Cat. No 4-544

DIAGNOSTIC KIT FOR DETERMINATION OF ALBUMIN CONCENTRATION IN URINE AND CEREBROSPINAL FLUID

HC – MICROALBUMIN

INTRODUCTION

Albumin is a protein that is formed within the liver and it makes up approximately 60% of the serum protein. Normally only small amounts of albumin are filtered through the renal glomeruli, and that small quantity can be reabsorbed by the renal tubules. In that case there is a low albumin concentration in the urine. When renal disorders appear, level of urine albumin increase but remains still undetectable by routine screening tests (microalbuminuria). The appearance of low but abnormal levels (30-300 mg/24h) of albumin in the urine is an early clinical evidence of nephropathy (mostly diabetic) and cardiovascular disorders.

To avoid the necessity of 24-hour urine collection it is common in clinical practice to measure albumin and creatinine simultaneously and give the result as a albumin/creatinine ratio.

METHOD PRINCIPLE

Immunoturbidimetric method. Albumin in the sample forms with anti-albumin antibodies in the reagent an insoluble complex. The turbidity caused by the complexes is measured spectrophotometrically at 340 nm and is proportional to the amount of albumin in the sample.

REAGENTS

Package

1-Reagent	2 x 48.6 ml
2-Reagent	2 x 10 ml

The reagents are stable up to the 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. Do not freeze the reagents. Protect from light and contamination!

Concentrations in the test

1-Reagent

Tris buffer (ph 7.6)	18.2 mmol/l
sodium chloride	123.2 mmol/l
PEG	< 4%

2-Reagent

sodium chloride	154 mmol/l
anti-human albumin antibodies	
preservatives	

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- 2-Reagent contains < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Urine.

Cerebrospinal fluid. If the total protein in CSF is greater than 2000 mg/l, the CSF sample needs to be diluted 1/9 and the result multiplied by 10.

It is recommended to follow NCCLS procedures regarding specimen collecting and handling.

Samples should be stored at 2-4ºC and analysed within 2 hours after collection.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.

These reagents 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 albumin 24 hours quantity, multiply the concentration (mg/l) with the volume (l) of the 24 hours urines.

REFERENCE VALUES [3]

urine	mg/24h	µg/min	mg/g creatinine
normal	< 30	< 20	< 30
microalbuminuria	30 – 300	20 – 200	30 – 300
clinical albuminuria (overt nephropathy)	> 300	> 200	> 300
cerebrospinal fluid, lumbar		177 – 251 mg/l	

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 MICROALBUMIN CONTROL (Cat. No 4-461) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MICROALBUMIN CALIBRATOR (Cat. No 5-193) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

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 analysers Hitachi 912 and Hitachi 911. Results may vary if a different instrument or a manual procedure is used.

- **Analytical range:** from 7.56 mg/l to concentration of highest calibrator.
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Ascorbate up to 200 mg/l, creatinine up to 300 mg/dl and glucose up to 3000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	61.35	0.88	1.44

Reproducibility (day to day) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	24.9	0.56	2.24
level 2	43.1	1.06	2.46

- **Method comparison**

A comparison between CORMAY kit (y) and another commercially available kit (x) using 50 samples gave following results:
y = 0.973 x + 1.366 mg/l;
R = 0.999 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. NCCLS Document: Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline - Second Edition.
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3. Burtis C.A., Ashwood E.R., Bruns D.E.: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., Elsevier Saunders, Philadelphia 2006, p. 886-888, 2254.
4. Kaplan L.A., Pesce A.J.: Clinical Chemistry, Mosby Ed., (1996), p. 575-576, 568.
5. Pagana K.D., Pagana T.J.: Diagnostic and Laboratory Test Reference, Ninth Edition, Mosby Elsevier, Missouri, (2009), p. 654-655.
6. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 118, 237, (1998).

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