

Evidence review

Automated urine screening systems

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The products

Laboratory testing of urine samples involves classification and enumeration of particles and is performed routinely to identify and monitor diseases of the kidney and urinary tract, as well as for metabolic, cholestatic and haemolytic diseases [1]. The microscopic examination of urine sediment or whole, uncentrifuged urine is a labour-intensive, time consuming procedure with limited precision. Automated urinalysis has been developed to streamline and standardise this procedure.

Automated urinalysis endeavours to measure or describe the formed elements in urine. This aim is achieved in different ways by different manufacturers of automated systems. One technique is to use fluorescence flow cytometry and staining to classify the particles. Another manufacturer uses uncentrifuged urine and classifies particles with microscopy and automated recognition software. Another system currently available uses centrifuged urine in specially designed cuvettes. The sediment is then visualised with microscopy and the high power field (HPF) digital images are analysed with recognition software.

This report is a review of the evidence relating to the use of automated urine screening systems. It includes an economic analysis of the cost effectiveness of these technologies. It should be read with additional reference to the accompanying Evaluation report from CEP [2].

Field of use

Automated urine screening devices are primarily used in diagnostic laboratories. Medical Laboratory Assistants are the main operators, however skilled users (Biomedical Scientists) are still needed for review and sub-classification of certain particles, e.g. dysmorphic erythrocytes, yeasts, *Trichomonas vaginalis*, oval fat bodies, spermatozoa, casts and certain crystals [1]. It is reported that automated systems are less time consuming [3]

National guidance

National guidance exists from the Health Protection Agency in the form of a national standard method (BSOP 41) [4] that includes standard operating procedures. The guidance aims to promote high quality practices and to help to assure the comparability of diagnostic information obtained in different laboratories. Laboratories should be aware of local requirements and may need to undertake additional investigations.

European urinalysis guidelines [5] exist under the auspices of the European Confederation of Laboratory Medicine. The guidelines are a summary of available knowledge aiming to promote consensus in urinalysis practice. Some sections have been further developed by the International Society of Laboratory Hematology [45].

Evidence reviewed

We systematically reviewed articles evaluating automated systems. We incorporated articles that included technical evidence as well as articles that included clinical evidence and reviewed technical performance data including sensitivity, predictive values and reproducibility.

CEP's verdict

Automated methods of urine microscopy have acceptable sensitivity for detection of white blood cells, red blood cells and bacteria when used as part of a clear operating procedure and with uniform cut-off values. The methods offer increases in speed of a negative screening service and savings in overall costs.

However, the optimum levels for these cut-off values are not yet clear in the literature. Further studies are needed to determine acceptable figures for these and to compare all currently available methods in the same trial.

Scope

This evidence review is focused on comparing currently available automated urinalysis devices against current manual laboratory techniques. This review endeavours to clarify whether some or all of the automated systems can produce results comparable to those obtained through manual examination. A review of literature containing performance information was included as was a user survey, economic analysis and market review. Digital and automated urine dipstick readers were excluded as they do not directly measure the formed elements in urine.

Product description

Urinalysis is one of the most frequently performed tests of a microbiology laboratory. However, it is a poorly standardised technique, suffering from variations in methods as well as operator subjectivity [6]. Automated systems have been developed to improve reproducibility and increase productivity. A fully automatic system should in theory increase efficiency and allow highly skilled technologists to manage multiple tasks, simultaneously providing increased efficiency in other important tasks.

This report has identified three devices currently available in the UK. Table 1 lists the technical specifications of the systems.

IRIS iQ 200 Sprint



Urine particles in the sample are imaged in a planar flow cell that orients and constrains particles hydrodynamically within the focal plane of a microscope objective. The IQ 200 uses digital imaging to capture and analyze 500 photographs of each sample and APR™ (auto particle recognition) software to classify isolated images of the urine particles on the basis of texture, contrast, shape and size. The iQ 200 device then presents the image classifications to the user. User defined settings can allow for samples to be auto-validated by the software and released for reporting or presented to the user allowing editing and reclassification if necessary [7, 8, 9]. Additionally, load / unload stations can be attached to increase cuvette capacity.

Sysmex UF 1000i



Automated fluorescence flow cytometry based on diode laser technology together with hydrodynamic focusing conductometry is employed by the UF-1000i. The sample is delivered to a flow cell using hydrodynamic focusing to ensure each particle passes the laser beam individually and is aligned in length. Two dedicated analytical channels stain the formed elements by use of specific fluorescent polymethine dyes. For each particle the scattered light is detected by a photodiode at two different positions (forward and side scattered light), together with fluorescence intensity, and converted into electric signals. The forward scatter provides information on the size and the side scatter gives information on the surface and internal complexity, whereas the fluorescence intensity provides information on nucleic acid contents of each particle [10]. Combining the information allows classification of the formed elements. The instrument produces colour coded scattergrams and clear cut numerical values for each particle type. Previous models were named UF-100i, UF-100 and UF-50.

SediMAX



Digital imaging and automatic particle recognition software are used to classify urine particles and semi-quantitatively report results. Size, shape and texture features are used by the software to classify each image into one of 14 categories [11]. Automated microscopy of urine sediment is achieved by a specially designed cuvette. Samples are centrifuged to form a monolayer in one plane at the bottom of the cuvette. A camera takes 5, 10, 15 or 20 digital images (number selectable by the user) from different locations on the cuvette. Image recognition software detects and classifies particles; the system can also be corrected and user interpretation given.

Table 1. Technical specifications

	iQ 200 Sprint	UF-1000i	SediMax
Particles identified	Red blood cells, white blood cells, bacteria, hyaline casts, pathological casts, crystals, squamous and non-squamous epithelial cells, yeast, white blood cell clumps, sperm, mucus	Red blood cells, white blood cells, epithelial cells, casts, bacteria, small round cells, yeast like cells, sperm, crystals, pathological cast, mucus	Red blood cells, white blood cells, hyaline casts, pathological casts(10 sub-classes), epithelial cells, non-epithelial cells, bacteria, yeasts, mucus, sperm, parasites, crystals: calcium oxalate monohydrate, calcium oxalate dihydrate, uric acid, tri-phosphate etc.
Technologies	Flow cell digital imaging with automatic particle recognition software	Fluorescence flow cytometry with diode laser and hydrodynamic focussing conductometry	Microscopic urine sediment analysis, digital imaging, automatic particle recognition
Throughput (samples/hour)	101	Normal mode- up to 100, Special mode- 80	80
Sample volume	2 ml	4 ml (1 ml in manual mode)	0.2 ml
Data Storage	10,000 patient results with images	10,000 samples (incl. graphics), 5,000 patients information, 1,000 selective test orders	50,000 sample results and images
Interfaces	Bi-directional with host query	Windows® xp user interface, host (ethernet or serial), graphic and/or line printer, bar code scanner	Bi-directional with host query
Size (mm) and weight	559x610x530, 46 kg	615x710x580, 75.5 kg	600x600x600, 58 kg

National guidance

Standardisation is essential not only for interpretation of results in individual patients, but also for epidemiological studies, determining which populations should be screened for urinary abnormalities and for the procedure to be followed when an abnormal result is found. In addition laboratories want to accredit their urine diagnostics by comparing their methods with acceptable references.

The Health Protection Agency Standard Operating Procedures BSOP41 [4] state that automated methods may be useful in laboratories as a more rapid alternative to microscopy for the majority of urines. They suggest that many non-culture methods for screening for bacteriuria and pyuria have been described and reviewed. Most urine analyser systems and chemical methods are not sufficiently sensitive to detect low levels of bacteriuria that may be clinically significant. Urine analysers may be used to screen for 'negatives' to allow earlier reporting and methods that detect pyuria as well as bacteriuria may be useful for the exclusion of non-infected patients. They further state that regardless of the screening result, culture is still recommended for all specimens from children, pregnant women, patients who are immunocompromised and requests for repeat culture.

The European Urinalysis Guidelines [5] contain effective diagnostic strategies on standard procedures for collection, transport and analysis to create a consensus on urinalysis practice. Reference may also be made to the International Society of Laboratory Hematology recommended procedure [45]. With regard to automated systems the European guidelines state that:

- rational combination of automated and visual particle analysis with chemical measurement and bacteriological procedures is crucial in the new urinalysis workflow strategy.
- chamber counting of uncentrifuged urine is recommended for comparisons of automated particle counting with visual methods because counts obtained from a chamber are more precise than those obtained under a coverslip on a microscope slide.
- for precise evaluation, at least 100 cells should be counted to reach a CV=10%, and 400 cells should be counted to reach a CV=5%, based on the Poisson distribution. Health associated reference intervals of many urine particles are, however, below 2 particles/ μ l.
- manufacturers of urine particle analysers should describe in detail the differentiation capability of their instrument, including sensitivity and specificity data against a manual comparison method.
- general as well as specific patient populations should be targeted in the evaluations to establish the optimal intended diagnostic use for a given

instrument. Based on the technical principles used, advice on specimen collection and storage is essential to obtain reliable results and avoid artefacts. Boric acid urine bottles can be used which help preserve cells and prevent bacterial multiplication. Lists of known interferences should be made generally available as soon as they are discovered during evaluations and clinical practice.

- customers should work out standard operating procedures with the help of manufacturers. These should include descriptions of regular working, combinations of different analyses from the same urine, quality assessment protocols and measures to be taken in the event of instrument alarms or error messages. Specimens not amenable to automated analysis should be listed, as well as the standardised alternative manual methods.

