ACCUTURB-100

MICROALBUMIN -Turbilatex

Latex-Enhanced Turbidimetry Assay.

INTENDED USE

For the Quantitative determination of micro albumin (µALB)
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
MAL 50T	1 X 15 ml
MAL 25T	1 X 7.5 ml

PRINCIPLE OF THE METHOD

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.

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.

KIT CONTENT

Reagent	25 tests/kit	50 tests/kit	Major ingredients
Reaction buffer (R1 reagent)	1×6ml	1 x 12ml	Glycine Buffer
R2 reagent	1×1.5ml	1 × 3 ml	Latex particles coated with goat IgG anti-human Albumin
Cuvette & Bead	25 no's	50 no's	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

SAMPLES 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.

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.

STORAGE AND STABILITY

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

ASSAY PROCEDURE

1.THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	240µl
Sample	5µl
anti-human Albumin - latex combo (R2 Reagent)	60µl

2.OPERATING STEP

(1). When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
(2). After confirm the lot number, dispense 240µl reaction buffer (R1) to a colorimetric cuvette and 5µl sample and mixing sticker. Do not produce bubbles when dispensing the sample.
(3). Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully
(4). When the analyzer shows "Add [R2]", dispense 60µl anti-human Albumin antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing…" it shows the result automatically and record the value
(5). After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
(6). If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
(7). If the result shows >230.00mg/L, may use 0.01 mol/L PBS to dilute the sample 1:5 (add 400µl PBS in 100µl sample), input dilution multiply 5, the analyser can calculate the sample concentration automatically.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

REFERENCE 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.

INTERFERENCES

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 interfere6.

BIBLIOGRAPHY

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6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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