Spectrum For Diagnostic Industries

CREATINE KINASE MB(CK-MB)-(4+1)

REF.	Pack size
167 05 005	(5 x 5 ml) 25 tests
167 05 010	(5 x10 ml) 50 tests

IVD

Intended Use

Creatine Kinase MB (CK-MB) reagent is intended for the in-vitro quantitative and diagnostic determination of Creatine kinase MB in human serum.

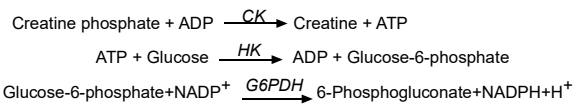
Introduction

CK is present in three different isoenzymatic forms, which could be separated by electrophoresis or column chromatography; each form is originated in different body tissues, paying off their diagnostic determinations. CK exists in serum in dimeric forms as CK-MM, CK-MB, and CK-BB and as macro-enzymes. Measurement of CK-MB is a quite specific test for detection of cardiac muscle damage and is therefore used for diagnosis and monitoring of myocardial infarction.

Method

According to the recommendations of the International Federation of Clinical Chemistry (IFCC).

Principle



Reagents

Reagent 1 (Buffer reagent)

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
Creatine phosphate	250 mmol/L
Hexokinase (HK)	3 KU/L
Anti-human-CK-M.	

Reagents preparation, storage, and stability

CK-MB reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 ^{O}C. Once opened, the reagent is stable for 2 months at the specified temperature.

Deterioration

Do not use CKMB reagent in case of presence of particles or turbidity.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

Serum free of hemolysis is the preferred specimen. Plasma containing heparin, EDTA, citrate or fluoride may produce unpredictable reaction rates. Stable for 2 hours at 20-25 ^{O}C, 5 days at 4-8 ^{O}C.Total CK concentration in the sample must be lower than 1000 U/L. Dilute the serum 1/2 if necessary, with NaCl (150 mmol/L).

Procedure

System Parameters

Wavelength	340 nm (334-365 nm)
Optical path	1 cm
Assay type	Fixed rate
Direction	Increase
Sample: Reagent Ratio	1:25
Temperature	37 ^{O}C
Zero adjustment	against air
Sensitivity	2 U/L
Linearity	2000 U/L

Procedure

Pipette into a cuvette:

Reagent (R1)	400 µl
Reagent (R2)	100 µl
Specimen	20 µl

Incubate 5 minutes at 37 ^{O}C then read A1 and after 5 minutes read A2.

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Calculation

$$(A2-A1) \times 1651 = \text{U/L CKMB}$$

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter of sample (U/L).

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Sensitivity

2.0 U/L

Linearity

The reaction is linear up to CK-MB concentration of 2000 U/l; specimens showing higher concentration should be diluted 1+2 using physiological saline and repeat the assay (result×3).

Interferences

Haemoglobin (> 2.5 g/L) , lipemia (triglycerides > 900 mg/dL) and Bilirubin (< 25 mg/dL) do not interfere. Presences CK-BB or adenilate kinase, and of macro or mitochondrial CK above normal concentrations interfere. Other drugs and substances may interfere.

Expected values

The discrimination value for myocardial infarction is around 25 U/L.

Performance Characteristics

A study using 20 human specimens between this CK-MB reagent and a reference method yielded a correlation coefficient of 0.998 and a linear regression equation of y = 1.050 x + 0.035

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	45	129
CV%	3.5	3.2

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	40	130
CV%	2.8	2.3

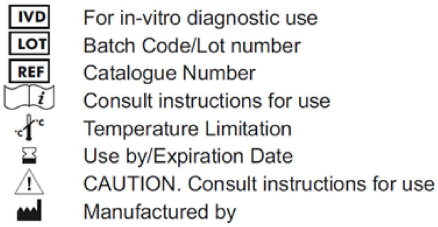
Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Urdal P and Landaas S. Clin Chem 1979; 25: 461-465.
2. Young DS. Effects of drugs on clinical laboratory tests, 3th ed. AACC Press, 1997
3. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1997.

SYMBOLS IN PRODUCT LABELLING



Spectrum For Diagnostics Industries
Ismailia Free Zone Industrial Area, Block 5,
Cairo Port Said Avenue, 41511 Ismailia, Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany