

PRODUCT CODE

CZ009

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of Creatine Kinase (CK) in serum or plasma.

METHOD

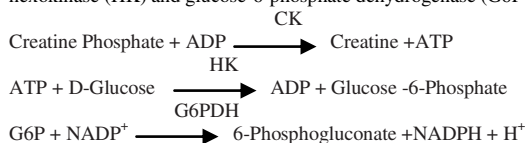
Kinetic determination of the Creatine Kinase based upon IFCC and DGKC recommendations.

CLINICAL SIGNIFICANCE

Creatine Kinase is a cellular enzyme with wide tissue distribution in the body. Its physiological role is associated with adenosine triphosphate (ATP) generation for contractile or transport systems. Elevated CK values are observed in diseases of skeletal muscle and after myocardial infarction^{1,5,6}. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

Creatine Kinase (CK) catalyses the reversible transfer of a phosphate group from phosphocreatine to ADP. This reaction is coupled to those catalyzed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH).



REAGENT COMPOSITION

REAGENT 1

Imidazole, pH 6.70	125 mmol/L
D-Glucose	25 mmol/L
N-Acetyl-L-Cysteine	25 mmol/L
Magnesium acetate	12.5 mmol/L
NADP	2.52 mmol/L
EDTA	2.02 mmol/L
Hexokinase	≥6800 U/L

REAGENT 2

ADP	15.2 mmol/L
AMP	25 mmol/L
di-Adenosine-5- pentaphosphate	103 mmol/L
Glucose-6-phosphate dehydrogenase	≥8800 U/L
Creatinine phosphate	250 mmol/L

PREPARATION OF WORKING REAGENT

Mix 4 volumes of R1 with 1 volume of R2, Stability: 2 weeks at 2-8°C or 48 hours at room temperature (15-25°C)

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.

Signs of reagent deterioration:

- Presence of particle and turbidity
- Blank absorbance (A) at 340nm ≥1

SPECIMEN

Fresh serum free of hemolysis or heparinized plasma
Stability 7 days at 2-8° C, protected from light. The Creatine Kinase activity decreases 10% after 1 day at 2-5° C or after 1 hour at 15-25° C.

PROCEDURE

1- Assay conditions

Wavelength	: 340 nm
Cuvette	: 1 cm light path
Temperature	: 25°C/ 30°C/37°C

2- Adjust the instrument to zero with distilled water

3- Pipette into cuvette

	25-30°C	37°C
Working reagent (µL)	1000 µL	1000 µL
Sample (µL)	40 µL	20 µL

4- Mix and incubate 2 minutes.

5- Read the initial absorbance (A) of the sample, start the stop watch and read the absorbance and average absorbance difference per minute (ΔA/min).

CALCULATION

$$\begin{array}{l}
 25-30^{\circ}\text{C} \quad \Delta A / \text{min} \times 4127 = \text{U/L CK} \\
 37^{\circ}\text{C} \quad \Delta A / \text{min} \times 8095 = \text{U/L CK}
 \end{array}$$

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).

Temperature conversion factors

To correct results to other temperatures, multiply by

Assay temperature	Conversion factor to		
25° C	1.00	1.56	2.44
30° C	0.64	1.00	1.56
37° C	0.41	0.63	1.00

QUALITY CONTROL

It is recommended to use CK NAC control sera of known value.

If control values are found out of the defined range, check the instrument, reagents and technique for problems.

NORMAL VALUES

	25° C	30° C	37° C
Men, up to	80 U/L	130 U/L	195 U/L
Women, up to	70 U/L	110 U/L	170 U/L

Each laboratory should establish its own normal range representing patient population

INTERFERENCES

No interferences were observed with glucose until 7 g/L, hemoglobin until 5 g/L and triglycerides 7 mmol/L. A list of drugs and other interfering substances with CK determination has been reported^{3,4}.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

BIBLIOGRAPHY

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