

# Evaluation of Aution Max AX-4280 Automated Urine Test-Strip Analyser

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**Aution Max AX-4280, an automated urine test-strip analyser, was evaluated in three centres. Method comparison, imprecision, carry-over, linearity, detection limit and drift studies were performed for glucose, protein, blood and leukocytes using Uriflet S 9UB strips. These strips enable measurement of pH, glucose, protein, blood, leukocytes, ketones, bilirubin, urobilinogen and nitrite. Specific gravity is determined by the refractive index method. Within-run and between-day imprecision, assessed using pooled urines and quality control materials, were good. No drift over 24 h or sample carry-over was observed. Method comparison with quantitative methods for glucose, protein and specific gravity yielded good correlations. Ascorbate negatively interfered with haemoglobin, glucose and nitrite measurements. Acetylsalicylic acid lowered pH, the effect being greatest when protein was absent. During the assessment period no malfunction or breakdown was reported. The Aution Max is easy to use and needs minimal maintenance.**

*Key words:* Automated urine test-strip analyser; Aution Max; Multicentre evaluation; Uriflet S; Urine test-strips.

*Abbreviations:* AM, Aution Max; CV, coefficient of variation, Hb, haemoglobin, IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; NCCLS, National Committee for Clinical Laboratory Standards; RBC, red blood cells; SG, specific gravity; WBC, white blood cells.

## Introduction

Aution Max AX-4280 (AM) is a recently introduced automated urine test-strip analyser. Like its predecessor, Super Aution SA 4220 (1), AM also uses the Uriflet S urine test-strips. However, it differs from Super Aution in some important respects (Table 1). One of these is that instead of dipping the test-strip into urine, the latter is pipetted on to the strip pads. This change in sampling mechanism brings with it the risk of sample carry-over.

The aim of this multicentre study was to evaluate the

technical and analytical performance and practicability characteristics of the analyser.

## Materials and Methods

The Aution Max AX-4280 (A. Menarini Dignostics, Florence, Italy) is largely similar to Super Aution (1). The differences between the two analysers are shown in Table 1. The principles of the methods used in analysis and the parameters determined by means of Uriflet S urine test-strip have already been described (1).

### Specimens

Patients' urines used in this study were selected from those sent to the laboratories for clinical reasons. Sample collection and handling were according to the National Committee for Clinical Laboratory Standards (NCCLS) protocol (2).

### Reagents

The same lots of calibrators, quality control materials (Aution Check I and II), test-strip and reagents (all from Menarini Diagnostics) were used by all the evaluators.

### Evaluation protocols

After the initial familiarisation period of 2 weeks, within-run precision was assessed by analysing 20 aliquots of normal and pathological urine pools in duplicate. For between-day precision, Aution Check I and II were analysed in duplicate for 20 days. In both cases the NCCLS procedures (3) were followed. Method comparisons (4), linearity (5), detection limits (6) and sample carry-over (7) tests were performed for glucose, protein, haemoglobin (erythrocytes) and leukocyte esterase (leukocytes). However, for calculating the detection limits and confirmation limits, the definitions suggested in the European Urinalysis Guide (8) were adopted. The NCCLS protocol (9) was also followed for studying analytical interference of acetylsalicylic acid, ascorbate,  $\beta$ -lactam antibiotics, nitrofurantoin and clavulanic acid. Maximum urinary concentrations of the antibiotics were obtained from Lorian (10). Drift in analytical results of all the test-strip parameters were determined

**Tab. 1** Differences between Aution Max (AM) and Super Aution (SA) analysers.

	AM	SA
Sample application	Pipetted	Strip dipped into urine
Wave lengths used (nm)	430, 500, 565, 635, 760	565, 635, 760
Sample throughput per h	225	300
Data memory (tests)	1000	500
Minimum sample volume	2 ml	10 ml

in two ways: freshly reconstituted Aution Check I and II were analysed every 2 h for 8 h in two laboratories and for 24 h in one laboratory; pools of Aution Check I and II were aliquoted in 2 x 13 tubes, refrigerated and measured every 2 h for 24 h.

#### *Interpretation of the results*

Urine test-strip analysis generates discrete semi-quantitative data. Such data cannot be analysed by standard statistical methods used for quantitative measurements. In this work, for method comparison we have adapted the approach recommended by the IFCC (11). The results are illustrated graphically as box-whisker plots with cumulative response (log scale) for each of the quantitative results (ordinate) and each set-point (abscissa). For the precision, we used the criterion described by Haeckel *et al.* (12) in which imprecision is represented as percent repeatability of each set-point.

