ELLEN F. ROSENBLUM
Attorney General

FREDERICK M. BOSS
Deputy Attorney General

DEPARTMENT OF JUSTICE
CRIMINAL JUSTICE DIVISION

April 2, 2021

Senator Chris Gorsek, Co-Chair
Representative Janeen Sollman, Co-Chair
Joint Committee on Ways and Means
Oregon State Legislature

Re: DOJ Response to Public Safety Subcommittee Meeting Question
(Criminal Justice Division)

Dear Senator Gorsek and Representative Sollman:

During our budget hearing on Wednesday, March 31st, Co-Chair Gorsek asked a question about the scope of our efforts to assist prosecutors with cases involving driving under the influence of marijuana. In asking the question, Co-Chair Gorsek noted that, unlike cases involving driving under the influence of alcohol, there is no breath test for driving under the influence of marijuana.

The scope of the Department's efforts to assist law enforcement and prosecutors regarding prosecutions for driving under the influence of marijuana is quite broad. Our DUII Resource Prosecutor, Deena Ryerson, regularly fields phone calls from both prosecutors and law enforcement officers relating to all aspects of marijuana-impaired driving, including, for example, questions relating to investigations, the use of experts, and the introduction of evidence at trial. Moreover, Ms. Ryerson presents training on issues related to marijuana-impaired driving for recruits at the Department of Public Safety Standards and Training, at the Advanced Roadside Impaired Driving Enforcement (ARIDE) training, at the annual Drug Recognition Expert (DRE) School, and at the various annual prosecutor conferences. In addition, Ms. Ryerson has presented webinars related to marijuana impaired driving, including presenting on topics such as jury selection and the differences between alcohol and marijuana related DUII investigations. She also posts webinars created by her counterparts around the country as well as other experts in the field. Finally, Ms. Ryerson coordinates a drugged driver training that brings prosecutors and DRE's from their local jurisdiction together to train on prosecutions of drugged driving cases. The training includes a specific emphasis on marijuana-impaired driving.

In addition to training, Ms. Ryerson is involved nationally on issues relating to marijuana impaired driving. For example, she participates on a drugged driving curriculum committee (through a grant with National Highway Traffic Safety Administration (NHTSA)) and previously worked with NHTSA to create a state self-assessment tool relating to drugged driving, which was heavily focused on marijuana.

As mentioned earlier, Co-Chair Gorsek noted that there is no breath test for driving under the influence of marijuana. That is correct, and due to the differences in marijuana and alcohol, and how it is processed in the body, whether such technology will be approved for use around the country remains in doubt. A potential alternative is oral fluid testing, which requires a non-invasive mouth swab. Several states have adopted oral fluid testing, including Michigan. Attached to this letter for your reference are two reports issued to the Michigan legislature that discuss the results of pilot project in that state. Also attached is a webinar presentation that provides an overview of the relating laws and the creation of the pilot project.

Please let me know if there is additional information I can provide.

Sincerely,

Michael J. Slauson
Chief Counsel

Michigan's Oral Fluid Roadside Testing Law

Presented by Kenneth Stecker
Prosecuting Attorneys Association of Michigan

March 2021

Background

NHTSA ROADSIDE SURVEY– FEBRUARY 6, 2015

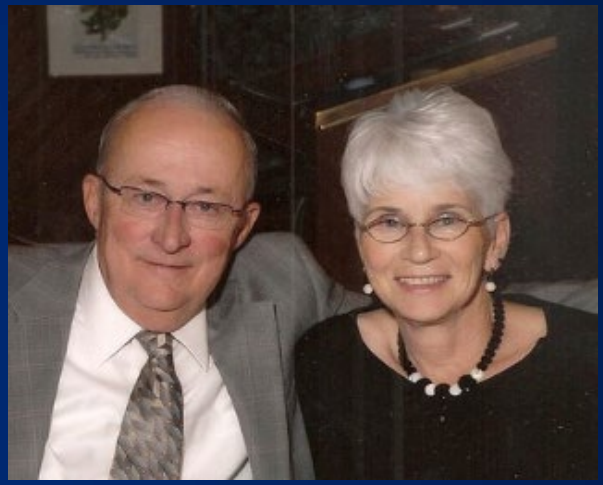
- Alcohol use has declined dramatically
  - Only 1.5% of weekend nighttime drivers had BACs at or above 0.08
- However, 22.5% tested positive for drugs, an increase from 16.3% in 2007; 12.6% were positive for marijuana, compared to 8.6% in 2007

MICHIGAN

- Fatal impaired driving crashes in Michigan have been steadily increasing over the last five years
- Michigan experienced a 32% increase in impaired driving fatalities, from 179 in 2015 to 236 in 2016
- Several major incidents involving impaired drivers: five bicyclists killed in Kalamazoo, tow-truck driver killed in St. Clair County, and Detroit police officer killed in Detroit

SWIFT FAMILY TRAGEDY

- Thomas and Barbara Swift, 73, of Escanaba, died due to injuries suffered when their car was struck by a logging truck that failed to stop for a red light on U.S. 2 and M-41 in Gladstone in March 2013
- Thomas Swift died at the scene; his wife, Barbara Swift, died several days later from injuries she sustained in the crash



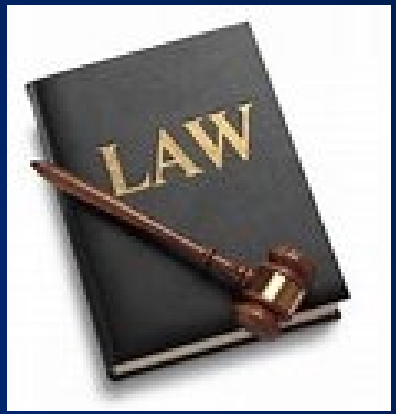
SWIFT FAMILY TRAGEDY

- Harley Durocher, the suspect in the deadly car crash, was found guilty on six counts after a two-day trial
- Durocher was found guilty on two counts of driving with a suspended or revoked license causing death, two counts of reckless driving causing death, and two counts of operating with the presence of THC in his system causing death (2 nanograms)

Legislation

Barbara J. and Thomas J. Swift Law

- Effective September 26, 2016, the law authorizes the Michigan Department of State Police (MSP) to establish a one-year pilot program in five counties for roadside drug testing
- Requires the MSP to develop a written policy for the implementation of the pilot program and the administration of roadside drug testing
- Allows the MSP to adopt rules to implement the pilot program
- Requires the MSP to report on the pilot program to certain committees of the legislature within 90 days after the pilot program concludes
- Allows the MSP, subject to appropriation, to establish additional pilot programs in other counties for up to one year



Barbara J. and Thomas J. Swift Law

- Further, the law authorizes a peace officer who is certified as a drug-recognition expert in a county participating in the pilot program to require a person to submit to a preliminary oral fluid analysis under certain conditions
- Authorizes an officer to arrest a person based on the results of a preliminary oral fluid analysis and to make those results admissible in a criminal prosecution for limited purposes and/or an administrative hearing
- Requires an officer to use the results of an oral fluid analysis to determine whether to order a commercial motor vehicle (CMV) driver out of service and requires an officer to order out of service a CMV driver who refuses to submit to a preliminary oral fluid analysis
- Provides that a person who refuses to submit to a preliminary oral analysis is responsible for a civil infraction

Committee

COMMITTEE AND MEMBERS

- Committee composed of subject matter experts to assist in making the pilot program successful
- Members:
  - Prosecuting Attorneys Association of Michigan (two TSRPs)
  - Traffic Services Section
  - Alcohol Enforcement Unit
  - Impaired Driving Unit
  - Drug Recognition Expert (DRE) coordinator from the Office of Highway Safety Planning (OHSP)
  - Forensic Science Division
  - Executive Resources Section

COUNTIES SELECTED

- The counties for the Oral Fluid Roadside Analysis were selected on the following criteria:
  - Number of serious injury and fatal impaired driving crashes
  - Number of impaired driving arrests
  - Number of DREs in the county
  - Number of DRE prosecutors in the county and their knowledge of the program
  - Geographic diversity around the state of Michigan

FIVE COUNTIES SELECTED

- Berrien
- Delta
- Kent
- St. Clair
- Washtenaw

DRUG RECOGNITION EXPERTS

- All law enforcement agencies were represented in this pilot program: state, local, township and county
- Twelve participating law enforcement agencies
- Only the 27 DRE officers within those five counties were participating in the Oral Fluid Roadside Analysis pilot program
- All law enforcement agencies in the selected counties agreed to participate in the pilot program

SELECTION CRITERIA

- Portable, hand-held
- Rechargeable and fully automated analyzer
- On-screen instructions
- Results within five minutes or less
- THC cutoff level no higher than 25 ng/mL
- On-board heater
- Battery life capable of running 50 tests
- Printer included with device

ORAL FLUID TEST INSTRUMENT

- The pilot program committee researched several vendors of Oral Fluid Roadside Analysis testing instruments
- Manufacturers were given an opportunity to give a presentation and demonstration to committee members
- Seven different oral fluid testing manufacturers gave presentations and were evaluated by committee members
- The committee members developed specifications that met the needs of the pilot program

SELECTED INSTRUMENT

- Formally known as the DDS2

SoToxa™

MOBILE TEST SYSTEM

SoToxa™ MOBILE ANALYZER

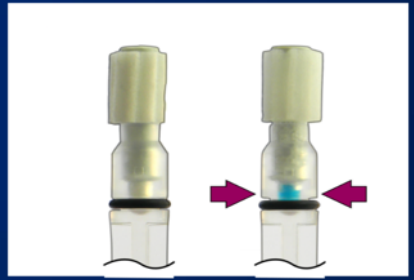
QUALITY CONTROL

QC testing

- QC testing to validate SoToxa™ device is correctly detecting positive and negative results each day prior to use

SoToxa™ ORAL FLUID DEVICE

- Rapid sample collection
- Sample volume adequacy indicator
- Robustly designed for active swabbing



BENEFITS OF THE TEST INSTRUMENT

- Compact and portable
- Easy to use
- Results within five minutes
- Easy-to-read positive or negative results
- Can store up to 10,000 tests, and comes with a printer
- Rapid, simple, noninvasive
- No medical professional required; saves time and money
- Parent drug reflects recent drug use
- Specimen taken proximate to time of driving, crash, workplace accident, etc.

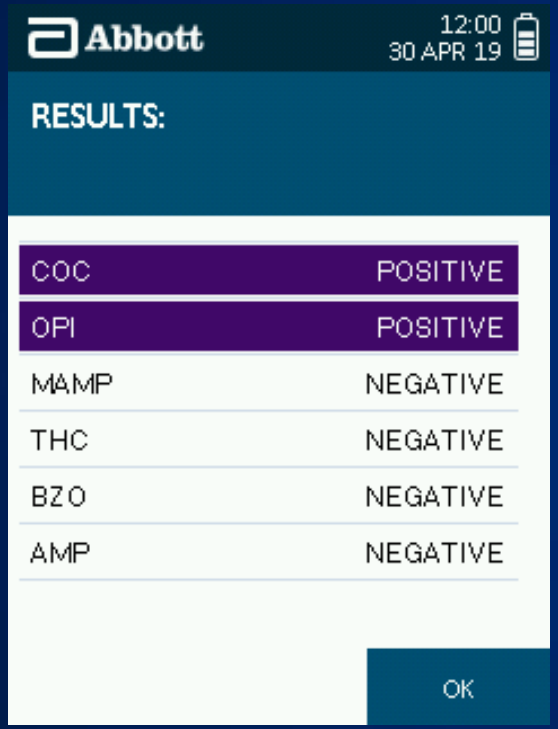
SoToxa™ DRUG PANEL

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

ROADSIDE USE

- Test instrument will display a positive, negative or invalid test reading for each drug category
  - Positive result: Indicates presence of drug in the driver's system; it does not detect impairment
  - Negative result: Below the cutoff level; negative result does not preclude a driver from being impaired
  - Invalid result: Normally insufficient volume of oral fluid

SoToxa™ SCREEN



VALIDATION TESTS

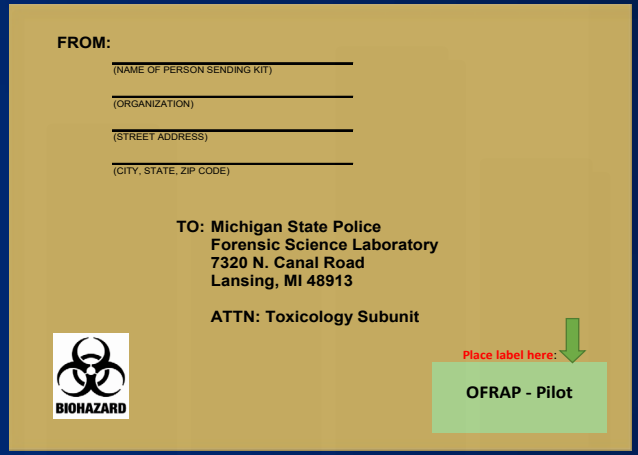
- A separate secondary oral fluid test is completed, when possible, from a suspect
  - The secondary test is completely voluntary
  - The voluntary test is sent to the Forensic Fluid Laboratory in Kalamazoo for analysis
    - Shipped overnight by UPS
    - Analysis results are normally returned within 24 hours

TRAINING

- In November 2017, DREs and prosecutors from the five selected counties were trained
- Trained in the following:
  - Laws governing the Oral Fluid Roadside Analysis pilot
  - Policies and procedures of the program and MOA
  - Proper utilization of the oral fluid test instrument
  - Proper procedure to collect independent lab sample
  - Reporting requirements and forms

BLOOD ANALYSIS

- Blood is collected when an arrest is made, either voluntarily or by search warrant
- Blood testing is done by MSP



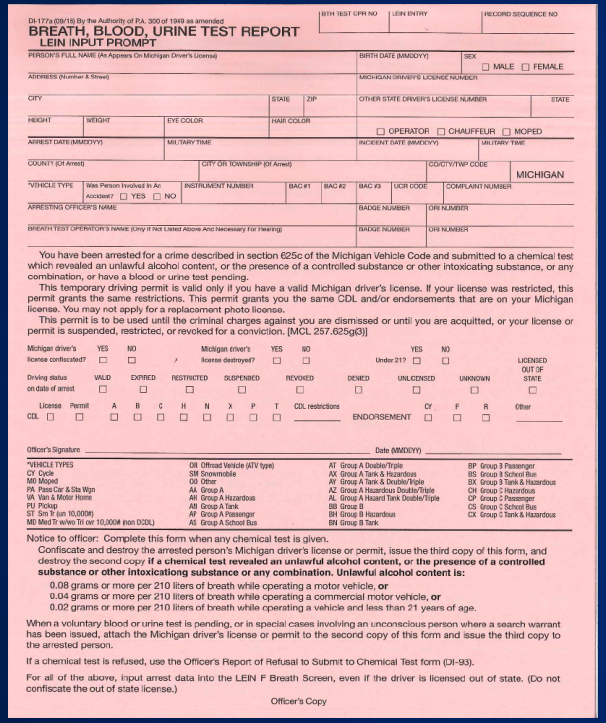
PROGRAM PROCESS

- Participating DREs shall fully develop probable-cause factors before administering the oral fluid test (SFST, PBT)
- Quality control
- 10-minute observation period
- SoToxa™ test
- Secondary test: forensic fluids
- Blood test

BEST PRACTICE

- DRE officer does not view the SoToxa™ results until the DRE has completed their investigation or evaluation
- DRE officer uses the SoToxa™ results in the affidavit for a blood search warrant

ORAL FLUID PROGRAM FORMS



DI-177a (09/18) By the Authority of P.A. 300 of 1949 as amended

BREATH, BLOOD, URINE TEST REPORT
LEIN INPUT PROMPT

BTH TEST CPR NO | LEIN ENTRY | RECORD SEQUENCE NO

PERSON'S FULL NAME (As Appears On Michigan Driver's License) | BIRTH DATE (MMDDYY) | SEX ☐ MALE ☐ FEMALE

ADDRESS (Number & Street) | MICHIGAN DRIVER'S LICENSE NUMBER

CITY | STATE | ZIP | OTHER STATE DRIVER'S LICENSE NUMBER | STATE

HEIGHT | WEIGHT | EYE COLOR | HAIR COLOR | ☐ OPERATOR ☐ CHAUFFEUR ☐ MOPED

ARREST DATE (MMDDYY) | MILITARY TIME | INCIDENT DATE (MMDDYY) | MILITARY TIME

COUNTY (Of Arrest) | CITY OR TOWNSHIP (Of Arrest) | CO/CITY/TWP CODE | MICHIGAN

VEHICLE TYPE | Was Person Involved In An Accident? ☐ YES ☐ NO | INSTRUMENT NUMBER | BAC #1 | BAC #2 | BAC #3 | UCR CODE | COMPLAINT NUMBER

ARRESTING OFFICER'S NAME | BADGE NUMBER | ORI NUMBER

BREATH TEST OPERATOR'S NAME (Only If Not Listed Above And Necessary For Hearing) | BADGE NUMBER | ORI NUMBER

You have been arrested for a crime described in section 625c of the Michigan Vehicle Code and submitted to a chemical test which revealed an unlawful alcohol content, or the presence of a controlled substance or other intoxicating substance, or any combination, or have a blood or urine test pending.

This temporary driving permit is valid only if you have a valid Michigan driver's license. If your license was restricted, this permit grants the same restrictions. This permit grants you the same CDL and/or endorsements that are on your Michigan license. You may not apply for a replacement photo license.

This permit is to be used until the criminal charges against you are dismissed or until you are acquitted, or your license or permit is suspended, restricted, or revoked for a conviction. [MCL 257.625g(3)]

Michigan driver's license confiscated? YES ☐ NO ☐ | Michigan driver's license destroyed? YES ☐ NO ☐ | Under 21? YES ☐ NO ☐ | LICENSED OUT OF STATE ☐

Driving status on date of arrest: VALID ☐ EXPIRED ☐ RESTRICTED ☐ SUSPENDED ☐ REVOKED ☐ DENIED ☐ UNLICENSED ☐ UNKNOWN ☐

License: Permit ☐ A ☐ B ☐ C ☐ H ☐ N ☐ X ☐ P ☐ T ☐ | CDL restrictions | CDL ☐ | ENDORSEMENT CY ☐ F ☐ R ☐ | Other

Officer's Signature _____ Date (MMDDYY) _____

*VEHICLE TYPES
CY Cycle
MH Moped
PA Pass Car & Sta Wgn
VA Van & Motor Home
PU Pickup
ST Sm Tr (un 10,000#)
MD Med Tr w/wo Tr or 10,000# (non CDL)
OR Offroad Vehicle (ATV type)
SM Snowmobile
OO Other
AA Group A
AH Group A Hazardous
AB Group A Tank
AF Group A Passenger
AS Group A School Bus
AT Group A Double/Triple
AX Group A Tank & Hazardous
AY Group A Tank & Double/Triple
AZ Group A Hazardous Double/Triple
AL Group A Hazard Tank Double/Triple
BB Group B
BH Group B Hazardous
BN Group B Tank
BP Group B Passenger
BS Group B School Bus
BX Group B Tank & Hazardous
CH Group C Hazardous
CP Group C Passenger
CS Group C School Bus
CX Group C Tank & Hazardous

Notice to officer: Complete this form when any chemical test is given.
Confiscate and destroy the arrested person's Michigan driver's license or permit, issue the third copy of this form, and destroy the second copy **if a chemical test revealed an unlawful alcohol content, or the presence of a controlled substance or other intoxicating substance or any combination. Unlawful alcohol content is:**

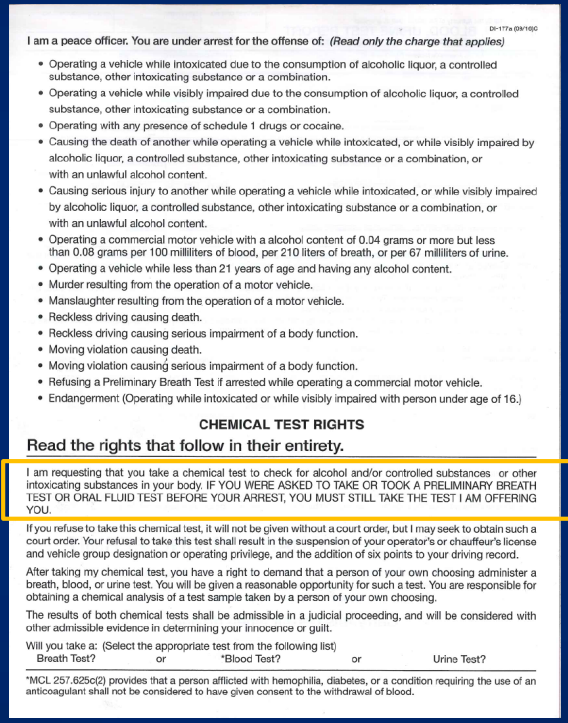
0.08 grams or more per 210 liters of breath while operating a motor vehicle, **or**
0.04 grams or more per 210 liters of breath while operating a commercial motor vehicle, **or**
0.02 grams or more per 210 liters of breath while operating a vehicle and less than 21 years of age.

When a voluntary blood or urine test is pending, or in special cases involving an unconscious person where a search warrant has been issued, attach the Michigan driver's license or permit to the second copy of this form and issue the third copy to the arrested person.

If a chemical test is refused, use the Officer's Report of Refusal to Submit to Chemical Test form (DI-93).

For all of the above, input arrest data into the LEIN F Breath Screen, even if the driver is licensed out of state. (Do not confiscate the out of state license.)

Officer's Copy



DI-177a (09/18)C

I am a peace officer. You are under arrest for the offense of: *(Read only the charge that applies)*

- Operating a vehicle while intoxicated due to the consumption of alcoholic liquor, a controlled substance, other intoxicating substance or a combination.
- Operating a vehicle while visibly impaired due to the consumption of alcoholic liquor, a controlled substance, other intoxicating substance or a combination.
- Operating with any presence of schedule 1 drugs or cocaine.
- Causing the death of another while operating a vehicle while intoxicated, or while visibly impaired by alcoholic liquor, a controlled substance, other intoxicating substance or a combination, or with an unlawful alcohol content.
- Causing serious injury to another while operating a vehicle while intoxicated, or while visibly impaired by alcoholic liquor, a controlled substance, other intoxicating substance or a combination, or with an unlawful alcohol content.
- Operating a commercial motor vehicle with a alcohol content of 0.04 grams or more but less than 0.08 grams per 100 milliliters of blood, per 210 liters of breath, or per 67 milliliters of urine.
- Operating a vehicle while less than 21 years of age and having any alcohol content.
- Murder resulting from the operation of a motor vehicle.
- Manslaughter resulting from the operation of a motor vehicle.
- Reckless driving causing death.
- Reckless driving causing serious impairment of a body function.
- Moving violation causing death.
- Moving violation causing serious impairment of a body function.
- Refusing a Preliminary Breath Test if arrested while operating a commercial motor vehicle.
- Endangerment (Operating while intoxicated or while visibly impaired with person under age of 16.)

CHEMICAL TEST RIGHTS

Read the rights that follow in their entirety.

I am requesting that you take a chemical test to check for alcohol and/or controlled substances or other intoxicating substances in your body. IF YOU WERE ASKED TO TAKE OR TOOK A PRELIMINARY BREATH TEST OR ORAL FLUID TEST BEFORE YOUR ARREST, YOU MUST STILL TAKE THE TEST I AM OFFERING YOU.

If you refuse to take this chemical test, it will not be given without a court order, but I may seek to obtain such a court order. Your refusal to take this test shall result in the suspension of your operator's or chauffeur's license and vehicle group designation or operating privilege, and the addition of six points to your driving record.

After taking my chemical test, you have a right to demand that a person of your own choosing administer a breath, blood, or urine test. You will be given a reasonable opportunity for such a test. You are responsible for obtaining a chemical analysis of a test sample taken by a person of your own choosing.

The results of both chemical tests shall be admissible in a judicial proceeding, and will be considered with other admissible evidence in determining your innocence or guilt.

Will you take a: (Select the appropriate test from the following list)
Breath Test? or *Blood Test? or Urine Test?

*MCL 257.625c(2) provides that a person afflicted with hemophilia, diabetes, or a condition requiring the use of an anticoagulant shall not be considered to have given consent to the withdrawal of blood.

I am requesting that you take a chemical test to check for alcohol and/or controlled substances or other intoxicating substances in your body. IF YOU WERE ASKED TO TAKE OR TOOK A PRELIMINARY BREATH TEST OR ORAL FLUID TEST BEFORE YOUR ARREST, YOU MUST STILL TAKE THE TEST I AM OFFERING YOU.

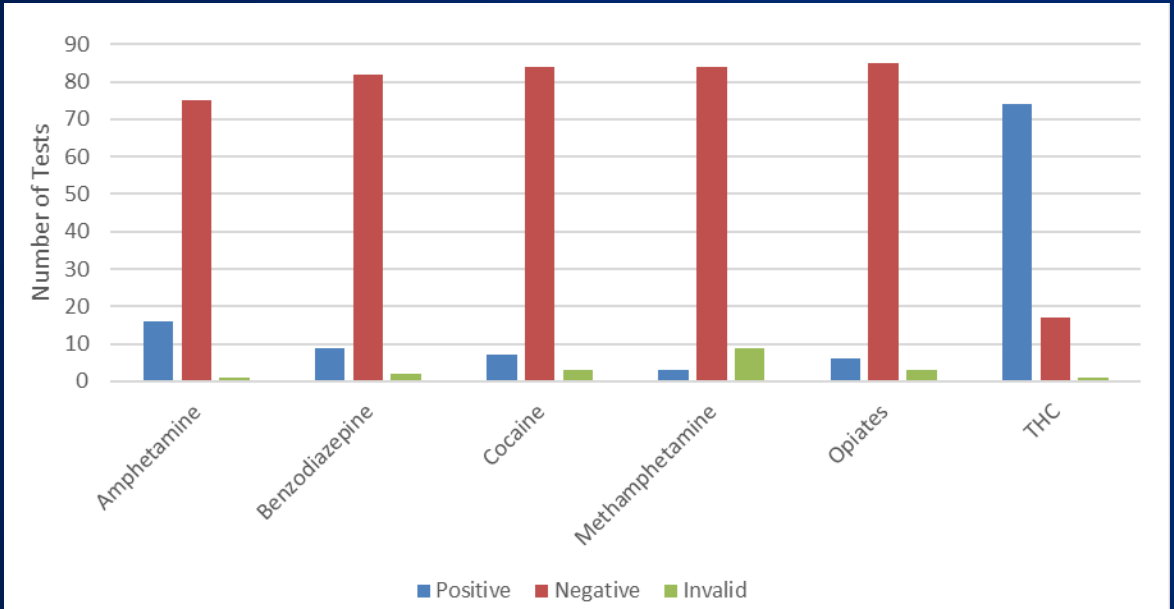
Phases I and II

PHASE I INFORMATION

- Counties that participated: Berrien, Delta, Kent, St. Clair and Washtenaw
- 31 DREs participated
- 92 oral fluid roadside tests conducted, with one refusal
- 89 drivers were arrested during the first pilot
  - 79 drivers consented to a blood draw
  - eight search warrants were obtained

PHASE I RESULTS

Roadside Oral Fluid Test Results



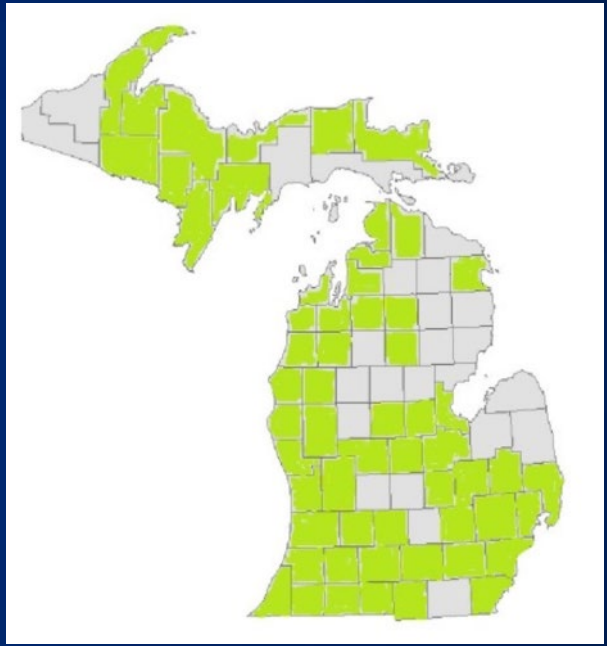
PHASE II RESULTS

- October 1, 2019, to September 30, 2020
- 69 counties had oral fluid cases
- 131 DREs from 65 law enforcement departments participated
- 661 oral fluid incidents
- 547 voluntary oral fluid tests
- 632 blood tests

PHASE II COUNTIES

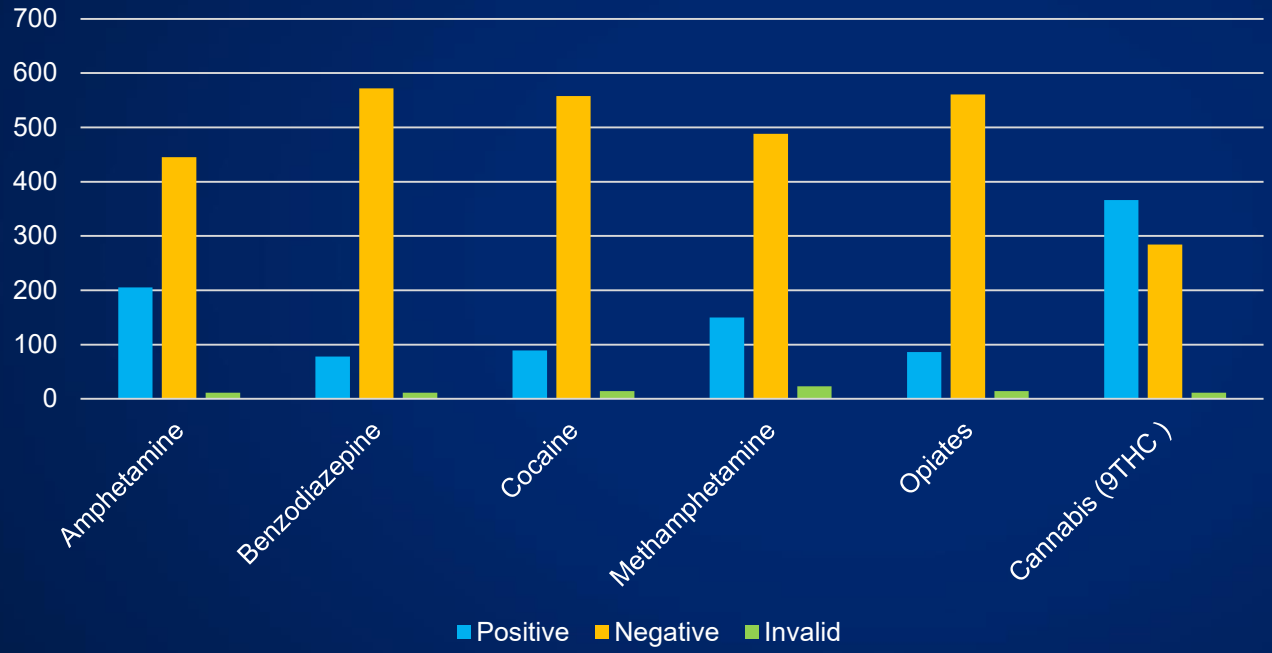
Michigan Counties Covered by OFRAP II
Expanded Oral Fluid Roadside Analysis Pilot Program

- 59 total counties covered
- 83 total DREs participating
  (30 MSP + 53 agencies)



PHASE II RESULTS

Roadside Oral Fluid Test Results



SoToxa™ COMPARED TO BLOOD METHAMPHETAMINES

- 121 true positives 22 false positives
- 6 false negatives 435 true negatives
- Accuracy
  - Estimate: 95.20%
  - Lower confidence level: 93.20%
  - Upper confidence level: 96.70%

SoToxa™ COMPARED TO BLOOD COCAINE

- 59 true positives 27 false positives
- 6 false negatives 501 true negatives
- Accuracy
  - Estimate: 94.40%
  - Lower confidence level: 92.30%
  - Upper confidence level: 96.00%

PHASE II SUMMARY

- Oral fluid has been found to be accurate for purposes of preliminary roadside testing
- It is one of many tools that officers can use during impaired driving investigations
- Roadside oral fluid test results alone do not determine if a driver is impaired or not impaired

ORAL FLUID TESTING IS A TEST TO DETERMINE RECENT DRUG USE

- Oral fluid testing is a test to determine drug use, not impairment
  - SFSTs, DRE evaluation, behavior noted and, poor driving, all equal signs of impairment
- Result can be used to support the DRE officer's opinion about which drug(s) is/are responsible for the observed impairment
- Oral fluid drug testing is a tool that assists with the DRE investigation, providing real-time chemical test information that can be used by the officer in questioning the subject about their drug use
- SFSTs first, followed by the oral fluid field test

