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Liquick Cor-UREA

Kit name	**(EN) Cat. No**
Liquick Cor-UREA mini	2-223
Liquick Cor-UREA 30	2-261
Liquick Cor-UREA 60	2-206
Liquick Cor-UREA 120	2-207

INTENDED USE

Diagnostic kit for determination of urea concentration intended to use both for manual assay (Sample Start and Reagent Start method) and in several automatic analyzers.

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

Urea is a product of amino acids catabolism. It is produced in liver and excreted in urine. Urea in the blood is reported as the blood urea nitrogen (BUN). Increased urea concentration in the serum, called uremia, is observed due to dehydration, renal failure, high-protein diet, increased protein catabolism caused by tissue injury or massive bleeding into the alimentary tract. The reason of reduced urea level could be overhydration, low-protein diet or starvation and severe liver disease.

METHOD PRINCIPLE

Kinetic, enzymatic method with urease and glutamate dehydrogenase.

$$\text{urea} + 2\,H_2O \xrightarrow{\text{urease}} 2\,NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \text{2-oxoglutarate} + NADH \xrightarrow{GLDH} \text{L-glutamate} + NAD^+ + H_2O$$

The rate of absorbance changing at λ=340 nm is proportional to the urea concentration.

REAGENTS

Package

	Liquick Cor-UREA mini	**Liquick Cor-UREA 30**	**Liquick Cor-UREA 60**	**Liquick Cor-UREA 120**
1-UREA	2 x 24 ml	5 x 24 ml	5 x 48 ml	5 x 96 ml
2-UREA	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 urea standard solution: 7.13 mmol/l (42.8 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 8 weeks on board the analyzer at 2-10°C.

Working reagent preparation and stability

Assay can be performed with use of separate 1-UREA and 2-UREA reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of 1-UREA with 1 part of 2-UREA. The working reagent should be prepared at least 30 min before use. Avoid foaming.

Stability of working reagent: 4 weeks at 2-8°C
5 days at 15-25°C

Protect from light and avoid contamination!

Concentrations in the test

Tris (pH 7.8)	96 mmol/l
ADP	0.6 mmol/l
urease	266.7 µkat/l
GLDH	16 µkat/l
NADH	0.26 mmol/l
2-oxoglutarate	9 mmol/l

Warnings and notes

- Protect from light and avoid contamination!
- The reagents are usable when the absorbance of the working reagent is higher than 1.200 (read against distilled water, wavelength λ=340 nm, cuvette l = 1 cm, at temp. 25°C).
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 340 nm (Hg 334 nm, 365 nm);
- thermostat at 25°C or 30°C or 37°C;
- general laboratory equipment;

SPECIMEN

Serum, EDTA or heparinized plasma free from hemolysis, 24-hours urine.

Do not use heparine ammonium salt and fluoride as anticoagulants.

Urine preparation: before analysis urine sample should be diluted 100-fold with 0.9% NaCl, and the results multiplied by 100. Mix well probes before measurement. 24-hours urine samples should be kept at 2-8ºC preserved by maintenance of pH less than 4.

Specimen can be stored up to 7 days at 2-8ºC.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

Applications for them are available on request.

Manual procedure

wavelength	340 nm (Hg 334 nm, 365 nm)
temperature	25ºC / 30°C / 37°C
cuvette	1 cm

Sample Start method

Pipette into the cuvettes:

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

Bring up to the temperature of determination. Then add:

standard / calibrator	-	10 µl
sample	10 µl	-

Mix well, after about 1 min. (25/30°C) or 30-40 sec. (37°C) read the absorbance A1 of the test (T) and standard (S) against air or water. After exactly 1 min. (for all temperature) read the absorbance A2 of the test (T) and standard (S). Calculate ΔA/min. (A1 - A2) for the test and standard.

Reagent Start method

The determination can be also performed with use of separate 1-UREA and 2-UREA reagents.

Pipette into the cuvettes:

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

Bring up to the temperature of determination. Then add:

standard / calibrator	-	-	10 µl
sample	-	10 µl	-

Mix well, incubate for 5 min. Then add:

2-UREA	250 µl	250 µl	250 µl

Mix well, after about 1 min. (25/30°C) or 30-40 sec. (37°C) read the absorbance A1 of test (T), standard (S) against reagent blank. After exactly 1 min. (for all temperature) read the absorbance A2 of test (T), standard (S) against reagent blank. Calculate ΔA/min. (A1 - A2) for test and standard.

Calculation

$$\text{urea concentration} = \frac{\Delta A(T)}{\Delta A(S)} \times \text{standard / calibrator concentration}$$

REFERENCE VALUES [8]

serum / plasma	mg/dl	mmol/l
	< 50	< 8.3
24-hours urine	g/24h	mmol/24h
	20 – 35	300 – 550

1 mg of urea corresponds to 0.467 mg of urea nitrogen.

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 following controls for each batch of samples:

CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum;

CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) or LEVEL 2 (Cat. No 5-162) for determination in urine.

For calibration when using the manual methods the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176), LEVEL 2 (Cat. No 5-175; 5-177) or UREA STANDARD 42 (Cat. No 5-128), UREA STANDARD 85 (Cat. No 5-129).

For calibration of the automatic analyzers 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 7 weeks, with 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 automatic analyzer Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 3.31 mg/dl (0.55 mmol/l).
- **Linearity:** up to 300 mg/dl (50 mmol/l).
- **Specificity / Interferences**

Haemoglobin up to 5 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	33.16	0.38	1.14
level 2	101.64	1.68	1.65
Reproducibility (day to day) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	36.35	0.84	2.31
level 2	105.60	1.01	0.95

- **Method comparison**

A comparison between urea values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 100 samples gave following results:

y = 1.0141 x - 0.2878 mg/dl;

R = 0.9968 (R – correlation coefficient)

TRACEABILITY

UREA STANDARD 42 and UREA STANDARD 85 are traceable to the SRM 1950 / 909C reference material.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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