# Microalbumin – Turbidimetric CE

| REF 3150005<br>1 x 50 mL<br>**CONTENTS**<br>R1.Reagent 1 x 40 mL<br>R2.Reagent 1 x 10 mL<br>CAL. 1 x 1 mL |
|---|
| For *in vitro* diagnostic use only |

## Microalbumin - Turbidimetric

*Latex Turbidimetry*

### PRINCIPLE

Latex particles coated with specific antibodies anti-human albumin are agglutinated when they react with samples that contain albumin. The latex particles agglutination is proportional to the concentration of the albumin in the sample and can be measured by turbidimetry.[1-3]

### REAGENTS COMPOSITION

**R1** **Diluent**. Glycin buffer, 100 mmol/L, pH 10.0.

**R2** **Latex**. Latex particles coated with goat IgG anti-human albumin, pH 8.2.

**CAL** **Calibrator.** (Ref. 3950005) Human albumin. Albumin concentration is stated on the label vial and it is traceable to the Certified Reference material BCR 470 (IRMM).

**Precautions:** The reagents contain sodium azide 0.95 g/L. Avoid any contact with skin or mucous.
The reagents from human donors have been given negative results to anti-HIV 1/2, HBsAg and anti-HCV. Handle cautiously is recommended.

### REAGENT PREPARATION

**R1** Ready to use.

**R2** Ready to use. Mix gently the vial by inversion before use (Note 5).

**CAL** Ready to use.

**Working reagent.** Swirl the latex vial before use. Mix Latex and Diluent in a 1:5 ratio (i.e. 2 mL R2 + 8 mL R1) prior to use.

### STORAGE AND STABILITY

1. The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.
2. Working reagent is stable during 7 days at 2-8 ºC. Shake gently the vial before use.
3. Reagent deterioration: Presence of particles and turbidity.

### SAMPLES

Fresh urine. It is recommended to adjust the pH at 7.0 with NaOH 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.

### MATERIAL REQUIRED

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 540 ± 20 nm filter.

### PROCEDURE

#### Preliminary Procedure

Prewarm the working reagent and the photometer (cuvette holder) to 37 ºC.

#### Analytic Procedure

1. Using distilled water zero the instrument at 540 nm.
2. Pipette into a cuvette:

| | |
|---|---|
| Sample / Calibrator | 7 µL |
| Working Reagent | 1.0 mL |

3. Mix well and record the absorbances inmediately ($A_1$) and 2 minutes ($A_2$) after the sample addition.

#### Calculation

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

### QUALITY CONTROL

Controls are recommended to monitor the performance of manual and automated assay procedures. It is recommended to use Microalbumin-Turbidimetric-Control (ref: 3945010). Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

### REFERENCE VALUES[7]

Adults: Up to 15 mg/L.
Each laboratory should establish its own reference range.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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## CLINICAL SIGNIFICANCE[4-6]

Microalbuminuria is an increased urinary albumin excretion (UAE) in the range of 20 to 200 µg/min (or 30-300 mg/24h) as a consecuence of changes in glomerular permeability[7].

Increased UAE precedes and is highly predictive of diabetic nephropathy, end-stage renal disease, and proliferative retinopathy in type 1 diabetes. In patients with type 2 diabetes, increased UAE is an independendent predictor of progressive renal disease, atherosclerotic disease, and cardiovascular mortality. In fact, microalbuminuria may show to be a risk factor of cardiovascular disease among otherwise apparently healthy people.

## ANALYTICAL PERFORMANCE

- ***Linearity limit.*** Up to 160 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 en ClNa 9 g/L and retested again.
- ***Detection limit.*** Values less than 0.78 mg/L give non-reproducible results.
- ***Analytical sensitivity.*** 5.64 mA /mg albumin/L.
- ***Prozone effect.*** Up to 1000 mg/L.
- ***Precision:***

| | Mean (mg/L) | CV (%) |
|---|---|---|
| Intra-assay N = 10 | 8.8 | 5.9 |
| | 40.6 | 2.1 |
| | 60.8 | 1.6 |
| Inter-assay N = 10 | 8.7 | 6.1 |
| | 40.6 | 2.8 |
| | 60.8 | 3.9 |

- ***Accuracy.*** Results obtained with this reagents did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.
- ***Interferences.*** Bilirubin (10 mg/dL), hemoglobin (12 g/L), urea (100 mg/L) and creatinine (300 mg/L), do not interfere. Other substances may interfere[8].

## NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.

2. 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.

3. Do not re-use plastic cuvettes, as they may produce erroneous values. Use a new cuvette for each microalbumin assay.

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

5. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

## BIBLIOGRAPHY


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**T3150-2/1308**
**R1.ing**





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