CONCLUSION

- On November 8, 2017, the Oral Fluid Roadside Analysis pilot program officially began
- With the ever-increasing impaired drivers and fatalities, the opioid epidemic, and states legalizing marijuana, it's a great time to implement the pilot program
- The Michigan State Police and the members of the committee are very proud of the accomplishments so far with the Oral Fluid pilot program
- We look forward to assisting other states and other countries

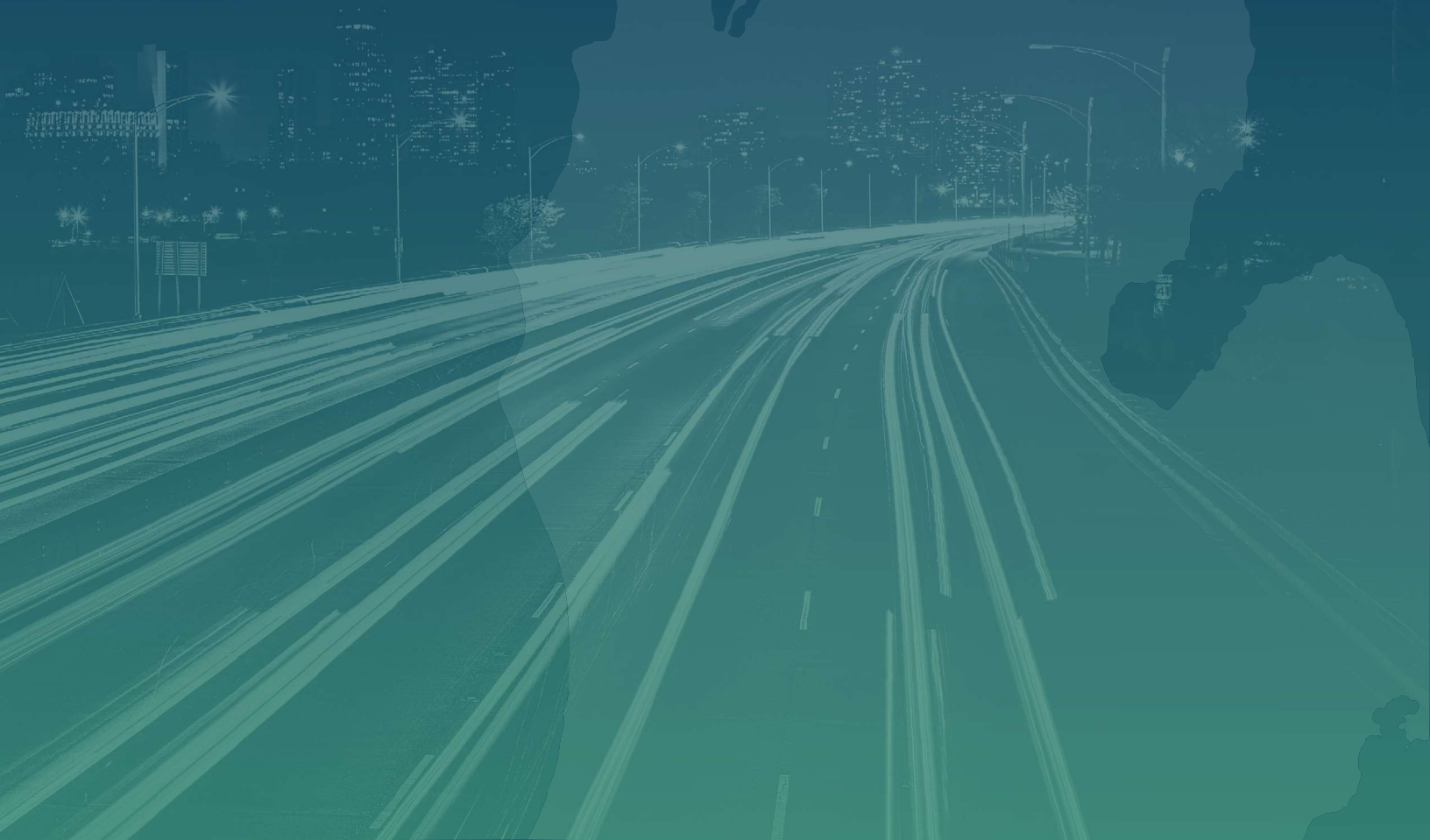
QUOTE FROM BRIAN SWIFT

"We have worked hard over the past year to turn the horror of losing our mom and dad into saving others. Our pain never goes away, but we know my parents would want to help others, and we think it is worth the fight."


Kenneth Stecker
Traffic Safety Resource Prosecutor
Prosecuting Attorneys Association of Michigan
116 West Ottawa
Lansing, MI 48913
Phone: (517) 334-6060, x827 or x816
Email: Steckerk@michigan.gov
JUSTICE
LAW ENFORCEMENT
PROSECUTING
ATTORNEYS
ASSOCIATION
COMMUNITY SERVICE
MICHIGAN

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.

CURRENT COMMITTEE MEMBERS:

F/Lt. James Flegel
Pilot Program Director, Michigan State Police

Sgt. Gina Gettel
Michigan State Police

F/Lt. Timothy Fitzgerald
Michigan State Police

Tpr. Gregory Primeau
Michigan State Police

Mr. Michael Harris
DRE Coordinator, Michigan State Police

Mr. Nicholas Fillinger
Toxicology Technical Leader, Michigan State Police

Mr. Kenneth Stecker
Prosecuting Attorneys Association of Michigan

Ms. Kinga Canike
Prosecuting Attorneys Association of Michigan

Ms. Julie Agueros
Michigan State Police

FORMER COMMITTEE MEMBERS:

Mr. Steven Beatty
Michigan State Police

Sgt. Perry Curtis, Ret.
Michigan State Police

Sgt. Kelly Goynes, Ret.
Michigan State Police

Ms. Kristie Jordan
Department of Licensing and Regulatory Affairs

Sgt. Dean York
Michigan State Police

OTHER CONTRIBUTORS:

Dr. Dhruv B. Sharma, Ph.D.
Senior Statistician, Michigan State University

Mr. David Bergland
Chief Operating Officer, Forensic Fluids Laboratories

Ms. Bridget Lorenz Lemberg
Laboratory Director, Forensic Fluids Laboratories

Lt. Col. Richard T. Arnold
Michigan State Police

Insp. L. Scott Marier
Michigan State Police

Ms. Nicole Brown
Michigan State Police

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:

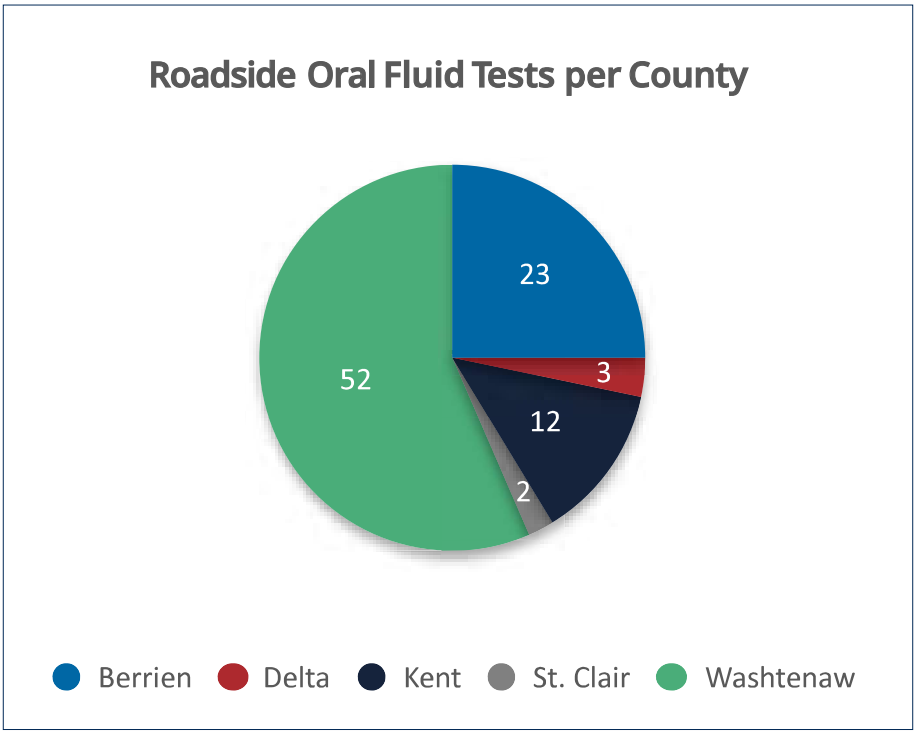
- History of the Oral Fluid Roadside Analysis Pilot Program
- Review of Public Acts 242 and 243 of 2016
- Proper Utilization of the Alere DDS2 Oral Fluid Test Instrument
- Forensic Fluids Independent Laboratory—collection of voluntary oral fluid test sample
- Reporting Requirements and Utilizing Proper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



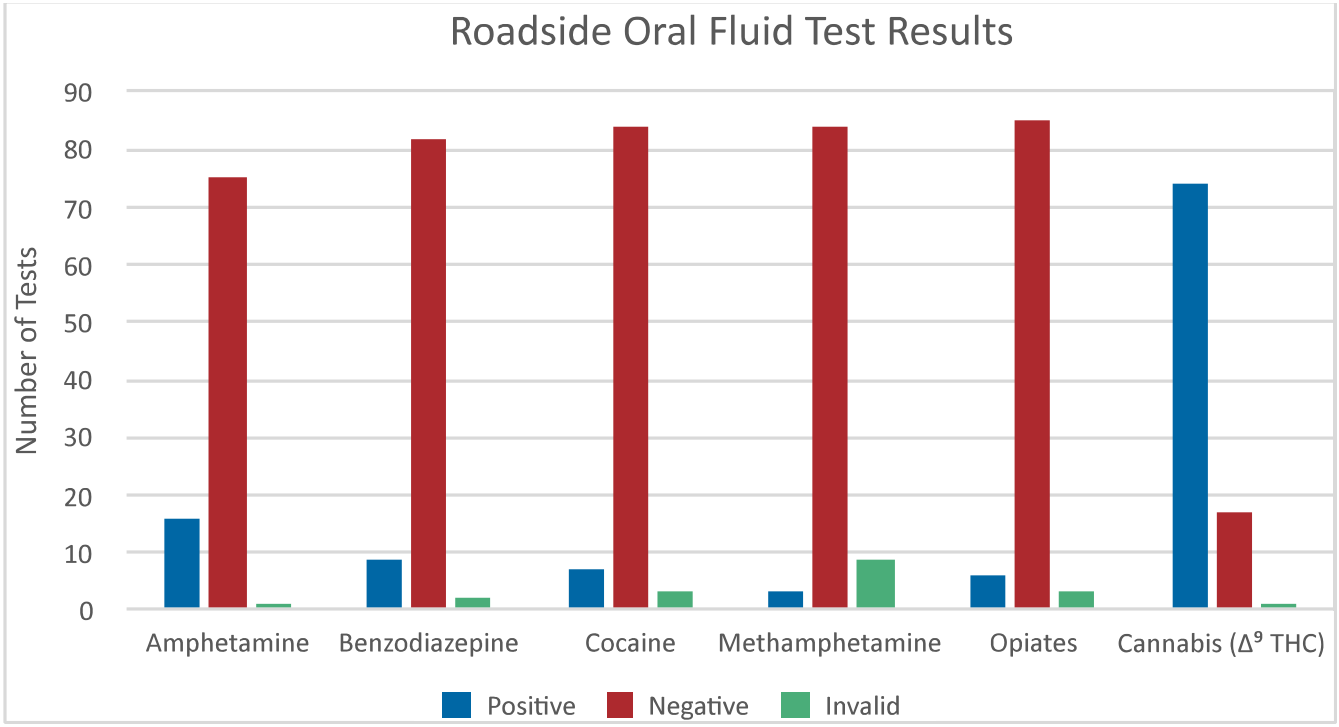
62 second voluntary oral fluid tests were collected using the Quantisal® oral fluid collection device with the balance of instances, 30, either being refused or not offered.

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.

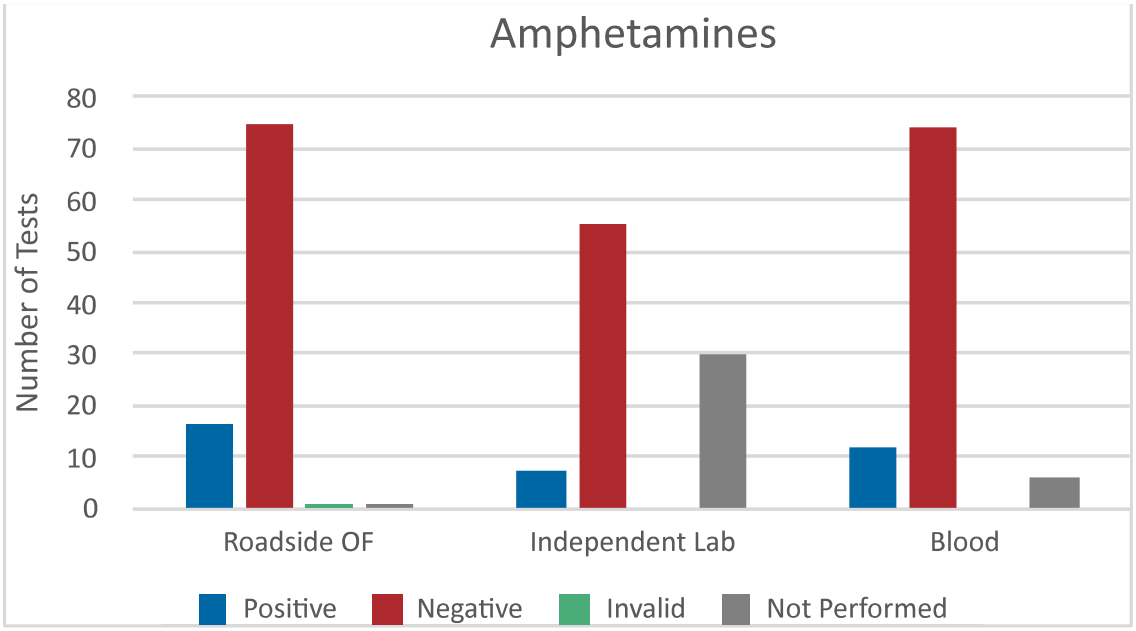
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

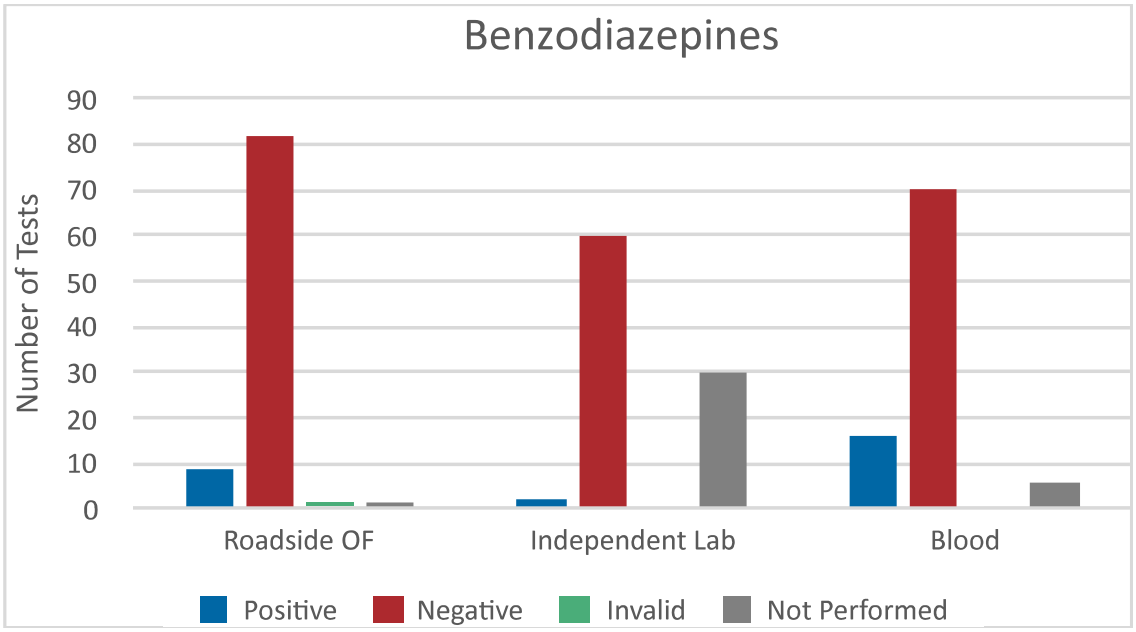


Results of the oral fluid roadside tests utilizing the Alere DDS2 instrument are detailed in the above chart. Of the 92 oral fluid roadside tests conducted, 21 returned positive results for the presence of two or more drugs. Eight tests provided negative results for all six drug categories. Six negative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

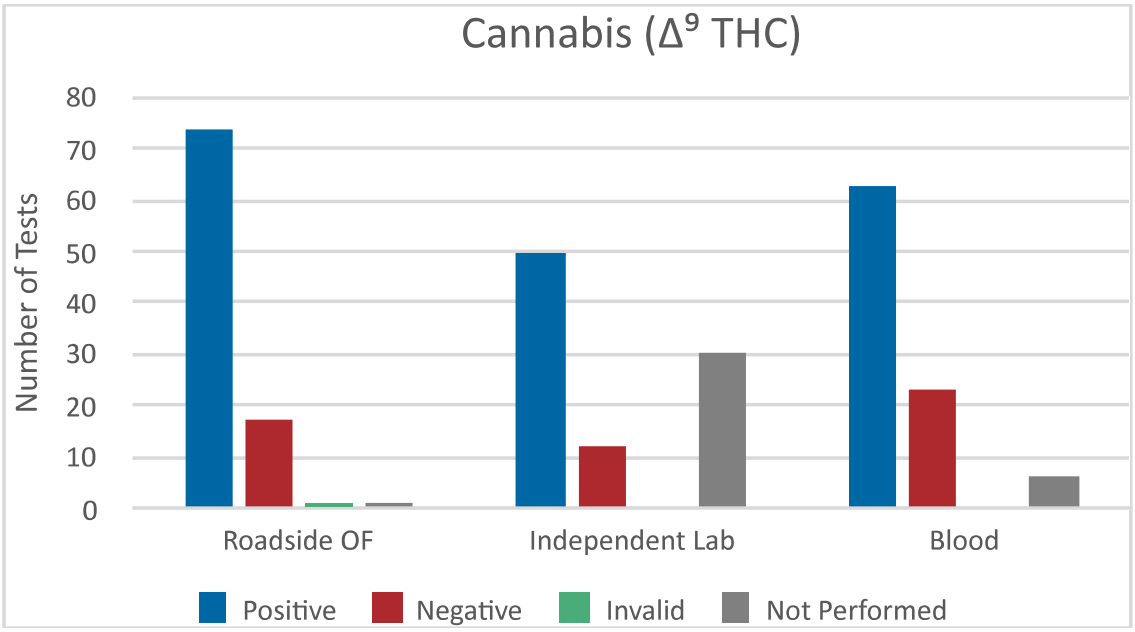
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM

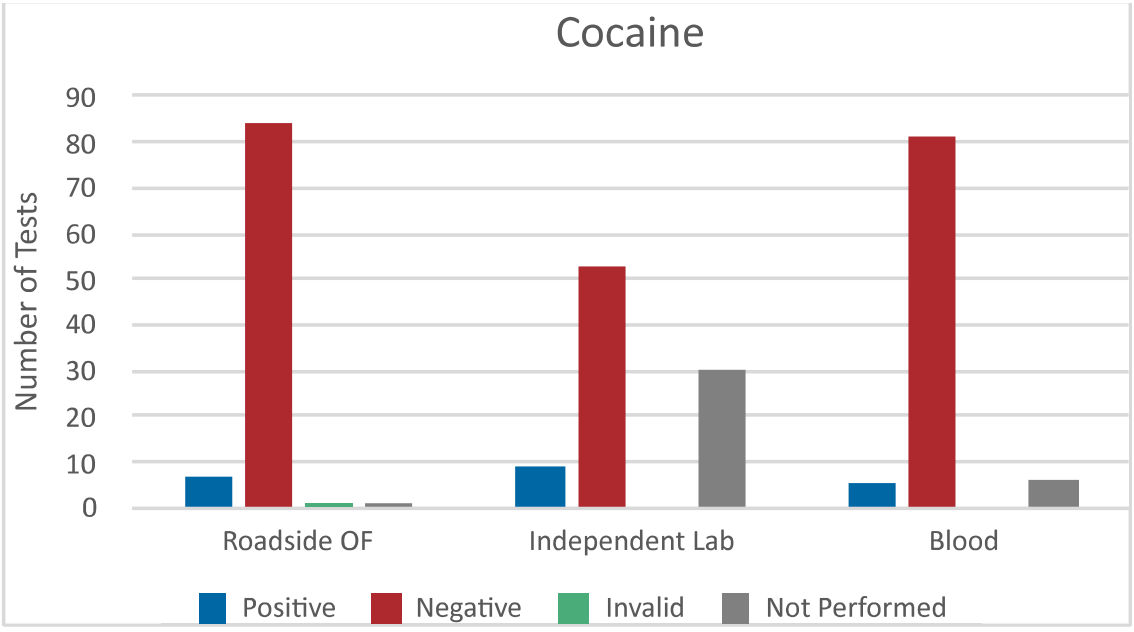
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:



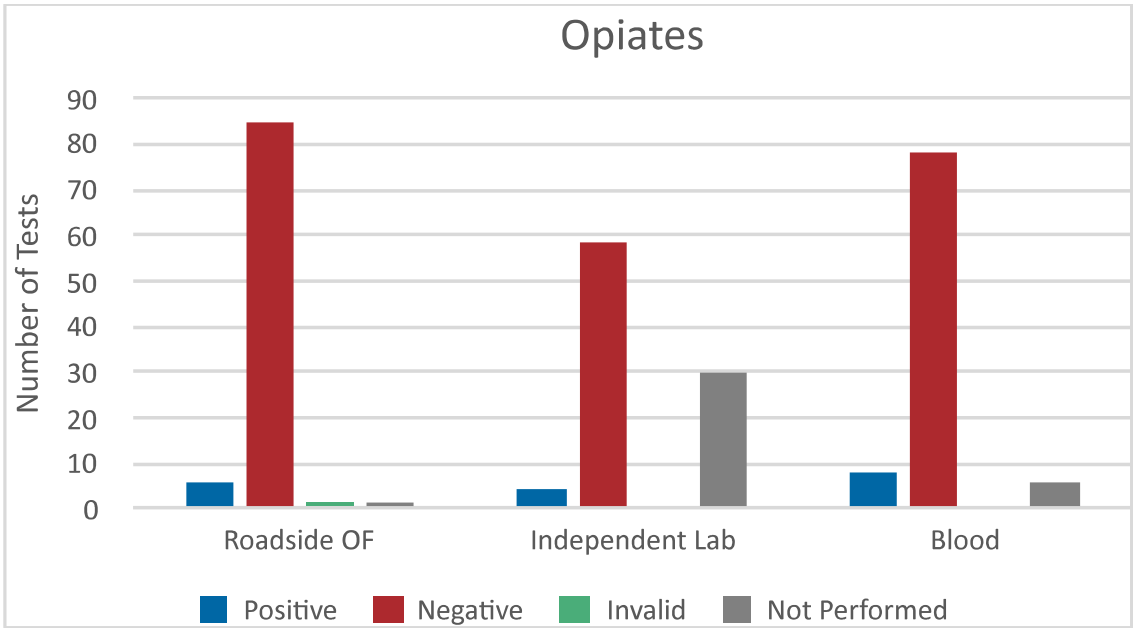


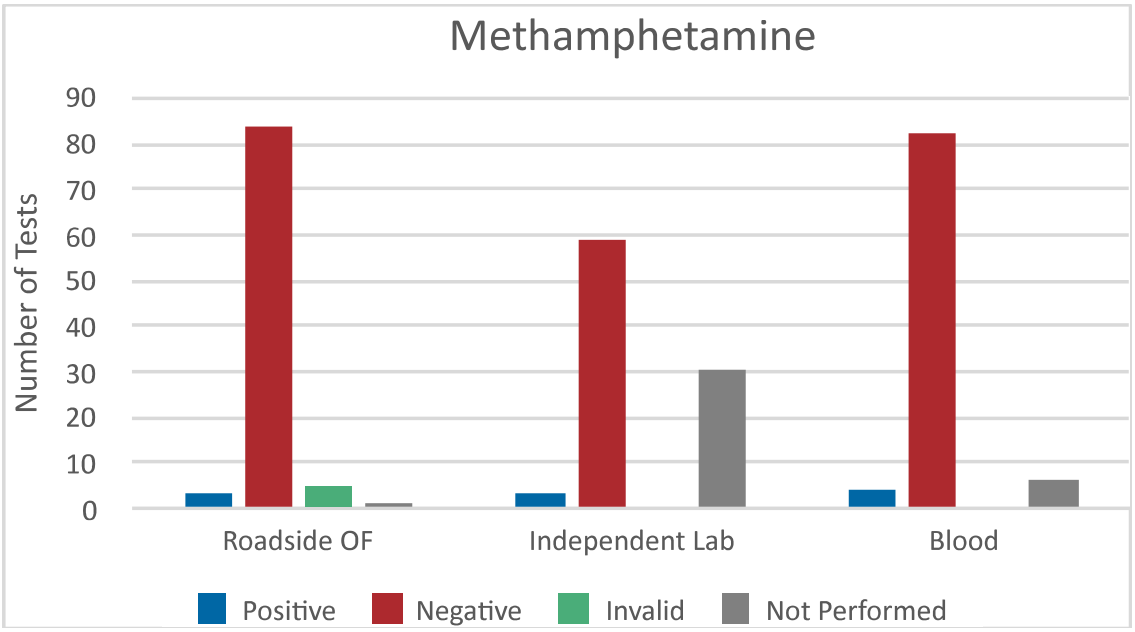
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM





RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM





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.

Senator Thomas Casperson

Mr. Brian Swift

MICHIGAN STATE POLICE EXECUTIVE COUNCIL:

Col. Joseph M. Gasper
Director, Michigan Department of State Police

Col. Kriste Etue, Ret.
Director, Michigan Department of State Police

Lt. Col. Richard T. Arnold
Deputy Director, State Services Bureau

Lt. Col. W. Thomas Sands
Deputy Director, Field Services Bureau

Lt. Col. Christopher Kelenske
Deputy Director, Specialized Services Bureau

Mr. Shawn Sible
Deputy Director, Administrative Services Bureau

Maj. Gregory Zarotney
Office of the Director

MICHIGAN STATE POLICE STATE SERVICES BUREAU:

Insp. L. Scott Marier

Ms. Nicole Brown

MICHIGAN STATE POLICE CRIMINAL JUSTICE INFORMATION CENTER:

Ms. Sherry Rosin

Mr. Ted Kilvington

MICHIGAN STATE POLICE FORENSIC SCIENCE DIVISION:

Mr. Jeffrey Nye

FORENSIC FLUIDS LABORATORIES:

Mr. David Bergland
Chief Operating Officer

Ms. Bridget Lorenz Lemberg
Laboratory Director

ABBOTTCORP. (FORMERLY ALERE):

Mr. Fred Delfino
Product Manager, DDS2 Forensic Test System

MICHIGAN STATE UNIVERSITY:

Dr. Dhruv B. Sharma, Ph.D.
Senior Statistician

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".

REFERENCES

Alabama Department of Forensic Sciences. (n.d.). Oral Fluid Drug Testing Program. Retrieved from https://adfs.alabama.gov/services/tox/toxicology-oral-testing-program

Alere Toxicology. (2019). Drug Testing Solutions. Retrieved from www.aleretoxicology.com/landing_pages/roadside.html

Alere Toxicology. (2015). Alere DDS2 Forensic Test Kit Instruction for Use.

Asbridge, M., & Ogilvie, R. (2015). A Feasibility Study of Roadside Oral Fluid Drug Testing. Retrieved from http://madd.ca/media/docs/feasibility-roadside-oral-fluid-drug-testing.pdf

Baselt, R. C. (1983). Stability of Cocaine in Biological Fluids. Journal of Chromatography, 268, 502-505. Retrieved from https://www.sciencedirect.com/science/article/pii/S0021967301954494?via%3Dihub

Brogan, W. C., Kemp, P. M., Bost, R. O., Glamann, D. B., Lange, R. A., & Hills, L. D. (1992). Collection and Handling of Clinical Blood Samples to Assure the Accurate Measurement of Cocaine Concentration. Journal of Analytical Toxicology, 16(3), 152-154. Retrieved from https://academic.oup.com/jat/article-abstract/16/3/152/718979?redirectedFrom=fulltext

Cone, D. J., & Huestis, M. (2007). Interpretation of Oral Fluid Tests for Drugs of Abuse. The New York Academy of Sciences. Retrieved from https://nyaspubs.onlinelibrary.wiley.com/doi/abs/10.1196/annals.1384.037

Edwards, L., Smith, K., & Savage, T. (2017). Drugged Driving in Wisconsin: Oral Fluid Versus Blood. Journal of Analytical Toxicology, Volume 41 (Issue 6). Retrieved from https://academic.oup.com/jat/CrossRef-CitedBy/3964594

Gjerde, H., Langel, K., & Favretto, D. V. (2014, March). Estimation of Equivalent Cutoff Thresholds in Blood and Oral Fluid for Drug Prevalence Studies. Journal of Analytical Toxicology, 38 (2). Retrieved from https://academic.oup.com/jat/article/38/2/92/753450

Gwinn Truck Driver Charged in Deadly Accident. (2013, June 4). The Mining Journal. Retrieved from http://www.miningjournal.net/news/front-page-news/2013/06/gwinn-truck-driver-charged-in-deadly-accident/

Hartman RL, Brown TL, Milavetz G, Spurgin A, Gorelick DA, Gaffney GR, & Huestis MA. (2016). Effect of Blood Collection Time on Measured Δ9-Tetrahydrocannabinol Concentrations: Implications for Driving Interpretation and Drug Policy. Clinical chemistry, 62(2), 367-77. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/26823611

Huestis, M. (2007, August). Human Cannabinoid Pharmacokinetics Chemical Biodiversity. Chemistry & Biodiversity, 4(8), 1770-1804. Retrieved from https://onlinelibrary.wiley.com/doi/abs/10.1002/cbdv.200790152

REFERENCES

International Association of Chiefs of Police. (n.d.). Drug Recognition Experts (DREs). Retrieved from https://www.theiacp.org/drug-recognition-experts-dres

IACP. (n.d.). 12 Step Process. Retrieved from https://www.theiacp.org/12-step-process

Isenchmid, D. S., Leving, B. S., & Caplan, Y. H. (1989). A Comprehensive Study of the Stability of Cocaine and Its Metabolites. Journal of Analytical Toxicology, 13(5), 250-256. Retrieved from https://academic.oup.com/jat/article-abstract/13/5/250/751066?redirectedFrom=fulltext

Kintz, P., Cirimele, V., Muhlmann, F., & Ludes, B. (2000). Drug Tests on 198 Drivers Involved in an Accident. Presse Medicale, 29(23), 1275-1278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/10923130

Legislature Service Bureau. (2019). Section 257.625. Retrieved from http://legislature.mi.gov/doc.aspx?mcl-257-625

Legislature Service Bureau. (2019). Section 257-625a. Retrieved from http://legislature.mi.gov/doc.aspx?mcl-257-625a

Legislature Service Bureau. (2019). Senate Bill 0434 (2015). Retrieved from http://legislature.mi.gov/doc.aspx?2015-SB-0434

Legislature Service Bureau. (2019). Senate Bill 0207 (2015). Retrieved from http://legislature.mi.gov/doc.aspx?2015-SB-0207

Logan, B. K., & Mohr, A. L. (2015). Final Report: Vermont Oral Fluid Drug Testing Study 2015. Center for Forensic Science Research & Education. Retrieved from https://docplayer.net/23222304-Final-report-vermont-oral-fluid-drug-testing-study-2015.html

Marquette County Man's Appeal Denied in Fatal Crash Case. (2015, December 31). The Mining Journal. Retrieved from http://www.miningjournal.net/news/region/2015/12/marquette-county-man-s-appeal-denied-in-fatal-crash-case/

Michigan State Police. (2018, March 28). Michigan Traffic Crash Decade-At-A-Glance. Retrieved from https://www.michigan.gov/documents/msp/DecadeGlanceFatals_382744_7.pdf

MSP. (2019). Toxicology. Retrieved from https://www.michigan.gov/msp/0,4643,7-123-72297_60141_60282_70710---,00.html

MSP. (2016). 2015 Michigan Annual Drunk Driving Audit. Retrieved from https://www.michigan.gov/documents/msp/2015_DDA_528502_7.pdf

Moore, C., & Kelley-Baker, T. L. (2013, April 4). Field Testing of the Alere DDS2 Mobile Test System for Drugs in Oral Fluid. Journal of Analytical Toxicology, Volume 37 (Issue 5), Retrieved from https://academic.oup.com/jat/article/37/5/305/786353

REFERENCES

Moore, C., & Miles, A. (2015). Oral Fluid in DUID Cases. Between the Lines, 23(2), Retrieved from http://www.ndaa.org/pdf/BTL-v23-no2-V2.pdf

National Highway Traffic Safety Association. (2018). SWI Detection and Standardized Field Sobriety Testing. Retrieved from https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/sfst_full_instructor_manual_2018.pdf

Peaire, A., Filber, A., Smith, D., Beirness, D., Viel, E., & Wallage, R. (2017). Report on Drug Per Se Limits. Retrieved from https://www.csfs.ca/wp-content/uploads/2017/09/Report-on-Drug-Per-Se-Limit.pdf

Scheidweiler, K. B., Schwope, D. M., Karschner, E. L., Desrosiers, N. A., Gorelick, D. A., & Huestis, M. A. (2013). In vitro stability of free and glucuronidated cannabinoids in blood and plasma following controlled smoked cannabis. Clinical chemistry, 59(7), 1108-17. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3844293/

Stecker, K. (2014). Traffic Safety Legal Update. Retrieved from https://komornlaw.com/wp-content/uploads/2018/02/Ken_Stecker_452069_7.pdf

Stefano, G., Solimini, R., Tittarelli, R., Mannocchi, G., & Busardo, F. (2016). A Study on the Reliability of an On-Site Oral Fluid Drug Tes in a Recreational Context. Journal of Analytical Methods in Chemistry. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5005587/

Steinmeyer, S., Ohr, H., Maurer, H. J., & Moeller, M. R. (2001). Practical Aspects of Roadside Tests For Adminstratvie Traffic Offences in Germany. Forensic Science International, 121, (1-2). Retrieved from https://www.sciencedirect.com/science/article/pii/S0379073801004509

Truck Driver Sentenced in Gladstone Fatal Crash. (2014, July 18). The Daily News. Retrieved from http://www.ironmountaindailynews.com/news/local-news/2014/07/truck-driver-sentenced-in-gladstone-fatal-crash/

Veitenheimer, A. M., & Wagner, J. R. (2017). Evaluation of Oral Fluid as a Specimen for DUID. Journal of Analytical Toxicology, 41 (6). Retrieved from https://academic.oup.com/jat/article/41/6/517/3867164

Yamada, K. & Yamada, K. & Katsuda, I. & Hida, T. (2008). Cubital fossa venipuncture sites based on anatomical variations and relationships of cutaneous veins and nerves. Clinical anatomy, 21, 307-13. Retrieved from https://www.researchgate.net/publication/5423881_Cubital_fossa_venipuncture_sites_based_on_anatomical_variations_and_relationships_of_cutaneous_veins_and_nerves

ORAL FLUID ROADSIDE ANALYSIS
PILOT PROGRAM - PHASE II

JANUARY 2021

ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

Pursuant to the reporting requirements of Public Act 243 of 2016, this supplemental report details the findings of the Second Phase of the Oral Fluid Roadside Analysis Pilot Program. This report has been prepared for submission to the Senate Judiciary and Public Safety Committee and the House Judiciary Committee. This report contains the 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 Phase II Committee.

CURRENT COMMITTEE MEMBERS:

F/Lt. Shannon Sims
Michigan State Police

Maj. Michael Krumm
Michigan State Police

Mr. Nicholas Fillinger
Michigan State Police

Mr. Kenneth Stecker
Prosecuting Attorneys Association of Michigan

Ms. Kinga Canike
Prosecuting Attorneys Association of Michigan

Mr. Michael Harris
DRE Coordinator, Michigan State Police

F/Lt. Matthew Williams
Michigan State Police

FORMER COMMITTEE MEMBERS:

Capt. Richard Arnold
Michigan State Police

F/Lt. James Flegel
Michigan State Police

Insp. Scott Marier, Ret.
Michigan State Police

Ms. Nicole Brown
Michigan State Police

OTHER CONTRIBUTORS:

Dr. Dhruv B. Sharma, Ph.D.
Statistician, Michigan State University

Mr. David Bergland
Chief Operating Officer, Forensic Fluids Laboratories

Ms. Bridget Lorenz Lemberg
Laboratory Director, Forensic Fluids Laboratories

Mr. Fred Delfino
Abbott SoToxa Mobile Test System

Ms. Sherry Rosin
Michigan State Police

INTRODUCTION

Phase I of the Oral Fluid Roadside Analysis Pilot Program provided valuable data on the overall performance and utility of the Roadside Oral Fluid Instrument. However, the data set for drug classes were not large enough to achieve a high confidence level in the obtained results. In December of 2018, the Michigan Legislature approved the expansion of the Oral Fluid Roadside Analysis Pilot Program. The purpose of Phase II was to collect and analyze additional data to better evaluate the roadside oral fluid test instrument. The expanded Oral Fluid Roadside Analysis Pilot Program will be referred to as Phase II throughout this report.

The expansion of the pilot, Phase II, began on October 1, 2019, and concluded on September 30, 2020. Phase II collected data from 693 incidents and 661 Roadside Oral Fluid Tests. There were 131 Drug Recognition Experts (DRE's) from 65 different law enforcement agencies that participated in Phase II. The expansion of the pilot included 69 counties in Michigan during Phase II.

This report is meant to supplement the initial Oral Fluid Roadside Analysis Pilot Program. The statistical information contained in this report only includes data collected during Phase II.

ROADSIDE ORAL FLUID TEST INSTRUMENT

The roadside oral fluid test instrument that was used during Phase II, was also used during Phase I. The Alere DDS2, which was the first name given to the roadside oral fluid test instrument, is now called the Abbott SoToxa Mobile Test System, and will be referred to as the SoToxa. The SoToxa is capable of testing six different drug classes, which are listed below. The SoToxa instrument is designed to report results within five minutes from the time the sample is entered into the instrument. The SoToxa requires one oral fluid sample to be taken from an individual for the instrument to analyze all six drug panels. The six drug panels are Amphetamine, Benzodiazepines, Cannabis (^9THC), Cocaine, Methamphetamine, and Opiates. The cut-off level for these drugs, which was established by Abbott, for each drug panel, is listed below.

SoToxa Drug Class Cut Off Levels

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

The SoToxa instrument provides either a positive, negative, or invalid result.

- A positive result is reported when the oral fluid sample contains at least the minimum cut-off amount of a drug for each specific panel.
- A negative result is reported when the oral fluid sample does not contain the minimum cut-off amount of a drug for each specific panel.
- An invalid result is reported when there is not enough oral fluid sample to be examined.

A positive or negative SoToxa test result by itself does not determine driver impairment. The SoToxa instrument merely provides an officer with additional information to consider during an investigation.

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 cut-off 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, 1ng/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 (^9THC)	1.0	44
Cocaine	10	190
Methamphetamine	20	630

INDEPENDENT LABORATORY CONFIRMATION TEST

The secondary oral fluid sample, considered a voluntary sample, is collected using the Quantisal oral fluid collection device. When a voluntary sample is collected, the DRE instructs the driver to remove the collector from the package, position the collector under their tongue, and then close their mouth. The driver is instructed not to chew on the pad or talk until the indicator turns blue, or until 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 as the accredited independent laboratory performing confirmation testing of the voluntary oral fluid sample to ensure the accuracy and reliability of the SoToxa oral fluid instrument in both phases. FFL tested for the six drug panels: Amphetamines, methamphetamines, opiates, cocaine, benzodiazepines, and cannabinoids, consistent with the SoToxa instrument.

PILOT PROGRAM POLICIES

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

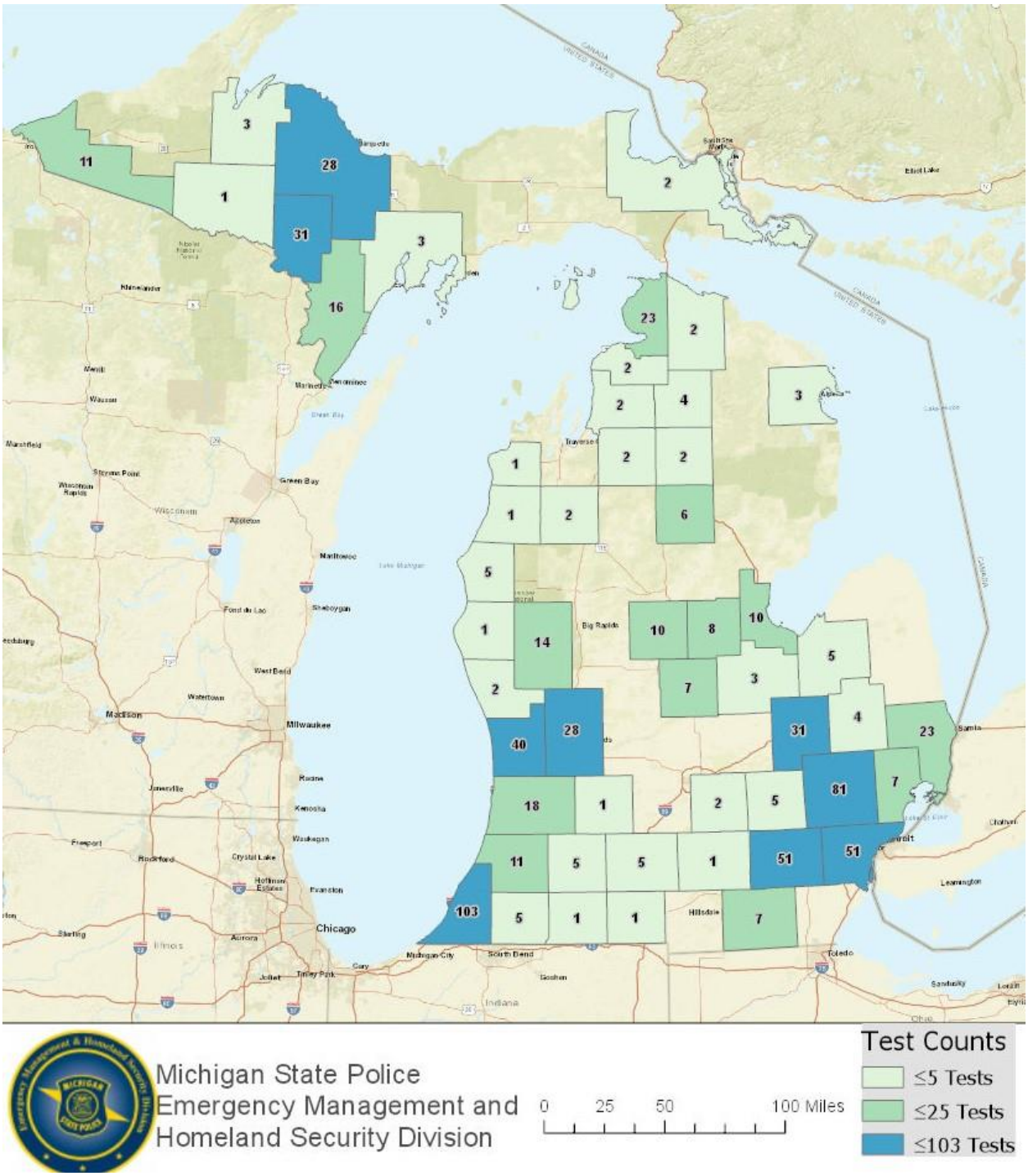
Prior to participation in the program, DREs attended a training session to include:

- History of the Oral Fluid Roadside Analysis Pilot Program
- Review of Public Acts 242 and 243 of 2016
- Proper use of the SoToxa 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 and procedures when investigating impaired driving incidents and crashes.

COUNTIES THAT PARTICIPATED IN PHASE II

The map below shows the counties that had a DRE assigned during the Oral Fluid Roadside Analysis Pilot Program Phase II. The number listed within the county is the total number of incidents reported during Phase II.



LAW ENFORCEMENT AGENCIES THAT PARTICIPATED IN PHASE II

Michigan State Police Hart Post
Michigan State Police Wayland Post
Michigan State Police Niles Post
Michigan State Police Calumet Post
Michigan State Police Paw Paw Post
Michigan State Police Iron Mountain Post
Michigan State Police Wakefield Post
Michigan State Police Negaunee Post
Michigan State Police Rockford Post
Michigan State Police Sault Ste. Marie Post
Michigan State Police Marshall Post
Michigan State Police Cadillac Post
Michigan State Police Gaylord Post
Michigan State Police Brighton Post
Michigan State Police Houghton Lake Post
Michigan State Police Jackson Post
Michigan State Police Tri-City Post
Michigan State Police Lapeer Post
Michigan State Police Caro Post
Michigan State Police Metro North Post
Michigan State Police Metro South Post
Michigan State Police Gladstone Post
Macomb County Sheriff's Office
Hamburg Township Police Department
Imlay City Police Department
Adrian Township Police Department
Novi Police Department
Canton Township Police Department
Troy Police Department
Clawson Police Department
University of Michigan Police Department
Battle Creek Police Department
Pokagon Tribal Police Department
Berrien County Sheriff's Office
Western Michigan University Department of Public Safety
Chikaming Township Police Department
Alpena Police Department
Grand Haven Department of Public Service
Cadillac Police Department
Grand Rapids Police Department
Charlevoix County Sheriff's Office
Grand Valley State University Department of Public Safety
Escanaba Department of Public Safety
Greenville Department of Public Safety
Gogebic County Sheriff's Office
Kent County Sheriff's Office
Kalkaska County Sheriff's Office
Monroe Department of Public Safety
Lapeer Police Department
Muskegon Police Department
Livonia Police Department
Ottawa County Sheriff's Office
Marquette County Sheriff's Office
Wayland Police Department
Menominee Police Department
Alma Police Department
Oscoda Township Police Department
Bay City Department of Public Safety
Petoskey Department of Public Safety
Bay County Sheriff's Office
Roscommon County Sheriff's Office
Grand Blanc Township Police Department
Southfield Police Department
Lake County Sheriff's Office
St. Clair County Sheriff's Office
Mt. Pleasant Police Department
Dearborn Police Department
Allegan County Sheriff's Office
Holland Department of Public Safety
Fremont Police Department
Ludington Police Department
Lincoln Township Police Department
Emmet County Sheriff's Office
Washtenaw County Sheriff's Office
Manistee County Sheriff's Office
Ypsilanti Police Department
Benton Township Police Department
Ann Arbor Police Department
Oakland County Sheriff's Office
Auburn Hills Police Department
Wayne State University Police Department
Bloomfield Township Police Department
Oxford Police Department
Ingham County Sheriff's Office
Midland Police Department
Port Huron Police Department

GENERAL DRUG CLASS INFORMATION
SUBMITTED BY MR. NICHOLAS FILLINGER, TOXICOLOGY TECHNICAL LEADER, MSP

The State of Michigan conducted a pilot study to assess the SoToxa oral fluid screening device, to determine if the SoToxa could be an effective tool for law enforcement, to assist in combating drugged driving. The following list of drugs are those that are detected by the SoToxa device, along with potential observations associated with impairment. Note that the device screens for a few common substances that can cause impairment, and a negative test result on the SoToxa does not rule out the presence of drugs that are not included in the assay or drugs that are present below the assay analytical cut-off. As not all side effects/adverse effects are expected to cause potential driving impairment, not all are given.

It should be noted that a positive result on the SoToxa does not automatically equate to impairment, and conversely a negative result does not automatically equate to lack of impairment.

AMPHETAMINE:

Amphetamine is a central nervous system stimulant typically used clinically for the treatment of ADHD, narcolepsy, and weight loss. Excessive doses of amphetamine can cause restlessness, anxiety, confusion, irritability, hyperactivity and aggressive or bizarre behavior.

There are two isomers of amphetamine, *d*-amphetamine, and *l*-amphetamine. Drugs containing *d*, *l*, or a combination of *d* and *l* amphetamine are Benzedrine, Adderall, and Dexedrine. The SoToxa targets *d*-amphetamine to determine whether the oral fluid is positive/negative. 3,4-methylenedioxyamphetamine (MDA, sass, sally) and 3,4-methylenedioxymethamphetamine (MDMA, ecstasy, molly) also yield a positive result if present in high enough concentrations.

BENZODIAZEPINES:

Benzodiazepines are central nervous system depressants, typically used clinically for the treatment of anxiety and depression. Adverse effects of benzodiazepine therapy include drowsiness and confusion.

The SoToxa targets temazepam (Restoril) to determine whether the oral fluid is positive/negative, however diazepam (Valium) and alprazolam (Xanax) will yield a positive result if present above the cut-off. Additional benzodiazepines will also result in a SoToxa positive, such as clonazepam (Klonopin) and lorazepam (Ativan), although these must be present in high concentrations.

GENERAL DRUG CLASS INFORMATION
SUBMITTED BY MR. NICHOLAS FILLINGER, TOXICOLOGY TECHNICAL LEADER, MSP

CANNABIS:

Cannabis (marijuana) is a psychoactive drug used for recreational and medicinal purposes. The acute psychological effects of cannabis use include euphoria, dysphoria, sedation, and altered perception. Reaction time, perception, short-term memory, attention, motor skills, tracking and skilled activities may be impaired due to acute cannabis intoxication.

