Albumin – Instructions for use

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

6 x 50 mL • REF A-R0100000001
3 x 18,5 mL • REF R3330000005

INTENDED USE
Product for use in the quantitative determination in vitro of the Albumin concentration in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical picture. For professional use only.

CLINICAL SIGNIFICANCE
Albumin is the plasma protein which is present in the largest quantities, constituting about half the total amount of proteins. It is synthesized in the hepatic parenchymal cells. The rate of synthesis is regulated primarily by COP (colloid osmotic pressure) and secondly, by the supply of protein. The normal half-life of albumin in plasma is 15-19 days. Increased albumin levels are present only in cases of acute dehydration. Decreased albumin levels are seen in numerous clinical conditions such as: analbuminemia, hepatopathic inflammation, loss in the urine, edema and ascites.
Rodkey in 1965 (1) and Hernandez in 1967 (2) described methods for the determination of albumin using Bromocresol Green (BCG). In 1972 Doumas (3) proposed a modified BCG method, establishing a reaction pH of 3.8. The method is based on Doumas's study, with a further modification to improve the linearity and stability of the final reaction colour.

PRINCIPLE
In a suitable buffer solution, serum or plasma albumin binds to Bromocresol Green (BCG). The intensity of the colour which develops is directly proportional to the amount of albumin present in the sample. The presence of a tensioactive agent in the reagent increases the linearity of the reaction.

REAGENTS
A-R0100000001 – 6 x 50 mL
Reagente: n°6 vials x 50.0 mL ready for use
A3330000005 - 3 x 18,5 mL
Reagente: n°3 vials x 14.0 mL ready for use

Concentrations

Reagent:		
	Conc.	**U.M.**
Bromocresol Green (BCG)	0.65	mM
Succinate buffer pH 3.9	61.0	mM
Polyoxyethylene sorbitan	14.0	mL/L

Precautions
In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, It is recommended to handle reagents according to the standards of good laboratory practice.

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 15-25°C; protect from direct light. When correctly stored, the reagent is stable up to the expiry date reported on the label. A slight variation in the composition of the components may occur between batches, but this has no effect on the test results. After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

Reagent Preparation
The reagent is liquid ready for use. After opening, the reagent is stable for 30 days if protect from direct light.

SAMPLE COLLECTION
Type of sample and storage
Serum or plasma samples should be used. Albumin is stable in serum for at least 7 days at room temperature and one month at 2 - 8°C (3). Use non hemolyzed samples. The presence of abnormal proteins can cause a gradual increase in the final colour (4).

Precautions
All human samples must be handled and disposed of as potentially infectious materials.

Procedure
Quality control
Control sera known as Albumin are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the calibration serum kit cod. R0300000006. For ISE srl instruments calibration is recommended every 10 days.
Traceability
The Albumin BCG value is reported in the package insert supplied with the "Calibrator Serum".

Reations Conditions

Wavelength (primary):	620 nm
Wavelength (secondary):	700 nm
Temperature:	37°C

Technique – Procedure with Serum as starter
Portare il reattivo alla temperatura di reazione.

	U.M.	**Calib.Serum**	**Simple**	**Blanck**
Reagent	µL	1000	1000	1000
Calib.Serum	µL	10	-	-
Simple	µL	-	10	-
Blanck	µL	-	-	10

Mix well and after a minute of waiting take the reading at 37 ° C.
Read the absorbances of the sample and the calibration serum by subtracting the absorbance of the reagent blank, completi the readings within 5 minutes. The presence of abnormal proteins causes a gradual increase in the final reaction color. **The reaction volumes can be varied proportionally, the calculation remains unchanged.**

Results
The concentration of BCG Albumin is obtained through the following formula:

$$\frac{\text{D.O Sample}}{\text{D.O. Calib. Serum}} \times \text{Conc. Calib.Serum} = \text{g/dL Albumin BCG}$$

Materials included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls and calibrators.

NORMAL VALUES
Serum or plasma:
- 3.5 – 5.5 g/dL (35 - 55 g/L)

Each laboratory must establish its own normal values on the basis of its local catchment area.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The method is linear up to 7.5 g/dL.

Specificity
The specificity of the Albumin BCG method is demonstrated by the close correlation with electrophoresis profiles, as reported in the literature (3.5.6).

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

Albumin – Instructions for use

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

6 x 50 mL • REF A-R0100000001

3 x 18,5 mL • REF R3330000005

Accuracy – Recovery
Accuracy studies were performed on normal samples to which known amounts of Albumin were added. The results indicate a recovery of 99% up to a concentration of 6 g/dL.

Interferences
The high dilution of the sample with the reagent reduces to a minimum interference by lipids. However, in the presence of high lipid concentrations, slightly raised results may be found. Bilirubin below 26 mg/dL does not interfere in the reaction (5). Hemoglobin does interfere: 100 mg/dL of hemoglobin correspond to about 100 g/dL of Albumin (3).

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	2.70	0.039	1.44	20
High	g/dL	4.28	0.062	1.46	20
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	2.70	0.118	4.36	20
High	g/dL	4.28	0.262	6.13	20

Sensitivity
At λ 630 nm corresponds to a concentration of about 0.007 g/dL of Albumin in the conditions established for this test.

Comparative method
The Albumin BCG method was compared with a similar (BCG) commercial method. A linear regression was calculated y = 1.0722x + 0.03; Coefficient Regression r = 0.9890; Sample Tested no. = 120.

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

Distributor:
I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 077 4579365; FAX +39 077 4579305
E-mail: info@logotech-ise.com
www.logotech-ise.com

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

1. Rodkey FL. Clin Chem 1965; 11: 478 - 487.
2. Hernandez O, Murray L, Doumas B. Clin Chem 1967; 13: 701.
3. Doumas BT, Briggs HG. Standard Methods of Clinical Chemistry. Academic Press, New York & London 1972; 7: 175.
4. Gustafsson JE. Clin Chem 1976; 22: 616 - 622.
5. Dow D, Pinto PV. Clin Chem 1969; 15: 1006 - 1008.
6. Lolekha PH, Charoenpol W. Clin Chem 1974; 20: 617 - 619.
7. Henry RJ. Clinical Chemistry: Principles and Techniques. Harper & Row Publishers, New York 1968; 222 - 226.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance