Final Report: Laboratory-Based Evaluation of the DrugWipe 5 S Performance

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Executive Summary

Oral fluid has become an increasingly popular biological sample for drug testing in the investigation of driving under the influence of drugs (DUID) cases. Performing oral fluid drug testing at the point of contact is an especially useful tool for producing timely investigative information and confirming officer suspicions about drug use immediately in the field. This approach may facilitate police investigations, provide actionable drug use information about suspects, and save time and resources in the field.

Other factors such as the ability to do same-sex observed collection, the less invasive nature of the collection, and the ability to perform a test proximate to the time of driving are significant benefits of oral fluid collection compared to blood or urine. In addition, savings on cost of transport time, officer time, phlebotomist costs, and a reduction in the number of witnesses required for eventual testimony may be substantial. Using point-of-contact (POC) oral fluid collection devices in conjunction with a structured assessment and documentation of the driver's behavior, appearance and demeanor, and performance in standardized field sobriety tests (SFST's) or the Drug Evaluation and Classification Program (DECP) provides a more objective basis to relate these observations to the subject's drug use, frequently eliciting admissions to drug use.

This is a report of a laboratory-based assessment of the performance of the Securtec DrugWipe® S 5-Panel (DrugWipe), which included evaluation of the WipeAlyser® (Securetec, Neubiberg, Germany) device which produces a printed record of the test results. The assessment included an evaluation of the cutoffs of each of the assays, an assessment of cross-reactivity, and the potential for various interfering substances to cause either false positive or false negative results.

Overall, the DrugWipe 5 S has a highly relevant test panel, testing for the most commonly encountered illicit drugs in drivers: THC, amphetamine/methamphetamine, cocaine and opiates. The Drug Wipe test cassettes and WipeAlyser® analyzer used in combination are portable and allow the results to be printed for inclusion in the officer's report. In our evaluation, collecting a sample was a simple, straightforward procedure. The device was often able to detect concentrations lower than the specified cutoff concentration provided by the manufacturer, particularly for the THC and amphetamine/methamphetamine assays. Recommendations related to device performance specifications have been previously described in the ROSITA and DRUID projects. The ROSITA project recommended greater than 95% accuracy compared to 80% recommended by the DRUID project. When evaluating the cutoff results, the Drug Wipe 5 S meets both sets of accuracy recommendations for all assays when using the WipeAlyser® analyzer. No false positive results were observed during the testing cutoff, mixed drug or cross-reactivity assessments. With respect to evaluating commonly encountered drugs and/or metabolites, none of the non-targeted drugs, produced false positives on any of the test platforms at concentrations of 1000 ng/mL. Generally, the device showed appropriate cross-reactivity to drugs that may be of interest in an impaired driving context, and which are included in the drugs of interest in the National Safety Council's guidelines.

Background

Oral fluid has seen an increase in popularity as a biological matrix for drug testing within the field of forensic toxicology, workplace testing, and traffic law enforcement. The main advantages of using oral fluid is that the sample can be easily collected using non-invasive procedures and is a simple matrix suitable for testing with minimal or no sample preparation. With respect to drug impaired driving, the major benefit of oral fluid is that the sample can be collected proximate to the time of the driving event, allowing for better correlation between signs and symptoms of impairment observed at the time of arrest and any drugs detected in a biological sample collected during the arrest. Additionally, these field tests can provide a laboratory with presumptive results and direct subsequent confirmatory testing. Both of these factors, when combined with the observations of a trained officer, can help support the case for drug impairment and enhance the strength of the evidence for prosecution of a drug impaired driving case.

The major limitation of oral fluid is that drug concentrations cannot be related to a specific degree of impairment in the driver, nor can they be used to predict blood drug concentrations, specifically in instances using a POC screening device. Many jurisdictions have concluded that the best use of oral fluid testing is as a corroborative test for drug ingestion in situations where a trained police officer has made observations of cognitive and psychomotor impairment in a suspected impaired driver. As such, oral fluid testing is a useful complement to investigative information from Standardized Field Sobriety Tests (SFST's), the Drug Evaluation and Classification Program (DECP), and the Advanced Roadside Impaired Driving Enforcement (ARIDE) program currently used in the United States.

