MICROALBUMIN (mALB)

IMMUNOTURBIDIMETRIC ASSAY FOR URINARY ALBUMIN
GENERAL INSERT

INTENDED USE

For the quantitative *in vitro* determination of Microalbumin in urine.

Cat. No.

MA 2426	R1.	Assay Buffer	1 x 60 ml
	R2.	Antibody Reagent	1 x 7 ml
	CAL.	Standards (Levels 1-6)	6 x 1 x 2 ml

GTIN: 05055273204544

CLINICAL SIGNIFICANCE

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevations of urinary albumin concentrations are called Microalbuminuria.

PRINCIPLE

Undiluted sample is added to a buffer containing antibody specific for human serum albumin. The absorbance (340 nm) of the resulting turbid solution is proportional to the concentration of albumin in the sample urine. By constructing a standard curve from the absorbances of standards, the albumin concentration of sample can be determined. The assay can be carried out manually (at room temperature) or using an automated analyser.

SAMPLE COLLECTION AND STORAGE [1, 2]

For random urinary albumin measurement, use an early morning mid-stream specimen. Alternatively, a sample taken during the day from a resting patient may be used. Centrifuge cloudy samples before use and analyse clear supernatant in the assay.

When performing albumin excretion measurements, use a portion of carefully timed well-mixed sample, again from a patient who has avoided exercise.

Samples should be stored at between +2 to +8°C prior to testing and should be stable for at least 2 weeks when stored with an anti-microbial agent, e.g. 0.02% sodium azide or thimerosal. Long-term storage at –20°C may be attempted, but some workers have noted reduced levels of urinary albumin after storage under these conditions. Some workers have advocated the addition of a surfactant such as Triton X-100 (0.1%) to urine samples so as to prevent absorption of albumin from samples onto the walls of collection vessels.

REAGENT COMPOSITION

Contents		Initial Concentration of Solutions
R1.	**Assay Buffer**	
	Polyethylene Glycol	6 % (w/v)
	Tris/HCl buffer	20 mmol/l, pH 7.4
	Sodium Chloride	150 mmol/l
	Sodium Azide	0.09% w/v
R2.	**Antibody Reagent**	
	Anti (human) albumin	
	Tris/HCl buffer	20 mmol/l, pH 7.4
	Sodium Chloride	150 mmol/l
	Sodium Azide	0.09% w/v
CAL.	**Standards**	nominally 0-200 mg/l
	Human serum albumin	see assigned values

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solutions R1 and R2 contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Caution: Standards

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Please dispose of all biological and chemical materials according to local guidelines.

Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS
All solutions supplied ready for use.

R1. Assay Buffer
Supplied ready for use. Stable up to expiry date when stored at +2 to +8°C.

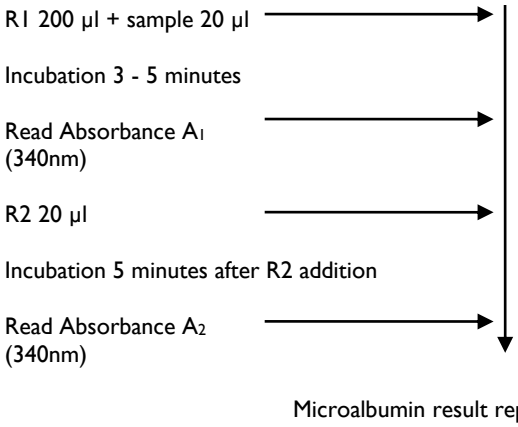
R2. Antibody Reagent
Supplied ready for use. Stable up to expiry date when stored at +2 to +8°C.

CAL. Standards
Supplied ready for use. Stable up to expiry date when stored at +2 to +8°C.

MATERIALS PROVIDED
Assay Buffer
Antibody Reagent
Standards

MATERIALS REQUIRED BUT NOT PROVIDED
Microalbumin Controls, Level 1 and Level 2 (Cat. No. MA 1361)

PROCEDURE



CALIBRATION
This assay should be calibrated using the Microalbumin Calibration Series supplied with the kit. This assay uses a log-logit calculation.

QUALITY CONTROL
Randox Microalbumin Controls, Level 1 and Level 2 are recommended for quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, United Kingdom +44 (0) 28 94451070.

SPECIFICITY
Urinary analytes other than albumin were dissolved in urine spiked with HSA at two levels.
(mean = 23.4 mg/l and 40.9 mg/l)
The following analytes were tested up to the following levels and found not to interfere: -

ascorbic acid	4 g/l
bilirubin	250 mg/l
creatinine	4 g/l
gentamicin	10 g/l
glucose	40 g/l
paracetemol	5 g/l
potassium chloride	10 g/l
sodium chloride	20 g/l
urea	40 g/l

Note also, that high levels of salicylate (5 g/l) can cause precipitation of urinary protein and give lower than expected values of urinary albumin. (This is, of course, true for all sensitive protein assays).

EXPECTED VALUES [4, 5, 6, 7, 8]

Category	24-h collection (mg/24h)	Timed collection (µg/min)	Spot collection (µg/mg creatinine)
Normal	<30	<20	<30
Microalbuminuria	30-299	20-199	30-299
Clinical albuminuria	300	200	300

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

INTERFERENCES
Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances[9]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following performance data was obtained using a RX **daytona** analyser at +37°C.

ASSAY RANGE
The range of this assay is approximately 5.11 - 234 mg/l depending on the lot specific value of calibration in use. In the event of a rerun, the upper limit of the assay range is increased to 440 mg/l.

PROZONE
Samples with concentrations in excess of 500 mg/l can be affected by prozone when run manually, which can lead to falsely low results. Therefore, it is recommended that all samples are screened with albumin test strips with a sensitivity of 200 mg/l. High samples should be diluted in 0.9% (w/v) NaCl prior to analysis so as to lie in the range of 4-200 mg/l. Prozone levels are increased significantly on automated instruments. Please refer to your instrument -specific application to confirm levels established for your system.

SENSITIVITY
The minimum detectable concentration of microalbumin with an acceptable level of precision was determined as 5.11 mg/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (mg/l)	21.2	48.0	116
SD	1.01	1.52	5.12
CV (%)	4.76	3.18	4.41
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (mg/l)	28.4	56.8	122
SD	0.616	2.24	10.3
CV (%)	2.17	3.94	8.45
n	20	20	20

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.94 X - 0.44
and a correlation coefficient of r = 0.99

40 patient samples were analyzed spanning the range 5.4 to 35.4 mg/l.

REFERENCES

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The presence of a vertical bar in the margin indicates a technical update from the previous revision.

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