MICROALBUMIN TURBILATEX

Code	Product Name	Pack Size
SE030A	Microalbumin Turbilatex	50 ml

Quantitative determination of microalbumin (µALB)

INTENDED USE

Microalbumin turbilatex is a quantitative turbidimetric test for the measurement of microalbumin (µALB) in human urine.

PRINCIPLE

Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing µALB. The agglutination causes as 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.

CONTENTS :

Reagent 1 : Microalbumin Diluent
Reagent 2 : Microalbumin Latex
Reagent 3 : Calibrator

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.

PREPARATION OF WORKING REAGENT:

Swirl the latex vial gently before use. Prepare the necessary amount as follows :

1 ml latex reagent + 9 ml Diluent.

Microalbumin Calibrator : Ready for use.

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.

Reagent deterioration : Presence of particles and turbidity.

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

MATERIAL REQUIRED BUT NOT PROVIDED

- Clean & dry Glassware.
- Laboratory Glass pipettes or Micropipettes & Tips.
- Biochemistry Analyzer.

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

GENERAL SYSTEM PARAMETERS

Reaction Type	: Fixed Time
Wavelength	: 540 nm (530-550 nm)
Cuvette Temperature	: 37° C
Delay Time	: 5 Sec.
Read Time	: 120 Sec.
Reagent Volume	: 1000 µl
Sample Volume	: 10 µl
Calibrator Concentration	: As Mentioned on Calibrator Vial
Zero Setting	: Distilled Water
Light Path	: 1 cm.

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PROCEDURE

1. Bring the working reagent and the photometer (cuvette holder) to 37ºC.
2. Assay conditions :
   Wavelength : 546 nm (530-550)
   Temperature : 37ºC
   Cuvette ligth path : 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette :

Working Reagent (mL)	1.0 mL
Calibrator or sample (µL)	10 µl

5. Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition.

CALCULATIONS

$$\frac{(A_2\text{-}A_1)\text{sample}}{(A_2\text{-}A_1)\text{calibrator}} \times \text{Calibrator concentration} = \text{mg/L albumin}$$

QUALITY CONTROL

It is recommended that each laboratory should prepare their own quality Control scheme.

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.

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** : Δ 3.8 mA. mg/L.
5. **Precision** :

	Intra-assay (n=10)			Inter-assay (n=10)		
Mean (mg/L)	12.4	27.3	83.5	12.4	27.3	83.5
SD	0.28	0.40	1.61	0.28	0.56	2.13
CV	2.25	1.48	1.93	2.28	2.06	2.55

INTERFERENCES

Glucose (2 g/L), hemoglobin (10 g/L) and creatinine (3 g/L), do not interfere. Urea (≥1 g/L) and bilirubin (≥10 mg/dL), interfere. Other substances may interfere.

NOTES

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

BIBLIOGRAPHY

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JAS-ANZ BSCIC ISO 9001 : 2015 | BSCIC ISO 13485:2016

SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use
LOT Lot Number | CONT Content | Storage Temperature
Expiry Date | IVD In Vitro Diagnostics

BEA/24/MAB/SE/IFU-02

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