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Final Report: Vermont Oral Fluid Drug Testing Study 2015

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Executive Summary:

Field oral fluid (OF) drug testing is a useful tool for producing investigative information and for confirming officer suspicions about drug use immediately in the field. This may facilitate police investigations in some circumstances. Other factors such as same sex collection, the less invasive nature of the collection, and the ability to perform a test proximate to the time of driving are significant benefits from use of OF 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. More timely information about a subject's drug use can be extremely useful to the officer in the heat of an investigation, and helps to validate the officer's opinion about the subject's intoxication.

This is a report of an assessment of the performance of the Dräger® Drug Test 5000 (DDT5000) and the Alere® DDS2 Mobile Test System (DDS2) in assessing their ability to detect presumptively and in the field, drug use by subjects suspected of having recently consumed drugs.

Both devices test for drug classes generally agreed upon to be most prevalent in drug driving enforcement encounters: cannabinoids, cocaine, amphetamines/methamphetamine, benzodiazepines, opiates, and methadone (DDT5000 only).

The Vermont Department of Public Safety used the devices to test subjects in the field from a mandatory urine drug testing program, and from suspected drug impaired driving arrests. A total of 58 subjects were evaluated between the two testing platforms.

The results were consistent with other similar previously reported studies, showing sensitivity (the ability to produce confirmable results) of approximately 60% with success rates as high as 100% for some drug categories. Some drugs, especially the benzodiazepines, still present a challenge for these drug platforms, but the most commonly encountered drugs – cannabinoids and cocaine – are well detected and confirmed. False positive rates were less than 1% on the DDT5000, and less than 4% on the DDS2. Accuracy for both field testing instruments was greater than 90%.

Objectives:

This is a report of the evaluation of field based OF drug test devices performed using the Dräger® Drug Test 5000 (DDT5000), and the Alere® DDS2 Mobile Test System (DDS2). The objective was to compare the results of OF drug tests conducted in the field on drug using subjects, to results from a confirmatory OF test performed on samples collected in the field and sent to the lab for testing; and to compare the field results with a urine screening test currently used in DRE certification programs; and finally to compare the field test OF results with blood drug testing results, which is the current standard practice in the state of Vermont. The purpose was to evaluate the feasibility of using field OF testing as an additional tool for law enforcement in detecting and documenting drug impairment in drivers.

Background:

The increased availability of OF collection and testing devices has led to increased interest in OF as a matrix for confirming the involvement of drugs in suspected impaired driving investigations. OF drug testing is suitable for preliminary screening for drugs at the roadside which can aid the officer in an arrest decision. In addition, OF can be collected proximate to the time of driving and used as the confirmatory specimen in place of blood and urine.

OF as a matrix offers many advantages to officers over blood and urine. These include easier sample collection using noninvasive procedures, and eliminating the need for a collection facility or same-sex observation. OF is difficult to adulterate, and there is a lower chance of the sample becoming contaminated, all of which help to save time and resources. A limitation of OF 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. Many jurisdictions have concluded that the best use of OF 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 OF 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.

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. The tests detect the presence of classes of drugs (e.g. opiates, benzodiazepines, etc) rather than individual compounds. 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 (NSC-ADID) compiled recommendations for scope and threshold for laboratory based drug screening and confirmation in OF. The recommendations were based on the most prevalent drugs 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.

There is currently no Federally approved list of devices for use in law enforcement OF drug testing as there is for breath alcohol testing devices. The purpose of this assessment was to compare results obtained in the field from two of the best characterized point of contact OF testing devices, the DDT5000 (Dräger, Lübeck, Germany) and the DDS2 (Alere, Pomona, CA). The goal was to assess their ability to detect drug use in subjects who had independently and voluntarily consumed drugs, and compare the result to more traditional drug testing approaches involving urine, blood, and also OF samples collected in the field.

