

## PRESTIGE 24i LQ UA PLUS

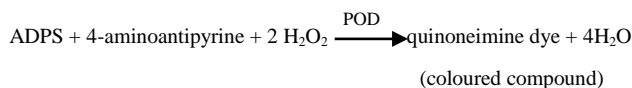
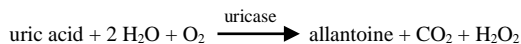
### DIAGNOSTIC KIT WITH ASCORBATE OXIDASE FOR DETERMINATION OF URIC ACID CONCENTRATION

#### 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 4-209 (24-TRAY)	Cat. No 4-409 (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
ascorbate oxidase	> 66.7 µkat/l
sodium hydroxide	< 1 %

#### 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

24- hours urine, serum, heparinized plasma free from hemolysis.

Do not use EDTA, fluoride and oxalate as anticoagulants!

Urine preparation: To prevent precipitation of salts of uric acid, 10 ml of NaOH (500 g/L) should be added to the collection bottle before collection of a 24-hour specimen. Urine should be diluted with distilled water in the ratio of 1 to 4 (multiply the result by 5).

Serum and plasma can be stored 3-5 days at 2-8°C or 6 months at -20°C. 24-hours urine samples can be stored approximately 3 days at room temperature.

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 <sup>5</sup>

serum / plasma	mg/dl	µmol/l
females	2.5 – 6.8	149 – 405
males	3.6 – 7.7	214 – 458
24-hours urine	mg/24h	mmol/24h
	250 – 750	1.49 – 4.46

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) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine 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 analyser Prestige 24i. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity (serum / plasma):** 0.16 mg/dl (9.52 µmol/l).  
**Sensitivity (urine):** 0.18 mg/dl (10.71 µmol/l).
- Linearity (serum / plasma):** up to 32 mg/dl (1903 µmol/l).  
**Linearity (urine):** up to 67 mg/dl (3985 µmol/l).  
For higher concentration of uric acid in serum or plasma, dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- Specificity / Interferences**  
Haemoglobin up to 1.25 g/dl, ascorbate up to 62 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	4.81	0.03	0.61
level 2	9.18	0.06	0.70

#### Method comparison

A comparison between uric acid values determined at Prestige 24i (y) and at COBAS INTEGRA 400 (x) using 60 serum samples gave following results:

$$y = 0.9909x + 0.1649 \text{ mg/dl};$$

$$R = 0.9970 \quad (R - \text{correlation coefficient})$$

A comparison between uric acid values determined at Prestige 24i (y) and at ADVIA 1650 (x) using 84 urine samples gave following results:

$$y = 0.9161x + 0.4401 \text{ mg/dl};$$

$$R = 0.9939 \quad (R - \text{correlation coefficient})$$

These metrological characteristics have been obtained using the automatic analyser Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity (serum / plasma):** 0.21 mg/dl (12.49 µmol/l).  
**Sensitivity (urine):** 0.71 mg/dl (42.23 µmol/l).

- **Linearity (serum / plasma):** up to 29 mg/dl (1725 µmol/l).  
**Linearity (urine):** up to 67 mg/dl (3985 µmol/l).  
For higher concentration of uric acid in serum or plasma, dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**  
Haemoglobin up to 1.25 g/dl, ascorbate up to 62 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	4.95	0.04	0.73
level 2	8.67	0.14	1.63

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.74	0.23	4.75
level 2	8.85	0.19	2.20

