



R1: 2 x 41,5 mL – R2: 2 x 10,5 mL •  A-R0200000401

R1: 2 x 16,7 mL – R2: 1 x 8,5 mL •  R3330000016



INTENDED USE

Product used for the quantitative in vitro determination of Creatine kinase MB (CK – MB) in human serum and plasma. The test results should always be interpreted with reference to the clinical picture. For professional use only.

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

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

REAGENTS

A-R0200000401 – R1: 2 x 41,5 mL – R2: 2 x 10,5 mL

Reagent 1: n° 2 vials x 41.5 mL ready to use

Reagent 2: n° 2 vials x 10.5 mL ready to use

R3330000016 – R1: 2 x 16,7 mL – R2: 1 x 8,5

Reagent 1: n° 2 vials x 16.7 mL ready to use

Reagent 2: n° 1 vials x 8,5 mL ready to use

Concentration

Reagent A		
	Conc.	U.M.
Imidazole buffer pH 6.1	125	mmol/L
D-glucose	25	mmol/L
NADP	2.5	mmol/L
Hexokinase	≥ 6800	U/L
Sodium Azide	< 0.1	%
The concentration of anti-CK-M antibodies contained in the RA reagent is sufficient to inhibit 2000 U/L of CK-M at 37 °C.		
Reagent B		
Imidazole buffer pH 8.9	125	mmol/L
Creatine phosphate	250	mmol/L
ADP	15.2	mmol/L
G6PDH	≥ 8800	U/L
Sodium azide	< 0.1	%
Contains also Magnesium salts, N-Acetyl-L-Cysteine, EDTA, Diadenosine pentaphosphate, and AMP		



GHS08*



GHS08*

* **Warning: DANGER** – Contains Imidazole (CAS 288-32-4)

H360D - May damage the unborn child.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P202 - Do not handle until all safety precautions have been read and understood.

P308 + P313 - IF exposed or concerned: Get medical advice/attention.

Precautions

Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to

any risk statements relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components are below the limits set out in EU Regulation 1272/2008 EC and subsequent amendments and additions. However, it is recommended to handle the reagents according to the rules of good laboratory practice.

Reports of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability

Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up to the expiry date reported on the label. A slight variation in the composition of the reagents may occur between batches, but this has no effect on the test results.

Reagent Preparation

The reagents are liquid, ready to use. The solutions must be limpid with no evident precipitate. Pay attention to avoid bacterial contamination during use. The stability of the reagents are 30 days if closed, stored at 2 - 8°C and protect from direct light.

Preparation: mix 4 volumes of Reagent R1 with 1 volume of Reagent R2. The working reagent is stable 7 days if stored refrigerated. Do not use the product if there is physical evidence of deterioration (ex. particle matter)

SAMPLE COLLECTION

Type of sample and storage

Use serum or plasma containing heparin. Samples can be stored 8 hours at room temperature, for 48 hours at 2 - 8°C and for at least 1 month at - 20°.

Precautions

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

Procedure

Quality control

Human control serum with known levels of CK MB is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Control serum is available as "CK MB Control" code R0400000400. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:

- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation

Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".

All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration

For calibration use the factor K = 8572 (determined by the molar absorption coefficient of NADPH).

Reaction Conditions

Wavelength: 340 nm

Temperature: 37°C

Read against distilled water

	U.M.	Sample
Reagent A+B	μL	1000
Sample	μL	80

Mix well and after 3 minutes of incubation at 37°C. Read the absorbances of the sample at 30 seconds intervals during 5 minutes (Δ D.O./min). The reaction volumes can be varied proportionately, the calculation remains unchanged.

Calculation of the results obtained with respect to the multiplication factor

Δ D.O./min x K-factor* = U/L of CK-MB

K-factor = $\frac{TV \times 1000 \times 2}{6.3 \times SV \times D}$ = 8254

TV = Total volume of action in ml


SV = Sample volume in ml

6,3 = Absorption coefficient in millimoles of NADH at 340 nm

P = Cuvette diameter (1 cm)

2 = Multiply by 2 to determine the activity of the CK-MB



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NORMAL VALUES

Serum : 0-24 U/L 37 °C

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

The following 3 factors are indicators of heart muscle damage:

Total CK: Men > 171 U/L Women > 145 U/L

CK-MB : > 25 U/L

Ratio : (CK-MB/ total CK) x 100: 6 - 25 %

Each laboratory should establish its own normal values according to the population in which it operates.

Reagents included in the kit

The reagents are described above.

Materials required but not supplied in the kit

Calibrators and controls.

ANALYTICAL CHARACTERISTICS/PERFORMANCE

Linearity

Reaction is linear up to 600 U/L (10 µkat/L). Samples having greater concentrations should be diluted 1:5 with normal saline and re-assayed. This procedure extends the measuring range up to 3000 U/L.

Interference

Haemolysed samples should not be used since significant hemolysis may lead to falsely increased CK concentration because of adenylate kinase release.

No significant interference is defined by a recovery <±10% of the initial value: triglycerides up to 1800 mg/dl (20.3 mmol/L); Unconjugated bilirubin up to 30 mg/dl (513 µmol/L); Conjugated bilirubin up to 29.5 mg/dl (505 µmol/L); Ascorbic Acid up to 20 mg/dl; Paracetamol up to 30 mg/dl; Acetylsalicylic Acid up to 200 mg/dl.

Precision of the method

Within series				
Range	U.M.	Average	C.V. (%)	N
Low	U/L	21	1.9	80
Medium	U/L	54	1.4	80
High	U/L	227	0.3	80
Between series				
Range	U.M.	Average	C.V. (%)	N
Low	U/L	21	6.2	80
Medium	U/L	54	1.8	80
High	U/L	227	1.2	80

Sensitivity

At λ340 nm a concentration of about 10 U/L of CK-MB in conditions established for this test.

Comparative method

The CK MB reagent has been compared with a similar method on the market using samples ranging from 10 to 600 U/L. The results of the comparison were a regression line $y = ,058x - 4$ U/L; Correlation Coefficient $r = 0.999$; number of samples analyzed $n = 99$.

Disposal of reagents

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

Manufacturer:








Sclavo Diagnostics International

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Symbols used in IFU and Packaging	
 In vitro diagnostic medical device vitro	 Manufacturer
 Catalogue Number	 Instruction for use
 Lot Number	 Temperature limitation
 Expiration date	

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REVISION	DATE	CHANGE
Rev.C	01/2024	Edit header and "Reagents" paragraph.

