CK-NAC
NAC-Kinetic UV, Liquid

IVD CE

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).

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

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

$$\text{G6P} + \text{NADP}^+ \xrightarrow{\text{G6PDH}} \text{6-Phosphogluconate} + \text{NADPH} + \text{H}^+$$

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 2-8ºC or 48 hours at room temperature (15-25ºC)

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, 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 2-8º C, protected from light. The Creatine Kinase activity decreases 10% after 1 day at 2-5º C or after 1 hour at 15-25º 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

	25-30ºC	37ºC
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

25-30ºC	ΔA / min x 4127 = U/L CK
37ºC	ΔA / min x 8095 = 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).

Temperature conversion factors
To correct results to other temperatures, multiply by

Assay temperature	Conversion factor to		
25º C	1.00	1.56	2.44
30º C	0.64	1.00	1.56
37º 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

	25º C	30º C	37º 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
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBILOGRAPHY

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration
8. catalytique de la créatinine kinase dans le sérum humain. Ann. Biol. Clin.,40, (1482), 87.

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany