

Performance evaluation of the DrugWipe® 5/5⁺ on-site oral fluid screening device

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Abstract This study presents a retrospective performance evaluation of an on-site oral fluid drug screening device DrugWipe® 5/5⁺ (Securetec). The results obtained by the device were compared with gas chromatography–mass spectrometry confirmation analysis results in whole blood. Data used in the comparison were based on 1,807 real cases in which the Finnish police had conducted an on-site drug test on persons suspected of driving under the influence of drugs. The present data cover only cases wherein the DrugWipe device has shown a positive result for at least one substance. The data were compiled from the databases of Alcohol and Drug Analytics Unit at the National Institute for Health and Welfare. The performance of the DrugWipe was evaluated for its relevant drug groups: amphetamines, cannabis, opiates, and cocaine. The evaluation was carried out by calculating the sensitivity, specificity, and accuracy as well as the positive and negative predictive values. These calculations were based on the classification of the results as true positives, false positives, true negatives, and false negatives. Additionally, the demographics of the cases and analytical findings in whole blood are discussed. According to this study, the DrugWipe device performed quite well in detecting amphetamines, the most frequently encountered group of illicit drugs in Finnish traffic. The performance of the cannabis, opiate, and cocaine tests was not at the same level.

Keywords On-site testing · Oral fluid · Driving under the influence · DrugWipe · Drugs of abuse · Police practice

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Introduction

Oral fluid is an interesting matrix for detecting drugs in clinical and forensic toxicology. Especially in the case of driving under the influence of drugs, it provides a desirable means for on-site testing. The development of on-site screening devices for drug testing in oral fluid started in the 1990s [1]. The conclusion of the European Roadside Testing Assessment (ROSITA) study emphasized the need for roadside drug tests and acted as a catalyst for new developments in on-site oral fluid screening devices to be used by the police officers [1, 2]. The final conclusions of the ROSITA project concerning the first generation of oral fluid testing devices demonstrated problems in operability; also, the sensitivity and/or specificity of the tests were insufficient for most classes of drugs [3]. Evaluations of on-site oral fluid screening devices have been performed since the first ROSITA project, for example in the Rosita-2 study [4].

In Finland, driving under influence (DUI) legislation is based on a combination of zero-tolerance legislation and impairment law. The zero-tolerance law implemented in 2003 covers situations where the individual has illicit drugs or their (relevant) metabolites in his or her blood either during or after driving. If a driver is entitled to use the controlled substance detected, e.g. as prescribed for therapeutic purposes, then the impairment law can be applied. In these cases, the impairment of driving ability due to the use of licit medication has to be proved in the court of law. The police are authorized by law to submit drivers to a preliminary test such as an alcohol breath test or an on-site oral fluid drug test. These tests can be conducted even without a suspicion of drug use, e.g. in cases of random stop checks and accidents [2], but in practice they are only used when drug use is suspected. The main reasons

for on-site oral fluid drug screening are accidents, observed dangerous or impaired driving or suspicion arising at a roadside control. The Finnish police officers performing on-site oral fluid screening are trained to recognize external symptoms of drug use and use a standardized field sobriety observation sheet (2). On-site oral fluid screening is not carried out on a large-scale random basis (i.e. to act as a deterrent) in Finland. Currently, the Finnish police use the DrugWipe 5/5⁺ device for on-site oral fluid testing. The DrugWipe tests were chosen for use in Finnish police practice largely based on the results of the ROSITA project. The DrugWipe devices were then further evaluated in Rosita-2 and still considered appropriate for use by the Finnish police.

