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# An assessment of oral fluid drug screening devices

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**ABSTRACT**

This project was to examine point-of-contact (POC) oral fluid drug screening devices to determine the suitability of such devices for potential use in the enforcement of drug-impaired driving in Canada. Oral fluid samples were collected from a group of individuals who admitted to having recently ingested drugs as well as a number of individuals who had not been using drugs. These samples were tested on one of three oral fluid screening devices to determine the presence of cannabis, cocaine, amphetamine, methamphetamine, opioids, and benzodiazepines. Each participant also provided a second oral fluid sample that was sent to a reference laboratory for independent analysis. Comparison of the results from the oral fluid screening device and those from the laboratory analysis provided estimates of sensitivity and specificity for each of the six drugs/drug categories. Sensitivity exceeded 0.80 for cannabis, cocaine, methamphetamine, and opioids. False positive rates for these drugs/drug categories were all between 3% and 7%. Specificity exceeded 0.90 for all drugs/drug categories. These findings indicate that oral fluid screening could prove to be a valuable tool in the detection of driver drug use in Canada.

**RÉSUMÉ**

Le but de ce projet était d'évaluer différents dispositifs, utilisés au bord de la route, d'analyses de drogues dans la salive, et ce, afin de déterminer leur utilité potentielle dans le cadre des enquêtes sur la conduite en capacités affaiblies par les drogues au Canada. Les échantillons de salive ont été prélevés sur un groupe d'individus ayant admis avoir récemment consommé des drogues ainsi que sur un groupe contrôle n'ayant pas consommé de drogues. Ces échantillons ont été analysés sur l'un des trois dispositifs d'analyses salivaires afin d'y déterminer la présence de cannabis, de cocaïne, d'amphétamine, de méthamphétamine, d'opioïdes et de benzodiazépines. Chaque participant fournissait également un deuxième échantillon de salive pour fins d'analyses dans un laboratoire de référence indépendant. La comparaison entre les résultats obtenus à partir des dispositifs d'analyses salivaires et ceux obtenus suite aux analyses en laboratoire a permis d'estimer la sensibilité et la spécificité des analyses, et ce, pour chacune des drogues/catégories de drogues visées. Une sensibilité supérieure à 0.80 a été établie pour le cannabis, la cocaïne, la méthamphétamine

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et les opioïdes. Le taux de faux-positifs se situait entre 3% et 7% pour ces mêmes drogues/catégories de drogues. Une spécificité supérieure à 0.90 a également été établie pour toutes les drogues/catégories de drogues. Ces différents résultats démontrent que l'analyse de la salive pourrait s'avérer utile dans le cadre des enquêtes sur la conduite en capacités affaiblies par les drogues au Canada.

## Introduction

In July 2008, revisions to the *Criminal Code of Canada* were implemented that provided police with the tools and powers to enhance the enforcement of drug-impaired driving. Police were given the authority to demand a suspected drug-impaired driver to submit to a Standardized Field Sobriety Test (SFST), a drug influence evaluation by a Drug Recognition Evaluator (DRE), and to provide a sample of blood, urine or oral fluid to test for the presence of impairing substances. Although these changes were widely applauded as a definite improvement, many challenges remained. There were insufficient numbers of trained and certified DREs; it was expensive to train DREs; the evaluation took considerably longer than a typical breath test; toxicological tests were conducted primarily on urine samples; and the courts were sometimes hesitant to accept the drug influence evidence from a DRE. These issues have prompted calls for improvements and greater efficiency.

Among the suggestions has been a call for a point-of-contact (POC) drug screening device that would provide a preliminary indication of driver drug use. Presumably, such a device could be utilized in a manner analogous to an approved screening device (ASD) used to detect alcohol. It is assumed that the availability of such a device would provide a presumptive test of drug use that would facilitate the detection and apprehension of drug-impaired drivers by providing reasonable grounds to make a demand for further testing.

The search for suitable drug screening devices that could be used at roadside has been ongoing for many years. Initial drug screening tests utilized urine samples. Several of these devices were tested in a large scale project in Europe by the ROSITA (Roadside Testing Assessment) consortium. The study concluded that for each drug category, several of the tests satisfied the analytical criteria of accuracy, sensitivity and specificity, but no test adequately screened for all drug categories [1]. In addition, the collection of urine samples required that special facilities be available at roadside; otherwise, the driver had to be taken to a suitable facility. Interpretation of positive test results could also be challenged on the basis that urine tests primarily detect the presence of drug metabolites, which may persist in the urine long after the active drug has disappeared from the body.

A subsequent study by the ROSITA consortium (known as ROSITA-2) was undertaken to evaluate newer on-site screening devices developed to detect drugs in oral fluid samples [2]. Five European countries plus the United States participated in the study. Of the nine devices evaluated, none was considered reliable enough to be recommended for drug screening at roadside. No device met the criteria of sensitivity[1] (>90%), specificity (>90%), and accuracy (>95%) for amphetamines, benzodiazepines and cannabis. In addition, the rate of device failure (e.g., no control line, insufficient sample collection, no analysis) was high, exceeding 25% for six of the devices.

The most recent large-scale evaluation of oral fluid screening devices was conducted as part of the DRUID (Driving Under the Influence of Drugs, Alcohol and Medicines) project in Europe [3,4]. Eight on-site tests were evaluated for their ability to accurately detect amphetamine, $\Delta^9$-tetrahydrocannabinol (THC), cocaine, opiates, benzodiazepines, methamphetamine, methylenedioxy-methamphetamine (MDMA), and phencyclidine. Sensitivity values for different drug types by the various devices varied considerably. For example, the average sensitivity value for cannabis was 0.38 with no device having a value over 0.60; for opiates, sensitivity ranged from 0.50 to 0.90 with three devices achieving a value over 0.80. None of the devices met the target values set for sensitivity, specificity, and accuracy (i.e., 0.80). Device failure was less pronounced than in the ROSITA-2 study, although for one device the failure rate was 12%.

The DRUID study did not recommend any oral fluid screening device as being adequate for use in law enforcement. However, the findings indicated improvements in the ability of these types of devices to accurately detect the presence of broad classes of potentially impairing substances. Indeed, if any positive drug result was confirmed, even if the wrong substance was indicated (e.g., cannabis detected but cocaine confirmed), three of the devices met the target criteria of 0.80 for sensitivity, specificity and accuracy.

Since the DRUID report was released, oral fluid screening technology has continued to improve. For example, a recent study found the Dräger DrugTest 5000® had acceptable sensitivity and specificity for the detection of THC using a cutoff value of 5 ng/mL in oral fluid [5]. Although the results are specific to only one substance, THC has traditionally been difficult to detect at low threshold values. This finding provides enhanced optimism in the search for a suitable device that can accurately identify primary drugs of interest at forensically and operationally relevant levels.

Other recent studies using a number of oral fluid drug screening devices reported sensitivity values for cannabis that range from 0.23 to 0.92 and specificity values from 0.09 to 1.0. Results for other drugs also showed variable performance across a range of devices [6–9].

Some countries and jurisdictions are currently using POC oral fluid screening devices to help identify drivers who have been using specific substances. Most notable is the state of Victoria in Australia, which operates a high visibility program of random drug testing using oral fluid screening [6]. Initial observations suggest that this program has increased the perceived probability of detection as a result of a high level of awareness, which has consequently resulted in considerable behaviour change. However, the detection thresholds for the three drugs screened for (THC, amphetamines and MDMA) have been set relatively high so as to avoid false positives. Unfortunately, the limitation of this approach is that many drivers who have used these substances fail to be detected.

As oral fluid screening technology improves and demand grows for a more efficient and effective approach to the enforcement of drug-impaired driving, POC oral fluid drug screening devices need to be evaluated for possible use in Canada. Hence, the purpose of this project was to examine a small number of POC oral fluid drug screening devices to determine the validity, accuracy and suitability of such devices for potential use in the enforcement of drug-impaired driving in Canada.

## Method

It was determined at the beginning of this project that the only method by which the required data could be collected in a timely manner would be to utilize a known population of drug users. To do so, we arranged to work with the Drug Evaluation and Classification Program (DECP) training courses at sites where they conducted their field certification events. The two sites utilized in this study were the Maricopa County Sheriff's Jail in Phoenix, Arizona and the River Region Human Services clinic in Jacksonville, Florida.

The Canadian DECP has a long history of utilizing these locations to conduct their certification events and one of the authors (DRS) has many years of involvement at both these sites due to his work with the DECP. Prior to the start of the project, both sites were contacted and the details discussed to ensure that the collection of oral fluid samples would not create difficulties with the evaluations being completed for certification of DREs. Participants were volunteers who were assisting with the DECP training. The rationale for the request for oral fluid samples was explained and if they provided verbal informed consent, samples were collected either prior to, during, or at the end of the drug influence evaluation sequence.

Limited additional information was collected from participants so as not to interfere with the DECP training. The participant population consisted of 70% males and 30% females with an age range of 19–60 years. All admitted having consumed drugs within the previous few hours. The population of "known negative" samples came from police officers who were instructing or participating in the DECP training.

