ORAL FLUID ROADSIDE ANALYSIS
PILOT PROGRAM

FEBRUARY 2019

ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

Pursuant to the reporting requirements of Public Act 243 of 2016, this report that details the findings of the Oral Fluid Roadside Analysis Pilot Program has been prepared for submission to the Senate Judiciary and Public Safety Committee and the House Judiciary Committee. This report contains all the minimum requirements listed in Public Act 243 of 2016, along with the statistical data relating to the outcomes of the oral fluid test instrument, comparative voluntary oral fluid sample independent laboratory analyses, and Michigan State Police (MSP) Forensic Science Division (FSD) evidentiary blood analyses.

This report is presented on behalf of the subject matter experts who were assembled to serve on the Oral Fluid Roadside Analysis Pilot Program Committee.

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INTRODUCTION

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

According to the MSP Criminal Justice Information Center, 98 people lost their lives in drug-impaired driving crashes in 2007. By 2017, drug-impaired traffic fatalities had increased by 151 percent to total 246 fatalities resulting from drug-impaired crashes in Michigan (Michigan State Police [MSP], 2018). Nationally, drugged driving is gaining attention due to increased prescription drug abuse and recent cannabis legalization (Veitenheimer & Wagner, 2017). In 2014, 10.1 million people 16 years of age and older reported driving under the influence of drugs within the past year in the United States (Veitenheimer & Wagner, 2017).

Currently, police officers in Michigan do not have instruments available for use on the roadside to assist with establishing probable cause pursuant to operating while impaired investigations, despite oral fluid preliminary screening devices becoming more robust and reliable (Stefano, Solimini, Tittarelli, Mannocchi, & Busardo, 2016).

Preliminary oral fluid drug screening on the roadside has many benefits. Studies have shown that drugs accumulate in the oral fluid by passive diffusion from the blood (Cone & Huestis, 2007). Certain drugs tested in oral fluid are well correlated with positive results from the same drug when tested in the blood (Moore & Miles, 2015). Collecting oral fluid from a driver on the roadside can be easy, quick, and non-invasive. There is limited risk of adulteration with the oral fluid sample and the collection is painless (Edwards, Smith, & Savage, 2017). Oral fluid collection can occur at the scene, close to the time the driver was operating a vehicle (Moore & Miles, 2015). The oral fluid test instrument provides the investigating police officer positive or negative test results, within five minutes, on recent drug intake (Alere Toxicology, 2019).

Michigan law states, “The amount of alcohol or presence of a controlled substance or other intoxicating substance in a driver’s blood or urine or the amount of alcohol in a person’s breath at the time alleged as shown by chemical analysis of the person’s blood, urine, or breath is admissible into evidence in any civil or criminal proceeding and is presumed to be the same as at the time the person operated the vehicle” (Legislative Service Bureau, 2019). An evidentiary chemical breath test is typically used to determine if a driver is impaired by alcoholic liquor. Both evidentiary blood and urine are generally used to determine identification and quantification of a controlled substance or other intoxicating substance. The Toxicology Unit of the MSP Forensic Science Division analyzes evidentiary biological (blood and urine) specimens. The Toxicology Unit tests approximately 16,000 evidentiary blood cases for the presence of alcohol, and approximately 5,500 cases for the presence of drugs per year (MSP, 2019). Evidentiary urine was tested by the Toxicology Unit approximately 140 times per year; the vast majority of which were not related to impaired driving investigations (Bowen, personal communication, January 16, 2019).

INTRODUCTION

Blood is considered the "gold standard" for drug analysis in driving under the influence of drugs (DUID) cases (Moore & Miles, 2015). However, there are some drawbacks to utilizing blood for evidentiary purposes. Obtaining a blood sample from a driver requires transporting a driver to a hospital to have blood drawn by a medical professional, which can take several hours, especially if the impaired driver does not consent to a blood draw and a search warrant must be obtained. Some drugs, such as Δ^9-tetrahydrocannabinol (THC) the most psychoactive of the principal constituents of marijuana, metabolize quickly within the body (Hartman, et al., 2016). The loss of THC in-vitro must be taken into consideration when analysis of cannabinoid positive blood samples is not immediate (Scheidweiler et al., 2013). Further, securing a blood sample requires phlebotomy or puncturing the skin with a needle. This process, also known as venipuncture, is considered invasive (Yamada, Yamada, Katsuda & Hida, 2008). Blood analysis may take several weeks to complete and despite efforts to preserve the blood in the test tube by using preservatives and optimizing storage conditions, some drugs inevitably break down and/or metabolize over time. One example of this is when cocaine breaks down into its primary metabolite, benzoylecgonine (Peaire, et al., 2017).

Utilizing oral fluid for preliminary drug screening has the potential to expedite the drug-impaired driving investigation process. Since oral fluid has a short drug detection window, it makes an ideal specimen to collect (Veitenheimer & Wagner, 2017). Oral fluid is collected very close to the time the driver was operating a vehicle, lending additional credibility to the test results and drivers may be more inclined to consent to a non-invasive oral fluid swab versus a blood draw.

A Feasibility Study of Roadside Oral Fluid Drug Testing concluded that officers preferred oral fluid as a test medium, over sweat or urine, due to the ease of collection and its minimally invasive nature (Asbridge & Ogilvie, 2015).

BACKGROUND

On March 20, 2013, a traffic crash at the intersection of US-2 and South Hill Road in Gladstone, Michigan took the lives of Thomas and Barbara Swift of Escanaba. The couple died of injuries sustained when their vehicle was struck by a semi-trailer truck that disregarded the red light at the intersection and collided with their vehicle (Truck Driver Sentenced in Gladstone Fatal Crash, 2014).

The driver of the at-fault semi-trailer truck was charged with six felonies in connection to the fatal crash: two counts of operating a motor vehicle with the presence of a controlled substance causing death (THC); two counts of reckless driving causing death; and two counts of operating with a suspended license causing death (Gwinn Truck Driver Charged in Deadly Accident, 2013). Following a trial, the jury found the driver guilty on all six felonies and he was sentenced to a minimum of five and a half years in prison (Marquette County Man's Appeal Denied in Fatal Crash Case, 2015).

Following the loss of his parents, Brian Swift contacted Senator Thomas Casperson who introduced Senate Bill 207 and Senate Bill 434 to combat drug-impaired driving by implementing an oral fluid roadside analysis pilot program. Both bills passed the Michigan House of Representatives and Michigan Senate and were signed into law by Governor Rick Snyder. Public Act 242 and 243 of 2016, known as the Barbara J. and Thomas J. Swift Law, became effective on September 22, 2016.

SUMMARY OF PUBLIC ACT 243 OF 2016:

Public Act 243 of 2016 authorized the Department of State Police to establish a pilot program in five counties in Michigan for roadside oral fluid testing to determine whether an individual is operating a vehicle while under the influence of a controlled substance. The legislation stipulates that the preliminary oral fluid test will be performed by a certified Drug Recognition Expert (DRE). A certified drug recognition expert means a law enforcement officer trained to recognize impairment in a driver under the influence of a controlled substance rather than, or in addition to, alcohol.

The MSP was tasked with developing a written policy and authorized to promulgate administrative rules as necessary for the implementation of the roadside oral fluid testing pilot program (Legislative Service Bureau, 2015).

SUMMARY OF PUBLIC ACT 242 OF 2016:

Public Act 242 of 2016 states that a peace officer who is certified as a DRE may administer a roadside oral fluid test if they have reason to believe a driver is operating a vehicle under the influence of a controlled substance, and the DRE may arrest a person in whole, or in part, upon the results of a preliminary oral fluid analysis. A person who refuses to submit to a preliminary oral fluid analysis upon a lawful request by a peace officer is responsible for a civil infraction.

A DRE participating in the pilot program shall order out of service, a person who was operating a commercial motor vehicle and who refuses to submit to a roadside oral fluid test. The DRE shall advise a commercial vehicle operator that refusing to submit to a preliminary roadside oral fluid test request is a civil infraction and will result in the issuance of a 24-hour out-of-service order (Legislative Service Bureau, 2015).

SELECTION OF ROADSIDE ORAL FLUID TEST INSTRUMENT

The Oral Fluid Roadside Analysis Pilot Program Committee researched the capabilities of several models of oral fluid test instruments by manufacturers that included: Noble, Securetec, Oranoxis, Protzek, Abbott (formerly Alere Toxicology), SmartTox, and Draeger.

Each instrument was evaluated with a goal of selecting an instrument that included the following criteria:

- Portable handheld instrument for ease of use in the field
- Rechargeable and fully automated Analyzer
- On-screen instructions
- Results within 5 minutes or less
- THC cutoff level no higher than 25 ng/ml
- Includes an on-board heater to ensure tests run at optimal temperature
- Battery life capable of running up to 50 tests
- Printer included with device
- Collection device separate from test cartridge
- Collection device has a volume adequacy indicator
- Capacity to retain at least 1000 test records
- Buffer solution integrated with test cartridge
- Positive and Negative quality control (QC) cartridges included with instrument
- Minimum test panel to include: amphetamines, methamphetamines, opiates, cocaine, benzodiazepines, and cannabinoids

After manufacturer presentations, the Committee selected the Alere DDS2 test instrument.

The Alere DDS2 oral fluid test instrument is capable of testing for the below six drug classes (cut-off levels are established by the oral fluid test instrument manufacturer).

Drug Class	Cutoff (ng/mL)
Amphetamine	50
Benzodiazepines	20
Cannabis (Δ^9 THC)	25
Cocaine	30
Methamphetamine	50
Opiates	40

PROCEDURES FOR THE USE OF ROADSIDE ORAL FLUID TEST INSTRUMENT

At the beginning of each shift, the DRE is required to perform negative and positive quality control checks with the oral fluid test instrument. These performance checks are done prior to each shift to ensure the instrument is functioning properly.

The nanogram per milliliter (ng/mL) in oral fluid is much different than the equivalent ng/mL in blood. A study in the Journal of Analytical Toxicology compared equivalent cutoff threshold levels in blood versus oral fluid and found that each drug class has varying degrees of differences in the ng/mL level found in blood versus the ng/mL level found in oral fluid.

For example, 1 ng/mL of THC in the blood would be equivalent to approximately 44 ng/mL in oral fluid (Gjerde, Langel, Favretto, & Verstraete, 2014).

Substance	Cut-off in Whole Blood (ng/mL)	Cut-off in Oral Fluid (ng/mL)
Amphetamine	20	290
Cannabis (Δ^9 THC)	1.0	44
Cocaine	10	190
Methamphetamine	20	630

ROADSIDE USE

Since 2010, the Michigan Commission on Law Enforcement Standards (MCOLES) has required all police officers completing a basic police academy training program to receive Standardized Field Sobriety Test (SFST) instruction. The SFST training curriculum prepares police officers and other qualified persons to conduct the SFSTs for use in driving while impaired investigations (National Highway Traffic Safety Administration, 2018).

A DRE receives additional, highly specialized training to assist in identifying drivers under the influence of drugs other than, or in addition to, alcohol (International Association of Chiefs of Police [IACP], n.d.). The DRE protocol is a standardized and systematic method of examining a suspected drug-impaired driver to determine the following: (1) whether or not the suspect is impaired; if so, (2) whether the impairment relates to drugs or a medical condition; and if drugs, (3) what category or combination of categories of drugs are the likely cause of the impairment. The process is systematic because it is based on a complete set of observable signs and symptoms that are known to be reliable indicators of drug impairment (IACP, n.d.).

There are a number of ways in which a DRE participating in the Oral Fluid Roadside Analysis Pilot Program might encounter a suspected drug-impaired driver. The contact may be the result of a traffic stop, a response to a dispatched call to check on a person/vehicle, a response to the scene of a traffic crash, or a request by another police officer to assist at a scene where a suspected drug-impaired driver is present. Impairment can be assessed through a variety of observations that precede the DRE process:

- Driving behaviors that may include: failure to maintain lane of travel, disregarding traffic control devices, driving with headlights off, weaving/drifting within and across lanes, excessively wide turns, following too closely, excessive speed, speed significantly slower than posted limits, etc.
- Driver behavior that may include: difficulty finding license, slurred speech, bloodshot glassy eyes, swaying, balance problems, odor of drugs / intoxicants about the driver, etc.
- Completion of SFSTs.
- If alcohol impairment is suspected, the driver may be asked to submit to a Preliminary Breath Test (PBT).

If drug impairment is suspected, the DRE may ask the driver to provide two oral fluid samples. With driver agreement, the first sample will be collected for the Alere DDS2 oral fluid test instrument. The DRE will insert a new sterile test cartridge into the test instrument. The instrument will detect the test cartridge and verify the cartridge as valid. The DRE will then remove the oral fluid collection device from the packaging by the handle. The DRE, or the driver, will then actively swab the device inside the mouth, around the gums, tongue, and inside the cheek, until the adequacy indicator on the collection device turns blue. Once enough oral fluid is obtained, the DRE will then insert the collection device into the Alere DDS2 oral fluid test instrument.

The Alere DDS2 will then analyze the results of the sample. The device will display “test in progress,” along with a countdown timer. Results of the test will be displayed in approximately five minutes.

ROADSIDE USE

After a test has been administered and analysis by the instrument completed, the instrument will display either positive, negative, or invalid for each of the listed drug classes.

A positive test result indicates the presence of the drug in the driver's oral fluid in an amount that exceeds the cutoff level. It does not indicate a level of impairment.

If the oral fluid results are below the cutoff level, the instrument will display a negative reading. A negative test result does not confirm the absence of drugs in the oral fluid, only that the specified level of a drug, or drugs, in a driver's oral fluid were below the threshold cutoff level (Alere Toxicology, 2015). A negative result may also be obtained if there is an intoxicating substance in the driver's system that is not part of the drug screening panel. Therefore, a negative reading does not preclude the driver from being impaired by another intoxicating substance that is not included on the drug screening panel.

The oral fluid test instrument may display an "invalid" reading for a specific drug category or categories. An invalid reading may be due to an insufficient volume of oral fluid within the test cartridge. A lack of oral fluid would cause the instrument to not properly read a category(s) of drug, resulting in an invalid result (Alere Toxicology, 2016). An invalid result in one or more drug categories does not negate positive and/or negative readings in other drug categories.

The second sample, considered a voluntary sample, is collected using the Quantisal® oral fluid collection device. The DRE will instruct the driver to remove the collector from the package then position the collector under the tongue then close his/her mouth. The driver will be instructed not to chew on the pad or talk until the indicator turns blue, or 10 minutes has lapsed. The DRE will then insert the collector into the Quantisal transport tube and securely replace the cap for transport. The DRE will complete the Quantisal paperwork and send the sample to the selected independent laboratory, Forensic Fluids Laboratories (FFL).

FFL was selected for this pilot as the accredited independent laboratory, used for confirmation testing of the second oral fluid sample to ensure the accuracy and reliability of the Alere DDS2 oral fluid test instrument. FFL tests for the six drug class panels: amphetamines, methamphetamines, opiates, cocaine, benzodiazepines, and cannabinoids, consistent with the selected oral fluid test instrument. FFL provides for a turn-around time of 24 hours or less.

COUNTIES SELECTED

The counties selected for the Oral Fluid Roadside Analysis Pilot Program were chosen based on the number of serious injury and fatal traffic crashes involving impaired driving, trained DRE and DRE prosecutors in the county, their knowledge of the program and willingness to participate in the pilot, and to reflect Michigan's highly varied population density.

Counties	DREs	DRE Prosecutor	Impaired Driving Arrests	Impaired Driving Traffic Crashes
Berrien Berrien County Sheriff's Office Lincoln Township Police Department Michigan State Police, Niles Post	7	1	761	177
Delta Escanaba Department of Public Safety Michigan State Police, Iron Mountain, and Gladstone posts	3	0	194	30
Kent Kent County Sheriff's office Grand Rapids Police Department Michigan State Police, Rockford Post	8	3	1842	817
St. Clair St. Clair County Sheriff's Office Michigan State Police, Lapeer Post	3	1	550	141
Washtenaw Ann Arbor Police Department University of Michigan Police Department Washtenaw County Sheriff's Office Pittsfield Township Police Department Ypsilanti Police Department Michigan State Police, Brighton Post	10	1	994	332

MSP (2016)

PILOT PROGRAM POLICIES

The MSP created policies and procedures regarding the Oral Fluid Roadside Analysis Pilot Program. In addition, a Memorandum of Agreement (MOA) was executed by the MSP and partnering agencies to ensure adherence to program policies and procedures.

Prior to participation in the program, DREs attended a one-day training session to include:

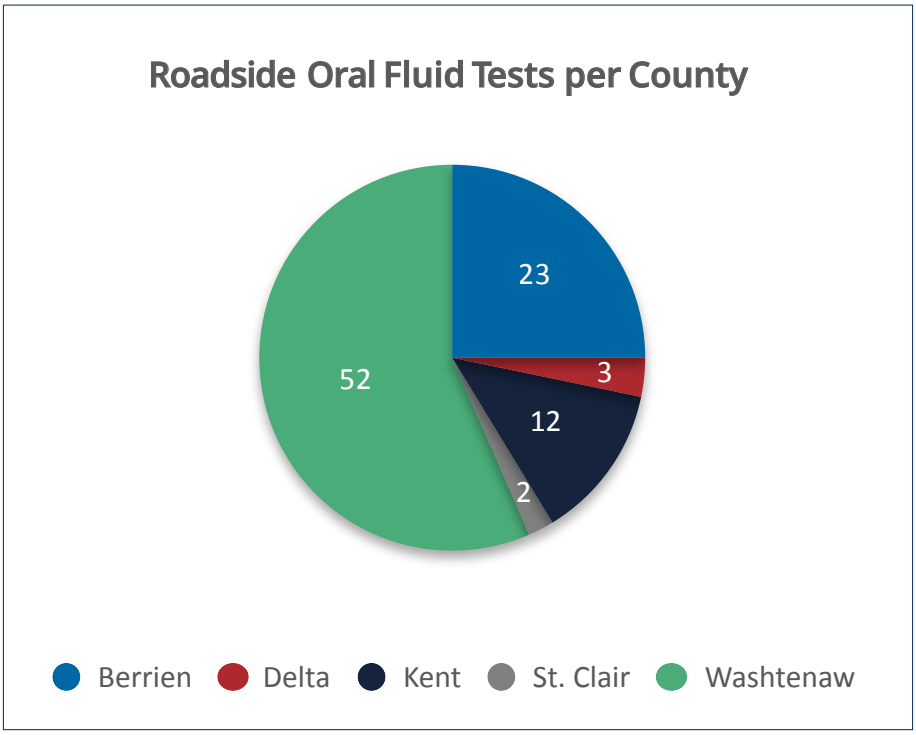
- History of the Oral Fluid Roadside Analysis Pilot Program
- Review of Public Acts 242 and 243 of 2016
- Proper Utilization of the Alere DDS2 Oral Fluid Test Instrument
- Forensic Fluids Independent Laboratory—collection of voluntary oral fluid test sample
- Reporting Requirements and Utilizing Proper Forms

Consistent with instructions outlined in the MOA, DREs were expected to follow MSP policies when investigating operating under the influence of drugs investigations.

RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

DRE initiated traffic stops and impaired driving investigation results, including traffic crashes, occurring between November 8, 2017 – November 8, 2018, are included in the pilot program results.

92 oral fluid roadside tests were conducted using the Alere DDS2 test instrument at the roadside, with one refusal to participate.



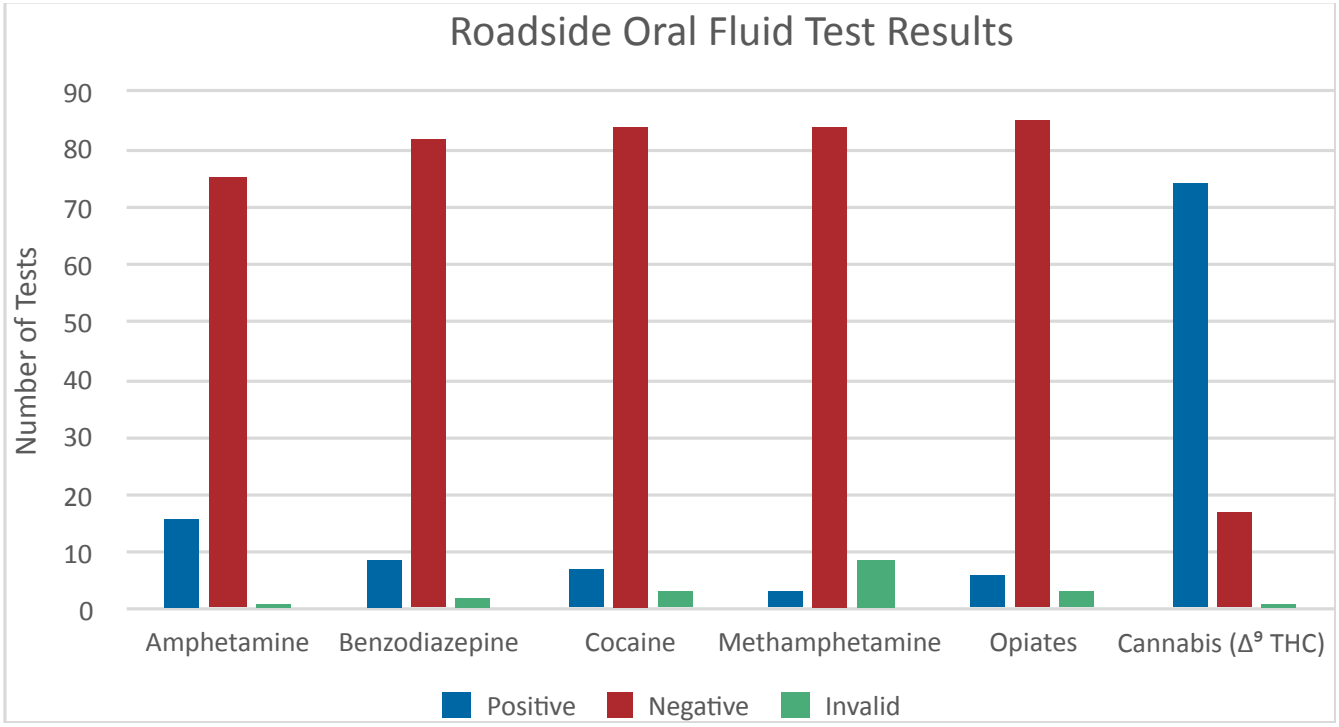
62 second voluntary oral fluid tests were collected using the Quantisal® oral fluid collection device with the balance of instances, 30, either being refused or not offered.

As a result of DRE-observed driver behavior and SFSTs, 89 drivers were arrested during the pilot program. Of those, positive oral fluid roadside test results were reported for 83 drivers.

Of the 89 drivers arrested, 79 consented to an evidentiary blood test. Additionally, eight search warrants were obtained. Two drivers were arrested without participating in the blood test: one fled and one was charged with marijuana possession.

Negative oral fluid roadside test results in all drug categories were recorded in four instances where drivers were released.

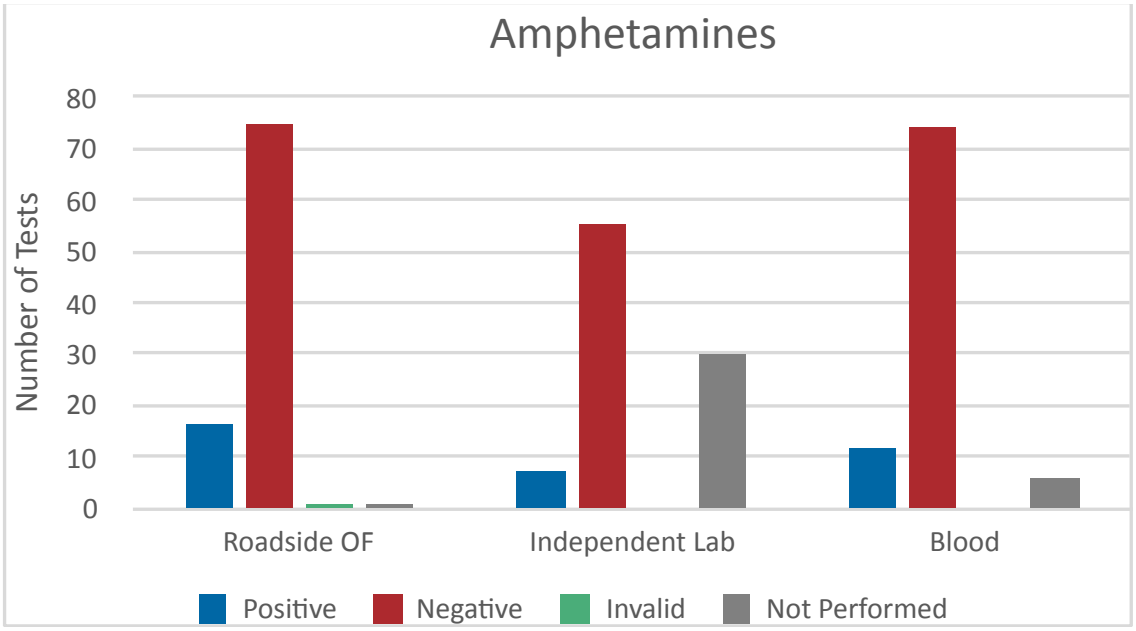
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

