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Liquick- Cor UA PLUS

Kit name	**Cat. No**
Liquick Cor-UA mini PLUS	2-225
Liquick Cor-UA 30 PLUS	2-260
Liquick Cor-UA 60 PLUS	2-258
Liquick Cor-UA 120 PLUS	2-259

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 mini PLUS	**Liquick Cor-UA 30 PLUS**	**Liquick Cor-UA 60 PLUS**	**Liquick Cor-UA 120 PLUS**
1-UA PLUS	2 x 24 ml	5 x 24 ml	5 x 48 ml	5 x 96 ml
2-UA PLUS	1 x 12 ml	1 x 30 ml	1 x 60 ml	1 x 120 ml
3-STANDARD	1 x 1 ml	1 x 2 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. The reagents are stable for 12 weeks on board the analyser at 2-10°C.

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

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

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
- Protect from light and avoid contamination!
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- 1-UA PLUS 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 them 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 PLUS and 2-UA PLUS reagents.

Pipette into the cuvettes:

	reagent blank (RB)	test (T)	standard (S)
1-UA PLUS	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 PLUS	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 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 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 and 5-176) and LEVEL 2 (Cat. No 5-175 and 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 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 29.0 mg/dl (1725 µmol/l).
  Linearity (urine): up to 67.0 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

- **Method comparison**

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 = 0.9804 x + 0.0771 mg/dl;
R = 0.9971 (R – 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 = 0.9154 x + 0.8018 mg/dl;
R = 0.9953 (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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