The SoToxa targets the main psychoactive cannabinoid, delta-9-tetrahydrocannabinol (THC), to determine whether the oral fluid is positive/negative. 11-hydroxy-delta-9-tetrahydrocannabinol (active metabolite of THC, also known as THC-OH) and 11-nor-9-carboxy-delta-9-tetrahydrocannabinol (inactive metabolite of THC, also known as THC-COOH) will also result in a SoToxa positive, although they are unlikely to be present in high enough concentrations in oral fluid.

COCAINE:

Cocaine is a central nervous system stimulant, used for recreational purposes, and medicinally as a local anesthetic. The symptoms of acute cocaine toxicity are similar to amphetamine: restlessness, anxiety, confusion, irritability, hyperactivity and aggressive or bizarre behavior.

The SoToxa targets benzoylecgonine (inactive cocaine metabolite) to determine whether the oral fluid is positive/negative. Cocaine and cocaethylene (a compound produced in the body when cocaine and alcohol are ingested together), will yield a positive result if present in high enough concentrations.

OPIATES:

Opiates are typically used clinically for the treatment of pain. Adverse effects of opiate therapy include drowsiness, dizziness, and confusion.

The SoToxa targets morphine to determine whether the oral fluid is positive/negative, however codeine, dihydrocodeine and diacetylmorphine (heroin) will yield a positive result if present in high enough concentrations.

GENERAL DRUG CLASS INFORMATION
SUBMITTED BY MR. NICHOLAS FILLINGER, TOXICOLOGY TECHNICAL LEADER, MSP

METHAMPHETAMINE:

Methamphetamine is a central nervous system stimulant typically used clinically for ADHD and weight loss. Adverse effects of methamphetamine include dizziness, confusion, anxiety, and hallucinations.

There are two isomers of methamphetamine, *d*-methamphetamine, and *l*-methamphetamine. *d*-methamphetamine is found in drugs such as Desoxyn, and, has gained notoriety as a recreational drug. *l*-methamphetamine is used in certain non-prescription inhalers as a decongestant, and, has weaker central stimulant action than the d-isomer.

The SoToxa targets *d*-methamphetamine to determine whether the oral fluid is positive/negative. Amphetamine, 3,4-methylenedioxymethamphetamine (MDMA, ecstasy, molly), 3,4-methylenedioxy-N-ethyl-amphetamine (MDEA, eve), ranitidine (Zantac), and 3,4-methylenedioxyamphetamine (MDA, sally) will yield a positive result if present in high enough concentrations.

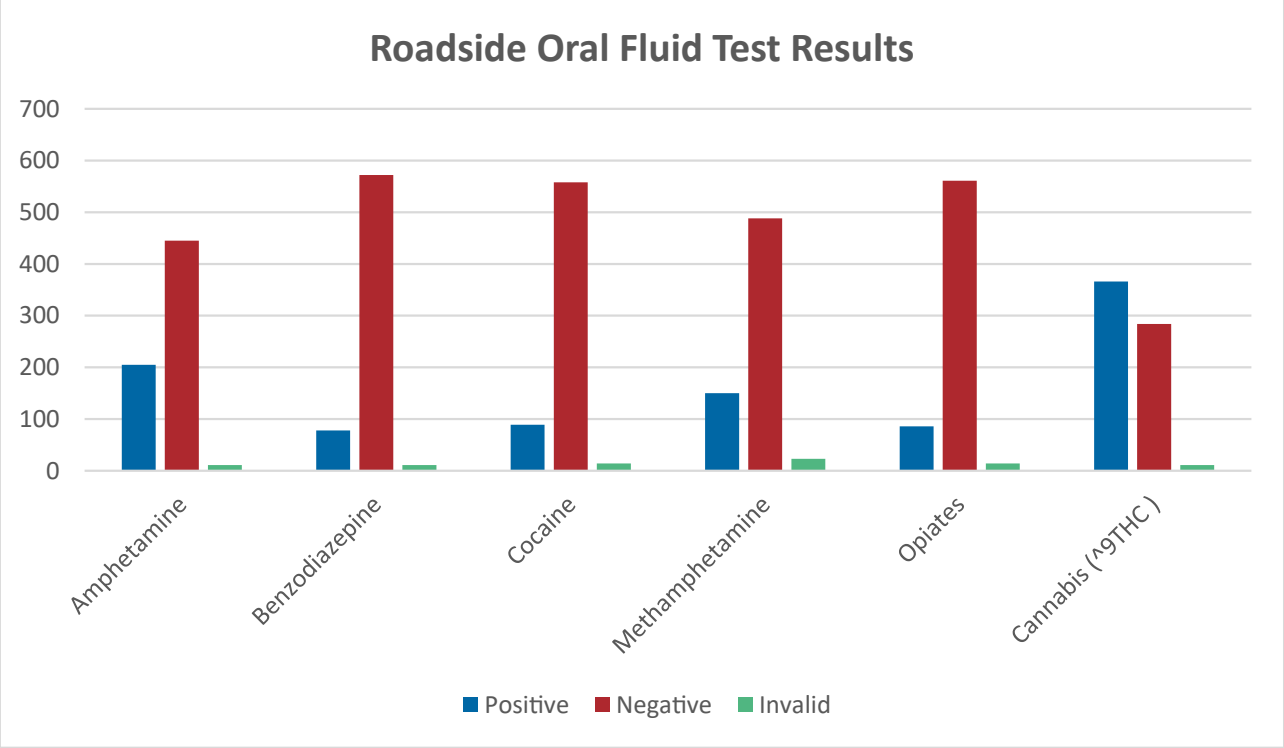
RESULT INTERPRETATION:

When comparing drug results from the SoToxa roadside instrument, the voluntary oral fluid confirmation, and the blood confirmation, the following should be considered:

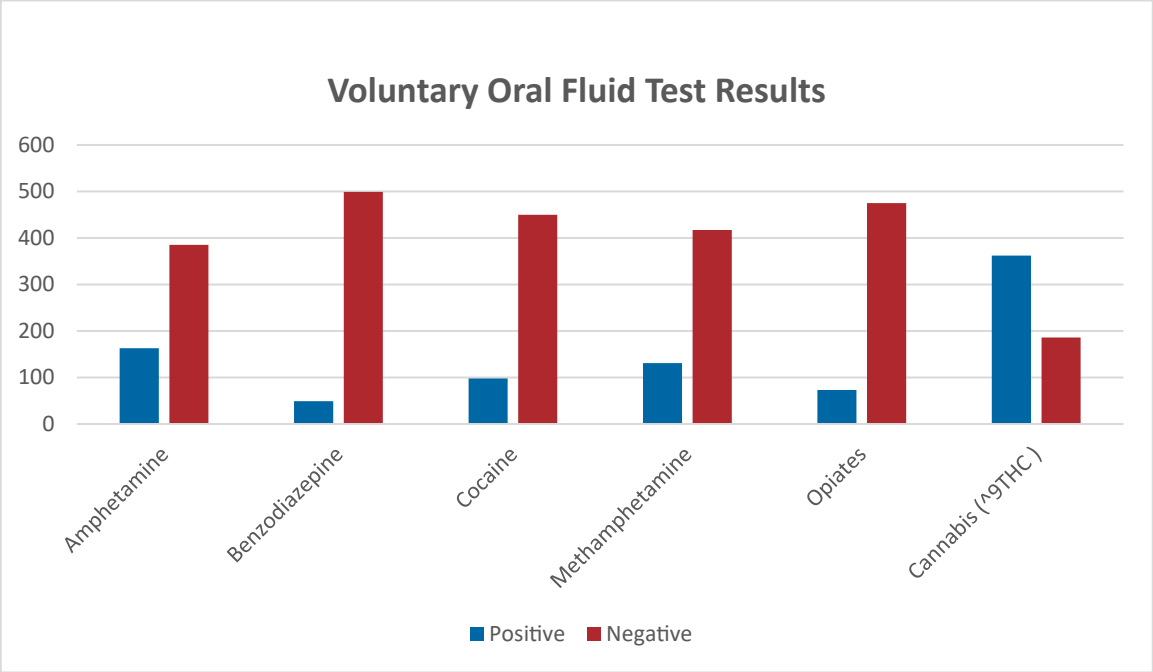
- Matrix analyzed
- Cut-off levels
- Limit of detection
- Limit of quantification
- Cross reactivity
- Confirmatory instrumentation
- Scope of analysis
- Incident time vs. sample collection time

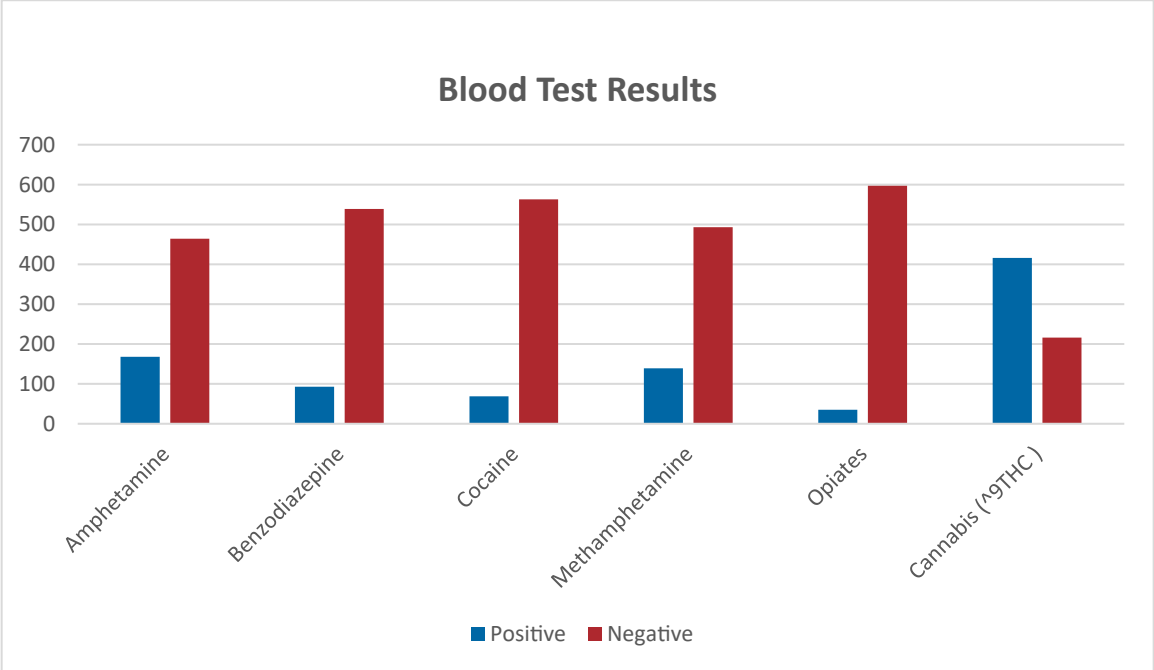
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

There were 693 total incidents that occurred between October 1, 2019, and September 30, 2020, that were reported and analyzed during Phase II. The following charts show the results from the 661 oral fluid roadside tests, 547 voluntary oral fluid tests, and 632 blood tests. There were 17 refusals to take the oral fluid roadside tests, and 15 times where the test was not offered. There were 57 refusals to take the voluntary oral fluid tests, and 88 times where the test was not offered.



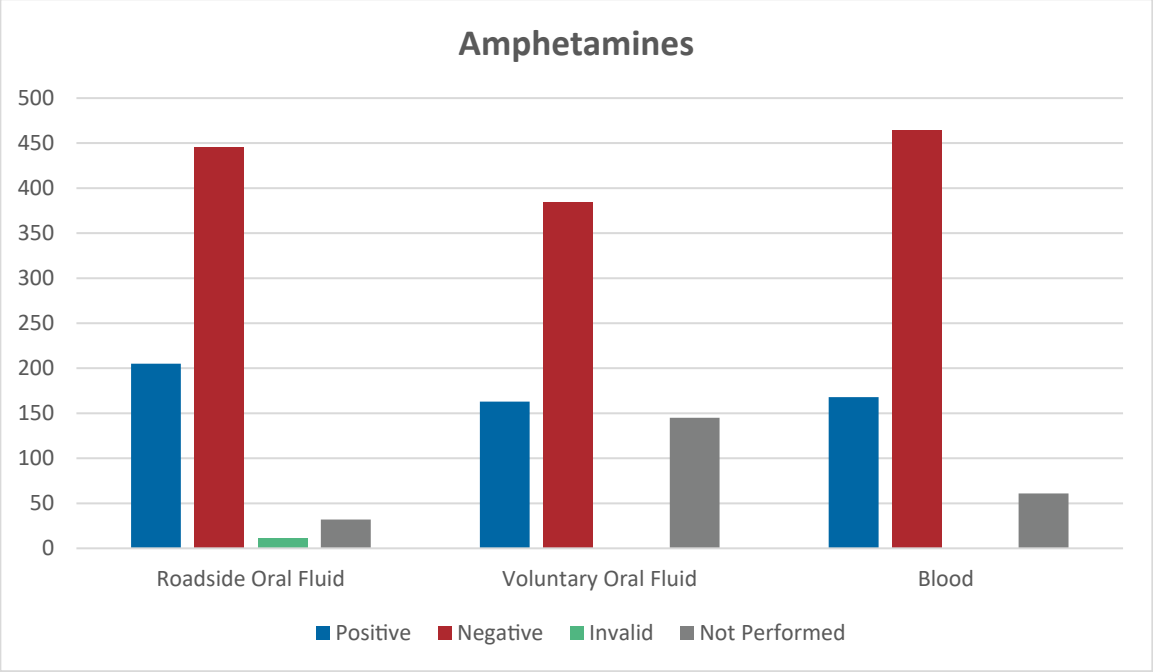
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

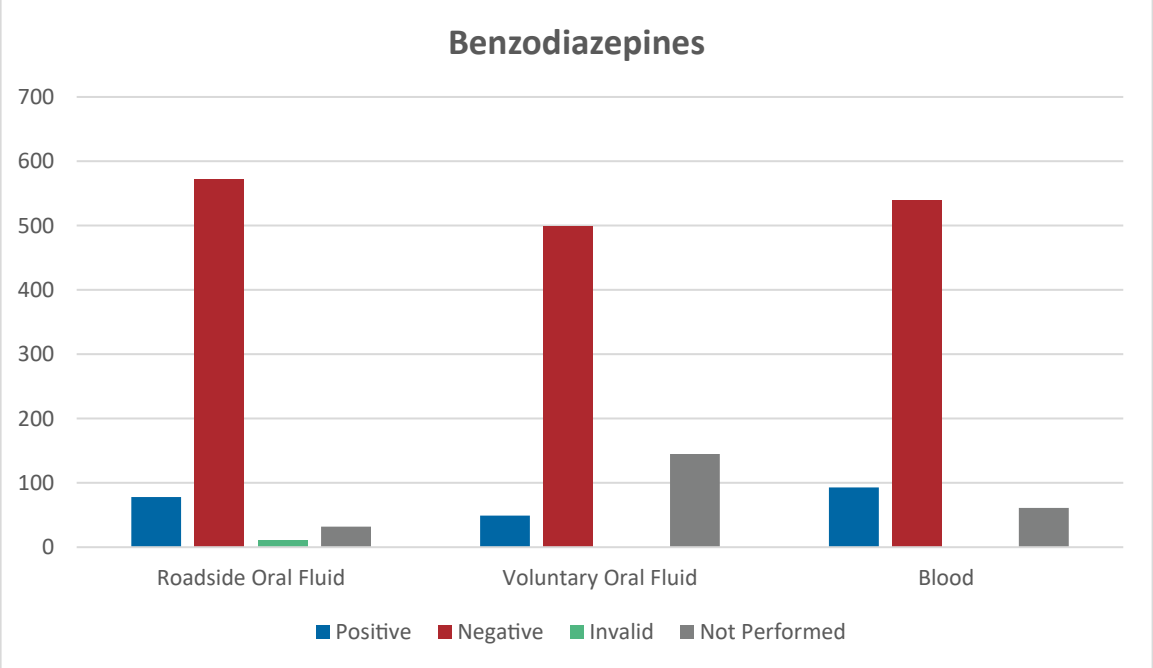




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

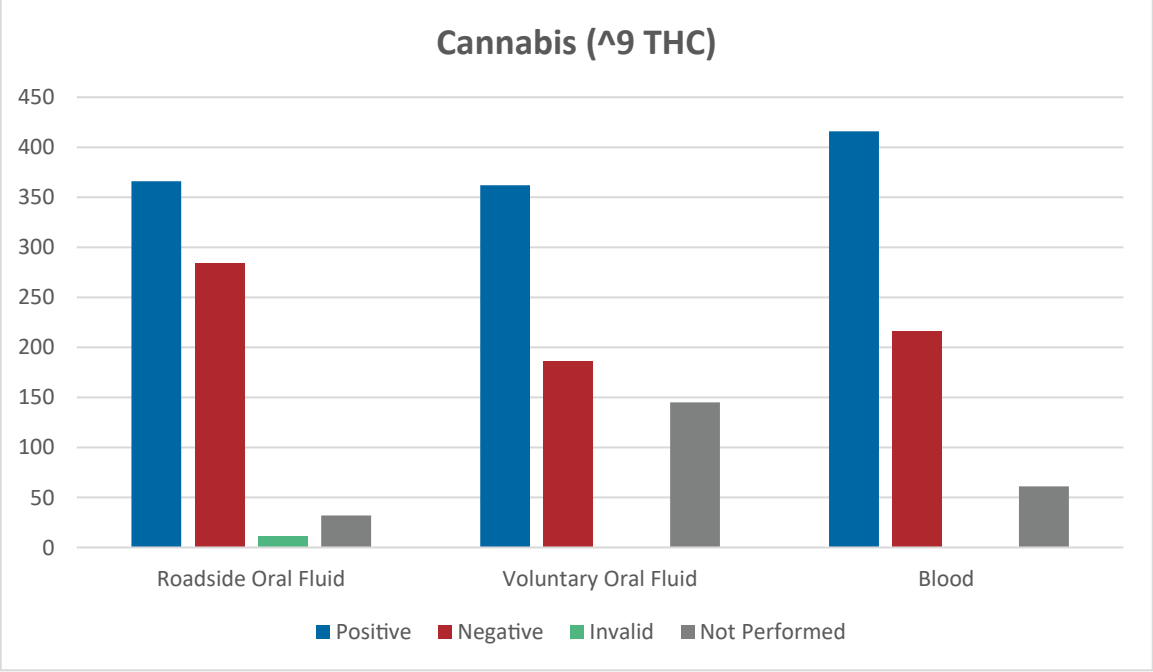
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

