

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 wavelength 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 \geq 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 \geq 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 μ l	-	-
calibrator	-	60 μ l	-
sample	-	-	60 μ l

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (A_{c_1}) and sample (A_{x_1}).

dispense:	blank	calibrator	sample
reagent R2	250 μ l	250 μ l	250 μ l

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (A_{c_2}) and sample (A_{x_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	\leq 160 mg/dl
haemoglobin	\leq 50 mg/dl
glucose	\leq 1780 mg/dl
urea	\leq 4600 mg/dl
creatinine	\leq 630 mg/dl
direct bilirubin	\leq 32 mg/dl
ascorbic acid	\leq 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:

$$\begin{aligned} \text{Microalbumin competitor} &= x \\ \text{Microalbumin FL CHEMA} &= y \\ n &= 81 \end{aligned}$$

$$y = 0.999x - 0.230 \text{ mg/l} \quad r^2 = 0.998$$

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

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