

# High-Q Microalbumin

## Latex Enhanced Turbidimetric Immuno Assay (LETIA)

### Intended Use:

Quantitative determination of microalbumin ( $\mu$ ALB) in human urine.

### Principle of the method:

Microalbumin-turbid latex is a quantitative turbidimetric test for the measurement of microalbumin ( $\mu$ ALB) in human urine.

Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing  $\mu$ ALB. The agglutination causes an absorbance change, dependent upon the  $\mu$ ALB contents of the patient sample that can be quantified by comparison from a calibrator of known  $\mu$ ALB 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.

### Reagents:

Diluent (R1) Glycine buffer 100 mmol/L, pH 10.0. Preservative.

Latex (R2) Particles coated goat IgG with anti-human albumin, pH 8.2. Preservative

$\mu$ ALB-CAL Liquid Calibrator. Microalbumin concentration is stated on the vial label.

Optional Ref.: 1107073 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:

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 ERM-DA 470K/IFCC. Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

**Preparation:** All the reagents are ready to use and stable till the expiry date mentioned on the label

### 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. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

### Samples:

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 2-8°C when sodium azide 1 g/L is added to prevent contamination. Urine should be centrifuged before testing.

### Quality Control:

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

### Reference Values:

Normal values up to 30 mg/24 hrs urine specimen  
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 (Greater than 1 g/L) and bilirubin (Greater than 10 mg/dL) interfere. Other substances may interfere.

### Test Procedure:

Microalbumin Diluent (R1)	400 $\mu$ l
Urine Sample	10 $\mu$ l
Microalbumin Latex Reagent (R2)	100 $\mu$ l

Mix well and immediately aspirate in to the analyzer. Read absorbances of Calibrator (C) and Test (T) against distilled water at 546 nm (540-550 nm) as follows:

Initial absorbance A1 - exactly after 5 sec.  
Final absorbance A2 - exactly 120 sec after A1  
Determine  $\Delta A$  for Calibrator (C) and Test (T)

### Calculations:

Calculate the average change in absorbance per minute ( $\Delta$  Abs/min).

### Activity of Microalbumin in mg/L at 546 nm

$$\text{Microalbumin in mg/L} = \frac{\Delta \text{Abs of Test}}{\Delta \text{Abs of Calibrator}} \times \text{Calibrator Conc (On the Label)}$$

# High-Q Microalbumin

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

## System Parameters:

Reaction Type	: Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	: Increasing
Sample Volume	: 10 $\mu$ l
Working Reagent Volume	: 0.5 ml
Wave Length	: 546 nm (540-550 nm)
Calibrator Conc.	: Concentration on the label
Flow Cell Temp.	: 37°C
Linearity	: 150
Zero setting with	: Distilled Water
Units	: mg/L
Delay	: 5 sec.
Interval	: 120 sec

## 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:** Delta 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.

**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)<sup>2</sup> was 0.99 and the regression equation  $y = 0,424x + 10,55$ .

The results of the performance characteristics depend on the analyzer used.

## 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.

















## Ordering information:

Ref./Cat. No.	Pack Size	Presentation
P-MALB(T) - 50	50 ml	Two Liquid Reagents with Calibrator

## Product Features

- Quantitative Turbi Latex Assay.
- Two liquid reagents (Turbilatex and Diluent).
- Linearity : 150 mg/L
- Liquid Calibrator provided .
- No Prozone effect was detected upon 1000 mg/L
- Can be used on semi and fully auto analyzers.

## Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry
	Catalog Number		Keep away from rain



Manufactured in India by :  
Pariksha Biotech Pvt Ltd,  
Plot no.1/B-14, SVICE,  
Balanagar,  
Hyderabad-500037  
Telangana State

+91 7075706709

info@parikshabio.com

www.parikshabio.com