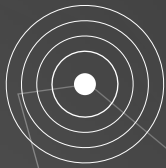




# SOTOXA™ ORAL FLUID MOBILE TEST SYSTEM

PUBLICATIONS



THC  
25 NG/ML



COC  
30 NG/ML



Rapid drug screening  
is in your hands

# GLOSSARY

ABBREVIATION	MEANING
AMP	Amphetamine
BZO	Benzodiazepines
COC	Cocaine
DRE	Drug Recognition Experts
DUID	Driving Under the Influence of Drugs
ELISA	Enzyme Linked Immunosorbent Assay
GC	Gas Chromatography
LC	Liquid Chromatography
MAMP	Methamphetamine
MS	Mass Spectrometry
NPV	Negative Predictive Value
OF	Oral Fluid
OPI	Opiates
OXY	Oxycodone
PPV	Positive Predictive Value
THC	Marijuana
VIFM	Victorian Institute of Forensic Medicine

# A POPULAR METHOD

Oral fluid testing has become a popular method for detecting the presence of drugs and its metabolites due to the speed of sample collection and ease of use. This is especially the case when testing in challenging environments such as the roadside, where collecting urine and other traditional specimens for preliminary screening is not practical.

## THE SOTOXA™ ORAL FLUID MOBILE TEST SYSTEM WAS PREVIOUSLY KNOWN AS THE DDS®2 MOBILE TEST SYSTEM

The system is referred to as the DDS2 Mobile Test System throughout the publications within this brochure.

The performance characteristics of the system remain unchanged and as such the performances stated within the publication review are still applicable.

## SMART SOLUTION

Oral fluid samples are harder to adulterate as collections can be easily observed with no requirement for specialist facilities to collect the sample. This makes it a suitable sample type for various users including law enforcement agencies such as police at the roadside, prison services, border controls and workplace drug testing particularly pre-employment testing to manage any risk associated with substance misuse at the workplace.

Abbott offers a smart solution for preliminary screening in the form of the SoToxa system, a handheld drug testing analyser to detect recent intake of common drugs within 5 minutes, making it ideal for roadside testing of drivers who may be under the influence of drugs.



The analyser is designed to excel in a range of conditions and the on-board heater ensures that the test runs at optimal temperature, reducing variability and allowing testing in challenging environments.

The analyser can store over 10,000 results which can be printed at the end of the test or reprinted from the memory card.

The following summaries of published articles highlight the importance of drug testing and the benefits of using the SoToxa system with your drug testing programme.



# DRUGGED DRIVING IN WISCONSIN

## ORAL FLUID VERSUS BLOOD

### OVERVIEW

Dane County, Wisconsin launched a pilot project in order to evaluate the frequency of individuals driving under the influence of drugs. In the state of Wisconsin, drug testing is often cancelled if the blood alcohol concentration is above the specified limit set by the state. This resulted in around 3,600 drug samples being cancelled between December 2015 and July 2016.

Impaired driving is difficult to recognise. Although the state has 265 Drug Recognition Experts (DRE) available, police forces in this state do not all have access to a DRE.

As oral fluid screening on the roadside has increased and gained in popularity, the authors set out to evaluate the DDS<sup>®</sup>2 Mobile Test System (now renamed the SoToxa<sup>™</sup> Oral Fluid Mobile Test System) for usability and performance on the roadside.

To evaluate the above, the authors deployed four DDS2 systems with police at the roadside. Once a driver was arrested, they could voluntarily provide an oral fluid sample to participate in this study, which was later compared to the evidentiary blood sample.

### KEY FINDINGS

- Around 68% of those samples that tested positive for drugs in this pilot study, would have previously been excluded as alcohol was above the specified limit. Therefore, the state may underestimate the full extent of DUID.
- Oral fluid is a preferred method for screening drivers at the roadside as it is a non-invasive and pain free sample to collect which can also be easily supervised.
- The authors reported that the DDS2 system provided screening results which were consistent with the evidentiary blood testing performed.
- The DDS2 system was found to have many benefits in testing including:
  - Ease of collection.
  - Limited risk of sample adulteration.
  - Mobile, fast and space conserving.

EDWARDS, E. D., SMITH, K. L., SAVAGE, T., | JOURNAL OF ANALYTICAL TOXICOLOGY, 2017, 41 (6), PP 523 - 529

### FIGURE 1

Diagnostic evaluation of the DDS2 OF screening instrument compared to evidentiary blood specimens collected from 104 Wisconsin drivers.

ANALYTE	SENSITIVITY	SPECIFICITY	PPV	NPV	ACCURACY
THC	0.8837	0.8689	0.8261	0.9134	0.8750
Cocaine	1.000	0.9898	0.8571	1.000	0.9904
Amphetamine	1.000	0.8824	0.1429	1.000	0.8846
Methamphetamine*	N/A	0.9903	0.0000	1.000	0.9904
Opioids	1.0000	0.9900	0.8000	1.000	0.9904
Benzodiazepines	0.4545	0.9892	0.8333	0.9388	0.9327
All categories	0.8333	0.9570	0.6962	0.9798	0.9439

\* Only one subject screened positive for methamphetamine in OF; MDMA was confirmed in blood.



# ORAL FLUID ROADSIDE

## ANALYSIS PILOT PROGRAM - PHASE 1

### OVERVIEW

Michigan law states that a person cannot operate a vehicle while under the influence of alcoholic liquor, a controlled substance, other intoxicating substance or a combination of these elements (Legislature Service Bureau, 2019). Over the last ten years in Michigan, drug-impaired driving has become more prevalent, and traffic fatalities have increased.

During an evaluation of oral fluid as matrix for drug detection, the Oral Fluid Roadside Analysis Pilot Program Committee selected DDS<sup>®</sup>2 Mobile Test System (now renamed the SoToxa<sup>™</sup> Oral Fluid Mobile Test System) as the test instrument of choice for this study.

If a DRE suspected drug impairment, the driver was asked to provide two oral fluid samples. The initial screening sample was collected using the DDS2 Oral Fluid Collection Device. The second sample, which was voluntary, was collected using the Quantisal<sup>™</sup> Oral Fluid Collection Device. In total:

- 92 samples were collected using the DDS2 collection device.
- 62 samples were collected using the Quantisal collection device.
- 30 Quantisal samples were either refused or not offered.
- 89 drivers were arrested during the pilot study of which 79 agreed to an evidentiary blood test.

### KEY FINDINGS

- Out of all the tests conducted, 21 returned positive results for the presence of two or more drugs.
- Comparing the DDS2 system results to the voluntary Quantisal<sup>™</sup> oral fluid laboratory confirmation resulted in the following performance characteristics:
- Sensitivity for all drug groups ranged from 94% - 100% with the exception of cocaine which was at 33.3%.
- Specificity ranged from 90.9% - 100%.
- Accuracy ranged from 88.3% - 100%.
- In summary, it was determined throughout the study that the DDS2 Mobile Test System has good performance properties when compared to blood and oral fluid confirmation results.

MICHIGAN STATE POLICE, 2019, ORAL FLUID ROADSIDE ANALYSIS- PILOT PROGRAM, (FULL REPORT AVAILABLE VIA WWW. MICHIGAN.GOV)

### FIGURE 1

Summary of sensitivity, specificity and accuracy of DDS2 Mobile Test System results versus voluntary Quantisal oral fluid collection.

	AMP	BZO	COC	MAMP	OPI	THC
Sensitivity (%)	100	100	33.3	100	100	94
Specificity (%)	96.4	96.6	98	98.2	100	90.9
Accuracy (%)	96.7	96.7	88.3	98.2	100	93.4



# ORAL FLUID ROADSIDE

## ANALYSIS PILOT PROGRAM - PHASE 2

### OVERVIEW

In a continuing effort to establish whether oral fluid screening is an effective and practical matrix for testing drivers for drugs, Michigan state police recently evaluated the SoToxa™ Oral Fluid Mobile Test System as a tool for roadside screening.

Police initially reported on the results from phase 1 of the oral fluid roadside pilot program in 2019. However, due to small data set, Michigan State police expanded the study to collect further data between October 2019 and September 2020 (Phase 2).

Similar to Phase 1 of the program, if impairment of a driver was suspected, an oral fluid sample was collected with the SoToxa system to screen for six of the most common drug classes (Table 1).

As well as a routine blood draw for confirmation, a second voluntary sample was collected using the Quantisal™ Oral Fluid Collection Device, which was sent to a commercial testing laboratory for analysis in line with the drug groups set out in Table 1.

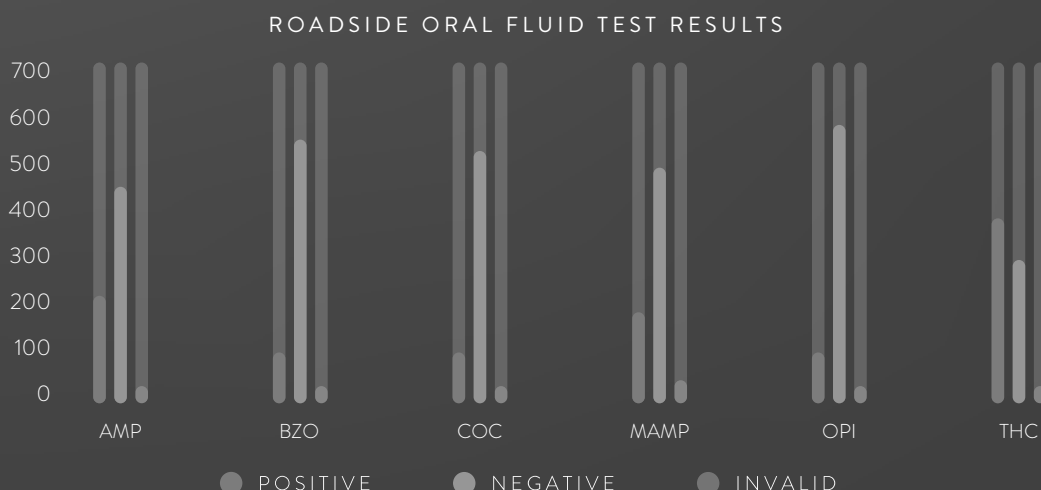
### KEY FINDINGS

- In total 693 incidents were reported throughout the test phase that resulted in 661 oral fluid roadside tests, 547 oral fluid confirmation samples as well as 632 blood confirmation results. The prevalence of positive results in the initial roadside screening is depicted in Figure 1.

**TABLE 1** SoToxa system: drug groups and their respective cutoffs

DRUG GROUP	TARGET COMPOUND	CUTOFF (NG/ML)
Amphetamine (AMP)	(S) Amphetamine	50
Benzodiazepine (BZO)	Temazepam	20
Cannabis (THC)	Delta-9-THC	25
Cocaine (COC)	Benzoyllecgonine	30
Methamphetamine (MAMP)	(S) Methamphetamine	50
Opiates (OPI)	Morphine	40

**FIGURE 1** – Results by drug group of tests conducted at the roadside using the SoToxa system.





# ORAL FLUID ROADSIDE

## ANALYSIS PILOT PROGRAM - PHASE 2

### KEY FINDINGS

- The accuracy of the SoToxa™ Oral Fluid Mobile Analyser ranged between 87% - 96% when compared to the voluntary oral fluid confirmation sample as shown in Table 2. The cutoffs for the SoToxa system are generally set at a higher level than those for the voluntary confirmation. However, as stated in this report, for benzodiazepines the cutoff for the oral fluid confirmation was set higher than that for the SoToxa system. Subsequently a result that may have screened positive at the roadside, may be below the confirmation cutoff.
- In comparison, the accuracy when compared to the blood draw analysis ranged between 82.60% and 95.20% across all drug groups (Table 3). The cutoff for benzodiazepines in blood is not stated within the report and with a wide range of benzodiazepines available, the report also does not clarify which benzodiazepines were confirmed for in blood.

- When interpreting these results, it is important to consider all variables within the study including the time between the screening and collection of the confirmatory sample, which was not provided in the report. As stated by the authors, the secondary confirmation sample could have been collected several hours after the initial oral fluid screen. During this time, drugs in the blood will continue to dissipate in the body which may cause a different confirmation result from the initial screen.
- During the analysis of the blood sample, any detected metabolites in the six drug groups listed in Table 1 resulted in the blood sample being reported as positive.

MICHIGAN STATE POLICE, 2021, ORAL FLUID ROADSIDE ANALYSIS - PILOT PROGRAM - PHASE II, (FULL REPORT AVAILABLE VIA WWW. MICHIGAN.GOV)

**TABLE 2** Reported sensitivity, specificity and accuracy of the SoToxa system when compared to the voluntary oral fluid confirmation sample collected with the Quantisal™ Oral Fluid Collection Device.

	AMP (ESTIMATE)	BZO (ESTIMATE)	THC (ESTIMATE)	COC (ESTIMATE)	OPI (ESTIMATE)	MAMP (ESTIMATE)
Sensitivity	81.80%	58.70%	84.20%	71.00%	85.50%	89.70%
Specificity	89.20%	92.30%	97.20%	97.70%	97.40%	98.00%
Accuracy	87.00%	89.40%	88.70%	93.00%	95.80%	96.00%

**TABLE 3**

Reported sensitivity, specificity and accuracy of the SoToxa system when compared to the blood confirmation results.

	AMP (ESTIMATE)	BZO (ESTIMATE)	THC (ESTIMATE)	COC (ESTIMATE)	OPI (ESTIMATE)	MAMP (ESTIMATE)
Sensitivity	83.80%	33.70%	85.80%	90.80%	93.50%	95.30%
Specificity	86.50%	91.10%	92.10%	94.90%	90.60%	95.20%
Accuracy	85.70%	82.60%	87.90%	94.40%	90.70%	95.20%

### CONCLUSION

The authors conclude that oral fluid testing is accurate for preliminary roadside testing. Furthermore, the authors concluded that the SoToxa system is easy to use, requires minimum training and provides a result within 5 minutes after collection of the sample.



# ROADSIDE DRUG TESTING

## AN EVALUATION OF THE DDS<sup>®</sup>2 MOBILE TEST SYSTEM

### OVERVIEW

Driving under the influence of drugs has increased over recent years and with the legalisation of cannabis in several US states, it is vital to monitor drug use whilst driving.

Oral fluid screening tests have become increasingly popular as a means of testing drivers for drugs at the roadside. Samples can be easily collected, and collection can be easily observed.

During this study, drivers who were identified as driving under the influence of drugs were asked to provide a voluntary oral fluid sample with the DDS2 Mobile Test System (now renamed the SoToxa<sup>™</sup> Oral Fluid Mobile Test System).

Results were later compared with the DRE examination, a secondary oral fluid sample which had been analysed by ELISA as well as LC-MS/MS, and a blood sample confirmed by GC-MS.

### KEY FINDINGS

- Out of 528 tests via the DDS2 Mobile Analyser that were performed, only four tests were shown to be invalid by the DDS2 system, which could be caused by factors such as insufficient sample volume.
- Authors determined that there was good correlation between the DRE observation and the results on the DDS2 system.
- The DDS2 system oral fluid screening tests showed good correlation (>80%) to the oral fluid laboratory-based confirmation testing as presented in the table below.

ROHRIG ET AL., DRUG TESTING AND ANALYSIS, 2018, 10(4), PP 663-670

### FIGURE 1

Overall comparison of DDS2 system with laboratory-based confirmation testing.

	DDS <sup>®</sup> 2 V ORAL FLUID	DDS <sup>®</sup> 2 V BLOOD
True Positives	33	32
True Negatives	38	41
False Negatives	5	3
False Positives	5	10
Sensitivity (%)	86.84	91.43
Specificity (%)	88.37	80.39
Accuracy (%)	87.65	84.88
Positive Predictive Value (%)	86.84	76.19
Negative Predictive Value (%)	88.37	93.18





# SOTOXA™ MOBILE ANALYSER ASSESSMENT

## OVERVIEW

In 2019, the updated Australian and New Zealand standards for procedures and requirements for oral fluid specimen collection, storage, handling, on-site screening and return to laboratory were released (AS/NZS 4760:2019)

In 2020 the Victorian Institute of Forensic Medicine (VIFM) evaluated the SoToxa system in a laboratory environment in order to assess the performance against the nominated cutoff per drug group (per Table 1 below) and establish compliance with the requirements of AS/NZS 4760:2019.

The laboratory investigated the performance of the 6 drug groups set out in the standard: amphetamines, methamphetamines, cocaine, opioids, oxycodone and cannabis. In addition to those regulated by the standard, VIFM also evaluated benzodiazepines as an additional drug class.

The study involved two parts:

1. Pooled negative human oral fluid to evaluate the prevalence of false positive samples.
2. Pooled human oral fluid samples spiked at -50% and +50% of the SoToxa Oral Fluid Test Kit cutoff for each drug as summarized in Table 1 below.

