GENESIS

Instructions For Use

Creatine Kinase (CK) MB (Immuno Inhibition Method (4+1))

Cat no.	size
1203 101	5*5
1203 102	10*5
1203 103	1*25

INTENDED USE

Creatine Kinase (CK) MB Reagent is intended for the in vitro Quantitative diagnostic determination of Creatine Kinase MB (CK-MB) in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Creatine kinase is composed of two polypeptide chains, denoted B (for brain) and M (for muscle); these give the three dimeric isoenzymes: MM (CK-1), MB (CK-2) and BB (CK-3).

The percentages of CK-MB activity versus total CK activity are usually less than 6 %, but after a myocardial infarction, these values can rise from 10 to 30% depending on the extent of myocardial damage and the location of the infarct. However, a myocardial infarction in a previously healthy heart may have a rather low serum CK-MB fraction. Therefore, the diagnosis of myocardial damage must be based on the clinical history and findings, the magnitude of the CK-MB elevation, and its temporal pattern.

PRINCIPLE OF THE METHOD

A specific antibody inhibits both M subunits of CK-MM (CK-3), and the single M subunit of CK-MB (CK-2) and thus allow determination of the B subunit of CK-MB (assuming the absence of CK-BB or CK-1).

CK-B catalytic concentration, which corresponds to half of CK-M concentration, is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH) coupled reactions.

Creatine phosphate + ADP $\xrightarrow{\text{CK-MB}}$ Creatine + ATP

ATP + Glucose $\xrightarrow{\text{HK}}$ ADP + Glucose - 6 - phosphate

Glucose - 6 - phosphate $\xrightarrow{\text{NADP}}$ Gluconate - 6 - phosphate + NADPH

COMPOSITION

Reagent (R 1)	**Imidazol, pH 6.7**	**125 mmol/L**
	D-Glucose	**25 mmol/L**
	N-Acetyl-L-Cysteine	**25 mmol/L**
	Magnesium acetate	**12.5 mmol/L**
	NADP	**2.52 mmol/L**
	EDTA	**2.02 mmol/L**
	Hexokinase	**≥6 800 U/L**
	Anti-human polyclonal CK-MB antibody (sheep) sufficient to inhibit up to 2000 U/L of CK-MM	
Reagent (R 2)	**ADP**	**15.2 mmol/L**
	AMP	**25 mmol/L**
	di-Adenosine-5- pentaphosphate	**103 mmol/L**
	Glucose-6-phosphate dehydrogenase	**≥8 800 U/L**
	Creatine phosphate	**250 mmol/L**

STORAGE

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.

REAGENT PREPARATION

Working reagent: (4) Parts of (R1) are mixed with(1) part of(R2) .

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

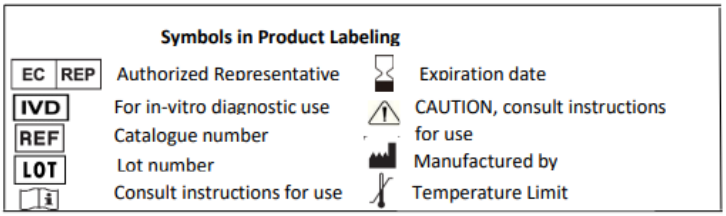
− Analyzer, spectrophotometer able to read at 340 nm.

SPECIMEN.

Serum or heparinized plasma collected by standard procedures.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.



PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Reaction……Fixed Time
Wavelength……..……..…..340 nm
Cuvette:…… 1 cm light path Constant temperature ……..37ºC
Delay time……..60 sec
Measuring time:……300 sec

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

Working Reagent	1.0 mL
Sample	40 µL

5. Mix and incubate for 60 Sec**.**
6. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance after 5 minutes.
7. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

ΔA x 1651 = U/L of CK-MB

REFERENCE VALUES

Up to 25 U/L

QUALITY CONTROL

It is recommended to use the Control Serum level Iand II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

− Detection limit: 3.0 U/L.

− Linearity limit: 1000 U/L .

For higher values dilute sample **1/3** with physiological saline and repeat measurement**.**

Precision:

− Repeatability (within run):

Mean Concentration	CV	n
45 U/L	2.8 %	20
129 U/L	2.3 %	20

− Reproducibility (run to run):

Mean Concentration	CV	n
45 U/L	3.5 %	25
129 U/L	3.2 %	25

Interferences:

Hemolysis (hemoglobin > 2.5 g/L) and lipemia (triglycerides > 1.25 g/L) interfere. Presence in the sample of above normal concentrations of CK-BB or adenilate kinase, and of macro or mitochondrial CK interfere . Bilirubin (< 20 mg/dL) does not interfere. Other drugs and substances may interfere.

BIBLIOGRAPHY

1. Wicks R and Usategui M. Immunochemical determination of CK-MB isoenzyme in human serum. II. An enzymic approach. Clin Chem 1982;28:54-58.

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CE

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