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CE CORMAY

UA

Kit name	(EN) Cat. No
Liquick Cor-UA 30	2-235
Liquick Cor-UA 60	2-208
Liquick Cor-UA 120	2-209
ACCENT-200 UA	7-208
PRESTIGE 24i LQ UA	4-408
OS-UA	9-409

INTENDED USE
Diagnostic kit with ascorbate oxidase for determination of uric acid concentration used both for manual assay (Sample Start and Reagent Start method) and in several automatic analysers.
The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

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

	Liquick Cor-UA 30	Liquick Cor-UA 60	Liquick Cor-UA 120
1-UA	5 x 24 ml	5 x 48 ml	5 x 96 ml
2-UA	1 x 30 ml	1 x 60 ml	1 x 120 ml
3-STANDARD	1 x 2 ml	-	-

	ACCENT-200 UA	PRESTIGE 24i LQ UA	OS-UA
1-REAGENT	2 x 30 ml	8 x 23 ml	2 x 56 ml
2-REAGENT	1 x 15 ml	8 x 7.5 ml	2 x 18.5 ml

3-STANDARD is uric acid standard solution: 300 µmol/l (5.05 mg/dl).

The reagents when stored at 2-8°C are stable up to expiry date printed on the package.

Working reagent preparation and stability
Assay can be performed with use of separate 1-UA and 2-UA reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of 1-UA with 1 part of 2-UA. Avoid foaming.

Stability of working reagent: 3 months at 2-8°C
2 weeks at 15-25°C

Concentrations in the reagent
1-Reagent

ascorbate oxidase	≤ 104 µkat/l
peroxidase (POD)	≤ 22.4 µkat/l
4-aminoantipyrine	≤ 1.2 mmol/l
sodium hydroxide	≤ 0.8 %
buffer PIPES (pH 7.0)	≤ 120 mmol/l
stabilizers, preservatives, detergent	

2-Reagent

buffer PIPES (pH 7.0)	≤ 60 mmol/l
ADPS	≤ 2 mmol/l
uricase	≤ 9.9 µkat/l
ferricyanide potassium	≤ 22.8 µmol/l
sodium hydroxide	≤ 0.4 %
stabilizers, preservatives, detergent	

Warnings and notes
- Protect from direct sunlight and avoid contamination!
- Please refer to the MSDS for detailed information concerning safe storage and use of the product.
- 1-UA 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 2-8ºC or 6 months at -20ºC. 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!

ADDITIONAL EQUIPMENT
- automatic analyzer or photometer able to read at 546 nm (Hg 530-550 nm);
- thermostat at 25°C or 37ºC;
- general laboratory equipment;

PROCEDURE
Applications for analyzers are available on request.

Manual procedure

Wavelength	546 nm (Hg 530-550 nm)
Temperature	25ºC / 37°C
Cuvette	1 cm

Sample Start method
Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
working reagent	1000 µl	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

standard	-	-	20 µl
sample	-	20 µl	-

Mix well, incubate for 10 min. at 25°C or 5 min. at 37°C. Read the absorbance of the test A(T) and standard A(S) against reagent blank (RB).

Reagent Start method
The determination can be also performed with use of separate 1-UA and 2-UA reagents.

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-UA	1000 µl	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

standard	-	-	20 µl
sample	-	20 µl	-

Mix well, incubate for 5 min. Then add:

2-UA	250 µl	250 µl	250 µl

Mix well; perform measurement as described for Sample Start method.

Calculation

$$\text{uric acid concentration} = \frac{A(T)}{A(S)} \times \text{standard concentration}$$

REFERENCE VALUES [5]

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, with each batch of samples, 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.
For calibration when using the manual methods URIC ACID STANDARD 5 (Cat. No 5-125) is recommended.
For calibration of the automatic analysers systems 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 with every change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
The following results have been obtained using a Multi + analyser for manual assay (Sample Start method) and/or an the automatic analyser Biolis 30i. Results may vary if a different instrument or a manual procedure is used.

- **LoB (Limit of Blank):**
  0.04 mg/dl (2.38 µmol/l) – Biolis 30i
- **LoD (Limit of Detection):**
  0.09 mg/dl (5.35 µmol/l) – Biolis 30i
- **LoQ (Limit of Quantitation):**
  0.3 mg/dl (17.84 µmol/l) – serum/plasma – Biolis30i
  0.14 mg/dl (8.33 µmol/l) – urine – Biolis30i
  0.6 mg/dl (35.69 µmol/l – serum/plasma – Multi+
- **Linearity:**
  up to 40 mg/dl (2379.2 µmol/l) – serum/plasma – Biolis 30i
  up to 56 mg/dl (3330.88 µmol/l) – urine – Biolis 30i
  up to 36 mg/dl (2141.28 µmol/l) – serum/plasma – Multi+

For higher concentration, 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 5 g/dl, ascorbate up to 30 mg/dl for determinations in serum, ascorbate up to 50 mg/dl for determinations in urine, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision (Multi+)**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	5.47	0.16	2.8
level 2	9.75	0.29	3.0

- **Precision (Biolis 30i)**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.87	0.06	1.27
level 2	9.35	0.06	0.67
Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.86	0.07	1.5
level 2	9.19	0.12	1.3

- **Method comparison**

A comparison between uric acid values determined at **Biolis 30i** (y) and at **BECKMAN COULTER AU680** (x) using 60 serum samples gave following results:
y = 0.973 x + 0.386 mg/dl;
R = 0.999 (R – correlation coefficient)

A comparison between uric acid values determined at **Biolis 30i** (y) and at **BECKMAN COULTER AU680** (x) using 34 plasma samples gave following results:
y = 0.9416 x + 0.4715 mg/dl;
R = 0.995 (R – correlation coefficient)

A comparison between uric acid values determined at **Biolis 30i** (y) and at **BECKMAN COULTER AU680** (x) using 30 urine samples gave following results:
y = 1.0126 x – 0.1377 mg/dl;
R = 0.997 (R – correlation coefficient)

A comparison between uric acid values determined at **Multi+**(y) and at **BECKMAN COULTER AU680** (x) using 21 serum samples gave following results:
y = 1.0227 x + 0.1646
R = 0.995 (R – correlation coefficient)

TRACEABILITY
URIC ACID STANDARD 5 is traceable to the SRM 1950/ 909C reference material.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE
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