


"URIN-PAK" Immunoturbidimetric Method Evaluated for Measuring Albumin in Urine, Angela S. Linton and David J. F. Rowe (Dept. of Chem. Pathol., The General Hospital, Southampton S09 4XY, U.K.)

"URIN-PAK" (Miles Laboratories Ltd., Stoke Poges, Slough SL2 4LY, U.K.) measures low concentrations of albumin in human urine by immunoturbidimetry, and thus can detect early increases in albumin excretion in diabetes. We evaluated the kit according to the manufacturer's instructions, except for changing the sample volume from 24 μL to 36 μL and increasing the reaction temperature to 30 °C, comparing results with those by an in-house immunoturbidimetric method (1). For both methods we used an IL Multistat III centrifugal analyzer. Three concentrations of quality-control samples were analyzed with each batch of samples.

Evaluation protocol:
1. Within- and between-batch precision data.
2. 100 patients' samples assayed by both methods.
3. Measurement of antigen excess limits with URIN-PAK.
4. Maximum-absorbance data for standards, with use of URIN-PAK vs in-house (Dako) antibody.

Within-batch

<table>
<thead>
<tr>
<th></th>
<th>Ames in-house</th>
<th>Between-batch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (15 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 14</td>
<td>n = 18</td>
<td>n = 16</td>
</tr>
<tr>
<td>x = 15.2</td>
<td>x = 17.1</td>
<td>x = 14.9</td>
</tr>
<tr>
<td>CV 1.02%</td>
<td>CV 1.88%</td>
<td>CV 2.48%</td>
</tr>
<tr>
<td>Medium (30 mmol/L)</td>
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<tr>
<td>n = 14</td>
<td>n = 18</td>
<td>n = 16</td>
</tr>
<tr>
<td>x = 30.5</td>
<td>x = 33.9</td>
<td>x = 32.9</td>
</tr>
<tr>
<td>CV 1.83%</td>
<td>CV 2.79%</td>
<td>CV 3.24%</td>
</tr>
<tr>
<td>High (60 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 18</td>
<td>n = 11</td>
<td>n = 15</td>
</tr>
<tr>
<td>x = 73.6</td>
<td>x = 65.8</td>
<td>x = 67.2</td>
</tr>
<tr>
<td>CV 1.03%</td>
<td>CV 0.99%</td>
<td>CV 1.78%</td>
</tr>
</tbody>
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2. There was a close correlation (r = 0.97) and little bias between the methods; mean urinary albumin concentration = 23.7 and 23.6 mg/L (URIN-PAK and in-house method, respectively).

3. Antigen excess (URIN-PAK) appeared at 200 mg/L.

4. Five and 10 mg/L URIN-PAK standards showed low reaction absorbances, whereas at higher albumin concentrations URIN-PAK produced greater net absorbances than did the in-house method (ΔA at 40 mg/L = 0.21 and 0.11, at 80 mg/L = 0.30 and 0.18, respectively).

The Ames URIN-PAK immunoturbidimetric albumin method thus correlated closely with an in-house method.

URIN-PAK performed with greater precision, perhaps related to the larger sample volume and to greater antibody avidity. A major disadvantage of URIN-PAK was that, in the Multistat III analyzer, a third of the assays gave no measurable reaction absorbance at 5 mg/L, preventing automatic calculation of results. This would need correcting before routine use with the Multistat III.

Reference


"Microbumintest" (Ames Division, Miles Laboratories Limited, Stoke Poges, Slough SL2 4LY, U.K.) is a qualitative tablet test for measurement of protein in urine, particularly for diabetes screening to detect "microalbuminuria," which predicts progression to diabetic nephropathy and renal failure (1, 2).

We assessed Microbumintest to determine its ease of use, its correlation with quantitative measurements of total protein and albumin, and its sensitivity and specificity in detecting albuminuria at a cutoff of 40 mg/L. We assessed it against a three-point reference chart: negative, 1+ positive, and 2+ positive. A negative result is stated to predict, >98% of the time, the presence of <120 mg of protein or <40 mg of albumin per liter.

