REPORT FOR THE MISSOURI SAFETY CENTER CONCERNING THE USE OF SALIVA AS A TOOL FOR LAW ENFORCEMENT IN MISSOURI

Dräger
DrugTest®
5000

University of Central Missouri
Warrensburg, MO
Oct/2011

Acknowledgments

The goal of this study was two-fold; to determine the reliability and applicability of oral fluid as a viable alternative to determining the presence of drugs in blood and urine to establish recent drug use and drug impairment, and to evaluate the capabilities of the Dräger DrugTest® 5000. This report was created by Brian M. Lutmer, B.S., DFTCB, as a result of a study developed, approved, conducted and supervised by Tracey Durbin and Robert Welsh at the Missouri Safety Center, University of Central Missouri. Special recognition and thanks is extended to all of those individuals and agencies who helped make the study possible. Specifically:

- Brian Lutmer, B.S., DFTCB, Missouri Department of Health and Senior Services
- Linda Salo, Drager Safety Diagnostics, Inc.
- Kevin Reeves and Ron Baltzer, Lee's Summit Missouri Police Department
- Mike Hoefle, St. Charles County Missouri Sheriff's Department
- Shawn Clawson, Springfield Police Department
- Missouri State Highway Patrol Crime Lab
- Friends Toxicology Lab

The conclusions and opinions within this report are solely those of the author.

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Abstract

Oral fluid has many advantages over other biological matrices for the determination of drugs of impairment within the human body, including ease of collection, noninvasive procedure, and inability to adulterate the sample. There are several disadvantages as well, including sample size and analyte concentration. The use of saliva as a biological matrix for drugs of impairment was examined, using comparisons of subjects' saliva and urine gathered during Drug Recognition Expert (DRE) evaluations. Duplicate saliva samples were analyzed on 76 subjects by two different methodologies, one within a forensic laboratory and the other by a point-of-collection analyzer, the Dräger DrugTest® 5000. While the laboratory showed greater analytical flexibility and improved sensitivity to benzodiazepines, the point-of-collection analyzer showed greater sensitivity to amines and cannabis, and both methodologies were considered comparable overall. When compared to subject urine results, oral fluid showed an apparent false-negative rate of 0.6% and a positive predictive value for the presence of drugs in a subject of 79.1%. These results are considered to be positive and evidence that oral fluid is fit-for-use in screening for drugs of impairment. The saliva test results were also compared to the DRE evaluation results, as the Drug Evaluation and Classification Program (DECP) has shown an accuracy in determining the correct drug impairment classification 92% of the time in previous studies[1], and part of the motivation for undertaking this study was to ascertain the viability of point-of-use saliva testing as a means to validate DRE evaluations. However, when saliva samples were used to validate DRE evaluations, the successful call rates were below 70% for both oral fluid methods, while the urine call rate was 92.9%. The use of oral fluid samples to validate DRE evaluations is not warranted at this time, but the application of saliva testing, especially point-of-collection testing, could be extremely beneficial to law enforcement and others who are need of a safe, noninvasive, practical and reliable matrix for the screening of subjects for drug impairment.

Introduction

The use of illicit drugs and the abuse of prescription drugs continue to be a growing concern within our society[2,3]. As subjects while under the influence are frequently encountered by law enforcement, the need for rapid and accurate methods for detecting drugs of impairment is high. This need extends beyond just law enforcement as drug courts, parole officers, employers, school systems and others must make reliable determinations concerning the impairment of subjects within their demesne[4].

It is generally accepted that the most objective means of establishing recent drug use and drug impairment is the chemical testing of biological fluids[5]. Testing for drugs of abuse has been done for decades primarily utilizing blood and urine, although saliva (oral fluid, OF) and sweat testing has increased in use and capability greatly over the past 20 years[6,7]. Oral fluid in particular has gathered increased attention of the past decade, and new technologies are constantly being introduced to improve and expand this biological matrix as a viable alternative to blood and urine[8,9].

Saliva has numerous advantages over blood or urine alone in the detection of drugs, including:

- No subject privacy issues
- Sample can be taken anywhere in less than two minutes
- Noninvasive
- Subjects unable to 'mask' or otherwise adulterate sample
- Saliva drug concentrations reflect current drug impairment

These advantages suggest that saliva should be the preferred biological sample for analysis. Unfortunately there are a few disadvantages to this matrix as well: 1) Samples are low in volume, with only between 1 – 3 mLs of oral fluid collected in most applications, and 2) while correlating well to blood, the actual concentrations of drugs in oral fluid are significantly lower than in either blood or urine[10]. However, the accuracy and sensitivity of oral fluid testing has increased steadily in the past 20 years, especially in the area of point-of-collection oral fluid testing[11,12].

Point-of-collection OF testing carries all of the advantages already discussed, with the added benefit of near instantaneous results. OF devices that are available analyze samples for drugs utilizing immunological techniques, normally a variation of enzyme immunoassay (EIA). In simplest terms, during analysis by EIA drugs found in the saliva become bound to enzyme-linked antibodies. The greater the concentration of a particular drug, the greater the extent of reaction, and therefore the greater signal difference detected.

Enzyme immunoassay is an extremely useful diagnostic tool utilized not only by traditional crime laboratories to screen toxicological samples for drugs but also in numerous medical, environmental and food industry applications. It is one of the accepted methods for initial testing for drugs of impairment in the Missouri Code of State Regulations[13]. The primary advantage of EIA in the context of saliva drug testing is its high sensitivity, a necessary counterpart to low oral fluid drug concentrations and small collection volumes.

There are certain disadvantages of this methodology that must be recognized as well. As can be inferred by the binding of the drugs to specific enzyme-linked antibodies, only drugs for which a specific enzyme-antibody microparticle has been added will be able to be detected. Therefore, binding microparticles utilized in the testing process need to be both as specific as possible for the drug class under investigation while also general enough to be able to cross react to the various chemical analogues or homologues within that same classification. The same cross-reactivity that allows various drugs from the same classification to be detected using a single test also negates the confirmatory prospects of this methodology. While certainly useful, EIA alone can only be used as an initial or screening test and must be followed up with a

confirmatory method, normally a chromatographic method employed with subsequent mass spectrometry.

This does not discount the reliability and applicability of this methodology, and oral fluid test results derived by EIA analysis are already accepted in numerous jurisdictions both in the United States and abroad[14,15]. It is also possible under current state statute 577.021[16] that a screening test for drugs using an oral fluid may be used as evidence of probable cause in the same manner that a portable breath test (PBT) instrument is used as probable cause for alcohol intoxication. One of the benefits of its use under this statute is that it would not count as one of the two evidential tests that an officer can require from a subject. These rules also do not apply to testing carried out in other areas where drug screenings are already regularly performed on urine. This includes settings in jailhouses, use by probation and parole, or by employers. In these settings, a point-of-collection oral fluid test could provide quick and relatively cheap evidence that could be backed up as necessary by more costly urine or blood tests on subjects showing positive initial screens. Another possibility is the use of oral fluid screenings in a school setting. School Resource Officers (SROs) or other authority personnel may be able to conduct saliva screenings when they suspect drug use by students, whereas urine and blood may be deemed too intrusive or invasive.

A further potential use of point-of-collection saliva screens is the validation of Drug Recognition Expert (DRE) subject evaluations. The Drug Evaluation and Classification (DEC) system that trains law enforcement officers as DREs requires those officers to perform a minimum of twelve subject evaluations initially, followed by a minimum of two subject evaluations annually thereafter. These evaluations must be corroborated by toxicological results with a minimum accuracy in correctly classifying the impairing substance of 80%[17]. The current standard within the DEC protocol is urine tests, although urine is not as reliable an indicator of current impairment as either blood or saliva. A point-of-collection test with sufficient accuracy and sensitivity could give the DRE an additional tool to immediately substantiate their opinions without the need to wait for crime lab results.

There are significant opportunities for application of saliva toxicological tests in general and even further applications for point-of-collection saliva tests. Before institutions can begin to employ oral fluid screenings in these contexts, however, it is practical to collect evidence concerning their accuracy, reliability, and sensitivity. Due to its recent release and the manufacturer support offered, this study was conducted utilizing a particular point-of-collection oral fluid analyzer; the Dräger DrugTest® 5000, manufactured by Dräger Safety Diagnostics Inc. in Irving, Texas.

Figure 1. The Dräger DrugTest® 5000

Figure 2. The Dräger DrugTest® 5000 with door open and test cassette and buffer cartridge inserted

The DrugTest® 5000 is a bench-top analyzer weighing approximately ten pounds, with an 8” x 9” base, and approximately 10” in height. It is equipped with a standard 110 Volt AC power cord; although a 12 Volt DC adapter for mobile applications is also available. The unit also has a battery inside it so that some amount of testing can occur without the unit being connected to an electrical supply. The DrugTest® 5000 utilizes the principle of competitive displacement enzyme immunoassay in a manner consistent with that described earlier. Dräger DrugTest® 5000 Test-Kits (In-Vitro Diagnostic Device) must be used in conjunction with the DrugTest® 5000 due to the proprietary nature of the reagents and buffers employed during analysis. The Test-Kit consists of a test cassette and a buffer cartridge.

Sampling is started by removing the protective cap from the oral fluid collector on the test cassette. The cassette is moved from one side of the mouth to the other, collecting oral fluid from the inside of the cheeks. Once an adequate sample has been collected, usually in 30 seconds to 2 minutes, an indicator on the cassette will turn blue, visually alerting the tester that a sufficient sample has been collected. At this point, the tester opens the door to the DrugTest® 5000 and inserts the test cassette in the lower compartment of the unit until it audibly engages. The buffer cartridge is then inserted until audibly engaged into the upper compartment of the unit. The door is then closed and the tester follows the instructions on the instrument screen to input subject data.

After subject information has been input, the DrugTest® 5000 will begin analysis of the saliva sample. The standard 6-panel test screens samples for amphetamines, benzodiazepines, cannabinoids, cocaine metabolites, methamphetamines and opiates. The testing takes approximately 8½ minutes to complete, at which time the results for each drug category are displayed on the screen and sent to the printer. Alternatively, results may also be downloaded to a computer via an integrated USB port.

After sample analysis is complete, the tester opens the door of the analyzer, removes the now-attached test cassette and buffer cartridge from the lower compartment, closes the door to the analyzer, and disposes of the used cassette.

With its small size, ease of use, and the variety of drugs that it is able to detect, the DrugTest® 5000 would seem an ideal candidate for application as a point-of-collection oral fluid screening device in Missouri. As stated earlier, however, evidence concerning the unit's accuracy, reliability, and sensitivity should be collected before this or any other saliva testing begins to be employed regularly. Therefore, this study was conducted to answer these concerns and to gather evidence to clearly ascertain the following questions:

- What is the viability of oral fluid, either point-of-collection or laboratory tested, as an alternative matrix for conducting screening tests for subjects suspected of being under the influence of drugs?

- What is the relative strength of the Dräger DrugTest® 5000 point-of-collection oral fluid tests compared to laboratory-tested oral fluid?

- Can oral fluid, either point-of-collection or laboratory tested, be used to validate Drug Recognition Expert (DRE) evaluations in lieu of urine or blood tests?

Materials and Methods

The study used in this evaluation was developed, organized, conducted, and approved by the Missouri Safety Center. Two Dräger DrugTest® 5000 units, serial numbers ARZE-0034 and ARZE-0039, were acquired from Dräger Safety Diagnostics Inc., along with 300 DrugTest® 5000 Test-Kits that were set to expire June 30, 2010. Agreements were made by the Missouri Safety Center with Lee's Summit Police Department and St. Charles County Sheriff's Department to house the units and to use them when feasible in a method consistent with the study directives.

