CK-MB

2 x 20 mL, 2 x 75 mL
51405004, 51405008

Intended Use

This reagent is intended for *in vitro* quantitative determination of CK-MB in human serum or plasma.

- Immuno – inhibition methodology
- Linear up to 600 U/L
- Convenient pack sizes for all laboratories

Clinical Significance

CK – MB levels increases significantly 4-6 hours following a myocardial infarction & peak at around 12 to 24 hours after the infarct. The levels return to normal in case of no further myocardial damage after 24 - 48 hours. Hence the increased levels of CK-MB along with elevated levels of CK-NAC is a good indicator of 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 & half of the activity of CK-MB, while not affecting the B subunit activity of CK-MB &CK –BB. Then we use CK method to quantitatively determine CK-B activity. The CK-MB activity is obtained by multiplying the CK-B activity by two.

Kit Components

Reagent/ Component	Product Code		Description
	51405004	51405008	
CK-MB (S.L) R1	2 x 16 mL	2 x 60 mL	Imidazole(pH 6.7) 125 mmol/L D-Glucose - 25 mmol/L N-Acetyle-L-Cysteine 25mmol/L Magnesium acetate 12.5mmol/L NADP -2.52 mmol/L EDTA - 2.02 mmol/L Hexokinase >6800 U/L Anti human polyclonal CK-M antibody(sheep)sufficient to inhibit up to 2000U/L of CK-MM
CK-MB (S.L) R2	2 x 4 mL	2 x 15 mL	Creatine phosphate 250 mmol/L ADP 15.2 mmol/L AMP 25 mmol/L Diadenosine pentaphosphate 103 mmol/L G-6-PDH > 8800 U/L

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Mix 4 volume of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

Working reagent is stable for 14 days at 2-8^{0}C.

Note: Discard the working reagent ,if the blank absorbance exceeds 1.0 at 340 nm.

Reagent Storage

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2-8^{0}C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2- 8^{0}C if contamination is avoided.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Avoid direct exposure of working reagent to light.

Waste Management

Reagent must be disposed off in accordance with local regulation.

Sample

Serum /Plasma (free of Haemolysis).

Interferences

No interference for

Bilirubin up to	6 mg/dL
Haemoglobin up to	5 g/L
Turbidity up to	580 mg/dL

Materials Provided

CK-MB reagent R1, R2 .

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	340 nm
Temperature	37^{0}C
Factor	8254
Linearity	600 U/L
Blank	DI Water
Delay	100 sec
No of reading	5
Interval	60 sec
Sample volume	40 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Calibration

Use provided factor (8254) for estimation of this assay on semi automated analyzer

Procedure notes

Laboratory procedure for Semi Auto Analyzer	
Working reagent	1000 µL
Sample	40 µL
Mix and incubate at 37^{0}C for100 seconds. Read the change in absorbance per minute (OD/ minute) during 5 minutes.	

Calculation

CK-MB Activity (U/L) = △OD/Min x 8254

Quality Control

It is recommended to use control to verify the performance of the assay.Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum up to : 24 U/L

% CK- MB : 6 - 25 %

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1.Linearity

This reagent is linear up to 600 U/L.

If the concentration is greater than linearity (600 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2.Sensitivity

Lower detection Limit is 1 U/L

Bibliography

1.DGKC, J.Clin. Chem Clin. Bioch. 15, 255(1977)

2.Di. Witt, C Trendelendurg, J. Clin. Chem, Clin Bioch. 20, 235 (1982)

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE SEE PACKAGE INSERT FOR PROCEDURE LOT LOT NUMBER MANUFACTURER'S ADDRESS MANUFACTURING DATE EXPIRY DATE TEMPERATURE LIMIT

BIOSS BioTechnology, GmbH
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ISO 9001 : 2008
ISO 13485 : 2003