



CK NAC LR liquid reagent

REF C1900420 338 Test

CE C1900420A 338 Test

IVD For in vitro medical device
ANALYTICAL PERFORMANCES Linearity

Reaction is linear up to a concentration of 1500 U/l. Samples with values exceeding this range must be diluted with saline solution. Then multiply the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 10 U/l.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (U/l)	N = 150.75	H = 450.85
S.D.	N = 2.21	H = 3.76
C.V.%	N = 1.47	H = 0.83

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H). Results:

MEAN (U/l)	N = 152.38	H = 449.18
S.D.	N = 2.77	H = 5.42
C.V.%	N = 1.82	H = 1.21

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.99$

$$y = 1.0181x + 5.247$$

Interferences

No interferences was observed by the presence of:

Bilirubin	≤ 25 mg/dl
Hemoglobin	≤ 200 mg/dl
Triglycerides	≤ 800 mg/dl
Ascorbate acid	≤ 25 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young.

Quality Controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Stein, W. "Creatine kinase (total activity), creatine kinase isoenzymes and variants". In: Thomas L, ed. Clinical laboratory diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, p. 71-80, (1998).
Recommendations of the German Society for Clinical Chemistry. "Standardization of methods for the estimation of enzyme activities in biological fluids: Standard method for the determination of creatine kinase activity". J. Clin. Chem. Clin. Biochem., 15, 255-60, (1977).
Moren, L.G., Clin. Chem., 23, 1569 (1977).
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed. 2000.

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
Hourglass	Use by
Thermometer	Storage temperature limits
Book	Read instruction for use
Factory	Gesana Production srl

Use

Kit for measurement of creatin kinase in serum or plasma.
Kinetic optimized method DGKC-IFCC.

Summary

CK measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne – type muscular dystrophy.

Principle

Kinetic analysis. Creatin kinase catalyzes reaction between creatine phosphate and ADP, giving creatine and ATP. This one, in presence of glucose and hexokinase is transformed into ADP and glucose-6-phosphate which, with glucose-6-phosphate-dehydrogenase intervention, forms glucose-6-phosphogluconate while NADP+ is reduced to NADPH. The CK activity in the sample is calculated measuring the absorbance variation, due to the transformation of NADP+ into NADPH.

Reagents

R1 Imidazole buffer	pH 6.3	150.0 mmol/l
AMP		25.0 mmol/l
NADP		2.0 mmol/l
D-glucose		25.0 mmol/l
diadenosine phosphate		12.0 mmol/l
hexokinase		3000 U/l
magnesium acetate		12.0 mmol/l
N-acetyl-cysteine		25.0 mmol/l
R2 Imidazole buffer	pH 6.3	150.0 mmol/l
ADP		12.0 mmol/l
G6P-DH		10000 U/l
creatine phosphate		35.0 mmol/l

Reagents Preparation

Reagents are liquid and ready to use. About using as monoreagent ("sample-starter" procedure) add the entire contents of one bottle of ALT R2 in the ALT R1 bottle and mix gently. For minor use add to every 4 ml of R1 reagent, 1 ml of R2 reagent. Keep out the reagents from refrigerator only for the use and recap them immediately.

Storage And Stability

- Store the kit at 2-8°C.
- After opening, the vials R1 and R2 are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 20 days at 2-8°C.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or heparinized plasma.
- Store the samples protected from light.
- The CK activity is stable for 7 days at 2-8°C or 30 days at -20°C

Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength λ: 340 (330 o 370) nm
 Working temperature 37°C
 Optical path 1 cm
 Reaction kinetic (increasing)
 Bring the reagents at 15-25°C before using them.

Monoreagent Procedure "sample starter"

	BLANK	SAMPLE
Working Reagent	1000 µl	1000 µl
Distilled Water	25 µl	--
Sample	--	25 µl

Mix, then incubate for 2' a 37°C. Measure the absorbance of sample (EC). Make at least two readings at a distance of 60". Calculate the absorbance variation ΔE/min from performed readings.

Bireagent Procedure "substrate starter"

	BLANK	SAMPLE
Reagent R1	800 µl	800 µl
Distilled Water	25 µl	--
Sample	--	25 µl

Mix, then incubate for 2' a 37°C. Then add:

	BLANK	SAMPLE
Reagent R2	200 µl	200 µl

Mix, then incubate for 2' a 37°C. Measure the absorbance of sample (EC). Make at least two readings at a distance of 60". Calculate the absorbance variation ΔE/min from performed readings.

Calculation

$$CK\ NAC\ [U/l] = \Delta E/min \times 6507$$

The factor and the reagent performances are related to 37°C, 1 cm and 340 nm.

Reference Values

	Siero	Plasma (U/l)	37°C
Adults		Women	24 - 170
		Men	24 - 195
Children		Babies	468 - 1200
		≤ 5 days	195 - 700
		< 6 months	41 - 330
		> 6 months	24 - 229

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.