Sources

We identified 576 articles from 10 PubMed searches, completed in November 2009.

Search terms

Search terms used were:

- automated urine microscopy (76 articles)
- automated urinalysis (183 articles)
- automated urine analyzer (131 articles)
- automated urine analyser (45 articles)
- automated urine flow cytometry (49 articles)
- automated urine sediment analysis (32 articles)
- automated urine sediment analyser (4 articles)
- automated urine sediment analyzer (10 articles)
- automated urinalysis analyzer (32 articles)
- automated urinalysis analyser (14 articles)

After removing duplicates there were 359 articles remaining. Articles were then classified according to relevance based on the subject matter of the abstract, after which 73 remained.

Inclusion and exclusion criteria

The articles reviewed in this study met the inclusion criteria described below. All other articles were excluded.

Inclusion criteria

- Articles from peer reviewed journals

Exclusion criteria

- Articles from journals which were not peer reviewed, including abstracts from meetings and conferences
- Papers on equipment no longer in use
- Articles in languages other than English

Following application of these criteria, 39 papers remained for review.

Evidence review methodology

The 39 papers were then reviewed and analysis summarised under these headings:

- Trial design
- Type of device(s) in the study
- Results
- Disclosures made or sponsors acknowledged
- Limitations

The detailed summary can be found in Appendix 2, where the papers are listed in chronological order, with the most recent listed first.

The papers are mostly technical comparisons with either other forms of analysis technology or manual methods. There were far more papers assessing the Sysmex UF-100 and the IRIS iQ200 as opposed to other currently available products. This simply reflects the time the devices have been available on the market. The papers that are not technical comparisons were deemed useful for background information.

Automation and urine analysis

Since the analysis of urine has an important role in diagnosing various disease states, it is important that results are reliable. Urine is a difficult matrix to analyse with particle sizes ranging from 1 to 100 μm [12]. Manual analysis procedures are standardized [14], however manual microscopy suffers from poor precision and wide inter-observer variability and the limited data published on the precision of microscopic urinalysis suggest high inter- and intra-run variations [6]. The process is also time consuming, an important factor to consider in laboratories' staffing costs and work volume.

Carlson noted in 1988 that automating the urinalysis procedure can save labour and time and is more feasible for the laboratory with high workload that also requires minimal healthcare scientist involvement in operation and maintenance [14, see also 8, 12]. However, the limitations encountered when analysing non-uniform cells or low cell concentrations mean that an expert will always be necessary to manually review results in certain categories [e.g. 9, 15, 16]. The design of the protocols and procedures within which automated systems are used are therefore critical in the delivery of a reliable clinical service [10, 12].

Statistical data was analysed from the literature available on automated systems. Automated systems have been updated since most articles were produced and analysis software has been improved. Only limited data exists on some of the newer systems, so an up to date, comprehensive review is not currently possible. Nonetheless an analysis has been undertaken using what published evidence exists.

Comparisons reported

Table 2 displays the study comparisons carried out in the papers reviewed. It is apparent that there is a significant weighting towards devices that have been available for a longer time, which is to be expected. This suggests that a full comparative study of all current devices against both manual microscopy and culture would be valuable, despite the size of such an undertaking. Certainly the evidence base as selected by this review's screening criteria should be strengthened.

Table 2. Comparisons made in reviewed papers

Comparison with:	Microscopy only	Both microscopy and culture	Culture only
Sysmex UF 1000 / 100 / 50	12	5	5
IRIS iQ200	10	0	0 ¹
SediMAX	1	0	0

There is consensus among the papers reviewed that the results of automated analysis correlate well with manual methods and have minimal carry over (i.e. minimal cross-contamination of samples). The limitations stated are that this correlation decreases when concentrations of cells are low, when cell clumping occurs, when crystals or yeast are present [9] [16] [17]. This is to be expected as manual methods will be challenged by low concentrations. It is therefore essential to follow the guideline recommendations [4] [5] to develop a clear review and culture protocol to ensure automation is used appropriately for the environment.

Predictive value

Reported negative predictive value (npv) and positive predictive value (ppv) are as follows in Table 3, with most recent listed first. We have not listed papers that only report likelihood ratios, as these figures are derived from sensitivity and specificity alone, thus not informing predictive value.

Table 3. Predictive values

Reference / device	WBC npv / ppv	RBC npv / ppv	Bacteria npv / ppv	Cut off value
Akin [9] iQ200	0.96 / 0.903	0.915 / 0.878		>5 wbc / HPF, >2 rbc / HPF
Lunn [15] UF-100			0.986 / 0.405	>8040 bact / µl or Wbc > 40/µl
Manoni [10] UF-1000			0.98 / 0.82	>125 bact / µl and >40 wbc / µl
Zaman [16] SediMAX	0.78 / 0.89	0.65 / 0.87	0.73 / 0.64	>9 wbc / µl, >5 rbc / µl >90 bact / µl

¹ One study in this category does, however, exist in the French language (Ledru 2008)

Reference / device	WBC npv / ppv	RBC npv / ppv	Bacteria npv / ppv	Cut off value
Grosso [18] UF-100			0.995 / 0.545	>4500 bact / μ l and 100 wbc / μ l
Okada 2006 [19] UF-1000			0.988 / 0.57	>10 ⁴ bact / ml
Kaneko [21] UF-100		0.967 / 0.163		Not stated
Okada 2000 [37] UF-50			0.907 / 0.62	>5 wbc / ml and 'scatter' >12 units

Note: wbc, rbc, bact and HPF refer to white blood cells, red blood cells, bacteria particles and high power field respectively

The results above back up the consensus that automated screening is acceptable for screening out negative samples, but is not acceptable for positive testing. See below, however, for comments on the cut-off values used.

Sensitivity

Given that the consistent recommendation is to use automated methods as a screening tool for negative samples which will then not need culture, the critical error to examine and avoid is that of false negative diagnosis [18, 19]. We therefore summarise the reported sensitivity of the method under investigation. The analysis, however, is confused by the fact that different cut-off values are proposed in order to increase the predictive values in different studies. For example Lunn *et al* [15] and Manoni *et al* [10] both use counts of 40 cells per μ l as cut-off value, whereas Grosso *et al* [18] use 100 cells per μ l, with bacterial cell densities also varying.

Papers reporting only sensitivity to different types of haematuria are not listed here.

Sensitivities reported are listed in Table 4, with the most recent papers listed first.

Table 4. Sensitivities reported

Reference / device	WBC sensitivity	RBC sensitivity	Bacteria sensitivity	Cut off value
Akin [9] iQ200	0.86	0.76		>5 wbc / HPF, >2 rbc / HPF
Lunn [15] UF-100			0.89	>8040 bact / μ l or wbc >40/ μ l
Manoni [10] UF-1000			0.99	>125 bact / μ l & >40 wbc / μ l
Zaman [16] SediMAX	0.87	0.81	0.75	> 9 wbc, > 5 rbc, > 90 bact / μ l
Grosso [18] UF-100			0.988	>4500 bact / μ l & > 100 wbc / μ l
Van den Broek [22] iQ200	0.87	0.83	0.58	> 28 wbc / μ l
Shayanfar [1] iQ200: UF-100:	0.76 0.92	0.70 0.76	0.85 0.95	>5wbc, rbc/HPF, >'few' bact/HPF
Okada 2006 [19] UF-1000			0.966	>10 ⁴ bact / ml
Scharnhorst [26] UF-100		0.99		> 20 rbc / μ l
Alves [27] iQ200		Combination 0.97		> 28 wbc and > 17 rbc / μ l
Kaneko [21] UF-100		0.61		Not stated
Dimech [31] UF-100	0.886	0.71		20 wbc, rbc / μ l
Roggeman [35] UF-100	0.82	0.58		20 wbc, rbc / μ l
Okada 2000 [37] UF-50			0.831	>5 wbc / ml and scatter >12 units
Hannemann-Pohl [38] UF-100	0.905	0.637		> 20 wbc, rbc / μ l
Kouri [13] UF-100	0.94	0.82	0.55	>20 wbc, >10 rbc, >600 bact / μ l

Note: wbc, rbc, bact and HPF refer to white blood cells, red blood cells, bacteria particles and high power field respectively

It can be seen that comparison of sensitivities are hard to make, as the cut off figures vary widely. This underlines the advice contained in the European Urinalysis Guidelines [5] to develop standard operating procedures and rational combinations of methods in cooperation with the manufacturer.

Economic evidence

Very few papers referred to health economic calculations or figures, and those that did are not clear on the methods used to calculate them. We have therefore made a comprehensive economic analysis in the next section.

Kouri *et al.* [13] estimate that a saving of 45% of labour time can be made by the regular use of automated screening and Shayanfar *et al.* [1] state a time saving of 30%, but neither factor in any other costs. Steinmetz *et al.* [20] give figures for salary cost per sample for four different analysis strategies, ranging from €0.27 per sample to €0.90 per sample. They also describe cost of the equipment per test, ranging from €0.41 per sample to €1.07 per sample, but do not detail exactly how these are calculated, e.g. whether maintenance costs are included. The discussion of economics by Kaneko *et al.* [21] shows clinical budget savings can be made by screening tests if automation is used for mass screening for nephritis, by reducing the number of referrals for further tests. The discussion does not, however, show how the quoted cost per automated test figure of US\$0.56 is calculated and whether it includes equipment replacement costs. Lunn *et al.* [15] mentions there will be savings due to reduced use of culture and resultant manual microscopy, since the automated system tested had a specificity of 0.85 compared to 0.72 for dipsticks.

