

DIAGNOSTIC KIT FOR DETERMINATION OF CK-MB FRACTION ACTIVITY



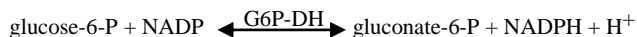
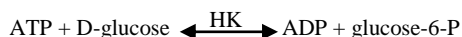
HC – CK-MB

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 dimer, 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.



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

REAGENTS

Package

1-Reagent	6 x 87.5 ml
2-Reagent	6 x 18.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Do not freeze reagents. Protect from light and avoid contamination!

Concentrations in the test

1-Reagent

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
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
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.

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 15-25°C or 1-2 days at 2-8°C or 1 month at -20°C.

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

PROCEDURE

The reagents are ready to use.

These reagents may be used in automatic analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

- Delete previous version of application and calibrators assigned to it and restart the analyser.
- Enter codes of calibrators according to the attached list.
- Enter barcoded application and assign proper values to calibrators.
- To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
- Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
- After calibration analyser is ready to use.

REFERENCE VALUES⁹

serum / plasma	37°C	
	adults	up to 0.401 µkat/l
	up to 24 U/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 the calibration the CORMAY CK-MB CALIBRATOR (Cat. No 5-182) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

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 Hitachi 912 and Hitachi 911. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity:** 10 U/l (0.167 µkat/l).
- Linearity:** up to 2600 U/l (43.33 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 = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	31.90	1.02	3.20
level 2	344.57	1.00	0.29

Reproducibility (day to day) n = 10	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.34	1.62	5.02
level 2	119.68	3.23	2.70

▪ **Method comparison**

A comparison between CK-MB values determined at Hitachi 912 (y) and at ADVIA 1650 (x) using 40 samples gave following results:

$$y = 0.9571 x + 0.0307 \text{ U/l};$$

$$R = 0.9988 \quad (R - \text{correlation coefficient})$$

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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