The DDT 5000 is a point of collection test for the simultaneous detection of up to eight drugs of abuse in human OF. The method is based on lateral flow immunoassay, with optical detection in an instrumented reader. The classes of compounds detected with the system used in this analysis include: amphetamine, benzodiazepines, cocaine, methadone, methamphetamine, opiates, and THC. The DDT 5000 is designed to be a qualitative tool by providing a printed preliminary analytical result. Laboratory confirmation of drug test results is critical to ensure their admissibility in court. The DDT 5000 results are considered preliminary or presumptive, and as with other forensic testing require a laboratory based confirmatory test. The DDS2 is similar in many respects, using the same lateral flow immunoassay technology, and testing for a similar range of drugs. A comparison of the scope and manufacturers cut-offs or detection thresholds for the two devices are shown in Table 1.

Table 1. Scope and cut-offs for DDS2 and DDT5000 as used in this study.

Drug class	**DDT 5000®**	**DDS2®**
Cannabinoids (THC)	5	25
Amphetamines	50	50
Methamphetamines	35	50
Cocaine	20	30
Benzodiazepines	15	20
Opiates	20	40
Methadone	20	-*

** Not included in this device for this study..*

Methods

Subjects

A total of 58 subjects were tested in this evaluation but each subject was tested on only one of the two field devices. 23 subjects were tested on the DDS2 and 35 subjects were tested on the DDT 5000. Samples were collected by the Vermont Department of Public Safety. The subjects included 49 individuals in a court-ordered rapid intervention program, from whom urine was also collected when available and tested using a screening method (with no confirmation) by Burlington Labs (Burlington, VT). Nine of the subjects were individuals under investigation for impaired driving related offenses. Blood was collected from these subjects and submitted to the Vermont Forensics Laboratory in the

Department of Public Safety, in Burlington VT. For these enforcement samples, the officers followed their routine arrest procedures, including advisement of rights, field sobriety tests, portable breath test, blood sample collection, and completion of the arrest paperwork before collecting the OF samples for further testing.

Field Testing

Field tests using the DDS2 and DDT 5000 were performed according to the manufacturer's specifications. Printouts of the results were obtained and preserved. Each subject was tested on either the DDS2 or the DDT 5000, but not both.

Confirmatory Sample Collection

Following administration of the field OF test, an additional OF sample was collected from the subject using a Quantisal™ (Immunalysis, Pomona, CA) OF collection device. The device collects approximately 1 mL of OF and stores it in a tube containing 3mL of a stabilizing buffer solution. The device has an adequacy indicator that indicates when the collection is complete. Samples were stored at room temperature for shipping to the laboratory for analysis, and were shipped to NMS Labs in Willow Grove PA for confirmatory testing. NMS Labs has performed stability studies that have demonstrated that the drugs of interest are stable in the Quantisal buffer at room temperature for up to seven days. Once received at NMS Labs, the OF samples were analyzed for the presence of the target drugs using Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) or Gas Chromatography Gas Chromatography Mass Spectrometry (GC-GC/MS) for cannabinoids at the concentrations listed in appendix A.

Urine samples were collected from subjects in a plastic cup, and forwarded to Burlington Labs for a presumptive immunoassay-based drug test for the same drug classes that were covered by the field test devices, and that are reflected in Table 1.

Blood samples from suspected impaired drivers involved in the study were forwarded to the Vermont Forensic Laboratory, and shipped to NMS Labs where they were tested by Enzyme Multiplied Immunoassay Technique (ELISA) and Liquid Chromatography, Time of Flight (LC-TOF) mass spectrometry for the presence of common therapeutic and abused drugs, including all those indicated in Appendix A.

The results of the OF field tests were compared to both the OF laboratory test, and to the results of the blood test in separate assessments.[1] Several comparisons were made for each of the field OF testing device for a total of six comparisons, including (i) field OF test compared to laboratory OF result (DDS2, n=23; DDT 5000, n=35) (ii) comparison of field OF test to blood (enforcement samples), (DDS2, n=3; DDT 5000, n=5); (iii) comparison of the field OF test results to laboratory urine result (court ordered programs), (DDS2, n=20; DDT 5000, n=28); and (iv) finally an overall comparison of the field test

[1] Blood testing is the procedure currently used in this jurisdiction for DUI investigations in Vermont.

results with any confirmed drug positive (regardless of matrix) was evaluated (DDS2, n=23; DDT 5000, n=35).

