ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CK-MB SL- Instruction for use

CE

IVD

R1: 2 x 50 mL REF A-R0200000401
R2: 2 x 20 mL

INTENDED USE
In addition to the possible risks regarding the reactive components, the product may contain non-reactive components such as preservatives (i.e. sodium azide or other) and detergents. The total concentration of these components is lower than the limits reported by the 67/548/EEC and 1999/45/EC directives and modifications and amendments regarding classification, labelling and packaging of dangerous preparations (reagents) have been made accordingly. However, it is recommended that this product be handled carefully, that ingestion and contact with eyes, skin and mucous membranes be avoided and that laboratory reagents are used according to good laboratory practice.

INTRODUCTION
Creatine kinase exists in 3 cytoplasmic forms: CK-MB (in cardiac muscle only), CK-MM (in striated and cardiac muscle) and CK BB (especially in brain).
Determination of CK in serum is used for the diagnosis and the follow-up of cardiac muscle damages. In myocardial infarction, the rates of total CK and CK-MB increase quickly until reaching a peak 10-24h after the onset of the infarction. The levels return to normal within 3 to 4 days. CK-MB levels higher than normal can also be observed after muscle damages..

PRINCIPLE
CKMB SL reagent contains an antibody inhibiting specifically CK-M subunits (i.e. 100% of CK-MM and 50% of CK-MB isozymes). The remaining activity, corresponding to CK-B fraction activity, is measured according to the IFCC reference method for measuring CK activity. CK-MB activity is then obtained by multi plying by 2 the remaining activity..

REAGENTS
Kit R1: 2x 50 mL R2: 2 x 20 mL
Reagent 1: no. 2 vials x 40 mL
Reagent 2: no. 2 vials x 10 mL

REAGENTS COMPOSITION
Reagent 1 : R1

Imidazole, pH 6.10	125 mmol/L
D-Glucose	25 mmol/L
N-Acetyl-L-Cystéine	25 mmol/L
Magnesium acetate	12.5 mmol/L
NADP	2.4 mmol/L
EDTA	2.0 mmol/L
Hexokinase	≥ 6 800 U/L

The concentration of anti-CK-M antibody contained in reagent R1 is sufficient to inhibit 2000 U/L of CK-M at 37 °C.

Reagent 2 : R2

Creatine phosphate	250 mmol/L
ADP	15.2 mmol/L
AMP	25 mmol/L
Diadenosine pentaphosphate	103 µmol/L
G-6-PDH	≥ 8 800 U/L

Classification
According to regulation (EC) N°1272/2008

GHS08
Repr. 1B H360D May demage the unborn child.

Storage and stability
The components of the kit, stored at 2-8 °C in unopened vials, are stable up to the expiry date indicated on the package. Components of the kit and concentration of reactive ingredients

STANDARDIZATION
Immuno-inhibition, IFCC Method.
Kinetic. UV.

SAMPLE COLLECTION

SAMPLE
Serum, plasma(LI-heparin, EDTA). Do not use emolyzed samples. Collect samples in accordance with the NCCLS procedure reported in the bibliography .

STABILITY OF THE SAMPLE
2 days at 2-8 °C or **4** weeks at -20°C.

Precaution
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Human control serum with known levels of CKmb is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available from I.S.E. S.r.l. "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. Obtained values must be within the range of acceptability. If erratic results occur, the following points should be checked:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. S.r.l. analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions - Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Calibration
For calibration use the factor **K= 8254**.

Method for automated instrumentation

Analyzer:	**I.S.E. Miura**		
Analyte Name :	**CKmb**	Ref.:	**A-R0200000401**
Method Code:	**CKmb**		
Type:	**Kinetic – Sample start**		
Unit:	**UI/L**		
Filter F1:	**340**		
Blank in:	**Not Used**		
Step	**Reaction volume**		**U.M.**
Volume reagent R1:	**160**		µL
Sample volume:	**8**		µL
Volume reagent R2:	**40**		µL
Final Incubation:	**300**		Sec.
Kinetic reading	**240**		Sec.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Calibrators and controls.

CONVERSION FACTOR
CK-MB [U/L] x 0. 01667 = CK-MB [µkat/L]

REFERENCE VALUES
Serum (37 °C) : 0-24 U/L

CK-MB activity must be compared to total CK activity (CK-MB/ total CK) x 100 < 6%.

The following 3 factors are indicators of damage of cardiac muscle :
Total CK: Men > 171 U/L Women > 145 U/L
CK-MB : > 25 U/L
Ratio : (CK-MB/ total CK) x 100: 6 - 25 %

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Note: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
SENSITIVITY:
4.0 U/L. Sensitivity was calculated on 20 replicates of normal saline and reported as the "mean zero value + 3 SD".

ANALYTICAL RANGE:
10 - 600 U/L.
Samples with values higher than 600 U/L must be diluted

1:10 with normal saline and the result multiplied by 10.
CK-MM activities up to 2000 U/L are inhibited. Therefore, samples with total activities above 2000 U/L require dilution because complete inhibition is no longer assured.

INTRA-ASSAY PRECISION:

U/L	L1	L2	L3
Mean	25	107	306
n	20	20	20
CV %	4.9	2.4	2.0

INTER-ASSAY PRECISION:

U/L	L1	L2	L3
Mean	23	103	298
n	20	20	20
CV %	6.6	4.7	2.6

ACCURACY:
this test (y) was compared with a commercially available method (x). The results were as follows:

N = 60, r = 0.9983, y = 1.046x -2.1 U/L

INTERFERENCES:
According to SFBC recommendations, studies have been per formed to determine the level of interference from different com pound :
Turbidity: Negative bias from 600 mg/dL (6.78 mmol/L) triglyce rides equivalent.
Unconjugated Bilirubin: Negative bias from 7 mg/dL (119.7 µmol/L)
Conjugated Bilirubin: Negative bias from 4 mg/dL (68.4 µmol/L) on normal sera. Negative bias from 6 mg/dL (102.6 µmol/L) on pathological sera.
In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

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Symbols used on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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