Pariksha Biotech
A game changer in IVD

CK-NAC Estimation Kit

High-Q CK-NAC

(IFCC Method)

HIGH
Command on Quality

Intended Use:
Kit for the determination of CKNAC Iso Enzyme in Human Serum and Plasma

Summary and Explanation:

CK is a dimeric enzyme occurring in 4 different forms, a mitochondrial iso-enzyme and 3 cytoplasmic iso-enzymes. CK MM is a muscle enzyme, CK BB is a brain enzyme and CK MB is the heart enzyme. CK activity has elevated many diseases including those involving skeletal muscle, heart, central nervous system and the thyroid. Most determinations of CK in the clinical laboratory are used for the early detection of Myocardial Infarction in which the enzyme is elevated within 3 to 8 hours after the onset .

Principle Of The Test:
This procedure for CK MB incorporates a polyclonal antibody to CK M in the Reagent 1. The antibody inhibits 99.6% of the CK M without affecting the CK B units. The remaining CK B activity therefore corresponds to half the CK MB activity and is determined by the method used for total CK.

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

$$\text{ATP} + \text{Glucose} \xrightarrow[\text{HK} + Mg^{2+}]{} \text{ADP} + \text{Glucose-6-phosphate (G-6-P)}$$

$$\text{G-6-P} + \text{NADP Analogue} \xrightarrow[\text{G6P-DH}]{} \text{6-phosphogluconate} + \text{NADP Analogue (Reduced)} + H^{+}$$

N.B: The CK activity should be determined using the CK-NAC method before performing the CK-MB assay.

Warnings And Precautions:
For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear Colourless liquid.
Reagent 2: Clear, pale yellow coloured liquid.

Component Composition:

	Ingredients	Concentration in Tests
Reagent 1	Imidazole Buffer pH 6.7	100 mmol/l
	Glucose	20 mmol/l
	Magnesium Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	NADP	2.0 mmol/l
	N-acetylcysteine	20 mmol/l
Reagent 2	**Creatine Phosphate**	**30 mmol/l**
	G6P-DH	> 1.5 U/ml
	Diadenosine pentaphosphate	10 µmol/l

Reagent Preparation and Stability:
Two Ready to use liquid reagents (R1 and R2) stable till the expiry date mentioned on the labels. Do not contaminate the reagents.

Calibrator: Calibrator is available as Lyophilized vial. Carefully open the vial without losing the materials.
Add 3.0 ml of Calibrator Diluent provided in the kit and keep for 30 Minutes at room temperature. Reconstituted Calibrator is stable for 15 Days at 2-8°C and 30 days when frozen as aliquots at -20 °C. Look for the Calibrator Concentration on the vial for the calibration.

Type of specimen:
Use serum, free from haemolysis, heparin plasma as specimen.
It is recommended to follow NCCLS procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/Plasma should be separated from cells immediately after collection and stored in the dark.
Stability of specimen up to 7 days at 2-8°C.

Assay Procedure:

Reaction Type (Mode)	:	Kinetic
Reaction Direction	:	Increasing
Wave Length	:	340nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay time	:	120 seconds
Measuring Time	:	240 Seconds
Reagent Volume	:	0.5 ml (400 µl R1+ 100 µl R2)
Sample Volume	:	25 µl
Factor	:	**4308**
Linearity	:	2000
Units	:	IU/L
High Normal	:	190 (Adult Male)
	:	167 (Adult Female)

Procedure :

Reagent 1	**400 µL**
Sample	**25 µL**
	Mix and incubate for 5 min at 37 °C
Reagent 2	**100 µL**

Mix well and immediately aspirate in to the analyzer. After 120 Seconds incubation, measure the change in optical density per 60 seconds during 240 seconds against distilled water at 340 nm as follows.

Ao - Exactly after 120 Seconds
A1, A2, A3, A4 - Exactly after every 60 seconds for 240 seconds.

Calculations:
Calculate the average change in absorbance per minute (Abs/min).

Activity of Creatine Kinase in iU/L

At 340 nm in iU/L = Abs / min x 4308

Expected Values:
Men up to 190 IU/L (37°C)
Women up to 167 IU/L (37°C)

Each Laboratory should establish its own reference range. Creatine Kinase results should always be reviewed with the patients' medical examination and history

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:
Prior to reporting patient results.
Following any maintenance procedure on the photometer used.
At intervals established by the Laboratory Q.C. Programme.

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Performance Characteristics:
Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linear up to 2000 IU/L . For samples with a higher concentration, dilute 1:1 with Saline (0.9 g/l NaCl) and reassay. Multiply result by 2.

Interfering substances:
Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 1.25 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 2.5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 2 U/l

Precision:

Within Run	Mean (U/l)	SD	% CV	Between Run	Mean (U/l)	SD N = 20	% CV
Level 1	177	2.5	1.41	Level 1	169	1.50	0.89
Level 2	408	3.43	0.84	Level 2	383	1.29	0.34

Mthod Comparison:
Using 50 samples, a comparison, between High-Q CK- NAC test (y) and another commercially available test (x) gave the following results:

$y = 0.997x - 5.765 \quad r = 0.986$

Bibliography:

1. Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352 390 and 974-975

Ordering information

Ref./Cat.	Pack Size	Presentation
P-NAC-10	10 ml	Liquid Stable Two Reagents
P-NAC-20	2 x 10 ml	
P-NAC-50	5 x 10 ml	

Product Features

- Liquid Stable, Ready to use Two Reagents (R1= Buffer, R2=Substrate)
- Kinetic Factor: 4308
- NADP analogues are used for better stability
- Linearity 2000 IU/L.
- 6 Minutes increasing Kinetic Reaction
- Measuring wavelength 340 nm.
- Serum and Plasma are the Specimens
- Available as multipurpose reagents and dedicated system packs

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Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709 info@parikshabio.com www.parikshabio.com

AN ISO 13485 Certified Company

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