SPECTRUM

The Creative Approach to Bioscience

Albumin

210 001	100 test
210 002	300 test
210 003	600 test
210 004	800 test
211 001	200 test
211 002	400 test
211 003	500 test
211 004	1000 test
ZL-211 001	200 test

Intended Use

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

Background

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

Standard albumin
4.0 g/dL.

Reagent (R)

Acetate Buffer	100 mmol/L
Bromocresol green	0.27 mmol/L
Detergent	

For further information, refer to the Albumin reagent material safety data sheet.

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.

Reagent Preparation, Storage and Stability

Spectrum albumin reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored at 2 – 8 °C. Once opened , the reagent is stable for 6 months and standard is stable for 3 months at the stated temperature.

Deterioration

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

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 °C; 4 weeks at 4 – 8 °C;
6 months at -20 °C

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

System Parameters

Wavelength	623 nm (or 578 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	20 – 25 °C
Incubation time	5 minutes at 20–25°C
Zero adjustment	Reagent Blank
Sensitivity	1 g/dL
Linearity	7 g/dL

Procedure

	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 °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 commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (g/dL)	3.28	4.78
SD	0.08	0.12
CV%	2.44	2.51

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (g/dL)	3.4	4.9
SD	0.09	0.14
CV%	2.65	2.86

Methods of Comparison

A comparison between Spectrum Albumin reagent and a commercial reagent of the same methodology was performed on 200 human sera. A correlation of 0.97 was obtained.

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

Adults

18 – 60 y	3.5 – 5.5 g/dL	(35 – 50 g/L)
>60 y	3.4 – 4.8 g/dL	(34 – 48 g/L)

Children

14-18 y	3.2-4.5 g/dL	(32-45 g/L)
4d-14 y	3.8-5.4 g/dL	(38-54 g/L)

Newborns

0-4 day	2.8-4.4 g/dL	(28-44 g/L)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure ; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

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. Doumas BT,Watson WA, Biggs HG. Albumin standard and the measurement of serum albumin with bromocresol green Clin Chim Acta. 1971;31:87-96.
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.
3. Tietz NW, ed. Clinical Guide to laboratory tests. 2 nd ed. Philadelphia: WB Saunders; 1990:26-29.

ORDERING INFORMATION	
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