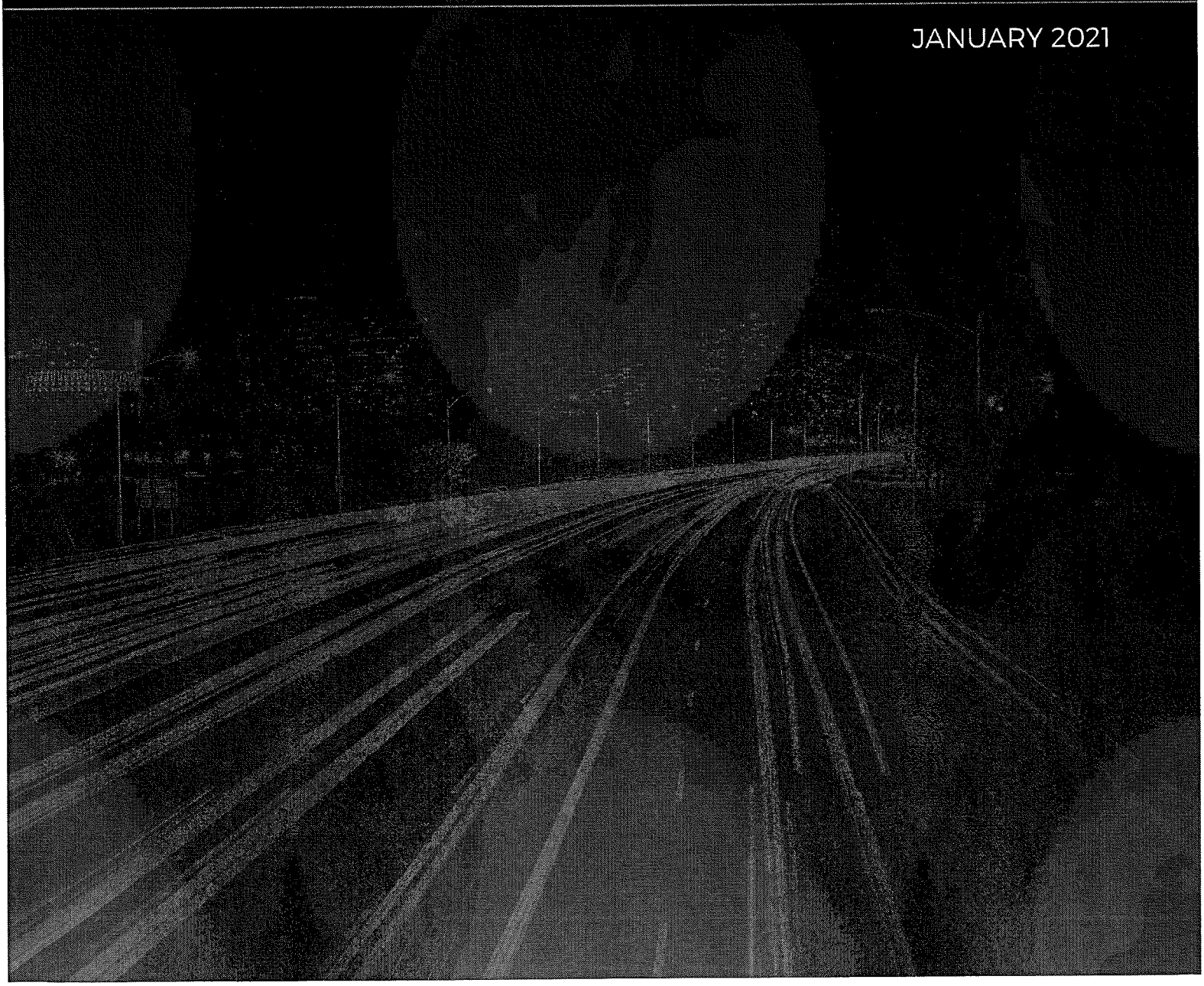
ORAL FLUID ROADSIDE ANALYSIS
PILOT PROGRAM - PHASE II

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.

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Michigan State Police

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Michigan State Police

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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.

