – correlation coefficient)

A comparison between uric acid values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 100 samples gave following results:
y = 0.9936 x + 0.1225 mg/dl;
R = 0.9965 (R – 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).

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

Item name	9	UA		
Data information				
Units	mg/dl			
Decimals	1			
Analysis				
Type	END			
Main W.Length1	546			
Sub W.Length2	700			
Method	Uricase			
Calibration				
Type	Linear			
Standard				
#1	*	#4		
#2	*	#5		
#3		#6		
Normal Range				
	Male		Female	
	Low	High	Low	High
Serum	3.6	7.7	2.5	6.8
Urine				
Plasma	3.6	7.7	2.5	6.8
CSF				
Dialysis				
Other				
Corr				
Y=	Slope	X+	Inter	
	1.000		0.000	

Item name	9	UA	
Aspiration			
Kind	Double		
Vol.			
Sample	4	µl	
Reagent1	200		
Reagent2	50		
Data Process			
Read	Start	End	
Main	53	54	
Sub	30	31	
Absorbance Limit			
Low	-0.100		
High	3.000		
Factor			
Blank correction	0.80314		
Endpoint Limit	2.000		
Linear Check (%)			
Dilution			
Diluent	100:Dil2		
Monitor			
0 Level Point	1		
Span	3.000		
Prozone Check			
	Start	End	Limit (%)
First			
Second			Low
Third			Low

Item name	9	UA
Auto Rerun SW		
ON		
Auto Rerun Condition (Absorbance)		
Absorbance Range	Lower	Higher
	OFF	OFF
Auto Rerun Range (Result)		
	ON	ON
	Lower	Higher
Serum	0.2	23
Urine		
Plasma		
CSF		
Dialysis		
Other		
Prozone Range		
	OFF	

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

Item No.	9	Item Name	UA	Optical	
Data information					
Units	mg/dl				
Decimals	1				
Calibration					
Type	Linear2				
Std sample conc.					
Blank	0	#1	*	#2	*
#3		#4		#5	
#6					
Analysis					
Type	END method				
Main Wave Length	546nm				
Sub Wave Length	700nm				
Method	Uricase				
Correlation					
	Slope		Intercept		
Y=	1	X+	0		

Item No.	9	Item Name	UA	Optical
Aspiration				
Kind	Double			
Vol.				
Kind	Vol.	Add	Units	
Sample	4	5	µl	
Reagent 1	160	10	µl	
Reagent 2	40	10	µl	
Data Process				
Read	Start	End		
Main	51	52		
Sub	30	31		
Abs.Limit				
	Low	High		
	-0.1	3		
Blank value				
Water Blank				
Correction value				
Blank correction				
End Point Limit				
2				
Linear Check (%)				
Reaction Monitor				
0 Level Point				
1				
Span				
3				
Third mixing				
OFF				
Prozone Check				
	Start	End	Limit (%)	
First				
Second			Low	

Item No.	9	Item Name	UA	Optical
Normal Range				
	Male		Female	
	Low	High	Low	High
Serum	3.6	7.7	2.5	6.8
Urine				
Plasma	3.6	7.7	2.5	6.8
CSF				
Dialysis				
Other				
Panic Range				
	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	9	Item Name	UA	Optical			
Auto Rerun SW							
ON							
Auto Rerun Condition (Absorbance)							
	Lower	Higher					
	OFF	OFF					
Auto Rerun Range (Conc.)							
	First Dil	Low		High			
		Re	Value	Dil	Re	Value	Dil
Serum			0.31			23	
Urine							
Plasma							
CSF							
Dialysis							
Other							
Auto Rerun Condition (Prozone)							
OFF							
Dilution							
100:Dil2							

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MANUFACTURER

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