Study subjects were volunteers that were being held in custody at one of these law enforcement agencies and appeared to be under the influence of a drug or drugs other than alcohol. While subjects were undergoing Drug Recognition Expert evaluations, the DRE performing the evaluation requested from the subjects not only urine but two additional saliva samples as well. Subjects were informed prior to sampling that the saliva samples were being requested as part of a scientific study and would not be used against them in any legal proceedings, nor would any subsequent test results be included in the arresting officer's case.

They were also informed that the samples would be anonymous, that their participation was voluntary, and that refusal to participate in the study could not be used against the subject in any manner. No consent forms were completed by subjects, as written consent forms would have removed subject anonymity.

Once subjects gave oral consent to providing the additional samples, the DRE report and all biological samples from each subject were given a single alphanumeric designator to protect subject anonymity. The first saliva sample collected was analyzed on the Dräger DrugTest® 5000, the second was sent out for analysis by Friends Medical Laboratory, Inc., in Baltimore, Maryland. Friends Medical Laboratory analyzed the samples using a laboratory EIA method. Urine samples were analyzed by either the Missouri State Highway Patrol (MSHP) Crime Laboratory in Jefferson City or by the Toxicology Laboratory within Children's Mercy Hospital in Kansas City. Samples sent to the MSHP Crime Laboratory were screened only using EIA, while samples sent to Children's Mercy were first screened by EIA and then sent to NMS Labs in Willow Grove, Pennsylvania for confirmation by tandem gas chromatography and mass spectrometry.

After initial testing with the DrugTest® 5000 in St. Charles County through December, 2009, the Dräger unit and associated equipment there returned to the Missouri Safety Center in Warrensburg. This unit was then reassigned in March 2010 to the Springfield Police Department for additional sampling through June 2010.

Results and Discussion

A summary of the number and types of samples collected are given in Table 1. The number of oral fluid tests sent to Friends Medical Laboratory was significantly less than the number tested using the DrugTest® 5000 due to miscommunications between testing facilities regarding testing criteria. The reduced number of urine tests reflects the refusal of eleven subjects to give urine samples that could be used against them in legal proceedings.

TABLE 1: TESTS PERFORMED AT ALL TESTING SITES

LOCATION	DRE EVALS	DT 5000 TESTS	FRIENDS LAB TESTS	URINE TESTS	SUBJECTS WITH RESULTS FOR ALL THREE*
LEES SUMMIT PD	60	59	36	58**	35
ST. CHARLES CO. SD	38	38	38	35	35
SPRINGFIELD PD	6	6	6	0***	0
TOTAL	**104**	**103**	**80**	**93**	**70**

*: This number only includes results where all tests gave results; some results were determined by labs to be 'untestable'.
**: 42 urine samples tested by MSHP Crime Lab, 20 were tested by Children's Mercy Hospital, and 4 had samples tested by both labs.
***: Six (6) blood samples rather than urine were collected, but the results have not been submitted.

The results of the tests are listed in Table 2 by drug category and frequency. Note that there were numerous instances of drugs being found in both saliva and urine that were not detected by the DrugTest® 5000. This is due to the issues regarding enzyme immunoassay addressed earlier. Phencyclidine, carisoprodol, and meprobamate are all substances unable to react to the standard 6-panel screen of the DrugTest® 5000[18]. Methadone can react to the standard panel and give a positive result as an opiate, but only at concentrations more than 3 orders of magnitude greater than target opiate compounds. There were also four occasions in which Friends Medical Laboratory found methadone concentrations in oral fluid that were not confirmed by urine toxicology. It is interesting to note that three of these samples were all analyzed by Friends Medical Laboratory on the same date, implying that the positive methadone results in at least three of the four tests conducted were potentially false positive results. Due to the seemingly aberrant nature of these three results, these three methadonepositive results will be dropped from consideration at this point.

