Liquick Cor-CREATININE

DIAGNOSTIC KIT FOR DETERMINATION OF CREATININE CONCENTRATION

Kit name	Cat. No
Liquick Cor-CREATININE 500	2-299
Liquick Cor-CREATININE "bulk"	2-276

INTRODUCTION

Creatinine is a product of creatine nonenzymatic dehydration in skeletal muscle. The amount of creatinine generated and excreted by kidney is proportional to muscle mass and usually is higher in men than women. Daily creatinine generation remains fairly constant, with the exception of crushing injury or degenerative diseases that cause massive damage to muscle. Creatinine blood and urine level depends on glomelural filtration so creatinine clearance is excellent index of renal function.

METHOD PRINCIPLE

Modificated Jaffe's method, without deproteinization. In alkaline solution picrate reacts with creatinine to form a yellow-red 2,4,6-trinitrocyclohexadienate. The colour intensity is proportional to the creatinine concentration.

REAGENTS

Package

	Liquick Cor-CREATININE 500	Liquick Cor-CREATININE "bulk"
1-CREATININE	3 x 400 ml	--*
2-CREATININE	1 x 300 ml	--*

*reagent volume is printed on the label.

The reagents when stored at 15-25°C are stable up to expiry date printed on the package. The reagents are stable for 2 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Working reagent preparation and stability

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

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

Working reagent should be stored in tightly closed vials. If stored in open vial, it is stable for 1 day at 15-25°C! Protect from light and avoid contamination!

Concentrations in the test

sodium hydroxide	300 mmol/l
carbonate buffer	100 mmol/l
picric acid	6.5 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents are usable when the absorbance of the working reagent is less than 0.750 (read against distilled water, wavelength λ = 500 nm, cuvette l = 1 cm, at temp. 25°C).
- 1-CREATININE and 2- CREATININE meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

1- CREATININE contains sodium hydroxide.
2- CREATININE contains picric acid.

Danger.
H314 Causes severe skin burns and eye damage.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 500 nm (492 nm);
- thermostat at 25ºC;
- general laboratory equipment;

SPECIMEN

Serum, EDTA or heparinized plasma free from hemolysis, 24-hours urine.
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.
Specimen can be stored up to 7 days at 2-8ºC. For longer storage samples should be frozen at -20ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used both for manual assay (Sample Start and Reagent Start method) and in several automatic analysers. Applications for them are available on request.

Manual procedure

wavelength	500 nm (492 nm)
temperature	25°C
cuvette	1 cm
reaction type	Fixed time

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	-	100 µl
sample	100 µl	-

Mix well and after exactly 30 sec read absorbance A1 of the test (T) and standard (S) against air. After next 60 sec repeat absorbance reading (A2) and calculate ΔA (A2 – A1) for the test and standard.

Reagent Start method

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

Pipette into the cuvettes:

	test (T)	standard (S)
1-CREATININE	1000 µl	1000 µl

Bring up to the temperature of determination. Then add:

standard	-	100 µl
sample	100 µl	-

Mix well, then add:

2-CREATININE	250 µl	250 µl

Mix well and after exactly 30 sec read absorbance A1 of the test (T) and standard (S) against air. After next 60 sec repeat absorbance reading (A2) and calculate ΔA (A2 – A1) for the test and standard.

Calculation

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

REFERENCE VALUES [7]

serum / plasma	mg/dl	µmol/l
female	0.6 – 1.1	53 – 97
male	0.7 – 1.3	62 – 115
24-hours urine	mg/kg/24h	µmol/kg/24h
female	11 – 20	97 – 177
male	14 – 26	124 – 230

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) or LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.

For calibration when using the manual methods CREATININE STANDARD 2 (Cat. No 5-123) or CREATININE STANDARD 5 (Cat. No 5-124) 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 week, 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:** 0.09 mg/dl (7.96 µmol/l).

- **Linearity:** up to 20 mg/dl (1770 µmol/l).
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 2.5 g/dl, triglycerides up to 500 mg/dl, ascorbate up to 62 mg/l and bilirubin up to 20 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	0.57	0.02	3.73
level 2	5.08	0.08	1.55

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	0.59	0.02	3.82
level 2	5.16	0.18	3.52

- **Method comparison**

A comparison between creatinine values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 54 samples gave following results:

y = 1.1062 x - 0.1435 mg/dl;

R = 0.9994 (R – correlation coefficient)

TRACEABILITY

CREATININE STANDARD 2 and CREATININE STANDARD 5 are traceable to the SRM 909B reference material.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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