Bioboon™

CK-MB Test Kit

Kinetic UV

Quantitative determination of CK-MB in human Serum / Plasma / other body fluids
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
CKM 10	1 X 10 ml
CKM 25	1 X 25 ml
CKM 50	1 X 50 ml
CKM 100	1X100 ml
CKM 1000	1X1000 ml
CKM 5000	1 X 5000 ml
CKM 10000	1X10000 ml

CLINICAL SIGNIFICANCE

CK-MB is an enzyme formed by the association of two subunits from muscle (M) and nerve cells (B). CK-MB is usually present in serum at low concentration; it is increases after an acute infarct of myocardium and later descends at normal levels. Also is increased, rarely, in skeletal muscle damage 5,6. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Optimized UV test according to DGKC (German Society of Clinical Chemistry) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) for CK with inhibition of CK-M isoenzymes by monoclonal antibodies

PRINCIPLE

This procedure involves measurement of Creatine kinase (CK) activity in the presence of an antibody to CK-M monomer. CK-M fractions of the CK-MM and the CK-MB in the sample are completely inhibited by an anti CK-M antibody present in the reagent. Then the activity of the CK-B fraction is measured by the CK (NAC act.) method. The CK-MB activity is obtained by multiplying the CK-B activity by two.

REAGENT

Reagent I : Buffer Reagent I
Reagent II : Enzyme Reagent II

REAGENT PREPARATION

Mix 4 Part (4 ml) of Buffer Reagent I with 1 Part (1 ml) of Enzyme Reagent II.

REAGENT STORAGE AND STABILITY

Prior to use:
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Reconstituted Reagent:
When stored capped at 2-8°C, the reagent is stable for at least 10 days and keep it closed container.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma
Stability: 7 days at 2 – 8°C
1 month at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	340nm
Cuvette	1 cm
Reaction Temperature	37°C
Measurement	Against distilled water
Reaction Type	Kinetic test
Reaction direction	Increasing
Sample Volume	50 µl
Reagent Volume	1000 µl
Delay/lag/time	300 Secs
Interval Time	60 Secs
No. of Readings	05
Blank Absorbance limit	≤ 0.7
Factor	6752
Low Normal at 37°C	0 IU/L
High Normal at 37°C	24 IU/L
Linearity	1500 IU/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

Working Reagent	1000 µl
Incubate at Assay temperature for 1 min and add.	
Sample	50 µl

Mix well and after 5 min. measure the change in absorbance. Read the initial absorbance and start timer simultaneously, read again after every 60 seconds for 5 minutes. Calculate Δ A/min.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 1500 IU/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

IU/L CKB = Δ A/min. x 6752

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

This method is traceable to the molar extinction coefficient.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
CRD Control 2	22.69	0.71	3.13%
CRD Control 3	154.84	1.05	0.68%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
CRD Control 2	22.84	0.79	3.44%
CRD Control 3	155.50	1.71	1.10%

LINEARITY

The method is linear upto a concentration of 1500 IU/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for CK-MB is 5 IU/L.

METHOD COMPARISON

A comparison of CK-MB with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum (37°C)	0 - 24 IU/L
Serum (30°C)	0 - 14 IU/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

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

INTERFERENCE

- Bilirubin: No interference found up to Bilirubin 40mg/dl.
- Hemoglobin: No interference found up to 4g/L (400mg/dL).
- Lipemia: No interference found up to 600mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Young s et al., Clin. Chem., 21:10 (1975)
2. IFCC methods for the measurement of catalytic concentrations of enzymes, JIFCC. (1989) 1 : 130.

Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop et.al. 5th Edition

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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