CK MB

IFCC (Immuno inhibition)

ENZOPAK

Last update 09-2020

Ref. CC1-CKM.007, 20x1.1 ml
CC2-CKM.07U, 10x3 ml
CC2-CKM.07V, 10x10 ml

INTENDED USE

Reagent kit for quantitative estimation of Creatine Kinase-MB activity in serum.

INTRODUCTION

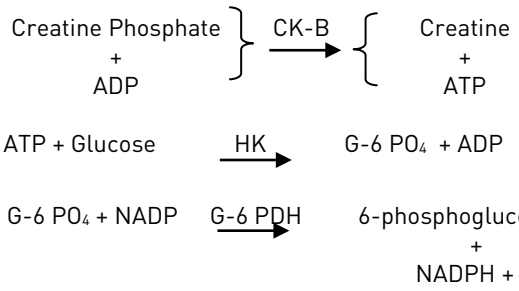
Creatine Kinase (CK) is a dimer of two non-identical subunits (B & M). The isoenzymes are CK-MM, CK-BB and CK-MB. CK-MM and CK-MB are primarily distributed in Skeletal muscle and Heart muscle respectively. Following myocardial infarction CK-MB activity increases rapidly and the increase is highly specific for myocardial infarction.

DIAGNOSTIC SIGNIFICANCE

The effective use of only total CK as a sensitive indicator of acute myocardial infarction has been diminished because CK elevation also occur due to non-cardiac conditions.
The CK-MB activity increase characteristically after cell break-down in myocardial infarction. The increase approximately occurs within 6 hours, peaks at 24 hours and comes back to normal levels within 2-3 days following myocardial infarction.

PRINCIPLE

CK-MB is based on the principle of specific immunoinhibition by a blend of monoclonal antibody which completely inhibit CK-MM activity and 50 % of CK-MB activity. While not affecting the B Subunit activity of CK-MB and CK-BB, the CK-B activity is measured. The CK-MB activity is obtained by multiplying the CK-B activity by two. Increased levels may be found due to severe exercise and by large multiple intra-muscular injuries.
With other symptoms and suggestive history, serum CK estimation is an important parameter of choice for myocardial infarction and follow up.



The reaction is monitored by measuring the increase in absorbance at 340 nm, which is directly proportional to CK-B subunit activity.

ATP = Adenosine triphosphate
ADP = Adenosine diphosphate
HK = Hexokinase
G-6PO4 = Glucose-6-Phosphate
NADP = Nicotinamide adenine di-nucleotide phosphate
G-6-PDH = Glucose-6 phosphate dehydrogenase

PRESENTATION

All reagents to be store at 2-8^{0}C	No. of Bottles		
	20x1.1 ml	10x3 ml	10x10 ml
• 1 CK-MB (Buffer-Antibody)	1	1	10
• 2 CK-MB (Enzymes-Activator)	20	10	10

FINAL REAGENT COMPOSITION

Active Ingredients	Concentration
• Buffer	100 mmol/L
• Detergent	0.5 mmol/L
• Monoclonal Antibody for CK MB	
• ADP	1.5 mmol/L
• Hexokinase	$\geq$ 2000 U/L
• G-6-PDH	$\geq$ 1.5 U/L
• NADP	1.2 mmol/L
• NAC	10 mmol/L
• C.P.	20 mmol/L
• AMP	2.5 mmol/L

pH 6.8 $\pm$ 0.1 at 25^{0}C
Also contains non-reactive fillers and Stabilizers.

PRECAUTION

CK-MB is for *IN-VITRO* diagnostic use only. Allow the reagents to attain room temperature prior to use.
Reagent contains Sodium Azide. DO NOT INGEST.

PREPARATION OF WORKING REAGENT

For 20 x 1.1 ml
Dissolve the contents of one bottle of 2 CK-MB with 1.1 ml. of 1 CK-MB. **Use after 15 minutes**.

For 10 x 3 ml
Dissolve the contents of one bottle of 2 CK-MB with 3 ml. of 1 CK-MB. **Use after 15 minutes.**

For 10 x 10 ml
Dissolve the contents of one bottle of 2 CK-MB with 10.0 ml. of 1 CK- MB. **Use after 15 minutes.**

REAGENT STORAGE AND STABILITY

CK-MB reagent is stable at 2-8 ^{0}C until the expiry date stated on the label.
The reconstituted reagent is stable for 21 days.

SPECIMEN COLLECTION

Fresh, clear serum is the specimen of choice. Plasma collected with heparin as an anticoagulant may also be used. The CK-MB activity is stable in the serum for 6-8 hours at 2-8^0 C.

REACTION PARAMETERS

• Type of Reaction	:	Kinetic
• Wavelength	:	340 nm
• Flowcell Temperature	:	37 ^{0}C
• Delay Time	:	300 Seconds
• Interval	:	30 Seconds
• No. of Readings	:	4
• Sample Volume	:	50 µl (0.05 ml.)
• Working Reagent Volume	:	1.0 ml
• Factor	:	6752
• Light Path	:	1.0 cm
• Zero setting with	:	Distilled Water

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TEST PROCEDURE

Pipette In To Test Tubes	TEST
Working Reagent (ml)	1.0
Incubate the reagent at 37^{0}C for 5 minutes. Add sample	
Sample (ml)	0.05
Mix and Incubate this reagent at 37^{0}C for 5 minutes.	

Aspirate, read first absorbance of test at 300 seconds and thereafter at 30, 60, 90 & 120 seconds at 340 nm. Determine the mean change in absorbance per minute.

TEST RESULTS

CK-MB activity (IU/L) = Δ A/min x F

= Δ A/min x 6752

$$\text{Where } F = \frac{1}{6.22} \times \frac{T.V}{S.V} \times 2 \times 1000$$

Where Δ A/min = Change in absorbance per minute.

T.V. = Total volume = 1.05 ml.

S.V. = Sample volume = 0.05 ml.

2 = To express CK-MB activity

1000 = To express CK-MB activity per liter.

6.22 = Milimolar absorption coefficient of NADPH at 340 nm.

F = 6752

LIMITATIONS FOR INTERFERENCE

This procedure assumes that CK-BB activity in the sample is negligible. However there are some studies which indicate the presence of CK-BB in the form of macro CK-BB in certain cases. Due to this a falsely elevated level of CK-MB may be obtained. In patients with normal CK-NAC if the CK-MB value is more than 20 % of the total CK-NAC the presence of macro CK-BB should be suspected.

Drugs and other substances which may interfere with the determination of CK-NAC / CK-MB have been listed by Young et al.

NORMAL VALUES

0-25 IU / L

LINEARITY

This method is linear upto 1500 IU/L. For CK-MB activity above 1500 IU/L, dilute the sample suitably with 0.9 % saline and repeat the assay. Apply correction due to dilution factor to obtain test results.

REFERENCE

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Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
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