

# CK-MB Estimation Kit

## High-Q CK-MB

(IFCC Method)

### Intended Use:

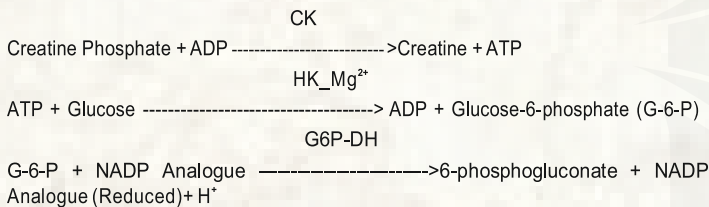
Kit for the quantitative determination of CK-MB Iso Enzyme in Human Serum and Plasma

### Summary and Explanation:

CK is a dimeric enzyme occurring in 4 different forms, a mitochondrial iso-enzyme and 3 cytoplasmic iso-enzymes. **CK MM** is a muscle enzyme, **CK BB** is a brain enzyme and **CK MB** is the heart enzyme. CK activity has elevated many diseases including those involving skeletal muscle, heart, central nervous system and the thyroid. Most determinations of CK in the clinical laboratory are used for the early detection of Myocardial Infarction in which the enzyme is elevated within 3 to 8 hours after the onset.

### Principle Of The Test:

This procedure for CK MB incorporates a polyclonal antibody to CK M in the Reagent 1. The antibody inhibits 99.6% of the CK M without affecting the CK B units. The remaining CK B activity therefore corresponds to half the CK MB activity and is determined by the method used for total CK.



N.B: The CK activity should be determined using the CK-NAC method before performing the CK-MB assay.

### Warnings And Precautions:

For In Vitro Diagnostics Use Only - For Professional Use Only  
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

### Components Colour and Appearance:

**Reagent 1:** Clear Colourless liquid.  
**Reagent 2:** Clear, pale yellow coloured liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

### Component Composition:

Reagent	Ingredients	Concentration in Tests
Reagent 1	Imidazole Buffer pH 6.7	100 mmol/l
	Glucose	20 mmol/l
	Magnesium Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	NADP	2.0 mmol/l
	CK-M Inhibiting Antibody	8000 U/l
	HK	> 2.5 U/ml
	N-acetylcysteine	20 mmol/l
Reagent 2	Creatine Phosphate	30 mmol/l
	G6P-DH	> 1.5 U/ml
	Diadenosine pentaphosphate	10 µmol/l

### Reagent Preparation and Stability:

Two Ready to use liquid reagents (R1 and R2) stable till the expiry date mentioned on the labels. Do not contaminate the reagents.

### Type Of Specimen:

Use serum, free from haemolysis, heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/Plasma should be separated from cells immediately after collection and stored in the dark.

Stability of specimen up to 7 days at 2-8°C.

### Assay Procedure:

Reaction Type (Mode)	: Fixed Time
Reaction Direction	: Increasing
Wave Length	: 340nm
Flow Cell Temp.	: 37°C
Zero Setting with	: Distilled Water
Delay time	: 300 seconds
Measuring Time	: 180 Seconds
Reagent Volume	: 0.5 ml ( 400 µl R1+ 100 µl R2)
Sample Volume	: 25 µl
Calibrator	: (Lot Specific)
Linearity	: 1000
Units	: IU/L
High Normal	: 24

### Procedure :

	Calibrator	Serum
Reagent 1	400 µL	400 µL
Calibrator	25 µL	-
Sample	-	25 µL
<b>Mix and incubate for 5 min at 37 °C</b>		
Reagent 2	100 µL	100 µL

Mix well and immediately aspirate in to the analyzer. Record the first absorbance (A1) at 300 seconds after adding the Calibrator / Sample. Exactly 180 Seconds after the first reading record the absorbance (A2) at 37 °C.

### Calculations:

$$\text{Activity of CK-MB [IU/L]} = \frac{\text{A1- A2 Sample}}{\text{A1- A2 Calibrator}} \times \text{Calibrator Concentration}$$

### Expected Values:

Adults up to 24 IU/L (37°C)

Myocardial Infarction (MI): the likelihood of myocardial damage is high when the following 3 conditions are met:

	IU/L (at 37°)
1. CK Men	>190
Women	> 167
2. CK- MB	> 24
3. CK-MB activity accounts for 6 – 25% of the total CK activity	

Each Laboratory should establish its own reference range. Creatine Kinase results should always be reviewed with the patients' medical examination and history

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### Performance Characteristics:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

### Linearity:

Linear up to 1000 U/L. For samples with a higher concentration, dilute 1:1 with Saline (0.9 g/l NaCl) and reassay. Multiply result by 2.

### Interfering substances:

Bilirubin (mixed isomers): Less than 10% interference up to 600 μmol/l Bilirubin.

Haemolysis: Less than 10% interference up to 1.25 g/l Haemoglobin.

Lipemia: Less than 10% interference up to 2.5 g/l Intralipid.

### Sensitivity:

The Lowest Detectable Level was estimated at 2 U/l

### Precision:

Within Run	Mean	SD	% CV	Between Run	Mean	SD	% CV
N = 20							
Level 1	172.1	4.88	2.83	Level 1	165.4	5.58	3.37
Level 2	776.4	13.46	1.73	Level 2	740.2	15.26	2.06

### Method Comparison:

Using 50 samples, a comparison, between High-Q CK MB test (y) and another commercially available test (x), gave the following results:

$$y = 0.976x - 0.269 \quad r = 0.999 \quad \text{Sample range: 0 to 329 U/l}$$

### Bibliography:

- Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5<sup>th</sup>ed. 30-54, 352390 and 974-975
















### Ordering information

Ref./Cat.	Pack Size	Presentation
P-CMB-10	10 ml	Two Liquid Stable Reagents
P-CMB-20	2 x 10 ml	
P-CMB-50	5 x 10 ml	

## Product Features

- Liquid Stable two reagents with Calibrator
- NADP analogues are used for better stability.
- Linearity 1000 IU/L.
- Two Point Kinetic (Fixed Time) Assay (300 Sec Delay+ 180 Sec Measuring)
- Measuring wavelength 340 nm.
- Serum and Plasma are the specimens
- Available as multipurpose reagents and dedicated system packs

### Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

