Spectrum For Diagnostic Industries

Creatine Kinase (CK) (4+1)

IVD

REF.	Pack size
164 05 005	(5 x 5 ml) 25 tests
164 05 010	(5 x 10 ml) 50 tests

Intended Use

Creatine Kinase (CK) reagent is intended for the in-vitro quantitative and diagnostic determination of Creatine Kinase in human serum on both automated and manual systems.

Introduction

Creatine kinase (CK) is an enzyme which is found in heart, brain and skeletal muscles. Thus, an increase of circulating level of CK may be associated to myocardial infarction, acute cerebrovascular disease, trauma or diseases of skeletal muscles. After a myocardial infarction, CK level begins rising between 4th and 6th hour after first acute symptoms, reaching the peak between 18th and 30th hour and coming back to normal values during the 3rd day. CK is present in three different isoenzymatic forms, which could be separated by electrophoresis or column chromatography; each form is originated in different body tissues, paying off their diagnostic determinations. The formula of present reagent is based on DGKC and IFCC recommendations.

Method

Kinetic determination based upon DGKC and IFCC recommendations.

Principle

Creatine kinase (CK) catalyzes the phosphorylation of ADP, in the presence of creatine phosphate, to form ATP and creatine. The catalytic concentration is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6PDH) coupled Reactions1,2.

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{CK} \text{Creatine} + \text{ATP}$$

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

$$\text{Glucose-6-phosphate} + NADP^{+} \xrightarrow{G6PDH} \text{6-Phosphogluconate} + NADPH + H^{+}$$

Reagents

Reagent 1 (Buffer reagent)

Imidazol	125 mmol/L
D-Glucose	25 mmol/L
N-Acetyl-L-Cysteine	25 mmol/L
Magnesium acetate	12.5 mmol/L
NADP	2.5 mmol/L
EDTA	2 mmol/L

Reagent 2 (Enzymes)

ADP	15.2 mmol/L
AMP	25 mmol/L
P1,P5-di (adenosine-5'-) penta-phosphate	103 mmol/L
Glucose-6-phosphate Dehydrogenase (G6PDH)	9 KU/L
Creatine phosphate	250 mmol/L
Hexokinase (HK)	3 KU/L

Reagents preparation, storage, and stability

Prepare working solution by adding 4 volumes from R1 and 1 volume of R2. Working solution is stable for 2 weeks at 2-8^{O}C.
The reagents are stable up to the expiration date specified when stored at 2 - 8 °C.Once opened, the reagent is stable for 2 months at the specified temperature.

Deterioration

Failure to recover control values within assigned range may indicate reagent deterioration

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

Serum free of haemolysis or heparin plasma. Stability: 2 days at 20-25 ^{O}C, 7 days at 2-8^{O}C, 4 weeks at -20^{O}C protected from light.

Procedure

Wavelength	340 nm (334-365 nm)
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Sample: Reagent Ratio	1:25
Temperature	37 ^{O}C
Equilibration time	60 seconds
Read time	1 to 3 minutes
Zero adjustment	against air

Working solution	0.5 ml
Serum	20 µL

1. Mix and incubate 60 seconds.
2. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minutes.
3. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

Calculation

ΔA/min x 4127 = U/L CK

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter of sample (U/L)

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Sensitivity

1 U/L

Linearity

2000 U/L

Interferences

No interferences were observed with haemoglobin until 5 g/L, bilirubin 20 mg/dL and triglycerides 7 mmol/L. Other drugs and substances may interfere.

Expected values

Men	24 -204 U/L
Women	24-173 U/L

Performance Characteristics

A study using 20 human specimens between this CK-reagent and a reference method yielded a correlation coefficient of 0.983.

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (U/L)	86	616
CV%	2.8	1.0

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	77	624
CV%	2.5	0.8

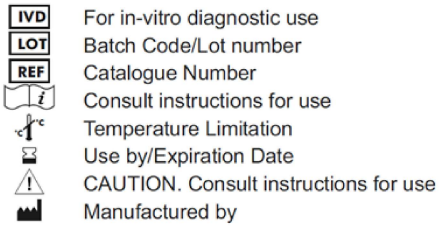
Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
2. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.

SYMBOLS IN PRODUCT LABELLING



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