Microalbumin-Turbilatex
Latex Turbidimetry

IVD CE

PRODUCT CODE
TL006

INTENDED USE
Quantitative determination of microalbumin (µALB) IVD

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

(R1) Diluent	Glycine buffer 100 mmol/L, pH 10,0. Preservative.
(R2) Latex	Particles coated goat IgG with anti -human albumin, pH 8,2. Preservative.
µALB- CAL	Liquid Calibrator. Microalbumin concentration is stated on the vial label.

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. Reagent deterioration: Presence of particles and turbidity. Do not freeze; frozen Latex or Diluent could change the functionality of the test
Reagent deterioration: Presence of particles and turbidity

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.

SPECIMEN AND SAMPLE PREPARATION
- 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.

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

	Blank
R1 Diluent (ml)	0.8
R2 Latex (ml)	0.2

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 (A1) and after 2 minutes (A2) of the sample addition.

CALCULATIONS

$$\frac{(A2-A1)\text{sample}}{(A2-A1)\text{calibrator}} \times \text{Calibrator concentration} = \text{mg/L albumin}$$

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.

PERFORMANCE CHARACTERISTICS
1. **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.
2. **Detection limit**: Values less than 2 mg/L give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected up to 1000 mg/L.
4. **Sensitivity**: 3,8 mA. mg/L.
5. **Precision**: The reagent has been tested for 20 days, using three different microalbumin concentrations in a EP5-based study

EP5	CV (%)		
	+/- 10,36 mg/L	+/- 16,95 mg/L	+/- 57,33 mg/L
Total	4.5%	3.1%	2.5%
Within Run	1.9%	1.4%	1.1%
Between Run	4.1%	2.7%	2.3%
Between Day	0.0%	0.0%	0.0%

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 49 samples of different concentrations of microalbumin were assayed. The correlation coefficient (r)2 was 0,99 and the regression equation y = 0,424x +10,55.
   The results of the performance characteristics depend on the analyzer used.

7. 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.

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

SYMBOL ON LABELS

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFRENCES

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.

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany