Albumin FS

Albumin Reagent Test Kit

Intended Use

Diagnostic reagent for quantitative determination of Albumin in Human Serum or Plasma on Photometric analyzers.

Order Information

Item Code	Pack size
102209934840	R:4 x 60 mL

Summary [1,2]

Albumin is an important binding and transport protein for various substances in plasma and the main contributor to the plasma osmotic pressure. Measurement of albumin in serum is used for diagnosis and monitoring of liver diseases, e.g. liver cirrhosis. Furthermore, albumin levels indicate the health and nutritional status of an individual and, therefore, are used for detecting malnutrition and for prognosis in elderly hospitalized patients.

Method

Photometric test using bromocresol green

Principle

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue.

Reagents

Components and Concentrations

Reagent :	Citrate buffer pH 4.2	30 mmol/L
	Bromocresol green	0.26 mmol/L
Standard :	Albumin	3.0 g/dL

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 15° – 30°C, protected from light and contamination is avoided. Do not freeze the reagent!

Warnings and Precautions

1. The standard contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
2. In very rare cases, samples of patients with gammopathy might give falsified results [6].
3. Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Traceability

The assigned values of TruCal U have been made traceable to the reference material ERM-DA470.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:

10 weeks	at	20 – 25°C
5 months	at	4 – 8°C
3 months	at	-20°C

Only freeze once!

Discard contaminated specimens

Assay Procedure

Application sheets for automated systems especially SYS200/400 are available on request.

Wavelength	546 nm (540 – 630 nm)
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample/ Standard/ Calibrator
Sample/ Standard/ Calibrator	-	10 µL
Dist. Water	10 µL	-
Reagent	1000 µL	1000 µL
Mix, incubate for approx. 10 min. and read the absorbance against reagent blank within 60 min.		

Calculation

With standard or calibrator

$$\text{Albumin [g/dL]} = \frac{\text{Sample}}{\text{Std/Cal}} \times \text{Conc. Std/Cal [g/dL]}$$

Conversion factor

Albumin [g/dL] x 144.9 = Albumin [µmol/L]

Calibrators and Controls

For the calibration of automated photometric systems the DiaSys TruCal U calibrator is recommended. The assigned values of TruCal U have been made traceable to the reference material ERM-DA470. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring Range

The test has been developed to determine albumin concentrations within a measuring range from 0.2 – 6 g/dL. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 400 mg/dL and lipemia up to 500 mg/dL triglycerides. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 0.2 g/dL.

Precision (at 25°C)

Intra-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	2.83	0.06	2.20
Sample 2	4.16	0.10	2.48
Sample 3	5.57	0.13	2.28

Inter-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	2.79	0.04	1.32
Sample 2	3.96	0.03	0.88
Sample 3	5.28	0.05	1.02

Method Comparison

A comparison of DiaSys Albumin (y) with a commercially available assay (x) using 59 samples gave following results:
y = 1.00 x – 0.11 g/dL; r = 0.998

Reference Range [4]

Adults: 3.5 – 5.2 g/dL
35 – 52 g/L
507 – 756 µmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Interpretation of Results

Decreased levels of albumin can be seen in kidney diseases,Liver diseases or Chrohn Disease.Increased levels of albumin can be seen in dehydration or high protein diet.

Results should be correlated clinically.

Limitations

Result Interreference can be observed in patient samples exceeding triglyceride concentration above 500 mg/dL

Literature

1. Johnson AM, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p.477–540.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
4. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996;34:517-20.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Assocation for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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