The use of oral fluid as a biological matrix for the detection of drugs of abuse at the roadside requires the availability of oral fluid testing devices that can easily be used on-site and provide reliable presumptive testing for the most frequently encountered drug classes. Currently, several point-of-contact (POC) devices are available and marketed as forensically suitable, but without a published structured assessment of their effectiveness or performance characteristics. In the United States, there is no federally approved list of devices for use in law enforcement oral fluid drug testing as there is for breath alcohol testing devices[1]. Most of the current generation of oral fluid field testing devices are based on lateral-flow immuno-chromatographic technology (1). As such, the results generated indicate the presence or absence of targeted drug classes, as opposed to individual analytes, and are considered presumptive. Following a field positive for any drug class, for forensic purposes, an additional specimen should be collected for laboratory-based confirmatory testing using chromatographic and mass spectrometric methods to meet standards for forensic admissibility in criminal casework.

Recently, the National Safety Council's Alcohol, Drugs and Impairment Division (NSC-ADID) compiled recommendations for scope and threshold for laboratory-based drug screening and confirmation in oral fluid (2). The recommendations were based on the most prevalent drugs

[1] NHTSA maintains a Conforming Products List for breath alcohol testing devices.

encountered in impaired drivers from various surveys and laboratory databases. The scope was also designed to be detectable by laboratories using readily available current generation technologies. The recommendations do not however address criteria for field-based testing devices. Despite the fact there are no federal regulations in the United States, several large-scale roadside studies have developed recommendations for device performance. Notably, the Roadside Testing Assessment (ROSITA) project recommended that devices have greater than 90% sensitivity and specificity, and greater than 95% accuracy, and the Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID) project recommend greater than 80% sensitivity, specificity and accuracy (3, 4). The United Kingdom has developed "A Guide to Type Approval Procedures for Preliminary Drug Testing Devices" which mandates that correct results must be obtained in 90% or more of the tests administered and the false positive rate should not exceed five percent (5). The Canadian Society of Forensic Sciences also recently issued standards and an evaluation procedure for approval of oral fluid testing devices in Canada which specified requirements for positivity at 25%, 60%, 140% and 175% of the cutoffs for THC, methamphetamine and cocaine (6).

The DrugWipe® S 5-panel (DrugWipe 5 S) is a POC test for the simultaneous detection of up to five drugs of abuse in human oral fluid. The device technology is based on lateral flow immunoassay, with optical detection in an instrumented reader (WipeAlyser®). The lateral flow devices can also be read manually. The classes of compounds detected with the system used in this analysis include: a combined amphetamine/methamphetamine test, cocaine, opiates and THC. The published scope and manufacturers cutoffs or detection thresholds for the device is shown in Table 1.

Table 1. Scope and cutoffs for the DrugWipe 5 S.

Drug Assay	DrugWipe 5 S Cutoff (ng/mL)
THC	5
Cocaine	10
Amphetamine	80†
Methamphetamine	80†
Opiates (morphine)	10

†DrugWipe has a combined amphetamine/methamphetamine panel

Objectives

As there is no federally approved process for the evaluation of oral fluid POC devices to evaluate their precision, and robustness, this independent evaluation was designed to objectively evaluate the performance of the Securetec DrugWipe® S 5-Panel against its claimed scope and analytical sensitivity. Specifically, the evaluation was designed to: 1) assess the device performance relative to the manufacturer's published cutoffs; 2) assess the ability to produce positive results in polydrug cases; 3) investigate the cross-reactivity of commonly encountered drugs, and metabolites and; 4) evaluate the effects of potential interferences (e.g. oral hygiene products, beverages and tobacco) on device performance.