The speed of delivery of a negative result is also cited as a major advantage of automation, e.g. Evans [23]: “Automated Microscopy can issue an instant negative report using pre set criteria based on bacterial and white cell counts. Only samples that are positive on Automated Microscopy criteria are sent for culture. This reduces the burden on laboratory staff and laboratory costs.” Mayo *et al.* [11] quote times for these results are around one minute for the automated systems and nearly three minutes for manual, although Akin *et al.* [9] suggest manual methods take five to ten minutes. The minutes taken by the machine per test, however, do not have a direct bearing on the financial cost to the user but rather on the promptness of the service.

We therefore suggest that there is not sufficient economic evidence in the literature reviewed to back up any recommendation to change method on that basis alone. However, further economic analysis is carried out in this review in the next section.

Conclusions

The papers reviewed agree with the published guidelines that automated microscopy can be a fast and sufficiently sensitive method to use specifically as screening for negatives, provided that the cut-off values are set correctly. There is thus a need for study comparing all currently available devices with manual method using standard cut-off values. European Urinalysis Guidelines [5] suggest in their Table XI that 10^5 CFU/L gives acceptably high sensitivity and negative predictive value for bacteria. These guidelines state that an acceptable level of false negatives is <10% (p.34).

Both Chien *et al.* [17] and Shayanfar *et al.* [1] demonstrate that the combination of dipstick testing in a protocol with automated microscopy increases the sensitivity of screening. Akin *et al.* [9] and Chien *et al.* [17] state that automated methods will need review by manual microscopy when concentrations of cells are low, when cell clumping occurs, when crystals or yeast are present. Zaman *et al.* [16] agree: “The presence of casts, crystals, bacteria, budding yeast and non-squamous epithelial cells need further characterization under a visual microscope.” In fact, two machines currently available (iQ200 and SediMax) offer on-screen review of images immediately post-analysis, meaning separate manual microscopy is unnecessary. The National Standard Method [4] adds that samples from children, pregnant women and immuno-compromised patients should be routinely cultured regardless of screening result.

The absolute accuracy of an automated method therefore depends upon the protocol used, the cut off values assigned and the type of particle investigated. Zaman *et al.* [16] conclude “it is not able to replace a properly trained medical technologist or the phase-contrast microscope”.

Van den Broek *et al.* [22] summarise as follows: Automation “strongly improves the reliability of urinalysis by standardisation, quantitative reports and improved work flow.” It also should be noted that the expert user will be needed when the machine is unavailable, broken or backup is needed [15]. Laboratories should therefore beware of the potential loss of these necessary skills if expert staff are completely replaced. As with any other competency, these skills require regular checks and updates.

Comparison of cost per test

Very few papers referred to health economic calculations or figures and so we have performed a comprehensive analysis.

The total cost per test was calculated for each automated system and compared with the manual process. Where possible, data used in the calculation was taken from the user survey carried out with this study [2] or from the sources quoted below. In other cases, values were assumed to be in line with other studies, e.g. standard lifetime of equipment is assumed to be seven years with two year warranty. The formulae used are included here to enable users to insert their own data.

Total cost per test = (staff costs + machine costs + consumable costs) per test

$$\frac{\text{Staff cost}}{\text{test}} = \left(\frac{\text{Assistant cost}}{\text{minute}} \times \frac{\text{effective minutes}}{\text{test}} \right) + \left(\frac{\text{Scientist cost}}{\text{minute}} \times \frac{\text{effective minutes}}{\text{test}} \right)$$

$$\text{where } \frac{\text{effective minutes}}{\text{test}} = \frac{\text{actual minutes for Y samples}}{Y}$$

$$\frac{\text{Machine cost}}{\text{test}} = \frac{\text{purchase \& maintenance cost}}{\text{No of tests in lifetime}} = \frac{\text{purchase price} + 5 \times \text{annual charges}}{(\text{actual no. tests per day}) \times (\text{lifetime days})}$$

where actual no of tests per day = (no of samples supplied) + (no of repeat samples needed)

$$\frac{\text{Consumable cost}}{\text{test}} = (\text{consumables per single test}) + \frac{\text{quality control (QC) per day}}{\text{actual no. of tests per day}}$$

Table 5. Assumptions made in economic analysis

Assumptions	Effect of deviation from assumption
Time taken and costs for QC in all methods the same	The method that takes more staff time or costs for QC will have increased cost / test
Facility costs (space etc) the same for all methods	If space, cleaning and drainage costs are considered, automated systems may incur some added cost
Workload is effectively spread through the day by variable turn around time (TAT)	User survey indicates that actual workload varies through the day, so the efficiency of an automated system may spread over a period of time when busiest, but that machines are in use continually. This may result in less efficient use during slower periods.
All cuvette trays / racks are full	Cost / test will increase if partially filled cuvettes are used
Utility costs (water, electricity) are equal for manual and auto	The cost/test will increase for the method that uses more resource
TAT is not considered as a cost	There may in fact be an effective cost due to business lost or inefficiencies introduced if TAT increases significantly.

We calculate the staff costs as follows, taking as our annual total time worked as:
 220 days = 220 x 7.5 hours = 220 x 7.5 x 60 minutes = 99,000 minutes.

$$\begin{aligned} \text{Assistant cost / minute} &= \frac{\pounds 14774 * 1.23}{99,000} \quad (\text{middle of band 2 in 2009 plus 23\% on-costs}) \\ &= \pounds 0.184 / \text{minute} \end{aligned}$$

$$\begin{aligned} \text{Scientist cost / minute} &= \frac{\pounds 35504 * 1.23}{99,000} \quad (\text{middle of band 7 in 2009 plus 23\% on-costs}) \\ &= \pounds 0.441 / \text{minute} \end{aligned}$$

Assumed lifetime of equipment = 7 years, running for 6 days per week on average
 = 7 x 6 x 52 days
 = 2184 days

This makes the above formulae (where N = no. of actual tests / day) condense to:

$$\begin{aligned} \text{Cost / test} &= 0.184 \times \frac{\text{Assistant minutes}}{\text{test}} + 0.441 \times \frac{\text{Scientist minutes}}{\text{test}} \\ &+ \frac{\text{price} + 5 \times \text{maintenance charge}}{N \times 2184} + \text{consumables} + \frac{\text{general daily costs}}{N} \end{aligned}$$

Table 6 shows the relevant values as provided by manufacturers, with any other sources identified, and the resultant calculated cost per test for different workloads.

Table 6. Calculated costs per test

	Manual microscopy	Automated microscopy (range)
MLA minutes / test	0	0.2 – 0.4
BMS minutes / test ²	2.7 [11]	0.05
Purchase cost	£ 4,300 (est.)	£ 31,000 – 58,000
Annual service charge	£ 650 (est.)	£ 4,500 – 7,000
Consumables / test	£ 0.14 ³	£ 0.30 – 0.31
Resultant total cost / test (using above equation) N = 100 samples /day	£ 1.37	£ 0.60 – 0.80
Cost / test, N = 200	£ 1.37	£ 0.48 – 0.60
Cost / test, N = 400	£ 1.37	£ 0.42 – 0.50
Cost / test, N = 600	£ 1.37	£ 0.40 – 0.47

² Automated figure is estimated average, based on 15% expert review rate, 20 seconds per review

³ Private communication, Royal Gwent Hospital

Note also that the cost of a standard microscope will normally be a given, as it will be needed for the back up and review services mentioned above. However, even with the cost of a microscope completely removed from the equations above, the automated methods still work out cheaper, simply because of the staff time saved.

Table 5 describes various assumptions that have been made in this analysis, with the possible effects of these assumptions being incorrect. We consider that even if the effects increase the cost of automated tests, the change will not be great enough to make manual microscopy cheaper per test. With regard to turn-around-time, a quicker diagnosis may mean savings in other departments due to earlier treatment or discharge being possible.

The figures in Table 6 suggest that the payback time for the purchase of an automated system, i.e. the time taken for cost savings to equal the purchase cost of the equipment, varies between 2 and 40 months, a range well within the expected lifetime of the equipment.

Summary

It can be seen from Table 6 that even for laboratories with only 100 samples per day, an automated method offers cost savings purely because of the labour costs saved. There may also be wider cost savings due to earlier patient discharge or surgery. However, in any comparative analysis, a laboratory will have to consider what other tasks can benefit from the staff time freed up by automation, as the skills must be retained for use when needed. If those other tasks do not exist, for instance in a small laboratory, the time saved will not be economically reemployed.

We have examined all peer reviewed publications and national guidelines relating to the assessment of automated urine microscopy. We have summarised the published results of sensitivity and predictive value calculations and compared the economics of using manual methods against these automated methods.

Automated methods of urine microscopy have acceptable sensitivity for detection of white blood cells, red blood cells and bacteria when used as part of a clear operating procedure and uniform cut-off values. National and European guidelines should be followed in the development of operating procedures. However, the optimum levels for cut-off values are not yet clear in the literature and the three currently available devices have never all been compared together with manual methods in the same study. Further studies are therefore needed to determine acceptable figures for cut-off values and to compare all currently available methods in the same trial.

The evidence suggests that automated methods strongly improve the reproducibility of urinalysis and offer increases in speed of negative screening service and savings in overall costs. When concentrations of cells are low, when cell clumping occurs or when crystals or yeast are present, automated urinalysis is insufficient and samples need further characterization under a manual microscope or through on-screen review by an expert user. Economic savings based on redeployment of staff time are only of benefit where staff can be redeployed to other tasks whilst retaining experts for visual microscopy confirmation.