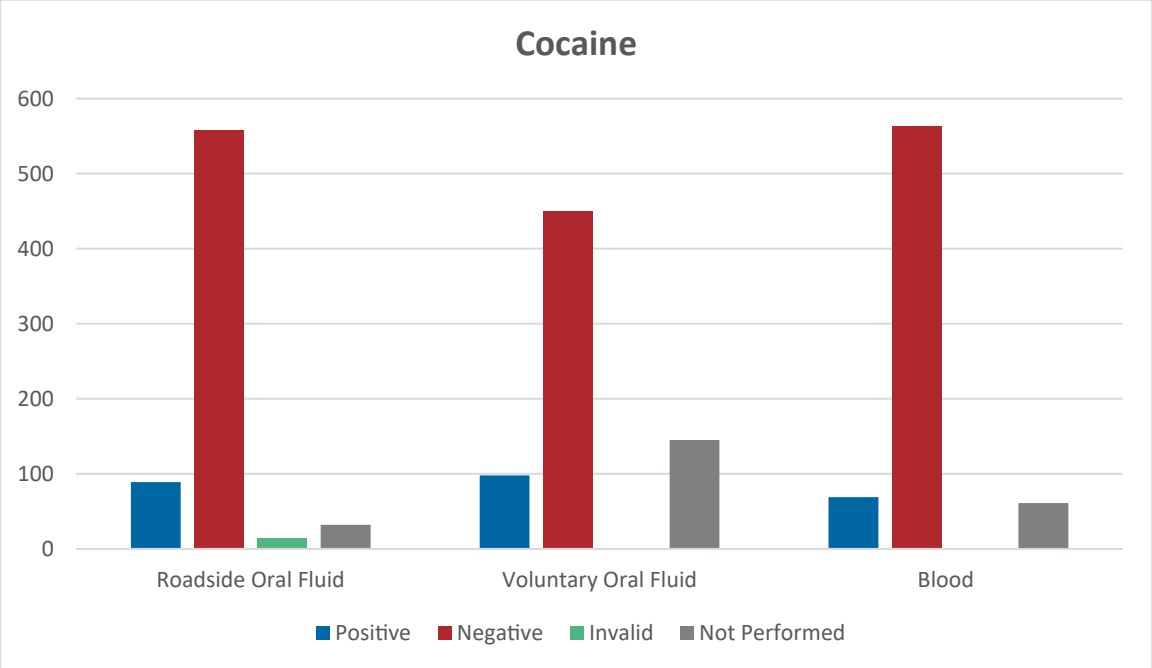




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

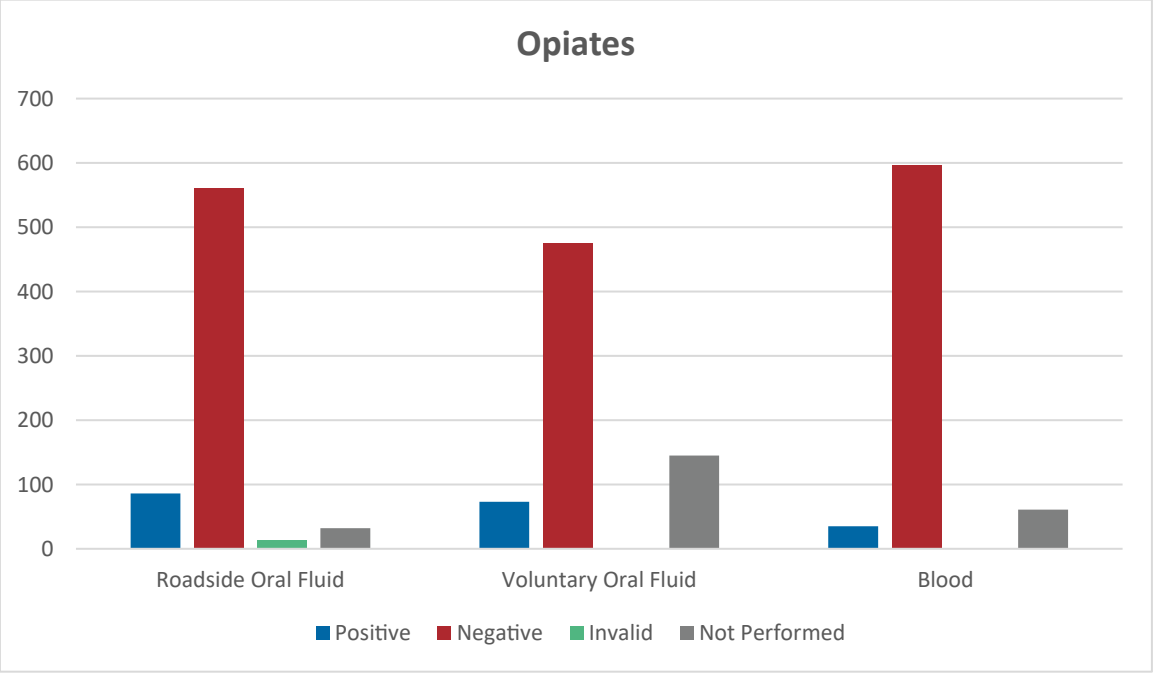
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

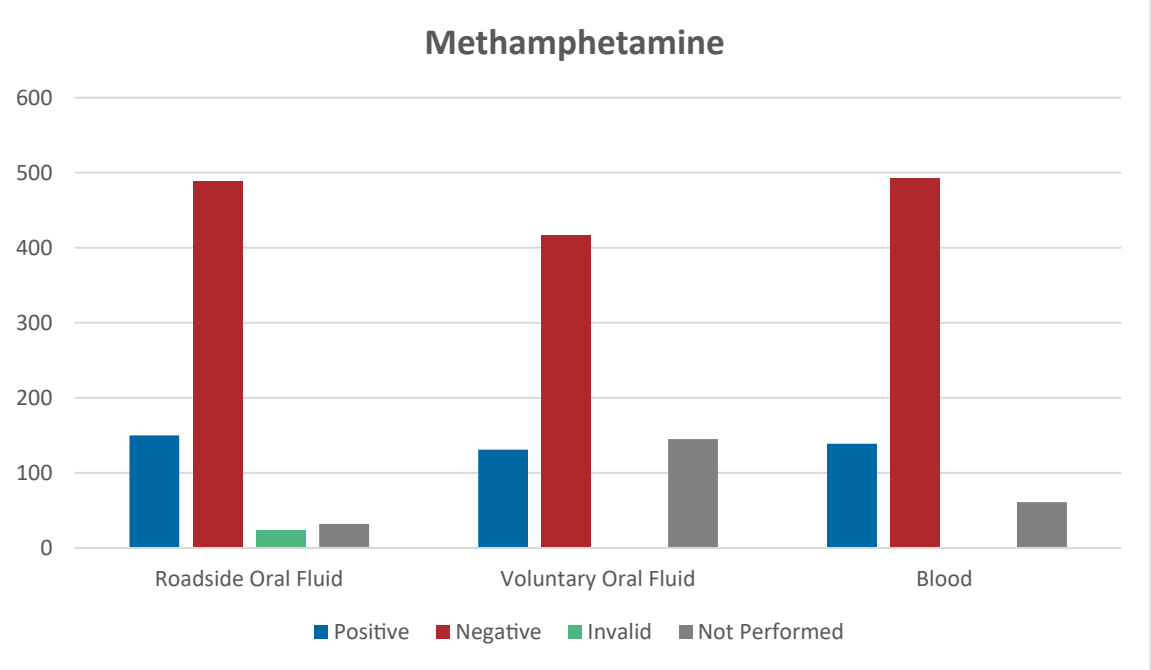




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

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





RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

As noted in Phase I of the pilot program, there are differences between roadside and voluntary oral fluid tests and blood tests. The 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 Phase II, 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 the blood test, i.e., 1 ng/ml in oral fluid does not equate to 1 ng/mL in blood. In many cases, 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 take place hours after the initial police contact, and the subsequent testing could take place 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. MSP Toxicology Forensic Technical Leader Nicholas Fillinger reviewed each blood test result in Phase II and if the blood result contained a metabolite of one of the six drug classes, that specific class was marked as positive for this report.

The Abbott SoToxa roadside oral fluid test instrument is a screening instrument, which gives a positive or negative test result, rather than a quantitative result (nanogram level). The Abbott SoToxa 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 cut-off levels are significantly higher. Consequently, the Abbott SoToxa roadside oral fluid test instrument may produce a negative result in a drug category while the voluntary test may indicate a positive result.

The specific procedures and instrumentation used to perform the voluntary oral fluid test analyses, and the blood analyses, are attached as appendix to the Phase I report and remained the same in Phase II.

TEST PERFORMANCE STATISTICS:

The reported Abbott SoToxa Oral Fluid (Roadside), Voluntary Oral Fluid (Independent Laboratory) & Blood test findings are compared two at a time for their performance. These are compared using a binary classifier (or a cross table). These tables are 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 are used to calculate the overall performance of the device testing approach. Only positive and negative values for both tests are used to study performance, so the number of cases in the tables is smaller than the total number of cases. Cross tabulation is demonstrated in the table below:

Device vs. Gold Standard				
Device	Results	Gold Standard		
		Positive	Negative	Rate
	Positive	True Positive (TP)	False Positive (FP)	PPV = TP/(TP+FP)
	Negative	False Negative (FN)	True Negative (TN)	Sensitivity = TP/(TP+FN)
	Rate	NPV = TN/(TN+FN)	Specificity = TN/(TN+FP)	ACC = (TP+TN)/(TP+FP+FN+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 where the device does not detect the drug while it is detected by the gold standard.

The performance of the device testing approaches is assessed using the five measures below:

1. Sensitivity = TP/(TP+FN). Sensitivity measures the number of true positives as a rate of all positives, i.e., sensitivity is the extent to which actual positives are not overlooked.
2. Specificity = TN/(TN+FP). Specificity measures the number of true negatives as a rate of all negatives, i.e., specificity is the extent to which actual negatives are not overlooked.

3. Positive Predictive Value (PPV) = TP/(TP+FP). PPV measures the number of true positives as a rate of reported positives and is the extent to which false positives are not overlooked.
4. Negative Predictive Value (NPV) = TN/(TN+FN). NPV measures the number of true negatives as a rate of reported negatives and is the extent to which false negatives are not overlooked.
5. Accuracy = (TP+TN)/(TP+FP+FN+TN). Accuracy measures the percentage of all samples correctly classified by the tests.

These rates are often expressed as percentages, and inference for these percentages is reported using sample estimates of the measures and their 95% confidence intervals (CI) for proportions (details in the appendix).

The key goal of confidence intervals is to draw inferences about unknown population percentages based on sample percentages (called the estimate), such as using sample accuracy percentages to estimate the unknown population accuracy percentages and provide a range of plausible values. The CI reflects the amount of random error in the sample and provides this likely range of values for the unknown population percentage. The estimate of the CI is the sample percentage, such as the sample accuracy percentage. The lower confidence limit (Lower CL) is essentially the smallest value of the percentage, while the upper confidence limit (Upper CL) is essentially the largest value of the percentage, based on the sample data. The tighter the confidence interval, the more confident we are in the findings.

AMPHETAMINE RESULTS

Abbott SoToxa Amphetamine		
	Frequency	Percent
Positive	205	29.58%
Negative	445	64.21%
Invalid	11	1.59%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Amphetamine		
	Frequency	Percent
Positive	163	23.52%
Negative	385	55.56%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Amphetamine		
	Frequency	Percent
Positive	168	24.24%
Negative	464	66.96%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - AMPHETAMINE PANEL

	Positive	Negative	Total
Positive	134 (True Positive)	59 (False Positive)	193
Negative	26 (False Negative)	377 (True Negative)	403
Total	160	436	596

	Estimate	Lower CL	Upper CL
Sensitivity	83.80%	77.30%	88.70%
Specificity	86.50%	82.90%	89.40%
PPV	69.40%	62.60%	75.50%
NPV	93.50%	90.70%	95.60%
Accuracy	85.70%	82.70%	88.30%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - AMPHETAMINE PANEL

	Positive	Negative	Total
Positive	130 (True Positive)	40 (False Positive)	170
Negative	29 (False Negative)	330 (True Negative)	359
Total	159	370	529

	Estimate	Lower CL	Upper CL
Sensitivity	81.80%	75.00%	87.00%
Specificity	89.20%	85.60%	92.00%
PPV	76.50%	69.60%	82.20%
NPV	91.90%	88.60%	94.30%
Accuracy	87.00%	83.80%	89.60%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - AMPHETAMINE

	Positive	Negative	Total
Positive	126 (True Positive)	22 (False Positive)	148
Negative	5 (False Negative)	348 (True Negative)	353
Total	131	370	501

	Estimate	Lower CL	Upper CL
Sensitivity	96.20%	91.40%	98.40%
Specificity	94.10%	91.20%	96.00%
PPV	85.10%	78.50%	90.00%
NPV	98.60%	96.70%	99.40%
Accuracy	94.60%	92.30%	96.30%

BENZODIAZEPINES RESULTS

Abbott SoToxa Benzodiazepines		
	Frequency	Percent
Positive	78	11.26%
Negative	572	82.54%
Invalid	11	1.59%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Benzodiazepines		
	Frequency	Percent
Positive	49	7.07%
Negative	499	72.01%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Benzodiazepines		
	Frequency	Percent
Positive	93	13.42%
Negative	539	77.78%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - BENZODIAZEPINES

	Positive	Negative	Total
Positive	30 (True Positive)	45 (Fales Positive)	75
Negative	59 (False Negative)	462 (True Negative)	521
Total	89	507	596

	Estimate	Lower CL	Upper CL
Sensitivity	33.70%	24.70%	44.00%
Specificity	91.10%	88.30%	93.30%
PPV	40.00%	29.70%	51.30%
NPV	88.70%	85.70%	91.10%
Accuracy	82.60%	79.30%	85.40%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - BENZODIAZEPINES

	Positive	Negative	Total
Positive	27 (True Positive)	37 (False Positive)	64
Negative	19 (False Negative)	446 (True Negative)	465
Total	46	483	529

	Estimate	Lower CL	Upper CL
Sensitivity	58.70%	44.30%	71.70%
Specificity	92.30%	89.60%	94.40%
PPV	42.20%	30.90%	54.40%
NPV	95.90%	93.70%	97.40%
Accuracy	89.40%	86.50%	91.80%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - BENZODIAZEPINES

	Positive	Negative	Total
Positive	27 (True Positive)	18 (False Positive)	45
Negative	44 (False Negative)	412 (True Negative)	456
Total	71	430	501

