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Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Evaluation report

Automated urine screening systems

CEP10031

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Informing procurement - Encouraging innovation

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Summary

The product

This evaluation report covers 3 automated urine analysers commercially available in the UK.

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 particules, e.g. dysmorphic erythrocytes, yeasts, Trichomonas *vaginalis*, oval fat bodies, spermatozoa, casts and certain crystals.

National guidance

National guidance exists from the Health Protection Agency in the form of a national standard method (BSOP 41) [1] 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 [2] 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 [16].

Methods

A questionnaire evaluating the use of automated urinalysis in comparison with manual urine microscopy was distributed to 250 diagnostic laboratories across the UK. User views on cost effectiveness, reproducibility, capacity and user skill level were assessed.

Technical performance

Users report that advantages of automated urinalysis are that it is more reproducible and accurate than manual analysis leading to increased confidence in results. Analysis time per sample is decreased and screening requires less staff time. Users report that lack of automated reports and low confidence in repeatability and accuracy were limiting factors of manual screening that were not associated with automated devices.

Operational considerations

Introduction of an automated urinalysis device reportedly increased the capacity of the laboratory to screen more samples producing results in less time than by manual microscopy screening. Urine screening was carried out by lower grade staff and existing staff were redeployed to other tasks.

Economic considerations

Accuracy and repeatability of results were the two most important considerations when purchasing a machine. Cost of purchase was important and cost was the largest factor preventing purchase of an automated urinalysis device with many laboratories lacking the budget. Redeployment and lower grading of staff with increased turnover and speed of urine screening gave economic advantages of automated screening over manual screening.

CEP verdict

Users report that automated methods of urine microscopy are reproducible, accurate and faster than standard manual microscopy methods. This finding concurs with the review of published evidence published by CEP [10]. The high cost of these machines is a prohibitive factor affecting purchase however the redeployment of staff and lower grade of staff needed to run the automated screening service could make this service more economical than manual methods.

Introduction

This evaluation report presents the findings of a user evaluation of automated urinalysis devices available in the UK, when compared to standard manual urine microscopy. It supplements CEP's Evidence review of Automated urine screening systems [10], which offers more general advice on the technical, operational, and economic considerations to be taken into account when selecting an appropriate product.

Scope

This evaluation report is focused on comparing users' perceptions and experience of currently available automated urinalysis devices against current manual laboratory techniques. Digital and automated urine dipstick readers were excluded as they do not directly measure the formed elements in urine.

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 [1] 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 [2] 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 [16]. 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 coefficient of variation (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/µl.
- 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.

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 [3]. Automated systems have been developed to improve repeatability 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 [4, 5, 6]. 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 [7]. 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 [8]. 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 the 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

User evaluation

A questionnaire evaluating the use of automated urinalysis devices in comparison with manual urine microscopy was distributed to 250 diagnostic laboratories across the UK. The results were collated by the Survey monkey online survey tool [9] and a copy of this survey is included as Appendix 2.

Laboratories were given 8 weeks to respond to the questionnaire and analyses were performed on the data obtained within this time.

The questionnaire addressed the method of urinalysis in each laboratory, automated devices in use, perceived time and economic efficiencies and reproducibility of the device used. The questionnaire used for assessment is included at Appendix 2. Users answering “no” at question 1 were forwarded straight to question 16 onwards without the option of answering questions 2-15. Users not answering ‘automatic’ at question 7 were similarly forwarded straight to question 16.

103 laboratories completed the questionnaire; all but three of these carry out urinalysis. The three laboratories that do not carry out urinalysis and answered no to question 1 were then forwarded to question 16 onwards.

User evaluation

Laboratories using an automated urinalysis device have recorded an increase in the number of samples screened and 88% of respondents state that time from receiving the sample to gaining a result has decreased. A decrease in test time may result in an increased capacity for testing in a set period of time.

The increase in number of tests and speed to results has not had a detrimental effect on the confidence of laboratory managers in results; 48% have the same confidence in results and 43% have an increased confidence in results. Service users' confidence in the service has largely stayed the same or increased however 28% of responders do not know what effect the introduction of automated screening has had on user confidence.

Visualising the formed elements in urine samples is important to 47% and essential to 27% of responders. This implies that it is necessary for the automated system to provide the option of visual display of elements for manual review of results when indicated.