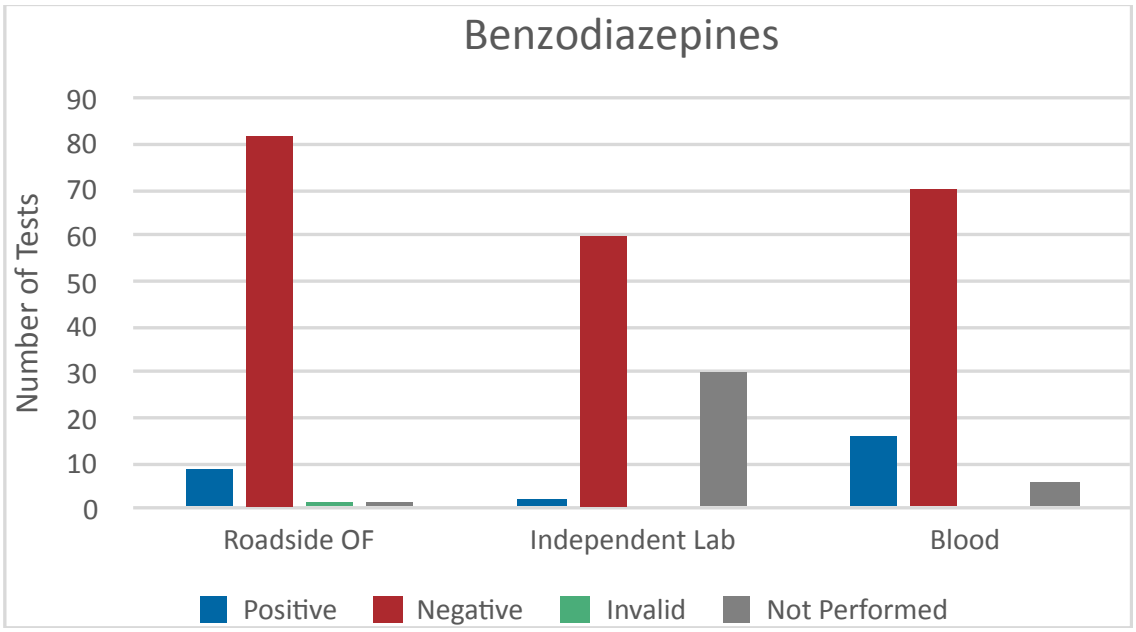


Results of the oral fluid roadside tests utilizing the Alere DDS2 instrument are detailed in the above chart. Of the 92 oral fluid roadside tests conducted, 21 returned positive results for the presence of two or more drugs. Eight tests provided negative results for all six drug categories. Six negative test results were further validated by either FFL independent lab results, MSP forensic lab results, or both, showing negative results as well.

RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:





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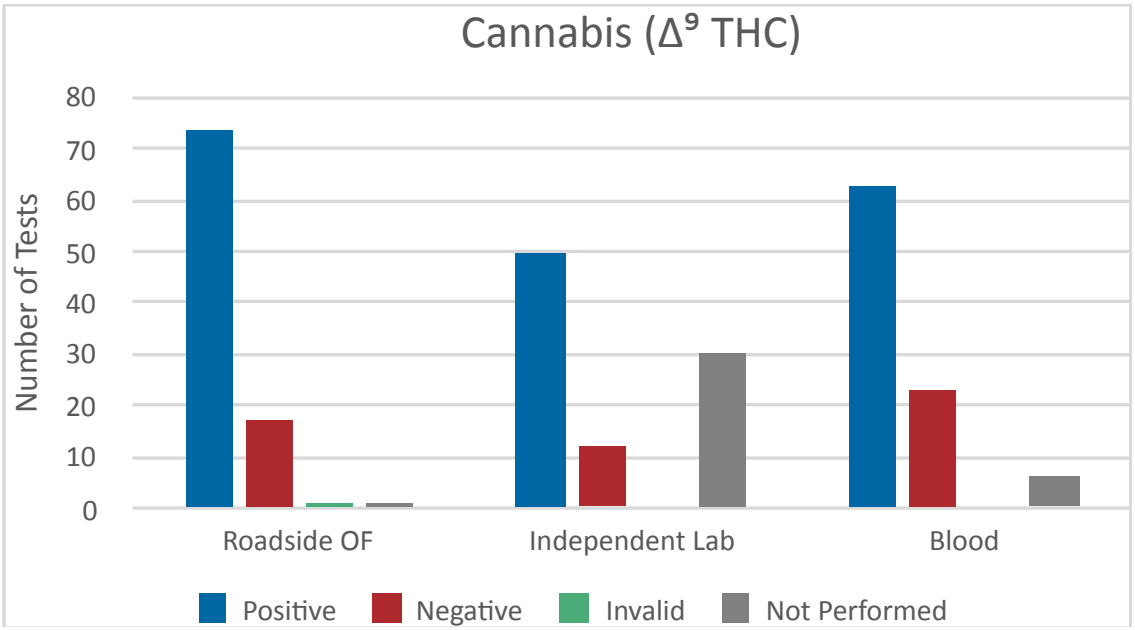

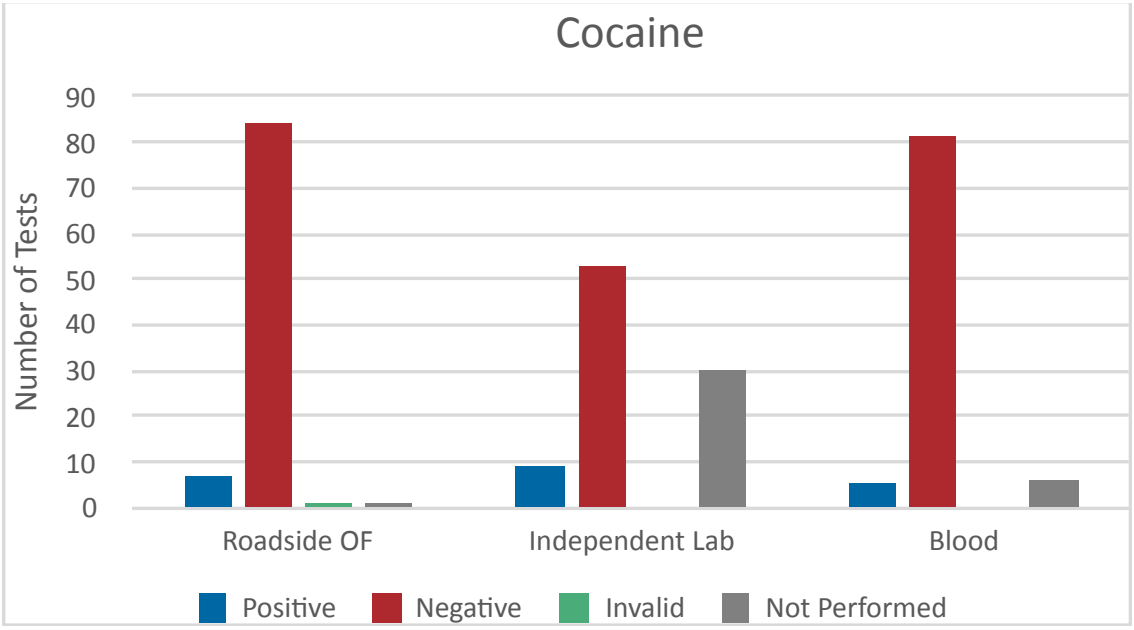

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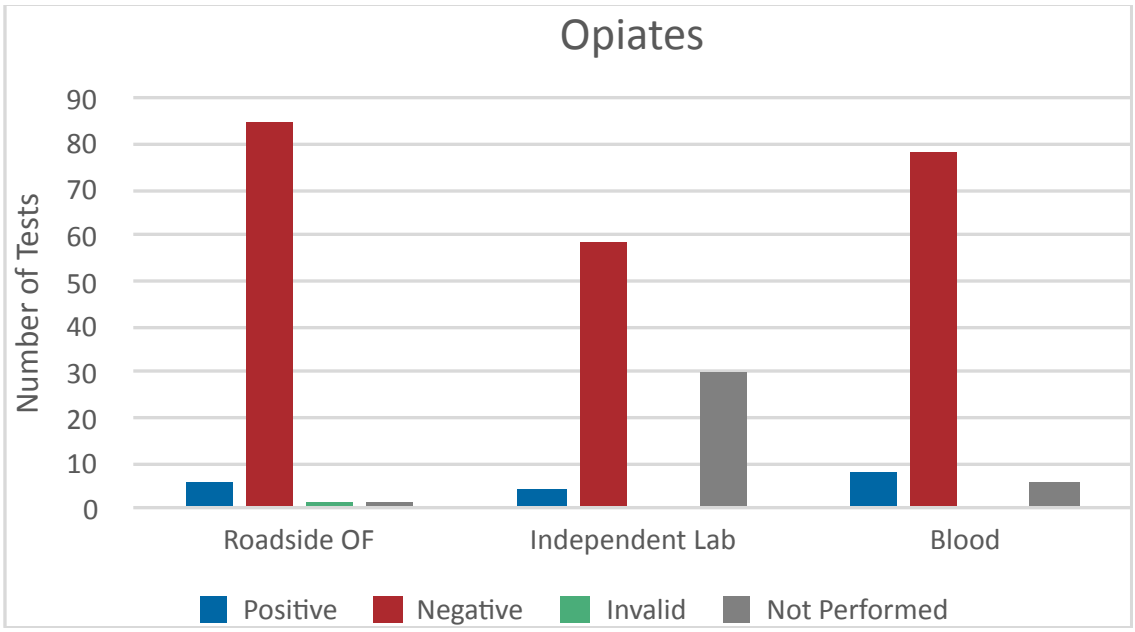

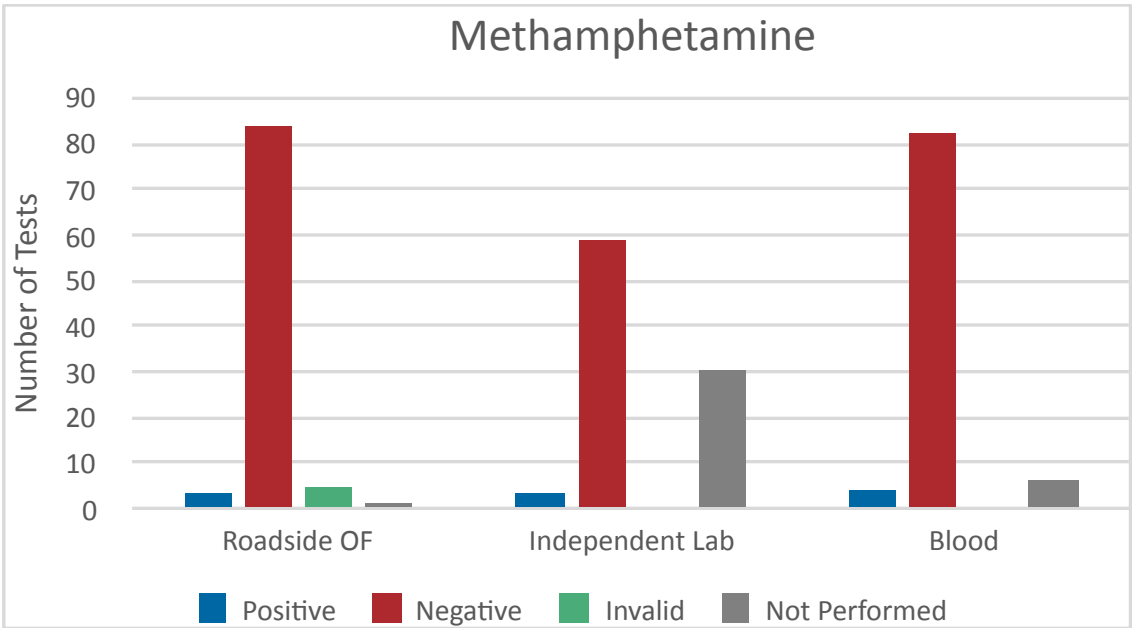

RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

When comparing test data from the oral fluid tests (roadside and voluntary) and blood tests, several differences are noted. These differences, depicted in the above charts, can be attributed to the variables present in this pilot project, including: number of samples in each test category, medium tested, time from sample collection to testing, instrument sensitivity (threshold cut-off levels), and testing procedures.

In this pilot, not every driver provided a sample for testing in all three subgroups (roadside, voluntary, blood). Both oral fluid and blood were tested for the presence of predetermined drug classes. However, there is no direct numeric correlation between the results of an oral fluid test and blood test, i.e. 1 ng/mL in oral fluid does not equate to 1 ng/mL in blood. The oral fluid test(s) were collected in close proximity to when the driver was operating the vehicle. Conversely, the collection of the blood sample could be hours after the initial police contact and the subsequent testing could be several weeks after. This time lapse could impact testing results as drugs breakdown into metabolites while in the bloodstream. Blood samples were tested for the presence of drug metabolites; oral fluid samples were not tested for metabolites.

The Alere DDS2 roadside oral fluid test instrument is a screening instrument, which gives a positive or negative test result, rather than a quantitative result (specific nanogram level). The Alere DDS2 also has specified threshold cut-off levels which are set by the manufacturer for each tested drug class. With one exception (Benzodiazepines), cut-off threshold levels are higher for the roadside test than the voluntary test. In some instances, the cutoff levels are significantly higher. Consequently, the Alere DDS2 roadside oral fluid test instrument may produce a negative result in a drug category while the voluntary test may indicate a positive result.

The presence of a metabolite is considered confirmation of the parent drug. Noting the above variables, 88 of the 92 oral fluid roadside test results were confirmed by the independent laboratory and/or evidentiary blood test results.

Statistical analyses was performed by Michigan State University statistician, Dr. Dhruv Sharma, Ph.D. The results of this analysis are attached as an appendix to this report.

The specific procedures and instrumentation used to perform the voluntary oral fluid test analyses, and the blood analyses, are also attached as appendixes to this report.

CONVICTIONS

Sixty-two traffic stops resulted in an arrest for operating under the influence of a controlled substance in violation of Section 625 as a result of roadside drug testing by a certified DRE. Twenty-seven additional arrests were made as a result of impaired driving investigations to include traffic crashes.

As of December 20, 2018, 38 drivers have been convicted of 47 charges, noting that individuals can be convicted in more than one category.

Forty-nine cases pend a final court disposition. One case was dismissed and one case was not prosecuted.

Number of Convictions	Applicable MCL
18	257.6253A - Operating - Impaired
11	257.6258 - Operating - With the Presence of a Controlled Substance
5	257.6251A - Operating While Intoxicated
2	257.6256B - Operating - While Intoxicated/Impaired - 2nd Offense Notice
1	257.6251C - Operating with a High BAC
1	257-6256D – Operating – While Intoxicated/Impaired – 3rd Offense
4	333.74032D - Controlled Substance - Possession of Marihuana/Synthetic Equivalents
1	333.74042B - Controlled Substance - Use of Marihuana/Synthetic Marihuana/Spice/Salvia
4	750.81D1 - Police Officer - Assaulting/Resisting/Obstructing

RECOMMENDATION

Traffic enforcement is critical to improving traffic safety and keeping Michigan motorists safe on our roadways. Improving traffic safety remains one of the MSP's highest priorities. Identifying drug-impaired drivers, a priority of traffic enforcement efforts, presents unique challenges not inherent to identifying those that are alcohol impaired. Not all police officers in Michigan have received specialized training enabling them to identify and properly investigate drug-impaired drivers. In addition to seeking such specialized training, making a roadside oral fluid analysis instrument available to a greater number of police officers warrants further consideration.

Pursuant to Public Act 243 of 2016, it is the recommendation of the Oral Fluid Roadside Analysis Pilot Program Committee that the pilot program be expanded for one year to include all DREs in the state of Michigan.

Expansion of this pilot program will allow a greater number of police departments in Michigan to take advantage of the expertise of participating DREs to assist with traffic stops and drug-impaired driving investigations. Arresting drug-impaired drivers can be expected to mitigate serious injury and fatal traffic crashes throughout Michigan.

All DREs in the state of Michigan will be eligible to participate in the expanded pilot program, subject to a properly executed MOA. Participating DREs will be issued an oral fluid test instrument and available to assist when called to respond to a traffic stop or impaired driving investigation. At the time of this report, there were 137 DREs in 46 counties throughout Michigan. A DRE school in January 2019 is expected to add up to 22 DREs, resulting in a total of up to 159 DREs throughout the state.
The MSP will continue to be responsible for the functions of the Oral Fluid Roadside Analysis Pilot Program, including, but not limited to; handling all policies and procedures, equipment and supplies management, capturing and analyzing data obtained from the extended pilot program, and program training for participating DREs.

The recently completed Oral Fluid Roadside Analysis Pilot Program provided valuable data on the overall performance and utility of the Alere DDS2 device. However, the data set for certain drug classes was not of a suitable sample size to achieve high confidence levels in the obtained result. The additional data expected to be obtained from an expanded pilot program may improve the overall confidence in the accuracy, sensitivity, specificity, positive predictive values, and negative predictive values of all six drug categories of the Alere DDS2 device. If analysis of this additional data set yields a high level of confidence, and the utility of the device is favorable in the opinion of the participating officers, the results of the pilot may support revision of the Michigan Vehicle Code to permit preliminary oral fluid analysis for the detection of certain drug categories. By conducting the much larger extended Oral Fluid Roadside Analysis Pilot Program, the state of Michigan may also provide invaluable information to other states.