	Estimate	Lower CL	Upper CL
Sensitivity	38.00%	27.60%	49.70%
Specificity	95.80%	93.50%	97.30%
PPV	60.00%	45.50%	73.00%
NPV	90.40%	87.30%	92.70%
Accuracy	87.60%	84.50%	90.20%

CANNABIS RESULTS

Abbott SoToxa Cannabis		
	Frequency	Percent
Positive	366	52.81%
Negative	284	40.98%
Invalid	11	1.59%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Cannabis		
	Frequency	Percent
Positive	362	52.24%
Negative	186	26.84%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Cannabis		
	Frequency	Percent
Positive	416	60.03%
Negative	216	31.17%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - CANNABIS

	Positive	Negative	Total
Positive	339 (True Positive)	16 (False Positive)	355
Negative	56 (False Negative)	186 (True Negative)	242
Total	395	202	597

	Estimate	Lower CL	Upper CL
Sensitivity	85.80%	82.00%	88.90%
Specificity	92.10%	87.50%	95.10%
PPV	95.50%	92.80%	97.20%
NPV	76.90%	71.20%	81.70%
Accuracy	87.90%	85.10%	90.30%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - CANNABIS

	Positive	Negative	Total
Positive	294 (True Positive)	5 (False Positive)	299
Negative	55 (False Negative)	175 (True Negative)	230
Total	349	180	529

	Estimate	Lower CL	Upper CL
Sensitivity	84.20%	80.00%	87.70%
Specificity	97.20%	93.70%	98.80%
PPV	98.30%	96.10%	99.30%
NPV	76.10%	70.20%	81.10%
Accuracy	88.70%	85.70%	91.10%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - CANNABIS

	Positive	Negative	Total
Positive	304 (True Positive)	38 (False Positive)	342
Negative	23 (False Negative)	136 (True Negative)	159
Total	327	174	501

	Estimate	Lower CL	Upper CL
Sensitivity	93.00%	89.70%	95.30%
Specificity	78.20%	71.50%	83.70%
PPV	88.90%	85.10%	91.80%
NPV	85.50%	79.20%	90.20%
Accuracy	87.80%	84.70%	90.40%

COCAINE RESULTS

Abbott SoToxa Cocaine		
	Frequency	Percent
Positive	89	12.84%
Negative	558	80.52%
Invalid	14	2.02%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Cocaine		
	Frequency	Percent
Positive	98	14.14%
Negative	450	64.94%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Cocaine		
	Frequency	Percent
Positive	69	9.96%
Negative	563	81.24%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - COCAINE

	Positive	Negative	Total
Positive	59 (True Positive)	27 (False Positive)	86
Negative	6 (False Negative)	501 (True Negative)	507
Total	65	528	593

	Estimate	Lower CL	Upper CL
Sensitivity	90.80%	81.30%	95.70%
Specificity	94.90%	92.70%	96.50%
PPV	68.60%	58.20%	77.40%
NPV	98.80%	97.40%	99.50%
Accuracy	94.40%	92.30%	96.00%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - COCAINE

	Positive	Negative	Total
Positive	66 (True Positive)	10 (False Positive)	76
Negative	27 (False Negative)	424 (True Negative)	451
Total	93	434	527

	Estimate	Lower CL	Upper CL
Sensitivity	71.00%	61.10%	79.20%
Specificity	97.70%	95.80%	98.70%
PPV	86.80%	77.40%	92.70%
NPV	94.00%	91.40%	95.90%
Accuracy	93.00%	90.50%	94.90%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - COCAINE

	Positive	Negative	Total
Positive	53 (True Positive)	40 (False Positive)	93
Negative	1 (False Negative)	407 (True Negative)	408
Total	54	447	501

	Estimate	Lower CL	Upper CL
Sensitivity	98.10%	90.20%	99.90%
Specificity	91.10%	88.00%	93.40%
PPV	57.00%	46.80%	66.60%
NPV	99.80%	98.60%	100.00%
Accuracy	91.80%	89.10%	93.90%

OPIATES RESULTS

Abbott SoToxa Opiates		
	Frequency	Percent
Positive	86	12.41%
Negative	561	80.95%
Invalid	14	2.02%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Opiates		
	Frequency	Percent
Positive	73	10.53%
Negative	475	68.54%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Opiates		
	Frequency	Percent
Positive	35	5.05%
Negative	597	86.15%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - OPIATES

	Positive	Negative	Total
Positive	29 (True Positive)	53 (False Positive)	82
Negative	2 (False Negative)	509 (True Negative)	511
Total	31	562	593

	Estimate	Lower CL	Upper CL
Sensitivity	93.50%	79.30%	98.20%
Specificity	90.60%	87.90%	92.70%
PPV	35.40%	25.90%	46.20%
NPV	99.60%	98.60%	99.90%
Accuracy	90.70%	88.10%	92.80%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - OPIATES

	Positive	Negative	Total
Positive	59 (True Positive)	12 (False Positive)	71
Negative	10 (False Negative)	446 (True Negative)	456
Total	69	458	527

	Estimate	Lower CL	Upper CL
Sensitivity	85.50%	75.30%	91.90%
Specificity	97.40%	95.50%	98.50%
PPV	83.10%	72.70%	90.10%
NPV	97.80%	96.00%	98.80%
Accuracy	95.80%	93.80%	97.20%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - OPIATES

	Positive	Negative	Total
Positive	28 (True Positive)	40 (False Positive)	68
Negative	1 (False Negative)	432 (True Negative)	433
Total	29	472	501

	Estimate	Lower CL	Upper CL
Sensitivity	96.60%	82.80%	99.80%
Specificity	91.50%	88.70%	93.70%
PPV	41.20%	30.30%	53.00%
NPV	99.80%	98.70%	100.00%
Accuracy	91.80%	89.10%	93.90%

METHAMPHETAMINES RESULTS

Abbott SoToxa Methamphetamines		
	Frequency	Percent
Positive	150	21.65%
Negative	488	70.42%
Invalid	23	3.32%
Refused	17	2.45%
Not Offered	15	2.17%
Total	693	100%
Voluntary Oral Fluid Methamphetamines		
	Frequency	Percent
Positive	131	18.90%
Negative	417	60.17%
Refused	57	8.23%
Not Offered	88	12.70%
Total	693	100%
Blood Methamphetamines		
	Frequency	Percent
Positive	139	20.06%
Negative	493	71.14%
Not Offered	61	8.80%
Total	693	100.00%

Performance of the Abbott SoToxa with Blood Test Results - METHAMPHETAMINES

	Positive	Negative	Total
Positive	121 (True Positive)	22 (False Positive)	143
Negative	6 (False Negative)	435 (True Negative)	441
Total	127	457	584

	Estimate	Lower CL	Upper CL
Sensitivity	95.30%	90.10%	97.80%
Specificity	95.20%	92.80%	96.80%
PPV	84.60%	77.80%	89.60%
NPV	98.60%	97.10%	99.40%
Accuracy	95.20%	93.20%	96.70%

Performance of the Abbott SoToxa with Voluntary Oral Fluid Test Results - METHAMPHETAMINES

	Positive	Negative	Total
Positive	113 (True Positive)	8 (False Positive)	121
Negative	13 (False Negative)	386 (True Negative)	399
Total	126	394	520

	Estimate	Lower CL	Upper CL
Sensitivity	89.70%	83.10%	93.90%
Specificity	98.00%	96.00%	99.00%
PPV	93.40%	87.50%	96.60%
NPV	96.70%	94.50%	98.10%
Accuracy	96.00%	93.90%	97.30%

Performance of the Voluntary Oral Fluid Test Results with Blood Test Results - METHAMPHETAMINES

	Positive	Negative	Total
Positive	101 (True Positive)	17 (False Positive)	118
Negative	3 (False Negative)	380 (True Negative)	383
Total	104	397	501

	Estimate	Lower CL	Upper CL
Sensitivity	97.10%	91.90%	99.00%
Specificity	95.70%	93.20%	97.30%
PPV	85.60%	78.10%	90.80%
NPV	99.20%	97.70%	99.70%
Accuracy	96.00%	93.90%	97.40%

CONVICTIONS
PROVIDED BY MSP CRIMINAL JUSTICE CENTER

As of December 17, 2020, the Michigan State Police Criminal Justice Information Center reported there were 200 charges, 80 charges closed with conviction, 33 charges closed without conviction, and 87 cases still pending that are related to Section 625.

PACC Code	Literal Description	Total Charges	Charges Closed w/Conviction	Charges Closed w/o Conviction	Cases Still Pending
10.33	Executive Orders-Violation	2	0	0	2
257.215	Operate Unregistered Vehicle	3	0	2	1
257.256	License Plate/Registration/Title-Unlawful Use	4	0	2	2
257.257	License Documents/Plate-Forgery	1	0	1	0
257.301	Operating - No License/Multiple Licenses	9	0	5	4
257.306	Motor Vehicles-Learner's Permit Violations	1	0	1	0
257.311	Operating w/o License on Peron	2	0	1	1
257.324	Operating-License-Forgery/Alteration/False ID	3	1	1	1
257.601D1	Moving Violation Causing Death	1	1	0	0
257.602A2	Police Officer-Fleeing-Forth Degree-Vehicle Code	2	0	0	2
257.602A3-A	Police Officer-Fleeing-Third Degree-Vehicle Code	1	0	1	0
257.618	Failure to Stop at Scene of Property Damage Accident	1	0	1	0
257.620	Failure to Stop After Collision	4	2	0	2
257.621	Failure to Report Accident to Fixtures	2	0	0	2
257.622	Failure to Report Accident	1	0	0	1
257.624A	Alcohol-Open Container in Vehicle	11	0	5	6
257.6251-A	Operating While Intoxicated	48	5	6	37
257.6251C	Operating with High BAC	1	0	1	0
257.6253-A	Operating Impaired	55	47	1	7

CONVICTIONS
PROVIDED BY MSP CRIMINAL JUSTICE CENTER

PACC Code	Literal Description	Total Charges	Charges Closed w/Conviction	Charges Closed w/o Conviction	Cases Still Pending
257.6255-A	Operating While Intoxicated Causing Serious Injury	2	1	0	1
257.6256-A	Operating-Minor with any BAC	3	3	0	0
257.6256B	Operating While Intoxicated/Impaired-Second Offense Notice	28	14	6	8
257.6256D	Operating While Intoxicated/Impaired-Third Offense Notice	16	1	2	13
257.6257A1	Operating While Intoxicated-Occupant Less Than 16	15	2	5	8
257.6257A2	Operating While Intoxicated-Occupant Less Than 16- Second or Subsequent Offense	1	0	0	1
257.6258	Operating with the Presence of a Controlled Substance	31	7	12	12
257.626	Driving Reckless	8	5	0	3
257.9041B	Operating-License Suspended, Revoked, Denied	38	6	10	22
257.9041C	Operating-License Suspended, Revoked, Denied/Allowing Suspended Person to Operate-Second Offense	13	2	4	7
28.173A	DNA Profiling-Refuse or Resist Providing Samples	1	0	0	1
28.425K2A	Weapons-Pistols-Carrying Concealed While Under the Influence	1	0	0	1
333.74012A3	Controlled Substance-Delivery/Manufacture (Cocaine, Heroin or Other Narcotic) 50-449 Grams	1	0	0	1
333.74012C-A	Controlled Substance-Delivery/Manufacture (Schedule four)	1	0	0	1
333.74032A4	Controlled Substance-Possess (Cocaine, Heroin, or Other Narcotic) 25 to 49 Grams	1	0	1	0
333.74032A5	Controlled Substance-Possess (Cocaine, Heroin, or Other Narcotic) Less than 25 Grams	20	4	1	15

CONVICTIONS
PROVIDED BY MSP CRIMINAL JUSTICE CENTER

PACC Code	Literal Description	Total Charges	Charges Closed w/Conviction	Charges Closed w/o Conviction	Cases Still Pending
333.74032B1	Controlled Substance-Possession of Methamphetamine/Ecstasy	28	11	3	14
333.74032B-A	Controlled Substance-Possession/Analogues	15	3	6	6
333.74032C-A	Controlled Substance-Possession (Schedule Five and LSD, etc.)	2	0	0	2
333.74032D	Controlled Substance-Possession of Marihuana or Synthetic Equivalents	2	2	0	0
333.74042A	Controlled Substance-Use (Narcotic/Cocaine/Ecstasy	7	4	2	1
333.74042A-A	Controlled Substance-Use Methamphetamine	3	3	0	0
333.74042B	Controlled Substance-Use	2	2	0	0
333.74042D	Controlled Substance-Use (Marihuana, Synthetic Marihuana/Spice/Salvia	1	0	1	0
333.7405D	Controlled Substance-Maintaining a Drug House	1	0	1	0
333.74132-A	Controlled Substance-Second or Subsequent Offense Notice	5	0	3	2
500.3102	Motor Vehicle-Operate w/o Security	11	2	5	4
750.167	Disorderly Person	2	2	0	0
750.136B5	Child Abuse-Fourth Degree	2			2
750.227	Weapons-Carrying Concealed	4	0	2	2
750.237	Weapons-Firearm-Possession Under the Influence	2	1	1	0
750.413	Motor Vehicle-Unlawful Driving Away	3	2	0	1
750.479A2	Police Officer-Fleeing-Fourth Degree-Penal Code	1	1	0	0
750.5357	Motor Vehicle-Stolen Property-Receiving and Concealing	2	1	0	1
750.81D1	Police Officer-Assaulting/Resisting/Obstructing	8	2	1	5
	Totals	433	137	94	202

SUMMARY

Roadside Oral Fluid testing in the Phase II Pilot has been proven to be accurate to a certain degree as demonstrated in the data contained within this report. Each of the six drug classes demonstrated varied percentages of accuracy when compared to the “Gold Standard”, which is a blood test. Oral fluid testing does not equal the “Gold Standard” but has been found to be accurate for purposes of preliminary roadside testing.

The Abbott SoToxa Roadside Oral Fluid instrument is easy to use, requires minimum training, and provides a result for each of the six drug classes within five minutes after a sample is collected. It is important to point out that a Roadside Oral Fluid test result regardless of positive or negative does not determine if a driver is impaired or not impaired.

ACKNOWLEDGEMENTS

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

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

MICHIGAN STATE POLICE LEADERSHIP TEAM:

Col. Joseph M. Gasper
Director, Michigan Department of State Police

Lt. Col. Amy Dehner
Deputy Director, Executive Operations

Lt. Col. Kyle Bowman
Deputy Director, Field Operations Bureau

Lt. Col. Christopher Kelenske
Deputy Director, Field Support Bureau

Maj. Beth Clark
Field Support Bureau

Maj. Michael Krumm
Field Operations Bureau

Maj. Emmitt McGowan
Field Operations Bureau

MICHIGAN STATE POLICE:

Ms. Sally Artibee

Ms. Chelsea Phillips

Ms. Jamie Hansen

Mr. Douglas Warner, Ret.

Ms. Christie Christman

FORENSIC FLUIDS LABORATORIES:

Mr. David Bergland
Chief Operating Officer

Ms. Bridget Lorenz Lemberg
Laboratory Director

ABBOTT CORPORATION:

Mr. Fred Delfino
Product Manager, SoToxa Test System

MICHIGAN STATE UNIVERSITY:

Dr. Dhruv B. Sharma, Ph.D.
Senior Statistician

MICHIGAN STATE POLICE CRIMINAL JUSTICE INFORMATION CENTER:

Ms. Sherry Rosin

MICHIGAN STATE POLICE FORENSIC SCIENCE DIVISION:

Mr. Jeffrey Nye

REFERENCES

Gjerde, H., Langel, K., & Favretto, D.V. (2014, March). Estimation of Equivalent Cutoff Thresholds in Blood and Oral Fluid for Drug Prevalence Studies. Journal of Analytical Toxicology, 38 (2).

Retrieved from https://academic.oup.com/jat/article/38/2/92/753450.

STATISTICS APPENDIX:

Inference for these percentages is reported using sample estimates of the performance measures and their 95% confidence interval of binomial proportions. To explain what we mean by 95% confidence interval, we note that the key goal in inferential statistics is to draw inferences about unknown population parameters based on sample statistics. We do so by selecting a representative sample (e.g., oral fluid roadside 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, we wish to use the sample percentages (e.g., sample accuracy) to draw inference about the population percentages (e.g., population accuracy). A 95% confidence interval means that if we were to take 100 different samples 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, we select one random sample 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.

MICHIGAN STATE POLICE LABORATORY ANALYSIS METHOD:

The Michigan State Police used the same process for analyzing blood samples that was used during the initial pilot program. Details can be found on page 40 of the first pilot program.

ORAL FLUID FORENSIC FLUIDS LABORATORIES LABORATORY METHOD:

The Forensic Fluids Laboratories used the same process for analyzing oral fluid samples that was used during the initial pilot program. Details can be found on page 41 of the first pilot program.