Cat. No 9-463

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

OS – 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 13.5 ml
2-Reagent	2 x 3.5 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.

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 intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not freeze the reagents. Protect from light and contamination!
- Do not use after expiry date.
- Do not interchange caps.
- Reagents with different lot numbers should not be interchanged or mixed.
- 2-Reagent contains < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Urine. Urine used for analysis may come from the first morning sample, random sample or timed collection sample [3].

Samples with visible turbidity should be centrifuged before analysis. Determination of uncentrifuged samples may give increased results.

Urine samples are stable for 2 days at room temperature, 14 days at the 8ºC [7].

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

Cerebrospinal fluid. CSF should be centrifuged before analysis. 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 analyzed within 2 hours after collection.

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

1-Reagent and 2-Reagent are ready to use. Before use mix reagent by gently inverting each bottle.

For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: **067**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **MALB** Type: **Urine/Other** Operation: **Yes**

Sample:	Volume	20	µL	Dilution	0	µL	Pre-Dilution Rate:	1
Reagents:	R1 Volume	250	µL	Dilution	0	µL	Min OD	Max OD
	R2 Volume	50	µL	Dilution	0	µL	L -2.0000	H 2.5000

Reagent OD Limit:

Wavelength:	Pri. 340	Sec. 700	First L	-2.0000	First H	2.5000
Method:	END		Last L	-2.0000	Last H	2.5000
Reaction Slope:	-		Dynamic Range:			
Measuring Point 1:	First 0	Last 27	L		H	
Measuring Point 2:	First 0	Last 10	Correlation Factor:			
Linearity:	%		A	1.000	B	0.000
No-Lag-Time:			On-board Stability Period:	84		

Specific Test Parameters

General | LIH | ISE | Range

Test name: **MALB** Type: **Urine/Other**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: **mg/l** Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **MALB** Type: **Urine/Other**

Calibration Type: **5AB** Formula: **Polygonal** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		*	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:					
Point 7:					

1-Point Cal.Point: [ ] [ ] with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period: **84**

\# User defined
* Calibrator value

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.

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 Olympus AU400 and Hitachi 911. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 4.8 mg/l

- **Linearity:** up 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**

Hemoglobin up to 2.5 g/dl, ascorbate up to 200 mg/dl, creatinine up to 6 g/l, uric acid up to 100 mg/dl, glucose up to 35 g/l, urea up to 50 g/l, bilirubin conjugated up to 60 mg/dl, calcium ion up to 130 mg/dl, magnesium ion up to 1.8 g/l, do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	28.74	0.48	1.68
level 2	219.53	5.25	2.39
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 23 samples gave following results:

$y = 0.8802 x + 1.9453$ mg/l;

$R = 0.998$ (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.
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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 ed. (1998), p. 118, 237.
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MANUFACTURER

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