Albumin BCG – Bromocresol Green Method

Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182515	n° 7 vials x 20 mL
CHEMILAB	REF B81180011	n° 3 vials x 26 mL
	REF B81180012	n° 5 vials x 31 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.

CLINICAL SIGNIFICANCE

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 green (BCG). In a suitable buffer solution, serum or plasma albumin binds to Bromocresol Green (BCG). The intensity of the colour 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 reagents are stable until the expiration date printed on the label.

Concentration

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

The product is not classified, according to CLP regulation

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

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.

PROCEDURE

Quality control

Control sera with a known titer of Albumin are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration

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

Traceability

The Albumin BCG traceability 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. Use non haemolyzed 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 maintained closed at 2 -8 °C and protected from direct light. Slight variations in colour, 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® and CHEMILAB 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)

Technique – procedure serum as starter

Bring the reagents to rection 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 read after 1 minute of incubation at 37°C.
Measure absorbance of the sample and calibrator serum against reagent blank within 5 minutes.
The presence of abnormal proteins may cause a gradual increase of final colour.
The reaction volumes can be varied proportionally without altering the results.

Results:

Manual Method

Calculation of Albumin BCG concentration:

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

Automation

The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the individual instruments.

REFERENCE RANGE

Serum or plasma: 3.5 – 5.5 g/dL (35 - 55 g/L)
Each laboratory must establish its own normal-range values on the basis of its population.

ANALYTICAL CHARACTERISTICS/PERFORMANCE

Linearity

The method is linear up to 11 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.

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	2.62	0.045	1.71	97%
High	5	4.12	0.045	1.09	98.1%

Interferences
The high dilution of the sample with the reagent minimizes interference due to lipids. In cases where these are present at high concentrations, slightly overestimated results may be obtained.

Interference	Limits
Bilirubin	**26 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	3.95	0.05	1.26	30
High	g/dL	2.69	0.05	1.86	30
Total precision (Within-lab precision)					
Range	**U.M.**	**Mean**	**S.D.**	**C.V. (%)**	**No.**
Low	g/dL	3.98	0.085	2.13	20
High	g/dL	2.73	0.075	2.75	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is 0.1 g/dL of Albumin.

Comparison between methods
The Sclavo Albumin BCG method was compared with a similar (BCG) commercial method analysing 36 human sera. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	- 0.1941
Slope	1.0411
Correlation Coeff. (R)	0.997

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

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12. **Clinical Laboratory Standards Institute (CLSI).** Interference Testing in Clinical Chemistry, – Third Edition. - EP07.
13. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition - EP06.

REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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