In December 2018, the Michigan Legislature agreed to support the ongoing funding of the oral fluid pilot and the expansion of the pilot program to additional interested, qualified counties around the state. An appropriation of $626,000 for the extension of the Oral Fluid Roadside Analysis Pilot Program was included in the supplemental funding bill that became Public Act 618 of 2018.

In the coming months, the MSP will continue its work to acquire the necessary equipment and develop specific policies, procedures, and data collection requirements to support the necessary analyses of the expanded pilot program.

ACKNOWLEDGEMENTS

The Oral Fluid Roadside Analysis Pilot Program Committee would like to thank the Michigan Legislature for the continued support, dedication, and appropriations for the Oral Fluid Roadside Analysis Pilot Program.

The Committee would also like to thank the following people, companies, and law enforcement agencies for their contributions to the success of the Oral Fluid Roadside Analysis Pilot Program.

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Mr. Brian Swift

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LAW ENFORCEMENT AGENCIES & DREs:

Berrien County Sheriff's Office

Lincoln Township Police Department

Escanaba Department of Public Safety

Grand Rapids Police Department

Kent County Sheriff's Office

St. Clair County Sheriff's Office

Ann Arbor Police Department

University of Michigan Police Department

Washtenaw County Sheriff's Office

Pittsfield Township Police Department

Ypsilanti Police Department

Michigan State Police Posts: Brighton, Gladstone, Iron Mountain, Lapeer, Niles, and Rockford

STATISTICAL ANALYSES AND RESULTS:

Two datasets were utilized in the statistical analyses. The first dataset (called Immediate Testing) summarized all the data as collected and tested. The second dataset (called Delayed Testing) summarized the previously listed information, such as test instrument threshold levels and the time delay between the incident and blood draw where the controlled substance in the blood breaks down into a metabolite. In the second dataset, since only Cocaine, Methamphetamines, and THC were affected, only those drugs were further summarized and analyzed. Results for each of the drugs tested are reported in alphabetic order; Amphetamines, Benzodiazepines, Cocaine, Methamphetamines, Opiates and THC. In addition, for Cocaine, Methamphetamines, and THC, the delayed blood testing results are reported, which results in an increase in positive blood test results. Descriptive statistics regarding on-site, voluntary and blood testing results for the six drugs tested are presented in the Appendix in table form (please see Tables A1-A6).

STATISTICAL METHODS:

For the Immediate Testing dataset, on-site, voluntary and blood testing results were compared, while for the Delayed Testing dataset, on-site and voluntary results were compared with blood testing results. These three testing results were compared two at a time, employing cross tables for visualization. Cross tabulation is commonly used for device testing, where the results from a device are compared with a 'gold standard' testing approach. These tables display positive and negative values for the two testing approaches and were used to calculate the overall performance of the device testing approach. Cross tabulation is demonstrated in the table (Table 1) below:

Table 1: Device vs. Gold Standard Cross Table

		Gold Standard	
Device	**Results**	Positive	Negative
	Positive	True Positive (TP)	False Positive (FP)
	Negative	False Negative (FN)	True Negative (TN)

A true positive (TP) result is one where the device detects the presence of a drug when the presence of the drug is confirmed by the gold standard. A true negative (TN) result is one where the drug is absent in device testing and this absence is confirmed by the gold standard. A false positive (FP) result is one where the device detects the presence of a drug when it is in fact absent. A false negative (FN) result is one there the device does not detect the drug while it is detected by the gold standard. The performance of the device testing approaches are assessed using the five measures on the next page.

1. Sensitivity = TP/(TP+FN). Sensitivity measures the number of true positives as a percentage of all positives.
2. Specificity = TN/(TN+FP). Specificity measures the number of true negatives as a percentage of all negatives.
3. Positive Predictive Value (PPV) = TP/(TP+FP). PPV measures the number of true positives as a percentage of reported positives.
4. Negative Predictive Value (NPV) = TN/(TN+FN). NPV measures the number of true negatives as a percentage of reported negatives.
5. Accuracy = (TP+TN)/(TP+FP+FN+TN). Accuracy measures the percentage of all samples correctly classified by the tests.

Inference for these percentages is reported using sample estimates of the measures and their 95% confidence interval using binomial proportions, with the 95% confidence interval calculated using the Agresti Approximation [Citation: Agresti, A., & Coull, B. (1998). Approximate Is Better than "Exact" for Interval Estimation of Binomial Proportions. The American Statistician, 52(2), 119-126. doi:10.2307/2685469]. To explain what is meant by *95% confidence interval*, it should be noted that the key goal in inferential statistics is to draw inferences about unknown *population parameters* based on *sample statistics*. This is done by selecting a representative sample (e.g., *pilot drug testing data*) from the target population and use sample statistics as estimates (the point estimate and confidence interval (CI) estimate) of the unknown parameter. In this case, the sample percentages are used (e.g., *sample accuracy*) to draw inference about the population percentages (e.g., *population accuracy*). A 95% confidence interval means that if 100 different samples were taken and compute a 95% confidence interval for each sample, then approximately 95 of the 100 confidence intervals will contain the true population value. In practice, however, one random sample is selected and generate one confidence interval, which may or may not contain the true mean. The observed interval may over or underestimate the true value. Consequently, the 95% CI is the likely range of the true, unknown parameter. The confidence interval does not reflect the variability in the unknown parameter. Rather, it reflects the amount of random error in the sample and provides a range of values that are likely to include the unknown parameter.

INVALID AND MISSING DATA:

As mentioned earlier in this report, invalid on-site test results occurred in a few samples. There was 1 invalid Amphetamine sample, 2 invalid Benzodiazepine samples, 3 invalid Cocaine samples, 9 invalid Methamphetamine samples, 3 invalid Opiates samples and 1 invalid THC sample. Due to the uncertainty associated with these invalid on-site testing results, the invalid results were considered to be missing while analyzing the results of the study. Please note, that this invalid (missing) data is different from missing data from the voluntary and blood samples. Only valid and non-missing data was used in the analysis.

RESULTS:

Results for the six drugs tested will be discussed in alphabetic order; Amphetamines, Benzodiazepines, Cocaine, Methamphetamines, Opiates and THC. In addition, for Cocaine, Methamphetamines, and THC, additional results for the findings of the delayed blood testing results will be presented. Please see Appendix Tables A1-A6 for descriptive statistics.

1. AMPHETAMINES:

The overall performance of the test instrument is good, apart from the positive on-site test results, which showed a presence of amphetamines in six samples that was not present in the blood. This resulted in a lower than expected PPV (estimate of 62.50%, 95% CI of 38.60% to 81.50%), although this result is improved when comparing the voluntary test results with the blood test results, where there were no FP or FN values, resulting in 100% performance measures. Performance results are presented in the Appendix in table form (please see Table A7).

2. BENZODIAZEPINES:

The overall performance of the test instrument is good, apart from the negative on-site test results, which failed to show a presence of benzodiazepines in eight samples that was present in the blood. This resulted in a lower than expected sensitivity (estimate of 50.00%, 95% CI of 28.00% to 72.00%), which is not improved when comparing the voluntary test results with the blood test results (estimate of 33.30%, 95% CI of 9.70% to 70.00%). Performance results are presented in the Appendix in table form (please see Table A8).

3. COCAINE:

The overall performance of the test instrument is good, with good results in the immediate sample, apart from the positive on-site test results, which showed a presence of cocaine in two samples that was not present in the blood. This resulted in a lower than expected PPV (estimate of 71.40%, 95% CI of 35.90% to 91.80%). These results continue with a higher number of negative blood results (total seven samples) while having higher voluntary results with lower than expected PPV (estimate of 22.20%, 95% CI of 6.30% to 54.70%). When looking at the delayed sample, due to the one sample positive change in the blood testing result in the delayed sample, the overall results are improved, calling attention the need for more efficient blood sample collection and testing. Performance results are presented in the Appendix in table form (please see Tables A9-A10).

4. METHAMPHETAMINES:

The overall performance of the test instrument is good, with good results in the immediate sample, apart from the positive on-site test results, which showed a presence of methamphetamines in one sample that was not present in the blood. This resulted in a lower than expected PPV (estimate of 66.70%, 95% CI of 20.80% to 98.30%). Please note, we caution that this measure was calculated from a very small sample of three. When looking at the delayed sample, due to the one sample positive change in the blood testing result in the delayed sample (the only change), the overall results are vastly improved, with no FP or FN readings, calling attention the need for more efficient blood sample collection and testing. Performance results are presented in the Appendix in table form (please see Tables A11-A12).

