MICROALBUMIN -TURBILATEX

PRINCIPLE OF THE METHOD

The micro albumin is a quantitative turbidimetric test for the measurement of micro albumin in 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 u ALB contents of the patient sample that can be quantified by comparison from a calibrator of known u ALB concentration between 20 and 200 mg/L, Wich is already above normal values but still below the vlues seen in patients with conventional protein urea. Microalbumin urea is a marker of an increase risk of diabetic nephropathy as well as cardiovascular disease 1 patient with insulin dependent diabetesmelitus as well as non insulin dependent diabetes melites. More recently microalbuminuria has been found to be associated with cardio vesicular disease also in the con diabetic population in fact microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

KIT CONTENTS & STORAGE:

Reagent 1	:	Microalbumin Diluent	-	40 ml
Reagent 2	:	Microalbumin Latex	-	10 ml
Reagent 3	:	Calibrator	-	1 ml

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially Infectious

CALIBRATION

Use Microalbumin calibrator. The sensitivity of the assay and the target value of the calibrator have been standardized against the µALB International Calibrator (WHO). Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PREPARATION

Working reagent: Swirl the latex Vial gently before use. Prepare the necessary amount as follow:
1 mL Latex Reagent + 9 mL Diluent.
µALB Calibrator: Ready for use.

WORKING REAGENT : Stable for 1day at 2-8°C Do not freeze or frozen Latex or Diluent Could change the test

REAGENT DETERIORATION:

Presence of particles and Turbidity

STORAGE AND STABILITY:

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations prevented during their use. Do. not use reagents over the expiration date

SAMPLES:

24hrs or random first morning urine Specimen It Is recommended to adjust the Ph AT 7.0 with

NaoH, HCL 1 mol/L Stabile 7 Days at 2-8c when urine should be centrifuged before testing

GENERAL SYSTEM PARAMETERS

Reaction Type	:	Fixed Time
Wavelength	:	540 nm (5305-50 nm)
Cuvette Temperature	:	37° C
Delay Time	:	5 Sec.
Read Time	:	120 Sec.
Reagent Volume	:	1000 µl
Sample Volume	:	7 µl
Calibrator Concentration	:	62 mg/L
Zero Setting	:	Distilled Water
Light Path	:	1 cm

PROCEDURE:

Bring the working reagent and the photometer to 37c

2. Assay conditions:

Wave Length : 540nm (530-550)

Temperature 37c

Cuvette length path 1cm

Pipette in to a cuvette

	Std/cal	Test
Working Reagent	1.0 ml	1.0 ml
Sample		7.0 ul
Calibrator	7.0 µl	-

ENSURE has instruction sheets for several automatic Analyzers instructions for many of them are available on request

CALCULATIONS

((A2-A1)Sample / (A2-A1)Calibrator) x Calibrator

Concentration = mg/L albumin

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedure .It should be used the BSM Microalbumin.

REFERENCE VALUES

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

Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS

1. Linearity limit: Up to 150 mg/L under the described assay conditions. Samples with higher concentrations, should be diluted 1/5in NaCl 9 g/L and retested again. The linearity limit depends on the sample-reagent ratio, as well the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. Detection limit: Values less than 2 mg/l give non-reproducible results
3. Prozone effect: No prozone effect was detected up to 1000mglL
4. Sensitivity: A.3.8mA. lU/ml.
5. Precision: The reagent has been tested for 20 days, using three

EP5	CV (°/o)		
	+/- 10.36 mg/ L	+/ - 16.95 mg/ L	+/- 57.33 mg/ L
Total	4.5%	3.1%	2.5%
Within Run	1.9%	1.4%	4.1%
Between Run	4.1%	2.7%	2.3%
Between Day	0.0%	0.0%	0.0%

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 40 samples of different concentrations of mircroalbumin were assayed. The correlation coefficient (r) was 0.99 and the regression equation y = 0. 424+10. 55 The results of the performance characteristics depend on the analyzer used

INTERFERENCES

Bilirubin (2 >10 mg/dL), hemoglobin (10 g/L), CreatInIne (3 g/L) do not Interfere Other substances may Interfere

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Alouf Jodeph E. Pharma Ther 1980; 11: 661-717.
2. M Fasani et al. Eur J Lab Med 1994; vol2.n°1: 67.
3. Todd E W. J Exp Med 1932; 55: 267 280.
4. Klein, GC. App lied Microbiology 1970; 19: 60-61.
5. Klein GC. App lied Microbiology 1971; 21: 9991001.
6. Haffejee I Quarterly Journal of Medicine 1992, New series 84; 305: 641 -658