We used 89 urine samples from diabetic patients, assessing them by Microbumintest, by quantitative tests for total protein (benzethonium chloride) and albumin (immunoturbidimetry) (3), and by Ames' "Multistix" for protein, relative density (specific gravity), and pH.

We found Microbumintest easy to use, and we could easily distinguish between a negative, 1+ positive, 2+ positive result—denoted 1, 2, and 3, respectively, in Figure 1, which shows comparative results for total protein and albumin. There was no correlation between Microbumintest results and Ames' "Microbumintest" Evaluated, and Its Correlation with Total Protein and Albumin Concentration in Urine, Angela S. Linton and David J. F. Rowe (Dept. of Chem. Pathol., The General Hospital, Southampton S09 4XY, U.K.)

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and urinary pH, which was between pH 5 and 8 for all samples. There was a weak positive correlation with urine specific gravity ($P < 0.05$). The predictive value of a negative Microbumintest result for urine albumin $>40$ mg/L was 90%, and that of a positive result (1+ or 2+) was 72%.

There was poorer sensitivity and specificity between a Microbumintest result and total protein concentration in urine than was the case for urinary albumin. Microbumintest is sensitive enough to operate with a urinary albumin concentration cutoff of 40 mg/L but with a considerable lack of specificity as compared with quantitative urinary albumin measurement.

We stress that the clinical significance of all such screening tests is diminished by the absence of any correction for urine-concentration differences.

References

Ward Level Evaluation of the “One Touch” Glucose Meter, Michael L. Leroux and P. R. E. Desjardins (Dept. of Clin. Chem., Health Sciences Centre, 820 Sherbrook St., Winnipeg, Manitoba, Canada R3A 1R9)

Glucose meters are now widely used in hospitals for monitoring blood glucose at the bedside. The precision and accuracy of these meters are affected by several factors, including the time the blood remains on the test strip (1). We evaluated a new meter, the “One Touch” (LifeScan, Mountain View, CA 94043), that initiates the reaction timing automatically when the blood sample is applied and requires no test-stripe wiping after the reaction is complete.

Blood glucose was measured in an adult outpatient diabetic clinic and a neonatal intensive-care unit with two glucose meters, the “One Touch” and the “Reflocheck” (Boehringer-Mannheim, Montreal, Quebec, Canada). An aliquot of each blood sample tested was sent to the laboratory, and serum glucose was measured in an Astra 8 (Beckman Instruments, Clinical Instruments Division, Brea, CA 92621), which measures glucose kinetically by use of glucose oxidase and an oxygen-sensitive electrode. Results from each meter were compared with the Astra 8 result (Figure 1). Linear regression and least squares analysis showed the correlation to be good for each meter. In our Centre, blood glucose results determined by glucose meter are clinically acceptable if they are within $\pm 0.5$ mmol/L of the serum glucose determined with the Astra 8 for serum glucose $<3.0$ mmol/L, within $\pm 1.0$ mmol/L for serum glucose 3.0 to 10.0 mmol/L, and within $\pm 2.0$ mmol/L (whichever is greater) for serum glucose $>10.0$ mmol/L. Evaluation of the individual blood glucose results determined by each meter against these criteria showed that eight and fifteen of the 51 results obtained with the Reflocheck and One Touch meter, respectively, were unacceptable.

Reference

Use of Patients’ Data to Control $\alpha$-Fetoprotein Assays When Screening for Neural Tube Defects, D. A. Hulin,$^*$ D. R. Hobbs, and J. S. Woodhead (Dept. of Med. Biochem., University Hospital of Wales, Cardiff, CF4 4XN, U.K.$^*$ Present address: Dept. of Biochem., East Glamorgan General Hospital, Pontypridd, CF38 1AB, U.K.; address for correspondence)

Laboratories that screen maternal serum for $\alpha$-fetoprotein (MS-AFP) to detect neural tube defects (NTD) (1) need to ensure that no NTDs are missed that should have been detected and, at the same time, that no unnecessary amniocenteses are carried out. Analytical accuracy is therefore crucial, and any shift in bias must be identified and correct-