Liquick Cor-CK

DIAGNOSTIC KIT FOR DETERMINATION OF CREATINE KINASE ACTIVITY

Kit name	Cat. No
Liquick Cor-CK 500	1-319
Liquick Cor-CK "bulk"	1-288

INTRODUCTION

Creatine kinase (CK) catalyzes the transfer of phosphate group between creatine phosphate and adenosine diphosphate (ADP). The product of this reaction is adenosine triphosphate (ATP) – molecular source of energy. CK is a dimmer, composed of two different subunits called M and B. Three different isoenzymes formed from these subunits are found in brain and smooth muscle (BB), skeletal muscle (MM) and cardiac muscle (MM and MB). Increased level of CK is usually the result of muscle injury, myocardial or pulmonary infarction.

METHOD PRINCIPLE

Optimized kinetic method according to International Federation of Clinical Chemistry (IFCC).

creatine phosphate + ADP $\xleftrightarrow{CK}$ creatine + ATP

ATP + glucose $\xleftrightarrow{HK}$ ADP + glucose-6-P

glucose-6-P + NADP $\xleftrightarrow{G6P\text{-}DH}$ gluconate-6-P + NADPH + H^+

The rate of absorbance changes at λ=340 nm is directly proportional to creatine kinase activity.

REAGENTS

Package

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

*****reagent volume is printed on the label

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 4 weeks on board the analyser at 2-10°C. Do not freeze reagents. Protect from light and avoid contamination!

Working reagent preparation and stability

Assay can be performed with use of separate 1-CK and 2-CK reagents or with use of working reagent. For working reagent preparation mix gently **5 parts** of 1-CK with **1 part** of 2-CK. Avoid foaming!

Stability of working reagent: 4 days at 2-8°C

Protect from light and avoid contamination!

Concentrations in the test

1-CK	
imidazole buffer	100 mmol/l
glucose	20 mmol/l
N-acetylcysteine	20 mmol/l
magnesium acetate	10 mmol/l
EDTA	2 mmol/l
NADP	2 mmol/l
ADP	2 mmol/l
AMP	5 mmol/l
HK	> 2.5 U/ml
2-CK	
diadenosinepentaphosphate	10 µmol/l
glucose-6-phosphate-dehydrogenase (G6P-DH)	> 1.5 U/ml
creatine phosphate	30 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes
- Do not use reagents past the expiry date.
- Do not interchange caps among reagents.
- 1-CK meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

1-CK contains imidazole.

Danger

H360 May damage fertility or the unborn child.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of the contents/containers in accordance with the current legislation on waste treatment.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 340 nm (334/365 nm); with resolving power of absorbance 0.0001;
- thermostat at 37ºC;
- general laboratory equipment;

SPECIMEN

Serum, free from hemolysis.

CK activity is unstable and is rapidly lost during storage. Probes should be stored tightly closed and protected from light.

Specimens can be stored up to 4-8 hours at 15-25 ºC or 1-2 days at 2-8ºC or 1 month 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	340 nm (365 nm / 334 nm)
temperature	37°C
cuvette	1 cm

Sample Start method

Pipette into the cuvettes:

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

Bring up to the temperature of determination. Then add:

sample	-	-	40 µl
calibrator	-	40 µl	-

Mix and incubate at adequate temperature (37 ºC). After about 2 min. read the absorbance A of standard sample A(S) and test sample A(T) against reagent blank (RB). Repeat the reading after exactly 1, 2 and 3 minutes. Calculate the mean absorbance change per minute for the standard sample ΔA/min.(S) and the test sample ΔA/min.(T).

Calculation

$$\text{CK activity } [U/l] = \frac{\Delta A/\text{min.}(T)}{\Delta A/\text{min.}(S)} \times \text{calibrator concentration } [U/l]$$

Reagent Start method

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

Pipette into the cuvettes:

	reagent blank (RB)	standard (S)	test (T)
1-CK	1000 µl	1000 µl	1000 µl
sample	-	-	40 µl
calibrator	-	40 µl	-

Mix gentle, incubate for 5 min. Then add:

2-CK	200 µl	200 µl	200 µl

Mix and incubate at adequate temperature (37 ºC). After about 2 min. read the absorbance A of standard sample A(S) and test sample A(T) against reagent blank (RB). Repeat the reading after exactly 1, 2, 3 and 4 minutes. Calculate the mean absorbance change per minute for the standard sample ΔA/min.(S) and the test sample ΔA/min.(T).

Calculation

$$\text{CK activity } [U/l] = \frac{\Delta A/min.(T)}{\Delta A/min.(S)} \text{ x calibrator concentration } [U/l]$$

REFERENCE VALUES [8]

serum	37ºC	
female	< 167 U/l	< 2.78 µkat/l
male	< 190 U/l	< 3.17 µkat/l

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 calibration the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or LEVEL 2 (Cat. No 5-175; 5-177) are recommended.

The calibration curve should be prepared every 4 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 analysers Biolis 24i Premium and Hitachi 911. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 4.4 U/l (0.072 µkat/l).

- **Linearity:** up to 1600 U/l (26.7 µkat/l).

Samples with higher CK activity dilute 1:1 with 0.9% NaCl and repeat the assay. Multiply the result by 2.

- **Specificity / Interferences**

Haemoglobin up to 0.156 g/dl, bilirubin up to 20 mg/dl, ascorbate up to 62 mg/l and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [U/l]	SD [U/l]	CV [%]
level 1	137.22	0.78	0.57
level 2	509.97	1.14	0.22

Reproducibility (day to day) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	140.43	2.33	1.66
level 2	521.19	5.06	0.97

- **Method comparison**

A comparison between CK values determined at Biolis 24i Premium (y) and at OLYMPUS AU400 (x) using 24 samples gave following results:

y = 0.9355 x + 2.3019 U/l;

R = 1.0 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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Date of issue: 05. 2016.

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05/16/05/16