

This reagent kit is for quantitative estimation of Creatine Kinase-MB activity in serum.

PRINCIPLE:

The principle is based on phenomenon of immunoinhibition whereby antibody developed against CK-M monomer renders CK-MM activity and inhibits activity of CK-MB by 50%. The CK method is used to estimate CK-B activity quantitatively, then CK-MB activity is obtained by multiply CK-B activity by two.



CLINICAL SIGNIFICANCE:

The CK-MB activity is characteristic parameter in follow up of myocardial infarction. CK-MB activity increases after cell break down in myocardial infarction. Within 6 hours, increase is seen, that reaches to peak at 24 hours and comes back to normal levels in 2-3 days following myocardial infarction. Elevated level of CK-MB seen is myocarditis, Duchennes, muscular dystrophy, polymyositis, Reye's syndrome and carbon monoxide poisoning.

SPECIMEN COLLECTION AND STORAGE:

- * Serum sample is preferred.
- > Enzyme activity in serum is unstable and rapidly lost during storage.

PRECAUTION:

- * Estrom CK-MB reagent is for In Vitro diagnostic use only

REAGENTS:

All the reagents are to be stored at 2-8°C.

	No. of bottles	
	12x1.1 ml	5x10 ml
Reagent 1 (Substrate)	12	5
Reagent 2 (Buffer)	1	5

REAGENT RECONSTITUTION:

- * **12x1.1 ml:** One vial of Reagent 1(Substrate) is to be dissolved in 1.1 ml of Reagent 2 (Buffer).
- * **5x10 ml:** Dissolve 1 vial of Reagent 1 (Substrate) using 10 ml of Reagent 2 (Buffer). Mix gently.

Mix gently. Keep for 5 minutes before use. Reconstituted reagent may be stored at 2-8°C, protected from light when not in use.

REAGENT STORAGE AND STABILITY:

All the reagents are stable up to expiry date stated on the label. Working reagent when stored at 2-8°C in a dark coloured bottle is stable for 5 days.

GENERAL INSTRUMENT PARAMETERS:

Reaction Type	: Kinetic
Slope of Reaction	: Increasing
Wavelength	: 340 nm
Flowcell Temperature	: 37°C
Reagent Volume	: 1.0 ml
Sample Volume	: 50 µl (0.05ml)
Delay Time	: 300 seconds
Interval	: 30 seconds
No. of readings	: 3
Factor	: 6752
Units	: IU/L
Zero Setting	: Distilled water
Path length	: 1.0 cm

PROCEDURE:

Allow the reagent to attain 37°C prior to use.

Dispense into test tubes	Test
Working Reagent	1.0 ml
Sample	50 µl

Mix and incubate at 37°C for 5 minutes. Aspirate, read first absorbance of test at 300 seconds and there after second and third reading at an interval of 30 seconds at 340 nm. Obtain the mean change in absorbance per minute (ΔA/min.)

LINEARITY:

This method is linear for CK-MB activity up to 1000 IU/L. For sample values exceeding the linearity limit, dilute the sample suitably with normal saline and repeat the assay. Apply proper dilution factor while calculation.

CALCULATION:

Concentration of CK-MB
in sample (IU/L) : Δ/min. x Factor
Factor = 6752

REFERENCE VALUES:

Normal Value : 0-25 IU/L at 37°C.

It is recommended that each laboratory establish its own reference values.

BIBLIOGRAPHY:

- * Young D.S., Clin Chem 21.10 (1975).
- * Morin L. Clin. Chem 23/4 (1977). 646.

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 2-8°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by