Methods

All testing was performed using authentic drug free, pooled oral fluid. Oral fluid was collected from volunteers in our laboratory by expectorating into a collection container. Saliva was collected from at least five or more individuals who had abstained from food or drink ingestion for at least 30 minutes. Following collection, the saliva was pooled and mixed before freezing (-20°C) for a minimum of 12 hours. After freezing the oral fluid was thawed and centrifuged at 4100 X g for 10 minutes. The clear supernatant was pooled. The pooled oral fluid was verified to be negative for target drug classes via liquid chromatography quadrupole time-of-flight mass spectrometry (LC-QTOF) and liquid chromatography tandem mass spectrometry (LC-MSMS). Residual oral fluid was frozen at -20°C until further use. An additional limited series of experiments (n=20) were performed where oral fluid was collected using Sarstedt Salivettes (Nümbrecht, Germany). Volunteers were instructed to insert the plain cotton swab into their mouth and gently chew on the swab for five minutes or until the pad was saturated. The cotton swab was then placed back into the collection container and centrifuged at 3,800 rpm for eight minutes. The residual oral fluid collected was pooled and used only in testing on the day the samples were collected.

The evaluation was designed as a blind assessment, meaning the technician administering the test was unaware of which drug(s) was in the matrix. Furthermore, blank, drug-free oral fluid samples were randomly inserted between positive samples to further counter confirmation bias by the technician making the reading. Drug-free oral fluid was fortified with the drug(s) of interest and tested within five minutes of spiking the matrix. Certified drug standard reference materials were purchased from Cerilliant® (Round Rock, TX). To test, 10 microliter (µL) aliquots of the fortified matrix was added to each of the sorbent pads on the collection device. Prior to testing, the technician ensured the volume adequacy indicator had changed color, signifying a sufficient volume of sample had been applied. Following, the buffer ampoule was broken and cassette was held vertically for 10 seconds prior to inserting the cassette into the WipeAlyser®. From there, the test was started, using the start option from the WipeAlyser® menu, as per the instructions. After the WipeAlyser® evaluation the DrugWipe 5 S was removed from the analyzer and reviewed by the technician who noted any faint or partially formed lines.

Following testing with the DrugWipe 5 S, all drug mixtures used for spiking were verified against qualitative controls, except for tetrahydrocannabinol (THC). THC was quantitively verified using LC-MSMS. For all testing, the following designations were made: Positive results were recorded as true positives (TP) if the analyte was present in the aliquot (representative of the sample) and detected by the device, irrespective of its concentration. With all negative results, the concentration of each drug in the aliquot was compared to the manufacturer's specified cutoff concentration and designated as a true negative (TN) or false negative (FN) relative to that cutoff. In the case of a positive result, when the analyte was not present in the aliquot, the result was designated as a false positive (FP). Definitions can be found in Table 2. Following these designations, the performance of test cassettes was evaluated by drug class and by how the device performance around the state cutoff concentration calculated using Receiver Operator Characteristic (ROC) analysis. The following were calculated for each experiment.

- Sensitivity (TP/(TP+FN))

- Specificity (TN/(TN+FP))
- Accuracy ((TP+TN)/(TP+TN+FP+FN))
- (PPV) positive predictive value (TP/(TP+FP))
- (NPV) negative predictive value (TN/(TN+FN))

Table 2. Definitions of terms used during the evaluation.

Condition	Defined as
True Positive	A positive finding in the field test confirmed positive by the confirmatory test.
True Negative	A negative finding in the field test confirmed negative by the confirmatory test.
False Negative	A positive finding from the confirmatory test not predicted by the field test.
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.
Specificity	Proportion of subjects who subsequently test negative in a confirmatory test whose negative status was correctly predicted by the field test.
Accuracy	Overall proportion of subjects whose drug status as determined by a subsequent confirmatory test was correctly predicted by the field test.
Positive Predictive Value (PPV)	Proportion of subjects whose field test correctly predicted they would test positive in the confirmatory test.
Negative Predictive Value (NPV)	Proportion of subjects whose field test correctly predicted they would test negative in the confirmatory test.