Three devices that appeared to have good performance characteristics in other studies (Alere DDS 2®, Dräger DrugTest 5000® and Securetec DrugWipe 6S®) were selected for use in this project. Oral fluid samples were collected according to the manufacturers' instructions. All collection devices had a colour indicator to show when a sufficient volume of sample had been collected. The screening devices tested for the presence of THC, cocaine (benzoylecognine), amphetamine, methamphetamine, opioids, and benzodiazepines.

Subjects were also asked to provide a second sample using the Quantisal® oral fluid collection device, which was sent to a reference laboratory for independent analysis.[2] The contemporaneous collection of oral fluid samples for the POC screening devices and for the laboratory analyses helped ensure consistency in the drug concentrations in the two samples. Most participants also provided a urine sample as part of the DECP process.

Financial considerations precluded the testing of every sample for all drugs/drug categories at the reference laboratory. Hence, a targeted approach was adopted. The reference laboratory was asked to test for only the drugs/drug categories identified by the results obtained on the oral fluid screen, the on-site urine test, and the results of the DECP evaluation. This approach was consistent with the goals of the project to determine how well the devices detected specific drugs/drug categories. At the reference laboratory drug presence was confirmed by either liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) or gas chromatography-mass spectrometry (GC-MS) depending upon the particular drug/drug category.

The cutoff values for the detection of drugs/drug categories for each of the three oral fluid screening devices as well as those used by the laboratory for analysis of the second

**Table 1.** Cutoff values (ng/mL) for drug/drug categories for the oral fluid screening devices and laboratory confirmation.

| | THC | Cocaine | Amphet | Mamph | Opioids | Benzo |
|---|---|---|---|---|---|---|
| Alere DDS 2 | 25 | 30* | 50 | 35 | 30 | 20 |
| Dräger DrugTest 5000 | 5 | 20 | 50 | 35 | 20 | 15 |
| Securetec DrugWipe 6S | 10 | 10 | 60 | 60 | None Stated | None Stated |
| Laboratory | 0.5 | 2.5 | 2.5 | 2.5 | 2.0 | 1.5 |

*Test is for benzoylecgonine.

(confirmatory) sample are presented in Table 1. The laboratory cutoffs were lower than those stated by the manufacturers of the screening devices. In the case that the result of the screening device was negative and the laboratory result was positive, the discrepancy might possibly be a consequence of the difference in the cutoff values. Hence, for all cases initially identified as "misses", the laboratory provided the concentration of drug found in the confirmatory sample. If the drug concentration reported for the confirmatory laboratory sample was lower than the cutoff of the screening device, the case was re-coded as a "correct negative" result rather than a "miss." This is because the concentration of the drug was too low to be identified by the screening device.

## Results

A total of 646 paired oral fluid samples were collected – one sample was analyzed on site with one of the three oral fluid screening devices; the other was sent to the laboratory for confirmatory analysis. The results of the oral fluid screening were compared to those of the confirmatory laboratory analysis using a number of standard measures of test performance.

Sensitivity is the proportion of true drug-positive cases correctly identified by the screening device. Specificity is the proportion of true drug-negative cases correctly identified by the screening device. These are measures of the extent to which the screening device correctly identifies drug-positive and drug-negative cases. It is desirable to have a screening test that has a high degree of sensitivity and specificity.

The miss rate and false alarm rate are the complements of sensitivity and specificity, respectively. The miss rate represents the proportion of drug-positive cases that are not detected by the screening device and the false alarm rate provides an indication of the likelihood that a screening test will mistakenly indicate a person is positive for a specific drug or drug category. An optimal procedure should minimize these types of detection errors.

Two additional performance measures are the positive predictive value (PPV) and accuracy. PPV is the proportion of cases identified by the screening device as drug positive that were subsequently confirmed positive by the laboratory. It represents the probability that a positive screen is a true drug-positive case. Accuracy represents the proportion of all cases that are correctly identified by the screening device as drug positive or drug negative.