TABLE 2: RESULTS BY TESTING AGENCY

	SALIVA		URINE	
	DT 5000	Friends Lab	MSHP	Children's Mercy
SAMPLES TESTED	103	80	77	20
AMPHETAMINES	13	*	10	4
BENZODIAZAPENES	4	18	19	11
COCAINE	6	6	9	3
METHAMPHETAMINES	10	10	11	4
OPIATES	22	23	23	5
TETRAHYDROCANNABINOL	41	27	45	12
NEGATIVE	30	19	6	0

* Friends Medical Laboratory did not test separately for amphetamines and methamphetamines, but uses an enzyme immunoassay methodology employing cross-reactivity

Additional Positive Results:
Friends Medical Laboratory had the additional positive screens: 4 phencyclidine (PCP), and 4 methadone
MSHP Crime Lab had the additional positive screens: 4 PCP, 3 carisoprodol, and 1 dextromethorphan
Children's Mercy and NMS Labs had the additional positive confirmed tests: 3 PCP, 1 carisoprodol, 1 meprobamate and 1 methadone

Saliva as a viable screening test for drug impairment

The average number of drugs detected per subject was 1.75 during urine analysis, and 61% of subjects tested positive for drugs from at least two different DECP categories. In direct contrast to this were the results obtained during OF testing, as the average number of drugs detected by the DrugTest® 5000 and Friends Medical Laboratory were 0.94 and 1.11, respectively. It is unclear in many cases whether this difference is due to a lack of sensitivity in oral fluid testing, or if some of the positive urine screens could be artifacts of earlier usage. Regardless, the results represented in Table 2 suggests that the DrugTest® 5000 displays a definite lack of sensitivity to the presence of benzodiazepines in the subjects' oral fluid.

If the ratios given above are considered alone, there is an implication that saliva may not be as sensitive as necessary for subject screening tests. However, as urinalysis confirmed the presence of two or more drugs in 61% of test subjects, a more meaningful question may be how frequently saliva would give a negative result when a positive result was obtained using urine. The results of this analysis are found in Table 3, with 87 direct comparisons between the DrugTest® 5000 and urine results and 70 comparisons between Friends Medical Laboratory results and urine results. These comparisons reflect only those in which a positive urine test result could have resulted in a positive saliva test result. In those cases where drugs that would not show up on the saliva tests conducted were found in urine (dextromethorphan, carisoprodol, phencyclidine on the DrugTest® 5000 , etc.), no comparison was made. However, the addition of this data as well would only account for an additional five comparisons on the DrugTest® 5000 and one additional comparison with the Friends Medical Laboratory-analyzed saliva, which would have brought the agreement levels down to 76.1% and 78.9% respectively. It has already been discussed that the DrugTest® 5000 during this study did not show a successful recovery rate of benzodiazepines in the oral fluid. If urine tests that were positive for benzodiazepines were not considered, the agreement between the Dräger unit and the urine would increase to 85.4%.

TABLE 3: TEST RESULTS BY SUBJECT -- INSTRUMENT COMPARISONS

	DT 5000 ONLY	URINE ONLY	DT & URINE	TOTAL	% BOTH
POSITIVE	**0**	**17**	**65**	**82**	**80.5%**
NEGATIVE	**N/A**	**N/A**	**5**	**5**	

	FRIENDS ONLY	URINE ONLY	FRIENDS & URINE	TOTAL	% BOTH
POSITIVE	**1**	**13**	**53**	**67**	**80.0%**
NEGATIVE	**N/A**	**N/A**	**3**	**3**	

Note: These results only reflect comparisons where positive drug results in urine could have reflected positive drug results in saliva.

It is also important to note that only 1 of 157 comparisons included in Table 3 showed a potentially false positive oral fluid result when compared to the urine. Even this result cannot be defined clearly as falsely positive, because it is very possible that the drug had been recently taken and had not yet undergone enough metabolism to wind up in sufficient concentration in the urine for a positive result.

With an apparent false positive rate of 0.6%, an apparent false negative rate of approximately 19.5%, and a positive predictive value of subject drug impairment of 79.1%, oral fluid is fit-for-purpose as a screening test for drugs of impairment.

Comparison of the point-of-collection to laboratory-analyzed oral fluid screening tests

As can be seen by the results in Table 3, the predictive nature of the Dräger DrugTest® 5000 point-of-collection oral fluid analyzer is very comparable to the saliva analyzed by Friends Medical Laboratory, Inc. This is in direct contrast to the apparent Limits of Detection (LOD) reported by the two methodologies as reported in Figure 3. If the reported LOD values for each methodology were correct, a much greater distinction in detection should have been reported, with Friends Medical Laboratory showing a significantly higher rate of detection than the rugTest® 5000. Specifically, the detection of opiates, tetrahydrocannabinol (THC), cocaine and benzodiazepines should have been significantly higher by Friends Medical Laboratory than by the DrugTest® 5000, and the detection rate of amphetamines should have been relatively similar. However, Friends Lab only detected benzodiazepines and opiates at a greater rate than the DrugTest® 5000, and detected THC and amines at a much lower rate. A direct comparison of the results obtained for Friends Medical Laboratory and the Dräger DrugTest® 5000 can be seen in Table 4.

Figure 3: Limits of Detection for the Drager DrugTest 5000 and Friends Medical Laboratory in ng/mL

	Drager DrugTest 5000	Friends Medical Laboratory
AMPHETAMINES	50	n/a
BENZODIAZAPINES	15	1
COCAINE	20	10
METHADONE	n/a	5
METHAMPHETAMINE	35	40
OPIATES	20	10
PHENCYCLIDINE	n/a	1
THC	5	1

The ability of the Dräger DrugTest® 5000 to determine the presence of benzodiazepines is clearly not an issue of matrix but of methodology. This could be due to the DrugTest® 5000's LOD of 15 ng/mL for benzodiazepines, which is less sensitive than Friends Medical Lab by more than an order of magnitude. If we were to set aside the benzodiazepine test results, the 5000 is seemingly as sensitive as or even more sensitive to the other 5 standard categories than Friends Medical Laboratory analysis. However, to confirm this, it would be necessary to test OF samples spiked with various concentrations of each drug classification.

The discovery that point-of-collection saliva testing results are comparable to the results from at least one laboratory regularly used by law enforcement to conduct this type of analysis is an important finding. For the purposes of law enforcement, these tests have the greatest applicability as screening tests for drug impairment. Law enforcement screening tests have two primary uses. The first of these is to help an officer make an accurate and reliable determination as to the presence drugs in the subject's body fluids. The second use for a screening test is as a test result to be given to a prosecutor as an initial analysis of the subject's body fluid. While not to be used as positive proof for court, rapid initial test results could be helpful to a prosecutor in successful case resolution prior to receipt of confirmatory drug analysis. A prosecutor who does not know what the final drug test results may give defendants very favorable plea agreements, while the same prosecutor with initial results showing the presence of one or more drugs in the subject's body fluids may seek an agreement that serves the community more judiciously.

