

TurbiMAX Microalbumin

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation (R1 / R2 / Cal)
AVMALBT-50	50 ml	(2 x 20 ml / 1 x 10 ml / 1 x 2 ml)

INTENDED USE

TurbiMAX Microalbumin is an in-vitro diagnostic kit for the Quantitative determination of microalbumin (μ ALB) in human urine. This kit is a automated.

INTENDED USER:

Laboratory Technician

PRODUCT FEATURES:

- Quantitative Turbi Latex Assay.
- Two liquid reagents (Turbilatex and Buffer).
- Linearity : 150 mg/L
- Liquid Calibrator provided .

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.

PRINCIPLE

Microalbumin-turbilatex is a quantitative turbidimetric test for the measurement of microalbumin (μ ALB) in human urine. Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing μ ALB. The agglutination causes an absorbance change, dependent upon the μ ALB contents of the patient sample that can be quantified by comparison from a calibrator of known μ ALB concentration.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8°C and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Turbi Latex Reagent R2
3. μ ALB Calibrators : Concentration as stated on the label

COMPOSITION

Buffer Reagent (R1) Glycine buffer 100 mmol/L, pH 10.0. Preservative.
 Latex Reagent (R2) Particles coated goat IgG with anti -human albumin, pH 8.2, Preservative
 μ ALB-CAL Liquid Calibrator. Microalbumin concentration is stated on the vial label. Optional Ref.: 1107073 Microalbumin control

REAGENT RECONSTITUTION & 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.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

- Discard reagent if blank reagent absorbance exceeds 1.3 at 546 nm against distilled water.
- Reagent deterioration: Presence of particles and turbidity. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

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.

SYSTEM PARAMETERS

Reaction Type	:	Fixed Time/InitialRate/TwoPointKinetic
Reaction Direction	:	Increasing
Sample Volume	:	10 μ l
Reagent Volume	:	500 μ l (R1 400 + R2 100)
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

TEST PROCEDURE

Reagent	Calibrator (C)	Test (T)
Reagent (R1)	400 μ l	400 μ l
Calibrator	10 μ l	—
Urine Sample	----	10 μ l
Reagent (R2)	100 μ l	100 μ 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 ΔA for Calibrator (C) and Test (T)

CALCULATIONS

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

Activity of Microalbumin in mg/L at 546 nm

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

QUALITY CONTROL & CALIBRATION

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

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.

EXPECTED 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.

PERFORMANCE CHARACTERISTICS:

1. Linearity

Linearity : 150 mg/L

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 3.8 mg/L

3. 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.

4. Precision: The reagent has been tested for 20 days, using two levels of serum in a EP5-based study (NCCLS).

Intra-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	14.9	0.41	2.75
Control serum 2	45.8	1.32	2.88

Inter-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	15.2	0.46	3.02
Control serum 2	46.8	1.45	3.09

5. Method Comparison:

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)² was 0.99 and the regression equation $y = 0,424x + 10,55$. The results of the performance characteristics depend on the analyzer used.

LIMITATIONS

3.8-150 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.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














NOTES:

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

REFERENCE

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

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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