# ACCUCARE
# MICROALBUMIN -Turbilatex
## Latex Turbidimetry.

**Quantitative determination of microalbumin (µALB)**
**Only for *In Vitro* Diagnostic use**

## ORDER INFORMATION

| REF | CONT |
|---|---|
| TMALB 50 | 1x50 ml |

## 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.

## 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.

## REAGENT COMPOSITION

Reagent I : Glycine Buffer 100 mmol/l,pH 10, Sodium Azide 0.95 g/L
Reagent II : Latex particles coated with goat IgG anti-human Albumin pH 7.3, Sodium Azide 0.95 g/L
µ Alb-CAL : Microalbumin concn. is stated on the vial label.

### SAMPLES COLLECTION AND PRESERVATION

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.

## 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 1107072.
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.

## REAGENT PREPARATION

**Working reagent:** Shake the latex vial gently before use. Prepare the necessary amount as follow:
2 mL Latex Reagent + 8 mL Diluent

**Microalbumin Calibrator:** Ready for use.

**Working reagent**: Stable for 1 day at 2-8ºC.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

## 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.

| AUTOMATED PARAMETERS | |
|---|---|
| Wavelength | 540 (530-550) nm |
| Cuvette | 1 cm light path |
| Reaction Temperature | 37 ºc |
| Measurement | Against Distilled water |
| Reaction | 2 point kinetics |
| Reaction Direction | Increasing |
| Sample Volume | 10 µl |
| Reagent Volume | 1000 µl |
| Linearity | 150 mg/L |

## ASSAY PROCEDURE

### PIPETTE INTO TEST TUBES

| | CAL | SAMPLE |
|---|---|---|
| **Sample** | - | 10 µl |
| **Standard** | 10 µl | - |
| **Reagent** | 1000 µl | 1000 µl |

Mix well, and read the absorbance immediately A1 and after 2 minutes A2 of the sample addition.

## CALCULATION

$$\text{Micro Alb(mg/L) concentration} = \frac{(A2\text{-}A1)\ \text{Sample}}{(A2\text{-}A1)\ \text{Calibrator}} \times \text{calibrator}$$

## QUALITY CONTROL

To ensure adequate quality control ,Normal and abnormal control with assayed values should be run as unknown samples.

## 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.

## 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 interfere6.

## BIBLIOGRAPHY


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