The National Standard Method [4] adds that samples from children, pregnant women and immunocompromised patients should be routinely cultured regardless of screening result.

Grosso *et al.* [18] summarise the need as follows. "Although the incidence of UTI is high, a large proportion of the samples tested by a routine microbiology laboratory will show no evidence of infection with up to 80% of the specimens with negative results for urine culture. Therefore a rapid and reliable screening method is useful to screen out negative samples, reducing unnecessary testing." Automated microscopy devices can give this rapid service in a cost effective manner. A sufficiently reliable service can be achieved when cut-off values for thresholds are set on the basis of proven protocols, but the values required for this are not yet established by peer reviewed consensus.

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The following abbreviations have been used in this review:

CFU	colony forming units
EC	epithelial cells
HPF	high power field
npv	negative predictive value
ppv	positive predictive value
QC	quality control
RBC	red blood cell
TAT	turn around time
WBC	white blood cell

1. Shayanfar N, Tobler U, von Eckardstein A, Bestmann L. Automated urinalysis: first experiences and a comparison between the Iris iQ200 urine microscopy system, the Sysmex UF-100 flow cytometer and manual microscopic particle counting. *Clinical Chemistry and Laboratory Medicine*. 2007; 45(9): 1251-6.
2. CEP Evaluation Report CEP10031, Automated urine screening systems 2010.
3. Tworek JA, Wilkinson DS, Walsh MK. The rate of manual microscopic examination of urine sediment: a College of American Pathologists Q-Probes study of 11,243 urinalysis tests from 88 institutions. *Archives of Pathology and Laboratory Medicine*. 2008; 132(12): 1868-73.
4. Investigation of Urine. National Standard Method BSOP 41 Issue 7. Health Protection Agency 2009.
5. European Urinalysis Guidelines, Summary. *Scandinavian Journal of Clinical and Laboratory Investigation*. 2000; (60): 1-96.
6. Winkel P, Statland BE, Jorgensen K. Urine microscopy, an ill-defined method, examined by a multifactorial technique. *Clinical Chemistry* 1974; 20(4): 436-9.
7. Wah DT, Wises PK, Butch AW. Analytic performance of the iQ200 automated urine microscopy analyzer and comparison with manual counts using Fuchs-Rosenthal cell chambers. *American Journal of Clinical Pathology*. 2005; 123(2): 290-6.
8. Linko S, Kouri TT, Toivonen E, Ranta PH, Chapoulaud E, Lalla M. Analytical performance of the Iris iQ200 automated urine microscopy analyzer. *Clinica Chimica Acta*. 2006; 372(1-2): 54-64.
9. Akin OK, Serdar MA, Cizmeci Z, Genc O, Aydin S. Comparison of LabUMat-with-UriSed and iQ200 fully automatic urine sediment analysers with manual urine analysis. *Biotechnology and Applied Biochemistry*. 2009; 53(2): 139-44.
10. Manoni F, Fornasiero L, Ercolin M, Tinello A, Ferrian M, Hoffer P, Valverde S, Gessoni G. Cutoff values for bacteria and leukocytes for urine flow cytometer Sysmex UF-1000i in urinary tract infections. *Diagnostic Microbiology and Infectious Disease*. 2009; (65): 103-107.
11. Mayo S, Acevedo D, Quiñones-Torrelo C, Canós I, Sancho M. Clinical laboratory automated urinalysis: comparison among automated microscopy, flow cytometry, two test strips analyzers, and manual microscopic examination

- of the urine sediments. *Journal of Clinical Laboratory Analysis*. 2008; 22(4): 262-70.
12. Delanghe J. New screening diagnostic techniques in urinalysis. *Acta Clinica Belgica*. 2007; 62(3): 155-61.
 13. Kouri TT, Gant VA, Fogazzi GB, Hofmann W, Hallander HO, Guder WG. *Clinica Chimica Acta*. 2000; 297(1-2): 305-11.
 14. Carlson DA, Statland BE. Automated Urinalysis. *Clinics in Laboratory Medicine*. 1988; 8(3): 449-61.
 15. Lunn A, Holden S, Boswell T, Watson AR. Automated Microscopy, Dipsticks and the Diagnosis of Urinary Tract Infection. *Archives of Disease in Childhood*. 2009 Oct; Epub ahead of print.
 16. Zaman Z, Fogazzi GB, Garigali G, Croci MD, Bayer G, Kráncz T. Urine sediment analysis: Analytical and diagnostic performance of sediMAX((R)) - A new automated microscopy image-based urine sediment analyser. *Clinica Chimica Acta*. 2009 Oct; Epub ahead of print.
 17. Chien TI, Kao JT, Liu HL, Lin PC, Hong JS, Hsieh HP, Chien MJ. Urine sediment examination: a comparison of automated urinalysis systems and manual microscopy. *Clinica Chimica Acta*. 2007; 384(1-2): 28-34.
 18. Grosso S, Bruschetta G, De Rosa R, Avolio M, Camporese A. Improving the efficiency and efficacy of pre-analytical and analytical work-flow of urine cultures with urinary flow cytometry. *The New Microbiologica*. 2008; 31(4): 501-5.
 19. Okada H, Shirakawa T, Gotoh A, Kamiyama Y, Muto S, Ide H, Hamaguchi Y, Horie S. Enumeration of bacterial cell numbers and detection of significant bacteriuria by use of a new flow cytometry-based device. *Journal of Clinical Microbiology*. 2006; 44(10): 3596-9.
 20. Steinmetz J, Henny J, Gueguen R. Stepwise strategies in analysing haematuria and leukocyturia in screening. *Clinical Chemistry and Laboratory Medicine*. 2006 ; 44(4): 464-70.
 21. Kaneko K, Murakami M, Shiraishi K, Matsumoto M, Yamauchi K, Kitagawa T, Yamashiro Y. Usefulness of an automated urinary flow cytometer in mass screening for nephritis. *Pediatric Nephrology*. 2004; 19(5): 499-502.

22. van den Broek D, Keularts IM, Wielders JP, Kraaijenhagen RJ. *Clinical Chemistry and Laboratory Medicine*. 2008; 46(11): 1635-1640.
23. Evans R, Davidson MM, Sim LR, Hay AJ. Testing by Sysmex UF-100 flow cytometer and with bacterial culture in a diagnostic laboratory: a comparison. *Journal of Clinical Pathology*. 2006; (59): 661-662.
24. Butch AW, Wises PK, Wah DT, Gornet TG, Fritsche HA. A multicenter evaluation of the Iris iQ200 automated urine microscopy analyzer body fluids module and comparison with hemacytometer cell counts. *American Journal of Clinical Pathology*. 2008; 129(3): 445-50
25. Ozdem S, Bayraktar T, Oktay C, Sari R, Gültekin M. The prevalence of asymptomatic pyuria in diabetic patients: comparison of the Sysmex UF-100 automated urinalysis analyzer with Fuchs-Rosenthal hemacytometer. *Clinical Biochemistry*. 2006; 39(9): 873-8.
26. Scharnhorst V, Gerlag PG, Nanlohy Manuhutu ML, van der Graaf F. Urine flow cytometry and detection of glomerular hematuria. *Clinical Chemistry and Laboratory Medicine*. 2006; 44(11): 1330-4.
27. Alves L, Ballester F, Camps J, Joven J. Preliminary evaluation of the Iris IQ 200 automated urine analyser. *Clinical Chemistry and Laboratory Medicine*. 2005; 43(9): 967-70.
28. Lamchiagdhase P, Preechaborisutkul K, Lomsomboon P, Srisuchart P, Tantiniti P, Khan-u-Ra N, Preechaborisutkul B. Urine sediment examination: a comparison between the manual method and the iQ200 automated urine microscopy analyzer. *Clinica Chimica Acta*. 2005; 358(1-2): 167-74.
29. Fogazzi GB, Garigali G. The clinical art and science of urine microscopy. *Current Opinion in Nephrology and Hypertension*. 2003; 12(6): 625-32.
30. Ottiger C, Huber AR. Quantitative urine particle analysis: integrative approach for the optimal combination of automation with UF-100 and microscopic review with KOVA cell chamber. *Clinical Chemistry*. 2003; 49(4): 617-23.
31. Dimech W, Roney K. Evaluation of an automated urinalysis system for testing urine chemistry, microscopy and culture. *Pathology*. 2002; 34(2): 170-7.
32. Sutheesophon K, Wiwanitkit V, Boonchalermvichian C, Charuruks N. Evaluation of the Sysmex UF-100 automated urinalysis analyzer and comparative study with JCCLS reference method. *Journal of the Medical Association of Thailand*. 2002; (85 Suppl 1): S246-52.

