# DIAGNOSTIC KIT FOR DETERMINATION OF ALBUMIN CONCENTRATION

Kit name	Cat. No
Liquick Cor-ALBUMIN 500	2-294
Liquick Cor-ALBUMIN "bulk"	2-270

# INTRODUCTION

Albumin is the major serum protein, but is present also in other body fluids: cerebrospinal, pleural and peritoneal. Albumin regulates blood oncotic pressure and serves as amino acids reservoir. Beyond of these functions albumin is very important transport protein – binds and keeps dispersed bilirubin, hormones, vitamins, calcium, magnesium, fatty acids and medicines. Decreased albumin blood level is caused usually by liver or kidney disease, malabsorption or malnutrition.

## METHOD PRINCIPLE

Bromocresol green (BCG) forms with albumin, in succinate buffer (acid medium), a coloured complex. The absorbance of this complex is proportional to the albumin concentration in the sample. The colour intensity of the formed complex measured at 630 nm is proportional to albumin concentration in the sample.

# REAGENTS

	Liquick Cor-	Liquick Cor-
	ALBUMIN 500	ALBUMIN "bulk"
1-ALBUMIN	4 x 500 ml	*

\*reagent volume is printed on the label.

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagents are stable for 8 weeks on board the analyser at 2-10°C.

# Concentrations in the test

succinate buffer	90 mmol/l
bromocresol green (BCG)	$\leq 0.29 \text{ mmol/l}$
sodium hydroxide	50 mmol/l

# Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Protect from light and contamination!
- Do not freeze the reagent.
- The reagent contains < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.
- 1-Reagent meets the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Warning.

H319 Causes serious eye irritation.

P280 Wear protective gloves, eye protection and face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

# ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 630 nm;
- thermostat at 25°C or 37°C;
- general laboratory equipment;

# SPECIMEN

Serum free from hemolysis.

Serum should be separated from red blood cells as soon as possible after blood collection.

Serum can be stored up to 3 days at 2-8°C or 6 months at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples!



## PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request. The reagent is ready to use.

### Manual procedure

630 nm
25°C / 37°C
1 cm

Pipette into the cuvette:

	blank	test	standard		
	(B)	(T)	(S)		
1-ALBUMIN	1000 µl	1000 µl	1000 µl		
Bring up to the temperature of determination. Then add:					
standard	-	-	10 µl		
sample	-	10 µl	-		
distilled water	10 µl	-	-		

Mix well and incubate for 5 minutes. Read the absorbance of test sample A(T) and standard sample A(S) against reagent blank (B).

#### Calculation

albumin	_	A(T)		standard
concentration	=	A(S)	Х	concentration

# **REFERENCE VALUES 6**

serum		g/dl	g/l
children	0-4 days	2.8 - 4.4	28 - 44
	4 days – 14 years	3.8 - 5.4	38 - 54
adults	20 - 60 years	3.5 - 5.2	35 - 52
	60 – 90 years	3.2 - 4.6	32 - 46

It is recommended for each laboratory to establish its own reference ranges for local population.

# QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.

For calibration when using <u>the manual method</u> ALBUMIN STANDARD (Cat. No 5-115) is recommended.

For calibration of the <u>automatic analysers systems</u> CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174 and 5-176) and LEVEL 2 (Cat. No 5-175 and 5-177) are recommended.

The calibration curve should be prepared every 7 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

# PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analyser Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity: 1.14 g/dl (11.4 g/l).
- Linearity: up to 6.5 g/dl (65.0 g/l).

For higher concentration of albumin dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

#### Specificity / Interferences

Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1200 mg/dl do not interfere with the test.

#### Precision

Repeatability (run to run)	Mean	SD	CV
n = 20	[g/dl]	[g/dl]	[%]
level 1	2.88	0.03	0.96
level 2	4.53	0.03	0.68

Reproducibility (day to day)	Mean	SD	CV
n = 80	[g/dl]	[g/dl]	[%]
level 1	4.37	0.04	0.94
level 2	2.86	0.02	0.87

### Method comparison

A comparison between albumin values determined at Biolis 24i Premium (y) and at ADVIA 1650 (x) using 21 samples gave following results:

(R - correlation coefficient)

y = 1.0372 x - 0.0167 g/dl;

R = 0.997

TRACEABILITY

ALBUMIN STANDARD is traceable to the ERM-DA470 reference material.

# WASTE MANAGEMENT

Please refer to local legal requirements.

#### LITERATURE

- Doumas B.T., Watson W.A., Biggs H.G.: Clin. Chim. Acta: 31, 87-96 (1971).
- 2. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 22 (1995).
- Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 703-4 (1994).
- Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 24-25, (1998).
- Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders, 1800, (1999).
- Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders, str. 2254, 2006.

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