Testing at the three levels, negative, +50% and -50% involved 20 aliquots in each instance.

## KEY FINDINGS

- 20 negative samples produced no false positive results for any of the seven drug groups being evaluated.
- Performance of 20 samples at -50% of the manufacturer's stated cutoff for the drug classes specified within the standard, yielded no false positives for AMP, COC, OPI, OXY and THC and one false positive sample detected for MAMP.
- For BZO, not specified in the AS/NZS standard, 2 false positive samples were detected at -50% of the cutoff.
- Performance of 20 samples at +50% of the manufacturer's cutoff resulted in 100% true positive results for all drug classes including BZO.

## CONCLUSION

- The SoToxa system and kits performance complies with onsite device verification requirements of Australian New Zealand standard, AS/NZS 4760:2019 (Appendix C).
- Investigation by VIFM determined a sensitivity of:
  - 100% for AMP, COC, OPI, OXY and THC
  - 95% for MAMP
  - 90% for BZO (not included in AS/NZS standard)
- The specificity of the SoToxa test panel is 100% for all drug classes evaluated in this study.

VICTORIAN INSTITUTE OF FORENSIC MEDICINE, 2020, ABBOTT SOTOXA MOBILE TEST SYSTEM PERFORMANCE REPORT.

TABLE 1

Cutoff concentration and the investigated spiked oral fluid concentrations used for performance testing of the SoToxa Test Kit.

DRUG GROUP	TARGET	CUTOFF	-50% CUTOFF	+50% CUTOFF
AMP	d-Amphetamine	50 ng/mL	25 ng/mL	75 ng/mL
MAMP	d-Methamphetamine	50 ng/mL	25 ng/mL	75 ng/mL
COC	Benzoylcegonine	50 ng/mL	25 ng/mL	75 ng/mL
OPI	Morphine	50 ng/mL	25 ng/mL	75 ng/mL
OXY	Oxycodone	40 ng/mL	20 ng/mL	60 ng/mL
BZO	Temazepam	20 ng/mL	10 ng/mL	30 ng/mL
THC	(-)-Δ <sup>9</sup> tetrahydrocannabinol	15 ng/mL	7.5 ng/mL	22.5 ng/mL



# PREVALENCE OF DRUG USE AMONG DRIVERS

## BASED ON MANDATORY, RANDOM TESTS IN A ROADSIDE SURVEY

### OVERVIEW

Several studies have described the increase of drivers driving under the influence of drugs. In Spain, legislation prohibits driving under the influence of narcotic and psychotropic, stimulants, and other substances. In addition to those mentioned above, this also includes medicines which can impair the physical or mental skills of drivers.

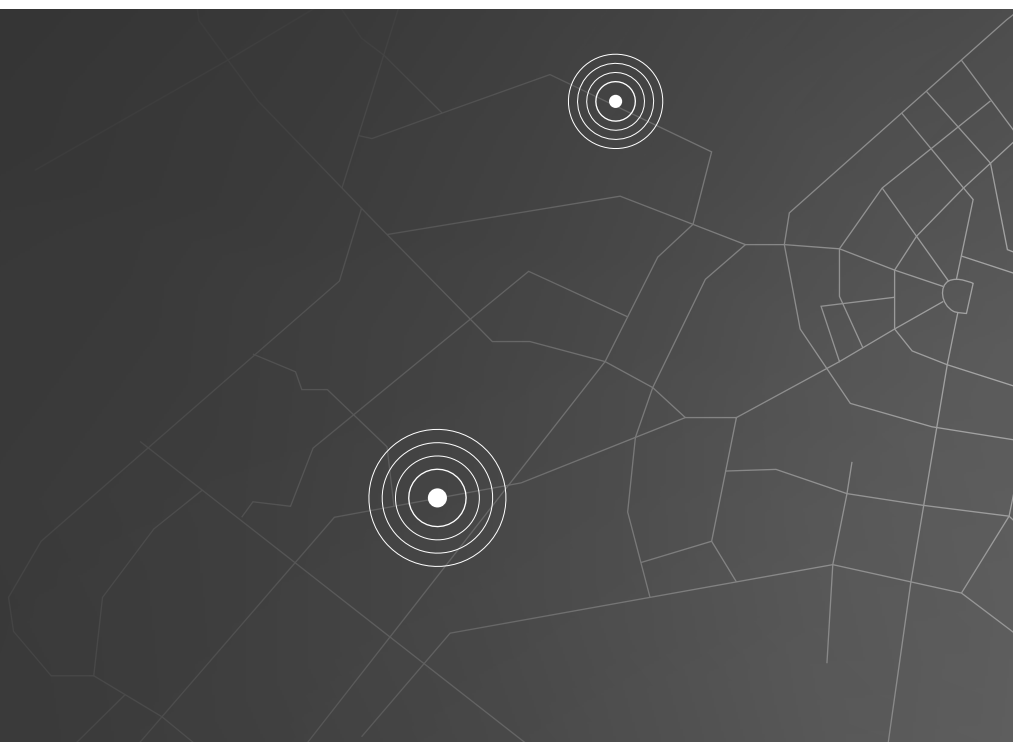
The authors in this study set out to evaluate the prevalence of drivers under the influence of drugs and their subsequent impact on road safety in the region of Catalonia, Spain. Study samples were randomly collected from drivers. Participation in this study was mandatory, and drivers had to provide a screening sample as well as a secondary confirmatory sample.