TABLE 4: RESULTS FOR 76 SUBJECTS WITH DUAL SALIVA RESULTS*

	Positive DrugTest 5000 Only	Positive Friends laboratory Only	Positive on Both
AMPHETAMINES	5	n/a	6**
METHAMPHETAMINES	2	3	5
BENZODIAZAPINES	0	16	2
COCAINE	1	1	4
OPIATES	4	9	14
THC	11	4	23
TOTAL	23	33	54
NEG	n/a	n/a	10

* Includes only positive results where substances could have appeared on both tests.
** These are tests where the DT 5000 was positive for amphetamines and Friends was positive for methamphetamines

Point-of-collection saliva tests are the only one of these two tests that can be used for both contexts. While Friends Medical Laboratory analyzes most saliva samples by EIA on the same day received, the time involved in shipping samples still precludes the officer's ability to use the evidence as the basis for probable cause. A test that can be collected and completed in less than ten minutes, however, fills this purpose more suitably. It is clear from the data on the Tables 3 and 4 that the predictive nature and analytical capability of the Dräger DrugTest® 5000 is comparable to oral fluid sent off for analysis, and a more advantageous platform for use as a screening test methodology.

Oral fluid as a basis for the validation of Drug Recognition Expert (DRE) evaluations

Although it may be possible to analyze saliva for drugs from all seven of the DEC classifications, only 4 and 5 categories can be observed on the standard 6-panel test-kit of the DrugTest® 5000 or were observed by Friends Medical Laboratory respectively. This is not surprising, as hallucinogens and inhalants are very rare DRE calls in general. No drugs from either of these categories were found in any of the subjects' urine specimens during this study, nor were they the conclusion of any of the DRE evaluations. Even the dissociative analgesic category that includes such drugs as phencyclidine and dextromethorphan comes up infrequently in DRE evaluations[19].

Table 5 gives a complete breakdown of every DRE evaluation that was performed as well as a determination of the success rate for confirmation of the DRE opinion based on the biological matrix and methodology performed. These evaluations included medical or alcohol rule-outs, as well as five instances in which the DRE did not record his opinion on the DRE face sheet. Overall, the successful call rate for the DREs involved with this study based on urine, the current standard, was 92.9%. This is well within the guidelines of a minimum 80% successful call rate. Also, this percentage varied significantly between the single drug call evaluations and the multidrug call evaluations. This is due most likely to the different standards for acceptance. For a call on a single drug category to be validated, a drug from that category must be found in the subject's body. If two drug categories are called, at least one of the named drug categories must be represented in the subject, and if three drugs are called, at least two of the named drug categories must be present. This approach makes a two-drug call much easier to validate, and is probably responsible for the increased success rate for the evaluation validations.

While the saliva samples also showed increased validation percentage on multidrug calls, the DRE validation rate by oral fluid was significantly lower than it was for urine. Also, the saliva methodology utilized did not make a significant difference in the overall results. Even if the dissociative anesthetics category was disregarded for the DrugTest® 5000 , the validation rate, while increasing, would only increase to 67.4% overall for the four categories that the standard 6-panel test-kit can analyze. This being the case, it can be stated without any codicil that oral fluid testing is not yet at a level sufficient to be used as a validation tool for Drug Recognition Expert subject evaluations.

Table 5: DRE Evaluation Conclusions by Category and by Test Methodology

Category	DRE CALLS	Evals with Urine	Calls Validated by Urine	% Validated by Urine	Evals with Friends Saliva	Calls Validated by Friends	% Validated by Friends	Evals with DT 5000	Calls Validated by DT 5000	% Validated by DT 5000
Single Drug Conclusions										
Cannabis	33	30	28	93.3%	29	17	58.6%	33	24	72.7%
CNS Depressant	9	7	6	85.7%	8	5	62.5%	9	1	11.1%
CNS Stimulant	6	5	4	80.0%	6	4	66.7%	5	4	80.0%
Dissociative Anasthetic	7	7	7	100.0%	4	3	75.0%	7	0	0.0%
Hallucinogen	0	0	0	n/a	0	0	n/a	0	0	n/a
Inhalant	0	0	0	n/a	0	0	n/a	0	0	n/a
Narcotic Analgesic	18	16	14	87.5%	16	11	68.8%	18	13	72.2%
Single Drug Totals	73	65	39	90.8%	63	40	63.5%	65	42	64.6%
Multi-Drug Conclusions										
Cannabis, Depressant	6	6	6	100.0%	4	4	100%	6	5	83.3%
Cannabis, Narcotic	3	3	3	100.0%	3	2	66.7%	3	2	66.7%
Cannabis, Stimulant	4	3	3	100.0%	3	3	100.0%	4	4	100.0%
Depressant, Narcotic	4	4	4	100.0%	0	0	n/a	4	3	75.0%
Depressant, Stimulant	2	2	2	100.0%	0	0	n/a	2	2	100.0%
Cannabis, Narcotic, Depressant	2	2	2	100.0%	1	0	0.0%	2	0	0.0%
Multi-Drug Totals	21	20	20	100.0%	11	9	81.8%	21	16	76.2%
Complete Totals	**104**	**85**	**79**	**92.9%**	**74**	**49**	**66.2%**	**86**	**58**	**67.4%**
Medical/Alcohol Ruleout	5	5	n/a	n/a	4	n/a	n/a	5	5	n/a
No Conclusion Listed	5	3	n/a	n/a	3	n/a	n/a	5	5	n/a

