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Review

Use of On-Site Testing for Drugs of Abuse

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Background: **There is currently a profusion of near-patient testing devices that have been specifically targeted at drug dependency units and clinics. Some of these devices have been shown to produce accurate results. However, some devices suffer from inappropriate labeling, which together with the subjective interpretation of poorly defined reaction end-point markers, leads to misinterpretation of the results generated.**

Methods: **A literature search was conducted regarding the use and evaluation of near-patient testing devices for drugs-of-abuse screening. The results of this research, together our own practical evaluations of such devices, have been collated into this review.**

Results: **It is proposed that although near-patient testing devices may be useful in remote areas or where rapid action needs to be taken, it should be remembered that they provide only initial screening data and may yield false-positive or -negative results. Such devices need to be used with caution because a rapid but unconfirmed result may lead to misdiagnosis and inappropriate treatment for those who have a drug problem. It should be noted that a single result, which may be inaccurate, could lead to the cessation of treatment and a failure to provide care for those in greatest need. In addition, false-positive results may also have medicolegal implications, especially with the initiation of the drug testing and treatment orders.**

Conclusions: **Near-patient testing devices for drugs of abuse could be an expensive and potentially inaccurate means to monitor patient treatment and drug abuse status.**

The use of on-site or near-patient testing (NPT)[1] devices as an aid in clinical diagnosis has long been recognized as a mechanism to allow rapid generation of biomedical results. NPT devices can be defined as any method that can be used to analyze specimens outside on the laboratory setting *(1)*. The simplest of such devices are the dipstick tests and meters used in clinics and for routine measurement of chemistry analytes, ranging from the breath analyzers used at the roadside and in clinics to determine alcohol intoxication to the current spate of dipstick and cartridge tests for drugs-of-abuse screening.

All of these NPT devices are classed by the Medical Devices Agency (an Executive Agency of the United Kingdom Department of Health that ensures that medical devices meet appropriate standards of safety, quality, and performance and comply with relevant Directives of the European Union) as in vitro diagnostic medical devices, defined under the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC as "any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures" *(2)*.

However, the use of such devices is fraught with questions concerning their appropriateness for the task in question; their maintenance, calibration, and control; the validity of the training of staff in their use and results reporting; and most importantly, good recordkeeping in line with current guidelines to ensure the validity of the results obtained by their use. In addition, most devices

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[1] Nonstandard abbreviations: NPT, near-patient testing; PCP, phencyclidine; GC-MS, gas chromatography–mass spectrometry; and Emit, enzyme-multiplied immunoassay.

have been produced with the North American market in mind, and the resulting screening panel is not necessarily applicable to the European or UK situation. In particular, a substantial proportion of devices target phencyclidine (PCP) and methamphetamine, whereas in the UK PCP is rarely (if ever) abused and amphetamine, not methamphetamine, is the chief sympathomimetic abused. It is also important to be able to monitor methadone if such devices are going to be routinely used to evaluate the compliance of individuals maintained on methadone but monitored only in drug dependency clinics.

It is for these reasons that the Medical Devices Agency regularly monitors the performance and safety of in vitro devices to ensure that "the products do not compromise the health and safety of patients and users, and are designed and manufactured to achieve the performance specified by the manufacturer for the stated medical purpose" *(3)*. Although the above issues relate to all NPT devices, this review will specifically concentrate on the application of NPT devices for drugs-of-abuse screening.

Application of NPT Devices for Drugs-of-Abuse Screening

One of the first evaluations of NPT products for drugs-of-abuse screening was published in 1988, in which the effectiveness of the KDI Quik Test system to detect cocaine was questioned *(4)*. The KDI Quik Test was based on a rapid paper chromatography method using a preconditioned syringe column and potassium iodoplatinate-impregnated test paper *(5, 6)*. Three different individuals, after appropriate training, read the results of 100 urine screens, and it was found that the methods correctly identified only 50% of the samples, "the same as would be expected through random generation of test results" *(5)*. Later reports described false-positive and -negative results from the use of the KDI Quik Test *(6)*, and it was concluded that paper chromatography tests such as the KDI Quik Test are inaccurate and unacceptable in any setting for the purposes of screening for drugs of abuse *(7)*.

In 1990, the results of a study investigating the application of the EZ-Screen enzyme immunoassay card test for cannabinoids and cocaine were published *(8)*. The test results obtained from the use of the EZ-Screen were compared with gas chromatography–mass spectrometry (GC-MS) for 36 specimens positive for cannabinoids, 38 specimens positive for benzoylecgonine, and 33 drug-free specimens. In that study, the system had a sensitivity of 92% and a specificity of 89% for cannabinoids, with only one false-positive result being obtained. Typically, sensitivity and specificity are calculated as outlined below *(9)*:

$$\text{Sensitivity} = \frac{\text{Number of positive specimens determined by the NPT devices}}{\text{Number of positive specimens determined by the comparison method(s)}}$$

$$\text{Specificity} = \frac{\text{Number of negative specimens determined by the NPT devices}}{\text{Number of negative specimens determined by the comparison method(s)}}$$

By 1992, the Roche "ONTRAK" assay, based on the use of a latex agglutination inhibition method, was evaluated as a reasonable method for conducting drugs-of-abuse screening because one acknowledged drawback of the system was the subjective nature of the reading of the assay results *(10)*. The ONTRAK cannabinoid assay had a sensitivity of 67–94% with a specificity of 80–100% *(10–12)*. One other interesting aspect of the ONTRAK system was the "morphine" test cartridge *(10)*, which would later be confirmed to detect other opiates such as codeine and dihydrocodeine *(12)*, leading to possible incorrect results and misinterpretation.

The "Triage" system from Biosite Diagnostics was initially launched as the Triage 7 NPT device, which could be used to monitor amphetamines, barbiturates, benzodiazepines, cocaine, opiates, PCP, and tetrahydrocannabinol. For the UK market, the PCP test was replaced by methadone. In 1993, Wu et al. *(13)* compared the results obtained by the Syva enzyme-multiplied immunoassay (Emit) to the Triage system for 606 positive and 325 negative specimens. They concluded that the Triage NPT device produced results identical to those produced by the Syva Emit commercial comparison method and that the Triage system had a sensitivity of 93–100% with a specificity of 95–100% depending on the drug being tested. The Triage system was also found to be better suited for the analysis of benzodiazepines than the Abbott Diagnostic fluorescence polarization immunoassay and the Syva Emit. The test was found to be reliable and reproducible, with no dependence on the analyst performing the work *(14)*.

A report concerning the validity of the Hycor accuPINCH competitive immunoassay for cannabinoids was published in 1995. It was found that specimen turbidity generally led to positive specimens being reported as negative. In addition, when the read time was increased from 5 min (manufacturer's recommendation) to 10 min, concentrations were reported as higher than their true value because the intensity of the color of the test generally increased with time. This led to negative specimens being reported as positive. Overall it was stated that substantial caution was needed in reporting specimens negative for cannabinoids and that appropriate confirmatory methods were needed to ensure the accuracy of any positive results generated *(15)*.

A review of five NPT devices, sold primarily on the basis of their cost and rapid generation of accurate results, was performed in 1995 *(12)*. All devices were used according to the manufacturers' instructions, and the results generated were read blind and compared with

recognized and established methodologies, including the Syva Emit, thin-layer chromatography, and GC. There was a lack of both sensitivity and specificity and an unacceptable proportion of false-negative and false-positive results, which raised the question of their usefulness in near-patient and clinical situations. One reason for the erroneous results was the nomenclature of the tests performed: for example, methamphetamine tests detected amphetamine and morphine tests detected all opiates. This practice has been continued with the Roche Diagnostics ONTRAK TESTCUP, which is used to detect morphine but also has a 100% cross-reactivity for codeine and a 75% cross-reactivity for dihydrocodeine *(16)*. This will again inevitably lead to misinterpretation of analytical results.

Another issue regarding the use of NPT devices, highlighted in 1995, was that of appropriate working conditions and knowledge of staff using these devices. Kranzler et al. *(17)* found that the EZ-Screen might not be suitable for use in the clinical setting unless specific measures were taken to ensure the accuracy of the test. These measures were listed as minimal interruptions, distractions, and the careful training of those staff involved in their use. In addition, the authors recommended that before routine use of NPT devices, the products should be evaluated under typical working conditions with the personnel who would be required to perform the work. The issue of appropriate on-site training was also raised with the use of the Triage system, in which the essential buffer bead could "pop out" of the reaction cup of the system when the lid was removed from the cup before its use. When subsequently used to analyze low-pH urines, although the device control test yielded acceptable results, the system was found to yield false-positive drug screening results *(18)*.

