

R1: 4 x 41,5 mL – R2: 4 x 10,5 mL •  A-R0200000301R1: 2 x 16,7 mL – R2: 1 x 8,5 mL •  R3330000017**INTENDED USE**

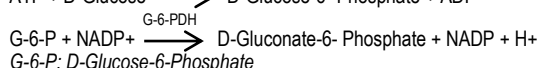
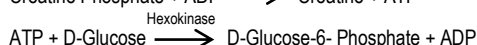
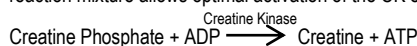
Product used for the quantitative invitro determination of creatinkinase (CK) in human serum and plasma. The test results should always be interpreted with reference to the clinical picture. For professional use only.

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

IFCC method - kinetics. Creatine kinase catalyzes the reaction between creatine phosphate and ADP with the formation of creatine and ATP. The ATP formed, in the presence of glucose and hexokinase (HK), gives ADP and glucose 6-phosphate. Glucose-6-phosphate formed in the presence of glucose 6-phosphate dehydrogenase (G6P-DH), reacts with the formation of β -NADP+6-phosphogluconate and β -NADPH. The increase in absorbance due to the β -NADP+ \rightarrow β -NADPH reaction is proportional to the CK activity in the sample. The presence of N-acetyl-L-cysteine (Nac) in the reaction mixture allows optimal activation of the CK enzyme.



G-6-PDH: Glucose-6-Phosphate Dehydrogenase.

The rate of increase in NADPH concentration measured at 340 nm is directly proportional to the enzymatic activity of CK.

REAGENTS

A-R0200000301 – R1: 4 x 41,5 mL – R2: 4 x 10,5 mL

Reagent 1: n° 4 vials x 41,5 mL ready to use



Reagent 2: n° 4 vials x 10,5 mL ready to use

R3330000017 – 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

Concentration			
Reagent A			
	Conc.	U.M.	
Imidazole buffer pH 6.1	125	mmol/L	 GHS08*
D-glucose	25	mmol/L	
NADP	2.5	mmol/L	
Hexokinase	≥ 6800	U/L	
Sodium Azide	< 0.1	%	
Reagent B			
Imidazole buffer pH 8.9	125	mmol/L	 GHS08*
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			

* **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 limp 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 sera with known levels of CK NAC are commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available as "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. 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 kit "Multicalibrator" code R0300000006. For ISE s.r.l. series instrumentation, it is recommended to perform calibration every 2 weeks. Repeat calibration at any reagent batch variation.

Reaction Conditions

Wavelength: 340 nm
Temperature: 37°C
Read against distilled water

	U.M.	Blank	Calibr. Serum.	Sample
Reagent	μL	1000	1000	1000
Calibration Serum	μL	-	40	-
Sample	μL	-	-	40
Water	μL	40	-	-

Mix well and after 2 minutes of incubation at 37°C. Read the absorbances of the sample at 60 seconds intervals during 3 minutes (Δ D.O./min). The reaction volumes can be varied proportionately, the calculation remains unchanged.



R1: 4 x 41,5 mL – R2: 4 x 10,5 mL •  A-R0200000301R1: 2 x 16,7 mL – R2: 1 x 8,5 mL •  R3330000017**Conversion Factor**

CK [U/L] x0.01667 = CK [µkat/L]

NORMAL VALUES

Serum / Plasma

Men ≤ 171 (U/L) ≤ 2.85 µkat/L

Women ≤ 145 (U/L) ≤ 2.41 µkat/L

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 1714 U/L (28.57 µkat/L). Samples having greater concentrations should be diluted 1:10 with normal saline and re-assayed. This procedure extends the measuring range up to 17140 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 3000 mg/dl (33.9 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; Acetaminophen 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	147	0.7	80
Medium	U/L	406	1.1	80
High	U/L	1154	1.1	80
Between series				
Range	U.M.	Average	C.V. (%)	N
Low	U/L	147	1.7	80
Medium	U/L	406	2.4	80
High	U/L	1154	3.9	80

Sensitivity

At λ340 nm a concentration of about 5 U/L of CK in conditions established for this test.

Comparative methodThe CK MB reagent has been compared with a similar method on the market using samples ranging from 10 to 1819 U/L. The results of the comparison were a regression line $y = 1.012x - 2$ U/L; Correlation Coefficient $r = 0.998$; number of samples analyzed $n = 100$.**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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Distributor:**I.S.E S.r.l.**








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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.