The current study focused on the ability of oral fluid screening devices to detect the presence of particular drugs/drug categories, not the performance of individual screening devices themselves. Hence, the results were pooled for all devices. Table 2 presents the performance measures for each drug/drug category along with the 95% confidence interval of each value. The range of values for sensitivity, specificity, and overall accuracy

**Table 2.** Performance measures (and 95% CI) for oral fluid screening devices by drug/drug category.

| | Sensitivity | Miss rate | Specificity | False alarm Rate | Positive Predictive Value | Accuracy |
|---|---|---|---|---|---|---|
| THC | 0.869 | 0.131 | 0.955 | 0.045 | 0.922 | 0.923 |
| N = 323 | (0.789–0.918) | (0.079–0.207) | (0.917–0.973) | (0.022–0.086) | (0.853–0.961) | (0.886–0.948) |
| Cocaine | 0.846 | 0.154 | 0.993 | 0.007 | 0.990 | 0.926 |
| N = 256 | (0.770–0.900 | (0.096–0.235) | (0.960–0.999) | (0.00–0.045) | (0.938–0.999) | (0.884–0.953) |
| Amphetamine | 0.771 | 0.229 | 0.964 | 0.036 | 0.923 | 0.895 |
| N = 306 | (0.683–0.839) | (0.156–0.322) | (0.928–0.983) | (0.015–0.075) | (0.845–0.966) | (0.854–0.926) |
| Methamphetamine | 0.840 | 0.160 | 0.965 | 0.035 | 0.965 | 0.899 |
| N = 306 | (0.776–0.889) | (0.109–0.227) | (0.920–0.985) | (0.013–0.084) | (0.915–0.987) | (0.858–0.929) |
| Opioids | 0.899 | 0.101 | 0.931 | 0.069 | 0.795 | 0.924 |
| N = 301 | (0.805–0.950) | (0.036–0.164) | (0.891–0.957) | (0.041–0.112) | (0.787–0.943) | (0.913–0.968) |
| Benzodiazepines | 0.592 | 0.408 | 0.976 | 0.024 | 0.918 | 0.855 |
| N = 241 | (0.480–0.696) | (0.298–0.527) | (0.939–0.990) | (0.008–0.065) | (0.795–0.973) | (0.802–0.895) |
| All Drug Categories | 0.874 | 0.126 | 0.932 | 0.068 | 0.965 | 0.892 |
| N = 641 | (0.838–0.903) | (0.097–0.162) | (0.886–0.961) | (0.039–0.114) | (0.940–0.980) | (0.865–0.915) |

deemed "high" (0.800–0.899) or "very high" (0.900–0.999) in the DRUID project [4] were used to assist in evaluating the performance of oral fluid screening devices in this project.

Overall, the screening devices performed well. Considering all drugs/drug categories together, the screening devices collectively were determined to have a sensitivity of 0.874 indicating that in 87% of cases where a person had used one of the substances included in the screen, it was detected by the screening device. The specificity, sometimes referred as the "correct rejection rate", of 0.932 indicates that subjects who had not used any of the substances were correctly identified as drug-negative. The PPV of 0.965 indicates that when a drug was detected by the screening device, in 96.5% of cases the positive result was confirmed by the laboratory analysis. The overall false alarm rate (0.068) reveals that approximately 7% of drug-positive screening tests were not confirmed by laboratory analysis. The miss rate (0.126) indicates that about 13% of drug-positive subjects were not detected with the screening device.

Table 2 also illustrates that the performance of the drug screening devices varied by drug type. The devices performed reasonably well in the detection of THC, cocaine, methamphetamine, and opioids, with sensitivity values >0.80 and specificity values >0.90. False alarm rates for these substances ranged from less than 1% (cocaine) to just under 7% (opioids). With the exception of opioids,[3] positive predictive values were in excess of 0.9.

The performance of the screening devices was not as good in the detection of benzodiazepines and amphetamine. Overall sensitivity for benzodiazepines was 0.592 with a range of 0.500 to 0.640 across the three devices; for amphetamines, sensitivity was 0.771 with a range of 0.719 to 0.842 across devices.

## Discussion

To assess the validity of point-of-contact oral fluid drug screening devices, oral fluid samples were collected from volunteers who were known or suspected to have ingested drugs in the previous few hours. This approach allowed for the collection of a large number of oral fluid samples for immediate testing, along with a second oral fluid sample that was sent to the laboratory for confirmation, over a relatively short period of time. This approach was considerably more efficient than attempts to collect a large number of drug-positive samples from drivers on the road or conducting a controlled dose study in a laboratory. The approach employed also helped ensure that the dose of drug ingested was

more in line with that of actual drug users and most likely to produce driving impairment. Hence, the method ensured a high degree of efficiency in data collection while at the same time provided a considerable degree of environmental validity.

The physical and practical characteristics of all three oral fluid screening devices were adequate and performed well under the field conditions utilized in this project. Manufacturers' instructions were easy to follow and the screen prompts, internal timing and messages ensured simple and straightforward collection and analysis phases. In several cases, the oral fluid collection time was longer than desirable, most likely as a consequence of the inhibitory effect of the drug on oral fluid production. On only two occasions were participants unable to provide sufficient sample volume. The Securetec did not have this issue due to the comparatively small volume of oral fluid required.

