Cat. No 4-536

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL PROTEIN CONCENTRATION

HC – TOTAL PROTEIN

INTRODUCTION

Most serum proteins except gamma globulins and hemoglobin are synthesized in the liver. Proteins participate in transport, catalysis and coagulation, act as hormones and receptors, antigens and antibodies, regulate osmotic pressure and play structural functions. Correct serum level of total protein depends mainly on balance between synthesis and degradation of albumin and immunoglobulins. Total protein level abnormalities are caused usually by dehydration, liver or kidney disease and starvation.

METHOD PRINCIPLE

The method is based on the biuret reaction. Protein forms the coloured complex with cupric ions in alkaline medium. The colour intensity is proportional to the protein concentration.

REAGENTS

Package

1-Reagent	6 x 96.5 ml

The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 9 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

copper sulfate	12 mmol/l
sodium-potassium tartrate	30 mmol/l
potassium iodide	30 mmol/l
sodium hydroxide	480 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- 1-Reagent is classified as an irritant and dangerous for the environment!

Ingredients: sodium hydroxide, copper sulfate;

Xi – Irritant.
N – Dangerous for the environment.
R 36/38: Irritating to eyes and skin.
R 51-53: Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
S 26-28-45-61: In case of contact with eyes, rinse immediately with plenty of water and see medical advice. After contact with skin, wash immediately with plenty of water. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Avoid release to the environment. Refer to special instructions/safety data sheet.

SPECIMEN

Nonhemolyzed, nonlipaemic, fresh serum is recommended. Results obtained from plasma analysis might be slightly elevated due to fibrinogen presence.
Recommended anticoagulants: EDTA, heparine lithium, sodium or ammonium salt.
Serum should be separated from red blood cells as soon as possible after blood collection.
Serum and plasma 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 [7]

serum		g/dl	g/l
premature	1 d	3.4 – 5.0	34 – 50
children	1d – 4 wk	4.6 – 6.8	46 – 68
	2 – 12 mo	4.8 – 7.6	48 – 76
	≥ 1 y	6.0 – 8.0	60 – 80
adults		6.6 – 8.7	66 – 87

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) is recommended. **Calibrator and deionized water** should be used for calibration.
The calibration curve should be prepared every 5 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:** 0.14 g/dl (1.4 g/l).

- **Linearity:** up to 16.70 g/dl (167 g/l).
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.31 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 950 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [g/dl]	SD [g/dl]	CV [%]
level 1	4.30	0.02	0.37
level 2	6.79	0.03	0.40

Reproducibility (day to day) n = 10	Mean [g/dl]	SD [g/dl]	CV [%]
level 1	4.24	0.05	1.11
level 2	6.71	0.08	1.19

- **Method comparison**

A comparison between total protein values determined at Hitachi 912 (y) and at ADVIA 1650 (x) using 42 samples gave following results:
y = 0.930 x + 0.295 g/dl;
R = 0.994 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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