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CREATINE KINASE (CK-NAC)

CONCENTRATED LIQUID REAGENT

CE

Order information:

Catalogue number	Size
9471C	10 x 65 + 10 x 17 ml
9472C	4 x 65 + 4 x 17 ml

Reagent kit for quantitative in vitro determination of creatine kinase (CK) in serum and plasma.

Summary

Creatine kinase (CK) is an enzyme which is found primarily in skeletal muscle, cardiac muscle and brain tissue. Elevated levels of CK are associated with myocardial infarction, various muscle disorders and diseases such as progressive Duchenne-type muscular dystrophy. In myocardial infarction, peak CK levels occur 24 to 36 hours after onset of chest pain and depending on the extent of damage can reach more than 10 times normal levels.

Method

Optimized IFCC/DGKC method

Creatine-phosphate + ADP $\xrightarrow{\text{Creatine kinase}}$ creatine + ATP

ATP + D-glucose $\xrightarrow{\text{Hexokinase}}$ glucose-6-phosphate + ADP

Glucose-6-phosphate + $NADP^+$ $\xrightarrow{\text{Glucose-6-phosphate dehydrogenase}}$ 6-phospho-gluconate + NADPH

Reagents

Composition and concentrations

Reagent 1	
HEPES buffer,pH 8,0	100 mmol/l
Creatine-phosphate	190 mmol/l
Magnesium-chloride	33 mmol/l
Glucose	25 mmol/l
AMP	18,26 mmol/l
ADP	2,5 mmol/l
Diadenozine-pentaphosphate	39 µmol/l
Hexokinase	18000 U/l
G6PDH	4000 U/l
Reagent 2	
Acetate buffer, pH 3,0	20 mmol/l
NADP	7 mmol/l
N-acetylcystein	75 mmol/l

Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!
Onboard stability after opening and the frequeny of calibration is 72 days.
The absorbance at 340 nm should not be higher than 0,8

Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

Preparation

The reagent is ready for use.

Sample

Serum, EDTA, heparin, citrate plasma.

Stability in serum:	1 week at 2 – 8°C
	1 day at 15 – 25°C
	4 weeks at -20°C

Expected values and reference range

Serum, female:	27 – 167 U/l
male:	27 – 191 U/l

It is recommended that each laboratory should assign its own normal range.

Assay procedure

Wavelength:	340 nm / 410 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against water blank
Reaction:	kinetic, increasing

	blank	sample or standard
reagent 1	300 µl	300 µl
dist. water (diluent)	600 µl	600 µl
dist. water (blank)	45 µl	-
sample or standard	-	45 µl
Mix and incubate for 3 minutes		
reagent 2	75 µl	75 µl
dist. water (diluent)	150 µl	150 µl
Mix and incubate for 2 minute then continuously read the absorbances for 3 minutes		

Calculation

CK[U/l]=ΔA sample/ΔA standard × standard concentration[U/l]

Conversion factor

[U/l]=[µkat/l]/0,0168

Calibration and quality control

S1: Distilled water
S2: Roche C.F.A.S. (Calibrator for automated system) or
Randox Calibration Serum Level I or
Randox Calibration Serum Level II
Calibration is recommended:

- after opening new reagent batch
- after system maitenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Preformance characteristics

Measuring range

The method is linear in the range 12 – 1032 U/l

Interferences

No significant intereference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 12 mmol/l, hemoglobin up to 2 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 1,52 U/l

Precision

Repeatability	mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
normal sample	176,3	1,22	0,69
pathological sample	484	4,74	0,98
Reproduceability	mean	SD	CV
n = 10	[U/l]	[U/l]	[%]
normal sample	182	4,7	2,59
pathological sample	489	5,18	1,06

Method comparison

Comparison with the non-concentrated reagent.
analyser: Advia 2400
number of samples: 123
range: 6 – 1277 U/l
correlation coefficient: 0,997
regression line equation: y = 0,958x + 4,488
(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

IVD	In vitro diagnostic device
	Manufacturer
CE	CE-marking
	Temperature limitations
	Use by (year/month)
LOT	Batch code
REF	Catalogue number
	This way up
	Biological risk

Literature

Mathieu M .et coll Recommendation pour la mesure de la concentration catalytique de la cratinine kinase dans le serum humain.Ann. Biol. Clin., 40, (1982) 87.
Tietz Clinical Guide To Laboratory Tests, 4th edition, Elsevier, 2006