33. Apeland T, Mestad O, Hetland O. Assessment of haematuria: automated urine flowmetry vs microscopy. *Nephrology, Dialysis, Transplantation*. 2001; 16(8): 1615-9.
34. Okada H, Sakai Y, Kawabata G, Fujisawa M, Arakawa S, Hamaguchi Y, Kamidono S. Automated urinalysis. Evaluation of the Sysmex UF-50. *American Journal of Clinical Pathology*. 2001; 115(4): 605-10.
35. Roggeman S, Zaman Z. Safely reducing manual urine microscopy analyses by combining urine flow cytometer and strip results. *American Journal of Clinical Pathology*. 2001; 116(6): 872-8.
36. Delanghe JR, Kouri TT, Huber AR, Hannemann-Pohl K, Guder WG, Lun A, Sinha P, Stamminger G, Beier L. The role of automated urine particle flow cytometry in clinical practice. *Clinica Chimica Acta*. 2000; 301(1-2): 1-18.
37. Okada H, Sakai Y, Miyazaki S, Arakawa S, Hamaguchi Y, Kamidono S. Detection of significant bacteriuria by automated urinalysis using flow cytometry. *Journal of Clinical Microbiology*. 2000; 38(8): 2870-2.
38. Hannemann-Pohl K, Kampf SC. Automation of urine sediment examination: a comparison of the Sysmex UF-100 automated flow cytometer with routine manual diagnosis (microscopy, test strips, and bacterial culture). *Clinical Chemistry and Laboratory Medicine*. 1999; 37(7): 753-64.
39. Hyodo T, Kumano K, Sakai T. Differential diagnosis between glomerular and nonglomerular hematuria by automated urinary flow cytometer. Kitasato University Kidney Center criteria. *Nephron*. 1999; 82(4): 312-23.
40. Langlois MR, Delanghe JR, Steyaert SR, Everaert KC, De Buyzere ML. Automated flow cytometry compared with an automated dipstick reader for urinalysis. *Clinical Chemistry*. 1999; 45(1): 118-22.
41. Ben-Ezra J, Bork L, McPherson RA. Evaluation of the Sysmex UF-100 automated urinalysis analyzer. *Clinical Chemistry*. 1998; 44(1): 92-5.
42. Fenili D, Pirovano B. The automation of sediment urinalysis using a new urine flow cytometer (UF-100). *Clinical Chemistry and Laboratory Medicine*. 1998; 36(12): 909-17.
43. King C. Automated methods in urinalysis. *Clinical Laboratory Science*. 1998; 11(1): 44-6.

44. Deindoerfer FH, Boris WB, Gangwer JR, Laird CW, Tittsler JW. Automated intelligent microscopy (AIM) and its potential application in the clinical laboratory. *Clinical Chemistry*. 1982; 28(9): 1910-6.
45. Kouri T, Gyory A, Rowan RM. ISLH Recommended Reference Procedure for the Enumeration of Particles in Urine. *Laboratory Hematology*. 2003;9(2);58-63

IRIS iQ200

IRIS Diagnostics (UK) Ltd
St John's Innovation Centre
Cowley Road
Cambridge
CB4 0WS

Tel: 01223 421 590
Fax: 01223 280 307
Email:
www.proiris.com

Sysmex UF-1000i

bioMérieux UK Ltd
Grafton Way,
Basingstoke,
RG22 6HY

Tel: 01256 461 881
Fax: 01256 816 863
Email:
www.biomerieux.co.uk

SediMAX

A.Menarini Diagnostics Ltd.
405 Wharfedale Road
Winnersh
Wokingham
RG41 5RA Berkshire

Tel: 01189 444 100
Fax: 01189 444 111
Email:
www.menarini diag.co.uk

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
Akin <i>et al</i> 2009 [9]	Comparison of the iQ 200 with UriSed and Manual microscopy using the KOVA system. 600 mid stream samples were analysed within 1h of arrival. Same technician performed all microscopic analysis.	iQ 200 UriSed (no longer available)	The results obtained using the UriSed and iQ@200 analysers were more reproducible (7.1–30.2 and 14.9–35.4% respectively) than those obtained using the manual technique (17.9–44.4%). Significant correlations were established among the three techniques in the evaluation of leucocytes, erythrocytes and epithelial cells. Although the UriSed, iQ200 and visual-microscopic measurements were in agreement, confirmation of the results from automated methods by manual urine analyses is significantly useful, especially for pathological cases that were close to the limits of the techniques.	Kecioren research and training hospital.	Tests assigned positive and negative on the basis of agreement between tests, not using manual as standard.
Lunn <i>et al</i> 2009 [15]	280 urine samples were collected from children with known or suspected nephrourological disease attending nephrology and urology clinics over a 6 week time period. Samples were tested with dipstick, the UF100 flow cytometer (AM) and culture. A gold standard of a positive culture of 10 ⁵ colony forming units per ml (cfu/ml) with a pathogenic organism was used and the sensitivity, specificity and likelihood ratios were calculated.	Sysmex UF-100	Automated Microscopy identified 42 of 186 samples as requiring culture and 17 of 19 samples which had a pure growth > 10 ⁵ cfu/ml. Two patients were not identified by AM, one was treated for vulvovaginitis, one commenced prophylactic antibiotics prior to the culture result being obtained. The sensitivity, specificity, positive and negative likelihood ratios were 0.89, 0.85, 5.98 and 0.17 respectively. This compared to 0.95, 0.72, 3.34 and 0.29 respectively with urine dipstick. AM performed comparably to urine dipstick in the diagnosis of UTI with improved specificity and likelihood ratios with a slight reduction in sensitivity. The data support the use of AM for screening urines for culture in children but different AM methods and algorithms require local evaluation.	None stated	None apparent
Manoni <i>et al</i> 2009 [10]	The analytic performance of the UF-1000i, has been tested on 1463 urine samples submitted for culture. Bacteria and	Sysmex UF-1000i	Analytical parameters such as sensitivity, specificity, positive predictive value, negative predictive value, and correctly classified incidence were satisfactory. Based on the results obtained in this study, when	None stated	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	leukocyte counts have been compared by means of the UF-1000i with CFU quantification on cysteine lactose electrolyte deficient (CLED) agar to assess the best cutoff values.		using the UF-1000i analyzer for a screening test for UTI, a cutoff value of 40 white blood cells/microL should be adopted. The cutoff value for bacteria should be 125/microL for those clinical conditions in which 10×10^5 CFU/mL indicates a positivity.		
Zaman <i>et al</i> 2009 [16]	Analytical and diagnostic performance of sediMAX in comparison with visual phase-contrast microscopy. The diagnostic performance with respect to visual phase-contrast microscopy was evaluated with results from two centres.	sediMAX	Within-run precision for RBC was 17.8% and 6.7% at 18×10^6 RBC/L and 447×10^6 RBC/L respectively and for WBC it was 17% and 4.4% at 4×10^6 WBC/L and 258×10^6 WBC/L respectively. Between-run imprecision for RBC was 14.7% for 30×10^6 RBC/L and 7.2% for 283×10^6 RBC/L. For WBC it was 5.4% at 25×10^6 WBC/L and 3% at 166×10^6 WBC/L. In both, areas under ROC curves (AUC) were 80-90% for RBC, WBC, squamous epithelial cells, yeast & calcium-oxalate crystals. For non-squamous epithelial cells and pathological and hyaline casts the AUC ranged 73-74%. There was no carry-over.	None stated, but manufacturer co-authored	Newer version of software available that has shown improvements.
Butch <i>et al</i> 2008 [24]	3 centre evaluation of the iQ200 compared to Haemocytometer cell counts of bodily fluid.	IRIS iQ200	Within-run imprecision, expressed as coefficient of variation (CV), ranged from 2.6% to 5.9% for RBC counts between 875 and 475×10^6 /L and from 4.2% to 6.5% for nucleated cell counts between 820 and 590×10^6 /L. The lower limits of detection, based on a CV of 20% or less, were 30 and 35×10^6 /L for RBCs and nucleated cells, respectively. There was very good agreement between automated iQ200 and manual body fluid cell counts based on slopes and r^2 values. The iQ200 has satisfactory performance for enumerating RBCs and nucleated cells in most body fluids, with the exception of cerebrospinal fluid specimens that contain low cell numbers.	IRIS Diagnostics	Not about urine, possible conflict of interests
Grosso <i>et al</i>	Investigated 1047 urine samples collected from inpatients and	Sysmex UF-	The results obtained with Sysmex UF-100 are very interesting, especially if this analyzer is used as a	None stated	None obvious

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
2008 [18]	outpatients with a commercial vacutainer system (Becton Dickinson, Milan, Italy) and compared a second-generation flow cytometry system with standard urine culture tested on agar plated by means of 10 microliter loop.	100	screening method for negative urine samples, and comparable to data obtained from culture examination. In fact, considering together bacteria and leukocyte count (> 4500 bacteria and/or > 50 leukocytes/microL) a negative predictive value of 99.5% in was obtained in comparison with the standard culture method. The classical culture method needs 24 hours for a result, whereas the Sysmex UF-100 analyzer gives results in a few minutes, thus reducing the microbiology turn around time (TAT) for negative samples with obvious benefits for patients and physicians.		
Mayo <i>et al</i> 2008 [11]	Studied 652 fresh samples. The samples were analysed without centrifugation in the 4 analysers considered, they were then centrifuged, and the routine diagnostic microscopic urinalysis was performed.	Atlas Urisys 2400 (dipsticks) Sysmex UF-100 IRIS iQ200	The Spearman's statistic (p) showed an adequate agreement between methods for RBC (iQ200=0.473; UF-100=0.439; Atlas=0.525; Urisys=0.539), WBC (iQ200=0.695; UF-100=0.761; Atlas=0.684; Urisys=0.620), and bacteria/nitrites (iQ200=0.538; UF-100=0.647; Atlas=0.532; Urisys=0.561) counts. By applying the Wilcoxon and McNemar tests, a concordance degree was found between 82-99 and 52-95% for the values obtained from the two test strips analyzers considered and from the iQ200 and UF-100 systems, respectively. From these results, we can conclude that both test strips analyzers are similar and, on the other hand, that automated urinalysis is needed to improve precision and the response time; but sometimes manual microscopic revisions are required, mainly when flags, because of crystals, are detected.	Bayer Diagnostics and Roche Diagnostics, provided reagents.	Two technicians used for microscopic analysis.
Tworek <i>et al</i> 2008 [3]	Participants selected 10 random urinalysis tests received during each shift and determined if an	None specifically	Less new information was learned from performing MME, 43% compared to 67% after automated examination.	None stated	Not statistically significant.

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	MME (manual microscopic examination) was performed until a total of 50 urinalysis tests with an MME were reviewed.				
Van den Broek <i>et al</i> 2008 [22]	Compared the performance of the iQ200 with traditional microscopy and strip analysis in routine urinalysis. A total of 1482 routine samples, positive in dipstick testing were evaluated for erythrocytes, leukocytes, casts, dysmorphic erythrocytes and bacteria using the iQ200 and traditional microscopy. The results of 320 of these samples were linked to underlying urological pathology as well as results from bacterial culturing.	IRIS iQ200	Analytically, the iQ200 surpasses traditional microscopy. The identification of casts and dysmorphic erythrocytes in routine samples improves when using the iQ200, although the sub-classification of casts required well-trained technicians. The auto-classification of particles was least reliable for yeast and bacterial cocci. The quantitative reports, and therefore the use of precise cut-off points allowed earlier and improved detection of urinary tract pathology.	None stated	None obvious
Chien <i>et al</i> 2007 [17]	436 urine samples were collected. The urine sediments were examined by microscopy and two automated urine microscopy devices.	IRIS iQ200 Sysmex UF-100	The within-run CVs for urine samples ranged from 3.4% to 22.3% for the iQ200, 1.6% to 24.2% for the UF-100 and 12.5% to 43.9% for manual microscopy. Between-run CVs on quality-control samples ranged from 6.1% to 32.4% for the iQ200 and 3.5% to 24.7% for the UF-100. The agreement between methods was good for RBC and WBC counts based on r values of 0.935 to 0.968. However, for epithelial cells, the values measured by different systems were poorly correlated (r=0.888-0.922). The Bland-Altman plot indicated a trend towards the automated cell count being greater than manual microscopy as the epithelial cell count increased. Casts were with difficulty differentiated by two automated systems.	None stated	Centrifugation of samples for conventional microscopy may affect the repeatability of manual method.

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
			They demonstrated good concordance with each other in urine sediment examination. The authors feel that automated processes could be used as a screening procedure but some manual microscopy will still be necessary.		
Delanghe 2007 [12]	Review of diagnostic techniques	Sysmex UFseries and Iris iQ200	Combining diagnostic techniques results in higher diagnostic efficiency. Still need for trained personal.	None Stated	Only a review of information, no testing carried out.
Shayanfar et al 2007 [1]	332 specimens analyzed by manual microscopy and two machines	Sysmex UF-100, IRIS iQ200	Automated urine sediment analysis is sufficiently precise and improves the workflow in a routine laboratory. Automation is not a substitute for microscopic sediment examination, but when combined with dipstick testing, it can reduce the number of specimens submitted for microscopy.	Axon Lab	None obvious
Evans et al 2006 [23]	1005 consecutive urine samples analyzed by both UF-100 and culture	Sysmex UF-100	Cut-off values of 3000 bacteria/ μ l and 111 WBC/ μ l provided the best discrimination. Of 1005 samples, 606 (60%) would be cultured. Sixteen samples that were not selected according to these criteria were culture positive. This was considered acceptable for our routine use. The use of a testing algorithm incorporating the Sysmex UF-100 flow cytometer has improved the quality and efficiency of urine testing within the routine microbiology laboratory		
Linko <i>et al</i> 2006 [8]	The iQ200 instrument results from 167 mid-stream, uncentrifuged urine specimens were compared to those obtained with phase contrast reference microscopy, and to those with routine bright field microscopy. Linearity, carry-over	IRIS iQ200	The iQ200 counted erythrocytes (RBC) at $r=0.894$ ($R(2)=0.799$) with Automated Particle Recognition (APR) software alone and at $r=0.948$ ($R(2)=0.898$) after re-classification. The performance for leukocytes (WBC) was $r=0.885$ with APR and $r=0.978$ after re-classification. The correlations of counting after user re-classification were $r=0.927$ for squamous epithelial cells (SQEP), $r=0.856$ for casts, and $r=0.706$ for non-	IRIS Diagnostics for financial and technical assistance	Re-classification by technician improved data Screening of samples to ensure best range for equipment. Hyaline and non hyaline casts were grouped

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	and precision were tested according to well-established protocols.		squamous epithelial cells. The iQ200 showed good linearity and precision and no carry-over was detected.		together in analysis.
Okada <i>et al</i> 2006 [19]	273 urine samples were obtained. Results from UBA were compared to urine culture.	UBA (Urine Bacterium Analyser)	The UBA detected significant bacteriuria with a sensitivity of 96.6%, a specificity of 79.9%, a positive predictive value of 57.0%, a negative predictive value of 98.8%, a false-positive rate of 15.8%, a false-negative rate of 0.7%, and an accuracy of 83.5%. These results were comparable to or better than those obtained with previously reported screening procedures. The UBA can perform accurate enumeration of bacterial cells automatically in 90 seconds and can be used for the screening of significant bacteriuria.	Sysmex grant, co-authored by manufacturer	None obvious
Ozdem <i>et al</i> 2006 [25]	Asymptomatic pyuria prevalence (ASP) was investigated in 227 diabetic patients. Imprecision, accuracy and correlation of UF-100 with hemacytometer in measuring leukocyte counts were determined.	Sysmex UF-100	Diabetic women and men had significantly higher asymptomatic pyuria prevalence than non-diabetic women (21.4 vs. 8.7%) and men (12.2 vs. 3.4%). Disease duration and HbA(1C) levels were similar in diabetic patients with and without ASP. UF-100 and hemacytometer readings correlated significantly ($r=0.88$) without a significant bias. Within-run coefficients of variations for UF-100 (8.14, 6.35 and 12.18%) and hemacytometer (5.14, 5.18 and 8.03%) did not differ significantly.	Akdeniz University Research Project Unit	Samples had to be processed before 2 hours.
Scharnhorst <i>et al</i> 2006 [26]	Results from flow cytometric urinalysis were used to classify urinary red blood cells (RBCs) according to glomerular and non-glomerular origin and the classification was compared to the patient's clinical diagnosis as the gold standard. In parallel,	Sysmex UF-100	Urine flow cytometry correctly classified 61% (sediment analysis 69%) of urine samples with overt hematuria. If inconclusive results are excluded, the UF-100 correctly diagnosed 85% (sediment analysis 98%) of urine samples with overt hematuria. The UF-100 and microscopic sediment analysis both showed sensitivity of 99% for the detection of glomerular hematuria. The specificity of the UF-100 for the	None Stated	

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	microscopic sediment analysis was carried out. A total of 206 urine samples from 129 patients were analyzed (127 from patients with glomerular hematuria, 79 from patients with non-glomerular hematuria). Of these, 136 samples (92 patients) showed overt hematuria (≥ 20 RBC/microL).		detection of glomerular bleeding was lower (42%) than the specificity of microscopic sediment analysis (93%). Owing to its low specificity, the UF-100 showed limited capacity to discriminate glomerular from non-glomerular causes of hematuria in a population with a high incidence of renal disease. Therefore, extensive microscopic urinalysis remains necessary to assess the origin of hematuria.		
Steinmetz <i>et al</i> 2006 [20]	The aim of the study was to compare in a supposed healthy population of 680 subjects several algorithms for positive selection of urine samples requiring microscopic examination for erythrocytes and leukocytes after screening by automated test-strip measurement and particle counting on a Sysmex UF-50 flow cytometer. Four strategies have been formulated and the sensitivity, specificity, positive predictive value, negative predictive value, false positive rate, false negative rate, and microscopic review rate were measured	Sysmex UF-50	The strategy combining test strip analysis and automated counting on all samples, followed by microscopic examination of only discordant samples gave the best results. When the two methods of haematuria screening were in agreement (91% of samples), the false negative rate for microscopy was 1.1%, with a false positive rate of 0.8%, sensitivity of 66% and specificity of 99%, and the results are acceptable without any other examination. When the two methods of haematuria screening were discrepant, visual microscopic analysis was necessary to obtain definitive results. For leukocyturia screening, 80% of results were in agreement by test strip and automatic sediment urinalysis, with only ten results considered as false negatives (1.8%) and four as false positives (0.7%). Agreement was good as were the other criteria (sensitivity 79%, specificity 99%). On conflicting samples, there was no agreement between methods and microscopic analysis was essential. The benefit of such an algorithm would be optimisation of workflow without any loss of sensitivity and specificity at the expense of a two-fold increase in cost.	A. Menarini Diagnostics and Sysmex	None obvious

