ALBUMIN

BCG

Intended use:
In vitro test for the quantitative determination of albumin in human serum and plasma.

Summary:
Albumin is a carbohydrate-free protein, which constitutes 55-65% of total plasma protein. It maintains oncotic plasma pressure, is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilized various compounds, e.g. bilirubin, calcium and long chain fatty acids. Furthermore albumin is capable of binding toxic heavy metals ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics. *Hyperalbuminemia* is of little diagnostic significance except in the case of dehydration. Hyperalbuminemia occurs during many illnesses and is caused by several factors: Compromised synthesis due either to liver disease or as a consequence of reduced protein uptake, elevated catabolism due to tissue damage (severe burns) or inflammation, malabsorption of amino acids (Crohn's disease), proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In several cases of hyperalbuminemia, the maximum albumin concentration of plasma is 2.5g/dl. Due to the low osmotic pressure of the plasma water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Test principle:
Colorimetric assay, endpoint method
· Sample and addition of R1
· Start of the reaction:
At a pH value of 4.1 albumin displays a sufficiently cationic character to be able to bind with bromocresol green (BCG), any anionic dyestuff, to form a blue-green complex.

albumin + BCG $\xrightarrow{\text{pH 4.1}}$ albumin BCG- complex

The color intensity of the blue-green color is directly proportional to the albumin concentration and can be determined photometrical

Reagent Concentration:
R1:

Succinate buffer, pH 4.	1 75 mmol/l
Brij 35	7 ml/l
Detergents and stabilizers	

Preparation and stability:
R1: Ready for use
Unopened kits: up to the expiration date at +2°C to +25°C.
Onboard stability: R1: 28 days.

Specimen:
Collect serum using standard sampling tubes. Heparin or EDTA plasma. Separate serum or plasma from the clot or cells within one hour and analyze immediately, or store as follows:

Stability:	< 3 days	at +4°C
	6 months	at -20°C

Measuring range:
0.2g/dl – 6.0 g/dl or 2 g/l – 60 g/l
Determine samples having higher concentrations via the rerun function. On Instruments without rerun function, manually dilute samples with 0.9% NaCl solution (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

Limitation interference:
Criterion: Recovery within ± 10% of initial value at an albumin concentration of 3.5g/dl.
Icterus: No significant interference up to an index I of 92 (approximate bilirubin concentration: 92 mg/dl).
Hemolysis: No significant interference up to an index H of 1100 (approximate hemoglobin concentration: 1100 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 1075 (approximate triglycerides concentration: 2150 mg/dl).There is poor correlation between turbidity and triglycerides concentration.

Testing procedure:
Applications for automated systems are available on request.
Materials provided
• Working solutions as described above
Additional materials required
• Calibrators and controls as indicated below
• 0.9% NaCl

Manual procedure	
Wavelength:	628 nm, (620 – 640 nm)
Temperature:	+37°C
Cuvette:	1 cm light path
Zero adjustment:	Reagent blank/each series needs one reagent
	Sample / Calibrator
Sample / Calibrator	10 µl
R1	1000 µl
Mix and incubate 3 minutes. Read the absorbance against blank within 30 minutes.	
Calculation: AA sample / AA Calibrator x Calibrator conc. = Albumin conc g/dl	

Reference value:
Expected values according to Tietz

Men	4.2 – 5.5 g/dl	
Woman	3.7 – 5.3 g/dl	
Newborn	0 - 4 days	2.8-4.4 g/dl or 28-44 g/l
Children	4 days - 14 years	3.8-5.4 g/dl or 38-54 g/l
	14 - 18 years	3.2-4.5 g/dl or 32-45 g/l

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, albumin results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

Analytical sensitivity (lower detection limit):
0.2 g/dl or 2 g/l
The lower detection limit represents the lowest measurable albumin concentration that can be distinguished from zero. It is calculated as three standard deviations of the lowest standard.

Imprecision:
Reproducibility was determined using in an internal protocol. The following results were obtained.

	Within run		
Sample	Mean g/dl	SD g/dl	CV (%)
Control Serum 1	3,35	0,04	1,16
Control Serum 2	3,5	0,03	0,94
Control Serum 3	3,71	0,03	0,83
	Betwen day		
Sample	Mean g/dl	SD g/dl	CV (%)
Control Serum 1	3,37	0,04	1,08
Control Serum 2	3,52	0,04	1,17
Control Serum 3	3,98	0,03	0,84

Method comparison:
A comparison of the BIOANALYTIC Albumin (y) with a commercial obtainable assay (x) gave the following result:

y = 0.914 x + 0.306; r =0.996

Quality Control:
Control Serum:

BIOCON N	5 x 5 ml	# B10814
BIOCON P	5 x 5 ml	# B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:
S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:
A two-point-calibration is recommended in case of:
1-change of lot

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2- quality control requirements

Notes:

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Literature:

1. Doumas B.T., Watson W.A., Biggs H.G.. Albumin standards and the measurement of serum albumin with bromocresol green. Clin Chim Acta 1971 ;31 :87-96.
2. Glick M.R., Ryder K.W., Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.
3. Grant G.H., Silverman L.M., Christenson R.H.. Amino acids and proteins. In: Tietz N.W. (ed.). Fundamentals of Clinical Chemistry, 3rd Philadelphia, Pa: W.B. Saunders, 1987:328-330.
4. Marshall WJ (ed.). Illustrated Textbook of Clinical Chemistry,3rd . London: Gower Medical Publishing, 1989:207-218.
5. Tietz NW (ed.). Clinical Guide to Laboratory Tests, 3rd . Philadelphia, Pa: WB Saunders, 1895:22-24.

Order information (Cat No.) :

CC320	AB320	B24005	B28006	B33006	B80006
SH320	BALB250	B25005	B30005	B34005	
CR320	BALB125	B25006	B30006	B35005	
OL320	B21005	B27005	B31005	B36005	
KL320	B21006	B27006	B32005	B37005	
BALB500	B22005	B28005	B33005	B80005	

Manufacturer

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SYMBOLS

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

ISO 9001:2015
ISO 13485:2016