MICROALBUMINE-TURBILATEX

Latex turbidimetry

*Quantitative determination of microalbumin (*µALB*).*

CE

IVD

PACKAGING

Ref.: 101-0481	Cont.: R1. Diluent: 1x45 mL
	R2. Latex: 1x5 mL
	µALB - cal: 1x1 mL

Store at 2 - 8º C.

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

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.

REAGENTS

Diluent (R1)	Glycine buffer 100 mmol/L, pH 10.0. Preservative.
Latex (R2)	Particles coated goat IgG with anti -human albumin, pH 8.2. Preservative.
µALB-CAL	Liquid Calibrator. Microalbumin concentration is stated on the vial label.
Optional	Ref.:101-0483 Microalbumin control.

Optional (not included in the kit)

MICROALBUMIN CONTROL	
Ref.: 101-0697	1 x 2 mL

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.

CALIBRATION

Use Microalbumin Calibrator Reference 101-0482 (included). 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

Microalbumin Calibrator: Ready for 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 are prevented during their use. Do not use reagents over the expiration date.

Signs of reagent deterioration:

Presence of particles and turbidity.

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

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 540 nm filter.

SAMPLES

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 2-8º C when sodium azide (1 g/L) is added to prevent contamination.
Urine should be centrifuged before testing.

PROCEDURE

Note: Chronolab Systems has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

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

	Blank
R1: Diluent (mL)	0.9
R2. Latex (mL)	0.1

5. Mix and read the absorbance (Blank reagent).
6. Add the sample/ calibrator.

	Blank	Calibrator /Sample
NaCl 9 g/L (µL)	7.0	--
Calibrator or sample (µL)	--	7.0

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

CHRONOLAB SYSTEMS, S.L., C/Diputación 260, 08007 Barcelona, SPAIN
Tel. +34 617722466, www.chronolab.com, e-mail: comercial@chronolab.es

CALCULATIONS

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

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

If control values are found outside the defined range, check the instrument, reagents and technique for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[1]

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.

PERFORMANCE CHARACTERISTICS

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 up to 1000 mg/L.

Sensitivity: Δ 3.8 mA. mg/L.

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

Accuracy: Results obtained using this reagent (y) were 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), 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 interfere[6].

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.

CHRONOLAB SYSTEMS, S.L., C/Diputación 260, 08007 Barcelona, SPAIN
Tel. +34 617722466, www.chronolab.com, e-mail: comercial@chronolab.es