CK-NAC MonlabTest®

NAC. Kinetic UV. Liquid

Quantitative determination of creatine kinase liquid (CK)

Only for professional in vitro diagnostic use
Store at 2-8°C

PRINCIPLE OF THE METHOD

Kinetic determination of the creatine kinase based upon IFCC and DGKC recommendations.
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):

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

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

$$\text{G6P + NADP}^+ \xrightarrow{G6P-DH} \text{6-Phosphogluconate + NADPH + H}^+$$

The rate of NADPH formation, measured photometrically, is proportional to the catalytic concentration of CK present in the sample[1,2].

CLINICAL SIGNIFICANCE

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 infarction[1,5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1	Imidazol, pH 6.7	125 mmol/L
	D-Glucose	25 mmol/L
	N-Acetyl-L-Cysteine	25 mmol/L
	Magnesium acetate	12.5 mmol/L
	NADP	2.52 mmol/L
	EDTA	2.02 mmol/L
	Hexokinase	≥6 800 U/L
R 2	ADP	15.2 mmol/L
	AMP	25 mmol/L
	di-Adenosine-5- pentaphosphate	103 mmol/L
	Glucose-6-phosphate dehydrogenase	≥8 800 U/L
	Creatine phosphate	250 mmol/L

Optional

CK-Nac / CK-MB CONTROL	Lyophilized human serum	Ref: MO-165110

PREPARATION

Mix 4 volumes of reagent 1 with 1 volume of reagent 2.
Stability: 21 days at 2-8ºC or 5 days at room temperature (15-25ºC).

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use.
Do not use the tablets if appears broken.
Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1,60.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 340 nm.
- Thermostatic bath at 25ºC, 30ºC ó 37º C (± 0.1ºC).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

Serum free of hemolysis or heparin plasma.
Stability 7 days at 2-8ºC, protected from light.
The creatin kinase activity decreases 10% after 1 day at 2-5ºC or after 1 hour at 15-25ºC.

PROCEDURE

1. Assay conditions:
   Wavelength: . . . . . 340 nm
   Cuvette: . . . . . .1 cm light path
   Constant temperature . . . . . .25ºC / 30ºC / 37ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	25 - 30ºC	37ºC
WR (mL)	1,0	1,0
Sample (µL)	40	20

3. Mix and incubate 2 minutes.
4. Read initial absorbance (A) of the sample, start the stopwatch and read absorbances at 1 minute intervals thereafter for 3 minutes.
5. Calculate the difference between absorbances and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

25º- 30ºC ΔA / min x 4127 = U/L CK

37ºC ΔA / min x 8095 = U/L CK

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per litre of sample (U/L).
Temperature conversion factors
To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to		
	25ºC	30ºC	37ºC
25ºC	1,00	1,56	2,44
30ºC	0,64	1,00	1,56
37ºC	0,41	0,63	1,00

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: CONTROL Normal and Pathologic (Ref. MO-165107 and MO-165108).
If control values are found outside the defined range, check the instrument, reagents and technique for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[1]

	25ºC	30ºC	37ºC
Men, up to	80 U/L	130 U/L	195 U/L
Women, up to	70 U/L	110 U/L	170 U/L

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 2,2 U/L to linearity limit of 2000 U/L.
If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.
Precision:

	Intra-assay		Inter-assay	
Mean (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensitivity: 1 U/L = 0,0012 ΔA/min.
Accuracy: Results obtained using MONLAB reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained were the following:
Correlation coefficient (r): 0,9995
Regression equation: y= 1,0846x – 0,3512.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No interferences were observed with glucose until 7 g/L, hemoglobin until 5 g/L and triglycerides 7 mmol/L. A list of drugs and other interfering substances with CK determination has been reported[3,4].

NOTES

MONLAB has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

BIBLIOGRAPHY

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3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
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PACKAGING

Ref.: MO-165080	R1: 1 x 60 mL R2: 1 x 15 mL

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer	IVD	For i*n vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by

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