ALBUMIN

(LIQUID)

4 x 60 ml

RE – ORDER ALB1000

INTENDED USE

This reagent is intended for the quantitative in vitro determination of albumin in serum or plasma.

CLINICAL SIGNIFICANCE

Elevated serum albumin is seldom encountered and it is usually a result of dehydration. Main causes of decreased serum albumin are malnutrition, decreased synthesis in liver diseases, proteinuria in the nephrotic syndrome, losses or decreased absorption in gastrointestinal diseases, carcinomatosis, congestive heart failure, losses from extensive skin lesions such as diffuse dermatitis and burns.

TEST SUMMARY

Determination of albumin after salt fractionation followed by quantitation using a biuret reaction of Kjeldahl technique is laborious and time consuming. Electrophoretic or immunological assays do not lend themselves to routine laboratory use. On the other hand, procedures based on the binding of a dye to albumin, are today routinely employed in the laboratory because of their simplicity and ease of performance. The dyes used include methyl orange, HABA, bromcresol purple and bromcresol green (BCG). The use of the latter compound was proposed by Rodkey and the procedure was further refined and optimized by Doumas et al. We use a modified version of this last procedure. The albumin-bromcresol green reaction is very sensitive. The reaction is not absolutely specific for albumin, rather the color increases with time, possibly as a result of the binding of the dye to other proteins. More specific results are obtained if the reaction is timed and read after a short period from the mixing of the sample and the reagent. The blue-green color produced in the reaction is measured at 628 nm and its intensity is proportional to the concentration of albumin in the sample.

REAGENTS COMPOSITION

Albumin Reagent

Reactive ingredients:	Bromcresol Green	0.36 mmol/L
Non-reactive ingredients:	Buffers, stabilizers and fillers	

Albumin Standard (4 g/dL)

Non-reactive ingredients: Buffers, stabilizers and fillers

REAGENTS PREPARATION

Albumin Reagent. The solution, as provided, is ready to use. Store in refrigerator or at room temperature below 25 °C.

Albumin Standard. The solution, as provided, does not require any treatment. Store in refrigerator or at room temperature below 25 °C.

REAGENTS STORAGE AND STABILITY

The Albumin Reagent is stable at room temperature until the expiration date on the label. Avoid exposing the Albumin Reagent to strong sunlight. Avoid contaminating the reagent and the standard: instead of direct pipetting in the original container, transfer required amount to suitable glassware. Do not return remnants to original bottle. The solution of the Albumin Reagent should be clear, yellow-green in color. If the reagent or the standard becomes turbid, this is evidence of contamination. If the absorbance of the reagent at 628 nm is higher than 0.400 when read against a water blank, do not use. The Albumin reagent is mildly acid; avoid contact with the skin, eyes and mucous membrane. If contact occurs, flush with water.

PRECAUTIONS

Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See GP17-T, Clinical Laboratory Safety; Tentative Guideline (1994), National Committee on Clinical Laboratory Standards, Wayne, PA.)

Intended for in vitro diagnostic use only.

SPECIMEN COLLECTION, PREPARATION AND STORAGE

Use only clear, unhemolyzed serum (preferable) or EDTA plasma.

Albumin in serum or plasma is stable for at least 1 month in the refrigerator (2–8 °C).

INTERFERING SUBSTANCES

Less than 10% Interference has been demonstrated from 20.0 mg/dL bilirubin, 500 mg/dL hemoglobin, and 467 mg/dL Intralipid (representative of triglycerides) spiked into serum. Less than 10% positive interference has been demonstrated from 3.0 g/dL γ-globulin. Some samples may show a greater positive bias due to globulin interference. Heparin has been reported to interfere with albumin determination by dye binding methods. Young et al. have published a comprehensive list of drugs and substances which may interfere with in vitro diagnostic assays, including the determination of albumin.

MATERIALS REQUIRED BUT NOT PROVIDED

Spectrophotometer or colorimeter capable of accurate measurements of absorbance at 628 nm.

Matched cuvettes.

Distilled or deionized water.

Pipettes to measure water, reagent, standard and samples.

Timer. This is not necessary if the assay is performed in an automated instrument, capable of accurate timing.

MATERIALS PROVIDED

Albumin Reagent, ready to use.

Albumin Standard, 4 g/dL.

TEST PROCEDURE

Wavelength: 628 nm

Temperature: Room temperature (22–28 °C).

Temperature should remain constant during assays.

Blank	Standard	Sample	
Water	0.02 mL	–	–
Standard	–	0.02 mL	
Sample	–	–	0.02 mL
Reagent	3 mL	3 mL	3 mL

Mix. Read absorbance within 60 seconds against the blank set at 0.

Notes:

The requirement that the absorbance be read within 60 seconds is necessary to obtain accurate results. However, the gradual increase in color noted with time in some serum samples will result in slightly higher results, so that for practical purposes it could be ignored.

CALIBRATION

The assay requires the use of an albumin standard. Use the standard provided with the reagent as directed or other commercially available standards or calibrators. The Raichem Albumin-Protein Standards Set,is recommended for multiple point calibration; the set contains 2 x 15 mL bottles, one each of the following concentra-tions: 4 and 8 g/dL.

A calibration curve can be made as follows, employing the Albumin Standard, 4 g/dL provided.

Blank	2 g/dL	4 g/dL	6 g/dL	
Water	0.03 mL	0.02 mL	0.01 mL	–
Standard	–	0.01 mL	0.02 mL	0.03 mL
Reagent	3mL	3mL	3 mL	3 mL

Mix and read absorbance within 60 seconds against the blank set at 0.

Plot the absorbance (y) on the vertical axis against the concen-tration in the horizontal (x) axis on graph paper.

QUALITY CONTROL

Serum controls recommended to monitor the performance of manual and automated assay procedures, providing a continued screening of the instrument, reagents and techniques. Commercially available control material with established values for albumin concentrations may be used.

CALCULATIONS

Value of Standard = 4 g/dL

$$\frac{\text{A sample}}{\text{A standard}} \times 4 = \text{albumin in sample in g/dL.}$$

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LIMITATIONS OF THE PROCEDURE

Samples with albumin concentrations higher than 8 g/dL should be diluted with an equal volume of physiological saline (150 mmol/L sodium chloride in water) and assayed again; multiply results by 2.

REAGENT PERFORMANCE

Linearity: The assay is linear to 8 g/dL.

Correlation: Employing as a reference a commercial Albumin reagent, based on the same formulation (Gilford) results obtained in 40 serum samples, varying in albumin concentration between 2.02 and 6.35 g/dL, were compared with those obtained using the present reagent. The correlation coefficient was: 0.994 and the regression equation was $y = 1.033x + 1.033$.

PRECISION:

Within Run		
Mean (g/dL)	5.17	2.66
SD	0.033	0.021
CV	0.64	0.79
N	12	12

REFERENCE RANGE

3.5-5.5 g/dL

It is recommended that each laboratory establish its own reference range.

REFERENCES

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