ALBUMIN

BCG Method - Endpoint

2 x 100 ml **CL04-200S**
4 x 100 ml **CL04-400S**

INTENDED USE

Kit for quantitative determination of Albumin in serum and plasma.

CLINICAL MEANING

Albumin is essential for the regulation and maintenance of oncotic pressure and for the correct distribution of bodily fluids in the vascular system and in tissues.
Albumin is the prevalent protein in the blood and it is also the main carrier of other proteins.
Lower values of Albumin may indicate a reduced production by the liver in case of severe Hepatic diseases, e.g. chronic Hepatitis and liver Cirrhosis.

PRINCIPLE

In a pH 3.8 buffered solution, the Albumin in the sample reacts with Bromocresol Green (BCG), causing a change in color. The color intensity is proportional to the albumin concentration in the serum or plasma.

SAMPLE

Serum, plasma.
Avoid hemolysed samples.
Stability: 1 week when kept at 15-25°C or over 1 month at 2-8°C.

REAGENTS

Only for in Vitro diagnostic use. Liquid monoreagent ready to use.

Package Content:	**CL04-200S**	**CL04-400S**
REAGENT 1 Citrate buffer (pH 3,8) 100 mmol/L, BCG 0,25 mmol/L, Triton X-100 10 g/L.	2 x 100 ml	4 x 100 ml
STANDARD (Std) Albumin 4 g/dl.	1 x 4 ml	1 x 4 ml

Stability: store the reagents at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wave length:	628 nm (600 - 650)
Optical Path:	1 cm
Reading:	Against blank reagent
Temperature:	25 - 37°C
Method:	Increasing endpoint
Reaction time:	immediate
Sample/Reagent Ratio:	1/150

Bring the reagents to the chosen temperature for the analysis.
Pipette in cuvette:

	Blank Reagent	Standard	Sample
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Reagent 1	1,5 ml	1,5 ml	1,5 ml

Stir and read the absorbance of the standard (AbsStd) and of the sample (AbsC) against the blank reagent.
Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the Albumin concentrations in the sample using the following formula:

[g/dl] albumin = AbsC / AbsStd x 4

REFERENCE VALUES

Serum / plasma: 3,5 ÷ 5,5 g/dl

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multi-parameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of the method is 0,1 g/dl.
Linearity
The method is linear up to 6 g/dl.
For higher values, dilute the samples 1:10 with saline solution and multiply the result by 10.
Precision

Within run (n=10)	Average [g/dl]	SD	CV %
Sample 1	3,47	0,08	2,25
Sample 2	3,40	0,09	2,76

Between run (n=20)	Average [g/dl]	SD	CV %
Sample 1	3,50	0,08	2,22
Sample 2	3,06	0,07	2,41

Interferences
Bilirubin does not interfere up to 20 mg/dl. The presence of Hemoglobin (Hemolysis) causes overestimated values.
Correlation against a reference method
The correlation of method (Y) with reference method (X) highlighted the following equation:

Y =0,9342X + 0,1617 r = 0,9948

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1. Rodkey F.L., Clin. Chem. 10,643 (1964)
2. Doumas B. T., Watson W.A., Biggs H.g., clin. Chim. Acta 31, 87 (1971)
3. Gustafsson J.E.C., Clin. Chem. 22, 616 (1976)
4. Kaplan LA, Pesce AJ:"Clinical Chemistry", Mosby Ed. 1989.

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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