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MICROALBUMIN

Diagnostic reagent for the in-vitro quantitative determination of Micro albumin in urine by means of Particle-enhanced turbidimetric immunoassay.

REF:BS.1/MI01.030.0030	50 test	REF:BS.1/MI01.060.0060	100 test

CLINICAL SIGNIFICANCE

Microalbuminuria is at present defined as an excretion rate for albumin between 20 and 200 mg/l. which is already above normal values but still below the values seen in patients with “conventional” proteinuria.
Microalbuminuria is a marker of an increased risk of diabetic nephropathy as well as cardiovascular disease in patients with insulin-dependent diabetes mellitus as well as with non-insulin-dependent diabetes mellitus. More recently, microalbuminuria has been found to be associated with cardiovascular disease also in the non-diabetic population. In fact, microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

METHOD PRINCIPLE

Microalbumin-turbilatex is a quantitative turbidimetric test for the measurement of microalbumin (µALB) in human urine.
Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing µALB. The agglutination causes an absorbance change, dependent upon the µALB contents of the patient sample that can be quantified by comparison from a calibrator of known µALB concentration.

REAGENT COMPOSITION

R 1: Diluent	Glycine buffer 100 mmol/l. pH 10. Preservative.
R 2: Latex Reagent	Particles coated goat IgG with anti - human albumin, pH 8.2. Preservative.
Calibrator	Concentration is stated on the vial label.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Microalbumin reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Bioscien Microalbumin reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2–8°C.

Deterioration
Presence of particles (R1, R2).

SPECIMEN COLLECTION AND PRESERVATION

24 hours or random/ first morning urine specimen. It is recommended to adjust the
pH at 7.0 with NaOH/HCL 1 mol/L.Stable 7 days at 2-8ºC when sodium azide 1 g/L is added to prevent contamination.
Urine should be centrifuged before testing.

SYSTEM PARAMETERS

Wavelength	546 nm
Optical path	1 cm
Assay type	Fixed time
Temperature	37°C
Sensitivity	0.7 mg/L
Linearity	350 mg/L

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes and automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Calibrator	*Sample*
Reagent (R1)	450 µl	450 µl
Reagent (R2)	150 µl	150 µl
Calibrator	5 µl	
Specimen		5 µl

Mix and read the initial absorbance after 10 seconds (A1), then after 2 minutes read the absorbance (A2).

CALCULATION

$\frac{\Delta A \text{ sample}}{\Delta A \text{ calibrator}}$ x Calibrator concentration =mg/L

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***Bioscien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
CV. %	1.9	1.4	2.7	2.3

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from ***Bioscien*** Microalbumin reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.99.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.7 mg/L.

Linearity
The reaction is linear up to Microalbumin concentration of 350 mg/L; specimens showing higher concentration should be diluted 1/5 using physiological saline and repeat the assay.

INTERFERING SUBSTANCES

Glucose (2 g/L), hemoglobine (10 g/L) and creatinine (3 g/L), do not interfere.
Urea (≥ 1 g/L) and bilirrubin (≥ 10 mg/dL), interfere. Other substances may interfere.

EXPECTED VALUES

Normal values up to 30 mg/24 hrs urine specimen and 20 mg/L in a first morning urine specimen.

Each laboratory should establish its own reference range.

DYNAMIC RANGE

0.7 - 350 mg/L.

REFERENCES

1. Panuyiotou B N. Journal International Medical Research 1994; 22:181-201. Medcalf E A et al. Clin Chem 1990; 36/3: 446-449.
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3. Feldt-Rasmussen B et al. J Diab Comp 1994; 8: 137-145.
4. Bar J et al. Diabetic Medicine 1995; 12: 649-656.
5. Gilbert R E et al. Diabetic Medicine 1994; 11: 636-645.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		