CALCIUM SYSTEM PACK

(ARSENAZO III 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
BA211	Calcium System Pack	5x40 ml
BA211A	Calcium System Pack	2x40 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Calcium in human serum.

CLINICAL SIGNIFICANCE

Calcium has numerous function within the body, not only as a structural factor in bones and teeth, but also in normal neuromuscular function and the clotting of blood.

Hypercalcemia may develop in patients with Paget's disease of bone and hyperparathyroidism. The cause of hypercalcemia in malignancy is an increased bone resorption either caused by metastasis or by humoral factors produced by the tumor cell.

In Rickets, Coeliac diseases, idiopathic steatorrhea, osteomalacia, tropical sprue and following surgical resection of the small intestine, serum calcium is often moderately reduced, usually in association with low plasma protein concentration.

PRINCIPLE

Arsenazo III combines with calcium ions at pH 6.5 to form a colored chromophore, the absorbance of which is measured at 650 nm (650-660nm) and is proportional to calcium concentration.

Arsenazo III has a high affinity ($k° = 1 \times 10^{7}$) for calcium ions and shows no interference from other cations normally present in serum, plasma or urine.

REAGENT COMPOSITION

Reagent 1 : Calcium Arsenazo (III) Reagent

Arsenazo III	< 0.10 mmol/l
Buffer	> 50 mmol/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 unheamolyse serum.

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

Stability in serum

7 days	at +20 - +25°C
3 weeks	at +4 - +8°C

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

mg/dl x 0.25 = mmol/L

EXPECTED VALUES

Serum:

8.5- 11.0 mg/dl

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: 0.6 mg/dl
Linearity: 15 mg/dl
Measuring range: 0.6 - 15 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	8.65	0.08	0.94
Sample 2	12.13	0.09	0.78

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	6.96	0.10	1.37

COMPARISON

A comparision between Calcium System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 1.064x - 0.472 mg/dl
r = 0.997

INTERFERENCES

Following substances do not interfere:
haemoglobin upto 10 g/l bilirubin up to 40 mg/dl, triglycerides up to 500 mg/dl.

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

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.
Reagents of the kits are not classified like dangerous.
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	CALCIUM
Full Name	CALCIUM
PRI Wave	630 nm
SEC Wave	-
Assay/Point	1 POINT END
Start	-
End	7
Decimal	3
Unit	mg/dl
Linearity Range Low	0.6
Linearity Range High	15
Sample Volume	4 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	-
Substrate Depleted/Abs.limit	-
Linearity	15 mg/dl
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. Bishop , M. C. Dubeb - on Laufen, J.L., Burtis, Carl Aa and Ashwood, Tietz 110,61.

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/CAL/SB/IFU Ver: 03
28/06/2025

JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016