Microalbumin
(Immunturbidimetry)

Cat. No	Package Size
849 002	R1 = 5 x 25 ml / R2 = 2 x 10 ml

Diagnostic Implications
Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus. An early sign of diabetic nephropathy are small Albumin secretions in urine, i.e. Microalbuminuria. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

Method
Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided
Antiserum R2
Phosphate buffered saline (pH 7.43).
Polyclonal goat anti-human Albumin (variable).
Sodium azide (0.95 g/L).
Buffer R1
Phosphate buffered saline (pH 7.43).
Polyethylene glycol (60 g/L).
Sodium azide (0.95 g/L).

Preparation and Stability of Reagents
Reagent Preparation
Liquid reagents, ready for use.
Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied
1. 0.9 g % sodium chloride
2. Calibrators and Controls

Microalbumin Standard
Microalbumin Standard Set
Microalbumin Controls normal and high

Dilution of pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert.

Sample collection
Collect urine during 24 hours or as a random midstream sample. If the test can not be carried out on the same day, the urine may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen. The use of centrifuged urine is recommended.

Automation
Application procedures on clinical chemistry analyzers are available upon request.

Reference curve: generate a reference curve by successive 1:2 dilutions of the Microalbumin standard in saline. Alternately use the Microalbumin Standard Set. Use saline as zero point.
Test: Mix 20 µL of standards, control(s) and samples with 1000 µL of MAL buffer. Read optical density (OD_1) of standards, control(s) and samples at 340 nm. Add 100 µL of antiserum. Mix and incubate for 5 minutes at room temperature. Read optical density (OD_2) of standards, control(s) and samples at 340 nm.
Calculate ΔOD's, plot a standardcurve and read the concentration of controls and samples.

Reference Values
0-25 mg/L (IFCC)
This range is given for orientation only. Each laboratory should establish its own reference values.

Performances
The performance characteristics for the Microalbumin reagents were measured on a clinical chemistry analyzer (Cobas Mira).

Measuring Range: 0 - 400 mg/L
Detection Limit: 12.5 mg/L
Hookeffect: > 4000 mg/L
Sensitivity: 0.000858 ABS units / concentration unit

Precision: [%CV]

	Low	Medium	High
Intra-Run	5.90	3.99	2.67
Inter-Run		3.35	

Accuracy : [mg/L]

Control	Assigned	Measured
APTEC	200 (170-230)	201

Specificity: Monospecific
Interferences: No interference for Triglyceriden (2500 mg/dL). Haemoglobin (>125 mg/dL) and Bilirubin (> 0.1 mg/dL) interfere with the test.
Limitations: None
Comparison with Nephelometry:
y = 1.1702 x+1.4811 / r = 0.9879
Stability at 4° C: at least 3 years after production

Precautions and warnings
1. The Microalbumin reagents are intended for in vitro diagnostic Use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. The polymer enhancer (polyethylene glycol) is non biohazardous.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

References

1. Mount, J.N., J. Clin. Pathology, 22, 12 (1986)
2. Schmidtz, A., et al., Diabetic Medicine, 5, 126 (1988)

Manual Procedure

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