5. OPIATES:

The overall performance of the test instrument is good with only one FN reading in both the on-site and voluntary test readings while compared to the blood test readings. Performance results are presented in the Appendix in table form (please see Table A13).

6. THC:

The overall performance of the test instrument is good, with good results in the immediate sample, apart from the positive on-site test results, which showed a presence of THC in 11 samples that were not present in the blood. This resulted in a lower than expected specificity (estimate of 50.00%, 95% CI of 30.70% to 69.30%). When looking at the delayed sample, due to the 6 samples positive change in the blood testing result in the delayed sample, the overall results are vastly improved (specificity improves (estimate of 68.80%, 95% CI of 44.40% to 85.80%)), calling attention the need for more efficient blood sample collection and testing. Performance results are presented in the Appendix in table form (please see Tables A14-A15).

DISCUSSION:

In this analysis, the findings have summarized for the pilot drug testing data, both immediate and delayed. Overall, the device has good performance properties, which are further improved when the blood testing results come from the 'delayed' dataset, calling into attention the need for improvements in the blood collection and testing approach. Although the pilot study yields good results for the utilization of the device, caution is urged due to the small number of samples collected in this pilot study. Some issues with a small sample size include the inflation of the negative effects caused by a FP or FN reading in even one sample. Further data collection would be needed to be more confident in the findings from the perspective of statistical analysis and inference.

NOTES:

Dhruv B. Sharma, Ph.D., who is a statistical consultant and Senior Statistician at the Center for Statistical Training and Consulting (CSTAT) at Michigan State University, East Lansing, Michigan, conducted this analysis. All analyses for this report are reproducible and all analysis was implemented using R statistical software [Citation: R Core Team (2018). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/].

APPENDIX TO STATISTICAL ANALYSES:

Table A1: Amphetamines Descriptive Statistics (Only Immediate)

On-site Test Results

	Frequency	Percentage	Valid %
Negative	75	81.5	82.4
Positive	16	17.4	17.6
Invalid (Missing)	1	1.1	
Total	92	100	100

Voluntary Test Results

	Frequency	Percentage	Valid %
Negative	55	59.8	88.7
Positive	7	7.6	11.3
Missing	30	32.6	
Total	92	100	100

Blood Test Results (Immediate)

	Frequency	Percentage	Valid %
Negative	74	80.4	86.1
Positive	12	13.0	14.0
Missing	6	6.5	
Total	92	100	100

Table A2: Benzodiazepines Descriptive Statistics (Only Immediate)			
On-site Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	81	88.0	90.0
Positive	9	9.8	10.0
Invalid (Missing)	2	2.2	
Total	92	100	100
Voluntary Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	60	65.2	96.8
Positive	2	2.2	3.2
Missing	30	32.6	
Total	92	100	100
Blood Test Results (Immediate)			
	Frequency	**Percentage**	**Valid %**
Negative	70	76.1	81.4
Positive	16	17.4	18.6
Missing	6	6.5	
Total	92	100	100

Table A3: Cocaine Descriptive Statistics (Immediate and Delayed)			
On-site Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	82	89.1	92.1
Positive	7	7.6	7.9
Invalid (Missing)	3	3.3	
Total	92	100	100
Voluntary Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	53	57.6	85.5
Positive	9	9.8	14.5
Missing	30	32.6	
Total	92	100	100
Blood Test Results (Immediate)			
	Frequency	**Percentage**	**Valid %**
Negative	81	88.0	94.2
Positive	5	5.4	5.8
Missing	6	6.5	
Total	92	100	100
Blood Test Results (Delayed)			
	Frequency	**Percentage**	**Valid %**
Negative	80	87.0	93.0
Positive	6	6.5	7.0
Missing	6	6.5	
Total	92	100.0	100.0

Table A4: Methamphetamines Descriptive Statistics (Immediate and Delayed)			
On-site Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	80	87.0	96.4
Positive	3	3.3	3.6
Invalid (Missing)	9	9.8	
Total	92	100	100
Voluntary Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	59	64.1	95.2
Positive	3	3.3	4.8
Missing	30	32.6	
Total	92	100	100
Blood Test Results (Immediate)			
	Frequency	**Percentage**	**Valid %**
Negative	82	89.1	95.3
Positive	4	4.3	4.7
Missing	6	6.5	
Total	92	100	100
Blood Test Results (Delayed)			
	Frequency	**Percentage**	**Valid %**
Negative	81	88.0	94.2
Positive	5	5.4	5.8
Missing	6	6.5	
Total	92	100.0	100.0

Table A5: Opiates Descriptive Statistics (Only Immediate)			
On-site Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	83	90.2	93.3
Positive	6	6.5	6.7
Invalid (Missing)	3	3.3	
Total	92	100	100
Voluntary Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	58	63	93.5
Positive	4	4.3	6.5
Missing	30	32.6	
Total	92	100	100
Blood Test Results (Immediate)			
	Frequency	**Percentage**	**Valid %**
Negative	78	84.8	90.7
Positive	8	8.7	9.3
Missing	6	6.5	
Total	92	100	100

Table A6: THC Descriptive Statistics (Immediate and Delayed)			
On-site Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	17	18.5	18.7
Positive	74	80.4	81.3
Invalid (Missing)	1	1.1	
Total	92	100	100
Voluntary Test Results			
	Frequency	**Percentage**	**Valid %**
Negative	12	13	19.4
Positive	50	54.4	80.7
Missing	30	32.6	
Total	92	100	100
Blood Test Results (Immediate)			
	Frequency	**Percentage**	**Valid %**
Negative	23	25.0	26.7
Positive	63	68.5	73.3
Missing	6	6.5	
Total	92	100	100
Blood Test Results (Delayed)			
	Frequency	**Percentage**	**Valid %**
Negative	17	18.5	19.8
Positive	69	75.0	80.2
Missing	6	6.5	
Total	92	100.0	100.0

Table A7: Amphetamines Performance Results (Only Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	10	6
	Negative	1	68
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	90.90%	62.30%	99.50%
Specificity	91.90%	83.40%	96.20%
PPV	62.50%	38.60%	81.50%
NPV	98.60%	92.20%	99.90%
Accuracy	91.80%	84.00%	96.00%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	6	2
	Negative	0	53
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	61.00%	100.00%
Specificity	96.40%	87.70%	99.00%
PPV	75.00%	40.90%	92.90%
NPV	100.00%	93.20%	100.00%
Accuracy	96.70%	88.80%	99.10%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	7	0
	Negative	0	49
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	64.60%	100.00%
Specificity	100.00%	92.70%	100.00%
PPV	100.00%	64.60%	100.00%
NPV	100.00%	92.70%	100.00%
Accuracy	100.00%	93.60%	100.00%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A8: Benzodiazepines Performance Results (Only Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	8	1
	Negative	8	67
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	50.00%	28.00%	72.00%
Specificity	98.50%	92.10%	99.90%
PPV	88.90%	56.50%	99.40%
NPV	89.30%	80.30%	94.50%
Accuracy	89.30%	80.90%	94.30%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	2	2
	Negative	0	57
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	34.20%	100.00%
Specificity	96.60%	88.50%	99.10%
PPV	50.00%	15.00%	85.00%
NPV	100.00%	93.70%	100.00%
Accuracy	96.70%	88.80%	99.10%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	2	0
	Negative	4	50
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	33.30%	9.70%	70.00%
Specificity	100.00%	92.90%	100.00%
PPV	100.00%	34.20%	100.00%
NPV	92.60%	82.40%	97.10%
Accuracy	92.90%	83.00%	97.20%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A9: Cocaine Performance Results (Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	5	2
	Negative	0	76
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	56.60%	100.00%
Specificity	97.40%	91.10%	99.30%
PPV	71.40%	35.90%	91.80%
NPV	100.00%	95.20%	100.00%
Accuracy	97.60%	91.60%	99.30%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	3	1
	Negative	6	50
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	33.30%	12.10%	64.60%
Specificity	98.00%	89.70%	99.90%
PPV	75.00%	30.10%	98.70%
NPV	89.30%	78.50%	95.00%
Accuracy	88.30%	77.80%	94.20%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	2	7
	Negative	0	47
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	34.20%	100.00%
Specificity	87.00%	75.60%	93.60%
PPV	22.20%	6.30%	54.70%
NPV	100.00%	92.40%	100.00%
Accuracy	87.50%	76.40%	93.80%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A10: Cocaine Performance Results (Delay)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	6	1
	Negative	0	76
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	61.00%	100.00%
Specificity	98.70%	93.00%	99.90%
PPV	85.70%	48.70%	99.30%
NPV	100.00%	95.20%	100.00%
Accuracy	98.80%	93.50%	99.90%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	3	6
	Negative	0	47
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	43.90%	100.00%
Specificity	88.70%	77.40%	94.70%
PPV	33.30%	12.10%	64.60%
NPV	100.00%	92.40%	100.00%
Accuracy	89.30%	78.50%	95.00%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A11: Methamphetamines Performance Results (Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	2	1
	Negative	0	74
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	34.20%	100.00%
Specificity	98.70%	92.80%	99.90%
PPV	66.70%	20.80%	98.30%
NPV	100.00%	95.10%	100.00%
Accuracy	98.70%	93.00%	99.90%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	1	1
	Negative	0	54
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	5.10%	100.00%
Specificity	98.20%	90.40%	99.90%
PPV	50.00%	2.60%	97.40%
NPV	100.00%	93.40%	100.00%
Accuracy	98.20%	90.60%	99.90%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	3	0
	Negative	0	53
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	43.90%	100.00%
Specificity	100.00%	93.20%	100.00%
PPV	100.00%	43.90%	100.00%
NPV	100.00%	93.20%	100.00%
Accuracy	100.00%	93.60%	100.00%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A12: Methamphetamines Performance Results (Delay)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	3	0
	Negative	0	74
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	43.90%	100.00%
Specificity	100.00%	95.10%	100.00%
PPV	100.00%	43.90%	100.00%
NPV	100.00%	95.10%	100.00%
Accuracy	100.00%	95.20%	100.00%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	3	0
	Negative	1	52
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	75.00%	30.10%	98.70%
Specificity	100.00%	93.10%	100.00%
PPV	100.00%	43.90%	100.00%
NPV	98.10%	90.10%	99.90%
Accuracy	98.20%	90.60%	99.90%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A13: Opiates Performance Results (Only Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	6	0
	Negative	1	76
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	85.70%	48.70%	99.30%
Specificity	100.00%	95.20%	100.00%
PPV	100.00%	61.00%	100.00%
NPV	98.70%	93.00%	99.90%
Accuracy	98.80%	93.50%	99.90%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	3	0
	Negative	0	57
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	43.90%	100.00%
Specificity	100.00%	93.70%	100.00%
PPV	100.00%	43.90%	100.00%
NPV	100.00%	93.70%	100.00%
Accuracy	100.00%	94.00%	100.00%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	4	0
	Negative	1	51
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	80.00%	37.60%	99.00%
Specificity	100.00%	93.00%	100.00%
PPV	100.00%	51.00%	100.00%
NPV	98.10%	89.90%	99.90%
Accuracy	98.20%	90.60%	99.90%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A14: THC Performance Results (Immediate)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	62	11
	Negative	1	11
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	98.40%	91.50%	99.90%
Specificity	50.00%	30.70%	69.30%
PPV	84.90%	75.00%	91.40%
NPV	91.70%	64.60%	99.60%
Accuracy	85.90%	76.90%	91.70%
On-site vs. Voluntary Cross Table			
Cross Table		**Voluntary**	
	Results	Positive	Negative
On-site	Positive	47	1
	Negative	3	10
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	94.00%	83.80%	97.90%
Specificity	90.90%	62.30%	99.50%
PPV	97.90%	89.10%	99.90%
NPV	76.90%	49.70%	91.80%
Accuracy	93.40%	84.30%	97.40%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	41	7
	Negative	0	8
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	91.40%	100.00%
Specificity	53.30%	30.10%	75.20%
PPV	85.40%	72.80%	92.80%
NPV	100.00%	67.60%	100.00%
Accuracy	87.50%	76.40%	93.80%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

Table A15: THC Performance Results (Delay)			
On-site vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
On-site	Positive	68	5
	Negative	1	11
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	98.60%	92.20%	99.90%
Specificity	68.80%	44.40%	85.80%
PPV	93.20%	84.90%	97.00%
NPV	91.70%	64.60%	99.60%
Accuracy	92.90%	85.40%	96.70%
Voluntary vs. Blood Cross Table			
Cross Table		**Blood**	
	Results	Positive	Negative
Voluntary	Positive	45	3
	Negative	0	8
Performance Statistics			
	Estimate	**Lower CL**	**Upper CL**
Sensitivity	100.00%	92.10%	100.00%
Specificity	72.70%	43.40%	90.30%
PPV	93.80%	83.20%	97.90%
NPV	100.00%	67.60%	100.00%
Accuracy	94.60%	85.40%	98.20%
Footnote: CL is the 95% Confidence Limit calculated using the Agresti Approximation.			

MICHIGAN STATE POLICE LABORATORY ANALYSIS
SUBMITTED BY MR. NICHOLAS FILLINGER, TOXICOLOGY TECHNICAL LEADER, MSP

Blood samples analyzed by the Michigan State Police toxicology discipline were collected in 10-mL grey-top vacutainer tubes containing 20 mg of potassium oxalate and 100 mg of sodium fluoride. Blood collection tubes are included in biological specimen collection kits which are distributed to all law enforcement agencies in Michigan. Samples are evidentiary and collected as part of routine investigation into OWI/OUID.

All samples were initially analyzed by headspace gas chromatography with flame ionization detector (GCHS-FID) for volatiles. Analysis was conducted on two Thermo Trace Ultra Gas Chromatographs. One gas chromatograph contains a Rtx-BAC Plus 1 column measuring 30 m x 0.53 mm ID x 3 µm. The other gas chromatograph contains a Rtx-BAC Plus 2 column measuring 30 m x 0.53 mm ID x 1 µm.

Samples that require drug analysis undergo preliminary drug screening by liquid chromatography tandem mass spectrometry (LC-MS/MS). Samples are analyzed on a SCIEX QTRAP 4500 containing an Agilent poroshell 120 column, EC-C18, 3.0 mm x 50 mm x 2.7 µm. Samples were screened for fifty-five drugs and sent on for confirmation if there were any positives. Protocol dictates that samples in which ethanol is ≥ 0.10 g/dL do not get analyzed for drugs, however that protocol was suspended for samples that were collected as part of this pilot program.

Confirmatory analysis was conducted by gas chromatography-mass spectrometry (GC/MS) and/or LC-MS/MS. GC/MS analyses were conducted on a Thermo Trace Ultra/Trace 1310 coupled with a DSQ II/ISQ containing a ZB-5MSi column, 15 m x .25 ID x .25 µm. LC-MS/MS analyses were conducted on a SCIEX QTRAP 4500 containing a Phenomenex Kintex Biphenyl column, 2.1 mm x 50 mm x 2.6 µm.

All instrument operating parameters were optimized, and method validation was conducted utilizing the guidelines from the Scientific Working Group for Forensic Toxicology (SWGTOX) Standard Practices for Method Validation in Forensic Toxicology.

ORAL FLUID FORENSIC FLUIDS LABORATORIES LABORATORY METHODS

SUBMITTED BY MS. BRIDGET LORENZ LEMBERG, LABORATORY DIRECTOR, FFL

- Samples are received at the lab sealed 3 times (sample tube sealed, clear specimen bag sealed, UPS bag sealed). Paperwork signed and dated by both the donor and observer.
- A Specimen Processing person checks chain-of-custody and logs sample into Laboratory Information Management System (LIMS).
- The specimen goes into the Screening Lab where FDA approved immunoassay tests are performed (ELISA, enzyme-linked immunoassay serum assay). If the sample is negative a lab report is generated. If the samples "screens" positive for any of the drugs or drug classes (Amphetamine, Methamphetamine, THC/ Marijuana, Cocaine, Opiates, Benzodiazepines, Oxycodone, etc.), it is considered "presumptive" and the sample goes to the Confirmation Lab.
- The Confirmation Lab uses LCMSMS (Liquid Chromatography Tandem Mass Spectrometry) to positively identify what drug(s) is in the sample and how much drug is there. LCMSMS is recognized as the most scientifically accurate instrument currently available. Mass Spectrometry positively identifies drugs, thus eliminating "false positives" that might occur in the Screening step above. A positive "confirmed" lab report is then generated.
- FFL is CLIA (Clinical Laboratory Improvement Amendments) certified Lab. CLIA is overseen by the CMS (Center for Medicare & Medicaid Services). CLIA certification assures that FFL follows Standard Operating Procedures and has an excellent Quality Control program. FFL also has to subscribe to Proficiency or blind-sample testing on a quarterly basis, and pass these tests with a grade of 85%. FFL normally get 100% on these tests. FFL currently can identify over 150 drugs.
- Due to the accuracy of our internal chain-of-custody for each sample and our scientific methods, our test results are admissible in court and have been accepted in over 10 states. FFL also has two court qualified Toxicologists with another Toxicologist "in-training".

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