Detection and Prevalence of Drug Use in Arrested Drivers Using the Dräger Drug Test 5000 and Affiniton DrugWipe Oral Fluid Drug Screening Devices

Barry K. Logan^{1,2*}, Amanda L. A. Mohr¹ and Stephen K. Talpins³

¹The Center for Forensic Science Research and Education, Willow Grove, PA, USA, ²NMS Labs, Willow Grove, PA, USA and ³Institute for Behavior and Health Inc., Rockville, MD, USA

*Author to whom correspondence should be addressed. Email: Barry.Logan@nmslabs.com

The use of oral fluid (OF) drug testing devices offers the ability to rapidly obtain a drug screening result at the time of a traffic stop. We describe an evaluation of two such devices, the Dräger Drug Test 5000 and the Affiniton DrugWipe, to detect drug use in a cohort of drivers arrested from an investigation of drug impaired driving (n =92). Overall, 41% of these drivers were ultimately confirmed positive by mass spectrometry for the presence of one or more drugs. The most frequently detected drugs were cannabinoids (30%), benzodiazepines (11%) and cocaine (10%). Thirty-nine percent of drivers with blood alcohol concentrations >0.08 g/100 mL were found to be drug positive. Field test results obtained from OF samples were compared with collected OF and urine samples subsequently analyzed in the laboratory by gas or liquid chromatography-mass spectrometry. The Dräger Drug Test 5000 (DDT5000) and DrugWipe returned overall sensitivities of 51 and 53%, and positive predictive values of 93 and 63%, respectively. The most notable difference in performance was the DDT5000's better sensitivity in detecting marijuana use. Both devices failed to detect benzodiazepine use. Oral fluid proved to be a more effective confirmatory specimen, with more drugs being confirmed in OF than urine.

Introduction

There is increasing interest in the use of oral fluid (OF) as a biological sample for drug testing in the investigation of driving under the influence of drugs (DUID) cases (1-3). Oral fluid is excreted from three major glands: the parotid, submaxillary and sublingual and may contain other cellular constituents and bacteria (3, 4). Sample collection can be affected by factors such as decreased salivary flow and dry mouth, which may be attributed to a lack of proper hydration or drug use itself. However, for drug screening purposes, OF testing offers many advantages over blood and urine including the ability to easily collect a biological sample proximate to the time of driving (5, 6). This is important for detecting rapidly metabolized drugs and being able to relate observed driving performance to a toxicological result. In addition, OF sample collection is quick, straightforward, noninvasive, and does not require use of a collection facility or samesex observation. Another major advantage is that technology is available to test the samples on-site, obtaining a drug screen result in the field to aid with the investigation and disposition of the case. Additionally, if OF is used as a confirmatory sample for subsequent laboratory analysis, then both the screen and confirmatory samples can be collected at the same time, improving the chances for concordant screen and confirmation results. Using point-of-contact (POC) OF collection devices in conjunction with a structured assessment and documentation of the drivers behavior, appearance and demeanor, and performance in

standardized field sobriety tests (SFSTs) provides a more objective basis to relate these observations to the subjects drug use.

OF drug testing of suspected impaired drivers has been successfully implemented in Europe and Australia (7-11), and there are several ongoing studies evaluating devices in North America (12–16). This growth of interest has led to a proliferation of POC OF testing devices being offered for sale to law enforcement groups, often without validation or effectiveness data being collected or made available to the consumer. There is no federally approved list of devices for use in law enforcement OF drug testing as there is for breath alcohol (BrAC) testing devices (17). The recently concluded DRUID project in Europe included an assessment of commercially available OF testing devices based on their performance and advertised capabilities (18, 19). They found both positive and negative aspects of the devices assessed including scope, sensitivity and field performance which were highly device dependent. Factors identified that will influence the effectiveness of devices for this purpose included the scope of drug classes being tested for, the nature of the targeted analytes (parent compound rather than metabolites should be tested for in OF) and the detection threshold (analytical cutoff for the devices). Equally important is the ease of use of the device in a field setting, its robustness, the quality of its manufacture and the amount of training required to use it effectively.

The current generation of OF field drug testing devices is based on lateral flow immunochromatographic technology, and results from these devices are considered to be presumptive, reacting with classes of drugs rather than individual compounds (20). As such, they require confirmatory laboratory-based testing using chromatographic and mass spectrometric methods in order to meet standards for forensic admissibility in criminal casework. Recently, the National Safety Council's Alcohol, Drugs and Impairment Division, compiled recommendations for scope and threshold for laboratory based drug screening in OF (21). The recommendations were based on prevalence of driver drug use from various surveys and laboratory databases, and readily available current generation laboratory testing technology. The recommendations do not however address criteria for field-based testing.

