N BIO - CK MB

(Mod.IFCC / Immunoinhibition method)

KIT NAME	KIT SIZE	CAT. NO
N BIO - CK MB	2 X 10 ml	DCKB02010M
N BIO - CK MB	2 x 25 ml	DCKB02050M

GENUINE BIOSYSTEM

INTRODUCTION

Creatine kinase (CK) catalyzes the transfer of phosphate group between creatine phosphate and adenosine diphosphate (ADP). The product of this reaction is adenosine triphosphate (ATP) – molecular source of energy. CK is a dimmer, composed of two different subunits called M and B. Three different isoenzymes formed from these subunits are found in brain and smooth muscle (BB), skeletal muscle (MM) and cardiac muscle (MM and MB). Increased CK-MB serum level is a strong marker of myocardial infarction.

METHOD PRINCIPLE

Optimized kinetic method according to International Federation of Clinical Chemistry (IFCC) with use of antibodies against CK-M fraction. Specific antibodies against CK-M inhibit the complete CKMM activity (which is the main part of total CK activity) and the CK-M subunit of CK-MB. Only CK-B activity is measured.

creatine phosphate + ADP $\xrightarrow{\text{CK-BB /CK-MB}}$ creatine + ATP

ATP + D-glucose $\xrightarrow{\text{HK}}$ ADP + D-glucose-6-P

D-glucose-6-P + NADP $\xrightarrow{\text{G6P-DH}}$ D-gluconate-6-P + NADPH + H+

The rate of absorbance changes at l=340 nm is directly proportional to half of CK-MB activity (B subunit activity).

KIT CONTENTS

Reagent Name	DCKB02010M	DCKB02050M
R1 CKMB Reagent	2 x 8 ml	2 x 20 ml
R2 CKMB Reagent	2 x 2 ml	2 x 5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-CK-MB and R2-CK-MB reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of R1-CK-MB with 1 part of R2-CK-MB. Avoid foaming.
Stability of working reagent : 10 days at 2-8°C 3 days at 15-25°C
Protect from light and avoid contamination

CONCENTRATIONS IN THE TEST

Imidazole buffer pH 6.7	100 mmol/l
D-glucose	20 mmol/l
Magnesium acetate	10 mmol/l
EDTA	2 mmol/l
ADP	2 mmol/l
AMP	5 mmol/l
Diadenosinepentaphosphate	≥ 10 µmol/l
N-acetylcystein	20 mmol/l
Creatine phosphate	30 mmol/l
NADP	2 mmol/l
Hexokinase (HK)	≥ 2.5 KU/l
Glucose-6-phosphate-dehydrogenase (G6P-DH)	≥ 1.5 KU/l
Mouse monoclonal antibodies agains CK-M	>75 mkat/l human (CK-MB inhibiting Capacity)

WARNINGS AND NOTES

Product for in vitro diagnostic use only.
The reagents contain 0.09% sodium azide as a preservative.
Avoid contact with skin and mucous membranes.
It is advisable to use instruments with resolving power of absorbance 0.0001.
Results CK-MB can be falsely high in case of prostate, kidney, ovary, breast and bladder cancer when isoenzyme CK-BB appears in the blood.

ADDITIONAL EQUIPMENT

-Automatic analyzer or photometer able to read at 340 nm with resolving power of absorbance 0.0001
-Thermostat at 37ºC
-General laboratory equipment

SPECIMEN

Serum, heparinized or EDTA plasma free from hemolysis.
As an anticoagulant for plasma preparation use EDTA or heparin lithium, sodium or ammonium salt.
CK activity is unstable and is rapidly lost during storage. Probes should be stored tightly closed and protected from light. Specimens can be stored up to 4-8 hours at 15-25°C or 1-2 days at 2-8°C or 1 month at -20°C, but it is recommended to perform the assay with freshly collected samples.

PROCEDURE

Wavelength	340 nm
Temperature	37°C
Cuvette	1 cm

Reagent	Test (T)
R1 CKMB reagent	800 µl
R2 CKMB reagent	200 µl
Bring to assay temperature, then add	
Sample	40 µl

Mix and incubate at adequate temperature. After about 7 min. read the absorbance against air or water. Repeat the reading after exactly 60, 120 and 180 secs interval. Calculate the mean absorbance change per minute (△A/min.).

CALCULATION

CK-MB activity [U/L] = △A/min.(T) x 6000 (Factor)

REFERENCE VALUES

up to 24 U/L

The probability that cardiac infarction has occurred is high when CKMB and total CK activities are above normal values and CK-MB activity is between 6 and 25% of the total CK activity. It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If some commercial controls are not available it is recommended that known value sample be aliquated, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

Sensitivity / Limit of Quantitation: 4.50 U/L

Linearity: up to 2000 U/L. If creatine kinase total activity exceeds 2000 U/l dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilute factor.

Specificity / Interferences

Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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SYSTEM PARAMETERS

Method	Kinetic
Wavelength	340 mm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	300 secs
Read Time	180 secs
No. of Reading	3
Interval Time	60 secs
Sample Volume	0.04 ml (40 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	----
Units	U/L
Factor	6000
Reaction Slope	Increasing
Linearity	2000 U/L

GBPL/DCKB/04 12.20

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Genuine Biosystem Private Limited
Plot No.97 & 98, kattabomman street,
Parvathy Nagar Extension,
Old Perungalathur, Chennai - 600063, India.
Ph: +91-44-48681845
Email: genuinebiosystem@gmail.com
website: www.genuinebiosystem.com