Microalbumin

INTENDED USE

Reagent for *in vitro* micro-quantitative determination of albumin in urine on Photometers or Clinical Biochemistry analysers.

SUMMARY AND BACKGROUND OF THE CLINICAL UTILITY

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.

TEST PRINCIPAL

Measurement of increasing turbidity of the antigen-antibody reaction.

KIT COMPOSITION

Reagents are ready for use.

Buffer R1

- Phosphate buffered saline (pH 7.43)
- Polyethylene glycol (60 g/L)
- Sodium azide (0.95 g/L)

Antiserum R2

- Phosphate buffered saline (pH 7.43)
- Polyclonal goat anti-human Albumin
- Sodium azide (0.95 g/L)

REAGENT STABILITY

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.

SPECIMEN COLLECTION AND PREPARATION

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.

TEST MANUAL PROCEDURE

Wavelength:	340 nm
Temperature:	37°C
Cuvette:	1 cm light path
Direction:	Increase
Zero adjustment:	Reagent blank

	Sample	Standard
Sample	60 µL	-
Standard	-	60 µL
Reagent R1	1000 µL	1000 µL
Mix, incubate for about 3 min and read absorbance A1, then pipet:		
Reagent R2	200 µL	200 µL
Mix, incubate for exactly 5 min and read absorbance A2, calculate the change of absorbance of calibrator, control and samples.		

CALCULATION

The concentration of microalbumin in patient must be calculated from the Log-Logit 4P calibration.

REFERENCE VALUES

Random sample: 0 – 25 mg/L (IFCC)
24 hours collected sample: 0 – 30 mg/24h

This range is given for orientation only; each laboratory should establish its own reference range.

PERFORMANCE DATA

Linearity: The method is linear up to higher calibrator concentration. At Higher concentrations, dilute the sample 1+1 with %0.9 NaCl or distilled water and multiply by 2.

The limit of detection: 5 mg/L.
Hook effect: >500 mg/L
Specificity: Monospecific
Interferences: Hemoglobin (>125 mg/dL) and Bilirubin (> 1.0 mg/dL) interfere with the test.

Comparison with Nephelometry:
y = 1.170 x + 1.481 / r = 0.988

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ATLAS BION CHEMISTRY GmbH - Kleiberstr.29 - 85591 Vaterstetten - Germany

www.atlasbion.com