The performance of the DrugWipe test for oral fluid analysis has been evaluated by many research groups [5–13]. It should be noted, however, that there are a lot of differences between the studies. Two of the studies were clinical studies, with low numbers of cases [8, 11]. In two studies [5, 13], fortified oral fluid was directly applied to the devices investigated, instead of testing real people. Most of the studies [6, 7, 9, 10, 12] were conducted on suspected drug users. Significant differences in the study protocols, e.g. type of study, result interpretation, types of cases/samples tested, and also the large variation in the number of tested cases, limit straightforward comparison of the aforementioned studies' results. In general, for amphetamines, most of the research groups [7, 10–13] got promising results, although there has also been one negative report published [6]. The performance of the DrugWipe in cannabis detection was not on a satisfactory level in any of the studies in which the cannabis test was evaluated [5–7, 9, 10, 12]. The opiate and cocaine tests got both positive and negative evaluations [5, 6, 8, 10, 12, 13]. In two studies [6, 10], it was noted that the police officers performing the tests were quite satisfied with the operability of the test. However, interpretation difficulties with the test results were noted and research groups concluded that proper training of the police officers performing the tests is of great importance [10, 12].

This is the first large-scale study on DUI suspect drivers. It is important to evaluate the performance of the device in a real situation as used by 'non-scientific' police officers. The study was performed as a supplementary part of the European DRUID project (www.druid-project.eu). In the study, 1,807 DUI suspect cases for which a DrugWipe on-site test result had been reported were taken from the database of the Alcohol and Drug Analytics Unit. The results of the on-site screening were evaluated against gas chromatography–mass spectrometry (GC–MS) whole blood confirmation results. Values for sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) were calculated.

Materials and methods

The data presented in this article consist of past real cases in which the Finnish police have conducted rapid on-site drug tests on the persons suspected of being under the influence of drugs of abuse. Positive Drugwipe 5/5⁺ screening results were recorded by the police officers and registered to the Alcohol and Drug Analytics Unit database. However, on-site test information is only reported for cases with a positive screening result for one or more substance classes. Hence, there is no information on the number of cases which were negative for all substance classes.

All cases included in the study were drivers of a motorized vehicle and occurred in the time period from 1st of July 2007 up until 31st of December 2008, during this period all samples with a positive on-site test result were included. Unfortunately, the results of the multi-analyte screening devices, the DrugWipe 5 and the DrugWipe 5⁺, could not be specifically classified according to the version of the device used. The police were supplied with the earlier version (DrugWipe 5) until the 6th of September 2007, and the first batch of the 5⁺ device with an integrated water ampoule was supplied on the 8th of October 2007. The device version was changed as a result of product development, addition of the water ampoule facilitated easier practical handling of the device. Oral fluid screening cut-offs for both types of device studied are shown in Table 1.

Following the positive on-site screening result, a whole blood sample of the suspect was taken by medical personnel and sent to the Alcohol and Drug Analytics Unit of the National Institute for Health and Welfare (THL) of Finland. The blood collection tubes (10 ml) contained sodium fluoride (100 mg) and potassium oxalate (22.50 mg) as chemical preservatives/anticoagulants. The screening and confirmation analyses of the whole blood samples were carried out at THL with methods or slightly modified methods described in [10, 14–17].

Table 1 Screening cut-offs (ng/ml) for the DrugWipe devices

Detected drug group (target compound)	DrugWipe 5 ⁺	Drugwipe 5
Amphetamines (D-amphetamine)	50	200
Methamphetamine (D-methamphetamine)	25	100
MDMA	25	100
Cocaine (benzoylecgonine)	30	50
Opiates (codeine)	10	20
Cannabis (Δ^9 -THC)	30	30

The investigated substances relevant to the DrugWipe device and their respective laboratory cut-offs in whole blood are listed in Table 2.

Based on the GC–MS confirmation results and laboratory cutoffs used in the Alcohol and Drug Analytics Unit, the cases were classified as true positive (TP), true negative (TN), false positive (FP), and false negative (FN). The criteria for classification are found in Table 3.

Only substances that were reported by the manufacturer to give a positive test result for the DrugWipe were taken into account in the classification of positive or negative cases. For amphetamines, if any of the amphetamine-type stimulant (ATS) drugs listed in Table 2 was detected above the laboratory cut-off, the case was interpreted as positive. For cannabis, the two reported substances were THC and THC-OH, and if at least one of these was detected above cut-off the case was interpreted as positive. For opiates, any cases containing morphine, codeine, or ethylmorphine, either alone or in combination, were interpreted as positive. For cocaine, cases in which cocaine and/or benzoylecgonine were found at above the laboratory cut-off in the whole blood sample were considered as positive. Cross-reactivity was not taken into account, nor were the device cut-offs as reported by the manufacturer.

