**MICROALBUMIN (MAU) Mono-Reagent Procedure**

**Intended Use**
In vitro diagnostic reagents for the quantitative determination of Microalbumin (MAU) in urine by means of particle-enhanced turbidimetric immunoassay in clinical chemistry analyzers.

**Background**
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 ischaemia, 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 to 20 times normal; and the rate must increase to 200 or 300 micrograms per minute (mg/min) before nephropathy becomes clinically apparent as persistent proteinuria. Interest in measuring subclinical elevations of albumin excretion rate has focused on individuals with an already established diagnosis of diabetes or essential hypertension. Providing proper care is taken to minimise the influence of exercise insult, is predictive of outcome, and is not associated with any other features of renal impairment.

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

**Reagents**
- **Buffer**
  phosphate buffer, pH: 8.5, < 0.1 % sodium azide as preservative.
- **Latex reagent**
  a suspension of latex microparticles covalently bound anti-albumin antibodies suspended in a neutral aqueous solution, and < 0.1 % sodium azide as preservative.
- **Dilution Buffer**
  TRIS with 0.1% gelatine, pH: 7.0. Preservative: sodium azide < 0.1%
- **Calibrator**
  Human - based reference fluid. Preservative: sodium azide, 0.075 %.
  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.

**Precautions and Warnings**
For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

**As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.**

**Material Required**
Spectrophotometric analyser. Controls.

**Storage and Stability**
Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC). 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 ºC) after use. Do not freeze reagents. The MAU latex reagent should have a white, turbid appearance free of granular particulates. Visual agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded. The MAU buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded. WR is stable for up to two weeks at 4º C. It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

**Specimen Collection and Preparation**
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), analyse the specimens undiluted. If the result is positive, dilute the specimen with specific protein sample diluent to obtain a concentration below 250 mg/L.

**Reagent 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 gently the reagents before pipetting.

**Procedure**
- **Wavelength**
  600 nm
- **Temperature**
  37º C
- **Cuvette**
  1 cm light path
- **Measurement against distilled water blank.**
- **Bring the reagents at 37º C and pipette:**

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>Sample</th>
<th>Blank</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample</td>
<td>3 µL</td>
<td></td>
</tr>
<tr>
<td>Distilled Water</td>
<td>3 µL</td>
<td></td>
</tr>
<tr>
<td>Work. Reagent</td>
<td>500 µL</td>
<td>500 µL</td>
</tr>
</tbody>
</table>

**Mix and measure absorbance immediately (A1) incubate 4 min (37º C), after incubation read absorbance (A2).**

**Calculation**
Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If A1 is one point calibration:

\[
\text{mg/L (MAU) = } \frac{A_2-A_1}{A_2-A_0} \times \text{Calibrator concentration}
\]

**Batch Code/Lot number**
**Temperature Limitation**
**For in-vitro diagnostic use**
**Use by/Expiration Date**
**CAUTION. Consult instructions for use**
**Manufactured by**

**SYMBOLS IN PRODUCT LABELLING**
**For conversion to µg/min:**

\[
\text{µg/min (Microalbumin)} = \frac{\text{µg Microalbumin in 24hrs Urine}}{1440}
\]

where 1440 = 24 x 60 (minutes / day)

**example:**

- If 24hrs urine is 1.8 L (1800 ml)
- Microalbumin concentration is 15 mg/L

Microalbumin Concentration in µg/day = 15 x 1000 x 1.8 = 27000 µg

*where 1000 is to convert from mg/L to µg/L

1.8 is the volume of 24hrs Urine.

\[
\text{µg/min (Microalbumin)} = \frac{27000}{1440} = 18.7
\]

**Linearity**

Up to 250 mg/L

**Calibration and Quality Control**

<table>
<thead>
<tr>
<th>Calibrator 1</th>
<th>100 µl of Spectrum 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 Saline Solution</td>
</tr>
</tbody>
</table>

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

For quality control use Spectrum Control or other 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.

**Expected Values**

For 24hrs Urine: Up to 20 µg/min.

These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

**References**

Winocour PH. Microalbuminuria Bmi 1992;1 304:1196-7


Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224