#### *Method comparisons with patients' samples*

Glucose was measured quantitatively by hexokinase/glucose-6-phosphate dehydrogenase method and protein by benzethonium chloride method on Roche/Hitachi 917 (Roche Diagnostics, Mannheim, Germany). In one centre, protein was assayed by the pyrogallol method on DAX 48 analyser (Bayer, Leverkusen, Germany). Erythrocytes/ $\mu\text{l}$  and leukocytes/ $\mu\text{l}$  were counted under a microscope (400 x magnification), using Uriglass counting chamber (Menarini Diagnostics) and on Sysmex UF-100 urine flow cytometer (Merck Eurolab, Belgium). The comparison analysers for urine test-strips were the Clinitek 200 and Atlas (Bayer, Leverkusen, Germany), and for specific gravity a manual refractometer (Atago Co. Ltd, Japan).

Haemoglobin (13) in urine was determined spectrophotometrically, and lipase used as a surrogate leucoesterase, was measured by the Sigma lipase kinetic enzymatic method (Sigma-Aldrich Co., Bornem, Belgium) on Roche/Hitachi 917.

#### *Practicability assessment*

The practicability characteristics (14) of the AM analyser were compared with the current situation in the participating centres by means of a detailed questionnaire about the laboratory facilities and resources needed, type and volume of reagents required, safety, skills and training necessary, sample processing, workflow, type and frequency of calibration and quality control, maintenance and troubleshooting. The answers were graded 1–10. A score of 0–3 meant that the analyser in question was worse than the present situation, 4–5 indicated that the new analyser was similar to the current situation and 6–10 showed that AM was better than the comparison analyser.

#### *Data analysis*

Data were processed using Analyse-it computer package (Analyse-it, Leeds, UK).

## **Results**

### *Imprecision*

A set-point on the parameter scale of the Uriflet S urine test-strip is not an exact concentration but a range of concentrations with borderline concentrations at each end of the range (12). Each set-point of the Uriflet S test-strip, therefore, represents a semi-quantitative result. Imprecision of these semi-quantitative results cannot be described as standard deviation, nor would

observing an agreement with another procedure yield meaningful results. However, imprecision may be determined as a percent repeatability of set-points (12). Optimally, each set-point would yield 100% repeatability except where the sample concentration corresponds to a borderline concentration. In the latter situation, the agreement between the results would not be 100%. Instead, a fraction of the results would agree with the next higher or lower set-point.

Within-run and between-day imprecision results are shown in Tables 2 and 3 respectively. In all cases the repeatability was good. Where the concentrations corresponded to borderline levels, the reproducibility for a set-point was less than 100%, but, as explained above, was acceptable.

In contrast to other parameters, the AM measures specific gravity with a refractometer on a continuous scale. For these results standard deviations and coefficients of variation (CV) are appropriate. Both within-run and between-day CVs were < 0.1% at mean specific gravities of 1.015 and 1.020.

### *Method comparisons*

#### *Glucose*

Since in all three evaluating laboratories urinary glucose was quantitatively determined by the same hexokinase/glucose-6-phosphate dehydrogenase method, the data were pooled for comparison purposes.

As explained earlier, the data were log-transformed and represented as box-whisker plot (Figure 1). With the exception of zero set-point, there was a good linear relationship between the AM set-points and the quantitatively determined glucose concentrations (Spearman correlation coefficient = 0.98,  $p < 0.0001$ ,  $n=299$ ). The graph also shows ranges of glucose concentrations for each set-point. For example, as can be seen in Figure 1, for set-points 10 and 30, the first quartiles are 28 mg/dl and 40 mg/dl and the third quartiles are 32 mg/dl and 47 mg/dl respectively.

#### *Protein*

In two laboratories urinary total protein was determined by the benzethonium chloride method on the same type of autoanalyser. These data were also pooled and, as for glucose above, log-transformed and represented as box-whisker plot (Figure 2). AM and quantitative protein determinations showed linear relationship between set-points 5 mg/dl and 250 mg/dl (Spearman correlation coefficient = 0.88,  $p < 0.0001$ ,  $n=140$ ). The graph also shows the span of each set-point. The pyrogallol method for protein determination yielded a similar picture (results not shown).

