Ana-Chek® CREATINE KINASE - NAC

METHOD – UV KINETIC
PRODUCT CODE – LC05

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of CK - NAC in serum / plasma using UV Kinetic method.

SUMMARY AND PRINCIPLE

Ana-Chek® CK-NAC is a reagent set for determination of Creatine Kinase activity in human serum/plasma based on UV kinetic method. Ana-Chek® CK-NAC is a two liquid reagent system.

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

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

Glucose-6-phosphate + NADP $\xrightarrow{G6PDH}$ 6-phosphogluconate + NADPH + H

KIT COMPONENTS

Reagent 1 : CK-NAC Reagent 1
Reagent 2 : CK-NAC Reagent 2

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagents. Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent prior to use. Do not shake vigorously. The working reagent is stable for 14 days at 2-8 °C. The reagent kit should be stored at 2 - 8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.700 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	CK-NAC	Reagent Volume	1000 µl
Reaction Type	UV Kinetic (↑)	Sample Volume	40 µl
Wavelength Primary	340 nm	Incubation Temperature	37 °C
Flow Cell Temp.	37 °C	Delay Time	180 sec
Instrument Blank setting	D.W.	Read Time	120 sec
Reagent Blank Abs Limit	<0.700	Factor	4127
Linearity	2000 IU/L		

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. The assay should be carried on the same day as far as possible. Serum or plasma are stable for 1 week at 4 °C and 1 month at -10 °C. Avoid use of haemolysed and grossly contaminated samples.

COMPONENTS OF REAGENT

Component	Concentration
Imidazole Buffer, pH 6.7	100 mmol/l
NAC	20 mmol/l
Glucose	20 mmol/l
Magnesium Acetate	10 mmol/l
Hexokinase	>4500 IU/L
ADP	2 mmol/l
AMP	5 mmol/l
Di (adenosine -5) - pentaphosphate	10 mol/l
NADP	2 mmol/l
EDTA	2 mmol/l
Stabilizers and inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	40 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Aspirate reaction mixture into flow cell and record the absorbance at 180th, 210th, 240th, 270th sec.	

CALCULATION

Absorbance/min = Absorbance per 30 sec. x 2
CK – NAC Activity (IU/L) = Δ Absorbance / min x 4127

REFERENCE VALUES FOR NORMAL PEOPLE

Men : <190 IU/L at 37 °C.
Women : <165 IU/L at 37 °C.
Babies : <325 IU/L at 37 °C.
Children : <225 IU/L at 37 °C.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 10 – 2000 IU/L. If the CK-NAC value exceeds linearity limit (2000 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct CK-NAC value of the specimen.

Interference: There is no significant interference in samples containing upto 20 mg/dl of bilirubin and 200 mg/dl of haemoglobin.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	141.47	1.72	1.2	147.03	1.96	1.3
High Value Serum	417.0	1.45	0.3	427.7	2.63	0.6

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for CK-NAC. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. The working reagent is considered unsatisfactory and should not be used if its absorbance exceeds 0.700 at 340 nm against distilled water.
2. If CK-NAC value exceeds 2000 IU/L then dilute the specimen suitably with normal saline & repeat the assay.
3. Avoid using haemolysed serum since red blood cells may release enzymes and intermediates such as ATP and G6P which may interfere.
4. CK-NAC Activity in serum may be elevated in patients receiving intramuscular injection upto one week prior to sample collection. Strenuous or unusual physical exercise may also cause elevated CK-NAC activity.

BIBLIOGRAPHY

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3. Tietz NW, ed. Clinical Guide to laboratory Tests, 3rd ed. Philadelphia, Pa: W.B. Saunders Company., 1995:181-181.
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Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE