ROBONIK®

CE

prietest™...Clinical Chemistry Reagents

ALBUMIN TEST KIT

INTENDED USE :

- in vitro determination of concentration of Albumin in serum or plasma on photometric systems.
- In vitro diagnostic test kit, for laboratory and professional use.
- This manual contains instructions for operation by qualified personnel only.

ORDERING INFORMATION	Pack Size	Cat No.
	2 X 50 ml	ALB 02 50
	4 X 50 ml	ALB 04 50
	2 X 500 ml	ALB 02 500

CLINICAL SIGNIFICANCE : Albumin is an important binding and transport protein for various substances in plasma and the main contributor to the plasma osmotic pressure. Measurement of Albumin in serum is used for diagnosis and monitoring of liver diseases, e.g. liver cirrhosis.
Increased levels of albumin are present only in acute dehydratation, especially critical for newborn. Hypoalbuminemia is seen in a multitude of diseases bound to different pathological states :

1) Acute and Chronic Inflammation
2) Decreased Synthesis : Hepatic Insufficiency, Malnutrition, Analbuminemia
3) Increased Loss : Nephrotic Syndrom, Gastrointestinal Loss, Sever and Large Bums, Bedsore,
4) Increased Catabolism : Fever, Hyperthyroidism.

METHOD : Photometric test using Bromocresol Green (BCG), End Point.

PRINCIPLE : Serum Albumin in the presence of Bromocresol Green at a slightly acid pH produces a color change of the indicator from yellow-green to green-blue.

$$\text{Albumin} + \text{BCG} \xrightarrow{pH=4.20} \text{Albumin - BCG complex}$$

REAGENTS :
COMPONENTS AND CONCENTRATIONS:
Concentration are those in final Test reaction.

Succinate Buffer	75 mmol/l
Bromocresol Green	0.15 mmol/l
Preservatives & Stabilizer	
Standard	4.0 g/dl (40 g/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY : The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 30°C, protected from light and contamination is avoided. Do not freeze the reagent!
The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C.

WARNINGS AND PRECAUTIONS : Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT : For disposal of these biomedical waste refer local biosafety regulations.

REAGENT PREPARATION : The reagent and the standard are ready-to-use.

MATERIAL REQUIRED BUT NOT PROVIDED : NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, pipettes etc.

SPECIMEN :
Serum, heparinized plasma or EDTA plasma.
Stability in serum:1 month at 2 to 8°C, 1week at 15 to 25°C, At least 3 months at – 20°C
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 630 nm, 623 nm
Optical path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank.
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below:

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after 5 minutes of incubation but within 60 minutes.

CALCULATION : With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard} - \text{Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR : Albumin [g/dl] x 10 = Albumin [g/L]

CALIBRATION : For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL : To ensure adequate quality, use of the commercially available control sera is recommended.

ADDITIONAL CALCULATIONS : following formulas are used to calculate Globulin & A to G Ratio

Globulin (g/dl) = Total Proteins – Albumin

A to G Ratio = Albumin / Globulin

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE : The test has been developed to determine Albumin concentrations within a measuring range from 0.2 to 6 g/dl (2 to 60 g/L). When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY/ INTERFERENCE : No interference was observed by Ascorbic Acid up to 30 mg/dl (1703.4 µmol/L), Bilirubin up to 40 mg/dl (684 µmol/L), Hemoglobin up to 0.4 g/dl (4 g/L) and lipemia up to 500 mg/dl (5.65 mmol/L) Triglycerides. A list of drugs and other interfering substances with Albumin determination has been reported by Young et al.

SENSITIVITY/ LIMIT OF DETECTION : The lower limit of detection is 0.2 g/dl (2 g/L).

PRECISION :

Intra-assay precision n = 20	Mean [g/dl]	SD [g/dl]	CV [%]
Sample 1	3.8	0.02	0.57
Sample 2	3.6	0.03	0.90
Sample 3	2.8	0.02	0.71

Inter-assay precision n = 20	Mean [g/dl]	SD [g/dl]	CV [%]
Sample 1	3.32	0.06	1.99
Sample 2	4.17	0.07	1.67
Sample 3	3.83	0.07	1.89

METHOD COMPARISON :
A comparison between Robonik Prietest Albumin (y) and a commercially available test (x) using 20 samples gave following results:
Linear Regression : y = 1.1493x - 0.5247 g/dl
Correlation Coefficient : r = 0.9638

REFERENCE RANGE :
Adults : 3.5 to 5.2 g/dl (35 to 52 g/L)
It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Johnson AM, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. Editors Tietz textbook of clinical chemistry. 3rd ed. Philadelphia : W.B. Saunders Company; 1999. p. 477-540.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt : TH-Books Verlagsgesellschaft; 1998. p. 652-6.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION prietest INSTRUMENTS	
Name : ALBUMIN,	Mod : END-P
Pri.: 630,	Sec.: 0
Temp: 37C,	KF : 1.000
Vol : 500ul,	Unit : g/dl
Lag : 5,	Read : NA
Blk : Y, QC : Y,	Norm : Y
Std : 1, Concen :	
Std.: 1 = 4.0	
Normal HI = 5.2	
Normal LO = 3.5	
QCNH : *	
QCNL : *	
QCABH = *	
QCABL = *	
Rgnt. Linearity : 6	
NOTE :	
* Indicates user definable parameter.	
NA Implies Not Applicable	

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	ALBUMIN
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	630 nm
Temperature	37°C
Zero Setting	Reagent Blank
Units	g/dl
Standard Conc.	4
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	5 minutes
Reference Range	3.5 to 5.2
Reagent Linearity	6

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