#### *Erythrocytes and leukocytes*

The box-whisker plot of the log-transformed erythrocyte/ $\mu\text{l}$  data from the UF-100 flow cytometer and the AM results is shown in Figure 3. The relationship is moderately linear (Spearman correlation coefficient = 0.73,

**Tab. 2** Within-run precision determined by using pooled urine samples. The numbers show the percentage reproducibility of the set-points.

	-	+/-	1+	2+	3+	4+
Glucose (mg/dl)	0-10	30 - 50	70 - 100	150 - 200	300 - 500	1000- >1000
Lab 1	100			100		
Lab 2	100				100	
Lab 3	100					15 85
	-	+/-	1+	2+	3+	4+
Protein (mg/dl)	0-5	10 - 20	30 - 70	100 - 200	250 - 400	>400
Lab 1	100			60	40	
Lab 2	100			100		
Lab 3	100		100			
	4.5	5.0 5.5	6.0 6.5	7.0 7.5	8.0 8.5	9.0
Lab 1			100	100		
Lab 2			ND	ND		
Lab 3			100			
	-	+/-	1+	2+	3+	
Haemoglobin (mg/dl)	0	0.03	0.06 - 0.10	0.2 - 0.5	>1	
Lab 1	100			50 50		
Lab 2	100		95	5		
Lab 3	100		20	80		
	-	1+	2+			
Nitrite						
Lab 1	100		100			
Lab 2	ND		ND			
Lab 3	100		100			
	-	+/-	+	2+	3+	
Leukocytes/ $\mu$ l	0	25	75	250	500	
Lab 1	100		5	95		
Lab 2	100				100	
Lab 3	100		15	85		

ND = not done

$p < 0.0001$ ,  $n=98$ ). The microscopic erythrocytes/ $\mu$ l and the AM results showed an identical pattern (results not shown). On the other hand, when the measurement of free haemoglobin in urine was used as a comparison method, AM results and the quantitatively determined haemoglobin concentrations, ranging from 0 to 1 mg/dl, yielded a perfectly linear correlation with the following regression equation:  $Y(AM) = 2.14 \times (Hb) - 0.012$  with the coefficient of variation of 0.99 and  $S_{y/x} = 0.027$  ( $n=15$ ).

The leukocytes/ $\mu$ l from the counting chamber or flow cytometer and AM results did not show linear relationship (Spearman correlation coefficient = 0.34,  $p < 0.0015$ ,  $n=86$ ) (Figure 4).

This was not entirely unexpected, since the urine test-strip measures leukocyte esterase rather than white blood cells (WBC), and in the absence of lysis of WBC no leukocyte esterase activity may be expected.

As an alternative to WBC, we studied the urines of kidney-pancreas transplant patients which contained trace or no WBC, but were very strongly positive ( $\geq 3+$ ) for leukocyte esterase and had very high concentrations of lipase (Table 5). Using quantitatively determined urinary lipase as a surrogate for leukocyte esterase, an excellent linear relationship was obtained between the AM results and the lipase activity, the regression equation being  $Y(AM) = 0.04 \times (\text{lipase}) - 44$  with a coefficient of correlation of 0.97 and  $S_{y/x} = 30$  ( $n=15$ ).

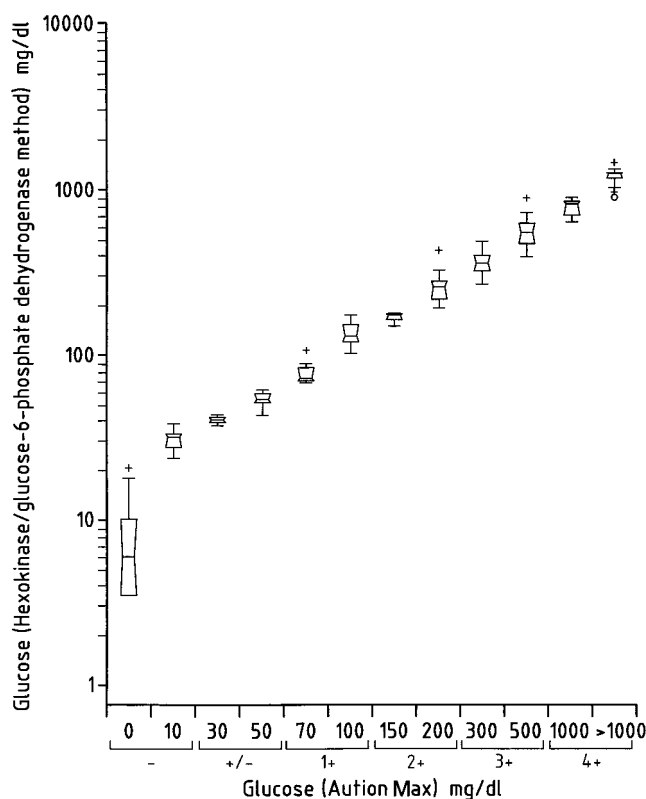
#### Specific gravity (SG)

The regression equation for the AM and the manual refractometer results for SG was  $Y(AM) = 0.91X$  (manual) + 0.1 with a coefficient of correlation of 0.99 and  $S_{y/x} = 0.017$ .

**Tab. 3** Between-run precision determined by using Aution Check levels I and II. The numbers show the percentage reproducibility of the set-points.

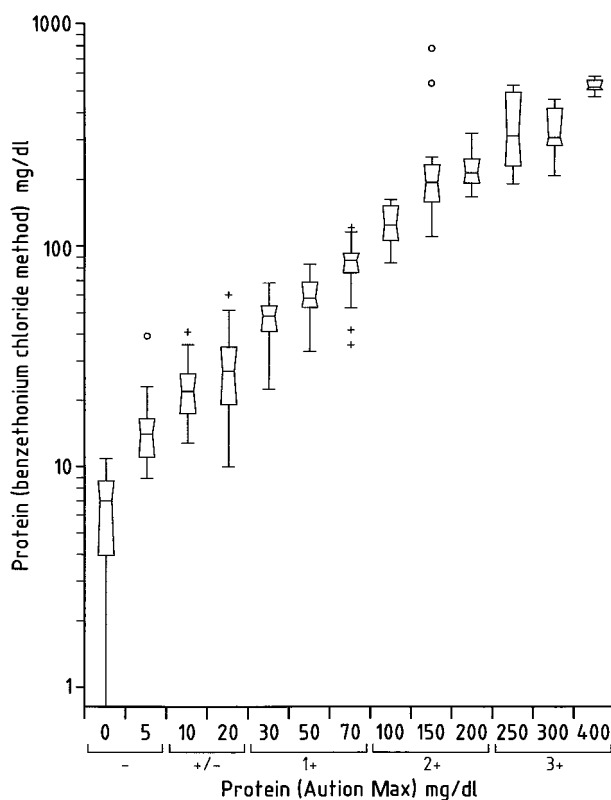
	-	+/-	1+	2+	3+	4+
Glucose (mg/dl)	0- 10	30-50	70-100	150-200	300-500	≥ 1000
Lab 1	100			15 85		
Lab 2	100			100		
Lab 3	100			55 45		
Protein (mg/dl)	0- 5	10-20	30-70	100-200	250-400	> 400
Lab 1	85	15		65 35		
Lab 2	100			65 35		
Lab 3	90	10		90 10		
Bilirubin (mg/dl)	0	0.2	0.5-1.0	2- 4	6-10	>10
Lab 1	100			70	30	
Lab 2	ND			ND	ND	
Lab 3	100			80	20	
Urobilin (mg/dl)		+/- 0.2-1.0	1+ 2-3	2+ 4-6	3+ 8-12	4+ >12
Lab 1		100		100		
Lab 2		ND		ND		
Lab 3		100		100		
Haemoglobin (mg/dl)	0	0.03	0.06-0.10	0.2-0.5	>1	
Lab 1	100		100			
Lab 2	100		95	5		
Lab 3	100		100			
Ketone (mg/dl)	0	5	10	20 30 45	60 80	>80
Lab 1	100				100	
Lab 2	ND				ND	
Lab 3	100				100	
Nitrite	-		1+	2+		
Lab 1	100			100		
Lab 2	ND			ND		
Lab 3	100			100		
Leukocytes/μl	0	25	75	250	500	
Lab 1	100		60	40		
Lab 2	100		15	85		
Lab 3	100		10	90		
pH	4.5 5.0	5.5 6.0	6.5 7.0	7.5 8.0	8.5 9.0	
Lab 1			100	90	10	
Lab 2			ND	ND	ND	
Lab 3			100	80	20	

ND = not done



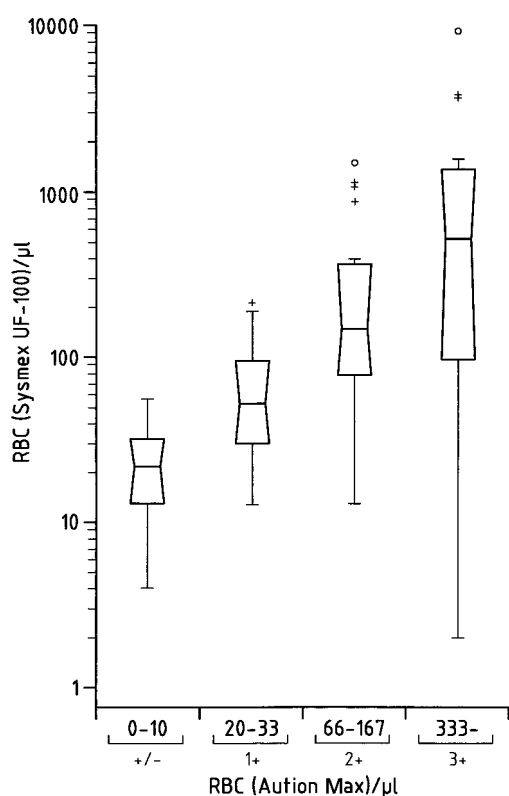
**Fig. 1** Box-whisker plot for urinary glucose, comparing the Aution Max results with the quantitative determinations of glucose by the hexokinase/glucose-6-phosphate dehydrogenase method. The Aution Max reports semi-quantitative data

as -, +/-, 1+, 2+, 3+, and 4+ corresponding to 0, 10, 30, 50, 70, 100, 150, 200, 300, 500, 1000 and > 1000 mg/dl.  $p < 0.0001$ , Spearman correlation coefficient  $r = 0.98$  and  $n = 299$ . + and O represent near and far outliers, respectively.



**Fig. 2** Box-whisker plot for urinary protein, comparing the Aution Max results with the quantitative determinations of protein by the benzethonium chloride method for total urinary protein. The Aution Max reports semi-quantitative results as

-, +/-, 1+, 2+, and 3+, and corresponding to 0, 5, 10, 20, 30, 70, 100, 200, 250, 400 and > 400 mg/dl.  $p < 0.0001$ , Spearman correlation coefficient  $r = 0.88$  and  $n = 140$ . + and O represent near and far outliers, respectively.



**Fig. 3** Box-whisker plot for comparing the Aution Max and flow cytometer (Sysmex UF-100) results for erythrocytes in urine. Significant agreement ( $p < 0.0001$ ) was obtained by Spearman rank analysis ( $r=0.73$ ). The Aution Max reports semi-quantitative results as +/-, 1+, 2+ and 3+ corresponding to negative, 10, 20, 30, 60, 150, 300 and  $> 300$  erythrocytes/ $\mu\text{l}$  or negative, 0.03, 0.06, 0.1, 0.2, 0.5, 1.0 and  $> 1.0$  mg haemoglobin/dl.  $n=98$ . + and O represent near and far outliers, respectively.

#### Linearity

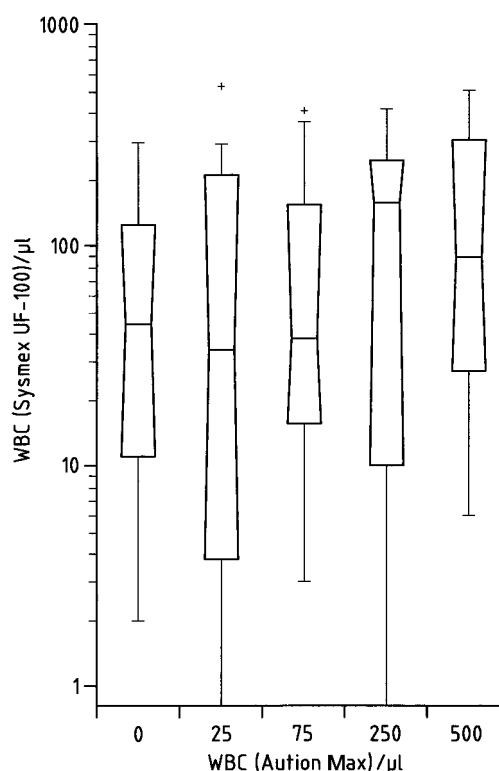
Linearity was tested for glucose, protein, haemoglobin and leukocyte esterase by diluting high concentration urine specimens with urine negative for these parameters. In the resulting specimens the analytes were measured on the AM and by a quantitative method. For leukocyte esterase, urinary lipase was used as a surrogate.

