CREATININE SYSTEM PACK

(ENZYMATIC 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
BA215	Creatinine System Pack	4x30 + 4x10 ml

INTENDED USE

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

CLINICAL SIGNIFICANCE

Creatinine is a waste product formed in muscle from the high energy storage compound, creatinine phosphate. The amount of creatinine produced is fairly constant (unlike Urea) and is primarily a function of muscle mass. It is not greatly affected by diet, age, sex or exercise. Creatinine is removed from plasma by glomerular filtration and then excreted in urine without any appreciable resorption by the tubules.

Creatinine is used to assess renal function, however, serum creatinine levels do not start to rise until renal function has decreased by at least 50%.

PRINCIPLE

In the first reaction, creatinase and sarcosine oxidase are used in the enzymatic hydrolysis of endogenous creatine to produce hydrogen peroxide, that is eliminated by catalase.

Creatininase and 4-aminoantipyrine are added, and only the creatine generated from creatinine by creatininase is hydrolysed sequentially by creatinase and sarcosine oxidase to produce hydrogen peroxide. This newly formed hydrogen peroxide is measured in a coupled reaction catalysed by peroxidase, with N-ethyl-N-sulphopropyl-m-toluidine (ESPMT) as a chromogen.

The absorbance of the produced complex at 546 nm is proportional to the creatinine concentration in the sample.

REACTION

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$2H_2O_2 + 4\text{-}AA^{1} + TOOS^{-2} \xrightarrow{\text{Peroxidase}} \text{Quinone} + 4H_2O$$

1 : 4-Aminoantipyrine

2 : N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine

Creatinine concentration can be obtained by measuring quinone pigment photometrically.

REAGENT COMPOSITION

Reagent 1 : Creatinine R1

Buffer pH 8.0	25 mmol/L
Creatinase	>20 KU/l
Sarcosine oxidase	>5 KU/l
Ascorbate oxidase	<3 KU/l
Catalase	>80 KU/l
ESPMT	0.5 mmol/L

Reagent 2 : Creatinine R2

Buffer pH- 7.6	>25 mmol/L
Creatininase	>250 KU
Peroxidase	>20 KU/l
4-aminoantipyrine	>2 mmol/L

REAGENT PREPARATION

Reagents R1 and R2 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 : Min30 days if refrigerated (+8 - +14°C) and not contaminated.

SPECIMEN COLLECTION & HANDLING

Use serum, Plasma(hepairin, EDTA), Urine.

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

Stability

in serum / plasma:	7 days at +4 - +25°C
	at least 3 months at -20°C
In urine:	2 days at +20 - +25°C
	6 days at +4 - +8°C
	6 months at -20°C

For the determination in urine use 24 hours specimen. It is important to exactly measure the volume of collected urine. Dilute urine samples in 1+19 ratio with distilled water and multiply results by 20.

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Muticalibrator is recommended.

QUALITY CONTROL

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

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UNIT CONVERSION

mg/dl x 88.4 = µmol/L

EXPECTED VALUES

Serum Male : 0.6 - 1.1 mg/dl Female : 0.5- 0.8 mg/dl
Urine 1070 - 2150 mg/dl (24 hrs. accumulated urine)
769 - 1200 mg/dl (24 hrs. accumulated urine)
It is recommended that each laboratory verify this range or derives reference 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 : 0.042 mg/dl
Linearity : 40 mg/dl (Serum) & 200 mg/dl (Urine)
Measuring range : 0.042-40 mg/dl (Serum) & 200 mg/dl (Urine)

Intra-assay precision Within run (n=20)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	5.50	0.08	1.48
Sample 2	1.61	0.06	3.77

Inter-assay precision Run to run (n=20)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.62	0.020	3.24

COMPARISON

A comparison between Creatinine System Pack (Enzymatic Method) (y) and a commercially available test (x) using 20samples gave following results:
y = 0.909x + 0.145 mg/dl
r = 0.999

INTERFERENCES

Following substances do not interfere:
haemoglobin upto 5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 1000 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but Reagent R2 contains less than 0.1% sodium azide - classified as toxic and dangerous substance for the environment. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For 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	CREATININE ENZYMATIC
Full Name	CREATININE ENZYMATIC
PRI Wave	546 nm
SEC Wave	700 nm
Assay/Point	2 POINT END
Start	16
End	34
Decimal	2
Unit	mg/dl
Linearity Range Low (Serum)	0.042
Linearity Range High(Serum)	40
Linearity Range Low (Urine)	0.042
Linearity Range High(Urine)	200
Sample Volume	6 µl
Reagent 1 (R1) Volume	150 µl
Reagent 1 (R2) Volume	50 µl
Substrate Depleted/Abs.limit	-
Linearity	-
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. Kaplan, L. A., Pesce, A. J.: Clinical Chemistry, Mosby Ed. (1996)
2. Jakobs, D. S., Kasten, Jr., B. L., DeMott, W. R. Wolfson, W. L.: Laboratory Test Handbook, Lexi-Comp and Wiliams & Wilkins Ed. (2nd Edition -1990)
3. Myers, G. L. et. al.: Recommendations for Improving Serum Creatinine Measurement: A repot from laboratory working group of the National kidney disease education program, Clinical Chemistry 52, 1, 5 - 18 (2006)
4. Bomer, U., Szaz, G. et. AL.: A specific fully enzymatic method for creatinine reference values in serum, J. Clin. Chem. Clin. Biochem 17: 679-882 (1979).
5. Searcy, R. L. "Diagnostic Biochemistry" McGraw-Hill, New York, NY. 1996

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

BEA/24/CRE/SB/IFU Ver-05
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