Sensitivity, specificity, and accuracy were calculated based on the classification of cases as TP, TN, FP, and FN. Also, the prevalence of each substance class in the studied population was calculated. Positive predictive value and negative predictive value were determined according to the Bayesian method. The equations for these calculations are listed in Table 4.

For the PPV and NPV calculations, prevalences of different substance categories from all suspect DUI cases

Table 2 Investigated substances and their laboratory cut-offs for confirmation analysis (ng/ml)

Substance	Cutoff
Amphetamine	25
Methamphetamine	25
MDA	25
MDMA	25
MDEA	25
Δ^9 -THC	1
THC-OH	1
Morphine	5
Codeine	10
6-MAM	1
Oxycodone	5
Ethylmorphine	10
Pholcodine	5
Cocaine	10
Benzoylecgonine	10
Ecgonine methyl ester	10

Table 3 Classification into true positive (TP), false positive (FP), true negative (TN), and false negative (FN) categories

		GC–MS result	
		+	–
DrugWipe test result	+	TP	FP
	–	FN	TN

analyzed at the Alcohol and Drugs Analytics Unit in the year 2008 were used (Table 5). Routine analysis of suspect DUI blood samples is not exclusive of those cases for which on-site screening was not performed. These prevalences were used in order to allow an assessment of the predictive value of the devices in Finnish suspect DUI cases as a whole, reflecting the population in which the devices are actually used rather than just the actual study population for which an on-site screening device result was recorded.

Results

Demographics of the study population

The total number of cases in the study was 1,807. Most of the cases (1,585; 88%) were male. The gender and age distribution of the cases is shown in Fig. 1. In four cases, information on either gender or age was missing. These cases were omitted from the gender/age distribution analysis. The distribution within the study population is very typical of the overall Finnish DUI population; most of the cases were male from age group between 20 and 39 years old and in particular from the age group 25 to 34 years old.

Most of the cases were driving a passenger car ($n=1,636$, 91%). Other frequently encountered vehicles were vans ($n=59$, 3.3%), mopeds ($n=46$, 2.5%), motorcycles ($n=35$, 1.9%), and lorries ($n=19$, 1.1%). A quarter of the cases were picked up by stop checks ($n=454$, 25%). Other reasons

Table 4 Calculations used for the device performance evaluation

Parameter	Calculation
Sensitivity	$\frac{TP}{TP+FN}$
Specificity	$\frac{TN}{TN+FP}$
Accuracy	$\frac{TP+TN}{TP+TN+FP+FN}$
Prevalence	$\frac{TP+FN}{\text{number of subjects}}$
PPV	$\frac{\text{sens} \times \text{prev}}{\text{sens} \times \text{prev} + (1 - \text{spec})(1 - \text{prev})}$
NPV	$\frac{\text{spec}(1 - \text{prev})}{\text{spec}(1 - \text{prev}) + \text{prev}(1 - \text{sens})}$

sens sensitivity, *spec* specificity, *prev* prevalence

Table 5 Prevalences of different substance categories among all DUI suspect cases (blood samples, $n=4,419$) submitted to the laboratory of the alcohol and drug analytics unit in 2008

Substance class	Prevalence (%)
Benzodiazepines and non-benzodiazepine hypnotic agents	58
Amphetamines	56
Cannabis	20
Morphine	0.9
Cocaine	0.7

for stopping the drivers were driving style ($n=164$, 9.1%), denunciation ($n=99$, 5.5%), traffic offenses ($n=94$, 5.2%), criminal offenses ($n=67$, 3.7%), speeding ($n=50$, 2.8%) and traffic accidents ($n=47$, 2.6%). However, in many of the cases, the reason for stopping the driver was marked as “other reason” ($n=754$, 42%). In 33 cases (1.8%), information on the reason for stopping the driver was missing and in one case improper use of driving lights was reported as the reason.

