



INTENDED USE:

This reagent kit is used for *in-vitro* quantitative determination of CK-NAC in human serum/plasma.

INTRODUCTION:

Creatine kinase (CK) catalyzes the transfer of phosphate group between creatine phosphate and adenosine diphosphate (ADP). The product of this reaction is adenosine triphosphate (ATP) – molecular source of energy. CK is a dimer, composed of two different subunits called M and B. Three different isoenzymes formed from these subunits are found in brain and smooth muscle (BB), skeletal muscle (MM) and cardiac muscle (MM and MB). Increased CK-MB serum level is a strong marker of myocardial infarction.

TEST PRINCIPLE:

Optimized kinetic method according to International Federation of Clinical Chemistry (IFCC)

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

ATP + D-glucose $\xrightarrow{\text{HK}}$ ADP + D-glucose-6-P

D-glucose-6-P + NADP $\xrightarrow{\text{G6P-DH}}$ D-gluconate-6-P + NADPH + H⁺

The rate of absorbance changes at $\lambda=340$ nm is directly proportional to creatine kinase activity.

KIT CONTENTS:

CK-NAC Reagent 1

CK-NAC Reagent 2

Product Insert

PREPARATION OF THE WORKING REAGENT:

Mix 4 parts of reagent 1 with 1 part of reagent 2.

REAGENT STABILITY AND STORAGE:



All the reagents must be stored at 2-8°C and are stable till expiry date mentioned on the labels.

WORKING REAGENT STABILITY:

Working Reagent is stable for 20 days at 2-8°C & 4 days at 21-25°C.

SPECIMEN COLLECTION AND STORAGE:

Unhemolysed serum or heparinised plasma from fasting patients is recommended.

Serum is stable for 1-2 days at 2-8°C & 4-8 hours at 21-25°C & at least 1 month at -20°C.

Discard contaminated specimens.

PRECAUTIONS:

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the reagents to room temperature.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.
6. Reagent ratio as mentioned here above must be strictly observed as may change into it will adversely effect the factor..

PROCEDURE (Automated):

Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

Wavelength: 340 nm & Temperature: 37°C.

Note : Bring reagents and samples to room temperature (21-25°C).

Pipette into Test Tube	Test
Working Reagent	1000 μ l
Sample	50 μ l
Mix and after 1 minute incubation, measure the change in absorbance (Δ OD/min) for 3 minutes. Determine the mean absorbance change per minute (Δ OD/min) and use this for calculation.	

CALCULATION:

CK-NAC activity (IU/L) = Δ OD/min x Factor (4127).

NORMAL VALUES*:

Female: 25 - 175 IU/L

Male: 25 - 200 IU/L

*It is recommended that each laboratory establish its own normal range.

PERFORMANCE:

1. **Linearity:** 2000 IU/L

2. **Specificity / Interferences**

Haemoglobin up to 3.75 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

SYSTEM PARAMETERS:

Input parameters for semi- auto / auto analyzers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Wavelength	340 nm
Factor	4127
Incubation time	60 sec.
Interval time	60 sec.
Interval No.	3
Flowcell temperature	37°C
Units	IU/L
Upper Normal value	200 IU/L
Lower Normal value	25 IU/L
Linearity	2000 IU/L
Working Reagent	1000 µl
Sample volume	50 µl

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

1. DGKC: J. Clin. Chem. Clin. Biochem.: 15, 249-254 (1977).
2. The Committee on Enzymes of The Scandinavian Society for Clinical Chemistry and Clinical Phys.: Scand.
3. Lott J.A., Stang J.M.: Clin. Chem. 26/9, 1241-1250 (1980).
4. Commission Enzymologie, Comité de Standardisation, Société Française de Biologie Clinique: Ann. Biol. Clin. 40, 138-149 (1981).
5. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 806-6 (1995).
6. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: Moss D. W., Henderson A.R., 652 (1999).