

# CKMB (2-8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCMB3	10x5ml / 2x5ml

## Intended Use:

For *In Vitro* diagnostic use by trained professionals only.

This reagent is intended for the quantitative determination of CKMB in human serum.

## Clinical Significance:

Creatinine kinase (CK) is a dimeric enzyme occurring in four different forms: a mitochondrial isoenzyme and the cytosolic isoenzymes CKMM (muscle) CK-BB (brain) and CK-MB (myocardial).

The determination of CK and CK-isoenzyme activities is used in the diagnosis and monitoring of myocardial infarction and myopathies such as progressive Duchenne muscular dystrophy.

## Test Principle:

CKMB is measured as CK activity, but with the addition of an antibody to CK-M monomer to the reagent which completely inhibits the activity of CK-MM and half of the activity of CK-MB. The activity of the B subunit of CK-MB and CK-BB is unaffected and since serum levels of CK-BB are negligible, the activity measured when multiplied by 2 represents the CK-MB activity.

## Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Buffer R1	Imidazole buffer pH 6.7	100 mmol/l
	Mg-acetate	10 mmol/l
	Glucose	20 mmol/l
	N-acetyl-cysteine	20 mmol/l
	NADP	2 mmol/l
	G6P-DH	2000 U/l
	HK	2500 U/l
	Diadenosine pentaphosphate	10 µmol/l
Substrate R2	CK-M antibody	1500 U/l
	Creatine phosphate	30 mmol/l
	ADP	2 mmol/l
	AMP	5 mmol/l
	Adenosine	10 µmol/l

## Reagent Preparation and Stability:

R1: Liquid, ready to use.

R2: Liquid, ready to use.

R1 and R2 are stable up to the expiry date when stored at 2 - 8°C.

## Sample Collection, Preparation and Stability:

Collect serum by separation after standard venepuncture technique. CK will be stable in the sample for up to 3 days when stored at 2 - 8°C.

Do not use haemolysed samples.

## Assay Procedure: Sample Start:

Prepare a suitable volume of Working Reagent by mixing 5 volumes of Reagent 1 with 1 volume of Reagent 2 (5 R1 + 1 R2). This mixture will be stable for up to 10 days at 2 - 8°C if stored sealed and free from contamination.

WAVELENGTH	340nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length

Description	Volumes
Working Reagent	1000 µl
Let the Working Reagent reach the assay temperature by incubating it at assay temperature for two minutes	
Sample	50 µl
Mix and incubate for 5 minutes at assay temperature. Start a timer and read the absorbance of the sample after exactly 1, 2 & 3 minutes. Calculate the mean absorbance/min (Δ Abs)	

## Calculation:

Calculate the ΔAbs/min of the sample

Concentration = ΔAbs Sample x 6666

## Performance Characteristics:

### Measuring range

6 to 1000 U/l.

Dilute samples with higher concentrations using Normal saline 1+9 and rerun the assay. Multiply the result by 10.

### Analytical Sensitivity: (Lowest detection limit):

6 U/l.

## Imprecision

### Intra-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	42.17	0.95	2.26
Pool 2	75.47	2.58	3.42

### Inter-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	11.15	0.45	3.99
Pool 2	32.81	1.86	5.68

## Reference Range:

	37°C
Serum	Up to 24 U/l

There is a high probability of myocardial damage when the following conditions for clinical test results apply:

Total CK men	>195 U/l
Total CK Women	>170 U/l
CK MB	>24 U/l
When the CK MB activity accounts for > 6 - 25% of the total CK activity.	

## Limitations:

The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

## Automated systems:

Contact AMS Diagnostics Technical Department for applications on a wide range of automated analysers.

For automation we recommend the use of a serum based calibrator.

## References:

1. IFCC methods for the measurement of catalytic concentrations of enzymes, JIFCC, 1989; 1: 130.
2. Clinical Chemistry, Principles, Procedures, Correlations. Michael L Bishop et al, 5<sup>th</sup> Edition.

REF	Catalogue number	LOT	Temperature limitation
LOT	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	LOT	Use by Date
MAN	Manufacturer		