Problems are still apparent in more recently marketed products. For example, the Bionike one-step tests were found to be rapid, simple to use, and relatively inexpensive. However, it was suggested *(19)* that interpretation of the results could be facilitated by increasing the read time of 3–10 min stated by the manufacturer to 15–30 min to overcome any ambiguity in results. The Morwell Diagnostics RapiTest devices were found to be quick and easy to perform and were practical and reliable. However, the subjective nature of the cannabinoid results meant that 9 of 41 specimens (22%) were reported as false negatives compared with the Syva Emit *(20)*. However, the Boehringer Mannheim FRONTLINE rapid tests were found to be rapid, reliable, and adequate for presumptive clinical and forensic screening, with only 6 of 1200 (0.5%) clinical urines positive for cannabinoids, cocaine, and opiates being undetected *(9, 21)*.

Following from the initial review of the appropriateness of NPT devices for drugs-of-abuse screening in 1995 *(12)*, there have been two additional reviews: one was somewhat more complimentary on their effectiveness and reliability, whereas the second agreed with the issues raised in 1995. The first review compared the EZ-Screen, ONTRAK, and Triage against the Syva Emit immunoassay and GC-MS. The report concluded that the EZ-Screen did not appear to adhere to a cutoff concentration, giving positive results at concentrations below the stated cutoff. In addition, comparing results generated from the use of NPT devices against those obtained with the Emit was very complex. Ensuring accuracy required a thorough knowledge of the performance of each device, Emit cross-reactivity, and GC-MS findings. Another issue raised was that an increased number of specimens would be reported as positive for cannabinoids with the NPT devices than with the Emit. However, because of the mandatory requirement to confirm these results according to federal workplace testing guidelines in the US, fewer would be reported as positive subsequent to the confirmatory testing, which would confirm the low concentrations detected *(22)*.

The second review reported the findings of the evaluation of five commercially available NPT devices: the PharmScreen, Roche TESTCUP, Accusign DOA2, Status DS, and American Bio Medica Rapid Drug Screen. Each device was challenged with 10 replicate analyses of quality-control specimens of known drug and metabolite concentrations and with known positive (n = 20) and negative (n = 22) clinical specimens previously analyzed by immunoassay and GC-MS. The devices were all used to detect the presence or absence of methamphetamine, benzoylecgonine, PCP, morphine, and Δ-9-tetrahydrocannabinol carboxylic acid. The results presented in the report indicated discrepancies between manufacturers' claims and performance for all products. The report concluded that caution was needed in the workplace environment because of the number of false positives and negatives determined in the study *(23)*.

Screening Saliva Rather Than Urine for Illicit Drug Abuse

The use of saliva as a specimen matrix for drugs-of-abuse screening has been cited in the literature for many years *(24)*. A recent comparison between saliva and urine as a specimen matrix for drugs-of-abuse screening outlined the following major differences *(25)*:

Parameter	Saliva	Urine
Collection	Noninvasive	Intrusion of privacy
Principal analyte	Parent drug	Metabolites
Analyte concentration	Low	Moderate to high
Potential problems	Oral contamination	Possibility of adulteration
	Influence of pH effects	Influence of pH effects

One of the major disadvantages of salivary drug testing is the shorter detection times for drugs compared with urine analysis, ~1 day compared with 3 days as a general rule. The short detection time of drugs in saliva could be

argued to parallel the pharmacologic actions or activities of the drugs being abused; therefore, saliva monitoring could be used for law enforcement purposes, e.g., as an added monitor to determine whether an individual is driving under the influence of drugs. However, the ability (or not) to detect drugs of abuse in saliva may be inappropriate when used for the screening of individuals suspected of drug abuse but who attend clinics infrequently for routine monitoring *(26)*. In addition, saliva cannot generally be screened by the standard methods that have been optimized to monitor the presence of drugs (parent and/or metabolite) in urine *(25)*.

The method of saliva collection may also impact on the analytical findings. If the collection is stimulated to obtain sufficient specimen volume for testing, then it is known that the saliva flow rate is increased, leading to increased saliva pH and potentially decreasing the concentrations of drugs found. This is particularly true when trying to determine cocaine abuse *(27)*. It was found that cocaine may not be detected in saliva if >2 h has elapsed since intravenous drug administration and the saliva sample was collected after stimulated production. This collection issue could therefore lead to misleading interpretation of the drug use pattern in individuals being screened.