The vast majority of the study population had a blood alcohol concentration of 0 ‰ ($n=1,732$, 96%) or below the legal limit 0.5 ‰ ($n=28$, 1.5%).

Findings in whole blood

Amphetamine-type stimulant drugs were the most frequent type of findings in the studied population with 1,509 (84%) positive cases. Amphetamine (AMP) was found in 1,466 cases (81%) with a concentration range 30–4,200 ng/ml. Methamphetamine (MAMP) was found in 183 cases (10%, concentration range 30–1,600 ng/ml), MDMA in 50 cases (2.8%, concentration range 30–600 ng/ml) and MDA in

four cases (0.2%, concentration range 30–40 ng/ml). MDEA was not found in any of the samples. The different combinations of ATS drugs in positive cases are shown in Table 6.

The second most prevalent substance class was cannabinoids. Δ^9 -THC was found in 196 whole blood samples (11%). In 71 cases THC-OH was also found. Concentration ranges for Δ^9 -THC and THC-OH were 1–200 ng/ml and 1–10 ng/ml, respectively.

Cocaine (COC) and opiates were less frequent findings in the studied population. Opiates were found in 47 cases (2.6%). A more detailed listing of the findings can be found in Table 7.

Benzoylcegonine (BZE) was found in 19 cases (1.1%) with concentration range 40–900 ng/ml; cocaine was found in nine cases (0.5%, concentration range 10–100 ng/ml); and ecgonine methyl ester (EME) was found in seven cases (0.4%, concentration range 10–200 ng/ml). The different combinations of substances of the cocaine category are shown in Table 8.

Results of the performance analysis

The results for the classifications into TP, FP, TN, and FN as well as performance calculations for all substance classes are presented in Table 9.

Amphetamines

There were 49 FN cases: 46 of these cases contained amphetamine with concentrations ranging between 40 and 1,500 ng/ml. In addition, methamphetamine was found in five cases and MDMA in two cases.

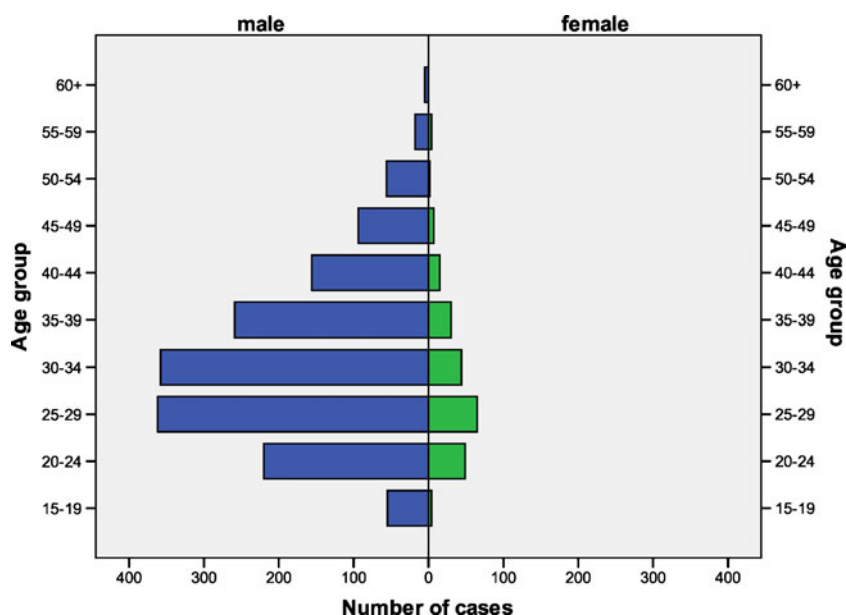
Fig. 1 Gender and age distribution of the study population. $N=1,804$; 1,583 male, 221 female

Table 6 Combinations of different ATS in the positive samples

Combination	N (% of all ATS cases)
AMP	1,279 (85)
AMP + MAMP	150 (9.9)
AMP + MDMA	33 (2.2)
MAMP	30 (2.0)
MDMA	10 (0.7)
MDA + MDMA	3 (0.2)
AMP + MAMP + MDMA	3 (0.2)
AMP + MDA + MDMA	1 (0.1)

Sensitivity for ATSs was very good (97%). Also, accuracy was good (89%) but specificity reached only 50%. The low value for specificity has a decreasing effect on PPV, which is moderate at 71%. However, due to the very good sensitivity score and the fact that ATSs are very prevalent in the Finnish DUI population, NPV reached a very high value, 92%.

