



# ALBUMIN LR liquid reagent

REF C1200620 518 Test

CE C1200620A 518 Test

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). 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  $\lambda$ : 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 $\mu$ l | 1500 $\mu$ l | 1500 $\mu$ l |
| Distilled Water | 10 $\mu$ l   | --           | --           |
| Sample          | --           | --           | 10 $\mu$ l   |
| Standard        | --           | 10 $\mu$ l   | --           |

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 2.5 – 6.0 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

Reaction is linear up to a concentration of 8 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  $\leq$  25 mg/dl.  
 Triglycerides  $\leq$  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 5<sup>th</sup> 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

Gesam Production srl