INTENDED USE

The TRUEchemie Microalbumin Inmunoturbidimetric assay is a quantitative turbidimetric test for the measurement of Microalbumin in human Urine.

INTRODUCTION

Microalbuminuria is defined as excretion of albumin between 20 and 200 micrograms/L. Persistent microalbuminuria indicates a high probability of damage to the glomerular filtration capacity of the kidney and is of great diagnostic relevance: (a) in diabetes, for early diagnosis of diabetic nephropathy; (b) in patients with hypertension, as an indicator of end-organ damage associated with a lowered life expectancy; (c) in pregnancy, as a possible predictor of developing pre-eclampsia. For screening, a concentration of 20-200 mg/L of albumin in the first morning urine has been proven to be a suitable indicator.

PRINCIPLE

Latex particles coated with specific antibodies anti-human albumin are agglutinated when mixed with samples containing Microalbumin (µALB). The agglutination causes an absorbance change, dependent upon the µALB contents of the patient sample that can be quantified by comparison from a calibrator of known µALB concentration.

PACK SIZE

<table>
<thead>
<tr>
<th>Kit Size</th>
<th>25 mL</th>
<th>50 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat No.</td>
<td>ADX931</td>
<td>ADX932</td>
</tr>
<tr>
<td>Kit Contents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microalbumin Reagent (R1)</td>
<td>1 x 20 mL</td>
<td>1 x 40 mL</td>
</tr>
<tr>
<td>Microalbumin Buffer Reagent (R2)</td>
<td>1 x 5 mL</td>
<td>1 x 10 mL</td>
</tr>
<tr>
<td>Microalbumin Calibrator</td>
<td>1 x 0.5 mL</td>
<td>1 x 0.5 mL</td>
</tr>
</tbody>
</table>

REAGENT COMPOSITION

| Microalbumin Reagent (R1) | Glycine buffer 100 mM, pH 10.0, Preservative |
| Microalbumin Buffer Reagent (R2) | Latex particles coated with goat IgG, antihuman Albumin, pH 8.2, Preservative |
| Microalbumin Calibrator | Microalbumin concentration is as stated in vial |

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 °C and contaminations are prevented during their use. Do not use reagents over the expiration date. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

Working reagent: Stable for 30 days at 2-8 °C. Microalbumin Calibrator: Stable till expiry when stored at 2-8 °C.

REAGENT PREPARATION

Ready to use reagents.

SAMPLE / SPECIMEN AND STORAGE

Fresh Urine. It is recommended to adjust the pH at 7.0 with NaOH/HCL (1 mol/L). Stable 7 days at 2-8 °C when sodium azide 1 g/L is added to prevent contamination. Urine should be centrifuged before testing.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Handle cautiously as potentially infectious.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/tack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of measuring absorbance at 540 nm filter

TEST PROCEDURE

Wavelength: 540 nm
Temperature: 37 °C
Cuvette light path: 1 cm
Prewarm the reagents to reaction temperature

<table>
<thead>
<tr>
<th></th>
<th>Blank (mL)</th>
<th>Calibrator (mL)</th>
<th>Sample (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distilled water</td>
<td>1.000</td>
<td>0.800</td>
<td>0.800</td>
</tr>
<tr>
<td>Microalbumin Reagent (R1)</td>
<td>-</td>
<td>0.200</td>
<td>0.200</td>
</tr>
<tr>
<td>Microalbumin Buffer Reagent (R2)</td>
<td>-</td>
<td>0.010</td>
<td>-</td>
</tr>
<tr>
<td>Microalbumin Calibrator</td>
<td>-</td>
<td>-</td>
<td>0.010</td>
</tr>
<tr>
<td>Sample</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Normal range: up to 15 mg/L

Calibrations:

Urine Microalbumin(mg/L) = ────────────────────────────────────────── x Calibrator concentration (mg/L)

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

Normal Values: Up To 15 mg/L. Each laboratory should establish its own reference

CALIBRATION

TRUEchemie Microalbumin calibrator is ready to use. Calibrate with each bottle change or lot change or if control results are found to be out of range.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

LIMITATIONS

Linearity limit: Up to 150 mg/L. Under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/l and retested again. The linearity limit depends on the sample reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Detection limit: Values less than 2 mg/L give non-reproducible results.

Prozone effect: No prozone effect was detected upon 1000 mg/L

INTERFERENCES

Glucose (2 g/L), hemoglobin (10 g/L) and creatinine (3 g/L) do not interfere. Urea (≥ 1 g/L) and bilirubin (≥ 10 mg/dL) interfere. Other substances may interfere

SYSTEMS PARAMETERS

Mode: Fixed kinetic
Calibrator concentration: As stated on vial
Wave length: 540 nm
Units: mg/L
Flow cell Temp: 37 °C
Blank: Distilled water
Reagent volume(mL): 1.000
Sample volume(mL): 0.010
Delay time: 10 Sec
Read time: 120 Sec
Normal range: up to 15 mg/L

REFERENCES


Index of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic</td>
</tr>
<tr>
<td>EC REP</td>
<td>Economic Referential</td>
</tr>
</tbody>
</table>

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