ISE S.r.l. Albumin – Instructions for use

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

CE IVD

R1: 4x 17,5 mL **R3330000005** REF

Diagnostic Reagent for quantitative in vitro determination of Albumin in human serum or plasma on photometric systems.

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, BCG
Wavelength:	Hg 546 nm, 540 – 600 nm
Temperature:	20 – 25 °C / 37 °C
Sample:	Serum, heparin or EDTA plasma
Linearity:	up to 6 g/dL
Sensitivity:	The lower limit of detection is 0.2 g/dL

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Citrate buffer, pH 4.2	30 mmol/L
Bromocresol green	0.26 mmol/L

REAGENT PREPARATION

The reagent provided is ready for use.

REAGENT STABILITY AND STORAGE

Conditions:	Protect from light Close immediately after use Avoid contamination Do not freeze the reagent.
Storage:	at 2 – 25 °C
Stability:	up to the indicated expiration date

SAMPLE STABILITY AND STORAGE

Stability [3]:	15 – 25 °C	10 weeks
	4 – 8 °C	5 months
	- 20 °C	3 months

Only freeze once!
Discard contaminated specimens.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit; has to be ordered separately)

Concentration	5 g/dL (50 g/L)
Storage:	2 – 8 °C
Stability:	up to the indicated expiration date

CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	400 mg/dL
Triglycerides	500 mg/dL

For further information on interfering substances refer to Young DS [5].

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Std./Cal.	-	10 µL	-
Dist. water	10 µL	-	-
Mix, Incubate for approx. 10 min. at 20 – 25 °C / 37 °C and read absorbance against reagent blank within 60 min.			

CALCULATION

$$\text{Albumin (g/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. of Std/Cal (g/dL)}$$

UNIT CONVERSION

g/dL x 10 = g/L
g/dL x 144.9 = µmol/L

REFERENCE RANGE [4] *

	g/dL	g/L	µmol/L
Adults:	3.5 - 5.2	35 - 52	507 - 756

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

SUMMARY [1,2]

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. Furthermore, albumin levels indicate the health and nutritional status of an individual and, therefore, are used for detecting malnutrition and for prognosis in elderly hospitalized patients.

TEST PRINCIPLE

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue. The intensity of the blue-green color is proportional to the concentration of albumin in the sample.

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PERFORMANCE CHARACTERISTICS

Linearity, Measuring range

The test has been developed to determine albumin concentrations within a measuring range from 0.2 to 6 g/dL. Samples with albumin concentrations higher than 6 g/dl should be diluted 1+1 with NaCl solution (9 g/L) and the result multiplied by 2.

SENSITIVITY / LIMIT OF DETECTION

The lower limit of detection is 0.2 g/dL.

Precision (AT 25 °C)

Intra-assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.52	0.03	0.91
Sample 2	4.50	0.05	1.12
Sample 3	6.89	0.12	1.79

Inter-assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.35	0.05	1.58
Sample 2	4.32	0.06	1.44
Sample 3	6.73	0.11	1.60

Method Comparison

A comparison of this Albumin (y) with a commercially available assay (x) using 59 samples gave following results:
y = 1.00 x – 0.11 g/dL; r = 0.998.

QUALITY CONTROL

All control sera with Albumin values determined by this method can be used. We recommend our serum controls Normal control serum (control serum with values in the normal range) and Pathological control serum (control serum with values in the abnormal range). Each laboratory should establish corrective action in case of deviations in control recovery.

CALIBRATION

The assay requires the use of an albumin standard or an albumin calibrator. We recommend to use our multicalibration serum, for which the assigned values have been made traceable to the reference material ERM-DA470.

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. The standard contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
2. In very rare cases, samples of patients with gammopathy might give falsified results. [6]
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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.447-540.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p.652-6.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p.14-5.
4. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mucke M. Gammopathy interference in clinical chemistry assays: mechanism, detection and prevention. ClinChemLabMEd 2007; 45 (9): 1240-1243.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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