Some of the barriers to adoption of OF drug testing in the United States have included a lack of information for potential users of the devices about device performance in a law enforcement setting; risks of selecting a sub-optimal device for a study or evaluation; management reticence around being an early adopter of a new technology; concern about how a change from blood or urine would change positivity rates from toxicology tests; a lack of information about the full costs of making such a switch; unavailability of validated laboratory-based OF tests to back up the field screens, and concerns about whether access to these tests would result in less thorough investigations or less complete documentation of observations of suspected drug impaired drivers which could impact prosecutions.

To address some of these barriers and evaluate the feasibility of using OF testing as a routine tool in traffic law enforcement, we describe a field-based evaluation of two POC OF drug testing devices, and compare their performance to each other, and to laboratory tests of contemporaneously collected urine and OF samples tested by liquid chromatography tandem–mass spectrometry (LC–MS-MS), except for delta-9-tetrahydrocannabinol (THC), which was tested by 3D gas chromatography–mass spectrometry (GC–MS). Finally, we assess the prevalence and co-morbidity of drug and alcohol use in this cohort of apprehended drivers.

Methods

Priority features identified for OF drug testing devices designed for police use include a need for it to be portable, easy to use, minimize the amount of time spent administering the test, provide results that can be easily interpreted and not subject to interpretation, and be confirmable by a subsequent toxicological test (18). Based on these considerations, two devices, the Dräger Drug Test 5000 (DDT5000) with a seven drug panel (amphetamine, methamphetamine, cannabinoids, opiates, cocaine, benzodiazepines and methadone) (Dräger Inc. Lubeck, Germany) and the Affiniton DrugWipe 5-Panel (amphetamine/methamphetamine, cannabinoids, opiates, cocaine and benzodiazepines) (Affinton, Williamsport, PA, USA) were selected for this study. In addition to both devices meeting the practical needs described above for field use, they both had cutoff concentrations appropriate for OF drug screening (21). The manufacturers' cutoffs for both devices are listed in Table I (22).

Subject selection

The sample population was drawn from the Miami, Florida area. Following a traffic stop based on an articulable suspicion of impairment, subjects included in the study were interviewed and assessed by the arresting officer, then placed under arrest based on specific evidence of impairment. Samples provided by 103 of these subjects who had been placed under arrest for DUI were included in the study. The study protocol, including informed consent, was reviewed and approved by legal counsel for Miami-Dade Police Department (MDPD). Officers of the MDPD DUI Squad conducted all the arrests. The officers followed routine arrest procedures including advisement of rights, performing SFSTs, conducting a Drug Recognition Expert (DRE) evaluation when appropriate and a portable BrAC test. At the conclusion of the arrest, a urine sample was collected for analysis at the University of Miami Toxicology Laboratory pursuant to the implied consent law for offenders with BrACs below the per se limit for alcohol. Following the conclusion of the arrest procedure and prior to their release or booking, subjects were offered the opportunity to provide OF samples for the purposes of this study. Subjects were advised in writing that the OF testing was for research purposes only and that their decision to participate or not, and the results of any OF drug test results would not be used against them in their criminal cases. Subjects signed an informed consent indicating their willingness to voluntarily participate. Each potential participant was evaluated by police officers

Table I

Scope and Cutoffs for the Field Screening Devices, DDT5000 and DrugWipe, Together with the Confirmatory Cutoffs by LC-MS-MS or GC-MS

Drug class	Manufacturers cutoff		Confirmed analyte	Confirmatory cutoff	
	DDT5000	DrugWipe		in UF (ng/mL)"	
Amphetamine	50	60 ^b			
Methamphetamine	35		Amphetamine	10	
			Methamphetamine	10	
			MDA	10	
			MDMA	10	
Benzodiazepines	15	10			
			Diazepam	6	
			Nordiazepam	6	
			Oxazenam	9	
			Temazenam	9	
			Chlordiazenoxide	200	
			Lorazenam	6	
			Clonazenam	6	
			Alprazolam	6	
			Midazolam	6	
Opiatos	20	10	Iviluazulatti	U	
Opiates	20	10	Codoino	0	
			Marphine	0	
			iviorprine	8	
			Hydrocodone	8	
			6-IVIAIVI	8	
			Hydromorphone	8	
			Uxycodone	8	
			Oxymorphone	8	
o .		10	Dihydrocodeine	8	
Cocaine	20	10	a		
			Cocaine	10	
			Benzoylecgonine	5	
			Cocaethylene	5	
Methadone	20	N/A			
			Methadone	10	
			EDDP	10	
Cannabinoids (THC) ^c	5	20			
			THC	2	
			THC-COOH	2	
			THC-OH	2	
PCP	N/A	N/A			
	/	/	PCP	4	
			Dextromethorphan	100	

^aBased on the use of Quantisal device.

^bCombined amphetamine/methamphetamine assay.

^cCannabinoids confirmation by GC-MS, all others by LC-MS-MS.

to determine if they were able to understand the study as described. Minors, subjects who could not understand the informed consent, and subjects involved in a single or multi-vehicle accident were excluded from the study per advice of the MDPD legal counsel.

Sample collection for field test devices

After agreeing to provide the necessary samples and a 10-min waiting period, subjects provided two OF samples for field tests: one using the DDT5000 sample collection cassette and one using the sample pad on the DrugWipe. The manufacturer's directions for collection were used for each device. Each device has a blue dye sufficiency indicator that indicated when adequate sample had been provided. The specimens collected on the DDT5000 and DrugWipe devices were then tested according to the manufacturer's instructions provided with the relevant device.

Sample collection for laboratory analysis

Following provision of the DDT5000 and DrugWipe samples, participants were asked to provide an additional OF sample collected with a Quantisal collection device (Immunalysis, Pomona, CA, USA) for laboratory based confirmatory analysis. The Quantisal device collects ~ 1 mL of OF and stores it in a tube containing 3 mL of stabilizing buffer solution. The Quantisal device also has an adequacy indicator that indicates when the sample collection is complete.

The data packet containing all documentation, including arrest records, were assembled after either transferring or releasing the subject, and were retained by the Miami-Dade Police Department. Each OF sample was labeled with the subjects arrest report number, citation number and case number. Identifiers such social security number and address were not provided to the study team, and subject names were used on a temporary basis to correlate all related results, then deleted from the data set. The OF samples were shipped overnight at ambient temperature to NMS Labs (Willow Grove, PA, USA) for analysis.

Storage information

All OF field test drug kits and devices were stored at a temperature $<30^{\circ}$ C for the DDT5000 and 40° C for the DrugWipe, as recommended by each manufacturer. Tests were not performed when temperatures exceeded 40° C and all remaining test kits were brought back to the police station at the conclusion of the shift to minimize the potential for errors associated with extreme temperature conditions. Test kits were placed in a cooler if they were transported during hot temperatures. Laboratory stability studies had demonstrated that the drugs within the scope of testing were stable in the Quantisal device at room temperature for up to 7 days (23).

Laboratory analysis

Laboratory confirmation of all presumptive field results is needed to ensure their admissibility in court. Both the DDT5000 and DrugWipe results are based on immunochromatographic methods and are considered presumptive, and as with other forensic testing require a laboratory-based confirmation test. Once received at the laboratory, the OF samples were analyzed for the presence of target drugs using GC-MS for cannabinoids and LC-MS-MS for the remaining drugs. Confirmatory cutoff concentrations are listed in Table I. The majority of subjects (82 of 92) from who OF samples were obtained also provided a urine sample either during the arrest procedure or in conjunction with OF sample collection. Urine samples were analyzed for the presence of drugs by immunoassay for cannabinoids, amphetamines, opiates, benzodiazepines, cocaine metabolite, methadone and phencyclidine (Immunalysis). Confirmations were performed by GC-MS and LC-MS-MS, at cutoffs below the screening thresholds.

Data analysis

For purposes of this evaluation, since the field test results were specific to class of compounds (amphetamines (combined amphetamine and methamphetamine), benzodiazepines, opiates, cocaine and metabolites, methadone and cannabinoids), and the laboratory confirmations in urine or OF were specific to compound, comparisons were made by assigning any laboratorybased positive to the corresponding drug class and comparing results by drug class (for assignments, see Table I). Several sets of data comparisons were undertaken as described below.

Comparison of field OF and laboratory-based OF confirmatory results

The field results obtained on both the DDT5000 and DrugWipe were compared with the results of the collected OF sample submitted to the laboratory. The purpose of this comparison was to establish the extent to which the field test could be confirmed in a paired collected OF sample, and which of the targeted drugs (see Table I) were undetected in the field but were detected with the greater level of sensitivity available in a laboratory-based test. Since the confirmatory tests are more sensitive than the field test, failure of the field test to detect a drug disclosed in the confirmatory test is not a false negative in the usual sense of the term; therefore, the following terms were used (see Table II). Instances where a positive field OF test corresponded with the laboratory confirmation were designated 'verified positives'; instances where a negative field OF test was also negative in the laboratorybased sample were designated as 'verified negatives'; samples in which the field test was positive and the laboratory test was negative were designated 'unverified positives'; and cases where the laboratory based test detected targeted drugs not detected in the field were designated 'additional findings (AFs)'. Sensitivity, specificity, accuracy, positive predictive value (PPV) and negative predictive value (NPV) were calculated for each device relative to the laboratory OF test result. A summary of these terms and how they are calculated is given in Table II.

Comparison of field OF and laboratory-based urine test results

The field results from the two devices were compared with the results of laboratory-based tests conducted on urine samples collected immediately before the OF field tests were performed. The purpose of this evaluation was to determine whether

Table II

Definitions of Terms Used in Evaluation

Condition	Defined as	Calculated as
Verified positive (VP)	'True Positive'; a positive finding in the field test confirmed positive by the confirmatory test.	_
Verified negative (VN)	'True Negative'; a negative finding in the field test confirmed negative by the confirmatory test.	-
Additional finding (AF)	'False Negative'; a positive finding from the confirmatory test not predicted by the field test.	-
Unconfirmed positive (UP)	'False Positive'; a positive finding from the field test not confirmed by the confirmatory test.	-
Sensitivity	Proportion of subjects who subsequently test positive in a confirmatory test whose positive status was correctly predicted by the field test.	VP/(VP + AF)
Specificity	Proportion of subjects who subsequently test negative in a confirmatory test whose negative status was correctly predicted by the field test.	VN/(VN + UP)
Accuracy	Overall proportion of subjects whose drug status as determined by a subsequent confirmatory test was correctly predicted by the field test	(VP + VN)/(VP + VN + AF + UN)
PPV	Proportion of subjects whose field test correctly predicted they would test positive in the confirmatory test	VP/(VP + UP)
NPV	Proportion of subjects whose field test correctly predicted they would test negative in the confirmatory test.	VN/(VN + AF)

Florida's current statutorily approved practice of collecting and analyzing urine samples would be able to confirm an OF field test result, and whether drugs which may be excreted in urine for several days following last use, were detected in urine but not detected in the field. The same designators (VP, AF, UP and VN) described above were used for results which were verified or not verified in the field OF test relative to the urine test.

Comparison of laboratory-based OF and urine results

We compared the laboratory OF result to the urine result to evaluate whether OF and urine were equivalent in detecting a subject's drug use in collected specimens, irrespective of whether any field test was performed. For this assessment, instances where the laboratory-based test results, either positive or negative for the targeted drug categories, agreed between the urine and OF tests were designated 'concordant results'; instances where the results were positive for the drug class in one matrix but negative in the other were designated 'discrepant results'.

Drug prevalence and co-morbidity of alcobol and drug use in the study population

All drug test data in aggregate were assessed for the prevalence of drug use by drug category, based on any confirmed drug positive result in either a urine or OF confirmatory drug test. In addition, drug test results were considered in the context of the subject's BrAC. The purpose of this assessment was to determine the prevalence of co-morbidity of drug and alcohol use as a function of the subject's BrAC, given that Miami and many other jurisdictions currently will not conduct drug testing if the subject has a BrAC equivalent of 0.08 g/100 mL or greater. This selective testing practice could lead to significant underreporting of prevalence of drug use by impaired drivers.

Results and Discussion

A total of 103 subjects participated in the study; however, 11 samples were excluded from the study because confirmatory OF results were not available for comparison. Ninety-one subjects provided valid samples on the DDT5000, and 90 provided

valid results on the DrugWipe. A total of 92 subjects completed at least one field OF test for which a confirmatory laboratorybased OF test was performed. Sixty-nine subjects were male and 22 were female. The mean age of the males was 32 (range 18–79, median 28) and 33 for females (range 20–60, median 29). The age and gender of one participant was unknown.

Comparison of field OF and laboratory-based OF confirmatory results

The data were assessed through the use of Receiver Operator Characteristic (ROC) analysis. Sensitivity, specificity, accuracy, PPV and NPV are defined in Table II and the values for both devices shown in Table III. Arguably, the most valuable indicators of performance from a law enforcement perspective are PPV and sensitivity. PPV describes the proportion of positive field test results that are confirmed as positive in the laboratory OF test. A high PPV helps ensure that no enforcement action is being taken against individuals whose field tests cannot be confirmed with a forensically defensible confirmatory test. Likewise, sensitivity is the ability of the field test devices to identify individuals whose drug use was later detected in the laboratory OF sample. A high sensitivity reflects the fact that individuals who would test positive in the laboratory test are being identified in the field test. Tests with high sensitivity favor a program with a goal of comprehensive detection; however, tests with lower sensitivity in this context can still be of value as a deterrent to the practice of drug use and driving if the offender believes their risk of being caught is high enough to moderate their behavior.

With respect to individual analytes, the DDT5000 had a lower cutoff or threshold for THC of 5 ng/mL relative to 20 ng/mL for the DrugWipe, and was correspondingly more successful in detecting THC in subject samples. Key performance characteristics for the DDT5000 and DrugWipe devices on the THC test were as follows (DDT5000%: DrugWipe %): sensitivity (58.3%: 43.5%), PPV (93.3%: 66.7%). The difference in the PPV is largely due to the fact that the DrugWipe produced five unverifiable field test positive results for THC, whereas the DDT5000 produced only one.

For cocaine, the second most frequently encountered drug in this cohort, the DDT5000 device has a cutoff of 20 ng/mL, and

Table III

ROC Analysis of Field Screen Results from (a) DDT5000 and (b) DrugWipe

Drug	VP	AF	UP	VN	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)
DDT5000-OF (n = 91)									
THC	14	10	1	66	58.3	98.5	87.9	93.3	86.8
Cocaine	8	1	0	80	88.9	100.0	98.9	100.0	98.8
Amphetamine	2	3	1	85	40.0	98.8	95.6	66.7	96.6
Methamphetamine	0	0	0	91	N/A	100.0	100.0	N/A	100.0
Benzodiazepines	0	6	0	85	N/A	100.0	93.4	N/A	93.4
Opiates	2	3	0	85	40.0	100.0	96.7	100.0	96.6
Methadone	0	0	0	91	N/A	100.0	100.0	N/A	100.0
Overall	26	23	2	583	53.1	99.7	96.1	92.9	96.2
DrugWipe-OF ($n = 90$)									
THC	10	13	5	62	43.5	100.0	80.0	66.7	82.7
Cocaine	9	1	5	75	90.0	93.8	93.3	64.3	98.7
Amphetamine/methamphetamine	3	2	3	82	60.0	96.5	94.4	50.0	97.6
Benzodiazepines	0	6	1	83	N/A	98.8	92.2	N/A	93.3
Opiates	3	2	1	84	60.0	98.8	96.7	75.0	97.7
Overall	25	24	15	386	51.0	96.3	91.3	62.5	94.1

VP, verified positive (cf. true positive); AF, additional findings (cf. false negative); UP, unconfirmed positive (cf. false positive); VN, verified negative (cf. true negative).

the DrugWipe had a lower cutoff of 10 ng/mL. Performance characteristics for the DDT5000 and DrugWipe devices on the cocaine test were as follows: (DDT5000%: DrugWipe %): sensitivity (88.9%: 90.0%), PPV (100%: 64.3%). The DrugWipe produced five unverified positive screening results for cocaine. None of these subjects however were positive for cocaine or its metabolites in the corresponding urine sample either. The lower sensitivity of the DrugWipe for cocaine produced one additional verified positive for cocaine compared with the DDT5000. The high rate of unverified positives on the DrugWipe resulted in the relatively low PPV of 66.3%. All of the DDT5000 cocaine positive results were confirmed in the laboratory based OF test.

There were other AFs of targeted drugs (benzodiazepines, ampletamines and opiates) in the laboratory-based test which were not detected in the field by either device (Table III). In total, there were 24 AFs for the DrugWipe and 23 for the DDT5000. Neither the DDT5000 nor the DrugWipe performed well with benzodiazepines. Six cases which tested positive for benzodiazepines in the laboratory OF samples (alprazolam (n = 4) and lorazepam (n = 2)) tested negative on both devices in the field.

In total, the DDT5000 produced a total of two unverified positive results, whereas the DrugWipe produced a total of 15, five of which were THC and five of which were cocaine. The DDT5000 and the DrugWipe were comparable in their overall performance (DDT5000%: DrugWipe %) with respect to sensitivity (53.1%: 51.0%) and PPV (92.9%: 62.5%) (Table III). The DDT5000 scored higher for PPV as a result of its lower number of unverifiable positives for THC and cocaine. Clearly, the overall ROC parameters would change depending on the relative prevalence of each drug class in any study population.

Comparison of field OF and laboratory-based urine test results

Table IV shows the total number of field positives for each device, along with the percentage of those positive field results that were confirmed in OF and urine, respectively. A total of 82 subjects had both OF and urine available for comparison. Urine tests were less effective than tests of collected OF in confirming a subject's drug use from a positive field test on either the DDT5000 or the DrugWipe devices. For cannabis, cocaine and opiate use, OF confirmed a positive field test more frequently than did a urine test.

The superiority of OF over urine for confirmatory testing is a key finding of this assessment, since it implies that jurisdictions

Table IV

Confirmation Rate (PPV) for Target Drug Classes in Urine versus Oral Fluid for Both Devices

	Positive Field	Test Result (n)	% of positive DDT5000 results confirmed (PPV)		% of positive DrugWipe results confirmed (PPV	
	DDT5000	DrugWipe	OF	Urine	OF	Urine
Cannabinoids	15	15	93	67	67	60
Cocaine	8	14	100	50	100	36
Amphetamine	3	6	67	67	50	33
Methamphetamine	0	see Amp ^a	n/a	n/a	n/a	n/a
Benzodiazepine	0	1	n/a	n/a	n/a	Ó
Opiate	2	4	100	, 50	, 75	0
Methadone	0	0	n/a	n/a	n/a	n/a

