Creatine kinase - MB (CK-MB) Diagnostic Reagent Kit (DGKC Method)
Product Instruction

Product name
Creatine kinase - MB (CK-MB) Diagnostic Reagent Kit (DGKC Method)
Abbreviation: CK-MB

Package Specifications

R1	R2
80ml×2	20ml×2

Calibrator (lyophilized):

Specification 1 (1.0mL×1; 1 level).

Intended use
Creatine kinase - MB (CK-MB) diagnostic reagent is used for quantitative in vitro determination of Creatine kinase - MB in human serum on photometric systems.

Clinical significance
Creatine kinases are dimeric molecules composed of M and B subunits and exist as the isoenzymes MM, MB, and BB. The subunits M and B are immunologically distinct; CK-MM and CK-MB are distributed primarily in the skeletal muscle and heart muscle, respectively. While CK-BB is present mainly in the brain and in tissues composed of smooth muscle. Following acute myocardial infarction, CK-MB activity increases significantly and this elevation is highly specific for the laboratory diagnosis of myocardial infarction. Although total CK activity usually increases following myocardial infarction, in some patients only the CK-MB activity increases, while the total CK remains in the normal range.

Principle
CK-MB consists of the subunits CK-M and CK-B. Specific polyclonal antibodies against CK-M inhibit the complete CK-MM activity (main part of the total CK activity) and the CK-M subunit of CK-MB. Only CK-B activity is measured, which is half of the CKMB activity.
The assay consists of three reaction steps:

1. $\text{Creatine phosphate} + \text{ADP} \xleftrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$
2. $\text{ATP} + \text{Glucose} \xleftrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-P}$
3. $\text{Glucose-6-P} + \text{NADP}^+ \xleftrightarrow{\text{G6P-DH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^+$

Main ingredient

Composition	Concentration
Imidazole Buffer	100mmol/L(pH=6.7)
Magnesium acetate	10mmoll/L
N-acetyl cysteine	20mmol/L
EDTA	2mmol/L
NADP	2mmol/L
G6P-DH	>1500U/L
Hexokinase	>2500U/L
CK-MM (human) inhibiting antibodies	>2000U/L
Glucose	20mmol/L
Creatine phosphate	30mmol/L
Di(adenosine-5')pentapho	10μmol/L
AMP	5mmol/L
ADP	2mmol/L

Storage and stability
This kit stays stable for 12 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Serum.
Serum CK-MB is an unstable enzyme. The activity is reduced approximately 10% by storage at 2-8°C for 24 hours or 18-22°C for 1 hour.

Assay procedure

	Blank	Sample
Reagent 1	200μl	200μl
Dist. water	10μl	-
Sample	-	10μl
Mix. Incubate for 2 minutes at 37°C. Then add:		
Reagent 2	50μl	50μl
Mix. Incubate for 2 minutes at 37°C. Read absorbance within 2 minutes and calculate the average rate of the absorbance change ΔA/min.		
Main wavelength	340 nm	
Sub wavelength	405nm	
Method	Rate	
Reaction direction	+	

Procedure (Manual):
1. Zero spectrophotometer at 340nm with distilled water.
2. Appropriately label cuvettes: reagent blank, sample, etc.
3. Pipette 1.0ml (1000μl) of reagent 1 into all cuvettes.

4. Add 0.05ml (50µl) of sample to respective cuvettes. Mix.
5. Incubate for 2 minutes at 37℃.
6. Then add 0.25ml (250µl) of reagent 2 to respective cuvettes. Mix gently.

7. Incubate for 2 minute at 37℃. Read absorbance within 2 minutes and calculate the average rate of the absorbance change ΔA/min.

Calculations

$$\text{Conc. of CKMB} = \frac{\text{A(sample)- A(blank)}}{\text{A(Cal.) - A(blank)}} \times \text{conc. of Cal.}$$

Reference interval

0-24 U/L

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

1. Measuring range

The method is linear up to 1000 U/L.

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Direct Bilirubin	20mg/dl
Total Bilirubin	20mg/dl
Haemoglobin	100mg/dl
Intralipid	0.4 %
VC	40mg/dl

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C

virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Quality control

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	/
Wave Length Prim	340
ABS. Limit	32000
Sample Volume（uL）	10
R1 Volume（uL）	150
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	SPLINE
Calibration Point	6
Span Point	4
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	10
Sample DIL. VOL.	/
R1 Volume（uL）	150
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	/
METHOD	END
SLOPE	-

Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	3
Dynamic Range H	180
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	6AB
Formula	spline
STD(1) Conc.#	*
Unit	ng/mL

Dubai - Global Office
Xportin Global FZE
Business Centre,
Sharjah Publishing City Free Zone,
Sharjah, United Arab Emirates
Formation No. 4307793.01
Mobile: +971 506938802 / +91 98241 88802
Email: xportinglobalfzellc@gmail.com
Website: www.xportin.com

India - Head Office:
Devasvi Enterprise LLP (Manufacturer)
Navsari, Gujarat – 396445
Email: devashvienterprisellp@gmail.com