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
Alves <i>et al</i> 2005 [27]	Evaluation of the IRIS iQ 200 was carried out with respect to linearity and precision, and compared results with microscopic examination of the urine sediment, and with the measurement of urine strips in a CLINITEK 500 analyser.	IRIS iQ 200	The assay was linear between 10 and 1030 particles/ μ l. The detection limit was 6 particles/ μ l. Intra- and inter-assay coefficients of variation were 1.9% and 2.3%. Results by the IQ 200 analyser showed highly significant correlations with those of the urine sediment (erythrocytes: $\rho=0.68$; leukocytes: $\rho=0.60$; epithelial cells: $\rho=0.66$; $p<0.001$), and urine strips (erythrocytes: $\rho=0.67$; leukocytes: $\rho=0.66$; $p<0.001$). These results indicate that the IRIS IQ 200 analyser may play a useful part in the automated examination and measurement of urine specimens.	IZASA, S.A	Compared with dipsticks, an inferior technology with poor sensitivity
Lamchiagdhasse <i>et al</i> 2005 [28]	Compared the IQ200's performance with manual routine slide and chamber counts. Fresh urine samples were obtained from 400 subjects.	IRIS iQ200	The reference values of white blood cells, red blood cells and squamous epithelial cells were not significantly different for the results reported as cells per high-power field. For the specimens of patients ($n=280$), a significant correlation was found when the iQ200 results of cellular elements were compared with those obtained from manual microscopy. No significant difference was found when the post-review results of the iQ200 were compared with the chamber count. However, the presence of casts, crystals, bacteria, and budding yeast needs further characterization under the microscope.	None Stated	The process of centrifugation, decantation, resuspension may cause a loss of cells as lysis or adhesion to surface of test tube. iQ200 therefore may be more accurate at very high and low concs.
Wah <i>et al</i> 2005 [7]	Evaluated the performance of the Iris iQ200 Automated Urine Microscopy Analyzer (Iris Diagnostics, Chatsworth, CA) and compared results with manual cell and particle counts using Fuchs-Rosenthal counting chambers.	IRIS iQ200	Within-run imprecision (coefficient of variation) of the iQ200 for urine samples ranged from 3.0% to 45% for RBC counts between 1,029 and 3×10^6 cells/L, 3.4% to 40% for WBC counts between 1,006 and 4×10^6 cells/L, and 8.9% to 35% for epithelial cell counts between 93 and 4×10^6 cells/L. Between-run imprecision was 3.3% at $1,017 \times 10^6$ cells/L and 19.2% at 28×10^6 cells/L. There was good	IRIS Diagnostics	Calcium oxalate crystals Oval can result in falsely high RBC counts. Hyaline casts are translucent and may have been missed by the

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
			agreement between the iQ200 and manual cell counts ($r > \text{or} = 0.94$); however; the iQ200 produced lower results based on slopes of 0.92 (RBC count), 0.81 (WBC count), and 0.94 (epithelial cell counts). The iQ200 has satisfactory performance and correlates well with manual cell counts. Most urine samples containing RBCs, WBCs, and epithelial cells can be reported without review of captured images.		human reader.
Kaneko <i>et al</i> 2004 [21]	To assess the utility of a newly developed automated urinary flow cytometer (UFCM) in differentiating the origin of hematuria in the mass screening system for renal diseases in school children. In total, 4,620 children aged 6-14 years with abnormal urinary findings by the screening program in Tokyo were enrolled.	UFCM-Automated Urinary Flow Cytometer	nephritis in 11, suspected nephritis in 104, hematuria in 771, minimal hematuria in 1,506, proteinuria in 477, urinary tract infection in 83, and healthy in 1,668. Glomerular hematuria, assessed by UFCM, was found in 81.8% of nephritis, 58.7% of suspected nephritis, 59.7% of hematuria, 57.4% of minimal hematuria, 13.4% of proteinuria, and 21.5% of the healthy group. The presence of glomerular hematuria assessed by UFCM had a sensitivity of 61.0%, specificity of 78.5%, positive predictive value of 16.3%, and negative predictive value of 96.7% for the diagnosis of nephritis and suspected nephritis. Thus, results imply that the absence of glomerular hematuria as assessed by UFCM is highly predictive of the absence of nephritis.	Not relevant	None apparent
Fogazzi <i>et al</i> 2003 [29]	The authors reviewed the main contributions dealing with urine sediment examination, published in international journals in the period from January 2002 to April 2003. After a section on methodological aspects, they described the importance of urine sediment examination in various diseases of urinary tract.	None-Review	The review of the literature on urine sediment examination shows that this test has important clinical implications in a large spectrum of diseases. Therefore, it should be more widely used by nephrologists.	None stated	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
Ottiger <i>et al</i> 2003 [30]	The standardized KOVA cell chamber system was used to count particles and results compared with the UF-100 flow cytometry as an alternative to traditional sediment analysis.	Sysmex UF-100	252 randomly selected urine samples were compared and a review rate of 33% was obtained. Microscopic verification was necessary because of the presence of casts, yeast, sperm, dysmorphic erythrocytes, and some misclassified erythrocytes or leukocytes that were detected by incongruent dipstick results and abnormal scattergrams. Correlation coefficients of 0.966 for erythrocytes and 0.935 for leukocytes were obtained. Criteria for an algorithm to identify samples that needed microscopic review were derived from comparisons between the number of particles from UF-100, dipstick results, cell chamber counting, and sediment analysis. Automated cell counting combined with microscopic counting with a standardized cell chamber system is useful. An objective algorithm for review criteria can be developed via systematic comparison of UF-100 flow cytometry and microscopy. Only urine samples that meet these criteria need to be confirmed microscopically.	Digitana	None apparent
Dimech <i>et al</i> 2002 [31]	The results of the automated system for 818 urine samples were compared with the results of manual processing which consisted of phase contrast microscopy, manual dipstick chemistry analysis and culture onto solid media.	Sysmex UF-100	The correlation between the two methods for urine chemistry was excellent with a concordance of 89, 97, 100 and 98% for pH, blood, glucose and protein, respectively. The quantification of red blood cells and white blood cells had an R ² of 0.855 and 0.92, respectively. A difference scatter plot indicated a trend towards the manual cell count being greater than the UF-100 count as both the red and white blood cell count increased. There was 98% agreement between the automated process and manual culture. Automation of urinalysis offers a reduction in variation and has comparable results to manual testing.	None Stated	Comparison of three technologies (urinalysis system) against manual alternatives. Evaluated the results of the system as a whole. Process time too great. RBC and WBC only used for microscopy.