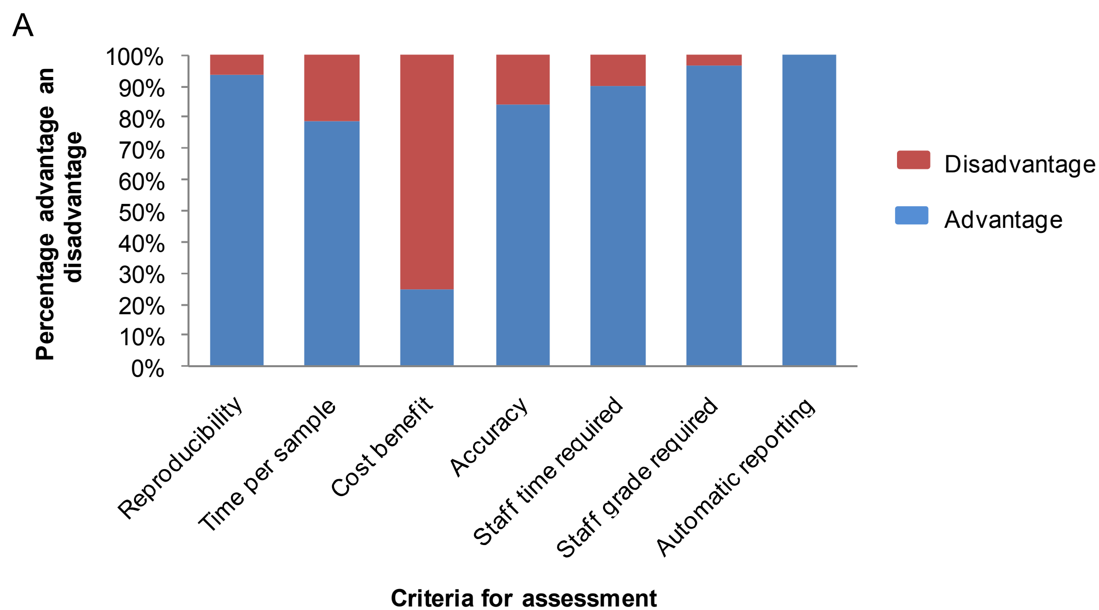
The perceived advantages and disadvantages of both automated and manual urinalysis were explored and were conversely related, with all of the advantages of automated urinalysis being perceived as disadvantages of manual urinalysis (Figure 1). Automated urinalysis is perceived to give more reproducibility and accuracy, decreases the analysis time per sample, requires less staff time and laboratories can be staffed with lower grade staff.

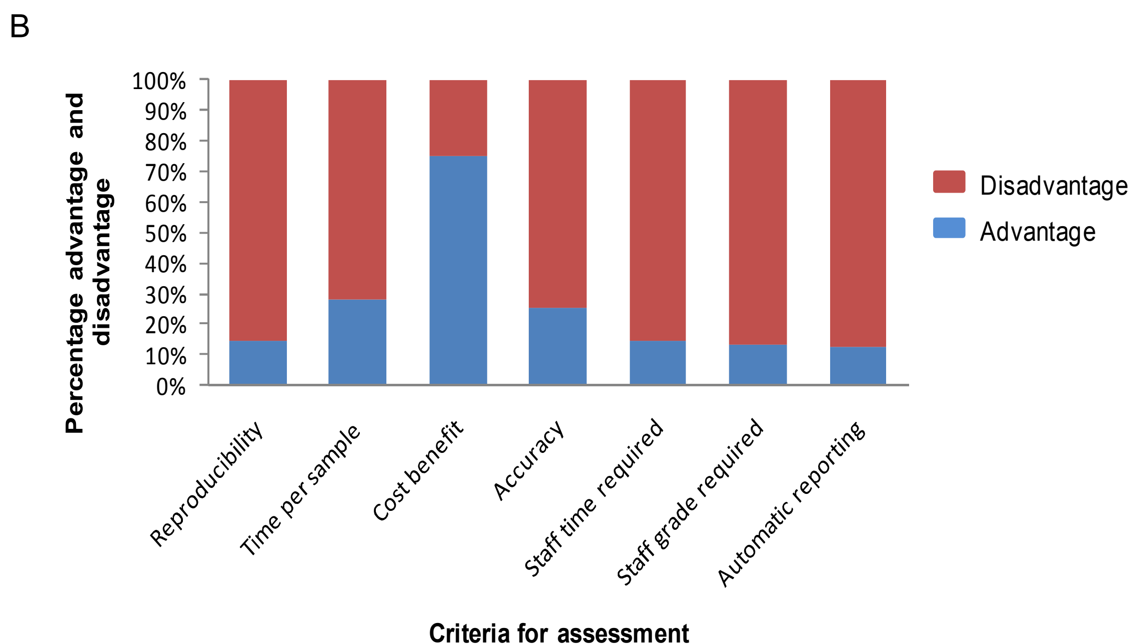
When asked for the advantages and disadvantages of an automated system one user stated "It is fantastic as a walkaway system. Workflow needs to be rearranged and avoid bottlenecks so that a continuous stream of samples are coming through for processing. Batching the work will delay results. Disadvantage is the loss of skill of recognising elements in a urine sample, training suffers, cast diagnosis is a problem, and will not pick up Trichomonas or Schistosoma - need manual microscopy for these".

