Cat. No 4-508

DIAGNOSTIC KIT FOR DETERMINATION OF URIC ACID CONCENTRATION

CE CORMAY

HC – 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.

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

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

(coloured compound)

The colour intensity is proportional to the uric acid concentration.

REAGENTS

Package

1-Reagent	6 x 78.5 ml
2-Reagent	6 x 20 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 < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.
- 1-Reagent is classified as an irritant!

Ingredients: Contains sodium hydroxide.

Xi – Irritating.
R 36/38: Irritating to eyes and skin.
S 26-28-45: In case of contact with eyes, rinse immediately with plenty of water and see medical advice. After contact with skin, wash immediately with plenty of water. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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. **Calibrators and 0.9% NaCl** should be used for calibration.
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 Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.3 mg/dl (17.84 µmol/l).
- **Linearity:** up to 26 mg/dl (1468.48 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	3.87	0.05	1.18
level 2	13.05	0.09	0.71

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.84	0.05	1.07
level 2	9.03	0.07	0.82

- **Method comparison**

A comparison between uric acid values determined at Hitachi 912 (y) and at Cobas Integra 400 (x) using 50 samples gave following results:
y = 0.9497 x + 0.1317 mg/dl;
R = 0.9922 (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).

Date of issue: 05. 2012.

MANUFACTURER

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

05/12/05/12