The problem of sample volumes has been discussed with respect to heroin and cocaine detection *(28)*. It has been found that to determine heroin and cocaine excretion profiles by a sensitive method requires the collection of 5 mL of saliva over a period of 30 s by getting individuals to expectorate three to four times after stimulation with citric acid. It was acknowledged that this stimulation would reduce the amount of drug present in saliva by between 25- and 54-fold, again giving rise to concerns regarding drug detection times.

The detection time for cocaine after intravenous or intranasal administration or smoking (without stimulated collection) has recently been reported to be ≤6 h post administration *(29)*. Other disadvantages of saliva as a specimen matrix for drugs-of-abuse screening were described as the variable nature of saliva pH, which affects drug excretion and detection; the influence of collection devices and procedures on drug concentration; and the possibility of saliva being contaminated by drug residues in the oral or nasal cavities.

The issue of oral contamination affecting the correlation of saliva to plasma codeine concentrations has been also been discussed *(30)*. It was found that despite the extensive decontamination procedures used (brushing teeth and vigorously rinsing the mouth after codeine administration), increased saliva codeine concentrations were detected as a result of oral cavity contamination. This has an obvious impact on the screening for opiates in saliva because someone could take an over-the-counter codeine preparation and be detected as positive for opiates.

The primary advantages of saliva drug testing are listed in Table 1. It can be seen that there are both pros and cons associated with saliva as a specimen matrix for drugs-of-abuse screening. However, from what has been stated above, it can be seen why the majority of people involved in drugs-of-abuse screening tend to use urine as the specimen of choice.

Clinical Situations Where NPT Devices May Be of Benefit

There are several situations where NPT devices could be required, such as immediate clinical challenges of alleged or supposed drug use, in the criminal justice system, in an emergency setting, and/or locations where laboratory-provided analytical services for drugs-of-abuse screening are not readily available *(16, 19, 21, 23)*. For example, it was envisaged that the Bionike tests could be valuable for obtaining rapid and reliable results for individual drugs such as methadone in a methadone clinic or for reviewing leave passes for psychiatric hospital patients suspected of using cannabis outside the hospital *(19)*. It was also proposed that such NPT devices could help general practitioners and their patients by providing results during consultation, leading to improved patient management. However, the authors also recognized the need for appropriate training in the use of these devices, including the sensitivity and specificity of the tests and the need for formal recordkeeping along with quality-control and quality-assurance policies. This agrees with the recommendations suggested in earlier studies in which training was proposed as essential to prevent misinterpretation of results generated by NPT devices *(17, 18)*. However, the author of all the studies acknowledge that NPT devices can be recommended only when an immediate presump-

Table 1. Advantages and disadvantages of saliva monitoring for drugs of abuse.

Advantages
• A relatively noninvasive method with specimen collection that can be observed without embarrassment to the person under investigation
• Little chance of sample adulteration because the whole sample collection procedure can be supervised
• Commercial screening devices are available for saliva monitoring that have been evaluated by some police forces for roadside drug screening use
• There is less chance of specimen collection problems or specimen adulteration than with urine
Disadvantages
• Small specimen volumes restricting the number of analyses that can be performed
• Contamination of the mouth may affect drug-screening results
• Adulteration feasible as a result of oral contamination
• Difficult to collect from those abusing stimulants such as amphetamines and Ecstasy
• Routine screening procedures not always applicable to screening saliva
• Low concentrations make detection difficult and necessitate the use of expensive equipment
• Small sample volumes make confirmation of screening results difficult

tive test is required *(19, 21, 23)*. These and other issues regarding the use of NPT devices are summarized in Table 2.

Advantages and Disadvantages of NPT Devices over Laboratory Screening

The primary reason behind the use of NPT devices is that they can provide immediate results to aid in patient management. In this respect they offer a very real advantage over laboratory screening and subsequent confirmatory methods, both of which inevitably take time to process. This delay in patient management or treatment may be further extended because of the pre- and postanalytical transport issues surrounding the receipt of specimens and reporting of analytical results. However, if NPT devices are required to be used, as in the situations cited above, it is essential that they are used with a full understanding of the specific test device limitations with respect to sensitivity and specificity. Training of the staff in the use of specific devices and recordkeeping is essential *(17)*. This should highlight the potential of misinterpretation of results attributable to poorly labeled NPT tests, i.e., morphine tests actually detecting any opiates *(12)*. In addition, appropriate quality-control specimens should also be analyzed to ensure the validity of the screening tests performed. Any positive results determined by NPT devices should be confirmed by a more specific laboratory method to ensure that no false-positive results are being used for diagnostic purposes. This is rarely performed in a clinical setting. Bearing this in mind, such devices can provide rapid and relatively accurate presumptive results (assuming that they are used appropriately and the results are interpreted accurately), which may be sufficient for the immediate intervention of medical support of drug-abusing individuals. The advantages and disadvantages of NPT devices compared with laboratory-based testing are summarized in Tables 3 and 4.