The DDS®2 Mobile Test System (now renamed the SoToxa™ Oral Fluid Mobile Test System) was used to collect the oral fluid samples at the roadside, followed by a secondary oral fluid sample collected with Quantisal™ Oral Fluid Collection Device which was analysed by a confirmatory method in the laboratory.

### KEY FINDINGS

- The prevalence of driving under the influence of drugs in this study was around 16.4%.
- A trend for a high positivity rate of methamphetamine was observed in drivers in charge of vans and lorries.
- THC was the most common compound detected during this study.
- Drug driving was not significantly higher during the weekends. The authors concluded that the patterns around drug driving times was dependent on the type of drug. For example, methamphetamine rates were higher during nighttime driving.
- This study highlights the need for a drug testing programme at the roadside as the prevalence of driving under the influence is high.

ALCANIZ, M., GUILLEN, M., SANTOLINO, M., | PLOS ONE, 2018, 13 (6), PP 1 - 14





# AN ASSESSMENT OF ORAL FLUID DRUG SCREENING DEVICES

## OVERVIEW

Since 2008, Canadian police have been authorised to perform a mandatory field sobriety test, evaluate individuals by a DRE and request blood samples from drivers.

However, with limited availability of DREs and lengthy delays during the examinations, requests were made for an onsite screening device for use at the roadside.

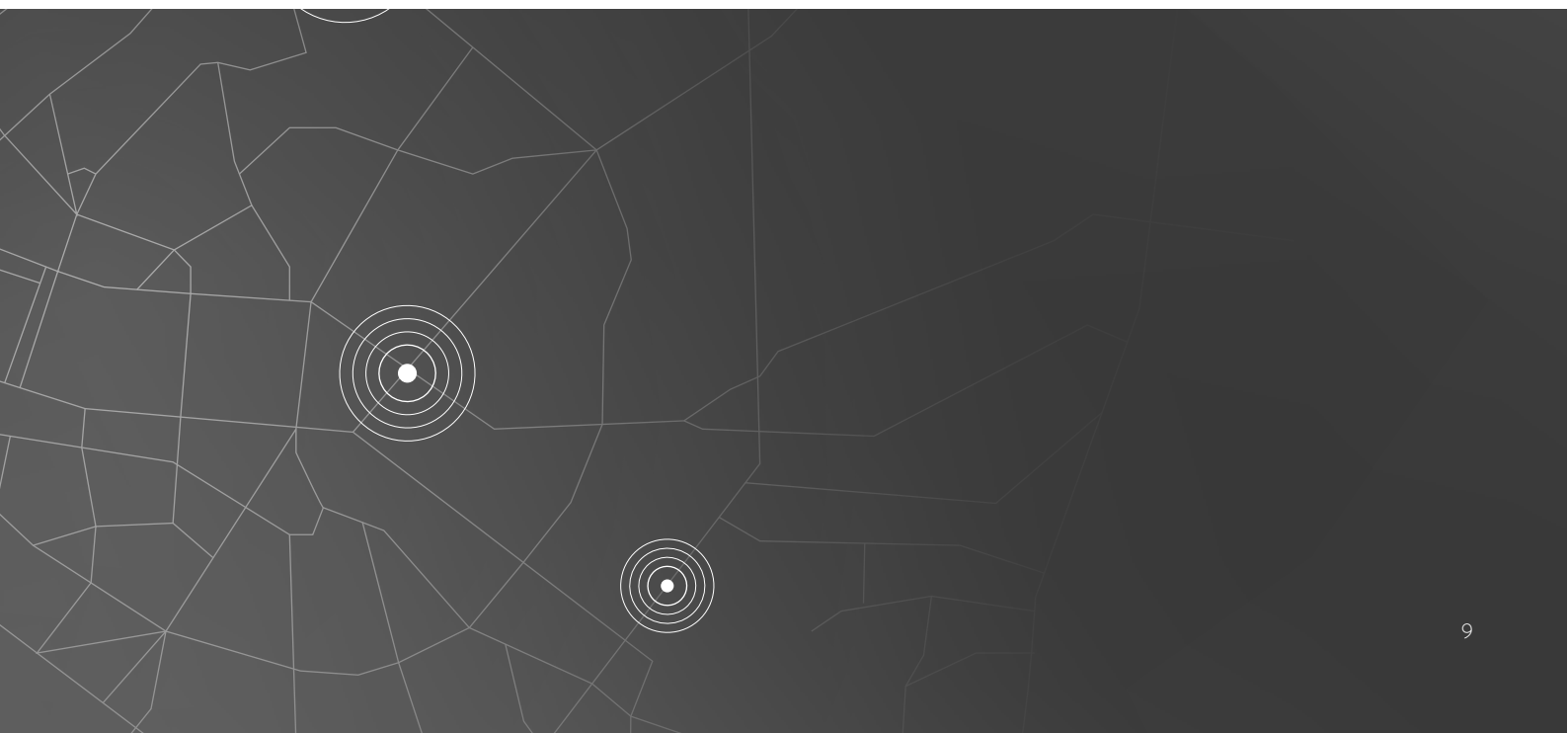
As such the authors of this study evaluated the performance of three of the most prevalent on-screen drug testing devices on the market. This included the DDS<sup>®</sup>2 Mobile Test System (now renamed the SoToxa<sup>™</sup> Oral Fluid Mobile Test System), Draeger Drug Test 5000 and Securetec Drug Wipe 500.

During this study, oral fluid samples were collected according to the manufacturer's instructions. A second oral fluid sample was collected following each screening test using the Oral Fluid Collection Devices. The samples collected using Quantisal<sup>™</sup> were sent to the laboratory for an independent confirmatory analysis.

## KEY FINDINGS

- The length of time for the analysis of the test once the sample was collected:
  - Draeger and Securetec – 8 minutes.
  - DDS2 system – 5 minutes.
- Police officers preferred the shorter analysis time of the DDS2 system.
- Devices in this study performed well. The sensitivity and specificity values for THC, cocaine, methamphetamine and opiates were all between 80% - 99%.
- Results showed a low positivity rate where screening devices indicated a presence of a drug in contrast to a negative confirmation in the laboratory.
- Overall, authors concluded that point of care oral fluid screening devices could be a useful tool for the detection of drivers who are under the influence of drugs.

BEIRNESS, D.J., AND SMITH, D., | CANADIAN SOCIETY OF FORENSIC SCIENCE JOURNAL, 2016, PP 55 - 63





# EVALUATION OF ORAL FLUID

## AS A SPECIMEN FOR DRIVING UNDER THE INFLUENCE OF DRUGS

### OVERVIEW

Due to the legalisation of cannabis in some states of the United States, the number of drivers driving under the influence of drugs has increased.

This study was set out to evaluate the effectiveness of oral fluid as a sample type for the use of drug detection in DUID cases.

Drivers suspected of driving under the influence of drugs and/or alcohol were stopped by police officers. In combination with a DRE exam, an oral fluid sample was collected using the DDS<sup>®</sup>2 Mobile Test System (now renamed the SoToxa<sup>™</sup> Oral Fluid Mobile Test System), and screened for six classes of drugs (AMP, MAMP, OPI, THC, BZO, COC).

Additionally, a second oral fluid sample was collected using the Quantisal<sup>™</sup> Oral Fluid Collection Device which was sent to the laboratory for confirmation.

Results from the DDS2 system were compared to laboratory screens using ELISA and confirmed using LC-MS-MS. The sensitivity, specificity, PPV, NPV and accuracy were calculated.

