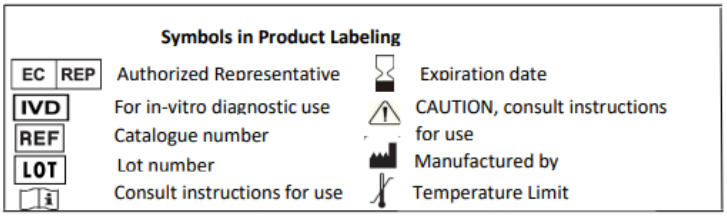
GENESIS

Instructions For Use

Creatine Kinase (CK) NAC (IFCC Method (4+1))

Cat no.	size
1202 101	5*5
1202 102	10*5
1202 103	1*25



INTENDED USE

Creatine Kinase (CK) NAC Reagent is intended for the in vitro Quantitative diagnostic determination of Creatine Kinase,(CK) activated by N-Acetyl Cysteine in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Creatine kinase (CK) plays an important role in muscle by providing ATP, when muscle contracts, from ADP and using creatine phosphate as the phosphorylation reservoir. Serum CK originates mainly in muscle and its concentration is subject to a number of physiological variations (sex, age, muscle mass, physical activity and race). Serum CK concentration is greatly elevated in patients with some diseases of skeletal muscle (muscular distrofy, myositis, polymyositis, malignant hyperthermia, trauma, acute rhabdomyolysis), of the central nervous system (acute cerebrovascular disease, cerebral ischemia, Reye's syndrome) and of the thyroid (hypothyroidism)After a myocardial infarction, CK elevation begins in 3-6 hours and peaks at 24-36 hours. The enzyme is rapidly cleared from the plasma, so that it is common for the activity to return tonormality in 3-4 days.

PRINCIPLE OF THE METHOD

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 (G6P-DH) coupled reactions.

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

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

Glucose - 6 - phosphate + $NADP^+$ $\xrightarrow{G6P\text{-}DH}$ 6 – Phosphogluconate +NADPH + H+

COMPOSITION

Reagent (R1)	**Imidazole, pH 6.7**	**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	**≥6 800 U/L**
Reagent (R2)	**ADP**	**15.2 mmol/L**
	AMP	**25 mmol/L**
	di-Adenosine-5- pentaphosphate	**103 mmol/L**
	Glucose-6-phosphate dehydrogen	**≥8 800 U/L**
	Creatine phosphate	**250 mmol/L**

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label.

REAGENT PREPARATION

Working reagent:(4) Parts of(R1) are mixed with(1)part of (R2).

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC.
- Analyzer, spectrophotometer able to read at 340 nm.

SPECIMEN.

1. Serum and plasma collected by standard procedures.
2. Creatine kinase in serum and plasma is stable for 7 days at 2-8ºC and Stable for 24 hrs at 15-25 °C
3. Use heparin as anticoagulant

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.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Mode..... Kinetic
Wavelength..... 340 nm
Cuvette.....1 cm light path Constant temperature..... 37ºC
Delay time.....120 sec
Measuring time ..... 180 sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working reagent	1.0 mL
Sample	20 µL

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

CALCULATIONS

ΔA/min x 8095 = U/L CK

REFERENCE VALUES

Men, up to	195 U/L
Women, up to	170 U/L

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

- Detection limit: 9.2 U/L
- Linearity limit: 1300 U/L

For higher values dilute sample **1/3** with physiological saline and repeat measurement.

- **Repeatability (within run):**

Mean Concentration	CV	n
175 U/L	1.8 %	20
587 U/L	0.7%	20

- **Reproducibility (run to run):**

Mean Concentration	CV	n
117 U/L = 1.95 µkat/L	1.3 %	25
431 U/L = 7.18 µkat/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.

BIBLIOGRAPHY

1. IFCC primary reference procedures for the measurement of catalytic activity concentrationsof enzymes at 37ºC, Part 2. Reference procedure for the measurement of catalytic concentration of creatine kinase. Clin Chem Lab Med 2002;40:635-642.
2.IFCC reference procedures for measurement of catalytic concentrations of enzymes: corrigendum, notes and useful advice. Clin Chem Lab Med 2010; 48: 615-62

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