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
Sutheesophon <i>et al</i> 2002 [32]	The analytical performance was evaluated and compared to the results of the reference method (JCCLS)	Sysmex UF-100	Between-run CVs for RBCs (mean = 182.46/ μ l), WBCs (mean = 193.37/ μ l), ECs (epithelial cells) (mean = 70.05/ μ l) and casts (mean = 12.21/ μ l) were 7.74%, 5.52%, 21.32% and 7.69%, respectively. Concerning the within-run CVs for the RBC analysis, the CV ranged from 16.28% for low numbers of RBCs (35.67/ μ l) to 2.93% at RBC concentrations (712.13/ μ l). Concerning within-run precision for the WBC analysis, the CV ranged from 22.31% for low numbers of WBCs (WBCs 12.53/ μ l) to 2.07% at a WBC count of 211.01/microl. Within-run precision ranged from 11.36% at 24.99 ECs/ μ l to 6.18% at 53.08 ECs/ μ l. Within-run precision for casts varied from 35% for samples with 1.33 casts/ μ l to 12.38% for samples with 4927.35 casts/ μ l. From the comparative study, good agreements ($p < 0.05$) were obtained between UF-100 and JCCLS reference method for RBCs counts ($p = 0.000$, $r = 0.974$) and WBCs counts ($p = 0.000$, $r = 0.913$). However, fair agreement ($p > 0.05$) was obtained between UF-100 and JCCLS reference method for ECs counts ($p = 0.017$, $r = 0.212$) and casts counts ($p = 0.624$, $r = 0.044$). In conclusion, the UF-100 analyzer is a new useful analyzer although it cannot be a substitute for microscopic sediment examination.	Sysmex and Meditop, which provided technical assistance and control material	None apparent
Apeland <i>et al</i> 2001 [33]	Compared bright-field microscopy with automated urine flow cytometry, examining their ability to differentiate between glomerular and non-glomerular haematuria.	Sysmex UF-100	The Sysmex UF-100 had a sensitivity and specificity of 0.83 and 0.94 respectively in detecting non-glomerular bleeding. The positive and negative predictive values were 0.95 and 0.78 respectively. The corresponding values of microscopy were 0.79 and 0.90 respectively, and 0.93 and 0.74 respectively. Automated flow cytometry can be used in the	Ulrike Balesio (Sysmex)	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
			distinction between glomerular and non-glomerular haematuria.		
Okada <i>et al</i> 2001 [34]	Assessed the Sysmex UF-50 for reproducibility of results and carryover rate by performing between- and within-run precision analyses on 315 urine samples, evaluated the feasibility of using the UF-50 to measure urinary cellular and noncellular components by comparing results from the UF-50 with results of manual urinalysis using the Kova system, and performed side-by-side comparison of the within-run reproducibility from the UF-50, the UF-100, and the Kova system.	Sysmex UF-50	Results from the UF-50 and UF-100 were highly reproducible, and the carryover rate was 0.5% or less for the urinary components. In between-run precision assays, the coefficients of variation for UF-50 results for all cellular components were less than 10%. The agreement (gamma statistics) between values from the UF-50 and the Kova system was excellent for RBC, WBC, and bacterial counts. The cell counts from the UF-50 for RBCs, WBCs, epithelial cells, and bacteria were 52%, 63%, 54%, and 110%, respectively, of those measured by manual urinalysis. The UF-50 performed quantitative analysis in 72 seconds, compared with 330 seconds for manual methods. The UF-50 is suitable for the first screening to detect hematuria, pyuria, and bacteriuria.	Sysmex, part grant. Co-authored by manufacturer	None apparent
Roggeman <i>et al</i> 2001 [35]	cross-interpretation of the Sysmex UF-100 (TOA Medical Electronics, Kobe, Japan) and urine strip results such that microscopy would be performed if there was discordance. performed 2 studies: study 1 to establish review rules for eventual microscopic examination; study 2, a validation study.	Sysmex UF-100	Review rates were 40% and 48% and those of UF-100 software were 16% and 32% for the 2 studies. False-positive and false-negative results, among the samples not flagged for microscopic review, were acceptably low. Did not find a good correlation between the microscopic classification of RBC morphologic features and the classification given by the UF-100. Since incorporation of the automated urine strip reader and the UF-100 in routine use, manual microscopy has been reduced to less than 40%.	Merck Eurolab and A. Menarini diagnostics for providing apparatus and reagents.	None apparent
Delanghe <i>et al</i>	Comparisons of UFC with chamber counts, quantitative	Sysmex UF-	A review of previously presented data concerning flow cytometry. Evaluations have established acceptable	None stated	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
2000 [36]	urine microscopy, sediment counts, test strips, bacterial culture and urine density are reviewed.	100	linearity over useful working ranges, with an imprecision that is consistently and significantly less than microscopy, and with negligible carry over.		
Okada <i>et al</i> 2000 [37]	Evaluated the ability to screen urine samples for significant bacteriuria. 186 urine specimens from patients attending an outpatient clinic of a university-based hospital were examined. The results obtained with the UF-50 were compared with those obtained by conventional quantitative urine culture.	Sysmex UF-50	A sensitivity of 83.1%, a specificity of 76.4%, a positive predictive value of 62.0%, a negative predictive value of 90.7%, and an accuracy of 78.5%.	Sysmex corp. Co-authored by manufacturer	Loop used for inoculating samples was inaccurate.
Hannemann-Pohl <i>et al</i> 1999 [38]	Urine specimens from 438 patients were examined with the UF-100 flow cytometer and by manual microscopy and test strips. 142 of these were also examined bacteriologically. The measurements with the UF-100 were performed on native urine without prior centrifugation.	Sysmex UF-100	Intraassay imprecision, CV of 1.3% (547/microliter) to 8.5% (24/microliter) for erythrocytes and CV of 2.4% (218/microliter) to 5.6% (10/microliter) for leukocytes, are similar to those usual in clinical chemistry, and are very much better than those seen in manual microscopy of sediment. In routine use, overloading the flow cytometer by an excessive concentration of particles was observed in 9% of specimens. Such specimens should be checked visually. In the authors opinion the Sysmex UF-100 is a suitable replacement for manual microscopy of urine sediment. In addition it offers an opportunity to improve standardization of basic urinalysis.	None stated	None apparent
Hyodo <i>et al</i> 1999 [39]	98 urine samples from 31 glomerular and 67 nonglomerular lesions were analyzed by the device, and the criteria to determine the origin of	UFCM Sysmex UF-100	The sensitivity for glomerular RBC in the first 98 cases was 90.3% and the specificity 92.5%, and in the second 108 cases the values were 100 and 86.6%, respectively. The automated urinary flow cytometer is useful as a means for routine differential diagnosis of	Sysmex	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	hematuria were established based on the results. Additional 108 cases were tested to evaluate the validity of these criteria.		hematuria, and at least it is promising as the screening test for differentiation between glomerular and nonglomerular hematuria, because it can examine numerous samples within a short time and does not necessitate any special skill or knowledge.		
Kouri <i>et al</i> 1999 [13]	Evaluated the Sysmex UF-100 urine flow cytometer with 269 uncentrifuged urine specimens by comparing it with Sternheimer staining and particle counting in 1-microL disposable chambers with both brightfield and phase-contrast microscopy (the reference method). Results of routine test strip analysis, sediment microscopy (182 specimens), and bacterial culture (204 specimens) were also available.	Sysmex UF-100	Detection of urinary WBCs and RBCs was highly reliable with the UF-100 compared with manual chamber counting ($r = .98$ and $.88$, respectively). Identification of bacteria was equal to that with visual microscopy of uncentrifuged specimens; sensitivity was 55%, and specificity 90%, compared with bacterial cultures at a cutoff of $> 10(3)$ colony-forming units per milliliter. Renal damage was difficult to evaluate even with manual methods because of the low counts of renal tubular cells and casts; with standard manual Sternheimer-stained sediment analysis, sensitivity was 65% to 69% and specificity 66% to 91%, compared with the uncentrifuged chamber method at a cutoff of 3 and 10 particles per microliter, respectively. Renal damage was demonstrated with the UF-100 with a sensitivity of 26% to 69% and specificity 92% to 94%, compared with chamber counts. Automated urinalysis with the UF-100 urine flow cytometer offers considerable savings in time and labor. When high sensitivity is needed, visual microscopic review should be performed to detect renal disease.	None Stated	None apparent
Langlois <i>et al</i> 1999 [40]	Compared UF-100 test results with those of an automated dipstick reader. A cross-check of UF-100, dipstick, and microscopic sediment data was	Sysmex UF-100	Good agreements ($P < 0.001$) were obtained between UF-100 and dipstick data for erythrocytes ($r = 0.636$) and leukocytes ($r = 0.785$). Even in urine with low conductivity, the UF-100 could detect lysed erythrocytes. The UF-100 bacterial count was higher	Sysmex, Boehringer Mannheim and Terumo Europe	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	performed in 1001 urine samples.		among nitrite-positive urine samples ($P < 0.0001$) and was positively correlated with the UF-100 leukocyte count ($r = 0.745$; $P < 0.001$). In stored urine (24 h), bacterial counts increased, whereas the forward light scatter of leukocytes decreased ($P < 0.01$). Casts and yeast cells reported by the UF-100 should be confirmed by microscopic review because false positives occurred. Suggest that a computer-assisted cross-check of UF-100 and dipstick data allows a clinically acceptable sieving system to reduce the workload of microscopic sediment urinalysis.		
Ben-Ezra <i>et al</i> 1998 [41]	Instrument accuracy was assessed by comparing continuous counts of microscopic elements from the UF-100 with ranges of cells (per low-power field or high-power field) from manual microscopy performed on centrifuged urines.	Sysmex UF-100	Counts showed good agreement between methods (gamma statistic: 0.880-0.970) for all microscopic elements in 252 urine samples. Within-run imprecision of cell counts expressed as CV (mean cell count/microL) was for erythrocytes (RBC) 31% (5), 18% (50), 2.4% (800); for leukocytes (WBC) 14% (10), 11% (100), 8.5% (400); for squamous epithelial cells (SEC) 18% (5), 12% (30), 7.0% (100); for casts 45% (1), 17% (4); for bacteria 2-12% (entire range of 40-2500). Between-run imprecision on quality-control cell suspensions expressed as CV (mean cell count/microL) was for RBC 6.1% (50), 2.7% (256); for WBC 26.9% (54), 4.9% (228). Cells counted on dilution were 99.1% of expected for RBC, 102.0% for WBC, and 121.8% for bacteria. Carryover was $< 0.04\%$ for RBC, $< 0.03\%$ for WBC, $< 0.14\%$ for SEC, $< 0.29\%$ for bacteria.	Sysmex, provided technical assistance, control material and a stipend	None apparent
Fenili <i>et al</i> 1998 [42]	1943 Urine samples were obtained and analysed with the UF-100 and Sediment microscopy. A further 608	Sysmex UF-100	No carryover was observed, while the linearity was higher than the upper limit (40000 total particles microl(-1)) suggested by the manufacturer. The within-run imprecision was low, ranging from 17.7 % to 2.4%	Dasit-Milano supplied the reagents	None apparent

Reference	Design	Devices	Results	Disclosures / Sponsors	Limitations
	samples were obtained for microbial culture.		and was up to threefold better than manual microscopy. Comparison of results obtained by sediment microscopy (performed according to National Committee for Clinical Laboratory Standards (NCCLS) recommendations) and by the UF-100 analyser showed a linear correlation with $r = 0.833$ for erythrocytes, $r = 0.934$ for leukocytes, $r = 0.880$ for epithelial cells and $r = 0.40$ for casts. To evaluate the reliability of the UF-100 analyser in detecting bacteria results were compared with the microbial culture ($n = 608$). Using a cut-off value of bacterial count above 1800 degrees I(-1) and at leukocyte count above 45 microl(-1), the analyser detected positive cultures with a sensitivity of 87 % and a specificity of 80 %.		
King 1998 [43]	Review of different methodologies employed in automation of urinalysis.	Yellow IRIS Sysmex UF-100	Automating the Urinalysis can involve several different methodologies, sometimes incorporated onto one platform. Some urinalysis methods are similar to those used in other laboratory disciplines. Others are unique. The goal of all these technologies is to optimize standardization, increase efficiency, and improve quality. Cost must be considered when selecting instrumentation for the urinalysis laboratory.	None stated	None apparent
Deindoerfer <i>et al</i> 1982 [44]	Discussed improvements in microscopy's use, in terms of "front-end" automation of specimen handling and "back-end" automation of image analysis.	None	Examples of spatial and spectral differentiation illustrate the potential of this automated version of microscopy as a useful tool with very powerful analytical capabilities for the clinical laboratory.	None stated	None apparent

Evidence review: Automated urine screening systems

**Richard Thompson, Andrew
Gammie, Debbie Lewis, Rebecca
Smith, Carolyn Edwards**

Bristol Urological Institute
Southmead Hospital
Bristol
BS10 5NB

Tel: 0117 323 5690
Email: cep@bui.ac.uk
www.bui.ac.uk

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