CK-NAC SL

Kinetic Method UV

Liquid reagents ready to use

REF. 0018 **5x 10 ml**
REF. 4054 **2x 50 ml**
REF. 4052 **2x100 ml**

CE
IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of Creatine kinase, CK, in serum and plasma.

PRINCIPLE

Creatinkinase catalyzes the hydrolysis reversible reaction of creatinphosphate in creatinine and ATP. ATP, in presence of exokinase and D-glucose, is transformed into ADP and D-glucose-6-phosphate, which reduces $NADP^+$ in NADPH, H^+ and D-gluconate-6-phosphate in presence of glucose-6P dehydrogenase. The increase absorbance at 340 nm in time unit, due to NADPH formation, defines the CK activity in the sample.

SAMPLE

Serum, plasma with heparin. Do not use hemolyzed samples.

A slight degree of hemolysis, up to 200 mg/dl of Hb, can be tolerated.

CK activity in serum is unstable and is rapidly lost during storage. CK is inactivated both by bright daylight and by increasing specimen pH owing to loss of carbon dioxide; accordingly, specimens should be stored in the dark in tightly closed tubes.

KIT COMPONENTS

Reagent (A) CK Volume = 10/40/80 ml	Good buffer	125 mmol/l
	Magnesium acetate	12 mmol/l
	EDTA	2 mmol/l
	D-glucose	25 mmol/l
	N-acetyl-L-cysteine	25 mmol/l
	NADP	2.5 mmol/l
	HK-hexokinase	6500 U/l
Reagent (B)) CK Volume = 10/20 ml	ADP	15 mmol/l
	AMP	25 mmol/l
	Diadenosine-5-phosphate	103 mmol/l
	G-6-PDH	8800 U/l
	Creatine phosphate	250 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not freeze. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.

Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid Reagent, bring to room temperature (15-25°C) before use.

For **use as monoreagent**: add a part of Reagent (B) to 4 parts of Reagent (A).

The working solution (A+B) is stable 2 days at 15-25°C and 2 weeks at 2-8°C.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm (334 – 365)
Lightpath :	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	Increasing Kinetic
Sample/Reagent:	1/25

Use as monoreagent:

pipette:	
Working solution (A+B)	1000 µl
sample	40 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Perform 3 readings at 60 seconds intervals.

Calculate the average value of the absorbance variations per minute. (ΔA/min).

Use as bireagent:

pipette:	
Reagent (A)	1000 µl
sample	50 µl
mix and after 1 minute add:	
Reagent (B)	250 µl

Mix, incubate at 37°C for 1 minute, read the initial absorbance against water. Perform 3 readings at 60 seconds intervals.

Calculate the average value of the absorbance variations per minute. (ΔA/min).

Reaction volumes can be proportionally varied.

This method describes the manual procedure to use the kit.

For automated procedure, ask for specific applications.

RESULTS CALCULATION

Perform calculation in Units per litre, multiplying the ΔA/min by the factor as it is indicated:

Activity in U/L: ΔA/min x 4127

EXPECTED VALUES

Men: **24 - 204 U/L**

Women: **24 - 173 U/L**

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of control sera: PRECISENORM (REF.6000) and PRECISEPATH (REF.6001).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 1 U/L

Linearity: the method is linear up to: 1200 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	73.41	156.9	499.1
DS	0.590	0.738	0.876
CV %	0.80	0.47	0.18

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	78.93	157.3	502.4
DS	0.523	1.059	1.430
CV %	0.66	0.67	0.29

Interferences: do not use anticoagulants different from heparin because they inhibit CK activity. Bilirubin does not interfere up to 5 mg/dl. Hemoglobin does not interfere up to 0.2 g/dl.

Correlation against a reference method: Y = 0.9712x – 2.5338 r = 0.9996

REFERENCES

1. Mathieu M. et al., Ann. Biol.Clin., 40, 99 (1982).
2. Young, D.S., et al., Clin. Chem. 21:1D (1975).
3. Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989.
4. Vassault, A. et al. Ann. Biol. Clin., 44,686 (1986).

Giesse Diagnostics srl
Via Cervinara, 45 – Colle Prenestino – Roma – Italia. Tel. +39 06 22429353 / +39 06 22429097 – Fax +39 06 22429098
e-mail: info@giessediagnostics.com – web site: www.giessediagnostics.com

405207
Ed. 2012/03 rev. 00