Cat. No 4-542

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL PROTEINS IN URINE

HC – URINE PROTEINS

INTRODUCTION

In healthy people with properly functioning kidneys, proteins are actively reabsorbed in the proximal tubules and only small amounts of proteins (several mg per day) are excreted in urine. The measurement of total proteins concentration in urine is used in the diagnosis and treatment of heart and thyroid diseases, which are characterized by proteinuria or albuminuria.

The measurement of total proteins concentration in cerebrospinal fluid (CSF) is especially useful in detecting increased permeability of the blood-brain barrier and in detecting increased intrathecal synthesis of immunoglobulins. Increased concentration of protein in CSF may indicate brain tumors, intracerebral hemorrhage, brain injury, bacterial and viral encephalitis and multiple sclerosis.

METHOD PRINCIPLE

Direct, colorimetric method with pyrogallol red.

At an acidic pH protein aminoacid groups with the pyrogallol red-molibdate complex form a coloured compound. Colour intensity is proportional to the concentration of proteins in the sample.

REAGENTS

Package

1-Reagent	2 x 95.5 ml

The reagent when stored at 15-30°C is stable up to expiry date printed on the package. The reagent is stable for 12 weeks on board the analyser at 2-10°C. Do not freeze the reagent. Protect from light and evaporation, avoid contamination!

Concentrations in the test

succinate buffer	50 mmol/l
pyrogallol red	0.06 mmol/l
sodium molibdate	0.04 mmol/l
detergent	2 %

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Reagent should be mixed before use by gentle inverting the bottle several times.
- The appearance of turbidity or control sera values outside the manufacturer's acceptable range may indicate of reagent instability.
- The reagent contains sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Urine. Collect samples in accordance with the NCCLS procedure reported in literature.

Cerebrospinal fluid. Centrifuge before analysis. For correct interpretation of results of CSF specimen must be collected and analysed simultaneously with a blood sample.

Urine sample can be stored up to 2 days at 2-8ºC.

CSF sample can be stored up to 3 days at 2-8ºC, 6 months at -20 ºC. 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.

Calculation

For the calculation of proteins excreted over 24 hours, multiply the concentration (mg/dl) by the volume (dl) of the 24 hours urine.

REFERENCE VALUES [5, 8]

urine (adults)	< 15 mg/dl (0.15 g/l)	
urine 24-h (adults)	< 100 mg (0.10 g)	
cerebrospinal fluid	mg/dl	g/l
0 – 4 weeks	20 – 80	0.20 – 0.80
1 month – adults	15 – 45	0.15 – 0.45

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 URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY URINE PROTEINS CALIBRATORS (Cat. No 5-181) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

The calibration curve should be prepared every 2 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 analysers Hitachi 912 and Hitachi 911. Results may vary if a different instrument is used.

- **Sensitivity:** 8.6 mg/dl (0.086 g/l).
- **Linearity:** up to 300 mg/dl (3 g/l).
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**
  Inorganic phosphate, calcium and magnesium ions, creatinine, urea, uric acid, glucose, sodium citrate, sodium oxalate and sodium ascorbate do not significantly interfere with the test (< 2%).

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	32.75	1.95	5.94
level 2	281.55	3.93	1.40

Reproducibility (day to day) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	25.4	0.59	2.32
level 2	43.0	0.85	1.98

- **Method comparison**

A comparison between total proteins values determined at Hitachi 912 (y) and at COBAS INTEGRA 400 (x) using 85 samples gave following results:
y = 1.0608 x + 1.3231 mg/dl;
R = 0.9898 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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