CK NAC SYSTEM PACK

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200
(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA214	CK NAC System Pack	2x20 + 2x5 ml

BEACON

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

CLINICAL SIGNIFICANCE
Creatine Kinase (CK) is a dimetic enzyme occuring in four different forms: amitochondrial 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 utililzed in the diagnosis and monitoring of myoardial infarction and myopathies such as the progressive Duchenne musclar dystrophy. Following injury to the myocardium, as occurs with acute mocardial 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 exceds 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 conditionsbySzasz. 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 adenhlate kinase is prevented by the addition of diadenosine pentaphosphate and AMP. Standardized methods for the determination for CK using the “referse 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

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

ATP + Glucose $\xrightarrow{HK}$ Glucose-6-Phosphate + ADP

Glucose-6-Phosphate + NADP $\xrightarrow{G6PDH}$ Glucose-6-P + NADPH + H^+

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

REAGENT COMPOSITION

Reagent 1 : Enzyme Reagent

Imdazole 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-glucoso-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 (2-10°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic 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.

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 comparision between CK NAC System Pack (y) and commercially available test (x) using 20 samples gave folloing 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 200, Unicorn 230, Unicorn 120 &
Bonavera Chem 200 (Fully Auto Biochemistry Analyzer)

TEST NAME	CK NAC
FULL NAME	CK NAC
PRI WAVE	340 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	20
END	30
DECIMAL	2
UNIT	U/L
LINEARITY RANGE LOW	10.4
LINEARITY RANGE HIGH	2000
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSATRATE DEPLETED	-
LINEARITY	2000 U/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

NOTE

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

REFERENCES

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IVD

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