

CK NAC SYSTEM PACK

(OPTIMIZED IFCC METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI14	CK NAC System Pack	4 x 40 + 4 x 10 ml

INTENDED USE

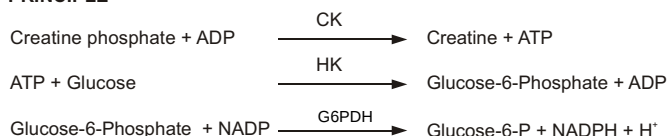
Diagnostic reagent for quantitative *in vitro* determination of Creatine Kinase in human serum and plasma.

CLINICAL SIGNIFICANCE

Creatine Kinase (CK) is a dimeric enzyme occurring in four different forms: mitochondrial isoenzyme and the cytosolic isoenzymes CK-MM (muscle type), CK-BB (brain type) and CK-MB (myocardial type). The determination of CK and CK-isoenzyme activities is utilized in the diagnosis and monitoring of myocardial infarction and myopathies such as the progressive Duchenne muscular dystrophy. Following injury to the myocardium, as occurs with acute myocardial infarction, CK is released from the damaged myocardial cells. In early cases a rise in the CK activity can be found just 4 hours after an infarction, the CK-activities reaches a maximum after 12-24 hours and then falls back to the normal range after 3-4 days. Myocardial damage is very likely when the total CK activity is above 190 U/l, the CK-MB activity is above 24 U/l (37°C) and the CK-MB activity fraction exceeds 6% of total.

The assay method using creatine phosphate and ADP was first described by Oliver, modified by Rosalki and further improved for optimal test conditions by Szasz. CK is rapidly inactivated by oxidation of the sulfhydryl groups in the active center. The enzyme can be reactivated by addition of N-acetyl cysteine (NAC). Interference by adenylate kinase is prevented by the addition of diadenosine pentaphosphate and AMP. Standardized methods for the determination for CK using the "reference reaction" and activation by NAC were recommended by the German society for Clinical chemistry (DGKC) and the International Federation of Clinical chemistry (IFCC) in 1977 and 1990 respectively. This assay meets the recommendations of the IFCC and DGKC.

PRINCIPLE



The rate of absorbance change at 340 nm is directly proportional to Creatine kinase activity.

REAGENT COMPOSITION

Reagent 1: Enzyme Reagent

Imidazole buffer, pH6.1	125 mmol/L
Glucose	25 mmol/L
Magnesium acetate	12.5 mmol/l
EDTA	2 mmol/l
N-acetylcysteine	25 mmol/l
NADP	2.4 mmol/l
Hexokinase	>6.8 U/ml

Reagent 2 : Starter Reagent

ADP	15.2 mmol/L
D-glucose -6-phosphate-dehydrogenase	>8.8 U/ml
AMP	250 mmol/l
Diadenosine pentaphosphate	103 µmol/l

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

On board stability: Min. 30 days if refrigerated (+8-+14°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unhemolytic serum or plasma (heparin, EDTA)

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Loss of activity: 1 week at +2-+8°C < 10 %
1 day at +15-+25°C < 10 %

Stability at -20°C: 4 weeks (in the dark)

Discard contaminated specimens.



BEACON

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

U/L x 0.017 = µkat/l

EXPECTED VALUES

At +37°C Male : 24 - 195 U/L

Female : 24 - 180 U/L

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon. Data obtained in your laboratory may differ from these values.

Limit of quantification: 10.4 U/L
Linearity: 2000 U/L
Measuring range: 10.4 – 2000 U/L

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	133	1.29	0.96
Sample 2	448	1.57	0.35

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	129	1.62	1.26

COMPARISON

A comparison between CK NAC System Pack (y) and commercially available test (x) using 20 samples gave following results:

$Y = 0.997x + 0.598$

$R_2 = 0.999$

INTERFERENCES

Following substances do not interfere:
haemoglobin interferes, bilirubin up to 15 mg/dl, triglycerides up to 600 mg/dl.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400,
Beaconnic B400 & Beaconnic Chem 400
(Fully Auto Biochemistry Analyzer)

TEST NAME	CK NAC
FULL NAME	CK NAC
PRI WAVE	340 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	16
END	33
DECIMAL	2
UNIT	U/L
LINEARITY RANGE LOW	10.4
LINEARITY RANGE HIGH	2000
SAMPLE VOLUME	2 µl
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSTRATE DEPLETED	-
LINEARITY	2000 U/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTRATION STD	Refer calibrator value sheet.

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

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SYMBOLS USED ON LABELS

REF	Catalogue Number		Manufacturer		See Instruction for Use
LOT	Lot Number	CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics		