

# ALBUMIN

Cat. No.	Pack Name	Packaging (Content)
BLT00001	ALB 250	R1: 5 x 50 ml, R2 standard: 1 x 2 ml
BLT00002	ALB 500	R1: 5 x 100 ml

EN

CE IVD

## INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Albumin in human serum and plasma.

## CLINICAL SIGNIFICANCE

Albumin, a major plasma protein, is synthesised in the liver from amino acids which are absorbed from the ileum. It's functions include regulation of distribution of extracellular fluid, transportation of various hormones, vitamins and trace metals.

### Increased levels are observed in

Dehydration due to reduced plasma water content.

Stasis during venipuncture which causes fluid to escape into the extravascular compartment.

### Decreased levels are observed in

Excessive protein loss (mainly albumin) - from kidney, skin or intestine.

Decreased synthesis due to dietary, hepatic disease or malabsorption.

Increased catabolism in fever, untreated diabetes mellitus and hypertension.

## PRINCIPLE

Albumin binds with Bromo Cresol Green (BCG) at pH 4.2 causing a shift in absorbance of the yellow BCG dye. The blue-green colour formed is proportional to the concentration of albumin, when measured photometrically between 540–630 nm with maximum absorbance at 625 nm.

## REAGENT COMPOSITION

### R1

Bromocresol green 0.21 mmol/l

Succinate Buffer 100 mmol/l

Sodium Azide 0.5 g/l

R2 standard See bottle label

## REAGENT PREPARATION

Reagents are liquid, ready to use.

## STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8 °C.

## SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum or plasma (EDTA, heparin)

It is recommended to follow NCCLS procedures (or similar standardized conditions).

**Stability in serum:**  
 1 month at 2–8 °C  
 1 week at 15–25 °C  
 at least 3 months at -20 °C

Discard contaminated specimens.

## CALIBRATION

Calibration with the standard included in the kit or the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

## QUALITY CONTROL

For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

## UNIT CONVERSION

g/dl x 10 = g/l

## EXPECTED VALUES <sup>2</sup>

Serum:

0 – 4 d 2.8 – 4.4 g/dl

4 d – 14 y 3.8 – 5.4 g/dl

14 – 18 y 3.2 – 4.5 g/dl

Adult

20 – 60 y 3.5 – 5.2 g/dl

60 – 90 y 3.2 – 4.6 g/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

## PERFORMANCE DATA

Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

**Limit of quantification:** 0.1 g/dl

**Linearity:** 6 g/dl

**Measuring range:** 0.1 – 6 g/dl

## PRECISION

Intra-assay precision Within run (n=20)	Mean (g/dl)	SD (g/dl)	CV (%)
Sample 1	3.303	0.017	0.51
Sample 2	4.926	0.044	0.88

Inter-assay precision Run to run (n=20)	Mean (g/dl)	SD (g/dl)	CV (%)
Sample 1	3.345	0.043	1.29
Sample 2	4.612	0.043	0.93

## COMPARISON

A comparison between XL-Systems Albumin (y) and a commercially available test (x) using 40 samples gave following results:

y = 1.000 x + 0.065 g/dl

r = 0.997

## INTERFERENCES

Following substances do not interfere:

haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

## WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

## WASTE MANAGEMENT

Please refer to local legal requirements.

## ASSAY PROCEDURE

**Wavelength** 578 (540–630) nm

**Cuvette** 1 cm

	Reagent blank	Standard (Cal.)	Sample
Reagent 1	1.00 ml	1.00 ml	1.00 ml
Sample	-	-	0.01 ml
Standard (Cal.)	-	0.01 ml	-
Distilled water	0.01 ml	-	-

Mix and incubate 1–5 min. at 37 °C. Measure absorbance of the sample A<sub>sam</sub> and standard A<sub>st</sub> against reagent blank.

## CALCULATION

$$\text{Albumin (g/dl)} = \frac{\Delta A_{\text{sam}}}{\Delta A_{\text{st}}} \times C_{\text{st}} \quad C_{\text{st}} = \text{standard (calibrator) concentration}$$

Applications for automatic analysers are available on request.


## ASSAY PARAMETERS FOR PHOTOMETERS


Mode	End point
Wavelength 1 (nm)	600
Sample Volume (µl)	5/10
Reagent Volume (µl)	500/1000
Incubation time (min.)	1
Incubation temp. (°C)	37
Normal Low (g/dl)	3.5
Normal High (g/dl)	5.2
Linearity Low (g/dl)	0
Linearity High (g/dl)	6
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	0.4
Units	g/dl


#### REFERENCES


1. Leonard, P. L., Persaud, J., Motwani, R.: Clin. Chim. Acta 35, 409, 1971.
2. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company, 2012.

#### SYMBOLS USED ON LABELS


 REF Catalogue Number


 Manufacturer


 See Instruction for Use

 LOT Lot Number

 CE Mark -  
Device comply with  
the Directive 98/79/EC


 Storage Temperature

 Expiry Date

 IVD In Vitro Diagnostics

 CONT Content

QUALITY SYSTEM CERTIFIED  
ISO 9001 ISO 13485

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