ALBUMIN

BC 0100 CH	2 x 50 ml
BC 0400 CH	4 x 100 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.

ALB R1 **0100: 2 x 50 ml (liquid) blue cap**
0400: 4 x 100 ml (liquid) blue cap
0500: 4 x 125 ml (liquid) blue cap

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

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

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

TEST PROCEDURE

Wavelenght:	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:

Albumin Chema = x
Albumin competitor = y
n = 73

$y = 1.009x - 0.195$ g/dl $r^2 = 0.956$

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

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use-by date
	caution
	consult instructions for use

CE