MICROALBUMIN
Turbilatex

Quantitative determination of Microalbumin (µALB) IVD.

DIAGNOSTIC 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 be shown to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

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.

PRESENTATION:

	No. of Bottles/ Vials 1x50 ml
• R1 Diluent	1
• R2 Latex	1
• Micro Albumin Calibrator (61 mg/L)	1

PREPARATION OF WORKING REAGENT:
Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).

PREPARATION OF WORKING CALIBRATOR:
Reconstitute with 1.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

REAGENT STORAGE AND STABILITY:
All reagents are stable at 2-8°C till the expiry date mentioned on the label

WORKING REAGENT: Stable for 1 day at 2-8°C

MICROALBUMIN CALIBRATOR: Calibrator is stable at 2-8°C till the expiry date mention on the label. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

SAMPLES:
Fresh urine. It is recommended to adjust the pH at 7.0 with NaOH / HCL 1 mol/L. Stable for 7 days at 2-8°C. Urine should be centrifuged before testing.

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.

REACTION PARAMETERS :

• Type of Reaction	:	Two Point Fix Time
• Wavelength	:	540 nm (530-550)
• Flow cell temperature	:	37°C
• Sample/Calibrator Volume	:	7 µl
• Reagent Volume	:	1 ml
• Delay time	:	5 Sec
• Interval	:	120 Sec
• Zero setting with	:	Distilled Water
• Light Path	:	1 cm

PROCEDURE:

PIPETTE IN TEST TUBE	TEST
• Working Reagent (mL)	1.0
• Calibrator or sample (µL)	7

Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition.

TEST RESULTS:

$$\frac{(A_2\text{-}A_1)\ \text{Sample}}{(A_2\text{-}A_1)\ \text{Calibrator}} \times \text{Calibrator concentration} = \text{mg/L Albumin}$$

QUALITY CONTROL:
Control Sera are recommended to monitor the performance of manual and automated assay procedure.

NORMAL VALUES:
Normal values up to 15 mg/L.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS:
1. **Linearity:** Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample reagent ratio, as well as 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. **Sensitivity:** Δ 3.8 mA.mg/L

INTERFERENCES:
Glucose (<2 g/L), Hemoglobin (<10 g/L), Creatinine (<3 g/L), do not interfere. Urea (≥ 1 g/L) and Bilirubin (≥ 10 mg/dl) interfere. Other substances may interfere.

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

REFERENCE:
1. Feldt-Rasmussen B et al. J Diab Comp 1994; 8: 137-145.
2. Panuyiotou B.N. Journal International Medical Research 1994; 22: 181-201.
3. Bar J et al. Diabetic Medicine 1995; 12: 649-6456,
4. Gilbert R E et al. Diabetic Medicine 1994; 11-636-645.
5. Medcalf E A et al. clin chem 1990; 36/3: 446-449,
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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