Reactivos GPL

Barcelona, España

CE

- μALB-Turbi -

MICROALBUMIN
Turbilatex

Store at: +2+8ºC.

Presentation:
Cod. TL090 R1 45 ml + R2 5 ml + R3 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

Diluent (R1)	Glycine buffer 100 mmol/L, pH 10. Sodium azide 0.95 g/L.
Latex (R2)	Suspension of latex particles coated goat IgG with anti-human albumin, pH 8.2. Sodium azide 0.95 g/L.
μALB-CAL	Calibrator. Microalbumin concentration is stated on the vial label.
Optional	Microalbumin control.

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 Diluent (R1)
Stable for 1 day at 2-8ºC.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Microalbumin Calibrator: Reconstitute (→)with 1.0 mL of distilled water. Stable for 1 month at 2-8ºC or 3 months at –20ºC.
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. Stored at tightly closed at 2-*8ºC*. Do not use reagents over the expiration date.

CALIBRATION

The assay is calibrated to the Reference Material CRM 470/RPPHS. The use of other commercially available microalbumin calibrators is not recommended.

SPECIMEN

Fresh urine. 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 analysis.
Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 540 nm filter.
- Cuvettes with 1 cm light path.

General laboratory equipment.

TEST PROCEDURE

1. Bring the working reagent and the photometer to 37ºC.
2. Set spectrophotometer wavelength to 540 nm and adjust to zero absorbance against water.
3. Pipette into a Cuvette:

	Calibrator	Sample
Working reagent (mL)	1	1
	7	--
Calibrator (μL) Sample (μL)	--	7

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

CALCULATIONS

$$\frac{(A_2-A_1)_{\text{sample}}}{(A_2-A_1)_{\text{calibrator}}} \times \text{Calibrator concentration} = \text{mg/L microalbumin}$$

QUALITY CONTROL

SERUM CONTROL: are recommended to monitor the performance
Serum controls microalbumin 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

Up to 15 mg/L.
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

1. *Linearity limit*: Up to 150 mg/L[(note 1)], under the described assay conditions.
2. *Prozone effect*: No prozone effect was detected upon 1000 mg/L.
3. *Detection limit:* Values less than 2 mg/L give non-reproducible results.
4. *Sensitivity:* Δ 3.8 mA.mg/L.
5. *Precision:*

	Intra-assay n=10			Inter-assay n=10		
Mean (mg/L)	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

6. *Accuracy:* Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 91 samples ranging from 1 to 150 mg/L 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 used analyzer.

INTERFERING SUBSTANCES

Do not interfere:

- Glucose (2 g/L)
- Haemoglobin (10 g/L)
- Creatinine (3 g/L)

Interfere:

- Urea (≥ 1 g/L) and Bilirubin (≥ 10 mg/dL)

Other substances may interfere[6]

NOTES

1- Samples with higher concentrations shoud 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.

BIBLIOGRAPHY

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: 649-656.
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.

CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nau J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75