Conclusion

There are certain elements of this capability and instrumentation that this study does not adequately answer. As methodologies with different limits of detection (LOD) were employed, a more thorough investigation involving spiked samples with known drug concentrations would give a more thorough basis for making methodology comparisons. Furthermore the use of urine, while helpful, makes uncertain the value of some of the comparisons given herein. A similar study, with blood collected rather than urine and with analyzation carried out by chromatography and mass spectrometry, would give quantitative results that could be compared to the qualitative appearance rate within saliva, especially if more concrete saliva LODs had been determined. It may also be advantageous to conduct OF testing in a laboratory that can provide quantitative results. These changes would give more defining values for the effectiveness of oral fluid as a biological matrix and would not potentially confound comparisons due to artifact drug presence in urine. It would also be beneficial for the Dräger DrugTest® 5000 to be tested in a mobile application, as one of the greatest benefits to law enforcement of point-of-collection OF analysis would be in the development of probable cause for arrest. Examination of its effectiveness in a Breath Alcohol Testing van or similar setting may be desirous.

Given these shortcomings, oral fluid still has many advantages over other biological matrices for the determination of drugs of impairment within the human body. While the use of OF testing to validate Drug Recognition Expert evaluations is not yet warranted, oral fluid's positive predictive ability makes saliva a safe, noninvasive, practical and reliable matrix for the screening of subjects for drug impairment. Additionally, the point-of-collection saliva analyzer examined through this study, the Dräger DrugTest® 5000, displayed comparable sensitivity to OF samples analyzed in a laboratory setting except in the case of benzodiazepines. For other drug categories, including cannabis, the DrugTest® 5000 was more sensitive than the laboratory analyzed saliva samples used in this study. For those institutions looking for a reliable method for screening for drugs of impairment, point-of-collection oral fluid analyzers, and the Dräger DrugTest® 5000 in particular, are fit-for-purpose in providing this capability in a meaningful and reliable way.

Acknowledgements

The Missouri Safety Center would like to thank the Lees Summit Police Department, the St. Charles County Sheriff Department, and the Springfield Police Department for collecting the samples, the Missouri State Highway Patrol Crime Laboratory for analyzing the urine samples for this study, and Dräger for their technical assistance and the loaning of equipment to aid in accomplishing this research project.

Explanation of Author Involvement

This research project remains the property of the Missouri Safety Center and the University of Central Missouri. The study used in this evaluation was developed, organized, conducted, and approved by the Missouri Safety Center. The UCM Human Subjects Review Committee gave approval for the performance of this study on October 9, 2009[20], the Missouri Safety Center and the University paid for all costs associated with instrumentation and supplies needed, and author

involvement with this study was restricted to 1) limited advice and expertise in study setup after submission to and approval by the Committee, 2) acting as the data collection point for all participants, and 3) evaluation of the collected data.

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