



CK-MB (Modified IFCC Method)

INTENDED USE:

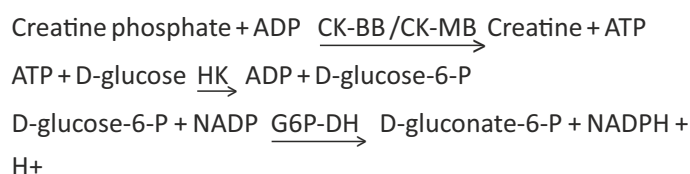
This reagent kit is used for *in-vitro* quantitative determination of CK-MB in human serum/plasma.

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.

TEST 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 CKMM 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 $\lambda=340 \text{ nm}$ is directly proportional to half of CK-MB activity (B subunit activity).

KIT CONTENTS:

CK-MB Reagent 1

CK-MB Reagent 2

Product Insert

PREPARATION OF THE WORKING REAGENT:

Mix 4 parts of reagent 1 with 1 part of reagent 2.

REAGENT STABILITY AND STORAGE:

All the reagents must be stored at $2-8^{\circ}\text{C}$ and are stable till expiry date mentioned on the labels.

WORKING REAGENT :

Working Reagent is stability for 10 days at $2-8^{\circ}\text{C}$ & 3 days at $21-25^{\circ}\text{C}$.

SPECIMEN COLLECTION AND STORAGE:

Unhemolysed serum or heparinised plasma from fasting patients is recommended.

Serum is stable for 1-2 days at $2-8^{\circ}\text{C}$ & 4-8 hours at $21-25^{\circ}\text{C}$ & at least 1 months at -20°C .

Discard contaminated specimens.

PRECAUTIONS:

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the reagents to room temperature.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.
6. Reagent ratio as mentioned here above must be strictly observed as may change into it will adversely effect the factor..

PROCEDURE (Automated):

Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

Wavelength: 340 nm & Temperature: 37°C .

Note : Bring reagents and samples to room temperature ($21-25^{\circ}\text{C}$).

Pipette into Test Tube	Test
Working Reagent	1000 μl
Sample	40 μl
Mix and after 5 minute incubation, measure the change in absorbance ($\Delta\text{OD}/\text{min}$) for 3 minutes. Determine the mean absorbance change per minute ($\Delta\text{OD}/\text{min}$) and use this for calculation.	

CALCULATION:

CK-MB activity (IU/L) = $\Delta\text{OD}/\text{min} \times \text{Factor (6000)}$.

NORMAL VALUES*:

Serum upto 24 IU/L

*It is recommended that each laboratory establish its own normal range.

PERFORMANCE:

1. **Linearity:** 2000 IU/L

2. **Specificity / Interferences**

Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

SYSTEM PARAMETERS:

Input parameters for semi- auto / auto analyzers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Wavelength	340 nm
Factor	6000
Incubation time	300 sec.
Interval time	60 sec.
Interval No.	3
Flowcell temperature	37°C
Units	IU/L
Upper Normal value	24 IU/L
Lower Normal value	0 IU/L
Linearity	2000 IU/L
Working Reagent	1000 µl
Sample volume	40 µl

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

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