For identifying negative samples the device is faster and more accurate but when samples are positive manual microscopy will be needed, requiring that staff are still trained to the same standard as previously. In addition one user quoted "Many samples with high levels of crystal deposit cannot be processed on analyser" whilst another stated "some problems encountered in higher pick up rate of haematuria,

leading to more referrals to urology services". Service users should be aware therefore that a new set of criteria for referral may be required when moving to automation.

Figure 1: Advantages versus disadvantages of A) automated urine screening systems and B) manual urine screening systems





The advantages and disadvantages of automated devices correlate well with people's views on published evidence for use of automated systems where greater accuracy and reproducibility are supported.

Table 2. Users' views on published evidence for the use of automated systems

How would you grade the published evidence for the use of automated systems? I believe there is good evidence that:	Percentage agreement
Automation gives greater accuracy	77.8%
Automation gives less accuracy	4.4%
Automation gives cheaper tests	17.8%
Automation gives more expensive tests	40.0%
Automation gives greater reproducibility	88.9%
Automation gives less reproducibility	2.2%

84% of laboratories would recommend their system to another lab with speed for delivery of negative results, reproducibility and ease of use/training requirements sited as the most frequent reasons. One user stated about their device that "In our opinion best system on the market for reliability, confidence in results, ability to screen (visual reviews), range of parameters".

In summary there is a widespread opinion that automation improves the accuracy and repeatability of urine screening, although the published evidence suggests this accuracy is very dependent upon an appropriate cut-off value being developed, as summarised in the accompanying CEP Evidence review [10]. There is a tendency to consider automated systems as more expensive to operate, whereas the same Review calculates the opposite, as long as staff time is effectively redeployed.