Cannabis

Altogether, 112 FN cases were found. In 31 FN cases, both Δ^9 -THC and THC-OH were found. The concentrations found in these cases were quite small, for Δ^9 -THC 1–20 ng/ml and for THC-OH 1–6 ng/ml. In 81 FN cases, Δ^9 -THC was the only cannabis constituent found. Again, all concentrations were very low (1–10 ng/ml) except for one very high concentration (200 ng/ml). For comparison, the concentration ranges of TP cannabis cases were 1–40 ng/ml for Δ^9 -THC and 1–10 ng/ml for THC-OH.

The sensitivity of the cannabis test was at a very low level (43%), as was the PPV (46%). For specificity, accuracy, and NPV, good values were achieved (87%, 82%, and 86%, respectively).

Opiates

Opiates were not found in any of the FP opiate cases (18) except one. In this one case, 200 ng/ml oxycodone was found in the blood sample. It is reported by the manufacturer that

Table 7 Opiate findings in the study population. Concentrations in nanograms per milliliter

Substance	N (% of all opiate cases)	Concentration range
Codeine	35 (69)	10–640
Morphine	11 (22)	5.2–12
Oxycodone	5 (9.8)	46–200
Pholcodine	3 (5.9)	38–110
6-MAM	2 (3.9)	40–210

Table 8 Combinations of cocaine-related compounds in positive cases

Combination	N (% of all cocaine cases)
BZE	7 (37)
COC + BZE	5 (26)
COC + BZE + EME	4 (21)
BZE + EME	3 (16)

COC cocaine, BZE benzoylecgonine, EME ecgonine methyl ester

oxycodone will only give a positive result when very high concentrations (>20,000 ng/ml) are present in the oral fluid.

The opiate findings in whole blood samples in case of a negative test result are found in Table 10.

The total number of cases in which the test gave a negative result, but some opiates were found in whole blood, was 42. However, not all of these cases were interpreted as FN. In 36 of these cases, morphine and/or codeine were detected and these cases were interpreted as FN. Other cases were interpreted as TN because the manufacturer does not report that the device will detect the opiates found in those samples. In addition, the concentrations of these non-cross-reacting compounds were quite low.

Sensitivity and PPV for the opiate test were very low (10% and 8.3%, respectively). Due to the high number of negative cases, specificity, accuracy, and NPV reached very high values (99%, 97%, and 99%, respectively).

Cocaine

Seven FN cases were detected. These contained either only benzoylecgonine (four cases, concentration range 25–100 ng/ml), all three substances analyzed (two cases, one

Table 9 Results of the performance evaluation

	AMP	CAN	OPI	COC
TP	1,460	84	4	12
FP	149	209	18	26
TN	149	1,402	1,749	1,762
FN	49	112	36	7
Prevalence ^a (%)	84	11	2.2	1.1
Sensitivity (%)	97	43	10	63
Specificity (%)	50	87	99	99
Accuracy (%)	89	82	97	98
PPV ^b (%)	71	46	8.3	22
NPV ^b (%)	92	86	99	100

^a Prevalence values obtained for a study population

^b Prevalence among people suspected of DUI in 2008 in Finland used for calculation of PPV and NPV

Table 10 Opiate findings in the cases with negative test results. Concentrations in nanogram per milliliter

Findings in the whole blood sample	N, number of samples	Concentration ranges ^a	Interpretation
Codeine	27	10–300	FN
Oxycodone	4	46–140	TN
Morphine + codeine	3	5.2–35; 48–290	FN
Morphine	3	5.5–9.2	FN
Morphine + 6-MAM	2	7.4–12; 40–210	FN
Pholcodine	2	38–110	TN
Codeine + pholcodine	1	38; 60	FN

^a When two substances were found in one sample, concentration ranges are reported respectively

containing 30 ng/ml cocaine, 300 ng/ml benzoylecgonine and 20 ng/ml EME and the second containing 100 ng/ml cocaine, 900 ng/ml benzoylecgonine and 200 ng/ml EME) or only the metabolites benzoylecgonine and EME (one case, 200 ng/ml benzoylecgonine and 10 ng/ml EME).

The sensitivity of the test was at a low level (63%) and, due to the very low prevalence, PPV is even lower (22%). Again, as with the opiates, specificity and accuracy were very high (99% and 98%, respectively) and NPV was excellent with 100% due to the very high number of negative cases.

Discussion

Oral fluid screening cut-offs proposed by the US body Substance Abuse & Mental Health Services Administration (SAMHSA) are shown in Table 11. A comparison to manufacturer cut-offs for the two devices (Table 1) shows that, for the ATS substances, the DrugWipe 5 cut-offs are considerably higher than the SAMHSA recommendations. For the DrugWipe 5⁺, the ATS cut-offs are all at, or below, the proposed 50 ng/ml. For cocaine, both devices have a cut-off above the SAMHSA proposal of 20 ng/ml and they are also both well above the recommendation of 4 ng/ml for cannabis. The cut-offs for opiates of both the DrugWipe 5 and 5⁺ devices are below the recommendation of 40 ng/ml. The DrugWipe 5⁺ cut-offs compared better to the SAMHSA proposals, whereas the cut-offs for the previous device were generally higher. Since the cut-offs of the devices are a measure of their performance, it is reasonable

Table 11 Proposed SAMHSA oral fluid screening cut-offs in nanogram per milliliter [1]

Detected drug group	Screening cutoff
Δ^9 -THC and metabolite	4
Cocaine metabolites	20
Opiate metabolites	40
Amphetamines	50
MDMA	50

to assume that the DrugWipe 5 would be less sensitive for most drugs at relatively low concentrations in oral fluid. However, information regarding which device was used was not available in this study and, crucially, the confirmation analyses were made in whole blood.

Evaluation of the on-site testing device against the findings for substances in the confirmation sample is complicated since the matrix for the screening is oral fluid whereas the confirmation analysis is performed using whole blood. Knowledge concerning the oral fluid-to-blood ratios remains incomplete and ratios in what literature does exist tend to vary [18]; nonetheless, it is widely seen that concentrations in oral fluid are significantly higher for amphetamines and, to a lesser extent, cocaine and opiates than in blood. It is conceivable that relatively low concentrations of amphetamines, opiates, and cocaine in oral fluid will not be detected above the limit of quantitation in the blood confirmation sample, which could at least partially explain the FP findings for these substances [19]. The relationship between oral fluid and blood concentrations for cannabis is less clear and is further complicated by the possibility of contamination of the oral cavity through inhalation of the drug. It is possible that a low concentration of Δ^9 -THC in blood will not be accompanied by any finding in oral fluid and vice versa—this could result in either FP or FN detections using the on-site device.

As noted earlier, previous performance evaluations have given mixed results for the opiates and cocaine tests of the device, whilst the cannabis test has widely been determined as at an unsatisfactory level [5–13]. This indicates that there are some difficulties to overcome in terms of the analytical sensitivity and specificity of the device, a conclusion that appears to be backed up by the results of this study. In particular, on-site screening for cannabis is problematic, which could be due in part to the analyte's hydrophobic nature hindering the flow of the compound in the test strip. One further factor that may affect this evaluation is difficulty in visually interpreting the results if the red lines that denote a positive test are very faint. Nevertheless, the authors feel that this would have only a minor effect on the results of this evaluation since the instructions for the device

are quite clear and it is reasonable to expect that, overall, the police are quite experienced in using a device which was first used in 2005.

