Pariksha Biotech
A game changer in IVD

CK-MB Estimation Kit

High-Q CK-MB

(IFCC Method)

HIGH®
Command on Quality

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.

$$\text{Creatine Phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{HK\_Mg}^{2+}} \text{ADP} + \text{Glucose-6-phosphate (G-6-P)}$$

$$\text{G-6-P} + \text{NADP Analogue} \xrightarrow{\text{G6P-DH}} \text{6-phosphogluconate} + \text{NADP Analogue (Reduced)} + H^{+}$$

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:

	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)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	340nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay time	:	120 seconds
Measuring Time	:	240 Seconds
Reagent Volume	:	0.5 ml (400 µl R1+ 100 µl R2)
Sample Volume	:	25 µl
Factor	**:**	**2200**
Linearity	:	1000
Units	:	IU/L
High Normal	:	24

Procedure :

Reagent 1	**400 µL**
Sample	**25 µL**
	Mix and incubate for 5 min at 37 °C
Reagent 2	**100 µL**

Mix well and immediately aspirate in to the analyzer. After 120 Seconds incubation, measure the change in optical density per 60 seconds during 240 seconds against distilled water at 340 nm as follows.

Ao - Exactly after 120 Seconds
A1, A2, A3, A4 - Exactly after every 60 seconds for 240 seconds.

Calculations:

Calculate the average change in absorbance per minute (△Abs/min).

Activity of CK-MB [IU/L]

At 340 nm in IU/L = △Abs / min x 2200

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 600µmol/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 N = 20	SD	% CV
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 r = 0.999 Sample range: 0 to 329 U/l

Bibliography:

1. Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th 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	

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Product Features

- Liquid Stable, Ready to use Two Reagents. (R1= Buffer, R2=Substrate)
- Kinetic Factor 2200
- NADP analogues are used for better stability.
- Linearity 1000 IU/L.
- 6 Minutes increasing Kinetic Reaction
- Measuring wavelength 340 nm.
- Serum and Plasma are the specimens
- Available as multipurpose reagents and dedicated system packs

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Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709 info@parikshabio.com www.parikshabio.com

AN ISO 13485 Certified Company

Rev # 2