Instructions for Use
For *in vitro* diagnostic use

ALBUMINA WS
Albumin WS

Anvisa 80115310206

ORDER INFORMATION

Cat. No.	Kit size
1110250KWS	R: 1 x 250 mL
1110060MWS	R: 2 x 30 mL
1110154.4RWS	R: 4 x 38,6 mL
1110040MKWS	R: 2 x 20 mL

INTENDED USE

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

SUMMARY [1,2]

Albumin is an important binding and transport protein for many substances in plasma and is a major contributor to plasma osmotic pressure. Serum albumin levels are used for the diagnosis and monitoring of liver diseases, such as cirrhosis. In addition, albumin levels indicate an individual's nutritional status and health and are therefore used for the detection of malnutrition and for prognosis in elderly hospitalized patients.

METHOD

Photometric test using bromocresol green.

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.

REAGENTS

Components and Concentrations

Citrate buffer	pH 4.2	30 mmol/L
Bromocresol green		<0.3 mmol/L

STORAGE AND STABILITY

The reagent is ready to use and is stable until the expiration date if stored at 2 - 8 °C, protected from light and if contamination is avoided. Do not freeze the reagent!

WARNINGS AND PRECAUTIONS

1. In very rare cases, samples of patients with gammopathy might give falsified results [6].
2. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

MATERIALS REQUIRED, BUT NOT PROVIDED

1. NaCl solution 9 g/L.
2. General laboratory equipment.

SPECIMEN

Serum, heparin plasma or EDTA-plasma.

Stability [3]:	10 weeks	at	20 - 25 ºC
	3 months	at	-20 ºC
	5 months	at	4 - 8 ºC

Only freeze once!
Discard contaminated specimens!

ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: www.kovalent.com.br

Wavelength	Hg 546 nm, (540-600)
Optical path	1 cm
Temperature	20 - 25 ºC / 37 ºC.
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	10 µL
Distilled water	10 µL	-
Reagent	1000 µL	1000 µL
Mix, incubate for approximately 10 minutes, then read the absorbance against the reagent blank within 60 minutes.		

CALCULATION

With calibrator

$$\text{Albumin [g/dL]} = \frac{A_{Sample}}{A_{Calibrator}} \times \text{Conc. Calibrator [g/dL]}$$

Conversion Factor

Albumin [g/dL] x 144.9 = Albumin [µmol/L]

CALIBRATORS AND CONTROLS

For calibration in automated photometric systems, Kovalent Topkal U calibrator is recommended. Use Kovalent Topkon N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

PERFORMANCE CHARACTERISTICS

Measuring range

The assay is designed to determine albumin concentrations within a measurement range of 0.2 - 6.0 g/dL. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity / Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 400 mg/dL, and lipemia up to 500 mg/dL of triglycerides. For more information on interfering substances, see Young DS [5].

Sensitivity / Limit of Detection

The lowest detection limit is 0.2 g/dL.

Precision

Within run n = 10	Mean [g/dL]	SD [g/dL]	CV [%]
Normal Control	3.64	0.07	1.92
Pathological Control	4.393	0.05	1.25

Between day n = 9	Mean [g/dL]	SD [g/dL]	CV [%]
Normal Control	3.79	0.11	2.81
Pathological Control	4.57	0.10	2.18

Method comparison

Method comparison between Kovalent Albumina WS (y) and a commercially available test (x) using 30 samples demonstrated the following results:
y = 0.9776 x – 0.1077; r = 0.993

REFERENCE VALUES [4]

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

Each laboratory should verify that reference values can be used in its own patient population and determine its own reference values, if necessary.

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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1 st 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: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:

Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 - Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310206	R: 2 x 50 mL
80115310206	R: 3 x 40 mL
80115310206	R: 5 x 40 mL

Costumer service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See labe