The best performance was achieved by the amphetamine test. Sensitivity and NPV were very good and accuracy was good. Specificity (the ability to pick the true negatives from all the negatives) was poor because only cases which gave positive results with the DrugWipe devices were included in the study. Sensitivity values for other substance categories were markedly lower than for the ATSS. Due to the much lower prevalence of cannabis, opiates, and cocaine, specificity, accuracy, and NPV values for other substances detected were on a good or very good level.

It is disturbing to note that only for amphetamines can a positive test result be taken as a clear indication of a positive case. For all of the other substances, positive test results were more frequently false positives than true positives. Similar results have also been noted previously in another study [6]. This is unacceptable for a roadside screening test, especially since the subject's personal freedom is limited after a positive test result when the person is taken to blood sampling and also the driver's license is temporarily withdrawn. However, in these cases, the apprehension might not be solely based on the on-site test result but also on other indications that give rise to suspicion of drug use. In earlier studies [10, 12], it has been noted that the training of the police officers performing the tests is very important. In this study, the police officers performing the tests were normal police officers with possibly only very little formal training on how to use the device. Furthermore, a large number of FPs might partly be due to difficulties in the interpretation of the test result as also noted in other studies [10, 12]. Also, it must be borne in mind that the study does not allow a comparison of the test result to confirmation analysis of an oral fluid sample. Comparison to toxicological analysis of oral fluid samples might lead to somewhat different results. For example, for amphetamines, the concentrations found in oral fluid have been reported to be higher than in whole blood [19].

For the classification into positive and negative cases, only substances reported to give a positive test result were taken into account. It is possible that molecular structures very similar to the substances detected by the test can give a positive result. In this study, however, this is only relevant for opiates. For this category of substances, the manufacturer reports that very high concentrations of oxycodone or buprenorphine will generate a positive test result. Some samples with these opiates were included in the study; however, the whole blood concentrations were not on a very high level. In this study, there was only one case in which the test was positive for opiates, but only oxycodone was found. In this case, the concentration of oxycodone was 200 ng/ml in

whole blood. Opiates are weakly basic drugs for which the oral fluid/plasma ratios are theoretically over 1 [20], but regardless of this fact the oral fluid concentration of oxycodone contained in this case would probably still be too low for the device to detect.

The performance of the DrugWipe test in Finnish police practice has previously been studied in the Rosita-2 project [10, 21]. For amphetamines, the results of the Rosita-2 study were on the same level with the results of the current study, except for specificity. The lower specificity value obtained in the current study can be mainly explained by the pre-selective nature of the study (i.e. due to the fact that data for cases with only negative screening results were not recorded). There were not enough negative cases to obtain a reliable specificity evaluation. For cannabis, sensitivity was on a higher level in Rosita-2. Some difficulties in interpretation of the cannabis test line were noted in the Rosita-2 study. These difficulties and the fact that the police officers involved in the current study did not receive any additional training for using the DrugWipe are definitely reasons for the low sensitivity obtained here. However, it should be noted that the sensitivity value obtained in the Rosita-2 study was also low. Hence, interpretation problems are likely not to be the only reason for the low sensitivity value and the test needs to be improved. The manufacturer of the test has since released a new, enhanced version of the cannabis test, but at the time of writing the new version had not yet been evaluated. For opiates and cocaine, similar results are seen when comparing the results of the current study to the Rosita-2 results; sensitivity values obtained in the current study are much lower than in the Rosita-2 study. This can be assumed to be for reasons similar to the ones discussed in relation to the cannabis test.

Blood samples taken from suspect DUI cases in Finland during routine enforcement processes by police are mainly evident of amphetamine and benzodiazepine users [2]. In order to detect amphetamine users, the DrugWipe 5/5⁺ appears to be a suitable device. During 2003–2008, there has been a twofold increase in the number of DUI suspects registered to the authors' laboratory. In 2003, 41% of the cases contained amphetamine in their whole blood samples. During the ensuing time period, the percentage of amphetamine cases has risen and has remained at a level of 56–57% for the years 2006–2008. This development can partly be attributed to the implementation of the zero-tolerance ('per se') law in February 2003 and also to the increasing use of the Drugwipe 5/5⁺ device, which was initially approved for police work in May 2005. It was noted in a previous study that the police officers using the devices were largely satisfied with the operability of the device [21]. Recently, the manufacturer of the on-site screening test has developed a new version, the DrugWipe 6⁺, which

