INTENDED USE
Diagnostic reagent for quantitative in vitro determination of microalbumin in urine.

CLINICAL SIGNIFICANCE
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.

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

REAGENT COMPOSITION
R1 (Buffer)
Saline (0.9%)
Accelerator
Sodium azide (0.09 %)
R2 (Antiserum)
Phosphate buffered saline
Polyclonal goat anti-human Albumin (variable).
Sodium azide (0.09 %).

REAGENT PREPARATION
Reagents are liquid, ready to 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.

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.

MATERIALS REQUIRED BUT NOT PROVIDED
- Any instrument with temperature control of 37 ± 0.5 °C that is capable of reading absorbance accurately at 340 nm may be used.
- Analysers specific consumables such as sample cups.
- Controls.
- Saline (9 g/l NaCl)

ASSAY PROCEDURE
Refer to the assay parameters for details.

CALIBRATION
Blank: Saline

Calibration curve: generate a 6 point calibration curve by diluting the calibrator 1:32, 1:16, 1:8, 1:4, 1:2 and undiluted in saline.

Quality Control

Quality control: Not necessary.

Results are calculated automatically by the instrument.

EXPECTED VALUES

0 – 25 mg/l (IFCC)

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

PERFORMANCE DATA

Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Detection limit: 0.57 mg/l
Measuring Range: 0.57 – 550 mg/l
Hook Effect: > 6000 mg/l

Intra-assay precision

<table>
<thead>
<tr>
<th>Mean (mg/l)</th>
<th>SD (mg/l)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>171</td>
<td>2.50</td>
</tr>
<tr>
<td>Sample 2</td>
<td>68.5</td>
<td>1.59</td>
</tr>
</tbody>
</table>

Inter-assay precision

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<thead>
<tr>
<th>Mean (mg/l)</th>
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</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>133.0</td>
<td>3.70</td>
</tr>
<tr>
<td>Sample 2</td>
<td>29.75</td>
<td>1.24</td>
</tr>
</tbody>
</table>

COMPARISON

A comparison between XL-Systems MAL (y) and a commercially available test (x) using 40 samples gave following results:

y = 0.984 x - 0.19 mg/l
r = 0.998

Specificity: Monospecific
Interferences: No interference for: Heparin (50 mg/dl), Na-citrate (1000 mg/dl), Hemoglobin (1000 mg/dl), Bilirubin (>15 mg/dl), Triglyceride (2500 mg/dl), EDTA (5 mg/dl), Turbidity (>0.63%) interfere with the test.

Stability at 4°C: At least 3 years after production

WARNING AND PRECAUTIONS
1. For in vitro diagnostic use. To be handled by entitled and professionally educated person.

2. 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.

3. Each donor unit used in the preparation of the standards 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.

WASTE MANAGEMENT
Please refer to local legal requirements.

REFERENCES