CK-NAC (BR-160/BR-120)

NAC-Kinetic UV, Liquid

IVD

PRODUCT
CODE CZ009

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

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
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	2.4 mmol/L
EDTA	2.0 mmol/L
Hexokinase	6000 U/L

REAGENT 2

ADP	15.0 mmol/L
AMP	25 mmol/L
P1, P5-di-Adenosine-5-pentaphosphate	102 µmol /L
Glucose-6-phosphate dehydrogenase	8000 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. **PRUCEDURE**
APPLICATION ON AUTO BIOCHEMISTRY ANALYSERS

PERFORMANCE CHARACTERISTICS
detection limit: 9.2 U/L =153 nkat/L
linearity limit of 1300 U/L= 21671 nkat/L
for higher values dilute sample 1/2 with distilled water and repeat measurement.

– Repeatability (within run): Mean Concentration

	c.v	n
175 U/L = 2917 nkat/L	1.8 %	20
567 U/L = 9452 nkat/L	0.7 %	20

– Reproducibility (run to run): Mean Concentration

	c.v	n
175 U/L = 2917 nkat/L	1.3 %	25
567 U/L = 9452 nkat/L	1.1%	25

INTERFERENCES
Bilirubin (< 20 mg/dL) and hemoglobin (< 10 g/L) do not interfere. Lipemia (triglycerides > 5 g/L) interfere. Other drugs and substances may interfere

QUALITY CONTROL

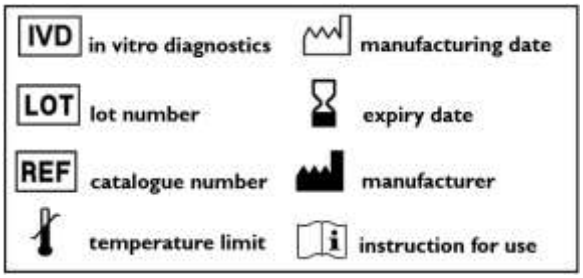
It is recommended to use CK NAC control sera of known value.
If control values are found out of the defined range, check the instrument, reagents and technique for problems.

NORMAL VALUES

	U/L	nkat/L
Men, up to	38-174	633-2900
Women, up to	26-140	433-2334

Each laboratory should establish its own normal range representing patient population

SYMBOL ON LABELS



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