

ALBUMIN SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI02	Albumin System Pack	4 x 50 ml

INTENDED USE

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

CLINICAL SIGNIFICANCE

Albumin, a major plasma protein, is synthesised in the liver from amino acids which are absorbed from the ileum. It's functions include regulation of distribution of extracellular fluid, transportation of various hormones, vitamins and trace metals.

Increased levels are observed in

Dehydration due to reduced plasma water content.

- Stasis during venipuncture which causes fluid to escape into the extravascular compartment.

Decreased levels are observed in

- Excessive protein loss (mainly albumin) - from kidney, skin or intestine.

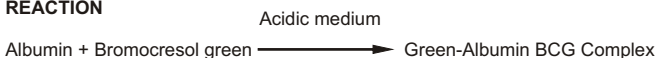
- Decreased synthesis due to dietary, hepatic disease or malabsorption.

- Increased catabolism in fever, untreated diabetes mellitus and hypertension.

PRINCIPLE

Albumin binds with Bromo Cresol Green (BCG) at pH 4.2 causing a shift in absorbance of the yellow BCG dye. The blue-green colour formed is proportional to the concentration of albumin, when measured photometrically between 540-630 nm with maximum absorbance at 630 nm.

REACTION



REAGENT COMPOSITION

Reagent 1 : BCG Reagent

Bromocresol green	<0.21 mmol/L
Succinate 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 (2–10°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolysed serum or plasma (EDTA, heparin)

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

Stability in serum:	1 month	at 2–8°C
	1 week	at 15–25°C
	at least 3 months	at -20°C

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

g/dl x 10 = g/l

EXPECTED VALUES

Serum: 3.4-5.5 gm/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.



BEACON

Limit of quantification: 0.1 gm/dl

Linearity: 10 gm/dl

Measuring range: 0.1 – 10 gm/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (gm/dl)	SD (gm/dl)	CV (%)
Sample 1	4.59	0.06	1.26
Sample 2	4.11	0.05	1.18
Inter-assay precision Run to run (n=20)	Mean (gm/dl)	SD (gm/dl)	CV (%)
Sample 1	6.79	0.209	3.09

COMPARISON

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

y = 1.028x - 0.106 g/dl

r = 0.986

INTERFERENCES

Following substances do not interfere:

haemoglobin up to 10 g/l, bilirubin up to 40mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &
Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	ALBUMIN
FULL NAME	ALBUMIN
PRI WAVE	630 nm
SEC WAVE	-
ASSAY/POINT	1 POINT END
START	-
END	7
DECIMAL	2
UNIT	gm/dl
LINEARITY RANGE LOW	0.1
LINEARITY RANGE HIGH	10
SAMPLE VOLUME	2 µl
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSTRATE DEPLETED	-
LINEARITY	10 gm/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.
SAMPLE VOLUME	2 µl

NOTE

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

REFERENCES

1. Leonard, P. L., Persaud, J., Motwani, R.: Clin. Chim. Acta 35, 409, 1971.
2. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company 2012.

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/ALB/UN/IFU-00

DATE :16/07/2022