Creatine Kinase - MB

IVD CE

Anti CK-M Immunoinhibition. Kinetic UV.Liquid

PRODUCT CODE
CZ012

INTENDED USE
The reagent is intended for in vitro quantitative determination of creatine kinase in serum or 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 damage5,6,7,8 . Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

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.

REAGENT COMPOSITION

R1	**Imidazol, PH 6.7** **D-Glcose** **N-Acetyl- Cysteine** **Magnesium acetate** **NADP** **EDTA** **Heaokinase**	**125 mmol/L** **25 mmol/L** **25 mmol/L** **12.5 mmol/L** **2.52 mmol/L** **2.02 mmol/L** **≥ 6 800 U/L**
Anti – human polyclonal CK -M antibody (sheep|) sufficient to inhibit up to 2000 U/L of CK-MM		
R2	**ADP** **AMP** **di-Adenosine -5- peentaphosphate** **Glucose – 6- phosphate dehydrogenase** **Creatine phosphate**	**15.2 mmol/L** **25 mmol/L** **103 mmol/L** **≥ 8 800 U/L** **250 mmol/L**

REAGENT PREPARATION
Both reagents are ready to use.

REAGENT STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented.
Do not use reagents over the expiration date.

Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1,2

SPECIMEN
Serum free of hemolysis or heparin plasma:
Stability 7 days at 2-8ºC, protected from light
. CK-MB activity decreases a 10% after 24 hours at 4ºC or 1 hour at 25ºC

PRECAUTION
Working reagent (WR): Mix 4 volumes of reagent 1 with 1 volume of reagent 2. Stability: 7 days at 2-8ºC or 12 hours at room temperature (20-25ºC).

PROCEDURE
1.Assay condition:

Wavelength	340 nm
Cuvette	1 cm light path
Constant temperature	25°C / 30 °C/ 37 °C

2. Adjust the instrument to zero with distilled water or air.
3. Pipette into a cuvette:

WR (ml)	1.0
Sample (μL	40

4. Mix and incubate 10 minutes.
5. Read initial absorbance (A) of the sample, start the stopwatch and read again after 5 minutes (A2). 6. Calculate the difference between absorbances ΔA= A2 – A1.

CALCULATION

$\Delta A\ X\ 825 = U/L\ of\ CK-MB$ $\Delta A\ X\ 1651 = \frac{U}{L}\ of\ CK-MB$

Calculating factor in automatic analyzers by kinetic method (ΔA/min.) is 8255.
Units: One international unit (IU) is the amount of enzyme that transforms 1µmol of substrate per minute, in standard conditions. The concentration is expressed in units per litre of sample (U/L).
Temperature conversion factors
To correct results to other temperatures 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

NORMAL RANGE
The suspicion of myocardial damage is based on the three following 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 U/L	130 U/L	195 U/L
Women , up to	70 U/L	110 U/L	170 U/L

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

These values are for orientation purpose. Each laboratory should establish its own reference range.

LINEARITY
From detection limit of 1.9 U/L to linearity limit of 318 U/L .
If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

QUALITY CONTROL
All control sera with CK-MB value estimated by this method can be used.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NOTES
1- It is important to ensure the working reagent and nitrite reagent are thoroughly mixed before adding the sample.
2- Bilirubin levels may be reduced if the sample is exposed to light.

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EC REP
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Haemolytic sample will also show low value.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

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