Glucose measurement was found to be linear from 50 mg/dl to 1000 mg/dl, protein from 5 mg/dl to 250 mg/dl, haemoglobin from 0.03 mg/dl to 1.0 mg/dl and (leukocyte esterase) lipase from 0–1200 IU/l.

#### Detection and confirmation limits

The detection limits, defined as concentrations below which the urine test-strip results remain negative (8), were found to be 20 mg/dl for glucose, 11 mg/dl for protein and 0.01 mg/dl for free haemoglobin. For specific gravity, the AM could detect a change of 0.001. These values are well within the detection limits, of 54 mg/dl for glucose, 20 mg/dl for protein and 0.005 for specific gravity, proposed by Kouri *et al.* (8).

The confirmation limits, defined as concentrations above which the urine test-strip results are positive (8), were found to be 82 mg/dl for glucose, 62 mg/dl for pro-



**Fig. 4** Box-whisker plot for comparing the Aution Max and flow cytometer (Sysmex UF-100) results for leukocytes in urine. Spearman rank correlation coefficient ( $r=0.34$ ) was low. The Aution Max reports semi-quantitative results as negative, 25, 75, 250 and 500 leucocytes/ $\mu\text{l}$ . + and O represent near and far outliers, respectively.

tein and 0.06 for free haemoglobin. The ratios of confirmation limit to detection limit were 4.1 for glucose, 4.7 for protein and 6.0 for free haemoglobin.

However, the found detection limits for glucose and protein differ from the 10 mg/dl for glucose and 5 mg/dl for protein reported in the Uriflet S insert.

#### Carry-over

The carry-over effect was determined by analysing, in the same run, three consecutive samples with a very high concentration, followed by three normal specimens. On the AM, no carry-over effect was detected for any of the parameters. However, one of the comparison analysers (Atlas) showed carry-over effect for haemoglobin.

#### Drift

The results showed that there was no systematic deviation of results over 24 h. This was true for the freshly reconstituted materials and for the aliquots of pooled quality control materials, Aution check I and II, kept at 0–4 °C.

#### Analytical interferences

Possible positive and/or negative interferences by some therapeutic drugs on the AM parameters mea-

sured by AM were studied by adding the drugs to positive and negative urine specimens.

Beta-lactam antibiotics (cefazolin 2 g/l, cefotaxime 1.5 g/l, cefalexine 10 g/l, ceftazidime 526 mg/l, ceftriaxone 855 mg/l, tazocin 13 g/l, amoxicillin 1.3 g/l) and other antibiotics such as meropenem (1.12 g/l), nitrofurantoin (300 mg/l), clavulanic acid (403 mg/l) gentamicin (500 mg/l) and doxycycline (134 mg/l) yielded no interference for up to 24 h.

The effect of ascorbate on the Uriflet S parameters was studied by adding it to urine in steps of 0.2 g/l up to a maximum of 1 g/l. Glucose, haemoglobin and nitrite were significantly negatively influenced by ascorbate. Initial urine glucose concentration of 300 mg/dl was reduced by 33% and 50% at ascorbate concentrations of 0.2–0.4 g/l and  $\geq 0.6$  mg/l respectively, while glucose concentration of 500 mg/dl was reduced by 20% at the ascorbate concentration of 1 g/l. At ascorbate concentrations of 0.2–0.4 g/l, 0.6–0.8 g/l and 1 g/l, haemoglobin (0.5 mg/dl) was reduced by 30%, 60% and 80% respectively. For nitrite, the initial concentration of 2+ was reduced to 1+ by  $\geq 0.2$  g/l ascorbate. In the absence of proteinuria, acetylsalicylic acid ( $\geq 0.6$  g/l) reduced the urine pH from 6.0 to 5.5. However, in the presence of  $\geq 490$  mg/dl protein in urine, acetylsalicylic acid up to 2.4 g/l had no effect on the urine pH. This may be due to the buffering effect of protein. As expected, high glucose concentrations 523 mg/dl raised specific gravity from 1.010 to 1.027.

