Albumin BCP – Bromocresol Purple Method

Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182539	n° 7 vials x 20 mL

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 context. FOR PROFESSIONAL USE ONLY.

INTRODUCTION

Albumin is the principal plasma protein, 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.

PRINCIPLE OF THE METHOD

Method of Bromocresol purple (BCP). In a suitable buffer solution, serum or plasma albumin binds to Bromocresol Purple (BCP). 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.

Storage and stability

= Storage temperature 15-25°C

Stored at 15 – 25 °C, avoiding direct light, the intact reagents are stable until the expiration date, printed on the label.

Concentration

Reagent:		
	Conc.	**U.M.**
Bromocresol Purple (BCP)	0.08	mmol/L
Acetate buffer pH 5.3	100	mmol/L
Surfactant	1	g/dL

Reagents included in the kit

The reagent is described above.

Materials required but not supplied in the kit

Controls, calibrators and pipettes with adequate volume.

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality control

Control sera of known title containing BCP albumin are commercially available for quality control, accompanied by certificates of analysis. Sclavo Diagnostics Clinicontrol N, 5x5 mL, Part Number B35181700 and Clinicontrol A, 5x5 mL, part number B35181701, are available. The values obtained must be contained within the acceptability range or your CQI.

Calibration

For calibration use the "Calibrator serum Sclavo" Code B35181702.

Traceability

The Albumin BCP value is reported in the package insert supplied with the calibrator serum.

SAMPLE

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.

PREPARATION OF THE REAGENT

The reagent is liquid ready for use. After opening, the reagent is stable for 30 days if protected from direct light. Slight variations in composition among batches will not affect test results.

Automation

The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R /C. Validated applications are available for Sclavo Konelab® - Indiko® instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD

The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength (primary): 620 nm
Temperature 37°C
Reaction: End point (Increasing reaction)

Technical – procedure serum as starter

Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Blank	Calib. Serum	Sample
Reagent	µL	1000	1000	1000
Calib. Serum	µL	-	10	-
Sample	µL	-	-	10
Blank	µL	10	-	-

Mix well and after one minute of incubation take the reading at 37°C. Read the absorbances of the calibration serum and the sample by subtracting the absorbance of the reagent blank, complete 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 without altering the results.**

Results:

Manual Method

Calculation of Albumin BCP concentration:

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

Automation

The results are automatically calculated by the analyzer based on the calibration curve/line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration curve/line is obtained through a special validated algorithm.

REFERENCE RANGE

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 7.1 g/dL. If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result for the dilution factor.

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Accuracy – Recovery
Commercial control sera were analyzed with the kit in question following the guidelines of the CLSI protocol. The data obtained are shown in the table.

Level	Replicates	Mean	SD	CV%	Recovery
Low	5	2.56	0.055	2.14	94,8%
High	5	4.02	0.045	1.11	95,7%

Interferences

Interference	Limits	Notes
Lipids	**N.A.**	Slight overestimation for very high lipid concentrations
Bilirubin	**58 mg/dL**	-
Hemoglobin	**100 mg/dL**	-

Precision of the method

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	4.10	0.098	2.39	30
High	g/dL	2.81	0.064	2.27	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	g/dL	3.89	0.065	1.67	20
High	g/dL	2.65	0.034	1.28	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is 0.10 g/dL of Albumin in the conditions established for this test.

Comparison between methods
The Sclavo method for Albumin BCP was compared with a similar commercially available method, analyzing 200 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	0.0585
Correlation Coeff. (R)	0.984

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	

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REVISION	DATE	CHANGE
Rev.B	05/2025	Out of production of chemilab line

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