



**Pariksha
Biotech**
A game changer in IVD

CK-NAC Estimation Kit

High-Q CK-NAC

(IFCC Method)



Intended Use:

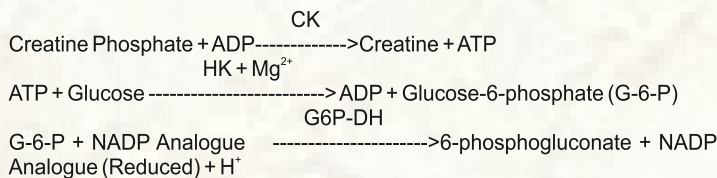
Kit for the determination of CKNAC Iso Enzyme in Human Serum and Plasma

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.



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:

Reagent	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)	: Fixed Time
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

Calibrator Concentration : Lot Specific(See on the labels)

Linearity	: 2000
Units	: IU/L
High Normal	: 190 (Adult Male)
	: 167 (Adult Female)

Procedure Fixed Time:

	(C)	(T)
Reagent -1	400 µl	400 µl
Calibrator	25 µl	----
Sample	-----	25 µl

Mix and Incubate for 5 Minutes at 37°C

Reagent -2	100 µl	100 µl
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Mix well and immediately aspirate in to the Analyzer. Read absorbance of Calibrator (C) and Test (T) against distilled water at 340 nm exactly after 120 sec (Delay) and exactly after 240 sec.(Measuring)

Determine absorbance for Calibrator (C) and Test (T)

Calculations:

$$\text{Activity of CK-NAC (IU/L)} = \frac{\text{Abs of Test}}{\text{Abs of Calibrator}} \times \text{Calibrator Concentration}$$

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	% 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

N = 20

Method 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:

- Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5thed. 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)
- Calibrator Provided
- 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
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