Cutoff Evaluations

The initial evaluation assessed the device performance relative the manufacturer's stated cutoff concentration. Oral fluid was collected using the procedures described above. Mixes of the target analytes were fortified and tested in replicates of ten at 50% above the stated cutoff concentration, at the cutoff concentration and 50% below the cutoff concentration. For the purposes of testing, amphetamine, THC, and cocaine were combined into one sample and methamphetamine and morphine were combined into another. Additionally, four random drug free samples were also incorporated into the analysis to minimize the potential for confirmation bias. Testing was split evenly between two randomly assigned WipeAlyser® instruments to counter instrumental bias or failure. The concentrations tested are provided in Table 3.

Table 3. Concentrations (ng/mL) used for the cutoff concentration evaluation.

Drug Category/Assay	**DrugWipe 5 S**	
	+50%	***-50%***
THC	7.5	2.5
Cocaine	15	5
Amphetamine	120†	40†
Methamphetamine	120†	40†
Opiates (morphine)	15	5

†The DrugWipe has a combined amphetamine/methamphetamine assay.

The second part of the cutoff evaluation consisted of running a series of mixed drug controls at various concentrations consistent with concentrations reported in the literature. A series of nine controls were fortified with mixtures of three to six target analytes at various concentrations (Table 4). An additional positive control containing all the target analytes at 100 ng/mL and a negative control (drug-free pooled oral fluid) were run during the analysis.

Table 4. Concentrations (ng/mL) used for the mixed drug blind control evaluation.

	Mixed Drug Controls										
Drug	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Positive**	**Negative**
THC	80	150		20	2	5	-	30	100	100	0
Cocaine	-	1000	30		80	-	400	50	10	100	0
d-Amphetamine	1000	60		10	160	50	-	300	40	100	0
d-Methamphetamine	-	-	1000	300	-	20	90	50	-	100	0
Morphine	-	40	90	500	-	80	10	-	30	100	0

Cross-Reactivity Evaluations

A series of cross-reactivity evaluations were performed to assess whether or not substances other than the target analyte may cause positive results on the device. Commonly encountered drug metabolites, therapeutic drugs and other drugs known to cross-react on immunoassay tests were prepared into five different mixes (Table 5). An additional sixth mix was prepared with drugs unlikely to cross-react on the device (Table 5). Each control was tested in triplicate initially at a concentration at 1,000 ng/mL. If any of the analytes produced a positive result, testing was repeated at concentrations of 500 ng/mL, 100 ng/mL, 10 ng/mL, or until a negative result was obtained.

Table 5. Mixed drug controls used in the cross-reactivity evaluations.

MIX 1
MDMA (3,4-methylenedioxymethamphetamine)
THC-COOH (11-nor-delta9-THC-COOH)
Hydrocodone
MIX 2
MDA (3,4-methylenedioxyamphetamine)
Codeine
MIX 3
Pseudoephedrine
Cannabidiol
Oxymorphone
MIX 4
L-Amphetamine
Oxycodone
MIX 5
L-methamphetamine
Hydromorphone
Cannabinol

Benzoylecgonine
MIX 6
Dextromethorphan
Caffeine
Nicotine
Tramadol
Acetaminophen
Diphenhydramine
Pentobarbital
Zolpidem
Fluoxetine
PCP (Phencyclidine)

Interferent Evaluations

Commonly encountered potential interferents (e.g. coffee, mouthwash, alcohol, tobacco) were assessed in a series of experiments. Commonly ingested beverages were mixed with pooled drug free oral fluid at a concentration of 5% of the total volume (v/v), with the exception of milk (2% milk fat), which was tested at a concentration of 2% of the total volume (v/v) (Table 6). For orally ingested products such as toothpaste, gum, and mints, the products were used and an oral fluid sample was collected immediately following use of the product from three different volunteers, voiding the ten-minute wait period (Table 6). For chewing tobacco, a small pinch or approximately 200 mg of product was placed into a test tube with 4 mL of oral fluid. It was then vortexed and centrifuged. Testing was performed in duplicate. For one set of experiments, oral fluid was fortified with the target analytes at 50% above the cutoff concentration (to test amphetamines, only d-methamphetamine was used) and combined with the interferent being evaluated to assess the potential risks of the interferent causing false negative results (signal suppression). The final set of experiments used drug-free pooled oral fluid combined with the potential interferent to evaluate the risk of false positive results. For each experiment testing was completed in duplicate.

Table 6. Substances used for the interference studies.

Potential Interferent	
Beer (Victory®: Prima Pils)	Coffee (Dunkin Donuts®, straight black)
Methanol	Toothpaste (Colgate®: cavity protection)
Orange juice	Chewing tobacco (Longhorn®: straight long cut)
Milk (2% fat)	Spearmint gum (Wrigley's®)
Mouthwash (Crest® Pro-Health)	Peppermint mints (Altoids®)
Soda (Coca Cola®)	Wintergreen mints (Altoids®)

Results and Discussion

Cutoff Evaluations

Using the WipeAlyser® analyzer to evaluate the DrugWipe 5 S test results returned an overall sensitivity of 96.9% (Table 7). The DrugWipe 5 S with the WipeAlyser® detected THC, cocaine,

amphetamine and methamphetamine with 100% sensitivity; recording positive results in all cases, at the cutoff concentration and 50% above the cutoff concentration (Table 7). The WipeAlyser® detected seven THC positive results, five morphine positive results, seven amphetamine and eight methamphetamine at 50% below the cutoff concentration. With amphetamine and methamphetamine sharing a common test line, the DrugWipe 5 S does not differentiate between the two drugs. So, when there was a true positive (TP) methamphetamine a true negative (TN) could not be recorded for amphetamine and vice versa. However, if the sample concentration for one was below the cutoff and not detected a true negative (TN) result was recorded for both methamphetamine and amphetamine (Table 7). With respect to opiates, morphine was successfully detected at 50% above the cutoff concentration in all ten replicates tested. At the cutoff concentration, there were four false negative results for morphine, which decreased the overall sensitivity to 80%. Morphine was not detected at all below the cutoff concentration.

Table 7. Cutoff evaluation of DrugWipe 5 S with results provided by the WipeAlyser® analyzer.

DrugWipe 5 S with WipeAlyser® Cutoff Evaluation									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	27	0	0	38	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	25	0	0	40	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	27	0	0	10	100.0%	100.0%	100.0%	100.0%	100.0%
Methamphetamine	28	0	0	10	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates	16	4	0	45	80.0%	100.0%	93.8%	100.0%	91.8%
Overall	123	4	0	143	96.9%	100.0%	98.5%	100.0%	97.3%

A limited set of evaluations were also performed at the cutoff concentration using oral fluid collected with the Salivettes that was tested immediately following collection without being frozen (Table 8). Results were consistent with the cutoff performance using saliva that had been collected, centrifuged and frozen prior to use. There were no false positive or negative results obtained using the native saliva.

Table 8. Cutoff evaluation of DrugWipe 5 S using native saliva with results provided by the WipeAlyser® analyzer.

DrugWipe 5 S with WipeAlyser® Cutoff Evaluation									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	8	0	0	12	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	10	0	0	10	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	10	0	0	0	100.0%	N/A	100.0%	100.0%	N/A
Methamphetamine	10	0	0	0	100.0%	N/A	100.0%	100.0%	N/A
Opiates	10	0	0	10	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	48	0	0	32	100.0%	100.0%	100.0%	100.0%	100.0%

The second part of the evaluation involved testing samples of polydrug mixes at high and low concentrations (Table 4). The DrugWipe 5 S scored 100% for sensitivity, specificity, accuracy, PPV, and NPV for all of the drug mixtures where the concentration in the sample was at the cutoff (Table 9). Positive results were for amphetamine at 40 ng/mL and 60 ng/mL, which is below the cutoff value of 80 ng/mL. It was also noted that when amphetamine and methamphetamine were in the same sample both below the cutoff concentration, positive results on the amphetamine/methamphetamine test strip were obtained. As mentioned above, when there was a true positive (TP) methamphetamine a true negative (TN) could not be recorded for amphetamine and vice versa due to both drugs being combined on a single test strip.

