# MICROALBUMIN TURBILATEX

**IMMUNOPAK**

(Latex Turbidimetric Test)

Last update 09-2020

Ref. IM-MIT.084 1x50 ml

## INTENDED USE

Quantitative determination of Microalbumin (µALB) IVD.

## DIAGNOSTIC 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 be shown 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.

## PRESENTATION

| Store all reagents at 2-8°C | No. of Bottles/ Vials |
|---|---|
| | 1x50 ml |
| • R1 Diluent | 1x45 ml |
| • R2 Latex | 1x5 ml |
| • Micro Albumin Calibrator (60 mg/L) | 1 |

## PRECAUTION

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.

## PREPARATION OF WORKING REAGENT

Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).

## PREPARATION OF WORKING CALIBRATOR

Ready to use.

## REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8°C till the expiry date mentioned on the label.

## WORKING REAGENT

Stable for 1 day at 2-8°C.

**MICROALBUMIN CALIBRATOR**: Calibrator is stable at 2-8°C till the expiry date mention on the label. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

## SPECIMEN COLLECTION

Fresh urine. It is recommended to adjust the pH at 7.0 with NaOH / HCL 1 mol/L. Stable for 7 days at 2-8°C. Urine should be centrifuged before testing.

## REACTION PARAMETERS

| | | |
|---|---|---|
| • Type of Reaction | : | Two Point / Fix Time |
| • Wavelength | : | 540 nm (530-550) |
| • Flow cell temperature | : | 37°C |
| • Sample/Calibrator Volume | : | 7 µl |
| • Reagent Volume | : | 1 ml |
| • Delay time | : | 5 Sec |
| • Interval | : | 120 Sec |
| • Zero setting with | : | Distilled Water |
| • Light Path | : | 1 cm |
| • Calibrator Concentration | : | 60 mg/L |

## TEST PROCEDURE

| Pipette in Test Tube | Test |
|---|---|
| Working Reagent (ml) | 1.0 |
| Calibrator or sample (µl) | 7 |

Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

## TEST RESULT

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

## LIMITATIONS FOR INTERFERENCES

Glucose (<2 g/L), Hemoglobin (<10 g/L), Creatinine (<3 g/L), do not interfere. Urea (≥ 1 g/L) and Bilirubin (≥ 10 mg/dl) interfere. Other substances may interfere.

## QUALITY CONTROL

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

## NORMAL VALUE

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

## PERFORMANCE CHARACTERISTICS

1. **Linearity:** 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. **Sensitivity:** Δ 3.8 mA.mg/L

## NOTE

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

## REFERENCES


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