

Reagent kit for quantitative estimation of CK-MB in Serum or Plasma.

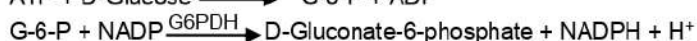
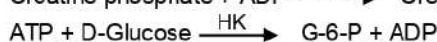
DIAGNOSTIC SIGNIFICANCE:

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 increases characteristically after cell breakdown in myocardial infarction. The increase approximately occurs within 6 hours, peaks at 34 hours and comes back to normal levels within 2-3 days following myocardial infarction.

PRINCIPLE:

The procedure involves measurement of CK activity in the presence of an antibody to CK-M monomer. This antibody completely inhibits the activity of CK-MM and half of the activity of CK-MB while not affecting the B subunit activity of CKMB and CK-BB. Then we use the CK method to quantitatively determine CK-B activity. The CK-MB activity is obtained by multiplying the CK-B activity by two.



CK = Creatine kinase **G-6-P** = D-Glucose-6-phosphate

HK = Hexokinase **G-6-PDH** = Glucose-6-phosphate Dehydrogenase

SPECIMEN COLLECTION:

Serum free of hemolysis. Heparinized or EDTA plasma.

KIT PRESENTATION:

| PACK SIZE | 2 X 10 ml | 2 X 20 ml |
|-------------------------------------|-----------|-----------|
| R1 - CK MB (Enzyme Reagent) | 2 X 8 ml | 2 X 16 ml |
| R2 - CK MB (Starter Reagent) | 2 X 2 ml | 2 X 04 ml |

WORKING REAGENT PREPARATION:

Mixing 4 volumes of R1-CK MB (Enzyme Reagent) with 1 volume of R2-CK MB (Starter Reagent). i.e. 800 µl R1 + 200 µl R2.

The working reagent is stable for 30 days at 2-8°C.

REAGENT STORAGE AND STABILITY:

CK-MB reagents are stable at 2-8°C until the expiry date stated on the label.

ASSAY PARAMETERS:

| | | | |
|-----------------|-----------|----------------|-------------------|
| Reaction | : Kinetic | Sample Volume | : 50 µl |
| Wavelength | : 340 nm | R1 + R2 Volume | : 800 µl + 200 µl |
| Flow Cell Temp. | : 37°C | Factor | : 6666 |
| Initial Delay | : 300 Sec | Reaction Slope | : Increasing |
| Read Time | : 180 Sec | Zero Setting | : Dist. Water |
| No. of Reading | : 03 | Linearity | : 1500 IU/L |

PROCEDURE:

| Addition Sequence | Test |
|---|--------|
| R1 - CK MB (Enzyme Reagent) | 800 µl |
| Sample (Test) | 50 µl |
| Mix well & incubate for 5 minutes at 37°C and add | |
| R2 - CK MB (Starter Reagent) | 200 µl |

Mix & aspirate immediately and read first absorbance of test exactly at 300 seconds and then, second, third and fourth at an interval of 60 seconds at 340 nm. Determine the mean change in absorbance per minute. ($\Delta A/\text{min}$) and calculate the test results.

CALCULATION

$$\text{CK MB Activity (IU/L)} = \Delta A/\text{min} \times 6666$$

NORMAL VALUES:

0 - 25 IU/L

Each laboratory should establish its own normal range.

LINEARITY:

This method is linear up to 1500 IU/L. For values above 1500 IU/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

REFERENCES:

- Lott J.A., Clin Lab Med., 6:546 (1986)
- Young, D.S. Effects of drugs on clinical laboratory tests, AACC Press Washington, PP 120-122 (1990)
- Ljungdahl I, Gerhardt W., Clin Chem 24:832 (1978)
- Burtis, C.A. and E.R. Ashwood, Tietz, Text book of Clin Chem, 2nd Ed., W.B. Saunders Co., Philadelphia P:562 (1994).

IFU No.: 014/00 Rev. No.: 00/120723



Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert