Reactivos GPL

Barcelona, España

CE

- MICROALB TURBI -

MICROALBUMIN
Turbilatex

Store at: +2+8ºC.

Presentation:
Cod. TL090 R1 45 ml + R2 5 ml + Cal 1 ml.

Procedure

Diagnostic reagent for quantitative measurement of microalbumin

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY
The microalbumin-turbilatex is a quantitative turbidimetric test for measurement microalbumin (µALB) in human urine.
Latex particles coated with specific human 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 COMPOSITION

Buffer (R1)	Phosphate buffer, pH 8.5 Preservative: < 0.1% Sodium azide.
Latex (R2)	Suspension of latex microparticles covalently bound anti-albumin antibodies suspended in a neutral aqueous solution. Preservative: < 0.1% Sodium azide
MICROALB-CAL	Calibrator. Human – based reference fluid. Preservative: 0.075% Sodium azide Microalbumin concentration is stated on the vial label.
Optional	Microalbumin control Ref.: TL092

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

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY
Working reagent: Shake the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent (R2) + 9 mL Buffer (R1)
Once opened the reagent is stable for 1 month at +2 - +8º C. It is recommended that each laboratory prepares a fresh Working Reagent based on its workload.
Do not freeze; frozen Latex or Buffer could change the functionality of the test.
Microalbumin Calibrator: Ready to use and stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-*8º C*. Carefully invert the bottles before use.
Signs of reagent deterioration:
- The presence of particles and turbidity indicates deterioration of reagents.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-*8º C*. Do not use reagents over the expiration date.

CALIBRATION
Use Microalbumin Calibrator.
The sensitivity of the assay has been standardized against the International Standard CRM 470. It is not recommended to use other comercial calibrators.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

SPECIMEN
Use 12 or 24-hour collection. Centrifuge urine specimens. Screen these specimens using an albumin test strip. If the result is negative (approx. below 300 mg/L), analyse the specimens undiluted. If the result is positive, dilute the specimen with specific protein sample diluent to obtain a concentration below 250 mg/L We recommend to dilute samples with dilution buffer.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED
- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 600 nm filter.
- Cuvettes with 1 cm light path.

General laboratory equipment.

TEST PROCEDURE
1. Bring the working reagent and the photometer to 37º C.
2. Set spectrophotometer wavelength to 600 nm and adjust to zero absorbance against water.
3. Pipette into a Cuvette:

	Calibrator	Sample	Blank
Working reagent (µL)	500	500	500
Calibrator (µL)	3	--	--
Sample (µL)	--	3	--
Distilled water (µL)	--	--	3

4. Mix and read the absorbance immediately (A_1) and after 4 minutes (A_2) of the sample addition.

CALCULATIONS

$$\frac{(A_2 - A_1)_{\text{Sample}} - (A_2 - A_1)_{\text{Blank}}}{(A_2 - A_1)_{\text{Calibrator}} - (A_2 - A_1)_{\text{Blank}}} \times \text{calibrator concentration}$$

QUALITY CONTROL
Control Ref.: TL092 are recommended to monitor the performance.

Controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES
For timed overnight urine collections an albumin excretion rate greater than 20µg/min is considered to anormal.

It is suggested that each laboratory establish its own reference range.

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 (IDDM) as well as with non-insulin-dependent diabetes mellitus (NIDDM). 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.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
- *Linearity limit*: The range interval for the calibration method is from 0.0 mg/L to 125 mg/L (note 1).
- *Prozone effect*: The system did not show prozone phenomenon at east up to 400 mg/L.
- *Sensitivity:* Calculating the mean plus 3SD of twenty replicates of zero standard resulted in a lower limit of detection less than 5 mg/L.
- *Precision:*

	Intra-assay n=10			Inter-assay n=10		
Concentration (mg/L)	30	60	130	30	60	160
CV %	3.4	3.7	1.9	4.5	2.4	4.5

- *Accuracy:* Results obtained using this reagent (y), were compared to those obtained using a commercial reagent (x) with similar characteristics. 70 samples ranging from 1 to 150 mg/L microalbumin were assayed.
  The correlation coefficient $(r)^2$: 0.981
  and the regression equation was y= 0.96x + 4.1

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

NOTES
1. 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. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased. In a one point calibration, when values exceed 100 mg/l, the samples should be diluted with saline solution and the result should be multiplied by the appropriated factor.

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