LIQUIZYME

ALBUMIN

(BCG Method)

BEACON

Code	Product Name	Pack Size
LS008D	Liquizyme Albumin (BCG Method)	1 x 120 ml
LS008E	Liquizyme Albumin (BCG Method)	5 x 120 ml
LS008F	Liquizyme Albumin (BCG Method)	10 x 120 ml
LS008H	Liquizyme Albumin (BCG Method)	2 x 100 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 extravasculer 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 absor-bance 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

Albumin + Bromocresol green $\xrightarrow{\text{Acidic medium}}$ Green-Albumin BCG Complex

Reagent Composition

Reagent 1 : BCG Reagent

Bromocresol green : <0.21 mmol/L
Succinate Buffer : >50 mmol/L

Reagent 2 : Albumin Standard : 4 gm/dl
Ready to use

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.

Materials Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pipettes or Micropipettes & Tips
- Colorimeter or Bio-Chemistry Analyzer.

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
Discard contaminated specimens.

Calibration

Calibration with the Albumin standard provided in the kit is recommended.

Quality Control

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

Unit Conversion

gm/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.

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	4.02	0.03	0.69
Sample 2	3.01	0.01	0.46

Inter-assay precision Run to run (n=20)	Mean (gm/dl)	SD (gm/dl)	CV (%)
Sample 1	2.38	0.05	2.26

Comparison

A comparison between Beacon Albumin (y) and a

commercially available test (x) using 20 samples gave following results :

y = 1.0038 x - 0.0865 gm/dl

r = 0.999

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.

Assay Procedure

Wavelength : 630 nm

Cuvette : 1 cm

Addition Sequence	Reagent Blank	Standard	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Standard	-	10 µl	-
Sample	-	-	10 µl
Distilled Water	10 µl	-	-

Mix and incubate 1 min. at R.T. Measure absorbance of the sample Abs. T and standard Abs. S against reagent blank.

Calculation

$$\text{Albumin (gm/dl)} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 4$$

Applications for automatic analysers are available on request.

Assay Parameters For Photometers

Mode	End point
Wavelength 1 (nm)	630
Sample Volume (µl)	10
Reagent Volume (µl)	1000
Incubation time (min.)	1
Incubation temp. (°C)	Room Temperature
Normal Low (gm/dl)	3.4
Normal High (gm/dl)	5.5
Linearity Low (gm/dl)	0.1
Linearity High (gm/dl)	10
Standard Concentration	4 gm/dl
Blank with	Reagent
Unit	gm/dl

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/LS/IFU Ver-05
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BSCIC JAS-ANZ ISO 9001 : 2015

BSCIC ISO 13485:2016