

# ALBUMIN

BC 0100 CH	2 x 50 ml
BC 0500 CH	4 x 125 ml

## INTENDED USE

Reagent for quantitative in vitro determination of albumin in biological fluids.

## SUMMARY OF TEST

Plasma levels of albumin, because they depend on protein intake, are frequently used to assess nutritional status. Moderate to large changes in plasma concentration of albumin have significant effects on the relative amounts of the bound and free concentrations of the ligands it carries, as a consequence on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones.

## PRINCIPLE OF THE METHOD

Albumin and BCG are followed to bind at pH 4.2, and absorption of the BCG-albumin complex is determined spectrophotometrically at 628 nm. At pH 4.2, albumin acts as a cation to bind the anionic dye.

## KIT COMPONENTS

### For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

<b>ALB R1</b>	<b>0100: 2 x 50 ml (liquid) blue cap</b>
	<b>0500: 4 x 125 ml (liquid) blue cap</b>

Composition: succinate buffer 100 mM pH 4.2, bromochresol green 0.2 mM, surfactant.

**Standard:** albumin solution 4 g/dl - 5 ml

Store all components at 2-8°C.

## MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

## REAGENT PREPARATION

Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C.

## PRECAUTIONS

**ALB R1: Warning.** Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

**Standard:** It is not classified as hazardous.

## SPECIMEN

Serum (preferred), plasma (heparinate or EDTA). Venostasis should be avoided in specimen collection because hemoconcentration increases the apparent concentrations of albumin and other plasma proteins.

## TEST PROCEDURE

Wavelength:	628 nm (allowed 580 ÷ 630 nm)
Lightpath:	1 cm
Temperature:	25, 30 or 37°C

dispense:	blank	standard	sample
reagent	3 ml	3 ml	3 ml
water	20 µl	-	-
standard	-	20 µl	-
sample	-	-	20 µl

Mix, incubate at 25, 30 or 37°C for 2 minutes. Read absorbances of standard (As) and samples (Ax) against reagent blank.

## RESULTS CALCULATION

serum/plasma sample:

albumin g/dl = Ax/As x 4 (standard value)

## EXPECTED VALUES

Men	4.2 - 5.5 g/dl
Women	3.7 - 5.3 g/dl

Each laboratory should establish appropriate reference intervals related to its population.

## QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

### QUANTINORM CHEMA

with normal or close to normal control values

### QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

### AUTOCAL H

Please contact Customer Care for further information.

## TEST PERFORMANCE

### Linearity

the method is linear up to 6 g/dl.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

### Sensitivity/limit of detection (LOD)

the limit of detection is 0.01 g/dl.

### Interferences

no interference was observed by the presence of:

hemoglobin	≤ 350 mg/dl
bilirubin	≤ 27 mg/dl
lipids	≤ 850 mg/dl

### Precision

intra-assay (n=10)	mean (g/dl)	SD (g/dl)	CV%
sample 1	3.37	0.04	1.10
sample 2	3.34	0.04	1.30

inter-assay (n=20)	mean (g/dl)	SD (g/dl)	CV%
sample 1	3.36	0.04	1.00
sample 2	3.35	0.07	2.00

### Methods comparison

a comparison between Chema and a commercially available product gave the following results:

$$\begin{aligned} \text{Albumin Chema} &= x \\ \text{Albumin competitor} &= y \\ n &= 73 \end{aligned}$$

$$y = 1.009x - 0.195 \text{ g/dl} \quad r^2 = 0.956$$

## WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

## REFERENCES








Doumas et al., Standard Methods of Clinical Chemistry, Vol. 7, pag. 175-189, Academic Press Chicago (1972).

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

## MANUFACTURER

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## SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use