MICROALBUMIN

Latex turbidimetry

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.

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.

Reagents

Diluent (A1)	Glycine buffer 100 mmol/L, pH 10.0 Sodium azide 0.95 g/L.
Latex (A2)	Latex particles coated with goat IgG anti-human Albumin, pH 8.2. Sodium azide 0.95 g/L.
Albumin-CAL	Calibrator. Microalbumin concentration is as stated in vial
Optional	Ref.:1107073 Microalbumin control

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

Microalbumin Calibrator: Stable for 1 month at 2-8ºC or 3

Calibration

Use Microalbumin Calibrator Reference 1107072.

The sensitivity of the assay and the target value of the calibrator have been standardized against the International Reference Material CRM 470/RPPHS.

Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

Preparation

Working Reagent:

Shake the latex vial gently before use. Prepare the necessary amount as follow:

2 mL Latex Reagent + 8 mL Diluent

Microalbumin Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and bring to room temperature for about 10 minutes before use..

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 prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

months at –20ºC.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Materials required

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostable at 37ºC with a 540 nm filter.

Specimen and Stability

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.

Assay Procedure

1. Bring the working reagent and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Wavelength: 540 nm (530-550)
   Temperature: 37ºC
   Cuvette light path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

A1 Diluent (µL)	**400**
A2 Latex (µL)	**100**
Calibrator or sample (µL) .	**5**

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

Calculations

$$\frac{(A2 - A1)_{Sample}}{(A2 - A1)_{Calibrator}} \times \text{Calibrator Conc.} = \text{mg/L Albumin}$$

Working reagent: Stable for 30 days at 2-8ºC.

Serum controls are recommended for internal Quality control. Each laboratory should establish its own Quality Control scheme and corrective actions

Reference Values

Normal Values : Up To 30 mg/24 Hrs Urine First morning urine specimen: 20 mg/L in a.

These values are for orientation purpose
Each laboratory should establish its own reference range

Reagent Performance

Linearity limit:

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.

Detection limit:

Values less than 2 mg/L give non-reproducible results. Prozone effect: No prozone effect was detected upon 1000 mg/L.

Sensitivity: 3.8 mA.mg/L

Precision:

	Intra assay(n=10)			Inter assay(n=10)		
Mean(IU/ML)	12.4	27.3	83.5	12.4	27.3	83.5
SD	0.28	0.40	1.61	0.28	0.56	2.13
CV	2.25	1.48	1.93	2.28	2.06	2.55

Accuracy:

Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 95 samples ranging from 1 to 150 mg/L of microalbumin were assayed. The correlation coefficient (r) was 0.99 and the regression equation was y= 0.964x – 0.576

The results of the performance characteristics depend on the analyzer used

Interferences

Glucose (2 g/L), hemoglobin (10 g/L) and creatinine (3 g/L) do not interfere. Urea (≥ 1 g/L) and bilirubin (≥ 10 mg/dL), interfere. Other substances may interfere6.

SYSTEM PARAMETERS

Mode	:	Two Point/Fixed time
Reaction	:	Ascending
Wavelength	:	540nm (530 – 550 nm)
Blank with	:	Distilled water
Sample Volume	:	5 µL
Reagent Volume	:	400 µL ; 100uL
Delay Time	:	10 (Sec)
Read Time	:	120 (Sec)
Calibrator	:	see vial label
Linearity limit	:	150 mg/L
Unit	:	mg/L

NOTES

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

Use clean disposable pipette tips for dispensation

Only for invitro use in Clinical laboratory (IVD)

Literature

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