Cat. No 9-409

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 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

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 2-8ºC 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 Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.

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 Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

	L	H		
Panic Value:	#	#	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 µmol/l;
R = 0.9724 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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