

# Manual/Automation ALBUMIN

IVD

REF		REAGENTI	
1003704125	4x125 ml Manual : 333 test Autom.:1428 test	R1:4x125 ml Standard 4 ml	

## 1.0 SUMMARY

Albumin is the most present plasmaprotein in circulation ; Its functions include extracellular liquid distribution regulation; aminoacid components are a part of organism pool. Moreover, albumin act as carrier of a variety of substances like hormones, lipids, vitamins, calcium and other oligoelements. Albumin is synthesized by liver from aminoacids absorbed with digestion and is the most responsible of plasmatic osmotic pressure, opposed to capillar sanguine pressure, that tend to force water in tissues. An increase of plasmatic albumin is present in : **dehydration**, venous stand during a sample.

A decrease is present : hyperhydration, excessive lost of protein from kidneys, skin or intestine; decreased synthesys, for alimantar deficiency , hepatic diseases of bad absorbtion, catabolism increasing, during fever or not treated diabetes and hyperthyroidism.

## 2.0 PRINCIPLE

The measurement of serum albumin is based on its quantitative binding to the bromocresol green (BCG). The albumin-BCG complex absorbs at 600-630 nm.

## 3.0 SAMPLE

Not hemolized serum, plasma .

- Samples are stable up to 7 days at 15-25°C, 30 days at 2-8°C.

## 4.0 REFERENCE VALUES

SERUM-PLASMA:

MEN	2.9 – 6.1	g/dL
WOMEN	2.5 – 5.4	g/dL

## 5.0 REAGENTS

For in vitro diagnostic use only. Kit components stored at +4-8 °C, are stable up to expiration date on kit label.

Initial concentrations :

<b>R1</b>	Buffer succinate 60.0 mmol/l; bromocresol green, sodium azide < 0.1%, surfactant and stabilizers.
<b>STD</b>	Standard Albumin (value indicated on vial label).

Liquid ready to use

## 6.0 PREPARATION AND STABILITY OF REAGENTS

Reagents are ready to use.

## 7.0 CONSERVATION AND STABILITY

Kit: Store at +15-25°C. Do not freeze .  
Stable up to expiration date on kit label.

## 8.0 MATERIALS REQUIRED BUT NOT PROVIDED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

## 9.0 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" guidelines.

## 10.0 PROCEDURE MANUAL

Wavelength	$\lambda = 630 \text{ nm (580-630)}$
Optical length	1 cm
Temperature	37°C
Reading	Against reagent blank
Reaction	end point (increment)

	BLANK	STANDARD	SAMPLE
Reagent	1500 uL	1500 uL	1500 uL
Distilled water	10 uL	-	-
Standard	-	10 uL	-
Sample	-	-	10 uL

Mix well and incubate at 37°C for 5 min. Read sample E<sub>c</sub> and standard E<sub>s</sub> OD against reagent blank.

## 11.0 CALCULATION OF RESULTS

Serum, plasma:

$$E_c/E_s \times \text{conc. std} = \text{g. of albumin / sample}$$

## 13.0 QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available :

101265 PRECISE NORMAL with normal or close to normal control values.

101267 PRECISE PATH with pathological control values.

If required, a multiparametric, human based calibrators available :

101031 BIOCAL HUMAN

## 14.0 TEST PERFORMANCES

### 14.1 INTERFERING SUBSTANCES

Do not interfere until concentration of :

Bilirubin	5	g/dL
Hemoglobin	Interfere at minimum concentration too.	

### 14.2 INTRA-ASSAY PRECISION

Control:	Low	High	
n:	20	20	
MEDIA:	3.8	3.0	g/dL
D.S.:	0.16	0.16	g/dL
C.V.(%):	4.29	5.42	g/dL

### 14.3 INTER-ASSAY PRECISION

Control:	Low	High	
n:	20	20	
MEDIA:	3.8	3.1	g/dL
D.S.:	0.13	0.12	g/dL
C.V.(%):	3.41	4.10	g/dL

### 14.4 CORRELATION

Evaluation performed on same samples, gave the following correlation parameters, with a equivalent method as reference :

$$y = 1,003 x - 0,0698$$

$$R^2 = 0,9743$$

$$n = 20$$

14.5 LINEARITY:	6	6
14.6 SENSIBILITY:	0.11	0.11
14.7 MEAS. RANGE:	0.11 – 6.0	0.11 – 6.0

## 15.0 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 sheet.

## 16.0 REFERENCES

E.M. Gindler and J.O. Westgard, Clin. Chem (1973) 6, 4. J.O. Westgard, M.A.

POQUETTE, CLIN. CHEM. (1973) 19, 647.

Kaplan, L.A., Pesce, A..J.: Clinical Chemistry, Mosby Ed. (1996).

## SYMBOLS - 98/79/EC DIRECTIVE

	Attenzione, consultare le istruzioni per l'uso		N°determinazioni per kit		Fabbricante
	Solo per uso diagnostico		Usare entro		Non riutilizzare
	Conservare a 2-30°C		Numero del lotto		Codice #



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# MeDia Diagnostici

If You need to be sure !