Cat. No 4-208 and 4-408

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 calculosis. 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.

$$\text{uric acid} + 2\,H_2O + O_2 \xrightarrow{\text{uricase}} \text{allantoine} + CO_2 + H_2O_2$$

$$\text{ADPS} + \text{4-aminoantipyrine} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{quinoneimine dye} + 4H_2O$$

(coloured compound)

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 2-8ºC or 6 months at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
These reagents may be used in automatic analysers 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.

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**

Corr

Slope		Inter
Y= **1.000**	X+	**0.000**

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				

Item name	9	UA

Aspiration

Kind	**Double**

	Volume	
Sample	**4**	µl
Reagent1	**200**	
Reagent2	**50**	

Third Mix.	**OFF**
R1 Blank	**Water-Blank**

Monitor

0 Level Point	**1**
Span	**3.000**

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**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**
Third				**Low**

Item name	9	UA

Auto Rerun SW

ON

Auto Rerun Range (Result)

	ON Lower	**ON** Higher
Serum	**0.2**	**23**
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range	
Lower	**OFF**
Higher	**OFF**

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**

Analysis

Type	**END method**
Main Wave Length	**546nm**
Sub Wave Length	**700nm**
Method	**Uricase**

Correlation

Slope		Intercept
Y= **1**	X+	**0**

Calibration

Type	**Linear2**					
Std sample conc.						
Blank	**0**	#1	*	#2	*	
#3		#4		#5		
#6						

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

Blank value

Water Blank

Reaction Monitor

0 Level Point	**1**
Span	**3**

Third mixing

OFF

Data Process

Read		Start	End
	Main	**51**	**52**
	Sub	**30**	**31**

Abs.Limit Low **-0.1** ~ High **3**

Correction value

Blank correction	
End Point Limit	**2**
Linear Check (%)	

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 Range (Conc.)

	First Dil	Low Re	Low Value	Low Dil	High Re	High Value	High Dil
Serum			**0.31**			**23**	
Urine							
Plasma							
CSF							
Dialysis							
Other							

Auto Rerun Condition (Absorbance)

Lower	**OFF**
Higher	**OFF**

Auto Rerun Condition (Prozone)

OFF

Dilution

100:Dil2

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MANUFACTURER

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