

Quantitative determination of microalbumin (μALB)

IVD

Store 2 - 8°C.

PRINCIPLE OF THE METHOD

The 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.

CLINICAL SIGNIFICANCE

Microalbuminuria is at present defined as an excretion rate for albumin between 20 and 200 μg/min, 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.

REAGENTS

R1	Glycine buffer 100 mmol/L, pH 10.0. Sodium azide 0.95 g/L.
R2	Particles coated goat IgG with anti -human albumin, pH 8.2. Sodium azide 0.95 g/L.
Saline Solution	NaCl 9% (for samples predilution)
Optional	Ref.: ACC16-033 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.

CALIBRATION

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

PREPARATION

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

- 1 mL Latex Reagent + 9 mL Diluent

Samples and Controls Pre-Dilution: Before the use, samples and/or controls must be diluted in this way:

- 25 μL sample or control + 300 μL NaCl 9 g/L (1:13)

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

Working reagent: Stable for 1 day at 2-8°C.

ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 μL
- Pipette 10 - 100 μL
- Cuvettes and microstirrers (ref. code ACC16-037)

SAMPLES

Fresh urine. It is recommended to adjust the pH at 7.0 with NaOH/HCL 1 mol/L. Stable 7 days at 2-8°C when sodium azide 1 g/L is added to prevent contamination.

Urine should be centrifuged before testing.

TEST PARAMETER

Filter: set filter on position A

Reading time: 120 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	μL
Working reagent	500

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 50 μL of the diluted sample or control
4. Read the result which will appear automatically on the reader's display after 120 sec.

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics Microalbumin Control ref: ACC16-033 is available.

REFERENCE VALUES

Up to 15 mg/L.

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity limit: Up to 50 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 upon 1000 mg/L.
4. Sensitivity: Δ 8 mA. mg/L.
5. Precision:

	Mean	SD	CV%
Intra-assay (n=10)	27.3	0.40	1.46
Inter-assay (n=10)	27.3	0.56	2.05

1. 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 0.98 and the regression equation was $y = 0.964x - 0.576$

INTERFERENCES

Glucose (2 g/L), hemoglobine (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.

NOTES

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

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.

PACKAGING

Ref: ACC16-024	Cont.	: 1 x 45 mL R1
		: 1 x 5 mL R2
		: 1 x 50 mL Saline Solution