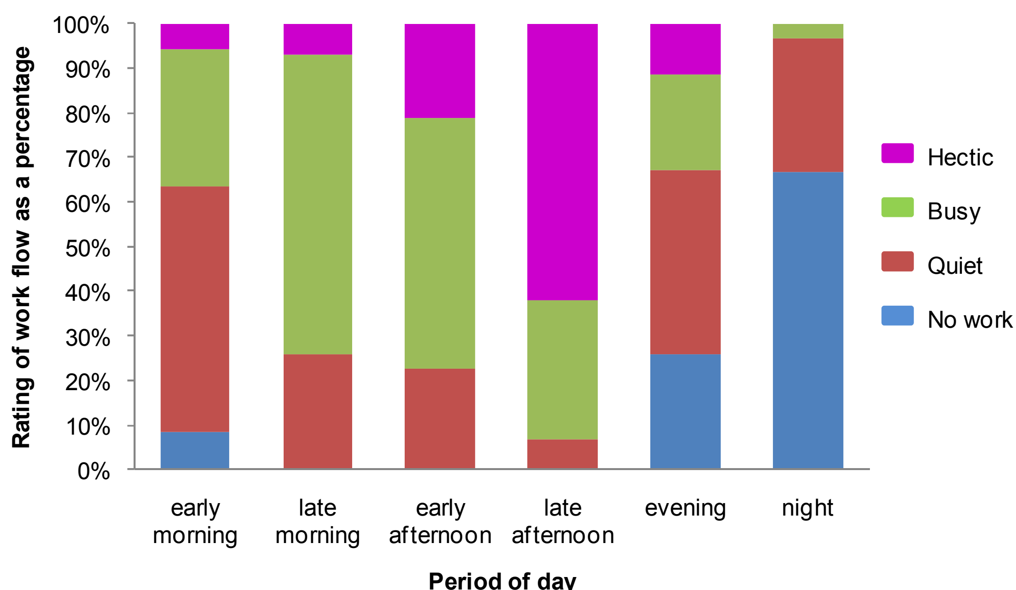
Clinical impact

In 78% of laboratories use of the automated urinalysis device has increased the number of samples processed per day. In addition to an increase in the number of samples screened 88% of respondents state that time from receiving the sample to gaining a result has decreased. This may be a factor in the noted increase of samples sent for screening. Faster results from urine screening should lead to faster diagnosis and treatment of patients. One reviewer commented that this issue is debated in Berry [15], although the paper was unavailable for our analysis.

Calibration and quality control

Laboratories process an average of 307 urine samples per day with the range of samples processed per day falling between 20 and 800. The busiest time of day for urine screening is in the afternoon, with 62% stating the level of work as hectic during late afternoon (Figure 2). All automated urinalysis devices are subject to daily quality control checks; these are mostly done in the morning when the level of screening work tends to be quieter.

Figure 2: Amount of urine screening work across different periods of the day



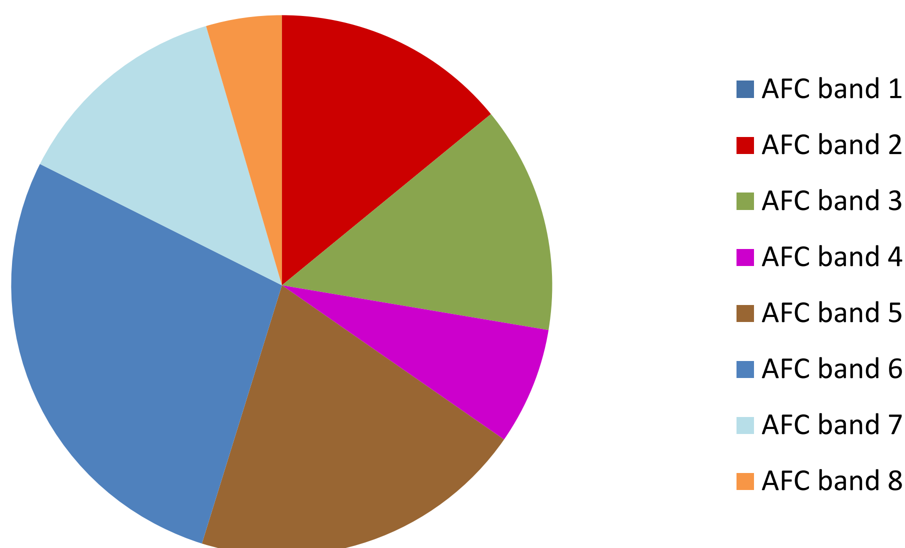
Staff requirements

Since introducing the automated urinalysis device one user commented that “less staff were required overall and the skill mix had shifted to less qualified”; they largely use AFC band 3 staff to carry out urine screening. In 55% of laboratories staff have been redeployed to other tasks and 32% require less staff overall due to use of the

automated screening. Laboratories use staff from grade 2 to grade 8 to carry out the urine screening and the majority of laboratories use 2 or more grades of staff. Figure 3 below indicates the usage of different grades of staff, grade 6 is the most frequent grade used.

One user commented that “Some of these are theoretical advantages, because it depends on whether staffing changes can be made, cost of interfacing analyser, etc”. Another user commented that “staffing has remained neutral due to an increase in workload”.