For purposes of this assessment, the laboratory based test was considered the reference or "true result," and the field test results for that subject were evaluated against the laboratory test. OF field test results that were confirmed in the blood, urine, or laboratory OF sample were considered "true positives" with respect to that particular matrix. OF results that were not confirmed in the corresponding laboratory test in that matrix were considered "false positives." Likewise, drugs within the targeted scope of the DDT 5000 or DDS2 that were not detected on the field OF test, but were found in the blood, urine, or OF in the laboratory were considered "false negatives"[2], and situations where the field test devices did not detect the drug and none was found in the collected OF or blood sample was considered a "true negative" for that matrix. The final comparison of the field OF result to any laboratory confirmed result was designed to be a comprehensive assessment of the performance of the field test device in detecting drug use by the subject as the reference condition, independent of confirmatory testing method or matrix.

The overall effectiveness of the field test was assessed based on sensitivity, specificity, accuracy, positive predictive value (PPV) and negative predictive value (NPV) for the DDT 5000 and DDS2 relative to the blood test or the laboratory-based OF test. These terms are defined in Table 2.

Table 2. Definitions of terms used in 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.

[2] Note that the laboratory confirmation methods are by design more sensitive than the field screens to ensure the ability to detect samples positive on the immunoassay for multiple immunoreactive species in samples. Consequently, the number of false negatives in the results section reflect the devices ability to detect drug using drivers as opposed to the reliability of the devices performance around their cut-offs.

Results and Discussion

The number of subjects overall testing positive for the various drugs detected in these populations is shown in Table 3.

Table 3. Overall drug positivity of the population included in the study.

Drug	*Number of Positive Individuals*
THC	*16*
Morphine	*14*
Codeine	*5*
6-MAM	*11*
Oxycodone	*6*
Hydrocodone	*1*
Hydromorphone	*1*
Methadone	*1*
Amphetamine	*4*
Cocaine/BZE	*5*
Clonazepam	*1*
Lorazepam	*1*
Nordiazepam	*1*

Note that each subject was tested on only one field device and that the mixture of drugs in the subjects tested on each field device differed. This makes direct comparisons of the performance of the devices with each other inappropriate based on this data. Note also, that the prevalence of many drugs including the synthetic opioids, benzodiazepines, and amphetamines was low, and subjects testing positive for the various drug classes were not evenly distributed between the two field testing devices. This further limits the ability to make comparisons of performance across all drug groups between the two platforms. In addition, only nine subjects provided blood samples so no statistical comparisons were possible of performance of field OF testing against the current practice of blood testing. At the higher level however, useful information was obtained about the rates of positive results on both devices overall. It was also possible to compare device performance to the overall detection rates in collected OF (internal validity) and urine (external validity). Finally, the performance of each of the platforms against drug use in the subjects as determined by any laboratory based method was assessed.

DDS2 and DDT 5000 vs. Laboratory Based Oral Fluid Test

Table 4a. Results of the DDS2 relative to confirmations in oral fluid by NMS Labs.

DDS2 vs. Oral Fluid (n=23)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC*	3	2	0	15	60.0%	100.0%	90.0%	100.0%	88.2%
Cocaine	2	0	0	21	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	3	0	3	17	100.0%	85.0%	87.0%	50.0%	100.0%
Methamphetamine	0	0	0	23	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	0	0	0	23	n/a	100.0%	100.0%	n/a	100.0%
Opiates	3	1	1	18	75.0%	94.7%	91.3%	75.0%	94.7%
Overall	11	3	4	117	78.6%	96.7%	94.8%	73.3%	97.5%

**Note: 3 subjects were invalid for THC*

Table 4b. Results of the DDT 5000 relative to confirmations in oral fluid by NMS Labs.