also encompasses a benzodiazepine test in the same device with amphetamines/ecstasy, cannabis, opiates, and cocaine. This version is not, as yet, in use by Finnish police. However, an improvement of the performance of the cannabis test to a satisfactory level is also very important, since 20% of the DUI suspect cases reported to the authors' laboratory in 2008 were positive for Δ^9 -THC and/or THC-OH. It seems possible that a more sensitive test for cannabis might reveal a greater prevalence of this substance in drugged drivers, similar to that seen for amphetamine. However, in Finnish DUI policing, on-site drug screening is normally performed after there is already suspicion of DUI rather than on a random basis. It should be remembered that symptoms of drug use and/or impairment due to cannabis can often be evident, e.g. a smell of cannabis smoke or reddened eyes. On the other hand, over-reliance on the results of a test which is not very sensitive for cannabis might cause the police to miss many cases which are in reality positive. So far, as the authors' are aware, at the time of writing the performance of an enhanced cannabis test, which has been incorporated to more recent versions of the DrugWipe devices, has not yet been evaluated in literature. It remains to be seen whether or not the improved cannabis test will result in a marked increase in the prevalence of cannabis positive DUI cases, as has been seen for amphetamines. In addition, some of the opiates found in the whole blood samples of the cases that gave a negative opiates test result indicate illegal use of drugs such as buprenorphine and oxycodone. It is desirable that a test would be developed to indicate the use of these substances at realistic levels, too.

Although the data presented here may be somewhat limited in purely analytical terms due to the lack of information regarding those cases where there were no positive findings with the device, it should be emphasized that this is a study of use of the DrugWipe in real DUI cases. It is to be expected that, if there is not sufficiently strong suspicion of drug use and the device gives all negative results, then no confirmation analysis will be requested by the police. Both the usefulness and limitations of the device as a policing tool in Finnish DUI can be seen. The study clearly illustrates the effectiveness of the amphetamines test in a DUI population such as Finland's. For the other substance categories, there are enough FN and FP cases in the study population to view the potential deficiencies of these individual tests. Together with careful consideration of external signs and symptoms of drug use, the device is an effective tool for policing DUI. On the other hand, over-reliance on results delivered by the device is a danger. Still, it is worth bearing in mind that 1,603 of the 1,807 cases included in this study were positive for one or more of the substances included in this evaluation, and this number increases to 1,683 if benzodiazepines, for which a prescription is required, are included.

Conclusions

The performance evaluation showed that the performance of the amphetamine test of the DrugWipe 5/5⁺ is already at a good level. Specificity for amphetamines was moderate, but this can be attributed to the high prevalence of amphetamine among the studied population. More negative cases would have been needed for obtaining a truer specificity evaluation, which would have been the case if it had been possible to include all the DUI cases where there were no positive screening results. Unfortunately, the test did not work as well for other substance classes (cannabis, opiates, and cocaine) included in the test panel. Sensitivity values obtained were much too low for reliable use as an on-site screening test. In addition, the proportion of false positive cases was very high. The specificity, accuracy, and NPV values for cannabis, opiate, and cocaine tests were good or very good, but it must be borne in mind that this is an expected result when testing a population with a greater proportion of non-users.

The DrugWipe 5⁺ device is currently used in normal police traffic control in Finland. The prevalence data from 2008 (Table 5) show that Finnish drug-using DUI population apparently largely consists of amphetamines and benzodiazepines users, although it is debateable whether or not this high prevalence for amphetamines is in some part due to the effectiveness of screening for these substances. The DrugWipe 5⁺ device has been seen to work quite well in detecting these compounds. Effective benzodiazepine and cannabis tests are also of importance for the police DUI work in Finnish traffic. Unfortunately, the performance of the cannabis test has yet to be seen as on a satisfactory level.

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