Table 9. Mixed positive samples on the DrugWipe 5 S with results provided by the WipeAlyser® analyzer.

DrugWipe 5 S with WipeAlyser® Cutoff Evaluation									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	7	0	0	4	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	6	0	0	5	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	8	0	0	1	100.0%	100.0%	100.0%	100.0%	100.0%
Methamphetamine	6	0	0	1	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates	7	0	0	4	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	34	0	0	15	100.0%	100.0%	100.0%	100.0%	100.0%

Cross-Reactivity Evaluations

The cross-reactivity evaluation ran a series of six mixtures of non-target drugs, drug metabolites, and commonly encountered therapeutic drugs to determine if they could produce a positive result and approximate the concentration which would do so. Results from the analysis of the mixtures are shown in Table 9. The lowest concentration which produced positive results for all three replicates was recorded.

For the amphetamine/phenethylamine class of drugs the DrugWipe 5 S did not show any cross-reactivity for L-enantiomers of methamphetamine or amphetamine at 1000 ng/mL. The WipeAlyser®, detected both MDMA and MDA down to a concentration of 100 ng/mL (Table 10). At 10 ng/mL neither MDMA nor MDA were detected. Benzoylecgonine was detected at 500 ng/mL. For the opiate class of drugs, the DrugWipe 5 S did not show any cross-reactivity for oxycodone or oxymorphone at 1000 ng/mL (Table 10). Codeine was detected at 10 ng/mL, while both hydromorphone and hydrocodone were detected at 100 ng/mL (Table 10). Regarding the cannabinoids, 11-nor-delta-9-THC-COOH was detected at 10 ng/mL and cannabinol at 100 ng/mL (Table 10). No cross-reactivity was detected for cannabidiol at 1000 ng/mL. The drugs in mixture six (Table 5) were not expected to produce any positive results on the DrugWipe 5 S, and they did not at concentrations of 1000 ng/mL.

Table 10. Cross-Reactivity. Lowest concentration testing positive (2/3) for indicated analyte.

	WipeAlyser®
Amphetamines/Phenethylamines	
MDMA	100 ng/mL
MDA	100 ng/mL
Pseudoephedrine	NCR
l-Methamphetamine	NCR
l-Amphetamine	NCR
Cocaine	
Benzoylecgonine	500 ng/mL
Opiates	
Hydrocodone	100 ng/mL
Codeine	10 ng/mL
Hydromorphone	100 ng/mL
Oxycodone	NCR
Oxymorphone	NCR
Cannabinoids	
11-nor-delta9-THC-COOH	10 ng/mL
Cannabidiol	NCR
Cannabinol	100 ng/mL
Other	
Dextromethorphan	NCR
Caffeine	NCR
Nicotine	NCR
Tramadol	NCR
Acetaminophen	NCR
Diphenhydramine	NCR
Pentobarbital	NCR
Zolpidem	NCR
Fluoxetine	NCR
PCP	NCR

NCR = no cross-reactivity

Interferent Evaluations

For the interferent evaluation, potential interferents were mixed with pooled oral fluid at high concentrations (50% above the cutoff), mimicking very recent oral use of the potentially interfering substance, and tested in duplicate. When oral fluid was collected immediately following subjects chewing Wrigley's® spearmint gum, two false negative results were obtained for opiates (Table 11). None of the other tested interferents caused false negative results. When the interferents were combined with negative oral fluid, a total of four false positive results were obtained (Table 11). All of the false positive results came from chewing tobacco, two of which were on amphetamines strip and two of which were on the opiates strip.

It was noted during the evaluation that with 2% milk, the THC control lined was very smeared, which initially resulted in a false positive result for THC. However, following an additional ten-minute wait period, the WipeAlyser® correctly identified the test sample as negative for THC. With toothpaste as the interferent, it was noted that methamphetamine control line was very faint and initially resulted in an invalid result. Following an additional ten-minute wait period, the control was detected by the WipeAlyser® and the results were correctly identified.