### Practicability

In two laboratories, the AM was found to be a significant improvement on the existing situation, in all functional categories (Table 4). In laboratory 2, the AM system was criticised on the following points: i) the wash solution being supplied only in small volume (250 ml) necessitated emptying of many of these to obtain adequate on-board volume; ii) capacities of the on-board wash solution container (2 l) and the waste container (3 l) were inadequate for a day's workload in a busy laboratory; iii) the containers for the specific gravity calibrators were not labelled and their concentrations were not given; iv) the quality control materials were quite costly.

### Discussion

A set-point on the parameter scale of the urine test-strip is not an exact concentration. Instead, a set-point represents a range of concentrations, all of which will yield urine test-strip results corresponding to the set-point. At borderline concentrations, as might be expected, there is an overlap between the adjacent set-points. Because of this, impression of the AM has been measured as percent reproducibility of set-points, with best repeatability being reported as 100% (11). However, owing to the overlap at the borderline concentrations, variation of one step higher or lower than the expected results may be accepted as good precision (1, 11). In the light of this reasoning, the AM yielded very low imprecision for all the parameters (Tables 2 and 3).

**Tab. 4** Practicability characteristics of the Aution Max analyser, graded in relation to Clinitek 200 and Atlas analysers.

Characteristics	Means of grades <sup>2</sup>		
	Lab 1	Lab 2	Lab 3
Space/space clearance	4	7	7
Heat production	9	7	6
Waste production	3	8	6
Noise production	9	7	7
Power consumption	5	6	6
Spatial arrangement of functional keys and units (10Q <sup>1</sup> )	6.8	6.4	7.3
Training/operation (7Q <sup>1</sup> )	8.1	8.1	7.6
Start up/shut down (3Q <sup>1</sup> )	7.3	8.3	8.3
Sample processing (19Q <sup>1</sup> )	7.3	7.5	6.5
Reagent and waste handling (33Q <sup>1</sup> )	6.3	6.3	7.3
Workflow (4Q <sup>1</sup> )	6.4	5.8	–
Time for analysis (6Q)	8	7.8	7
Calibration (3Q <sup>1</sup> )	5.8	6.8	6.6
Quality control (7Q <sup>1</sup> )	5.1	6.3	6.0
Data processing (7Q <sup>1</sup> )	7.3	5.8	–
Versatility	8	–	–
Maintenance and trouble shooting (12Q)	7.4	6.6	6.3

<sup>1</sup> Q = question(s) and numbers in parentheses refer to the number of questions asked in each category. <sup>2</sup> Answer to each question was graded 0–10; 0–3 meant that Aution Max was worse than the existing conditions in a laboratory; 4–5 indicated that the new analyser was similar to the current situation; and 6–10 showed that AM was better than the comparison analyser. Means of the grades in each category are shown in the Table. Laboratories 1 and 3 had Clinitek 200 analyser and laboratory 2 worked with Atlas analyser.

Method evaluation can be performed either by comparing a candidate method with a reference method or with a most commonly used analytical method. Both of these approaches were used in this evaluation. The AM results for patient urine samples were compared with those obtained from the Clinitek 200 and Atlas urine test-strip analysers. Qualitatively there was excellent agreement amongst the three analysers (results not shown). However, because the AM has more set-points on the scale of each of its (strip) parameters, the relationship between the AM results and those of the Clinitek or Atlas were not always linear. On the other hand, a comparison with the quantitative methods for glucose and protein produced good linear correlations (Figures 1 and 2). Representation of data as box-whisker plots also enabled determination of concentration ranges for each set-point level. The means, medians or modal values of the quantitatively determined set-point ranges are not identical to the set-point concentrations on the glucose and protein scales of the Uriflet strips. The reason for this may be that not only the comparison methods are differently calibrated, but also that the principles of the quantitative methods and those of the AM methods for glucose and protein differ.

