

ALBUMIN

BC 0500 CH

4 x 125 ml

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; because free ligands are those that interact with tissue receptor sites and that can be excreted, plasma albumin levels have important influences on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones. Albumin levels, although important for management and follow-up, have very little value in diagnosis. Hyperalbuminemia is of little diagnostic significance except in dehydration. Hypoalbuminemia, however, is very common in many illnesses and results in most instances from one or more of the following factors:

1. Impaired synthesis, either primary as in liver disease or secondary to diminished protein intake.
 2. Increased catabolism as a result of tissue damage and inflammation.
 3. Reduced absorption of amino acids caused by malabsorption syndromes or malnutrition.
 4. Protein loss: in urine, due to nephrotic syndrome, chronic glomerulonephritis, diabetes, or systemic lupus erythematosus; in feces, due to protein-losing enteropathy arising from inflammatory or neoplastic disease; or from the skin through burns.
 5. Altered distribution that may sequester large amounts of albumin in an extravascular compartment, as for instance in ascites, when high pressure in the portal circulation drives albumin into the peritoneal fluid.
- Determination of albumin in serum or plasma is usually based on the binding behavior of the protein with the anionic dyes bromocresol green (BCG) or bromocresol purple (BCP) in a manual or automated procedure. The present method is based on BCG in acidic environment.

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.

Reagent A: 4 x 125 ml (liquid) blue cap

Composition: succinate buffer 100 mM pH 4.20, bromocresol green 0.2 mM, surfactant.

Standard: albumin solution 4 g/dl - 5 ml

Store all components at 15-25°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 15-25°C.

Stability since first opening of vials: ≥ 60 days at 15-25°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), 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 = $A_x/A_s \times 4$ (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:

QN 0050 CH QUANTINORM CHEMA 10 x 5 ml
with normal or close to normal control values

QP 0050 CH QUANTIPATH CHEMA 10 x 5 ml
with pathological control values.

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

AT 0030 CH AUTOCAL H 10 x 3 ml

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 0.1 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 $r = 0.956$

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.








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

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	read the directions