**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%)
  - Acccelerator
  - Sodium azide 0.09 %
  - Phosphate buffered saline
  - Polyclonal goat anti-human Albumin (variable).
- **Calibrator**
  - Dilution of pooled human serum, liquid and stabilized.
  - Contains 0.09 % sodium azide as preservative.
  - Concentration : see bottle label
- **Antiserum**
  - Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
  - 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.

**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.

**References**

**Limitations**
None

**Comparison with Nephelometry**
\[ y = 1.0096 \times 0.2344 / r = 0.9978 \]

**Precautions and warnings**
1. In vitro diagnostic Use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. 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**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Product name</th>
<th>Pack name</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLT20032</td>
<td>MAL CALIBRATOR</td>
<td>MAL CAL</td>
<td>1 x 1 ml</td>
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<tr>
<td>BLT20033</td>
<td>MAL CONTROL</td>
<td>MAL CON</td>
<td>1 x 1 ml</td>
</tr>
</tbody>
</table>

**Used symbols**

- **LOT** Lot Number
- **REF** Catalogue Number
- **IVD** In vitro Diagnostics
- **CONT** Content