Figure 3: Grade of staff, by band, carrying out automated urinalysis

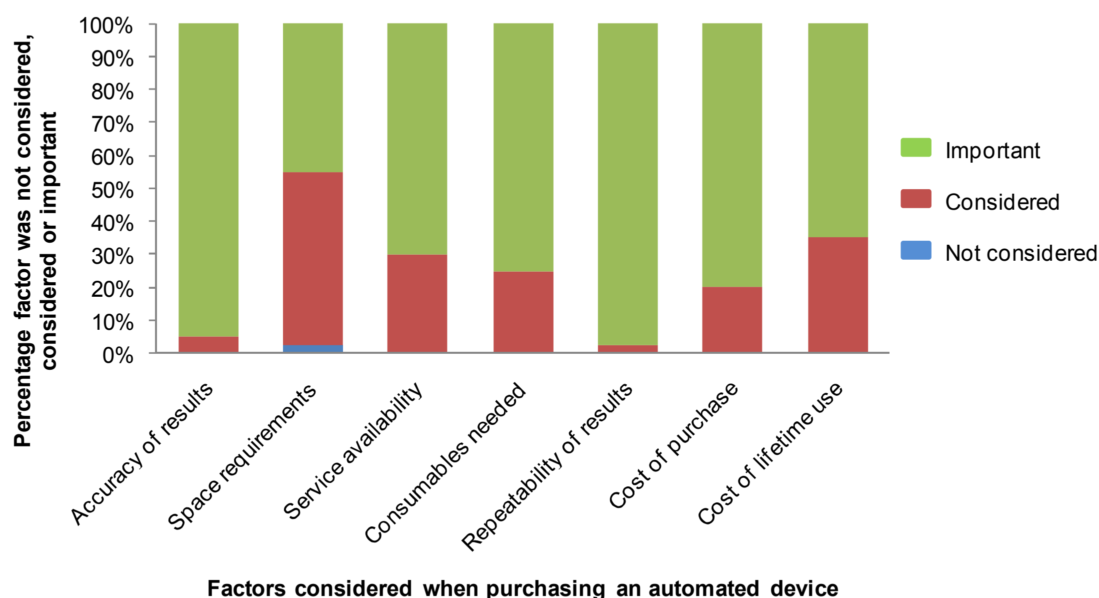


The combination of the times of day having different levels of activity and the need to keep staff skills refreshed for review purposes suggests there may be advantages in using the automated machines for the busier times of day only, keeping the quieter periods available for staff training and manual experience.

Economic considerations

Accuracy and repeatability of results were the two most important considerations when purchasing a machine. Service availability, consumables, cost of purchase and cost of lifetime use were also important considerations. Space requirements were often considered and deemed important by purchasers. Cost was the largest factor preventing purchase of an automated urinalysis device with 87% of laboratories lacking the budget, presumably referring to capital expenditure.

Figure 4: Factors considered when purchasing an automated device



In 78% of laboratories use of the automated urinalysis device has increased the number of samples processed per day, it has not changed in the remaining 22%. In 55% of laboratories staff have been redeployed to other tasks and 32% require less staff overall due to use of the automated screening. In addition to an increase in the number of samples screened 88% of respondents state that time from receiving the sample to gaining a result has decreased. Increased testing capacity and reductions in staff grade and the number of staff needed to perform urine screening should be represented by an economic saving associated with use of automated urinalysis devices (please refer to CEP's Evidence review of Automated urine screening systems for a full economic analysis and comparison [10]).

Purchasing procedures

The Trust operational purchasing procedures manual provides details of the procurement process [11].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [12]. The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, *Securing the Future* [13] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

End-of-life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [14]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

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Andrew Sladen, Product Manager, A.Menarini Diagnostics Ltd

Daniel White, Product Manager, bioMérieux UK Ltd

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IRIS iQ200

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1. Default Section

Thank you for helping with this survey. It should only take a few minutes, but will add valuable information to the assessment of automated devices in urine screening in the UK.

The results will be available in April 2010, in the form of an evaluation report from the PASA Centre for Evidence-Based Purchasing (www.pasa.nhs.uk/cep).

We anticipate it will take you 10-15 minutes to complete.

* 1. Does your laboratory carry out screening or microscopy of urine?

- Yes
- No

2. Urine Screening Services

2. What level of staff carries out the work? (tick all that apply)

- AFC Band 1
- AFC Band 2
- AFC Band 3
- AFC Band 4
- AFC Band 5
- AFC Band 6
- AFC Band 7
- AFC Band 8

3. How many urine samples per day on average are processed in your department?

No of samples / day

4. Please rate the periods of the day in terms of amount of work

	no work	quiet	busy	hectic
early morning				
late morning				
early afternoon				
late afternoon				
evening				
night				

5. Is visualising the formed elements in a sample important to you?

- Not important
- Important
- Essential
- Don't know

3. Screening method used

6. From which sources do you receive samples?

	Never	Occasionally	Weekly	Every day
Departments in this hospital	◯	◯	◯	◯
Other hospitals	◯	◯	◯	◯
GP surgeries	◯	◯	◯	◯
Maternity services	◯	◯	◯	◯
Paediatric services	◯	◯	◯	◯
Renal services	◯	◯	◯	◯
Other (describe below)	◯	◯	◯	◯

other

* 7. What method do you mostly use for urine screening?