^aThe Drugwipe has a combined amphetamine/methamphetamine panel.

that currently use urine as their statutorily directed sample may be missing key confirmatory evidence in DUID cases. Two of the major advantages in using OF include the fact that in both the field tests described here and the confirmatory laboratory tests in OF, the target is the parent drug (which is psychoactive), rather than the typical target in urine which is the inactive metabolite and less relevant with respect to impairment. In addition, drug metabolites become concentrated in urine and may be excreted for many hours, or days after use, and are less probative with respect to whether a person's drug use was recent or more historical. Another consideration is the fact that urine collection in a law enforcement setting does not involve a urinary void prior to collection of the sample for analysis, meaning that drug or metabolite excreted into the bladder over the period of time since last urination will show up in the collected sample, even if that was many hours before the driving in question. In this population, rather than finding evidence of historical drug use unrelated to the person's current state of sobriety, urine failed to provide evidence of recent drug use associated with impairment observed in these arrested drivers. This may reflect the fact that the drug use was recent and the drugs had not been sufficiently metabolized to reach detectable levels in the urine.

Comparison of laboratory-based OF and urine results

The relative effectiveness of collecting and sending an OF sample to the laboratory without the benefit of a preliminary field screen was also assessed. These data are presented in Table V. In general, there was good agreement between the two types of specimens, with a somewhat higher detection rate of drugs in the OF samples. The highest level of discrepancy was for detection of marijuana use, with 90% of the cannabinoid results being in agreement, and 10% discrepant. Of those, there were three cases of THC being detected in the OF, with no THC metabolite being detected in the urine, consistent with recent use. There were five cases in which an individual's urine tested positive for THC metabolite, but no THC was detected in the OF. This finding is less probative with respect to impairment, since urine may test positive for several days after heavy use, whereas THC in OF above a cutoff of 1 ng/mL is consistent with recent use (24).

Both laboratory-based urine and OF tests were more effective in detecting benzodiazepine use than either field test device, with 93% of the results being concordant between OF and urine. In two cases, the sedating benzodiazepine lorazepam was detected only in the laboratory-based OF test. For cocaine, there were two cases where cocaine and its metabolite were detected in OF only, and one case where they were detected in urine only. In summary, OF represents a more effective sample for detection of drug use in this impaired driving population, irrespective of whether a preliminary field OF test was given.

Drug prevalence and co-morbidity of alcobol and drug use in the study population

Combined alcohol and drug use is an emerging area for concern in DUI populations, so both the prevalence of alcohol and drug use and their co-morbidity were assessed. In this cohort, 41% of the 92 subjects were positive for at least one of the target drug

Table V

Concordant and Discrepant Results (Positives and Negatives) Between Urine and Oral Fluid Samples Tested in the Laboratory (n = 82 Pairs)

	Percentage (%)		Explanation		
	Concordant	Discrepant			
Cannabinoids	90	10	Three cases of THC in OF only; 5 cases THC–COOH in urine with no THC in OF		
Cocaine and metabolite	96	4	Two cases of Coc/Met in OF only; 1 case of Coc and BE in urine only		
Amphetamine	98	2	One case with Amp in OF only		
Methamphetamine	100	0	No meth positives		
Benzodiazepines	93	7	Two cases with lorazepam in OF only; 4 cases with alprazolam/met in urine only		
Opiate	98	2	One case with oxycodone in urine only; 1 case with codeine in urine only		
Methadone	100	0	No methadone positives		

Table VI

Percent Positivity for Target Drug Categories by BrAC (n = 92 Drivers)

BrAC (g/100 mL)	N/A	< 0.01%	0.01-0.079%	>0.08	Total
Any drug positive (% pos.)	-	78	22	39	41
Cannabinoids (% pos.)	-	72	22	22	30
Cocaine (% pos.)	-	22	0	10	10
Amphetamine (% pos.)	-	17	0	2	4
Methamphetamine (% pos.)	-	0	0	0	0
Benzodiazepine (% pos.)	-	28	11	6	11
Opiate (% pos.)	-	11	0	2	3
Methadone (% pos.)	-	0	0	0	0
TOTAL subjects (n)	5	18	18	51	92
ND (n)	-	4	14	30	48
Any positive (n)	-	14	4	20	38

N/A, BrAC not available; ND, no drug detected.

categories (Table VI). Thirty percent of the cohort was positive for cannabinoids, 11% for benzodiazepines and 10% for cocaine.

No BrAC data were available for five subjects. Of the 87 subjects with known alcohol results, 79% were alcohol positive, with 21% having BrAC between 0.01 and 0.079 g/100 mL blood alcohol equivalent and 59% having levels at or > 0.08 g/100 mL (mean 0.17, median 0.16 g/100 mL). 0.08 g/100 mL is the threshold for *per se* impairment in Florida and most US states.

