

CK-NAC

(Creatinine Kinase – N-Acetylcysteine)

Diagnostic reagent for determination of CK-NAC concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

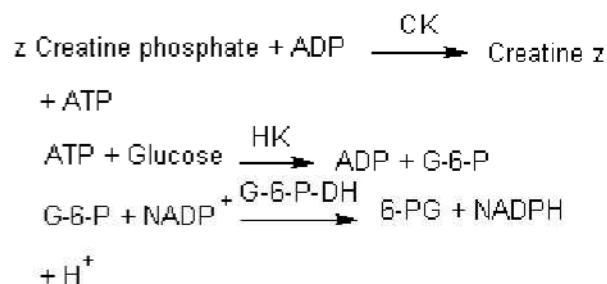
Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2140	5 x 50 mL	N2140	800 Tests	S2140	3077 Tests	RD2140	750 Tests
A2141	5 x 25 mL	N2141	400 Tests	S2141	1477 Tests	M2140	2512 Tests
A2142	5 x 10 mL	T2140	3474 Tests	K2140	5455 Tests	M2141	1675 Tests
DM2140	960 Tests	T2141	1795 Tests	K2141	2727 Tests	HT2140	4091 Tests
EC50	2663 Tests	L2140	3750 Tests	BY2140	7670 Tests	HT2141	2727 Tests
EC51	1183 Tests	L2141	2000 Tests	BY2141	5114 Tests		

INTENDED USE

The test is applied for the quantitative determination of CK-NAC in serum or EDTA plasma.

TEST PRINCIPLE

This is an optimized standard method according to the recommendations of the Deutsche Gesellschaft für Klinische Chemie.



The coupled enzyme system is completely "down hill", i.e., all reactions proceed in a favorable direction. The pH optimum for the system is 6.7.

TEST PARAMETERS

Method	: UV, Kinetic, Increasing Reaction
	Optimized DGKC
Wavelength	: Hg 334 nm, Hg 365 nm, 340 nm
Temperature	: 25°C, 30°C, 37°C
Sample	: Serum, EDTA-Plasma, heparinized Plasma
Linearity	: 2 IU/mL - 1000 U/L

REAGENT COMPOSITION

Reagent 1 and Reagent 2

Imidazole pH 6.7	≤ 120 mmol/L
Creatinephosphate	≤ 34 mmol/L
D-Glucose	≤ 22 mmol/L
N-Acetylcystein	≤ 22 mmol/L
Magnesiumacetate	≤ 12 mmol/L

EDTA	≤ 2.2 mmol/L
ADP	≤ 2.2 mmol/L
AMP	≤ 5.5 mmol/L
Diadenosinpentaphosphate	≤ 15 μmol/L
Glucose-6-Phosphate-DH	> 1.5 kU/L
Hexokinase	> 2.5 kU/L
NADP	≤ 2 mmol/L

REAGENT PREPARATION

Working Reagents:

Substrate start:

Reagents are ready for use.

Sample start:

Mix 4 parts of Reagent 1 with 1 part of Reagent 2. For example: 4 ml Reagent 1 and 1 ml Reagent 2.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before adding its contents into the Reagent 1 bottle by the same preparation ratio. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

Working reagents are stable at 2-8°C in case of closed vials and avoiding contamination after preparation.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

Store unopened and opened reagents at 2°C - 8°C. Protect from light. Note expiration date on the label. Close immediately after use. Avoid contamination of the opened reagents. The working reagent is stable for 3 weeks at 2°C - 8°C and for 5 days at room temperature.

Incompetent handling will release ARCHEM from any responsibility.

SAMPLE

Samples are collected by standard procedures. Creatinine in sample is stable for 2 days at 20 - 25°C, 6 days at 2-8°C and 6 months at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{A \text{ Sample}}{A \text{ Standard}} \times \text{conc. of standard}$$

= U/L CK-NAC in sample

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

	25°C	30°C	37°C
Women	< 70 U/L	< 110 U/L	< 175 U/L
Men	< 80 U/L	< 130 U/L	< 200 U/L

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a CK-NAC Calibrator (Standard). Any commercially available Standard or Calibrator suitable for this method may be used. We recommend:

ARCHEM Calibrator ("Arcal Auto")

Cat.No. A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 2 IU/mL

High Linearity: The method is linear up to 1000 U/L.

If limit value is exceeded dilute the sample with physiological NaCl (150 mmol/L) and reassay multiplying the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (Intra-assay)

Mean con.	SD	CV	n
151 U/L	2.42	1.60%	20
306 U/L	5.43	1.78%	20
504 U/L	8.61	1.71%	20

Reproducibility (run to run) (Inter-assay)

Mean con.	SD	CV	n
167 U/L	2.79	1.67%	10
342 U/L	4.41	1.30%	10
486 U/L	7.05	1.45%	10

Sensitivity (LOD) (Based on CLSI EP17 document): Limit of detection of the test is 1.5 IU/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.

4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

ABBREVIATIONS








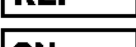




CK-NAC	: Creatinine Kinase N-acetylsystein
CLSI	: Clinical and Laboratory Standards Institute
CV%	: Coefficient of Variation Percentage
EP	: Evaluation Protocols
GLP	: Good Laboratory Practice
IU	: International Unit
mA	: miliabsorbance
mL	: mililiter
NCCLS	: National Committee for Clinical Laboratory Standards
QC	: Quality Control

REFERENCES

1. Szasz G. Gruber at al: Clin. Chem. 22/65
2. DGKC, J. Clin. Chem. Clin. Bioch. 15, 255 (1977).
3. Di. Witt, C. Trendelenburg, J. Clin. Chemie, Clin. Bioch. 20, 235 (1982).

4. Rec. GSCC (DGKC); J. Clin. Chem. Clin. Biochem 1977; 15: 255.
5. Stein, W. (1985), Med. Welt 36: 57
6. Szasz, G., et al. Clin. Chem 1976; 22: 650

SYMBOLS

	Only for invitro diagnostic use
	Lot of manufacturing
	Reagent 1
	Reagent 2
	Concentration
	Reagent Ingredients
	Reference Number (Catalog No)
	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk



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