CALCIUM SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI11	Calcium System Pack	4 x 50 ml

BEACON

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.

Hypercalcaemia may devlop in patients with Paget's disease of bone and hyperparathyroidism. The cause of hypercalcaemia 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 (650-660 nm) 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 Arseneso (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.

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
8 months	at –20°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	9.89	0.07	0.67
Sample 2	11.97	0.11	0.95

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	8.39	0.01	0.15

COMPARISON

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

y = 0.992 x + 0.139 mg/dl
r = 0.995

INTERFERENCES

Following substances do not interfere:
haemoglobin upto10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 500 mg/dl.

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.

WASTE MENAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	Calcium
FULL NAME	Calcium
PRI WAVE	630 nm
SEC WAVE	-
ASSAY/POINT	1 Point end
START	-
END	13
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	0.6
LINEARITY RANGE HIGH	15
SAMPLE VOLUME	4 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	15 mg/dl
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	4 µ l

NOTE

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

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/UN/IFU-00 DATE :16/07/2022