MICROALBUMIN SYSTEM PACK

(Latex Turbidimetry Method)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA272	Microalbumin System Pack	1 x 20 + 1 x 5 ml

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, micro-albuminuria 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 1: Microalbumin Diluent
Reagent 2: Microalbumin latex
Reagent 3: Microalbumin Calibrator
Reagent & Calibrator are liquid, ready to used

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.

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.

On board stability: Min 30 days if refrigerated (+8-+14°C) and not contaminated.

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

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

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 precision Within run (n=20)	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	23.70	1.10	4.66
Inter-assay precision Run to run (n=20)	**Mean (mg/L)**	**SD (mg/L)**	**CV (%)**
Sample 1	27.985	0.53	1.90

Comparison

A comparison between Beacon microalbumin (y) and a commercially available test (x) using 20 samples gave following results :

y = 1.0045x+0.0.1988

r = 0.9995

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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.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100
(Fully Auto Biochemistry Analyzer)

Test Name	MICROALBUMIN TURBILATEX
Full Name	MICROALBUMIN TURBILATEX
Pri Wave	546 nm
Sec Wave	-
Assay/point	Fixed time
Start	18
End	25
Decimal	2
Unit	mg/L
Linearity Range Low	2 mg/L
Linearity Range High	150 mg/L
Sample Volume	2.0 µl
Reagent 1 (R1) Volume	160 µl
Reagent 2 (R2) Volume	40 µl
Substrate Depleted	-
Linearity	150 mg/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator vial label

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

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