

Albumin Fluid Monoreagent



BROMCRESOL GREEN METHOD

IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA.

REF	88 72 83	1x1000ml
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CALIBRATION

Albumin Standard (4g/dl)	5ml	88 08 35
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QUALITY CONTROL

Control Serum N	6x5ml	88 41 48B
Control Serum P	6x5ml	88 46 85B

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

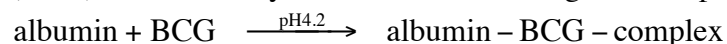
SUMMARY

Albumin is a carbohydrate-free protein, which constitutes 55-65% of total plasma protein. It maintains oncotic plasma pressure, is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e. g. bilirubin, calcium and long-chain fatty acids. Furthermore albumin is capable of binding toxic heavy metals ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics. Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: Compromised synthesis due either to liver disease or as a consequence of reduced protein uptake, elevated catabolism due to tissue damage (severe burns) or inflammation, malabsorption of amino acids (Crohn's disease), proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dl. Due to the low osmotic pressure of the plasma water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

TEST PRINCIPLE

Colorimetric assay, endpoint method

At a pH value of 4.2 albumin displays a sufficiently cationic character to be able to bind with bromocresol green (BCG), an anionic dyestuff, to form a blue-green complex.



The colour intensity of the blue-green color is directly proportional to the albumin concentration and can be determined photometrically

NOTES

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

LIMITATIONS - INTERFERENCE

Criterion: Recovery within $\pm 10\%$ of initial value at an albumin concentration of 3.5 g/dl.

Icterus: No significant interference up to an index I of 92 (approximate bilirubin concentration: 92 mg/dl).

Hemolysis: No significant interference up to an index H of 1100 (approximate hemoglobin concentration: 1100 mg/dl).

Lipemia (Intralipid): No significant interference up to an index L of 1075 (approximate triglycerides concentration: 2150 mg/dl). There is poor correlation between turbidity and triglycerides concentration.



MEASURING/REPORTABLE RANGE

0.2g/dl – 6.0 g/dl or 2 g/l – 60 g/l

Determine samples having higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with 0.9% NaCl solution (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

REFERENCE VALUE*Expected values according to Tietz*

Adults	3.4-4.8 g/dl or 34-48 g/l
Newborn 0 - 4 days	2.8-4.4 g/dl or 28-44 g/l
Children 4 days - 14 years	3.8-5.4 g/dl or 38-54 g/l
14 - 18 years	3.2-4.5 g/dl or 32-45 g/l

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, albumin results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

ANALYTICAL SENSITIVITY (LOWER DETECTION LIMIT)

0.2 g/dl or 2 g/l

The lower detection limit represents the lowest measurable albumin concentration that can be distinguished from zero.

IMPRECISION

Reproducibility was determined using in an internal protocol. The following results were obtained.

	Within run		
<i>Sample</i>	<i>Mean g/dl</i>	<i>SD g/dl</i>	<i>CV %</i>
Sample 1	3.32	0.05	1.58
Sample 2	3.49	0.05	1.38
Sample 3	3.78	0.04	1.18

	Between day		
<i>Sample</i>	<i>Mean g/dl</i>	<i>SD g/dl</i>	<i>CV %</i>
Sample 1	3.32	0.05	1.56
Sample 2	3.49	0.05	1.44
Sample 3	3.78	0.04	1.48

METHOD COMPARISON

A comparison of the Albumin Fluid Monoreagent (y) with a commercial obtainable assay (x) gave with 44 samples the following result:

$$y = 0.983 x + 0.253; r = 0.983$$

REAGENT CONCENTRATION**R1:**

Succinate buffer, pH 4.2	75 mmol/l
Bromcresol green	0.15 mmol/l
Brij 35	7 ml/l
Detergents and stabilizers	>0.1 %

PREPARATION AND STABILITY

All reagents are ready to use.

The reagent is stable at +2°C to +8°C up to the date of expiration specified. Avoid direct sunlight.

SPECIMEN

Collect serum using standard sampling tubes. Heparin or EDTA plasma. Separate serum or plasma from the clot or cells within one hour and analyze immediately, or store as follows:

< 3 days	at +4°C
6 months	at -20°C

Centrifuge samples containing precipitates before performing the assay.



TESTING PROCEDURE*Materials provided*

- Working solutions as described above

Additional materials required

- Controls as indicated below
- 0.9% NaCl

Manual procedure

Wavelength	578nm, Hg 623 (320 – 640nm)
Temperature	+ 20 to + 37°C
Cuvette	1 cm light path
Zero adjustment	Reagent blank/each series needs one reagent blank only

	<i>Blank</i>	<i>Control Serum/Standard</i>	<i>Sample</i>
<i>Sample</i>	---	---	10 µl
<i>Standard / Control</i>	---	10 µl	---
<i>Reagent / RI</i>	1000 µl	1000 µl	1000 µl

Mix and incubate 10 minutes. Read the absorbance against blank within 30 min.

Calculation:

$$\frac{\Delta A_{\text{sample}}}{\Delta A_{\text{standard}}} \times \text{conc. standard (4 g/dl)} = \text{Albumin in g/dl}$$

DISPOSAL

Please note the legal regulations.

LITERATURE

1. Bablok W. et al. A General Regression Procedure for Method Transformation. Clin Chem Clin Biochem 1988;26:783-790.
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3. Glick M.R., Ryder K.W., Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.
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AXIOM Product range Clinical Chemistry

Enzymes	Ions	Other Metabolites
Acid Phosphatase	Ammonium fluid	Bilirubin T/D
Alkaline Phosphatase	Copper fluid	Creatinine fluid
α -Amylase direct	Calcium fluid	Glucose GOD-PAP fluid
CK-NAC activated	Chloride fluid	Glucose Hexokinase fluid
CK-MB (NAC- activated)	Inorganic Phosphorus UV fluid	Urea Enzymatic fluid
γ -GT fluid	Iron fluid	Urea UV fluid
LDH fluid	TIBC	Uric Acid PAP fluid
Cholinesterase	Magnesium fluid	
GOT/ASAT fluid	Potassium fluid	
GPT/ALAT fluid	Sodium fluid	Controls
Lipase UV fluid		Control Serum N
Lactate PAP		Control Serum P
α -HBDH	Proteins	
	Albumin	
	CSF-Protein fluid	
Lipids		
Cholesterol fluid	Microprotein fluid	
HDL Cholesterol	Hemoglobin	
LDL Cholesterol	Protein Total fluid	
Triglycerides fluid		

