CREATINE KINASE MB

Cat. No.	Pack Name	Packaging (Content)
BLT00018	CK MB 100	R1: 4 x 20 ml, R2: 1 x 20 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Creatine Kinase MB in human serum and plasma.

CLINICAL SIGNIFICANCE
Creatine Kinase is a dimeric enzyme composed of 2 types of monomers subunits, M (Muscular) & B (Brain). These subunits combine to form 3 distinct CK isoenzymes, CK-BB (CK-1), CK-MB (CK-2) and CK-MM (CK-3). CK-MB is found in a high concentration in the myocardium (between 14 to 42 %) and to a lesser extent in skeletal muscle. Damage to the myocardium, as will occur in acute myocardial infarction (AMI), will result in increased circulating levels of the CK-MB isoform. Typically CK-MB levels become elevated 4-6 hours after the onset of chest pain, peak between 12 to 24 hours and return to baseline within 48 hours. This assay meets the recommendation of DGKC and IFCC.

PRINCIPLE
Specific antibodies against CK-M inhibit the complete CKMM activity and the CK-M subunit of CKMB. Only CK-B activity is measured.

Creatine phosphate + ADP $\xrightarrow{\text{CKBB/CKMB}}$ Creatine + ATP

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

Glucose-6-phosphate + NAD $\xrightarrow{\text{G6PDH}}$ Gluconate-6-P+ NADH+H+

REAGENT COMPOSITION
R1

Imidazole buffer, pH 6.1	125 mmol/l
Glucose	25 mmol/l
Magnesium acetate	12.5 mmol/l
EDTA	2 mmol/l
N-acetyl-L-cysteine	25 mmol/l
NADP	2.4 mmol/l
Hexokinase	> 6.8 U/ml

Anti-CK antibodies (goat) blocking capacity up to 2000 U/l CK-MM

R2

ADP	15.2 mmol/l
D-glukoso-6-phosphate-dehydrogenase	> 8.8 U/ml
Creatine phosphate	250 mmol/l
AMP	25 mmol/l
Diadenosine pentaphosphate	103 µmol/l

REAGENT PREPARATION
Reagents are liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

Two reagents method – substrate start
Reagents are ready to use. After the first opening the vials, reagents are stable for 30 days at 2–8°C in the dark.

Monoreagent method – sample start
Mix 4 portion of reagent R1 with 1 portion of reagent R2.
Stability: 1 day at 20–25°C in the dark
14 days at 2–8°C in the dark

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (EDTA, heparin)
It is recommended to follow NCCLS procedures (or similar standardized conditions).
Loss of activity:
after 24 h at 2–8°C <10 %
after 1 h at 15–25°C <10 %

Stability 4 weeks at –20 °C in the dark
Discard contaminated specimens.

CALIBRATION
Calibration with the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
U/l x 0.017 = µkat/l

EXPECTED VALUES [6]
At 37°C < 25 U/l
CK-MB activity ranging between 6% and 25% of the total CK activity.
It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.
Limit of quantification: 7.1 U/l
Linearity: 1200 U/l
Measuring range: 7.1 – 1200 U/l

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/l)	SD (U/l)	CV (%)
Sample 1	43.98	1.14	2.65
Sample 2	144.54	2.10	1.46

Inter-assay precision Run to run (n=20)	Mean (U/l)	SD (U/l)	CV (%)
Sample 1	156.18	4.32	2.79
Sample 2	203.4	4.8	2.34

COMPARISON
A comparison between XL-Systems CK MB (y) and a commercially available test (x) using 40 samples gave following results:

y = 0.989 x - 1.08 U/l
r = 1.000

INTERFERENCES
Following substances do not interfere:
haemoglobin interferes, bilirubin up to 18 mg/dl, triglycerides up to 870 mg/dl.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE
Wavelength 340 nm
Cuvette 1 cm

Two reagents method – substrate start

Reagent 1 (buffer)	1.000 ml
Sample	0.050 ml

Mix and incubate for 3 min. at 37°C. Then add:

Reagent 2 (substrate)	0.250 ml

Mix and incubate for 3 min. at 37 °C. Then measure the absorbance and at the same time start the stopwatch. Read the absorbance again exactly after 1, 2 and 3 minutes. Calculate the average 1 minute absorbance change (ΔA).

Monoreagent method – sample start

Working solution	1.000 ml
Sample	0.040 ml

Mix and incubate for 3 min. at 37 °C. Then measure the absorbance and at the same time start the stopwatch. Read the absorbance again exactly after 1, 2 and 3 minutes. Calculate the average 1 minute absorbance change (ΔA).
Applications for automatic analysers will be supplied on request.

CALCULATION
1. CK-MB (U/l) = $\frac{\Delta A_{sam}}{\Delta A_{cal}} \times C_{cal}$ C_{cal} = calibrator concentration

2. Using factor:
CK-MB (U/l) = f x ΔA/min
f = factor
f = 8254 (at 340 nm)
Note: for CHEM 7 it is reccomended to use factor 8360

Applications for automatic analysers are available on request.

ASSAY PARAMETERS FOR PHOTOMETERS

Mode	Kinetic
Wavelength 1 (nm)	340
Sample Volume (µl)	40
Reagent Volume (µl)	1000
Lag Time (sec.)	180
Kinetic Interval (sec.)	60
No. of readings	3
Kinetic factor	8360
Reaction temperature (°C)	37
Reaction direction	Increasing
Normal Low (U/l)	0
Normal High (U/l)	24
Linearity Low (U/l)	0
Linearity High (U/l)	1200
Absorbance Limit (Max.)	0.7
Blank with	Water
Units	U/l

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SYMBOLS USED ON LABELS

REF Catalogue Number	Manufacturer	See Instruction for Use
LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC	Storage Temperature
Expiry Date	IVD In Vitro Diagnostics	CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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