

LiquiMAX CK-MB

(IFCC Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVCMB - 10	10 ml	1 x 8 / 1 x 2 ml
AVCMB - 20	20 ml	2 x 8 / 2 x 2 ml
AVCMB - 50	50 ml	5 x 8 / 5 x 2 ml

INTENDED USE:

Kit is use for the quantitative determination of CK-MB Iso Enzyme in Human Serum and Plasma

PRODUCT FEATURES

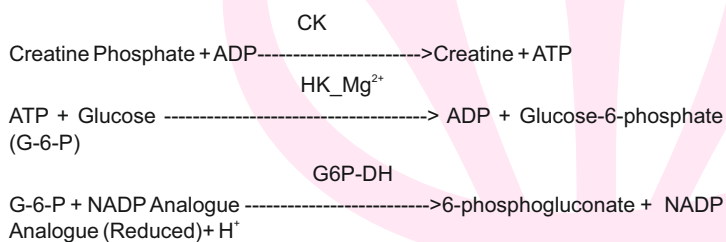
- Liquid Stable, Ready to use Two Reagents. (R1= Buffer, R2=Substrate)
- Kinetic Factor 8655
- NADP analogues are used for better stability.
- Linearity 1000 IU/L.
- 8 Minutes increasing Kinetic Reaction
- Measuring wavelength 340 nm.
- Serum and Plasma are the specimens
- Available as multipurpose reagents and dedicated system packs

CLINICAL SIGNIFICANCE :

CK is a dimeric enzyme occurring in 4 different forms, a mitochondrial iso-enzyme and 3 cytoplasmic iso-enzymes. CK MM is a muscle enzyme, CK BB is a brain enzyme and CK MB is the heart enzyme. CK activity has elevated many diseases including those involving skeletal muscle, heart, central nervous system and the thyroid. Most determinations of CK in the clinical laboratory are used for the early detection of Myocardial Infarction in which the enzyme is elevated within 3 to 8 hours after the onset .

PRINCIPLE

This procedure for CK MB incorporates a polyclonal antibody to CK M in the Reagent 1. The antibody inhibits 99.6% of the CK M without affecting the CK B units. The remaining CK B activity therefore corresponds to half the CK MB activity and is determined by the method used for total CK.



N.B: The CK activity should be determined using the CK-NAC method before performing the CK-MB assay.

STORAGE AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions are maintained.

KIT COMPONENTS

- Buffer Reagent R1
- Substrate Reagent R2

COMPOSITION

	Ingredients	Concentration
Reagent 1	Imidazole Buffer	pH 6.7 100 mmol/l
	Glucose	20 mmol/l
	Magnesium Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	NADP	2.0 mmol/l
	CK-M Inhibiting Antibody	8000 U/l
	HK	> 2.5 U/ml
	N-acetylcysteine	20 mmol/l
Reagent 2	Creatine Phosphate	30 mmol/l
	G6P-DH	> 1.5 U/ml
	Diadenosine pentaphosphate	10 µmol/l

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.3 at 340 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general "Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

Use serum, free from haemolysis, heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/Plasma should be separated from cells immediately after collection and stored in the dark.

Stability of specimen up to 7 days at 2-8°C.

SYSTEM PARAMETERS

Reaction Type (Mode)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	340nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay time	:	300 seconds
Measuring Time	:	180 Seconds
Reagent Volume	:	0.5 ml (400 µl R1+ 100 µl R2)
Sample Volume	:	25 µl
Factor	:	8655
Linearity	:	1000
Units	:	IU/L
High Normal	:	24

TEST PROCEDURE :

Reagent	Test
Reagent 1	400 µL
Sample	25 µL
Mix and incubate for 5 min at 37 °C	
Reagent 2	100 µL

Mix well and immediately aspirate in to the analyzer. After 300 Seconds incubation, measure the change in optical density per 60 seconds during 180 seconds against distilled water at 340 nm as follows.

- Ao - Exactly after 300 Seconds
A1, A2, A3 - Exactly after every 60 seconds for 180 seconds.

CALCULATIONS:

Calculate the average change in absorbance per minute (Δ Abs/min).

Activity of CK-MB [IU/L]
At 340 nm in IU/L = Δ Abs / min x 8655

EXPECTED VALUES:

Adults up to 24 IU/L (37°C)

QUALITY CONTROL & CALIBRATION:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed: Prior to reporting patient results. Following any maintenance procedure on the photometer used. At intervals established by the Laboratory Q.C. Programme.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1000 IU/L

2. Sensitivity/ Limit of Detection (LOD)

The Lowest Detectable Level was estimated at 2 IU/L

3. Interferences

Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l
Bilirubin. Haemolysis: Less than 10% interference up to 1.25 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 2.5 g/l Intralipid.

4. Precision:

Intra-Assay

Sample	Mean (IU/L)	SD (IU/L)	CV%
Level 1	17.21	4.88	2.83
Level 2	77.64	3.8	0.49

Inter-Assay

Sample	Mean (IU/L)	SD (IU/L)	CV%
Level 1	16.54	5.58	3.37
Level 2	74.02	3.8	0.51

5. Method Comparison:

Using 50 samples, a comparison, between LiquiMAX CK-MB test (y) and another commercially available test (x), gave the following results:

$y = 0.976x - 0.269$ $r = 0.999$ Sample range: 0 to 329 U/l

LIMITATIONS

Linear up to 1000 U/L. For samples with a higher concentration, dilute 1:1 with Saline (0.9 g/l NaCl) and reassay. Multiply result by 2.














WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCE

- Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352390 and 974-975

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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