

ALBUMIN

COD 12547 5 x 50 mL

For *in vitro* use in the clinical laboratory only
ALBUMIN
 BROMOCRESOL GREEN

INTENDED USE

Reagent for the measurement of albumin concentration in human serum or plasma. The obtained values are useful as an aid in the evaluation of protein synthesis of the liver in the chronic liver diseases and for the study of the nutritional status.

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Albumin is the most abundant protein in human plasma. It has three main functions: it contributes towards maintaining the colloid oncotic pressure of plasma, it acts as non-specific transport vehicle for many nonpolar compounds and it is a source of endogenous amino acids.

Hyperalbuminemia is of little diagnostic significance except in dehydration¹.

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 diagnosis¹.

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 spectrophotometry³.

CONTENTS AND COMPOSITION

A. Reagent. 5 x 50 mL. 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.

STORAGE AND STABILITY

Store at 2-8°C.

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: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

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

REAGENT PREPARATION

Reagent is 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 2-8°C.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

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 plasma²:

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

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 1.1 g/L.
- Linearity limit: 70 g/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
26.2 g/L	1.4 %	1.9 %
42.1 g/L	1.0 %	1.9 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: Bilirubin (up to 30 mg/dL), hemolysis (hemoglobin up to 300 mg/dL) and lipemia (triglycerides up to 325 mg/dL) do not interfere. Other drugs and substances may interfere⁴.

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. Dumas BT, Watson WA and Biggs HG. Albumin standards and the measurement of serum albumin with bromocresol green. *Clin Chim Acta* 1971; 31: 87-96.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: Use Reagent A.

	A25	A15
GENERAL		
Name	ALBUMIN	ALBUMIN
Sample type	SER	SER
Analysis mode	endpoint mon.	endpoint mon.
Units	g/L	g/L
Turbidimetry test	no	No
Decimals	0	0
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	bichrom.	bichrom.
Main filter	635	635
Reference filter	670	670
Sample	3	3
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	6	4
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	-	-
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.200	0.200
Kinetic blank limit	-	-
Linearity limit	70	70
Substrate depletion	-	-