CREATINE KINASE (CK-NAC)

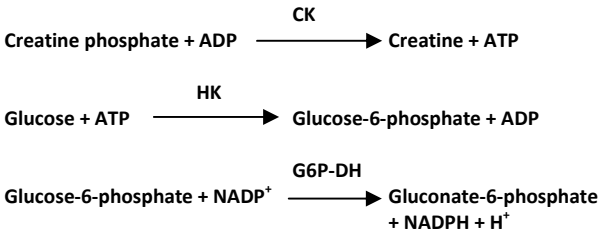
Invitro Diagnostic reagent kit for quantitative determination of Creatine Kinase (CK-NAC) activity in serum/plasma sample on Photometric System.

Reagent

Reagent 1: Buffer Solution
Reagent 2: Substrate Solution

Principle

This assay estimates the activity of Creatine Kinase in the presence of an antibody against CK-M monomer. This antibody completely inhibits the activity of CK-MM and half of the activity of CK-MB while not affecting the B subunit activity of CK-MB and CK-BB. Then it is used to quantitatively determine CK-B activity. The CK-MB activity is obtained by multiplying the CK-B activity by two.



Summary

Creatine Kinase (CK) is an enzyme which consists of isoenzymes mainly of the muscle (CK-M) and the brain (CK-B). CK exists in the human body in dimeric form as CK-MM, CK-MB, CK-BB and as macro enzymes. Measurement of CK-MB is a speci・c test for the detection of cardiac muscle damage and therefore, is used for diagnosis and monitoring of myocardial infarction.

Storage Instructions and Reagent Stability
Reagent are stable up to the end of the indicated month of expiry, if stored at 2° – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Mix, 4 parts of reagent 1 and 1 part of reagent 2 for working reagent.
The stability of the working reagent: 2 weeks at 2° - 8°C.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiodacetate, mannose):

7 days	**at**	**2° – 8°C**
30 days	**at**	**–20°C**

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor:

8 h	**at**	**25°C**
72 h	**at**	**4°C**

Only freeze once! Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	**340nm**
Optical path	**1 cm**
Temperature	**37°C**

	Sample
Working Reagent	**1000 µL**
Incubate time	**R1,R2 mix and 2 min at 37°C**
Sample	**40 µL**

After adding sample mix well,don't incubate and aspirate to photometer with in 5 sec. Incubation and reading 37°C will be started inside photometer.
Read absorbance after 60sec.perfrom other 3 readings at 60 sec. intervals.

Calculation

Note: ΔA/min and multiply by the corresponding factor from table below:

CK NACactivity U/L = ΔA/min x factor. (4450)

Quality Control

Forinternalqualitynormal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in controlrecovery.

Warnings and Precautions

1. **The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.**
2. **In very rare cases, samples of patients with gammopathy might give falsified results.**
3. **Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.**
4. **For professional use only!**

Performance Characteristics

Measuring range

The test has been developed to determine the activity of Creatine Kinase (CK-NAC) within a measuring range from 2-2000 U/L. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Linearity/Limit of Maximum Detection

The higher limit of detection is 2000 U/L.

Sensitivity/Limit of Detection

The lower limit of detection is 3 U/L.

Specificity/Interferences

No interference was observed by, Ascorbic Acid up to 30 mg/dL, Bilirubin upto 40 mg/dLand triglycerides up to 1000 mg/dL.

Precision

Intra-assay n = 20	Sample 1	Sample 2	Sample 3
Mean[U/L]	106.98	322.55	679.61
SD[U/L]	1.17	1.52	1.23
CV [%]	1.09	0.47	0.18

Inter-assay n = 20	Sample 1	Sample 2	Sample 3
Mean[U/L]	108.81	327.40	686.38
SD[U/L]	0.73	1.65	1.74
CV [%]	0.67	0.50	0.25

Method Comparison

A comparison of Precision Biomed Creatine Kinase (CK-NAC) (y) with a commercially available test (x) using 15 samples gave following results:

y = 0.994x +1.149; r2 = 0.994

Reference Range

In healthy individuals different values are found depending on raceand age.

Children:

Umbilical cord blood: 175 - 402U/L

Umbilical cord blood: 468 - 1200 U/L

Newborns: 468 - 1200 U/L

< 5 days 195 - 700 U/L

< 6 months 41 - 330 U/L

> 6 months 24 - 229 U/L

The risk of myocardial infarction is high if these conditions are met:

CK (Men)	> 200 U/L
CK (Women)	> 168 U/L
CK-MB	> 24 U/L
CK-MB activity is between 6% and 24 % of total CK activity.	

If myocardial infarction is suspected and the conditions are not fulfilled, the infarction may be fresh. In this case the measurements should be repeated after 4 hours with fresh samples. In healthy individuals different values are found depending on race and age.

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	CK-NAC
Mode	Kinetic
Reaction slope	Increasing
Wavelength	340 nm
Path length	10 mm
Temperature	37°C
Working Reagent	4 Part Reagent 1
	1 Part Reagent 2
Working Reagent volume	1000 µL
Sample volume	40 µL
Delay	120 sec.
Rate	180 sec.
Intervals	60 sec.
Factor	4450
Normal range	Female : < 168 U/L
	Male : < 200 U/L
Linearity	2000 U/L
Sensitivity	3 U/L

Pack Size :

Cat No.	Configuration	Pack
CNA00025	Reagent R1 - 1 x 20mL Reagent R2 - 1 x 5mL	25mL

Literature

1. Stein W. Creatine kinase (total activity), creatine kinase isoenzymes and variants. In: Thomas L, ed. Clinical Laboratory Diagnostics. Frankfurt : TH - Books Verlagsgesellschaft; 1998. p. 71-80.
2. Moss DW, Henderson Ar. Clinical Enzymology. In :Burtis CA,\ Ashwood ER, editors, Tietz Textbook of Clinical Chemistry. 3rd ed. philadelphia : W.B Saunders Company : 1999. P. 917-721.
3. Recommendations of the German Society for clinical Chemistry. Standardization of methods for the estimation of enzyme activities in biological ·uids : Standard method for the determination of creatine kinase activity. J ClinChemClinBiochem1977 : 15:255-60.
4. Lorents K, Rohle G, Siekmann L, Introduction of new standard methods 1994 for the determination of catalytic enzyme concentrations at 37°C. DG KlinischeChemieMitteilungen 1995:26:290-3.

Version : CNA/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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