BioMed-CK-NAC

Kinetic

REF: CK107003 (1 x 5 ml)
CK107025 (5 x 5 ml)
CK107050 (10 x 5 ml)

INTENDED FOR USE:

For the quantitative determination of CK activity in serum and plasma.

Principle :

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

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

$$\text{G-6-Phosphate+NADP+} \xrightarrow{\text{G-6-PDH}} \text{6-P-G+NADPH + H+}$$

Creatine Kinase (CK) catalyzes the reaction between creatine phosphate and ADP to yield creatine and ATP. The ATP and Glucose are converted to ADP and glucose-6-phosphate by Hexokuinase (HK). Glucose-6-phosphate dehydrogenase (G-6-PDH) oxidizes the glucose-6-phosphate and reduces the nictonamide adenine dinucleotide phosphate (NADP). The rate of NADPH formation measured at 340 nm, is directly proportional to serum CK activity.

SPECIMEN COLLECTION:

Non hemolyzed serum and plasma

Note :

Slightly hemolized sample , upto200 mg\dl of Hb , will not interfere with results . Anticoagulants such as heparin or EDTA may be used CK in serum or plasma is reported stable for 48 hours at + 15-25°C , 7 days at +2- 8°C, and approximately 4weeks when stored in the refrigerator at -20°C . Shake and being the samples at room temperature (+15-25°C) before using .

REAGENT COMPOSITION:

Reagent 1(pH 6.7) (Buffer/Coenzyme)	
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
Creatin phosphate	250 mmol/L
Hexokinase (HK)	3 KU/L

PACKAGE : Collection & storage .

Store at +2-8°C.
Stable until expiration date reported upon the package.
After the unsealing and the collection of reagent, it is advised to close up the bottle immediately in order to avoid evaporation and bacterial contamination.

PRECAUTIONS & WARNING:

Avoid pipetting with mouth.
The preparation, according to current regulation, is classified as not dangerous.
The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.
Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes.
The samples must be handle as potentially infected from HIV or Hepatitis.

REAGENT PREPARATION & STABILITY

Add 1.0 ml of R2 to one vial of R1 or prepare the working solution according to the number of test required by mixing 4 volume of R1 with 1 volume of R2.

Stability of the W R is:

2 weeks at 2-8°C & 4 weeks at -20°C protected from light.

REQUIRED MATERIALS NOT PROVIDED

General Laboratory Equipment and instruments .

PROCEDURE :

Wavelength	340 nm (334 -365 nm)
Optical path	1 cm
Incubation temperature	25, 30 or 37°C
Zero adjustment	against air

Working solution	1 ml
serum	40 µl

1. Mix and incubate 2 minutes.
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 absorbance and the average absorbance difference per minute (ΔA/min).

CALCULATION :

To calculate the CK activity use the formula:

$$\Delta A/\text{min} \times 4130 = \text{U/L CK}$$

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

EXPECTED VALUE :

	25°C	30°C	37°C
Men	10-80 U/l	15-130 U/l	24-195 U/l
Women	10-70 U/l	15-110 U/l	24-170 U/l

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

PERFORMANCE :		
MEASURE INTERVAL/LINEARITY :	5 – 1200 U/L	
LOWEST MEASURABLE LIMIT	5 U /L	
SENSITIVITY :	1 U/L = 0.00015ΔE/min .	
PRECSION AMONG SERIES : n=20		
MEDIUM LEVEL	M = 152 U /L	C.V. = 0.9%
HIGH LEVEL	M = 483 U /L	C.V. = 0.4%
PRECISION AMONG SERIES : n=20		
MEDIUM LEVEL	M = 155 U /L	C.V. = 1.0%
HIGH LEVEL	M = 486 U /L	C.V. = 0.5%
INTER.ANALIZED	25-2047 U /L	
CORRELATION	r = 0.999	n = 50
LIN. REGRESSION	y = 1.07 x -5.6	n = 50

INTERFERENCE : (IN ACCORDDANCE WITH RACCOMANDATION SFBC)

Interferences are negligible up to :			
Bilirubin	20 mg/dL	Triglycerids	500mg/dL
Hemoglobin	500 mh/dL	Glucose	500 mg/dL

METHOD LIMITATIONS :

For concentration higher than 1200 U/L repeat the measure on a sample diluted 1:2 with physiological solution e multiply the results x 2. For a thorough evaluation of the interfering substances , consult : Young , D. S.,et al , Clin. Chem.. 21:1D (1975).

REFERENCES:

1. Tietz, N.W.(ed) Fundamentals of Clinical Chemistry, 2nd Ed., W.B. Saunders, Philadelphia, PA., 1976
2. Szasz, G., Clin. Chem. 22(650), 1976.
3.Moren, L.G., et al., Clin. Chem. 23 (1569),1977.
4.Young, D.S., et al., Clin. Chem. 21(10),1975

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical Device
2°C 8°C	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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