In the subset of subjects who were alcohol free (21% of total subjects having a known alcohol result), 78% were positive for at least one psychoactive substance in the target drug categories in at least one of the confirmatory tests described earlier. The most commonly encountered drug was marijuana, followed by benzo-diazepines (alprazolam and lorazepam) and cocaine.

For subjects with BrAC between 0.010 and 0.079 g/100 mL, 22% were positive for at least one drug. Marijuana and benzodiazepines were the only drugs detected in this low blood alcohol range.

In the elevated BrAC category (>0.08 g/100 mL), 39% of the 51 subjects were positive for at least one drug category. Twenty-two percent (22%) of the elevated BrAC subjects were positive for cannabinoid use, 10% for cocaine use and 6% for benzodiazepine use. This group is especially interesting from a traffic safety perspective since many states and drug testing laboratories have policies of not testing for drugs in subjects with BrAC over the *per se* threshold. The justification for this policy includes the fact that there currently is no enhancement in penalty for

combined drug and alcohol use, laboratories have limited resources for drug testing and prosecuting DUID cases are more complex, requiring DRE testimony and at least one toxicology witness to get the result admitted. This practice however results in an incomplete epidemiological picture of the overall prevalence of drug impaired driving and fails on the individual level to identify patterns of combined alcohol and drug use, both of which should be addressed during a defendants sentencing and any associated treatment.

A total of 38 subjects were positive for one or more drugs, 20 of whom had BrACs at or above 0.08 g/100 mL, a threshold above which drug testing is not commonly performed. Consequently, in this cohort the policies currently in place would result in 53% of drug positive subjects going undetected. Having information about a defendant's poly-substance use is highly relevant to the court, increases the likelihood of conviction, and may direct defendants into sentencing based on treatment and behavioral change, in order to address both the alcohol and drug components. These findings are consistent with other studied populations that repeatedly find high percentages of drivers with blood alcohol concentrations over the *per se* threshold with drugs in their system.

Conclusions

The use of OF drug testing devices like the DDT5000 and DrugWipe offers the ability to rapidly obtain a screening result in the field at the time of a traffic stop. In this evaluation, both devices were highly effective in generating confirmable positives in either urine or OF, although the confirmation rate was consistently higher when OF was used as the confirmatory specimen. The devices performed comparably with the DDT5000 being more effective in detecting marijuana use. The devices were less effective in detecting some drug categories, especially benzodiazepines. This is a limitation resulting from the low partitioning of acidic drugs from blood into OF in vivo and the limited sensitivity of the current lateral flow immunochromatographic technology. The detection rates we encountered were consistent with previously reported studies involving these and similar devices. Sensitivities (the proportion of drug using subjects whose drug use is detected by the field device) were between 50 and 60%, while the DRUID project recommended optimum sensitivity of 90% (25). Sensitivities in the 50-60% range however should still make these devices effective as tools for deterrence and enforcement, and as such they have been effectively used in enforcement programs in Australia and many European countries.

This dataset with its collection of both urine and laboratorybased OF results has shown that OF is a valuable specimen for demonstrating drug use in a DUI population selected on the basis of objective impairment and driving behavior, and in fact a more effective specimen than urine for detecting drug use.

Finally, the data confirm reports in other related populations with respect to prevalence of combined alcohol and drug use on the impaired driving population. Policies that exclude drivers with blood or BrAC concentrations above the alcohol *per se* limit are missing substantial numbers of drivers with co-morbid drug and alcohol problems—in this cohort as high as 53% of all drug using drivers.

