OBio...
Supporting Care to Cure
A Division of Orchard Medical

CREATINE KINASE (CK-NAC)

IVD

Order Information

Cat. No.	Kit Configuration
OMR1073	Reagent 1: 2 x 20 mL
	Reagent 2: 1 x 10 mL

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.

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.

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

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

$$\text{Glucose-6-phosphate + NADP}^{+} \xrightarrow{\text{G6P-DH}} \text{Gluconate-6-phosphate + NADPH + H}^{+}$$

Reagents

Storage Instructions and Reagent Stability
Reagent and standard 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!

Reagent 1: Buffer
Solution Reagent 2:
Substrate Solution

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!

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	340 nm
Optical path	1 cm
Temperature	37°C

	Blank	Sample/Calibrator
Sample	-	40 µL
Dist. water	40 µL	-
Working Reagent	1000 µL	1000 µL
Mix, incubate for 3 min at 37°C and read absorbance after every 1 min. for 3 min.		

Calculation

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

CK NAC activity U/L = ΔA/min x factor. (4127)

Quality Control

For internal quality normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics and Measuring range

The test has been developed to determine the activity of Creatine Kinase (CK-NAC) within a measuring range from 2-1000 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.

Specificity/Interferences

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

Sensitivity/Limit of Detection

The lower limit of detection is 2 U/L.

Linearity

The higher limit of detection is 1000 U/L.

Precision

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	128.11	1.06	0.83
Sample 2	189.20	1.69	0.89

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	88.21	1.21	1.37
Sample 2	183.03	1.35	0.74

Method Comparison

A comparison of Nucleus Diagnosys Creatine Kinase (CK-NAC) (y) with a commercially available test (x) using 15 samples gave following results:
y = 0.976x + 3.165; r2 = 0.995

Reference Range

In healthy individuals different values are found depending on race and 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)	> 190 U/L
CK (Women)	> 167 U/L
CK-MB	> 24 U/L
CK-MB activity is between 6% and 25 % 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.
Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. **Stein W. Creatine kinase (total activity), creatine kinase isoenzymes and variants. In: Thomas L, ed. Clinical Laboratory Diagnostics. Frankfurt : TH - Books Verlagsge sellschaft; 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 Clin Chem Clin Biochem 1977 : 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 Klinische Chemie Mitteilungen 1995:26:290-3.**

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