CK - MB

Kinetic UV

R1: 2 x 30 ml + R2: 2 x 7,5 ml CL18-75

INTENDED USE

Quantitative dtermination of Creatine Kinase MB (CK-MB) in serum and plasma.

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 increased after an acute infarct of myocardium and later descends at normal levels. Also is increased, rarely, in skeletal muscle damage.

PRINCIPLE

The procedure involves measurement of CK activity in the presence of an antibody to CK-M monomer. This antibody completely inhibits the activity of CKMM and half of the activity of CK-MB while not affecting the B subunit activity of CK-MB and CK-BB. Then it's used the CK method to quantitatively determine CKB activity1,2. The CK-MB activity is obtained by multiplying the CK-B activity by two.

SAMPLE

Serum, heparinized plasma o EDTA. Avoid hemolyzed samples.
STABILITY: 1 week at 2-8°C protected from light.
CK-MB activity decreases a 10% after 24 hours at 4ºC or 1 hour at 25ºC.

REAGENTS

Only for in Vitro diagnostics.
Liquid reagents ready to use.

Package content:	CL18-75
REAGENT 1 Imidazol 125 mM, D-Glucose 25 mM, NAC 25 mM, Magnesium Acetate 12, mM, NADP 2,52 mM, EDTA 2,02 mM, Hexokinase ≥ 6800 U/L	2 x 30 ml
REAGENT 2 ADP 15,2 mM, AMP 25mM , Diadenosine 103 mM, G6PDH ≥ 8800U/L, Creatine phoaphate 250 mM	2 x 7,5 ml

STABILITY: the reagent is ready to use. Store at 2-8°C and protect from light to keep the reagent stable up to the expiration date on the label. Do not freeze. Once opened the reagent is stable for 2 months at 2-8°C, if contamination is avoided. Keep bottles closed when not in use.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; saline solution.

PREPARATION OF THE WORKING REAGENT

Working Reagent: mix 4 volumes of Reagent 1 with 1 volume di Reagent 2.
Stability: 7 days at 2-8°C or 12 hours at room temperature if stored tightly closed and protected from light.

MANUAL ASSAY PROCEDURE

Method:	decreasing kinetic
Wavelength:	340 nm
Cuvette:	1 cm
Temperature:	25, 30, 37°C
Reading time:	5 minutes
Reading:	against air or water

Bring the reagents necessary for the test to the chosen temperature for the analysis.
Pipette into a cuvette:

Sample	40 µl
Working Reagent	1,0 ml

Mix and incubate at the chosen temperature for 10 minutes.
Read initial absorbance (A1), read again after 5 minutes (A2). Calcolate the difference between Absorbance:
ΔA = A2-A1.

Reaction volumes can be proportionally varied without any change.

Calculate the enzymatic activity in the sample analyzed by multiplying the ΔA found by the appropriate factor shown in the following table.

U/L CK-MB = ΔA x 1651

Temperature conversion factors:
To correct results to other temperature multiply by

Assay Temperature	Conversion factor to		
	25°C	30°C	37°C
25°C	1,00	1,53	2,38
30°C	0,65	1,00	1,56
37°C	0,42	0,64	1,00

REFERENCE VALUES

The suspicion of myocardial damage is based on the three followig factors

	25°C	30°C	37°C
CK-MB	> 10 U/L	> 15 U/L	> 24 U/L
TOTAL CK	25°C	30°C	37°C
Men, up to	80	130	195
Wemen, up to	70	110	170

$$\frac{\text{CK-MB Activity}}{\text{CK Total Activity}} \times 100 = \text{6-25\% CK-MB Activity in the sample}$$

Each laboratory should define its own reference values for this method.

QUALITY CONTROL - CALIBRATION

A quality control program is recommended for all clinical chemistry laboratories. Contact FAR for more information.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 1,9 U/L.

Linearity: up to 1000 U/L.
For higher values, dilute the samples 1:2 with physiological solution and multiply the result obtained by 2.

Precision

Intra-assay (n=10)	Mean [U/L]	CV %
Sample 1	33,7	2,96
Sample 2	166,5	2,26

Inter-assay (n=20)	Mean [U/L]	CV %
Sample1	31,0	3,80
Sample 2	161,0	2,15

Interferences
Bilirubin do not interfere up to 600 µm/L.
Hemoglobin do not interfere up to 1,25 g/l.

Correlation against a reference method:
the correlation of the method (Y) against a reference method (X) gives this equation:

Y = 0,976x – 0,269 r = 0,999 (n = 50)

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behaviour in laboratory.

REFERENCES

1) Mathieu M. Et al., Ann. Biol. Clin., 40,99 (1982).
2) Vassault, A. et al. Ann.Biol.Clin., 44, 686,(1986).
3) Young, D.S., et al., Clin. Chem. 21:1D (1975

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

Edition 01 - Jen 2021 RR