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References

- Bosker, W.M., Huestis, M.A. (2009) Oral fluid testing for drugs of abuse. *Clinical Chemistry*, 55, 1910–1931.
- Pil, K., Verstraete, A.G. (2008) Current developments in drug testing in oral fluid. *Therapeutic Drug Monitoring*, 30, 196–202.
- 3. Drummer, O.H. (2006) Drug testing in oral fluid. *The Clinical Biochemist Reviews*, 27, 147–159.
- Aps, J.K.M., Martens, L.C. (2005) Review: the physiology of saliva and transfer of drugs into saliva. *Forensic Science International*, 150, 119–131.
- Moore, C., Crouch, D. (2013) Oral fluid for the detection of drugs of abuse using immunoassay and LC-MS/MS. *Bioanalysis*, 5, 1555–1569.
- Crouch, D.J. (2005) Oral fluid collection: the neglected variable in oral fluid testing. *Forensic Science International*, **150**, 165–173.
- Houwing, S., Legrand, S.A., Mathijssen, R., Hagenzieker, M., Verstraete, A.G., Brookhuis, K. (2012) Prevalence of psychoactive substances in Dutch and Belgian traffic. *Journal of Studies on Alcohol Drugs*, 73, 951–960.
- Chu, M., Gerostamoulos, D., Beyer, J., Rodda, L., Boorman, M., Drummer, O.H. (2012) The incidence of drugs of impairment in oral fluid from random roadside testing. *Forensic Science International*, 215, 28–31.
- Drummer, O.H., Gerostamoulos, D., Chu, M., Swann, P., Boorman, M., Cairns, I. (2007) Drugs in oral fluid in randomly selected drivers. *Forensic Science International*, **170**, 105–110.
- Davey, J., Armstrong, K., Martin, P. (2014) Results of the Queensland 2007–2012 roadside drug testing program: the prevalence of three illicit. Accident Analysis and Prevention, 65, 11–17.
- Bladock, M.R.J., Woolley, J.R. (2013) Reviews of the effectiveness of random drug testing in Australia: the absence of crash-based evaluations. Proceedings of the 2013 Australasian Road Safety Research, Policing & Education Conference, 28th–30th August, Brisbane, Queensland.
- 12. Kelley-Baker, T., Moore, C., Lacey, J.H., Yao, J. (2014) Comparing drug detection in oral fluid and blood: data from a national sample of night-time drivers. *Traffic Injury Prevention*, **15**, 111–118.

- 13. Voas, R.B., Lacey, J.H., Jones, K., Scherer, M., Compton, R. (2013) Drinking drivers and drug use on weekend nights in the United States. *Drug Alcobol Dependence*, **130**, 215–221.
- Moore, C., Kelley-Baker, T., Lacey, J. (2013) Field testing of the Alere DDS2 Mobile Test System for drugs in oral fluid. *Journal of Analytical Toxicology*, 37, 305–307.
- Lacey, J.H., Kelly-Baker, T., Furr-Holden, D., Voas, R.B., Romano, E., Ramirez, A. *et al.* (2009) 2007 National roadside survey of alcohol and drug use by drivers: Drug results. US Department of Transportation National Highway Traffic Safety Administration. Washington, DC.
- 16. Beirness, D.J., Beasley, E.E. (2010) A roadside survey of alcohol and drug use among drivers in British Columbia. *Traffic Injury Prevention*, **11**, 215–222.
- Federal Register (2012) Conforming Products List Of Alcohol Screening Device. http://www.gpo.gov/fdsys/pkg/FR-2012-06-14/ pdf/2012-14581.pdf (January 2014, date last accessed).
- 18. Driving Under the Influence of Drugs, Alcohol, and Medicines (DRUID) (2009) Evaluation of oral fluid screen devices by TISPOL to harmonise European police requirements (ESTHER). http:// www.druid-project.eu/cln_031/nn_107548/Druid/EN/deliveraleslist/downloads/Deliverable_3_1_1,templateId = raw,property = publicationFile.pdf/Deliverable_3_1_1.pdf (January 2014, date last accessed).
- Driving Under the Influence of Drugs, Alcohol, and Medicines (DRUID) (2010) Analytical evaluation of oral fluid screening devices and preceding selection procedures. http://www.druid-project.eu/ nn_107548/Druid/EN/deliverales-list/downloads/Deliverable_3_ 2__2,templateId = raw,property = publicationFile.pdf/Deliverable_ 3_2_2,pdf (January 2014, date last accessed).
- Posthuma-Trumpie, G.A., Korf, J., van Amerongen, A. (2009) Lateral flow (immuno)assay: its strengths, weaknesses, opportunities and threats. A literature survey. *Analytical and Bioanalytical Chemistry*. 393, 569–582.
- Logan, B.K., Lowrie, K.J., Turri, J.L., Yeakel, J.K., Limoges, J.F., Miles, A.K. *et al.* (2013) Recommendations for Toxicological Investigation of Drug Impaired Driving and Motor Vehicle Fatalities. *Journal of Analytical Toxicology*, 37, 554–557.
- Dräger Drug Test[®] 5000 STK: Instructions for Use. (2011) Drager Safety AG and Co., Lübeck Germany, Edition 01, 1–69.
- Maggitti, A., Logan, B.K., McMullin, M. (2012) Tools, techniques, and findings for the qualitative analysis of delta-9-tetrahydrocannabinol (THC) in oral fluids. *Proceedings: American Academy of Forensic Sciences*, XIX, 474–475.
- Lee, D., Huestis, M. (2014) Current knowledge on cannabinoids in oral fluid. *Drug Testing and Analysis*, 6, 88–111.
- Raes, E., Verstraete, A. (2006) Evaluation of rapid point-of-collection oral fluid testing devices. Roadside Testing Assessment (ROSITA-2) Project: Final Report. http://www.rosita.org/ (accessed December 2013).