

CK MB SYSTEM PACK

(Immunoinhibition Method)

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

Code	Product Name	Pack Size
UNI113	CK MB System Pack	1X40+1X10 ml

INTENDED USE

Quantitative determination of CK MB levels in serum.

CLINICAL SIGNIFICANCE

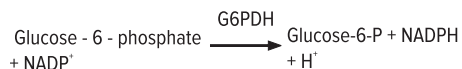
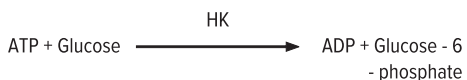
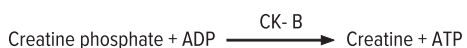
Creatine kinase is composed of two polypeptide chains, denoted B (for brain) and M (for muscle); these give the three dimeric isoenzymes: MM (CK-1), MB (CK-2) and BB (CK-3).

The percentages of CK-MB activity versus total CK activity are usually less than 6%, but after a myocardial infarction, these values can rise from 10 to 30% depending on the extent of myocardial damage and the location of the infarct. However, a myocardial infarction in a previously healthy heart may have a rather low serum CK-MB fraction. Therefore, the diagnosis of myocardial damage must be based on the clinical history and findings, the magnitude of the CK-MB elevation, and its temporal pattern.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE

A specific antibody inhibits both M subunits of CK-MM (CK-3), and the single M subunit of CK-MB (CK-2) and thus allow determination of the B subunit of CK-MB (assuming the absence of CK-BB or CK-1)3,4. CK-B catalytic concentration, which corresponds to half of CK-MB concentration, is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH) coupled reactions.



REAGENT COMPOSITION

Reagent 1 : Enzyme Reagent

Anti-human-CK-M able to inhibit 2000 U/L of CK-M

Imidazol	: 125 mmol/L
EDTA	: 2 mmol/L
magnesium acetate	: 12.5 mmol/L
D-glucose	: 25 mmol/L



N-acetyl cysteine	: 25 mmol/L
hexokinase	: 6800 U/L,
NADP	: 2.4 mmol/L
pH	: 6.1

Reagent 2 : Starter Reagent

Creatine phosphate	: 250 mmol/L
ADP	: 15.2 mmol/L
AMP	: 25 mmol/L
P1,P5-di(adenosine-5'-)pentaphosphate	: 103 mol/L,
glucose-6-phosphate dehydrogenase	: 8800 U/L.

REAGENT PREPARATION

Reagent is 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

Serum or heparinized plasma collected by standard procedures.

Total CK concentration in the sample must be lower than 1000 U/L. Dilute the serum 1/2 if necessary, with NaCl 150 mmol/L.

CK-MB is stable for 7 days at +2 - +8°C.

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

Expected Values

At +37°C

Male/female : 0-25 U/L

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

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 system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 7.88 U/L
 Linearity : 1000 U/L
 Measuring range : 7.88 – 1000 U/L

Precision

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	10.69	0.53	4.92
Sample 2	50.74	2.19	4.32

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	16.12	0.79	4.91

Comparison

A comparison between Beacon CK-MB (y) and a commercially available test (x) using 20 samples gave following results :

$$y = 0.9947x - 0.2528 \text{ U/L}$$

$$r = 0.997$$

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.

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

Test Name	CK MB
Full Name	CK MB
Pri Wave	340 nm
Sec Wave	630 nm
Assay/point	Kinetic
Start	10
End	33
Decimal	2
Unit	U/L
Linearity Range Low	7.88
Linearity Range High	1000
Sample Volume	10 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Substrate Depleted	-
Linearity	1000 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.









LIMITATIONS OF THE PROCEDURE

Interferences: bilirubin (up to 20 mg/dL), hemolysis (hemoglobin up to 250 mg/dL) and lipemia (triglycerides up to 125 mg/dL) do not interfere. Presence in the sample of above normal concentrations of CK-BB or adenilate kinase, and of macro or mitochondrial CK interfere6. Other drugs and substances may interfere.

REFERENCES

1. Tietz Textbook of Clinical Chemistry, 3rd edition. Burtis CA, Ashwood ER. WB Saunders Co., 1999.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Würzburg U, Hennrich N, Lang H, Prellwitz W, Neumeier D and Knedel M. Bestimmung der aktivitat von creatinkinase MB im serum unter verwendung inhibitorischer antikörper. Klinische Wochenschrift 1976 ;54: 357-360.
4. Gerhardt W and Waldenstrom G. Creatine kinase B-subunit activity in serum after immunoinhibition of — subunit activity. Clin Chem 1979; 25: 1274-1279.
5. IFCC methods for the measurement of catalytic concentration of enzymes. Part 7: IFCC method for creatine kinase. JIFCC 1989; 1: 130-139.
6. Urdal P and Landaas S. Macro creatine kinase BB in serum, and some data on its prevalence. Clin Chem 1979; 25: 461-465.
7. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

Symbols Used On Labels

-  Catalogue Number  Manufacturer
-  See Instruction for Use  Lot Number
-  Content  Storage Temperature
-  Expiry Date  In Vitro Diagnostics

BEA/24/CMB/UN/IFU Ver-00
02/12/2025