The length of time required to analyze the sample after collection (Dräger and Securetec, 8 minutes; Alere, 5 minutes) allowed the entire process to be completed within 10–15 minutes. This should be acceptable in an enforcement situation at roadside.

As opportunities arose, some of the police officers involved in the DRE training were invited to utilize the instruments so as to obtain feedback from an 'end user' perspective. As expected, the officers preferred the oral fluid sample collection cartridge with the shortest collection time (i.e., Securetec DrugWipe). This was also the one over which they maintained continuous 'control'. They also had a preference for the shorter analysis time of the Alere device. There was a definite consensus that collecting an oral fluid sample was preferable to collecting a urine sample. From an operational and maintenance perspective, all of the devices display a message when servicing is required. It is, however, possible to override the message and continue testing, which allows the test in progress to be completed.

Overall, the oral fluid screening devices used in this study performed well. The sensitivity and specificity values for THC, cocaine, methamphetamine and opioids were within the "high" (0.800–0.899) to "very high" (0.900–0.999) range according to the designations used in the DRUID project [4] and were comparable to values of the best performing devices in other recent studies [5–9]. These results indicate that the devices were able to correctly detect the drug/drug category when the drug/drug category was present and to correctly indicate the absence of a drug/drug category when none was present.

The screening devices performed less well in the detection of benzodiazepines and amphetamines, with sensitivity values of 0.592 and 0.771, respectively. These results indicate that further work is required to improve the performance of the devices before the screening results for these latter two types of substances can be relied on in an enforcement setting.

The results also demonstrated low false alarm rates, indicating that in only a small percentage of cases did the screening device indicate the presence of a drug that was not confirmed by the laboratory. In an enforcement setting it is desirable to have the false alarm rate to be as low as possible to avoid imposing sanctions or additional testing procedures on individuals who have not ingested drugs. This is particularly important in jurisdictions that might ultimately use the results of the screening test to impose immediate administrative sanctions at roadside. To some extent, however, the false alarm rate can be reduced by establishing a higher detection threshold for the drug. This would require a person to have a higher concentration of the drug in order to get a positive reading.

This project served to provide guidance for a framework for the development of standards that POC oral fluid screening devices would have to meet in order to be approved for use in Canada. For example, the results of this study indicate the drugs/drug categories

that might reasonably be included in the test panel and the standard of performance accuracy that should be met as determined by the CSFS Drugs and Driving Committee. Once standards are developed, the process for approval would presumably be analogous to that currently in place for the approval of alcohol test devices by the Alcohol Test Committee. Essentially, devices would be submitted by manufacturers for testing by the Drugs and Driving Committee of the Canadian Society of Forensic Science. Devices that meet the standards would be recommended to the Minister of Justice for approval.

POC oral fluid screening devices could prove to be a valuable tool for the police in the detection of drug-impaired drivers. It will, however, be necessary to establish the legal and policy parameters for their use. One approach is to provide for the use of drug screening devices in a manner similar to that for alcohol screening devices. Drivers suspected of drug use would be required to provide a sample of oral fluid to be analyzed using an approved POC oral fluid screening device. A positive result could lead to a demand for a more comprehensive drug influence evaluation by a DRE and/or a demand for a blood sample. Provinces and territories may also consider using POC oral fluid screening devices as grounds to issue an immediate short-term administrative licence suspension comparable to the administrative sanctions currently issued for having a blood alcohol concentration between 50 and 80 mg/dL in most jurisdictions in Canada [10].

It must also be recognized that there remain many potentially impairing substances used by drivers that are not detected well by existing oral fluid screening devices (e.g., benzodiazepines) or are not included in the oral fluid screening device test panel (e.g., synthetic cannabinoids, dissociative anesthetics, cathinones). As manufacturers develop improved capacity for their devices, new test panels for these drugs could be added to expand the scope of drug detection.

Should oral fluid screening be approved for use in Canada, it will not eliminate the need for comprehensive evaluations of drug influence using the DECP. Evidence of impairment consistent with the category of drug used will still be required in many cases to support impaired driving charges. In fact, roadside oral fluid drug screening may serve to identify more drivers under the influence of drugs, thereby enhancing the need for officers trained in the DECP.

## Notes

1. See Results section for definitions of sensitivity, specificity and accuracy.
2. NMS Laboratories, Willow Grove PA.
3. Although the cross-reactivity of the test for opioids encompassed a wide variety of commonly used substances, it did not include oxycodone.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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