

MICROALBUMIN

Cat. No.:	Pack name:	Packaging (Content):
BLT20030	MAL	5 x 25 ml MAL Buffer 1 x 10 ml MAL Antiserum 1 x 1 ml MAL Calibrator
BLT20031	MAL	2 x 25 ml MAL Buffer 1 x 5 ml MAL Antiserum 1 x 1 ml MAL Calibrator



Intended use

Diagnostic reagent for in vitro quantitative determination of Microalbumin (MAL) in human urine by turbidimetric immunoassay.

Diagnostic Implications

Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus. An early sign of diabetic nephropathy are small Albumin secretions in urine, i.e. Microalbuminuria. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

Method

Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided

Buffer

Saline (0.9%)
Accelerator
Sodium azide 0.09 %).

Antiserum

Phosphate buffered saline
Polyclonal goat anti-human Albumin (variable).
Sodium azide (0.09 %).

Calibrator

Dilution of pooled human serum, liquid and stabilized.
Contains 0.09 % sodium azide as preservative.
Concentration : see bottle label

Preparation and Stability of Reagents

Reagent Preparation

Liquid reagents, ready for use.

Stability and Storage

The reagents are stable until expiry date when kept at 2–8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied

Saline (9 g/l NaCl)

Sample collection

Collect urine during 24 hours or as a random midstream sample. If the test can not be carried out on the same day, the urine may be stored at 2–8°C for 48 hours. If stored for a longer period, the sample should be frozen. The use of centrifuged urine is recommended.

Automation

Application procedures on clinical chemistry analyzers are available upon request.
Manual Procedure
Sample/Control: Ready for use

Reference curve: Generate a reference curve by successive 1:2 dilutions of Microalbumin calibrator in saline or use the ready for use calibrator set.
Use saline as zero point.

Test: Mix 60 µl of calibrators, control(s) and samples with 900 µl of MAL buffer.
Read optical density (OD1) of calibrators, controls and samples at 340 nm. Add 150 µl of antiserum. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of calibrators, controls and samples at 340 nm.
Calculate µOD's, plot a calibrator curve and read the concentration of controls and samples.

Reference Values

0–25 mg/l (IFCC)

This range is given for orientation only. Each laboratory should establish its own reference values.

Performances

The performance characteristics for the Microalbumin reagents were measured on a clinical chemistry analyzer (Hitachi 911).

Measuring Range: 0–400 mg/l

Detection Limit: 0.7 mg/l

Hook Effect: > 6000 mg/l

Sensitivity: 28.5 ABS units / concentration unit

Precision:
[%CV]

	Low	Medium	High
Intra-Run	0.91	0.88	1.52
Inter-Run	2.93	0.66	0.53

Accuracy:
[mg/l]

Control	Assigned	Measured	High
ERBA	196 (166–225)	196.7	1.52
Beckmann	21.5 (18–25)	22.5	0.53

Specificity : Monospecific

Interferences :

No interference for Heparin (50 mg/dl), Na Citrate (1000 mg/dl), Triglyceride (2500 mg/dl), EDTA (5 mg/dl) and Hemoglobin (1000 mg/dl). Bilirubin (> 15 mg/dl) and Turbidity (> 0.63 %) interfere with the test.

Limitations : None

Comparison with Nephelometry: $y = 1.0096 x - 0.2344$ / $r = 0.9978$

Precautions and warnings

- In vitro diagnostic Use only.
- Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
- Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

Also available Calibrators and Controls

Cat. No.	Product name	Pack name	Content
BLT20032	MAL CALIBRATOR	MAL CAL	1 x 1 ml
BLT20033	MAL CONTROL	MAL CON	1 x 1 ml

References

- Mount, J.N., J. Clin. Pathology, 22, 12 (1986)
- Schmidtz, A., et al., Diabetic Medicine, 5, 126 (1988)

Used symbols

Lot Number

In vitro Diagnostics

Catalogue Number

See Instruction for Use

Expiry date

Storage Temperature

Manufacturer

Content