Table 2. Problems associated with NPT devices for drugs-of-abuse screening.

- Limited range of drug tests available
- Designed primarily for US market, which is reflected in the range of tests available
- Lack of specificity for individual drugs not always highlighted by NPT device inserts
- Limited or variable test sensitivity that may deviate from manufacturers' stated values
- Poor or no quality control for the tests performed
- Not suitable for automation or volume use for multiple specimens
- Potential medico-legal problems attributable to misinterpretation of results
- Relatively high costs for both single- and multiple-analyte test devices
- Health and safety hazards associated with the use of these devices by untrained staff
- Limited or no training of staff before using these devices to generate drug screening results
- It is difficult to record actual raw test result data
- Very subjective results interpretation by the person performing the screening
- Not an ideal method for busy drug clinics and staff under pressure to deliver results

Guidelines for the Use of NPT Devices

The Joint Working Group on Quality Assurance recently published guidelines for the use of near-patient or on-site drug screening devices that outlined the main issues that need to be addressed in the provision of NPT *(31)*. These issues are summarized in Table 5, which identifies who should perform the tasks and who should be responsible for ensuring that the issue has been properly addressed. In addition, it was acknowledged that to ensure reliable performance and manage the risks associated with point-of-care testing, the pathology laboratory must have a central role in management of these devices because the pathology staff are recognized experts in the methodologies of the tests; troubleshooting, training, and support; limitations of the methods; quality control and quality assurance; patient preparation; risk management; interpretation of results; health and safety; and infection control.

One of the benefits of using trained personnel who are accustomed to the review and validation of new techniques and methods of analysis is that they are aware of the consequences of any performance issues that may arise from the use of new analytical techniques or equip-

Table 3. Advantages and disadvantages of NPT for drugs of abuse.

Advantages

- Rapid turnaround of results because screening tests can be performed on site
- Rapid clinical action with patient actually being screened by drug worker or general practitioner
- Confidentiality of individuals assured because specimens do not need to be sent away for analysis
- Local control of all drug-testing issues
- Chain of custody is not an issue because testing is performed on site
- The person being screened can see the test being performed

Disadvantages

- Relatively high cost especially when using individual tests to create a multiple drug screen
- Limited specificity of NPT devices, especially for amphetamines and opiates
- Limited range of drug tests available (product developed for the North American market)
- Poor or nonexistent quality control of the testing devices
- Poor recordkeeping after testing with NPT devices
- Interpretation may be a problem because of the lack of specificity of the NPT devices
- Subjective interpretation of occasional poor end-point colouration
- Screening results are difficult to defend in court
- Inability to detect adulteration or falsification of specimens (e.g., diluted or adulterated samples)

Table 4. Advantages and disadvantages of laboratory testing for drugs of abuse.

Advantages
- Economies of scale possible from high workloads, which lower costs per test
- Wider range of drug tests because of availability of additional chromatographic methods
- More reliable screening because of regular quality-control audit of laboratory systems
- Confirmation of results by secondary and more specific methods
- Good recordkeeping of analytical results and raw data from analytical systems
- Interpretation of results to distinguish drug use from over-the-counter medication
- Ability to detect adulteration and/or dilution of specimens
- Advice on the interpretation of analytical results is available

Disadvantages
- Slower turnaround of results because of delays in receipt of specimens for analysis
- Transport of specimens may cause delays and problems
- Chain-of-custody issues to ensure results can be linked to the person being tested
- Delays in clinical action are likely because of pre- and postanalytical transport issues
- Screening is performed remote to the person being tested
- Budget constraints on reagents and consumables required to perform drug-screening work

ment. This is especially true for NPT devices. Some examples of advertising that is misleading to those inexperienced in drugs-of-abuse testing are illustrated below. The data were supplied with a NPT testing device and stated that:

- The most common form of D-methamphetamine is Ecstasy. [Ecstasy (methylenedioxymethamphetamine) is chemically related to methamphetamine, but it is obviously not the same compound. This is apparent from the package insert for the methamphetamine assay sold, which has a cutoff of 500 mg/L for methamphetamine, but 3500 mg/L for Ecstasy].
- Morphine glucuronide is an opiate with morphine-like pharmacologic action. [Morphine glucuronide is a metabolite of morphine and is therefore not an opiate in its own right].
- The Substance Abuse and Mental Health Services Administration (SAMHSA) specifies cutoff concentrations for barbiturates, benzodiazepines, and methadone. [SAMHSA does not provide cutoff concentrations for barbiturates, benzodiazepines, and methadone because these are not covered by the mandatory guidelines for drugs-of-abuse testing laboratories in the US].
- The opiates "strip", "cassette", or "multiTest" detects deoxyephedrine at a cutoff concentration of 1000 mg/L (data on file). [Deoxyephedrine is another name for methamphetamine. This demonstrates that the opiate screening assay will yield positive results for an abuser of amphetamines. This has obvious implications for both the person being screened, in terms of continued treatment and medical management, and the person performing the screen, who is responsible for the analytical result produced by the NPT device].

Future Role of NPT Devices

With the increased use of the internet to purchase goods, it is only a matter of time before NPT devices are available "off the shelf" to all who require them. Such customers will include employers who wish to check on their employees (not always with their consent). This could lead to career-altering decisions being made without reasoning or confirmation of results. Other purchasers will be anxious parents with real concern for their children but without the knowledge of the true limitations of the test devices that they are buying. A third group may well be those on drug treatment programs who wish to know what their screening result is likely to be before

Table 5. Joint Working Group on Quality Assurance recommendations for the implementation and evaluation of a near-patient drug screening service.

Issues considered in the Working Group report	Implementation to be actioned by	Who will be responsible	Who will perform the evaluations
Cost-benefit analysis (business case)	Clinical unit/Pathology	Hospital management board	Hospital management board/Pathology
Health and safety	Pathology	Hospital management board	Hospital management board
Training (including recordkeeping)	Pathology	Hospital management board	Hospital management board
Standard operating procedures	Pathology	Hospital management board	Laboratory accreditation body [CPA(UK) Ltd.][a]
Routine operation	Users	Line manager (e.g., ward sister)	Pathology
Recording results	Users	Line manager	Pathology
Support	Pathology	Hospital management board	Hospital management board
Quality control and external quality assurance	Users	Pathology	Pathology
Budgetary arrangements	Clinical unit/Pathology	Hospital management board	Pathology

[a] CPA, Clinical Pathology Accreditation.

attending the drug clinic to give a specimen for formal testing.

None of these groups of people are in reality likely to read the package insert; others will be unable to understand the jargon, which has already been demonstrated (above) to be misleading. Still fewer will bother with the confirmation of positive results before taking action, which may not even be mentioned in the package insert accompanying the NPT devices. In this respect, work and family conflicts are bound to occur, probably as a result of false-positive results being acted on. Ultimately, those who are most concerned may only destabilize their environments rather than help those they want to help. It is for these reasons that there need to be some formal regulations concerning the sale and use of NPT devices for drugs-of-abuse screening outside of the hands of professionals.

The use of NPT devices in drug clinics and drug dependency units must also be regulated to ensure that any device used has been appropriately tested before its routine use and that all limitations are understood by those using them.

Recommendations for the Use of NPT Devices

It is for the reasons cited above, which highlight some of the problems associated with NPT devices for drugs-of-abuse screening, that:

- All such devices should be initially evaluated by professional laboratory staff who are experienced in the field of drugs-of-abuse screening.
- Once a NPT device is evaluated and reviewed in a controlled laboratory setting, a cost–benefit analysis should be performed to determine whether the use of that device is cost-effective, taking into account both staff time and consumables.
- Adequate training must be given to all those wishing to use the NPT devices in those areas that cannot be adequately controlled by laboratory testing. Such training must ensure that operators fully understand the method and its limitations and that they are responsible for any errors that may arise in interpretation of results. All training should be recorded.
- Quality control and quality assurance must be covered in addition to appropriate storage, maintenance, and calibration of any NPT device used. Records of these procedures have to be kept for a period of 11 years to defend any action brought against the person performing the drug testing *(32)*.
- Any NPT device should also undergo a rigorous evaluation to determine its suitability or whether it is "fit for purpose" before it can be marketed.

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