

## Kinetic

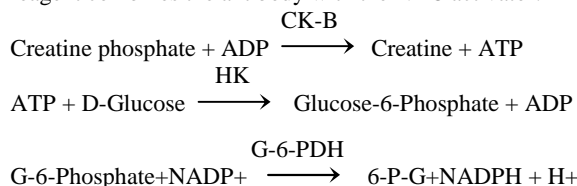
**REF:** CKM108025 (5 x 5 ml)  
CKM108050 (10 x 5 ml)

## 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 1.0 ml of R2 to on vial of R1 or prepare the working solution according to the number of test required by **mixing 4 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	
	<b>25,30 or 37°C</b>
<b>Specimen</b>	40 µl
<b>Working reagent</b>	1 ml
Mix, read initial absorbance after 120 sec. and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute ( A/min).	

## CALCULATION:

To calculate the CK-MB activity use the formula

$$\text{A/min} \times 8254 = \text{U/L CKMB}$$

### EXPECTED VALUE :

	25°C	30°C	37°C
<b>Adult</b>	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 .

### 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 )



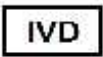
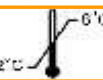

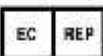



Interferences are negligible up to :		
Ascorbic Acid 40 mg/dl	Triglycerids 1200	mg/dl
Hemoglobin 500 mg/dl	Glucose 600	mg/dl
IgG 5 g/fl		

### 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

### 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.

	Consult Instructions for Use
	Caution, Consult accompanying
	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

 <b>EGY- CHEM</b> for lab technology Badr City, Industrial Area Piece 170 250 Fadan In East of Elrubaki, EGYPT Office Tel: +202 26236727 / +202 26236598 Factory Tel: +202 23108170 / +202 23108171 Fax: +202 26240986 <a href="http://www.egy-chem.com">www.egy-chem.com</a>	  <b>MDSS GmbH</b> Schiffgraben 41 30175 Hannover, Germany
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