Clinical Significance
Increased albumin excretion detectable only by sensitive immunoassay (microalbuminuria) has been used for some years as a predictor of incipient nephropathy and cardiovascular disease in diabetic patients. Microalbuminuria has also been associated with hypertension and increased risk of cardiovascular disease in non-diabetic patients. Microalbuminuria occurs in response to acute inflammatory conditions such as ischemia, trauma, and thermal injury, surgery, pancreatitis, and inflammatory bowel disease. In many of these conditions albumin excretion increases within minutes or hours of the initiating stimulus and only last for 24 to 72 h. The degree of microalbuminuria is proportional to the severity of the inflammatory insult, is predictive of outcome, and is not associated with any other features of renal impairment.

Conventional dip-stick and acid precipitation tests for detecting protein in urine lack the sensitivity required to delineate this condition. Dip-stick may yield negative or trace results even when the albumin excretion rate is 10 or 20 times normal; and the rate must increase to 200 or 300 micrograms per minute (μg/min) before nephropathy becomes clinically apparent as persistent proteinuria. Interest in measuring subclinical elevations in the albumin excretion rate has focused on individuals with an already established diagnosis of diabetes or essential hypertension. Providing proper care is taken to minimize the influence of exercise and poor metabolic control of diabetes or essential hypertension. The MAU latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

Principle
MAU test is based upon the reactions between albumin and latex-covalently bound antibodies against human albumin. MAU values are determined photometrically.

Reagents

<table>
<thead>
<tr>
<th>Buffer (R1)</th>
<th>Latex (R2)</th>
<th>MAU-CAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphate buffer, pH: 7.2, &lt; 0.1 % sodium azide as preservative.</td>
<td>Suspension of latex micro particles covalently bound anti-albumin antibodies suspended in a neutral aqueous solution, and &lt; 0.1 % sodium azide as preservative.</td>
<td>Calibrator. Human - based reference fluid. Preservative: sodium azide, 0.075 %. MAU concentration is stated on the vial label.</td>
</tr>
</tbody>
</table>

Precautions
All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases.

Calibration
Analytical Range up to 250 mg/L.

<table>
<thead>
<tr>
<th>Calibrator 1</th>
<th>100 μL of MAU Calibrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrator 2</td>
<td>100 μL of Calibrator 1 + 100 μL of Saline Solution</td>
</tr>
<tr>
<td>Calibrator 3</td>
<td>100 μL of Calibrator 2 + 100 μL of Saline Solution</td>
</tr>
<tr>
<td>Calibrator 4</td>
<td>100 μL of Calibrator 3 + 100 μL of Saline Solution</td>
</tr>
<tr>
<td>Calibrator 5</td>
<td>100 μL of Calibrator 4 + 100 μL of Saline Solution</td>
</tr>
<tr>
<td>Calibrator 6</td>
<td>100 μL of Saline Solution</td>
</tr>
</tbody>
</table>

(*) See values on the label or on the insert. Multiply by the appropriate factor.

For quality control use a suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Preparation
Working Reagent is prepared with 1 part of Latex Reagent and 9 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake the reagents gently before Pipetting.

Storage and Stability
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at 2 - 8°C. Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at 2 - 8°C after use. Do not freeze reagents.

Materials Required but not Provided
- Thermostatic bath at 37°C
- Spectrophotometer or photometer thermostable at 37°C with a 600 nm filter.

Specimen and Stability
Use 12 or 24 hour collection. Centrifuge urine specimens. Screen these specimens using an albumin test strip. If the result is negative (approx. below 300 mg/L), analyze the specimens undiluted. If the result is positive, dilute the specimen with saline solution below 250 mg/L.

Assay Procedure
1. Assay conditions:
   Wavelength: ................. ................. 600 nm
   Cuvette: ................. ................. 1 cm light path
   Constant temperature ................. 37°C
2. Bring the working reagent and the photometer (cuvette holder) to 37°C.
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette: Working Reagent (μL) 500
   Calibrator or sample (μL) 5
5. Mix and read the absorbance immediately (A1) and after 4 minutes (A2) of the sample addition.

Application sheets for automated systems are available on request.

Calculations

(A2-A1)sample X Calibrator concentration = mg/L MAU

(A2-A1)calibrator

Quality Control
Control sera are recommended to monitor the performance of manual and automated assay procedures.

Serum controls are recommended for internal quality control. Each laboratory should establish its own quality control scheme and corrective actions.

Reference Values
Normal values up to 30 mg/24 hrs urine specimen and 20 mg/L in a first morning urine specimen.

These values are for orientation purpose. Each laboratory should establish its own reference range.
Reagent Performance.
1. Linearity limit: The range interval for the multipoint calibration method is from 0 to 250 mg/L. When values exceed the range the samples should be diluted with saline solution and the result should be multiplied by the appropriated factor.
2. Sensitivity: Calculating the mean plus 3SD of twenty replicates of zero standards resulted in a lower limit of detection less than 5 mg/L.
3. Prozone Effect: The system did not show prozone phenomenon at least up to 400 mg/L.
4. Assay Precision: Intra-assay coefficients of variation (CV) for three samples (MAU values ranging from 30 to 150 mg/L) were between 1.9 and 3.7 %. Inter-assay CVs were between 2.4 and 4.5 %.
5. Method comparison: 70 samples were correlated with a commercial procedure. When comparing the results by linear regression the result was: \( y = 0.96 \times + 4.1 \) and \( r = 0.981 \)

Analytical characteristics have been obtained in a single experiment in a conventional spectrophotometer. Therefore, the data expressed in the present document should be interpreted as a guide example.

Test parameters

<table>
<thead>
<tr>
<th>SYSTEM PARAMETERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
</tr>
<tr>
<td>Reaction</td>
</tr>
<tr>
<td>Wavelength</td>
</tr>
<tr>
<td>Calibrator</td>
</tr>
<tr>
<td>Unit</td>
</tr>
<tr>
<td>Linearity</td>
</tr>
<tr>
<td>Reagent</td>
</tr>
<tr>
<td>Sample</td>
</tr>
<tr>
<td>Delay Time</td>
</tr>
<tr>
<td>Read Time</td>
</tr>
</tbody>
</table>

EURO Diagnostic Systems Microalbumin Calibrator

Intended use
The Micralbumin calibrator is used for making the calibration curve.

Summary
Liquid calibrator. This product has been standardized against the CRM 470 international standard.

Reagent: contents and concentrations
Reactive components: albumin (human).
Additives: stabilizers, preservatives. This product is supplied in vials with 1 ml. The concentration is lot-specific.

Precautions and warnings
For in vitro diagnostic use.
This product has been prepared exclusively from the blood of donors tested individually and found by FDA approved methods to be free from HbsAg and antibodies to HIV and HCV. However, as no testing method can rule out the risk of potential infection with certainty, the product must be handles just as carefully as patient specimens. In the event of exposure the directives of the responsible health authorities should be followed.

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

Only for in vitro use in Clinical laboratory (IVD)

Literature

Manufactured by: Biolatex, S.A.
Marketed By: EURO Diagnostic Systems Pvt. Ltd.,
Millennium House, M.K.Srinivasan Nagar Main Road,
No. 144, Old Mahabalipuram Road, Perungudi, Chennai - 600 096; Email: eurods@vsnl.net, www.eurods.in

<table>
<thead>
<tr>
<th>Lot</th>
<th>Expire Date</th>
<th>Concentration</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>3149A/1</td>
<td>2014/05</td>
<td>60</td>
<td>mg/L</td>
</tr>
</tbody>
</table>