DDT 5000 vs. OF (n=35)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	10	1	0	24	90.9%	100.0%	97.1%	100.0%	96.0%
Cocaine	3	0	0	32	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	0	0	0	35	n/a	100.0%	100.0%	n/a	100.0%
Methamphetamine	0	0	0	35	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	2	0	0	33	100.0%	100.0%	100.0%	100.0%	100.0%
Methadone	1	0	0	34	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates	14	1	3	17	93.3%	85.0%	88.6%	82.4%	94.4%
Overall	30	2	3	210	93.8%	98.6%	98.0%	90.9%	99.1%

The overall sensitivity, specificity, and accuracy of the DDS2 and DDT 5000 compared to compounds confirmed in OF are shown in Table 5.

Table 5. Overall sensitivity, specificity and accuracy for the DDS2 and DDT 5000 for comparison of field result to laboratory oral fluid result.

ROC Result	DDS2	DDT 5000
Sensitivity	78.6%	93.8%
Specificity	96.7%	98.6%
Accuracy	94.8%	98.0%
PPV	73.3%	99.1%

The differences in performance between the two platforms were largely due to a higher proportion of false negative results on the DDS2 for THC, compared to the DDT 5000. The DDT 5000 has a lower cut-off for THC of 5ng/mL versus 25ng/mL. In addition, a greater proportion of the subjects tested on the DDT5000 had been using THC, based on any positive test. Device performance for methamphetamine, benzodiazepines and methadone could not be assessed in this comparison for the DDS2, since none of the subjects were positive for the former two drugs and the DDS2 does not test for methadone.

Positive predictive value (PPV) reflects the proportion of subjects whose field test correctly predicted they would test positive in the confirmatory test. This is an important characteristic since it avoids unwarranted negative consequences for the driver that could result from a false positive. The DDT 5000 had a higher PPV as a result of a smaller proportion of unconfirmed positives, mostly amphetamine. It is possible that these samples contained other species that cross react with the amphetamine antibody that are not part of the scope of the confirmatory test, such as other phenethylamines, some cold medications, and designer amphetamines ("bath salts").

The opiate most frequently found in OF in the laboratory test was morphine, frequently accompanied by the heroin metabolite 6-MAM. The DDS2 had a sensitivity of 75.0% for opiates, failing to detect one of seven individuals who subsequently tested positive in OF in the laboratory, and generated one false positive. The DDT 5000 detected fourteen of sixteen opiate positive subjects, and generated three false positives, and one false negative. Positivity for opiates in this population was comparable to rates reported in other studies of treatment center populations, but is higher than typically seen in the DUID population.

DDS2 and DDT 5000 vs. Laboratory based urine test

Table 6a. Results of the DDS2 relative to confirmations in urine by Burlington Labs.

DDS2 vs. Urine (n= 20)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC*	2	0	0	15	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	2	0	0	18	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	3	0	3	14	100.0%	82.4%	85.0%	50.0%	100.0%
Methamphetamine	0	0	0	20	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	0	0	0	20	n/a	100.0%	100.0%	n/a	100.0%
Opiates†	2	0	1	16	100%	94.1%	95.0%	66.7%	100.0%
Overall	9	0	4	104	100%	96.3%	96.6%	69.2%	100.0%

**Note: 3 subjects were invalid for THC*

†Urine results were limited to drug class, therefore, an opiate positive result in the urine that was not detected by the device was left as a true negative due to the inability to evaluate if the opiate detected would cross-react on the device.

Table 6b. Results of the DDT 5000 relative to confirmations in urine by Burlington Labs.

DDT 5000 vs. Urine (n=28)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	5	5	0	18	50.0%	100.0%	82.1%	100.0%	78.3%
Cocaine	2	3	1	22	40.0%	95.7%	85.7%	66.7%	88.0%
Amphetamine	0	1	0	27	0.0%	100.0%	96.4%	n/a	96.4%
Methamphetamine	0	0	0	28	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	2	0	0	26	100.0%	100.0%	100.0%	100.0%	100.0%
Methadone	1	0	0	27	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates†	14	0	2	12	100.0%	85.7%	92.9%	87.5%	100.0%
Overall	24	9	3	160	72.7%	98.2%	93.9%	88.9%	94.7%

†Urine results were limited to drug class, therefore, an opiate positive result in the urine that was not detected by the device was left as a true negative due to the inability to evaluate if the opiate detected would cross-react on the device.

