COD 11547 2 x 250 mL	COD 11573 1 x 250 mL
Only for *in vitro* use in the clinical laboratory	

ALBUMIN

BioSystems

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ALBUMIN

BROMOCRESOL GREEN

INTENDED USE

Reagent for the measurement of albumin concentration in human serum or plasma for the assessment of its imbalance.

CLINICAL BENEFIT

Hyperalbuminemia is of little diagnostic significance except in dehydration[1].

Hypoalbuminemia is found as a result of several factors: reduced synthesis caused by liver diseases; reduced absorption of amino acids due to malabsorption syndromes or malnutrition; increased catabolism as a result of inflammation or tissue damage; altered distribution between intravascular and extravascular space due to increased capillary permeability, overhydration or ascites; abnormal losses caused by renal disease (nephrotic syndrome, diabetes mellitus, chronic glomerulonephritis, systemic lupus erythematosus), gastrointestinal tract disease (ulcerative colitis, Crohn's disease) or skin damage (exfoliative dermatitis, extensive burns); congenital absence of albumin or analbuminemia[1,2].

Albumin plasma concentrations, although important for management and follow-up, have very little value in diagnosis[1]. Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of albumin imbalance.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Albumin in the sample reacts with bromocresol green in acid medium forming a coloured complex that can be measured by spectrophotometry[3].

CONTENTS

	COD 11547	COD 11573
A. Reagent	2 x 250 mL	1 x 250 mL
S. Standard	1 x 5 mL	1 x 5 mL

COMPOSITION

A. Reagent. Acetate buffer 100 mmol/L, bromocresol green 0.27 mmol/L, detergent, pH 4.1.

WARNING: H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P362: Take off contaminated clothing and wash before reuse.

S. Albumin Standard: Bovine albumin. Concentration is given on the label. Concentration value is traceable to the Standard Reference Material 927 (National Institute of Standards and Technology, USA).

STORAGE AND STABILITY

Store at 2-8 ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration:

– Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.200 at 630 nm (1 cm cuvette).

– Standard: Presence of particulate material, turbidity.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

– Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

– Analyzer, spectrophotometer or photometer able to read at 630 nm (610 - 670 nm).

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

SAMPLES

Serum or plasma (EDTA, citrate or heparine) collected by standard procedures.

Albumin in serum is stable for 3 days at 2-8ºC.

PROCEDURE

1. Pipette into labelled test tubes: (Notes 1, 2)

	Blank	Standard	Sample
Albumin Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

2. Mix thoroughly and let stand the tubes for 1 minute at room temperature.
3. Read the absorbance (A) of the Standard and the Sample at 630 nm against the Blank. The colour is stable for 30 minutes.

CALCULATIONS

The albumin concentration in the sample is calculated using the following general formula:

$$\frac{A_{Sample}}{A_{Standard}} \times C_{Standard} = C_{Sample}$$

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma[2]:

Newborn, 2 to 4 days	28-44 g/L
4 days to 14 years	38-54 g/L
Adult	35-52 g/L
> 60 years	32-46 g/L

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

– Detection limit: 1.43 g/L. Quantification limit: 3.72 g/L.

– Linearity limit: 70 g/L. Measuring range: 3.72 – 70 g/L. For samples with higher values, dilute manually or refer to the Test Parameterization for Automatic dilution (note that all these samples will be diluted with the same dilution ratio).

– Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
8.04 g/L	4.9 %	5.9 %
38.4 g/L	0.8 %	1.2 %
57.1 g/L	0.7 %	1.1 %

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Albumin values for human serum and plasma samples obtained on BA400 analyzer (y) were compared with those determined on a Roche Cobas 8000 analyzer (x). Serum: Sample size (n)=118; Linear regression y=0.08+0.996x, r=0.993. Plasma: Sample size (n)=127; Linear regression y=-0.8+1.03x, r=0.988. The sample concentrations were between 6 and 58 g/L.

LIMITATIONS OF THE PROCEDURE

– Interferences: Bilirubin (up to 30 mg/dL), hemolysis (hemoglobin up to 400 mg/dL) and lipemia (triglycerides up to 655 mg/dL) do not interfere. Other drugs and substances may interfere[4].

NOTES

1. This reagent may be used in several automated analysers. Instructions for many of them are available on request.
2. Albumin reaction with bromocresol green is immediate. It is not recommended to delay readings, since other proteins react slowly.
3. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2012.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
3. Doumas BT, Watson WA and Biggs HG. Albumin standards and the measurement of serum albumin with bromocresol green. *Clin Chim Acta* 1971: 31: 87-96.
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