CK - NAC

Kinetic IFCC/DGKC method

R1: 2 x 30 ml + R2: 2 x 7,5 ml CL19-75
R1: 2 x 80 ml + R2: 2 x 20 ml CL19-200

INTENDED USE

Kit for quantitative determination of CK-NAC in serum and plasma according to IFCC/DGKC recommendations.

CLINICAL MEANING

Creatine kinase is a cellular enzyme with wide tissue distribution in the body. Its physiological role is associated with adenosine triphosphate (ATP) generation for contractile or transport systems. Elevated CK values are observed in diseases of skeletal muscle and after myocardial infarction1,5,6. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

Creatine kinase (CK) catalyses the reversible transfer of a phosphate group from phosphocreatine to ADP. This reaction is coupled to those catalysed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH):

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

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

$$\text{G-6-P} + \text{NADP}^{+} \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate} + \text{NADPH} + \text{H}^{+}$$

The rate of NADPH formation, measured photometrically, is proportional to the catalytic concentration of CK present in the sample

SAMPLE

Serum, plasma (EDTA, Li Heparine)
STABILITY: 7 days at 2-8°C – 48 hours at 15-25°C or 4 weeks at -20°C.

REAGENTS

Only for in Vitro diagnostics. Liquid monoreagent ready to use.

Package content	CL19-75	CL19-200
REAGENT 1 Good Buffer 125 mM, Mg Acetate 12 mM, EDTA 2 mM, D-Glucose 25 mM, NAC 25 mM, NADP 2,5mM, HK ≥ 6500 U/L	2 x 30 ml	2 x 80 ml
REAGENT 2 ADP 15 mM, AMP 25mM , Diadenosine 103 mM, G6PDH ≥ 8800U/L, Creatine phosphate 250 mM	2 x 7,5 ml	2 x 20 ml

Stability: reagents are ready to use. Store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Do not freeze. Once opened the reagents are stable for 30 days at 2-8°C if contamination is avoided. Keep bottles closed when not in use . Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

WORKING REAGENT PREPARATION

Working Reagent: mix 4 volumes of Reagent 1 with 1 volume of Reagent 2.
Stability: 24 hours at 20-25°C or 5 days at 2-8°C stored tightly closed and protected from light.

MANUAL ASSAY PROCEDURE

Analysis:	increasing kinetic
Wavelength:	340 nm
Cuvette:	1 cm optical path
Temperature:	37°C
Reaction Time:	3 minutes
Reading:	against air or ditilled water

Let reagents necessary to perform the test reach the chosen temperature for the analysis.

Pipette in cuvette:

	25-30°C	37°C
Sample	40 µl	20 µl
Warking Reagent	1,0 ml	1,0 ml

Mix and incubate for 2 minutes at 37°C. Read initial absorbance, repeat reading at constant 1 minute intervals for 3 minutes. Calculate the mean value of the absorbance changes per minute.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the enzymatic activity in the sample analyzed by multiplying the ΔA/min found by the appropriate factor shown in the following table

25-30°C	37°C
ΔA/min x 4127	ΔA/min x 8095

REFERENCE VALUES

The expected values for HDL Cholesterol are as follow:

	25°C	30°C	37°C
Men	10 ÷ 80	15 ÷ 130	24 ÷ 194
Women	10 ÷ 70	15 ÷ 110	24 ÷ 170

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

A quality control program is recommended for all clinical laboratories.
Control serums of human origin are available for this purpose on request:
PRE-NORM (REF 7526) serums with normal values
PRE-PATH (REF7528) serums with pathological values
If the method requires it, a multi-parameter calibrator **(REF7532)** of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of the method is U/L.
The measurable limit is 5 U/L.

Linearity: up to 1200 U/L.
For higher values, dilute the samples 1:2 with saline solution and multiply the result by 2.

Precision

Within run (n=20)	Average [U/Ll]	CV %
Sample 1	152	0.9
Sample 2	483	0.4

Between-run (n=20)	Average [U/L]	CV %
Sample 1	155	1.0
Sample 2	486	0.5

Interferences: up to 20 mg/dl of bilirubin does not interfere. Up to 500 mg/dl of hemoglobin does not interfere. Up to 200 mg/dl of hemoglobin does not interfere. Up to 500 mg/dl of glucose does not interfere.

Correlation against a reference method: the correlation of the method (Y) against a reference method (X) gives this equation:

Y = 1,07x – 5,6 (n= 50) r = 0,997 (n = 50)

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behaviour in laboratory.

REFERENCES

1) Mathieu M. Et al., Ann. Biol. Clin., 40,99 (1982).
2) Vassault, A. et al. Ann.Biol.Clin., 44, 686,(1986).
3) Young, D.S., et al., Clin. Chem. 21:1D (1975

MANUFACTURER

FAR
Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
tel +39 045 6700870
website http://www.fardiag.com
e-mail: order@fardiag.com e-mail: fardiag@fardiag.com

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

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