The overall sensitivity, specificity, and accuracy of the DDS2 and DDT 5000 compared to compounds confirmed in urine are shown in Table 7.

Table 7. Overall sensitivity, specificity and accuracy for the DDS2 and DDT 5000 for comparison of field result to laboratory oral fluid result.

ROC Result	DDS2	DT5000
Sensitivity	100%	72.7%
Specificity	96.3%	98.2%
Accuracy	96.6%	93.9%
PPV	69.2%	88.9%

The differences between the two platforms were largely due to a higher proportion of false negative results on the DDT5000 for THC, compared to the DDS2, the opposite trend from that noted in the laboratory OF result. This led to a lower sensitivity overall for the DDT5000. Urine samples however tend to test positive for cannabinoid metabolites for up to several days following last use in heavy users, outside of the window when OF would be expected to be positive (several hours). This is one of the major recognized limitations of urine testing in the impaired driving environment. Overall accuracy and positive predictive value for the DDT5000 was slightly higher in spite of the false negatives for cannabinoids, due to the proportionally higher number of unconfirmed positives for amphetamines on the DDS2.

DDS2 and DDT 5000 vs. Laboratory based blood test

Table 8a. Results of the DDS2 relative to confirmations in blood by NMS Labs.

DDS2 vs. Blood (n=3)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	2	0	0	1	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	0	0	0	3	n/a	100.0%	100.0%	n/a	100.0%
Amphetamine	0	0	0	3	n/a	100.0%	100.0%	n/a	100.0%
Methamphetamine	0	0	0	3	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	0	1	0	2	0.0%	100.0%	66.7%	n/a	66.7%
Opiates	1	0	0	2	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	3	1	0	14	75.0%	100.0%	94.4%	100.0%	93.3%

Table 8b. Results of the DDT5000 relative to confirmations in blood by NMS Labs.

DDT5000 vs. Blood (n=5)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	4	0	0	1	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	0	0	0	5	n/a	100.0%	100.0%	n/a	100.0%
Amphetamine	0	0	0	5	n/a	100.0%	100.0%	n/a	100.0%
Methamphetamine	0	0	0	5	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	0	0	0	5	n/a	100.0%	100.0%	n/a	100.0%
Methadone	0	0	0	5	n/a	100.0%	100.0%	n/a	100.0%
Opiates	1	0	0	4	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	5	0	0	30	100.0%	100.0%	100.0%	100.0%	100.0%

The comparisons between the field OF test result and the blood tests are presented for informational purposes, and without further analysis as the number was too small for meaningful analysis of the sensitivity, accuracy or positive predictive value. Generally the drugs detected in the field were confirmed in all but one case where a benzodiazepine positive from the blood was undetected by the DDS2 in the field, however, benzodiazepines are known to represent a challenge due to low rates of partitioning, and none of the subjects tested on the DDT5000 had been taking benzodiazepines, preventing any meaningful comparison. The previous two sections of this report and the final comprehensive comparison below give more meaningful information about field device performance relative to confirmatory tests.

Overall Performance of DDS2 and DDT 5000 versus any confirmed positive result

Table 9a. Results of the DDS2 relative to any confirmed positive

DDS2 vs. Any Confirmed Positive in Any Fluid (n=23)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC*	4	3	0	13	57.1%	100.0%	85.0%	100.0%	81.3%
Cocaine	2	0	0	21	100.0%	100.0%	100.0%	100.0%	100.0%
Amphetamine	3	0	3	17	100.0%	85.0%	87.0%	50.0%	100.0%
Methamphetamine	0	0	0	23	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	0	1	0	22	0.0%	100.0%	95.7%	n/a	95.7%
Opiates†	3	1	1	18	75.0%	94.7%	91.3%	75.0%	94.7%
Overall	12	5	4	114	70.6%	96.6%	93.3%	75.0%	95.8%

**Note: 3 subjects were invalid for THC*

†Urine results were limited to drug class, therefore, an opiate positive result in the urine that was not detected by the device was left as a true negative due to the inability to evaluate if the opiate detected would cross-react on the device.