Overall, there was very little difference in performance relative to the performance during the cutoff evaluations with the exception of the four false positive results. In the instruction booklet included with the WipeAlyser® analyzer, it states that a ten-minute waiting period should be observed between any food, beverage, or tobacco use and sample collection. Our testing admittedly deviated from the ten-minute waiting period protocol in an attempt to illustrate potential problems in the field if the protocol is not observed.

Table 11. Matrix mixed interferences on the DrugWipe 5 S with results provided by the WipeAlyser® analyzer.

DrugWipe 5 S with WipeAlyser® Interferent Evaluation									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	24	0	0	24	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	24	0	0	24	100.0%	100.0%	100.0%	100.0%	100.0%
Methamphet/Amphet	24	0	2	22	100.0%	91.7%	95.8%	92.3%	100.0%
Opiates	22	2	2	22	91.7%	91.7%	91.7%	91.7%	91.7%
Overall	94	2	4	92	97.9%	95.8%	96.9%	95.9%	97.9%

Conclusions

With the increased popularity of oral fluid drug testing devices designed for use in the field, and a lack of standardization regarding device performance specifications, independent evaluations that objectively evaluate device performance are important. The ultimate marker of overall performance is the accuracy of a device, which evaluates the number of times the device produces a correct answer, takes into account the number of times a negative sample is correctly identified, and accounts for the devices' ability to correctly identify drug users. Recommendations related to device performance specifications have previously been described in the ROSITA and DRUID projects. The ROSITA project recommended greater than 95% accuracy compared to 80% recommended by the DRUID project. When evaluating the cutoff results, the Drug Wipe 5 S meets both sets of accuracy recommendations for all assays when using the WipeAlyser® analyzer (Table 7). No false positives were observed during the testing cutoff, mixed drug or cross-reactivity assessments, which is another important performance characteristic that demonstrates the utility of the device as the implications of wrongly accusing someone of drug use have several potential legal ramifications. The only time false positive or false negative results were obtained were during the interference evaluations, which was performed outside the normal testing protocol. Irrespective, the best practice in any forensic test is to collect a secondary oral fluid that could be confirmed using analytical techniques that are more sensitive and specific.

With respect to evaluating commonly encountered drugs and/or metabolites, none of the non-targeted drugs, which included caffeine, nicotine, non-steroidal anti-inflammatory drugs (NSAIDs), over-the-counter analgesics, selective serotonin/noradrenaline reuptake inhibitors (SSRIs/SNRIs), zolpidem, dextromethorphan or PCP produced false positives on any of the test platforms at concentrations of 1000 ng/mL (Table 9). Other members of the drug classes to which the devices are targeted showed varying degrees of cross-reactivity. Hydrocodone and hydromorphone were well detected at concentrations of 100 ng/mL. Codeine was detected at 10 ng/mL using the WipeAlyser®. MDMA and MDA were detected at concentrations of 100 ng/mL. For cannabinoids, cannabinol was detected at 100 ng/mL and 11-nor-delta-9-THC-COOH was detected at 10 ng/mL. Benzoylecgonine was detected at 500 ng/mL. Generally, the devices showed appropriate cross-reactivity to drugs that may be of interest in an impaired driving context, and which are included in the drugs of interest in the National Safety Council's guidelines.

Overall, the DrugWipe 5 S has a relevant test panel, testing for THC, amphetamine/methamphetamine, cocaine and opiates, which are among the most frequently detected drugs in impaired driving investigations (2). The test cassettes and WipeAlyser® analyzer are portable and allow the ability for the results to be printed. Collecting a sample is a simple straightforward procedure. Importantly, only a few microliters of oral fluid is required for the test, an advantage over other POC devices which often require up to one milliliter of volume. This would be beneficial in instances of dry mouth, a common side-effect of narcotic abuse which can make collecting oral fluid difficult. The results obtained were reproducible, and the device was often able to detect concentrations lower than cutoff concentration provided by the manufacturer, particularly for the THC and amphetamine/methamphetamine assays.

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