Liquick Cor-CK-MB

DIAGNOSTIC KIT FOR DETERMINATION OF CK-MB FRACTION ACTIVITY

Kit name	Cat. No
Liquick Cor-CK-MB 500	1-320
Liquick Cor-CK-MB "bulk"	1-259

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 CK-MB serum level is a strong marker of myocardial infarction.

METHOD PRINCIPLE

Optimized kinetic method according to International Federation of Clinical Chemistry (IFCC) with use of antibodies against CK-M fraction. Specific antibodies against CK-M inhibit the complete CK-MM activity (which is the main part of total CK activity) and the CK-M subunit of CK-MB. Only CK-B activity is measured.

creatine phosphate + ADP $\xrightarrow{\text{CK-BB /CK-MB}}$ creatine + ATP

ATP + D-glucose $\xrightarrow{\text{HK}}$ ADP + glucose-6-P

glucose-6-P + $NADP^+$ $\xrightarrow{\text{G6P-DH}}$ 6-P-glucono lacton + NADPH + H^+

The rate of absorbance changes at λ=340 nm is directly proportional to half of CK-MB activity (B subunit activity).

REAGENTS

Package

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

*reagent volume is printed on the label.

Reagents preparation and stability

The reagents are ready to use.

The reagents are stable up to the kit expiry date printed on the package when stored at 2-8°C. On board stability of the reagents depends on type of analyser used for analysis. Do not freeze reagents. Protect from light and avoid contamination! Avoid foaming!

Concentrations in the test

1-CK-MB	
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
hexokinase (HK)	> 2.5 U/ml
polyclonal antibodies against human CK-M; inhibiting capacity	8000 U/l
2-CK-MB	
diadenosinepentaphosphate	10 µmol/l
glucose-6-phosphate-dehydrogenase (G6P-DH)	> 1.5 U/ml
creatine phosphate	30 mmol/l
preservatives	

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.
- Results CK-MB can be falsely high in case of prostate, kidney, ovary, breast and bladder cancer when isoenzyme CK-BB appears in the blood.

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, heparinized or EDTA plasma free from hemolysis.

As an anticoagulant for plasma preparation use EDTA or heparin lithium, sodium or ammonium salt!

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 15-25ºC 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 (Reagent Start method) and in automatic analysers. Applications for them are available on request.

Manual procedure

wavelength	340 nm (334/365 nm)
temperature	37ºC
cuvette	1 cm

Reagent Start method

Pipette into the cuvettes:

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

Mix gentle, incubate for 5 min. Then add:

2-CK-MB	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

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

REFERENCE VALUES [9]

serum / plasma	37ºC	
adults	up to 24 U/l	up to 0.401 µkat/l

The probability that cardiac infarction has occurred is high when CK-MB and total CK activities are above normal values and CK-MB activity is between 6 and 25% of the total CK activity.

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 CK-MB CONTROL N (Cat. No 5-183) and CORMAY CK-MB CONTROL P (Cat. No 5-184) with each batch of samples.

For calibration the CORMAY CK-MB CALIBRATOR (Cat. No 5-182) is recommended.

Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared 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:** 6 U/l (0.10 μkat/l).

- **Linearity:** up to 2100 U/l (35.1 μkat/l).
  Samples with higher CK-MB activity dilute 1:1 with 0.9% NaCl and repeat the assay. Multiply the result by 2.

- **Specificity / Interferences**
  Haemoglobin up to 0.125 g/dl, bilirubin up to 0.644 mg/dl, ascorbate up to 62 mg/l and triglycerides up to 750 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.47	1.13	3.49
level 2	144.39	1.81	1.25

Reproducibility (day to day) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.36	1.26	3.90
level 2	141.10	5.79	4.10

- **Method comparison**

A comparison between CK-MB values determined at Biolis 24i Premium (y) and at COBAS INTEGRA 400 (x) using 34 samples gave following results:

$y = 0.8845 x + 0.9602$ U/l;

$R = 0.997$ (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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MANUFACTURER

PZ CORMAY S.A.
22 Wiosenna Street,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.cormay.pl

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