Table 9b. Results of the DDT5000 relative to any confirmed positive

DDT 5000 vs. Any Confirmed Positive in Any Fluid (n=35)									
Drug	**TP**	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**Accuracy**	**PPV**	**NPV**
THC	10	5	0	20	66.7%	100.0%	85.7%	100.0%	80.0%
Cocaine	3	3	0	29	50.0%	100.0%	91.4%	100.0%	90.6%
Amphetamine	0	1	0	34	0.0%	100.0%	97.1%	n/a	97.1%
Methamphetamine	0	0	0	35	n/a	100.0%	100.0%	n/a	100.0%
Benzodiazepines	2	0	0	33	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates†	16	0	2	17	100.0%	89.5%	94.3%	88.9%	100.0%
Methadone	1	0	0	34	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	32	9	2	202	78.0%	99.0%	95.5%	94.1%	95.7%

†Urine results were limited to drug class, therefore, an opiate positive result in the urine that was not detected by the device was considered as a true negative due to the inability to evaluate if the opiate detected would cross-react on the device.

Table 10. Overall Sensitivity, specificity and accuracy for the DDS2 and DDT5000 for comparison of field result to laboratory oral fluid result.

ROC Result	DDS2	DT5000
Sensitivity	70.6%	78.0%
Specificity	96.6%	99.0%
Accuracy	93.3%	95.5%
PPV	75%	94.1%

The caveat to this comparison is that different confirmatory matrices (blood, urine, OF) contain different concentrations of drugs in the same user, and that the tests themselves have different cut-offs. Also some of the positives in the urine may reflect more distant drug use, not related to the subjects state of intoxication at the time of sampling. However, if the aggregate result of all the laboratory-based tests are considered as an indication of some recent drug use by the subject with residual drug still in the body, then this comparison answers the question, "relative to any other type of drug test that could be performed subsequent to a field test on either the DDS2 or DDT 5000, what is the rate of agreement?". The overall sensitivity, specificity, and accuracy of the DDS2 and DDT 5000 compared to compounds confirmed in any laboratory based test are shown in Table 10. Note that the DDS2 also produced three invalid results on the THC test, while the DDT5000 produced none.

Sensitivity in this comparison appears weaker than when comparing the field OF results to the collected OF ample, because of the longer excretion profile of cannabinoids in the urine, as noted above. Specificity (the tests ability to detect true negatives) were high on both devices (DDS2, 96.6%; DDT5000 99%) a favorable property of the tests for drug-free subjects who might be tested. The DDT5000 had poorer performance for cocaine (50% sensitivity), resulting from detection of the cocaine metabolite benzoylecgonine in urine, which can also be considered evidence of drug use. The field tests however are targeted to the parent drug (cocaine) rather than the inactive metabolite.

Conclusions

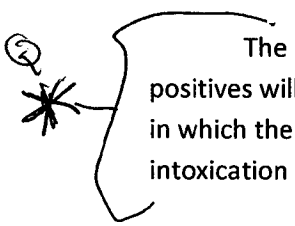
As noted in previous sections of this report, sensitivity is the proportion of subjects who subsequently test positive in a confirmatory test whose positive status was correctly predicted by the field test. Sensitivity suffers when the test fails to find some drugs that are detected in subsequent confirmatory methods, however the negative consequences to the subject from a false negative are arguably minimal and would accrue to a defendants favor in any investigation. The positive predictive value (PPV) of the tests was high. Greater than 94.1% of positive tests on the DDT 5000 were subsequently confirmed in some other toxicological test. PPV was lower (75%) for the DDS2, which can be attributed to the amphetamine class generating several unconfirmable positives on that DDS2, which may reflect other non-target drugs such as bath salts or over the counter cold medications, and is inflated by the proportionally lower drug positivity rate in the DDS2 subjects. Overall false positive rates were less than 1% on the DDT 5000, and less than 4% on the DDS2.

