BIOLABO
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MANUFACTURER:
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ALBUMIN BCG Method

Reagent for quantitative determination of albumin in human serum and plasma.

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

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows the quantification of global activity of the alkaline phosphatase enzyme in human serum or plasma.

GENERALITIES (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 extra vascular 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.

PRINCIPLE (1) (2)

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

REAGENT COMPOSITION

R1 ALBUMIN Reagent

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

ATTENTION, Met. Corr.1: H290 – May be corrosive for metals

P234: Keep only in original container, P390: Absorb spillage to prevent material damage. Classification due to: Sodium Hydroxide < 1% For more details, refer to Safety data sheet (SDS)

R2 ALBUMIN Standard

Bovine albumin 5.0 g/dL (725 µmol/L)

According to 1272/2008 regulation, this reagent is not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENT PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- Transfer requested quantity, well cap vials, store at 2-8°C.
- Reagents are stable at least 1 year.
- Discard reagent R1 if cloudy or if absorbance at 630 nm is > 0.300.

SPECIMEN COLLECTION AND HANDLING (4)

Serum or plasma. Serum must be separated from blood cells within 2 hours.

Serum albumin is stable in serum for:

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

LIMITS (4) (5) (6) (7)

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

Clofibrate and Phenylbutazone decrease albumin value with this procedure.

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. Spectrophotometer or Biochemistry Clinical Analyzer

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

REEERENCE INTERVAL (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 at 37°C on KENZA 240TX

Linearity Range: between 0.4 and 7.0 g/dL

Detection limit: approx. 0.01 g/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (g/dL)	2.15	3.23	4.7
S.D. g/dL	0.03	0.05	0.4
C.V. %	1.2	1.5	0.8

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (g/dL)	2.14	3.16	4.62
S.D. g/dL	0.03	0.04	0.03
C.V. %	1.3	1.2	0.7

Comparison studies with commercially available reagent:
In clinical environment with specimens between 1.1 and 4.5 g/dL (n=108)
y = 0.9028 x + 0.2441 R= 0.9865

Analytical Sensitivity: approx. 0.0125 abs for 0.1g/dL

Interferences:

Turbidity	Positive interference from 0.292 OD
Total bilirubin	No interference up to 541 µmol/L
Direct bilirubin	No interference up to 397 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1059 mg/dL
Hemoglobin	Positive interference from 304 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 1month

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

CALIBRATION (8)

- REF 95015 Multicalibrator traceable to SRM 927
- Standard enclosed in the Kit (vial R2)

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

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- 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. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and re-assay

If control is still out of range, please contact BIOLABO technical support or your local Agent

MANUAL PROCEDURE (7)

Let stand reagents and specimens at room temperature

Reagent R1	1000 µL
Blank, Standard, Control or Specimen	5 µL

Mix well. Read absorbance at 630 nm (620-640), against reagent blank after exactly 1 minute or within 3 minutes (7)

1. Performances with manual procedure should be validated by user.
2. Kenza applications and other applications proposal are available on request.

CALCULATION

Serum, plasma :

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

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 ®*