### KEY FINDINGS

- The authors did not report any significant differences between the onsite screen using the DDS2 system and the laboratory screen using ELISA.
- The accuracy of the DDS2 system was reported as:
  - 100% for drug classes AMP, MAMP, OPI.
  - 85.71 % for drug classes BZO, COC, THC.
- Overall, authors concluded that devices such as the DDS2 system have the ability to provide law enforcement agencies with a valuable tool in detecting driving under the influence of drugs.
- Oral fluid was found to be a viable option for roadside testing as well as laboratory confirmation.

VEITENHEIMER, A.M. AND WAGNER, J.R. | JOURNAL OF ANALYTICAL TOXICOLOGY, 2017, 41 (6), PP 517 - 522

### FIGURE 1

Sensitivity, specificity, PPV, NPV and accuracy of DDS2 Mobile Test System.

	AMP	BZO	COC	MAMP	OPI	THC
Sensitivity (%)	100	66.7	100	100	Undefined	75
Specificity (%)	100	100	80	100	100	100
PPV (%)	100	100	66.7	100	Undefined	100
NPV (%)	100	80	100	100	100	75
Accuracy (%)	100	85.7	85.7	100	100	85.7



# USER EXPERIENCE AND OPERATIONAL FEASIBILITY

## OF FOUR POINT-OF-COLLECTION ORAL FLUID DRUG TESTING DEVICES ACCORDING TO BRAZILIAN TRAFFIC AGENTS

### OVERVIEW

In Brazil it is estimated that around 43,000 people die annually in traffic collisions of which some of these are contributed to the presence of psychoactive substances.

Whilst Brazil has a zero tolerance for alcohol whilst driving and police regularly use breathalysers, there are no devices approved for drug testing on the roadside.

The authors of this article evaluated the user experience of traffic agents with the following four point-of-collection devices:

- DDS®2 Mobile Test System
- UltiMed DOA MultiScreen
- Alere Multi-Drug Multi Line (MDML) Twist Screen Device
- Draeger Drug Test 5000

These were used as part of routine traffic checkpoints in Porte Alegre.

Additionally, this study shows the performance between the different devices.

### KEY FINDINGS

- 164 samples were collected over the four difference point-of-collection devices.
- Out of the 164 samples collected: 33 screened positive for at least one drug. 44 results were positive overall for different drugs.
- Cocaine and cannabis were the most prevalent drugs detected during the study.
- Agents scored all four devices on numerous factors such as simplicity of use, operational success and hygiene and safety for police procedures.
- The authors determined that the most relevant aspects for the traffic agents was the time taken to collect the sample.
- Overall, the DDS2 received the highest score when agents were asked to rate the operational feasibility and user experience of each device (See Table 1 below).

PECHANSKY, F., SCHERER, J., SCHUCH, J., ROGLIO, V., MORESCHI, Y., SIVESTRIN, R., PASA, G., SOUSA, T., 2019, TRAFFIC INJURY PREVENTION, 20 (1), PP 30 - 36

**TABLE 1 –** Operational feasibility and user experience of the evaluated devices.<sup>a</sup>

CRITERION	DDS®2 N (%)	DOA MULTISCREEN N (%)	MDML N (%)	DRAEGER N (%)
Simplicity of use	7 (87.5)	3 (27.3)	8 (88.9)	8 (88.9)
Operational success	8 (100)	5 (45.5)	8 (88.9)	9 (100)
Acceptable oral fluid collection time	8 (100)	3 (27.3)	8 (88.9)	6 (66.7)
Acceptable sample analysis time	8 (100)	4 (36.4)	7 (77.8)	5 (55.6)
Sample collection and analysis procedures can be conducted on the road by police	7 (87.5)	5 (45.5)	8 (88.9)	9 (100)
The results corroborate observed clinical signs of impairment	8 (87.5)	9 (81.8)	9 (100)	9 (100)
Hygiene and safety for police procedures	8 (100)	9 (81.8)	9 (100)	9 (100)
Sufficient usage instructions included in the package	7 (87.5)	8 (72.7)	8 (88.9)	8 (88.9)
Oral fluid could be collected hygienically	6 (75.0)	6 (54.5)	7 (88.0)	6 (66.7)
Final score	88.4	49.3	84.3	82.4

<sup>a</sup> Values represent the total (%) affirmative answers to each question.

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