

Albumin MonlabTest®



Bromcresol green. Colorimetric.

Quantitative determination of albumin

IVD Only for professional in vitro diagnostic use
Store at 2-8°C

PRINCIPLE OF THE METHOD

Albumin in the presence of bromcresol green at a slightly acid pH, produces a colour change of the indicator from yellow-green to green-blue. The intensity of the color formed is proportional to the albumin concentration in the sample^{1,2,3,4}.

CLINICAL SIGNIFICANCE

One of the most important serum proteins produced in the liver is albumin. This molecule has an extraordinarily wide range of functions, including nutrition, maintenance of oncotic pressure and transport of Ca⁺⁺, bilirubin, free fatty acid, drugs and steroids. Variation in albumin levels indicate liver diseases, malnutrition, skin lesions such as dermatitis and burns or dehydration^{1,7,8}. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R	Bromcresol green pH 4.2	0.12 mmol/L
ALBUMIN CAL	Albumin aqueous primary standard 5 g/dL	

PREPARATION

Reagent and calibrator are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 630 nm ≥ 0.40 .

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 630 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

Serum or plasma, free of hemolysis¹: Stability 1 month at 2-8°C or 1 week at 15-25°C.

PROCEDURE

- Assay conditions:
Wavelength: 630 nm (600-650)
Cuvette: 1 cm light path
Temperature 15-25°C
- Adjust the instrument to zero with distilled water.
- Pipette into a cuvette:

	Blank	Standard	Sample
R (mL)	1.0	1.0	1.0
Standard (Note 1-2) (µL)	--	5	--
Sample (µL)	--	--	5

- Mix and incubate for 10 min at room temperature (15-25°C).
- Read the absorbance (A) of the samples and Standard, against the Blank.
The colour is stable 1 hour at room temperature.

CALCULATIONS

$$\frac{(A)_{\text{Sample}}}{(A)_{\text{Standard}}} \times 5 \text{ (Standard conc.)} = \text{g/dL albumin in the sample}$$

Conversion factor: g/dL x 144.9 = µmol/L

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: Normal and Pathologic CONTROL (MO-165107 and MO-165108).

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

3.5 to 5.0 g/dL¹.

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 0.04 g/dL to *linearity limit* of 6 g/dL.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (g/dL)	3.38	5.80	3.30	5.67
SD	0.02	0.03	0.26	0.04
CV (%)	0.52	0.49	0.78	0.69

Sensitivity: 1 g/dL = 0.126 A.

Accuracy: Results obtained using MONLABTEST reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 50 samples were the following:

Correlation coefficient (r): 0.99.

Regression equation: y = 0.98x + 0.09.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirubin up to 110 mg/L, hemoglobin up to 1 g/L and lipemic sera up to 10 g/L no interfere^{1,4}.

A list of drugs and other interfering substances with albumin determination has been reported by Young et. al^{5,6}.

NOTES

- ALBUMIN CAL: Proceed carefully with this product because due its nature it can get contaminated easily.
- Calibration with the aqueous Standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.
- MONLAB has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.**

BIBLIOGRAPHY

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PACKAGING

Ref.: MO-165063
 R: 2 x 50 mL
 CAL: 1 x 2 mL

Ref: MO-1651064
 R: 1 x 1000 mL
 CAL: 1 x 5 mL

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

- | | | | |
|---|-----------------------------------|---|---|
|  | Manufacturer |  | For <i>in vitro</i> diagnostic use only |
|  | Don't re-use |  | Consult instructions for use |
|  | Contains sufficient for <n> tests |  | Keep dry |
|  | Catalogue Code |  | Temperature limitation |
|  | Lot Number |  | Use by |