A comparison between uric acid values determined at Biolis 24i Premium (y) and at COBAS INTEGRA 400 (x) using 41 serum samples gave following results:

$$y = 0.9804x + 0.0771 \text{ mg/dl};$$

$$R = 0.9971 \quad (R - \text{correlation coefficient})$$

A comparison between uric acid values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 83 urine samples gave following results:

$$y = 0.9154x + 0.8018 \text{ mg/dl};$$

$$R = 0.9953 \quad (R - \text{correlation coefficient})$$

**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).

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

Item name	48	UA plus		
<b>Data information</b>				
Units	mg/dl			
Decimals	1			
<b>Analysis</b>				
Type	END			
Main W.Length1	546			
Sub W.Length2	700			
Method	Uricase			
<b>Corr</b>				
Y=	Slope	X+ Inter		
	1.000	0.000		
<b>Calibration</b>				
Type	Linear			
Standard				
#1	*	#4		
#2	*	#5		
#3		#6		
<b>Normal Range</b>				
	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	48	UA plus	
<b>Aspiration</b>			
Kind	Double		
<b>Data Process</b>			
Read	Start	End	
Main	53	54	
Sub	30	31	
<b>Absorbance Limit</b>			
Low	-0.100		
High	3.000		
<b>Factor</b>			
Blank correction	1.0000	Endpoint Limit	
		2.000	
<b>Dilution</b>			
Diluent	100:Di12		
<b>Prozone Check</b>			
	Start	End	Limit (%)
First			
Second			Low
Third			Low
<b>Monitor</b>			
0 Level Point	1		
Span	3.000		
<b>Third Mix.</b>			
R1 Blank	Water-Blank		

Item name	48	UA plus
<b>Auto Rerun SW</b>		
ON		
<b>Auto Rerun Range (Result)</b>		
	ON	ON
	Lower	Higher
Serum	0.16	23
Urine	0.18	67
Plasma	0.16	32
CSF		
Dialysis		
Other		
<b>Auto Rerun Condition (Absorbance)</b>		
Absorbance Range		
Lower	OFF	
Higher	OFF	
Prozone Range		OFF

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

Item No.	48	Item Name	UA plus	Optical
<b>Data information</b>				
Units	mg/dl			
Decimals	1			
<b>Analysis</b>				
Type	END method			
Main Wave Length	546nm			
Sub Wave Length	700nm			
Method	Uricase			
<b>Correlation</b>				
Y=	Slope	X+	Intercept	
	1	0		
<b>Calibration</b>				
Type	Linear2			
Std sample conc.				
Blank	0	#1	*	#2 *
#3		#4		#5
#6				

Item No.	48	Item Name	UA plus	Optical
<b>Aspiration</b>				
Kind	Double			
<b>Data Process</b>				
Read	Start	End		
Main	51	52		
Sub	30	31		
<b>Vol.</b>				
	Kind	Vol.	Add	Units
Sample	4	5		µl
Reagent 1	160	10		µl
Reagent 2	40	10		µl
<b>Abs.Limit</b>				
	Low	High		
	-0.1	3		
<b>Blank value</b>				
Water Blank				
<b>Correction value</b>				
Blank correction				
End Point Limit				
2				
Linear Check (%)				
<b>Prozone Check</b>				
	Start	End	Limit (%)	
First				
Second			Low	
<b>Reaction Monitor</b>				
0 Level Point				
1				
Span				
3				
<b>Third mixing</b>				
OFF				

Item No.	48	Item Name	UA plus	Optical
<b>Normal Range</b>				
	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				
<b>Panic Range</b>				
	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	48	Item Name	UA plus	Optical
<b>Auto Rerun SW</b>				
ON				
<b>Auto Rerun Range (Conc.)</b>				
	First Dil	Low		High
		Re	Value	Dil
Serum			0.21	29
Urine			0.71	67
Plasma			0.21	29
CSF				
Dialysis				
Other				
<b>Auto Rerun Condition (Absorbance)</b>				
Lower		OFF		
Higher		OFF		
<b>Auto Rerun Condition (Prozone)</b>				
OFF				
<b>Dilution</b>				
100:Di12				

Date of issue: 06. 2015.

**MANUFACTURER**

**PZ CORMAY S.A.**  
22 Wiosenna Street,  
05-092 Lomianki, POLAND  
tel.: +48 (0) 22 751 79 10  
fax: +48 (0) 22 751 79 14  
<http://www.cormay.pl>