Spectrum For Diagnostic Industries

Albumin - BCG

IVD

REF.	Pack size
101 02 125 101 05 125 101 04 250	(2 x 125 ml) 250 tests (5 x 125 ml) 625 tests (4 x 250 ml)1000 tests

Intended Use

Albumin reagent is intended for the in-vitro quantitative and diagnostic determination of albumin in human serum on both automated and manual systems.

Introduction

Albumin is the major serum protein in normal individuals. It maintains the plasma colloidal osmotic pressure, binds and solubilizes many compounds such as calcium and bilirubin. Elevated serum albumin levels are usually the result of dehydration. Hyperalbuminemia is of little diagnostic significance. Hypoalbuminemia is very common in many diseases including malabsorption, liver diseases. kidney diseases, severe burns, infections, cancer and some genetic abnormalities. In severe hypoalbuminemia (less than 2.5 g/dL), the low plasma oncotic pressure allows water to move out of the blood capillaries into the tissues causing edema.

Method

Modified Bromocresol green colorimetric method.

Assay principle

Measurement of albumin is based on its binding to the indicator dye bromocresol green (BCG) in pH 4.1 to form a blue-green colored complex. The intensity of the blue-green color is directly proportional to the concentration of albumin in the sample. It is determined by monitoring the increase in absorbance at 623 nm, or 578 nm.

Albumin + BCG $\xrightarrow{pH\ 4.1}$ Albumin-BCG Complex

Reagents

Reagent (R)

Acetate buffer	100 mmol/L
Bromocresol green	0.27 mmol/L

Standard albumin
4.0 g/dL.

Reagent preparation, storage and stability

Albumin reagents are supplied ready-to-use and stable till the expiration date stated on the vial label when stored at 2 – 8 ^{o}C.Once opened, the reagent is stable for 6 months and the standard is stable for 3 months at the specified temperature.

Deterioration

Do not use the albumin regents if precipitate forms. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

The only acceptable anticoagulats are heparin and EDTA. Use preferably fresh serum, serum should be separated immediately from the clot. The biological half-life of albumin in blood is 3 weeks.

Stability: 1 day at 15 – 25 ^{o}C; 4 weeks at 4 – 8 ^{o}C;
6 months at -20 ^{o}C

Procedure

Wavelength	578 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
Temperature	20 – 25 ^{o}C
Incubation time	5 minutes at 20–25^{o}C
Zero adjustment	Reagent Blank
Reagent Blank Limits	Low 0.00 AU High 2.5 AU
Sensitivity	1 g/dL
Linearity	7 g/dL

	Reagent blank	Standard	Specimen
Reagent (**R**)	1 ml	1 ml	1 ml
Standard	-------	10 µl	-------
Specimen	-------	-------	10 µl

Mix and incubate for approximately 5 minutes at 20-25 ^{o}C.Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank within 60 minutes.

Calculation

$$\text{Albumin concentration (g/dL)} = \frac{A_{specimen}}{A_{standard}} \times 4$$

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Performance characteristics

Method Comparison
A study using 20 human specimens between this Albumin procedure and the reference method yielded a correlation coefficient of 0.97.

Precision
Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (g/dL)	3.28	4.78
SD	0.8	0.12
CV%	2.66	2.68

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (g/dL)	3.4	4.9
SD	0.9	0.14
CV%	3.1	2.9

Sensitivity

When run as recommended, the minimum detection limit of this assay is 1.0 g/dL.

Linearity

The reaction is linear up to an albumin concentration of 7.0 g/dL; specimens showing higher concentration should be diluted 1+1 with physiological saline and repeat the assay (result × 2).

Interfering Substances

Haemolysis
A haemoglobin level of 800 mg/dL results in 13% positive bias.

Icterus
No significant interference up to a bilirubin level of 40 mg/dL.

Lipemia
No significant interference up to an intralipid level of 1000 mg/dL.

Expected Values

1- Adults		
a) 18 – 60 y	3.5 – 5.5 g/dL	(35 – 50 g/L)
b) >60 y	3.4 – 4.8 g/dL	(34 – 48 g/L)
2- Childern		
a) 14-18 y	3.2-4.5 g/dL	(32-45 g/L)
b) 4 d-14 y	3.8-5.4 g/dL	(38-54 g/L)
3- Newborns		
0-4 day	2.8-4.4 g/dL	(28-44 g/L)

Analytical Range

1.0 – 7.0 g/dL.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. Refer to special instructions/safety data sheets.

References

1. Tietz NW, ed. Clinical Guide to laboratory tests. 2 nd ed. Philadelphia: WB Saunders; 1990:26-29.
2. Grant GH, Silverman LM, Christenson RH. Amino acids and proteins. In:Tietz NW, ed. Fundamentals of Clinical Chemistry. 3 rd ed. Philadelphia:WB Saunders;1987:291 345.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch Code/Lot number
REF	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

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