

BioMed-CK-MB



Kinetic

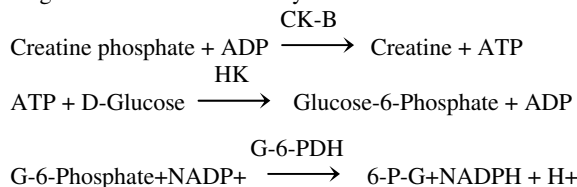
REF: CKM108015 (5x3 ml)
CKM108036 (12x3 ml)

INTENDED FOR USE:

For the quantitative determination of CK-MB fraction activity in serum and plasma.

PRINCIPLE :

This procedure involves measurement of CK activity in the presence of an antibody to CK-M monomer. This antibody completely inhibits the activity of CK-M and half activity of CK-MB. Our reagent combines the antibody with the NAC activator.



The rate of NADPH formation measured at 340 nm is directly proportional to serum CK-B activity. CK-MB activity is obtained by multiplying the CK-B activity by 2.

SPECIMEN COLLECTION:

Non hemolyzed serum and plasma

Note :

Slightly hemolyzed sample , upto 200 mg/dl of Hb , will not interfere with results . Anticoagulants such as heparin or EDTA may be used .

CK in serum or plasma is reported stable for 48 hours at +15-25°C, 7 days at + 2- 8°C, and approximately 4 weeks when stored in the refrigerator at – 20°C.

Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENT COMPOSITION:

Reagent 1 (pH 6.7) (Buffer/Coenzyme)	
Imidazol	125 mmol/L
D-Glucose	25 mmol/L
N-Acetyl-L-Cysteine	25 mmol/L
Magnesium acetate	12.5 mmol/L
NADP	2.5 mmol/L
EDTA	2 mmol/L
Reagent 2 (Enzymes)	
ADP	15.2 mmol/L
AMP	25 mmol/L
P1,P5-di (adenosine-5'-) penta-phosphate	103 mmol/L
Glucose-6-phosphate Dehydrogenase (G6PDH)	9 KU/L
Creatin phosphate	250 mmol/L
Hexokinase (HK)	3 KU/L
Anti-human-CK-M	

PACKAGE : Collection & storage .

Store at + 2-8°C.

Stable until expiration date reported upon the package .

After the unsealing and the collection of reagent, it is advised to close up the bottle immediately in order to avoid evaporation and bacterial contamination .

PRECAUTIONS & WARNING:

Do not pipette by mouth .

The preparation , according to current regulation , is classified as not dangerous .

The total concentration of non active components (preservatives , detergents , stabilizers) is below the minimum required for citation .

Anyway handle with care, avoid ingestion ,avoid contact with eyes , skin and mucous membranes . The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPARATION & STABILITY

Add 0.5 ml of R2 to on vial of R1 or prepare the working solution according to the number of test required by mixing 5 volume of R1 with 1 volume of R2.

Stability of the **W R** 2 weeks at 2-8°C or 48 hours at room temperature (15-20 °C)

REQUIRED MATERIALS NOT PROVIDED

General Laboratory Equipment and instruments .

PROCEDURE :

Wavelength	340nm (334-365 nm)
Optical path	1 cm
Incubation temperature	25,30 or 37°C
Zero adjustment	Against air

Semi-micro method	
Pipette into cuvette	
	25,30 or 37°C
Specimen	50 µl
Working reagent	1 ml
1. Mix and incubate 3 minutes. 2. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minute. 3. Calculate the difference between absorbance and the average absorbance differences per minute (Δ A/min)	

CALCULATION:

To calculate the CK-MB activity use the formula

$$\Delta A/\text{min} \times 6666 = \text{U/L CKMB}$$

EXPECTED VALUE :

	25°C	30°C	37°C
Adult	10 U/l	16 U/l	25 U/l
CK-MB activity between 6-25 % of total CK activity.			

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology .

REFERENCES:

1. Wu, A.H.B., Bowers, C.N., Clin. Chem. 28(2017), 1982.
2. Szasz, G., Clin. Chem. 22(650), 1976.
3. Moren, L.G., et al., Clin. Chem.23(1569), 1977.
4. Young, D.S., et al., Clin. Chem. 21(10),1975.

PERFORMANCE:

MEASURE INTERVAL/LINEARITY :	3 – 600 U/l
LOWEST MEASURABLE LIMIT	3 U /l
SENSITIVITY :	1 U/l = 0.00015ΔE/min .

PRECISION AMONG SERIES : n=20

MEDIUM LEVEL	M = 5.2 U/L	C.V. = 2.9%
HIGH LEVEL	M = 13 U /L	C.V. = 2.4%

PRECISION AMONG SERIES : n=20






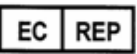



MEDIUM LEVEL	M = 5.0 U /L	C.V. = 4.0%
HIGH LEVEL	M = 13.5 U /L	C.V. = 5.1%
INTER.ANALYZED	5-37 U /L	
CORRELATION	R = 0.9950	n = 30
LIN. REGRESSION	Y = 1.0183x + 0.308	n = 30

INTERFERENCE : (IN ACCORDDANCE WITH RACCOMANDATION SFBC)

Interferences are negligible up to :		
Ascorbic Acid 40 mg/dl	Triglycerids 1200	mg/dl
Hemoglobin 500 mg/dl	Glucose 600	mg/dl
IgG 5 g/fl		

METHOD LIMITATIONS :

For concentration higher than 1200 u/L of Total CK and higher than 400 mg/dL for total cholesterol , repeat the measure of CK-MB on a sample diluted 1:2 with physiological solution and multiply the results . For a thorough evaluation of the interfering substances , consult : Young , D . S,et al , clin. Chem.. 21:1D (1975) . This method reveal the presence of the CK-B iso-enzyme , which activity is normally negligible . Nevertheless if a significative CK-B concentration is presenting the sample , the CK-MB activity will be overvalued . A BB macro-form (immunoglobuline complex) has been reported , which is measured as a B form of the enzyme

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

 Egy-Chem for lab technology	 
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