ALBUMIN LR liquid reagent

REF **1200430** 4x30 ml
E1200650 6x50 ml
E1206100 6x100 ml

CE IVD For in vitro medical device

Use
Kit for measurement of albumin in serum or plasma. Colorimetric Bromocresol green BCG method.

Summary
Albumin measurements are used in the diagnosis and treatment of inflammatory processes or disease of the liver or kidney.

Principle
End point analysis . Bromocresol green (BCG) binds, quantitatively and specifically, with the albumin, giving a green/blue compound whose colour intensity is proportional to the albumin concentration in the tested sample.

Reagents

R1	Succinate buffer	60.0 mmol/l
	bromocresol green (BCG)	0.15 mmol/l
	surface-active agents not anionic	

Reagent Preparation
Reagents are liquid and ready to use.

Storage and stability
- Store the kit at 15-25°C.
- After opening, the R1 vial is stable up to 60 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use
The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.
However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management
Please refer to the local legal requirements.

Specimen Collection and Preparation
- Serum or plasma.
- Do not use samples with haemolysis.
- It's advisable to make the withdrawal before meals.
- The albumin is stable in the sample up to 7 days at 15-25°C or 30 days at 2-8°C.

Note
- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength	λ: 630 (600-670) nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"end point"

-- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1500 µl	1500 µl	1500 µl
Distilled Water	10 µl	--	--
Sample	--	--	10 µl
Standard	--	10 µl	--

Mix, then incubate for 5' at 37°C (15-25°C). Measure the absorbance of the sample (EC) and standard (ESTD) against the reagent blank.

Calculation
Albumin [g/dl] = EC/ES x Conc. STD

The reagent performances are related to 37°C, 1 cm and 630 nm.

Reference Values

Serum or plasma	Men 2,9 - 6.1 g/dl
	Women 2.5 – 5.4 g/dl

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity
The reaction is linear in concentration range between 0.56 and 8.0 g/dl. Samples with values exceeding 8 g/dl must be diluted with saline solution. Then, multiply, the result for diluting factor.

"Intra-Assay" precision (within-Run)
Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (g/dl)	N = 4.42	H = 3.00
S.D.	N = 0.11	H = 0.08
C.V.%	N = 2.44	H = 4.15

"Inter-Assay" precision (between-Run)
Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (g/dl)	N = 4.43	H = 2.97
S.D.	N = 0.12	H = 0.12
C.V.%	N = 2.61	H = 2.70

Analytical sensitivity
The test sensitivity in terms of detection limit is: 0.56 g/dl.

Correlation
A study made in comparison of this method with a similar one, on 20 samples, has given a correlating factor **r = 0.98**

y = 1.0211x + 0.3082

Interferences
No interference was observed by the presence of:

Bilirubin	≤ 25 mg/dl.
Triglycerides	≤ 800 mg/dl.

Hemoglobin interferes also at minimum concentrations.
For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls
It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A..J.: "Clinical Chemistry", Barham D, Trinder P: Analyst, 97 142 (1972).
Fossati P, Prencipe L, Berti G: Clin. Chem., 26(2) 227 (1980).
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Simbols

CE	CE Mark (requirement of 98/79 regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl