MICROALBUMIN FL

MA 0050 CH	1 x 50 ml
MA 0100 CH	2 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of albumin in biological fluids.

SUMMARY OF TEST

Measurement of urinary albumin is performed both for detection of microalbuminuria and for establishing the selectivity of urinary protein excretion when renal function deteriorates. Persistent urinary albumin excretion is an indicator of early diabetic nephropathy; increased concentrations have been associated with cardiovascular disease in both diabetic and non-diabetic patients.

PRINCIPLE OF THE METHOD

Albumin selectively reacts with an anti-albumin antibody and forms an immunocomplex. The produced turbidity is proportional to the concentration of albumin in the sample and can be measured at the wavelenght of 340 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

MALB R1 **0050: 1 x 40 ml (liquid) white cap**
0100: 2 x 40 ml (liquid) white cap

Composition: Buffer pH 7.50, PEG ≥ 2%, stabilizers and preservatives.

MALB R2 **0050: 1 x 10 ml (liquid) red cap**
0100: 2 x 10 ml (liquid) red cap

Composition: Anti-human albumin antibody ≥ 10%, stabilizers and preservatives.

Store all components at 2-8°C.

REAGENT PREPARATION

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: use preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

SPECIMEN

Urine.
Keep specimens away from direct light sources.
Samples are stable 7 days when stored at 15-25°C, 1 month at 2-8°C and 6 months at -20°C.

TEST PROCEDURE

Wavelength: 340 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	60 µl	-	-
calibrator	-	60 µl	-
sample	-	-	60 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_1) and sample (Ax_1).

dispense:	blank	calibrator	sample
reagent R2	250 µl	250 µl	250 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_2) and sample (Ax_2).

RESULTS CALCULATION

For calibrators and samples, calculate $\Delta A=A_2-A_1$.
A calibration curve is plotted by the use of a set of standards with increasing albumin concentrations.
Successively, albumin concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Adults < 25 mg/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control.
If required, a multiparametric, human based calibrator is available:
MICROALBUMIN CALIBRATOR

Please contact Customer Care for further information.

TEST PERFORMANCE

Measure interval
Measure interval depends on the concentration of the highest standard used for calibration.
If such a limit value is exceeded, it is suggested to dilute sample 1+4 with distilled water and to repeat the test, multiplying the result by 5.

Hook effect
No Hook effect is observed with concentrations lower than 7200 mg/l.

Sensitivity/limit of detection
The limit of detection is 1 mg/l.

Interferences
No interference was observed by the presence of:

uric acid	≤ 160 mg/dl
haemoglobin	≤ 50 mg/dl
glucose	≤ 1780 mg/dl
urea	≤ 4600 mg/dl
creatinine	≤ 630 mg/dl
direct bilirubin	≤ 32 mg/dl
ascorbic acid	≤ 300 mg/dl

Precision

intra-assay (n=10)	mean (mg/l)	SD (mg/l)	CV%
sample 1	17.8	0.26	1.46
sample 2	63.6	0.36	0.56

inter-assay (n=10)	mean (mg/l)	SD (mg/l)	CV%
sample 1	18.1	0.85	4.73
sample 2	63.3	2.23	3.53

Methods comparison
A comparison between CHEMA and a commercially available product gave the following results:

Microalbumin competitor = x
Microalbumin FL CHEMA = y
n = 81

y = 0.999x - 0.230 mg/l $r^2 = 0.998$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Greene D. N. et al. *Clinica Chimica Acta* 2016, 460, 114-119
Bakker A. J. et al. *Clinical Chemistry* 2005, 51 (6), 1070-1

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE