BIOLABO
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ALBUMIN BCG Method

Reagent for quantitative determination of albumin in human serum or plasma

REF 80002	**R1** 2 x 200 mL	**R2** 1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (3)

Albumin is the most abundant plasma protein. The primary function of albumin is generally considered to be the maintenance of colloidal osmotic pressure (COP) in both the vascular and extravascular spaces. Albumin have the ability to bind and transport a large number of compounds such as free fatty acids, phospholipids, metallic ions, amino acids, drugs, hormones, bilirubin, among many others.
A measurably increased level of albumin is seen only in acute dehydratation and has no clinical utility. Decreased levels may be the result of decreased synthesis (dietary deficiency), increased loss (urinary loss), or combinations of these (hepatic diseases). Decreased synthesis may be primary or genetic (as in analbuminemia) or aquired (as in inflammatory processes).

PRINCIPLE (1) (2)

In buffered solution at pH 4.2, bromocresol green binds albumin to form a coloured compound which absorbance, measured at 630 nm (620-640) is proportional to the albumin concentration in the specimen.

REAGENT COMPOSITION

Vial R1 **BROMOCRESOL GREEN**

Succinic acid	83	mmol/L
Bromocresol green (BCG)	167	µmol/L
Sodium hydroxide	50	mmol/L
Polyoxyethylene monolauryl ether	1.00	g/L
Preservative		

Vial R2 **STANDARD**

Bovine albumin 5.0 g/dL (725 µmol/L)

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENT PREPARATION

Reagents are ready for use.

STABILITY AND STORAGE

Store at 2-8°C, well cap in the original vial and away from light.

- Standard stability (vial R2): Transfer the requested quantity, recap and store at 2-8°C.
- Reagents are stable until expiry date stated on the label of the kit when stored and used as described in the insert and free from contamination.
- Discard reagent if cloudy or if absorbance at 630 nm > 0.300.

SPECIMEN COLLECTION AND HANDLING

Serum or plasma (see § **INTERFERENCES**).

Serum albumin is stable in serum for:

- ✓72 hours at 2-8°C.
- ✓6 months at – 20°C.

INTERFERENCES (4) (5) (6) (7)

Heparinised plasma gives higher values than serum. This interference can be avoided by working with bichromatic procedure (2nd wavelength is 550 nm or 700 nm).

Clofibrate and Phenylbutazone decrease albumin value with this procedure.

Due to the dilution ratio, serum hemolysis or turbidity do not significantly affect the result.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Normal and pathological control sera.

CALIBRATION (8)

- Standard enclosed in the Kit (vial R2) or BIOLABO Multicalibrator REF 95015 traceable to SRM 927d.
- Or any calibrator traceable to a reference method or material.

The calibration frequency depends on proper instrument functions and on preservation of the reagent.

It is recommended to calibrate in the following cases:

1. When changing batch of reagent.
2. After maintenance operations on the instrument .
3. When control values are out of range, even after using a new vial of fresh control serum.

QUALITY CONTROL

- BIOLABO EXATROL-N Level I REF 95010.
- BIOLABO EXATROL-P Level II REF 95011.
- Assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control serum and repeat the test.
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (4)

Albumin	g/dL	[µmol/L]
0 to 4 days	2.8-4.4	[421-662]
4 days to 14 years	3.8-5.4	[572-813]
14 to 18 years	3.2-4.5	[482-677]
18 to 60 years	3.4-4.8	[512-722]
60 to 90 years	3.2-4.6	[482-692]
> 90 years	2.9-4.5	[436-677]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES CHARACTERISTICS (7)

According to Procedure n°2:

Within run n = 20	***Low level***	***Normal level***
Mean g/dL	3.22	3.81
S.D. g/dL	0.034	0.040
C.V. %	1.07	1.05

Between run n = 20	***Low level***	***Normal level***
Mean g/dL	3.28	3.85
S.D. g/dL	0.080	0.082
C.V. %	2.4	2.1

Detection limit: approximately 0.3 g/dL

Sensitivity for 0.1 g/dL: 0.006 Abs at 630 nm.

Comparison study with commercially available reagent:

y = 1.044 x - 0.034 r = 0.9954

Analytic specificity is better when reading within the first minute.

LINEARITY

Procedure n°1: up to 6.0 g/dL (903 µmol/L).

Procedure n°2: up to 10.0 g/dL (1505 µmol/L).

Above, dilute the specimen with saline solution and reassay taking into account the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE (7)

Let stand reagents and specimens at room temperature

Procedure n°1: Specimen volume 10 µL

Pipette into well identified test tubes:	**Blank**	**Standard**	**Assay**
Reagent	2 mL	2 mL	2 mL
Demineralised water	10 µL		
Specimen			10 µL
Standard		10 µL	

Mix well. Record absorbance at 630 nm (620-640) within 3 minutes against reagent blank or better after exactly 1 minute (note 2).

Procedure n°2: Specimen volume 5 µL

Pipette into well identified test tubes:	**Blank**	**Standard**	**Assay**
Reagent	2.5 mL	2.5 mL	2.5 mL
Demineralised water	5 µL		
Specimen			5 µL
Standard		5 µL	

Mix well. Record absorbance at 630 nm (620-640) within 3 minutes against reagent blank or better after exactly 1 minute (note 2).

Notes:

1- Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

2- To reduce the interference of other proteins (especially in case of inflammatory processes).

CALCULATION

Calculate the result as follows:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

REFERENCES

(1) Albumin standards and the measurement of serum albumin with bromcresol green, DOUMAS B.T., WATSON W.A., BIGGS H.G. - Clin. Chim. Acta., 31, (1971), p. 87-96.

(2) Determination of serum albumin, DOUMAS B.T. and BIGGS H.G. – Standard methods of clinical chemistry – Acad. Press. N.Y. Vol 7 (1972) p. 175-188.

(3) TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 482-485.

(4) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 68-71

(5) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-16 to 3-22

(6) Overestimation of Albumin in Heparinized Plasma, HALLBACH J., HOFFMANN G.E., GUDER W.G., Clin. Chem. Vol 37 No 4 (1991), p. 566-568.

(7) Improved specificity of serum Albumin determination and estimation of "acute phase reactants" by use of the bromcresol green reaction. Jan E. C. Gustafsson, Clin. Chem., Vol 22,n°5, (1976) p.616-622

(8) SRM: Standard Reference Material ®

Manufacturer | Use by | In vitro diagnostic | Temperature limitation | Catalogue number | See insert | Batch number | Store away from light | sufficient for | dilute with