◯ Manual microscopy

◯ Automated analyzer

◯ Outsourced services

◯ Other (please specify)

4. Automated machines

8. Please give details of the machine that is used the most for urine screening.

Manufacturer

Model

Approx age (years)

Expected lifetime (years)

9. What factors did you consider when purchasing this machine?

	Not considered	Considered	Important
Accuracy of results	○	○	○
Space requirements	○	○	○
Service availability	○	○	○
Consumables needed	○	○	○
Repeatability of results	○	○	○
Cost of purchase	○	○	○
Cost of lifetime use	○	○	○

10. Since purchasing the machine, has the number of samples processed per day:

○ Decreased?

○ Remained the same?

○ Increased?

5. Changes due to automation

11. What staffing changes have occurred since moving to automated screening?

- [ ] More staff required overall
- [ ] Less staff required overall
- [ ] Staff redeployed to other tasks
- [ ] Other (please specify)

12. What changes have occurred in the following areas since moving to automated screening ?

	Decrease	Same	Increase	Don't know
Time from sample received to result sent	○	○	○	○
Your confidence in the results	○	○	○	○
Users' confidence in the service	○	○	○	○

6. Use of automated systems

13. How many hours per day is the machine kept switched on?

- ◯ 0-7 hours
- ◯ 8-15 hours
- ◯ 16-23 hours
- ◯ 24 hours

14. When do you carry out Quality Control checks?

- ☐ Daily, mornings
- ☐ Daily, afternoons
- ☐ Daily, evening / night
- ☐ Less than once a day

15. Would you recommend your system to another lab?

- ◯ Yes
- ◯ No

Please describe any reasons for your answer

7. Manual services

16. If you have considered purchasing an automated system, please indicate any factors that have prevented you.

	Was a preventing factor	Not a preventing factor
Lack of budget	◯	◯
Lack of sample volume	◯	◯
Lack of evidence of benefit	◯	◯
Hard to change practice	◯	◯
Staff constraints	◯	◯

Other (please specify)

8. General issues

17. In your opinion, what are the advantages and disadvantages of AUTOMATED urine screening systems?

	Advantage (+)	Disadvantage (-)
Reproducibility	◯	◯
Time per sample	◯	◯
Cost benefit	◯	◯
Accuracy	◯	◯
Staff time required	◯	◯
Staff grade required	◯	◯
Automatic reporting	◯	◯

Other (please specify + or -)

18. In your opinion, what are the advantages and disadvantages of MANUAL urine screening systems?

	Advantage (+)	Disadvantage (-)
Reproducibility	◯	◯
Time per sample	◯	◯
Cost benefit	◯	◯
Accuracy	◯	◯
Staff time required	◯	◯
Staff grade required	◯	◯
Automatic reporting	◯	◯

Other (please specify + or -)

9. User perceptions

19. Please tick the machines of which you are aware.

- [ ] Sysmex UF-100 / 1000
- [ ] Iris IQ200
- [ ] Sedimax
- [ ] Other (please specify)

20. How would you grade the published evidence for the use of automated systems?

I believe there is good evidence that: (select all that apply)

- [ ] Automation gives greater accuracy
- [ ] Automation gives less accuracy
- [ ] Automation gives cheaper tests
- [ ] Automation gives more expensive tests
- [ ] Automation gives greater reproducibility
- [ ] Automation gives less reproducibility

10. Department Details

21. Which description best fits your host facility?

- Laboratory only
- Hospital department
- Academic department
- Other

22. (Optional)
If you would like to be contacted further, or would like to be notified when the review is published, please either reply to the original survey email or enter your contact details here:

Author and report information

Evaluation report: Automated urine screening systems

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We are here to help you make informed purchasing decisions by gathering evidence globally to support the use of innovative technologies, assess value and cost effectiveness of products, and develop nationally agreed protocols.

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