In case of red blood cells (RBC) and leukocytes (WBC), the AM, like other urine test-strip analysers,

measures pseudoperoxidase activity of haem/haemoglobin/myoglobin and esterase, but reports the respective results as RBC/ $\mu\text{l}$  and WBC/ $\mu\text{l}$ . Enzymatic detection of RBC or WBC contents differs markedly from counting of cells in a counting chamber under a microscope or by flow cytometer. It is because of this methodological difference that the correlation between RBC or WBC from a counting chamber or flow cytometer and the AM results is poor. Furthermore, haemoglobin and leukocyte esterase are only detectable if there is lysis of RBC and WBC in the urine. In the absence of lysis of these cells, anomalous situation develops, whereby the urine test-strip is negative, but microscopy is positive, for RBC and/or WBC. The opposite is also found, particularly with urines of patients with pancreas-kidney transplantations. In these cases, esterase (derived from the pancreas) is very strongly positive, but the WBC may be completely absent or normal (Table 5). This serves to emphasise that the urine test-strip esterase method is not specific for leukocyte esterase, and that the only appropriate comparison methods for urine stick blood and WBC are free haemoglobin and leukocyte esterase. It is for these reasons that the linearity of the AM blood and WBC methods was determined using quantitatively determined haemoglobin and lipase as surrogate markers of leukocyte esterase.

It has previously been reported that in the presence of certain antibiotics some urine test-strips can give false-positive results for leukocytes (15). At the concentrations we tested none of the commonly used antibiotics produced analytical interference with any of the parameters tested with the Uriflet S strips.

It has been proposed that the trueness of multiple test-strip measurements should be expressed by defining detection limits and confirmation limits with respect to appropriate comparison measurement (11). Below the detection limit a strip test remains negative while above the confirmation limit it is always positive. For gradual transition from negative to positive results, it is recommended that the ratio of the confirmation limit to the detection limit should be 5. As shown in the Results section, the experimentally observed detection and

confirmation limits for glucose and protein were well within the recommended limits and the ratios of the confirmation limits to detection limits were also reasonably close to the recommended levels. For specific gravity, the AM is more sensitive than the proposed detection limit. The principle of confirmation limit does not apply to specific gravity (11). For haemoglobin and leukocyte esterase the proposed detection and confirmation limits are expressed as RBC/ $\mu\text{l}$  and WBC/ $\mu\text{l}$ . For reasons outlined above, counting of cells is not an appropriate comparison method for cell content, particularly since pseudoperoxidase and esterase activities can also arise from sources other than RBC and WBC.

The test reactions for glucose and haem/haemoglobin/myoglobin determinations produce hydrogen peroxide in proportion to the concentrations of these substrates. Ascorbate consumes peroxide and thereby leads to false underestimation of glucose and haemoglobin. Ascorbate can also react with diazonium salts to yield colourless complex. This explains the falsely low results for nitrite in the presence of ascorbate. On a normal Western diet containing 40–100 mg vitamin C, 5–50 mg of ascorbate are excreted in urine per day (16). On the recently proposed modified recommended daily allowance of 200 mg/d (17), the urinary excretion of ascorbate would be about 100 mg/24 h. These concentrations are likely to cause some interference with the test-strip results.

In all practically important areas, the AM was an improvement compared to the existing situation in all three laboratories. The manufacturer has already adapted some of the suggestions made during the evaluation period. For example, the wash solution will now also be available in 1 l containers and the specific gravity calibration vials will be differently packaged and properly labelled.

In conclusion, the AM is a high throughput, easy-to-use automated urine test-strip analyser that is capable of analysing small volumes of urine. It has good precision and accuracy, is free of sample carry-over, and it performed well both technically and operationally during the evaluation period.

**Tab. 5** Testing the urines from kidney-pancreas transplant patients.

Flow cytometer		Aution Max				
RBC <sup>a</sup> / $\mu\text{l}$	WBC <sup>a</sup> / $\mu\text{l}$	Haemoglobin	Leucocyte esterase	Protein	Amylase (IU/l)	Lipase (IU/l)
22	19	Neg	3+	1+	67000	157000
16	4	Neg	3+	Trace	38500	45800
41	13	Trace	3+	1+	68000	66400
1	8	Neg	3+	1+	93000	206800
15	23	Neg	3+	1+	79000	118400
4	22	Neg	3+	1+	82000	162400
168	10	3+	3+	Tr	46400	147600

<sup>a</sup> for flow cytometer Sysmex UF-100 the upper limits of normal for RBC and WBC were 20/ $\mu\text{l}$

## Acknowledgements

The evaluators would like to thank A. Menarini Diagnostics for providing the analysers, the reagents and materials for this evaluation and for facilitating communications amongst the evaluators.

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Received 7 May 2001, accepted 17 May 2001

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