PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLSKA
tel.: +48 (0) 81 749 44 00
fax: +48 (0) 81 749 44 34
http://www.cormay.pl

CE CORMAY

Liquick Cor - CK-MB

(EN)

Kit name:	**Cat. no**
Liquick Cor-CK-MB mini	1-295
Liquick Cor-CK-MB 30	1-227
Liquick Cor-CK-MB 500	1-320

INTENDED USE

Diagnostic kit for determination of CK-MB fraction activity. These reagents may be used both for manual assay (Reagent Start method) and in 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

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 mini	**Liquick Cor-CK-MB 30**	**Liquick Cor-CK-MB 500**
R1	2 x 25 ml	5 x 25 ml	3 x 500 ml
R2	1 x 10 ml	1 x 25 ml	1 x 300 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagents stored on board are stable for 12 weeks(Biolis 24i Premium).

Concentrations in the test

1-Reagent	
imidazole buffer pH 6.7	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
polyclonal antibodies against CK-M; inhibiting capacity	8000 U/l
2-Reagent	
diadenosinepentaphosphate	10 µmol/l
glucose-6-phosphate-dehydrogenase (G6P-DH)	> 1.5 U/ml
creatine phosphate	30 mmol/l
preservativess	

Warnings and notes

- Protect from direct sunlight and avoid contamination!
- Do not freeze reagents
- Do not interchange caps among reagents.
- Please refer to the MSDS for detailed information concerning safe storage and use of the product.
- 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.
- 1-Reagent meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:
1-Reagent 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 15-25ºC 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

1-Reagent and 2-Reagent are ready to use.
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

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

REFERENCE VALUES [9]

serum	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.
the calibration curve stability are 12 weeks(Biolis 24i Premium).
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 interfere even in small amounts, 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	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

1. Würzburg U., Hennrich H., Lang H., Prellwitz W., Neumeier D., Knedel M.: Klin. Wschr. 54, 357 (1976).
2. Würzburg U., Hennrich H., Ortz H., Lang W., Prellwitz W., Neumeier D., Knedel M., Rick W.: J. Clin. Chem. Clin. Biochem. 15, 131 (1977).
3. DGKC: J. Clin. Chem. Clin. Biochem.: 15, 255 (1977).
4. Witt I., Trendelenburg C.: J. Clin. Chem. Clin. Biochem. 20, 235 (1982).
5. Commission on Enzymes of the Scandinavian Society for Clinical Chemistry and Clinical Phys.: Scand. J. Clin. Lab. Invest. 36, 711 (1976).
6. Chemnitz G., Schmidt E., Koller P.U., Busch E.W.: Dt. Med. Wschr. 104, 257 (1979).
7. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 804-6 (1994).
8. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 806-6 (1995).
9. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 786, (1998).

Date of issue: 02.2020.