The results in this study are comparable to other previously published studies and assessments of both devices (see bibliography). In particular, in a previous evaluation of the DDT 5000 device in suspected impaired drivers arrested in Miami FL, (Logan et al, 2014) the DDT 5000 returned overall sensitivity of 51%, and positive predictive values (PPV) of 93%. The differences between those findings and the ones in the study can be attributed to the mix of drugs present in the drug positive subjects. Oral fluid proved to be a more effective confirmatory specimen, with more drugs being confirmed in OF than urine. These results are comparable to the findings in this assessment in Vermont. In another assessment in Lancaster PA, with a total of 33 subjects who were being placed under arrest for impaired

driving. In that assessment, with respect to individual analytes, THC was detected in the field and confirmed in the laboratory in OF 14 times out of the 33 cases analyzed. Five samples tested positive for THC in the laboratory that were not detected in the field, giving an overall sensitivity of 73.7%. There were no false positives, resulting in 100% selectivity for THC. In the Lancaster study, the overall sensitivity, specificity, and accuracy of the device compared to compounds confirmed in OF were 61.4%, 99.2%, and 87.7%, respectively. These findings are similar to those described in this study.

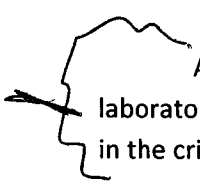
In a field study of the DDS2 in which samples from 38 subjects were tested in the field by the DDS2 (Moore et al, 2013), in 12 cases (24%), the device produced an invalid result. Thirty-two of the 38 collected samples were negative for all drugs; five were positive for THC and one was positive for methamphetamine using the mobile device. These results corresponded exactly with the laboratory-based results from the Quantisal oral fluid collection. There was one false negative on the field device for methamphetamine/amphetamine. Given the low number of subjects and the low frequency of positives in the cohort, the specificity and sensitivity and accuracy cannot be calculated with any statistical significance, but generally the experience of those researchers was similar to our in this study.

The ultimate marker of overall performance, the accuracy of the devices, which evaluates the number of time the device produces a correct answer, takes account of the many times that subjects free of a particular drug or drug class were correctly identified, as well as the devices' ability to correctly identify drug users, was over 90% for both devices.



The purpose of the field test is to provide additional information to the investigator, and all positives will be subject to a laboratory-based confirmatory test for forensic purposes. In addition, cases in which the field test is negative or its results are inconsistent with the appearance and degree of intoxication of the subject, supplemental tests should be ordered of either blood or collected OF.

Although no quantitative comparison of the devices is possible from this data due to the fact that different populations were being tested and the sample size in the DDS2 and DDT 5000 were different, the overall performance of the devices would seem to meet the immediate need of providing useful supplemental investigative information to officers in the field.



As with all good practice, the totality of the circumstances must be considered in addition to laboratory-based confirmation of any results generated in the field to ensure accurate data is presented in the criminal prosecution of drug impaired driving cases.

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Appendix A. Target scope for confirmatory LC-MS-MS analysis (LC-MS for cannabinoids) (note that a total of 4mL is available for testing) .**

Analyte	Target Cut-off in OF (ng/mL)[1]
Amphetamines	
Amphetamine	10
Methamphetamine	10
MDA	10
MDMA	10
Benzodiazepines	
Diazepam	6
Nordiazepam	6
Oxazepam	9
Temazepam	9
Chlordiazepoxide	200
Lorazepam	6
Clonazepam	6
Alprazolam	6
Midazolam	6
Opiates	
Codeine	8
Morphine	8
Hydrocodone	8
6-MAM	8
Hydromorphone	8
Oxycodone	8
Oxymorphone	8
Dihydrocodeine	8
Cocaine	
Cocaine	10
Benzoylecgonine	5
Cocaethylene	5
Methadone	
Methadone	10
EDDP	10
Cannabinoids	
THC	2
THC-COOH	2
THC-OH	2
PCP	
PCP	4
Dextromethorphan	100