Cat. No 4-538

DIAGNOSTIC KIT FOR DETERMINATION OF ALBUMIN CONCENTRATION

HC – ALBUMIN

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 colour intensity of the formed complex measured at 630 nm is proportional to albumin concentration in the sample.

REAGENTS
Package

1-Reagent	6 x 100 ml

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 12 weeks on board the analyser at 2-10°C. Protect from light and contamination!

Concentrations in the test

succinate buffer	90 mmol/l
bromocresol green (BCG)	0.29 mmol/l
sodium hydroxide	50 mmol/l

Warnings and notes
- Product for in vitro diagnostic use only.
- Do not freeze the reagent.
- The reagent contains < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

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 2-8ºC or 6 months at -20ºC. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
The reagent is ready to use.
This reagent may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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 the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.
The calibration curve should be prepared every 12 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 the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 1.17 g/dl (11.7 g/l).

- **Linearity:** up to 9.9 g/dl (99 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) n = 20	Mean [g/dl]	SD [g/dl]	CV [%]
level 1	2.80	0.02	0.81
level 2	4.85	0.03	0.65

Reproducibility (day to day) n = 80	Mean [g/dl]	SD [g/dl]	CV [%]
level 1	4.41	0.03	0.77
level 2	2.88	0.03	0.94

- **Method comparison**

A comparison between albumin values determined at Hitachi 912 (y) and at ADVIA 1650 (x) using 43 samples gave following results:
y = 0.9486 x + 0.3129 g/dl;
R = 0.9911 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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