CK NAC SYSTEM PACK

(OPTIMIZED IFCC METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA214	CK NAC System Pack	2x20 + 2x5 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 dimetic enzyme occurring in four different forms: a 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 centre. 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 "reverse 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

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

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

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

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-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 (+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.

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

BEACON DIAGNOSTICS PVT. LTD. *424, NEW GIDC, KABILPORE, NAVSARI - 396 424. INDIA*

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 = 0.999

INTERFERENCES

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

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (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 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (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
Concentration Std	Refer calibrator value sheet

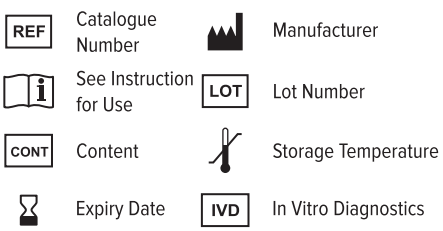
NOTE

The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Henderson, AR., Donald WM., Enzymes, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burts, C.. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 352.
2. Sanhai, W.R., Christenson, R H., Cardiac and muscle disease. Clinical Chemistry: Theory Analysis, Correlation, 4th Ed., Kalpan, LA. Pesce, A.u., Kazmierczak, S.C., (Mosby Inc. Eds St Louis USA), (2003), 566 and appendix.
3. Schumann, G., et al, Clin Chem Lab Med., (2002), 40, 635.
4. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burs, C.A., Ashwood, E-R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.
5. Vassault, A, et al., Ann. Biol. Clin., (1986), 44, 686.
6. Vassault, A, et al., Ann. Biol. Clin. (1999), 57, 685.
7. Young, D. S., Effects of pre analytical variables on clilnical labobratory tests, 2nd Ed., AACC Press, (1997).
8. Young. D. S>, Effects of drugs on clinical laoratory tests, 4th Ed., AACC Press, (1995).
9. Berth, M. & Delanghe, J. Protein precipitation as a possible important pitfall in the ciinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of iterature, Acta Clin Belg., (2004),59, 263.
10. Stein W. Creatine Kinase (total activity), creatine kinase isoenzymes and Variants. In: Thomas L., ed. Ciinical laboratory diagnostics. Frankfurt: TH- Books Verlagsgesellschaft; 1998.p.71-80.

Symbols Used On Labels



BEA/24/CKN/SB/IFU Ver-02
05/10/2024