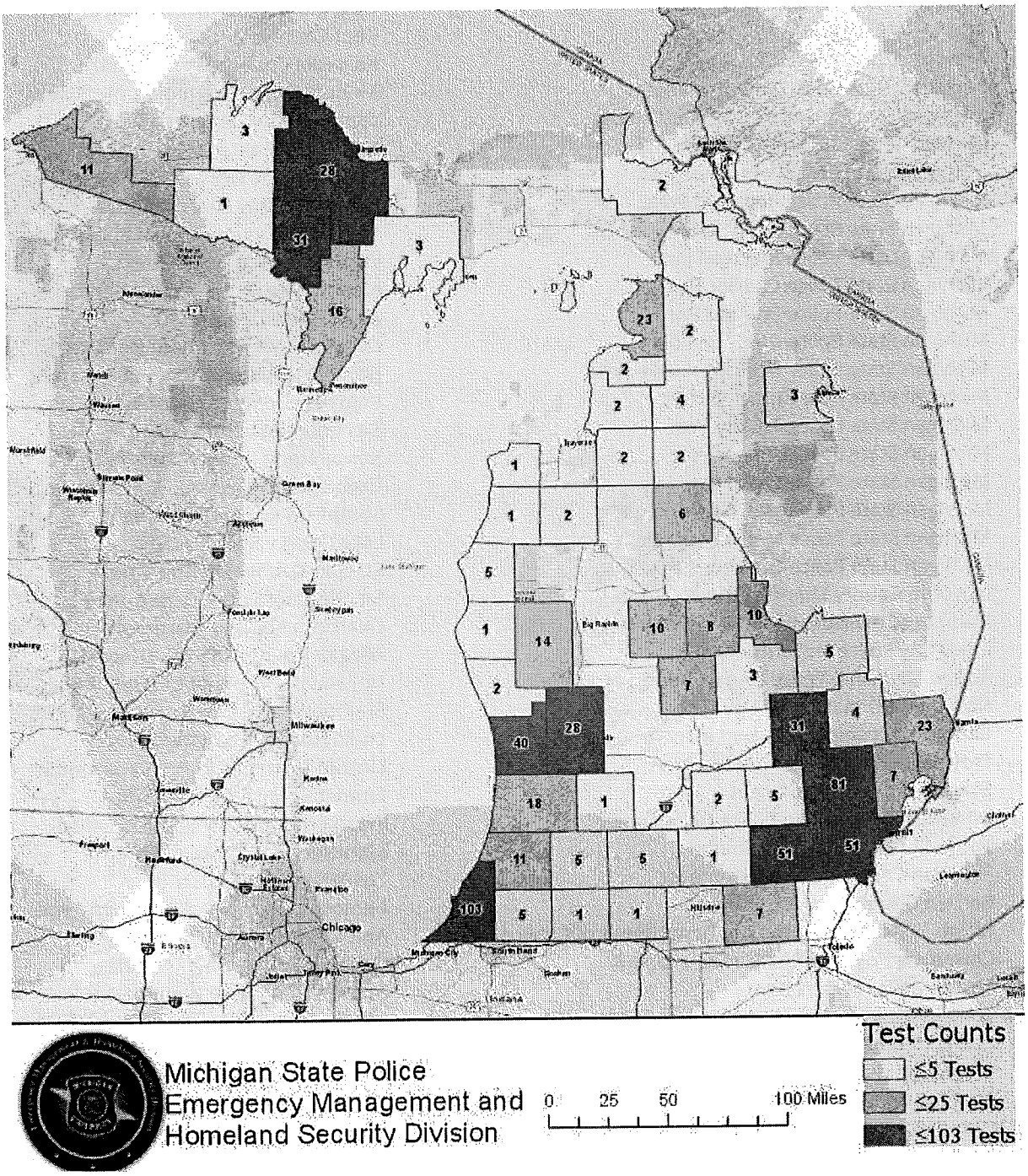
Prior to participation in the program, DREs attended a training session to include:

- 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.

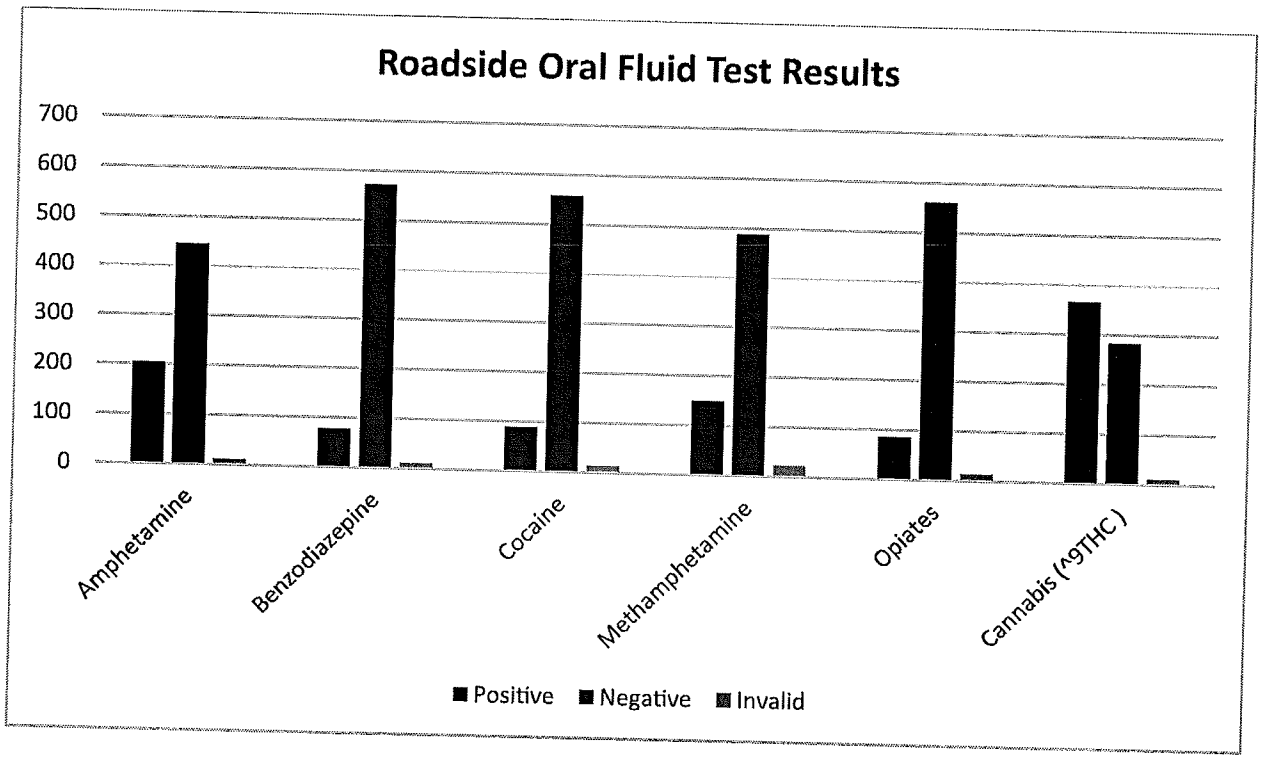
RESULT INTERPRETATION:

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

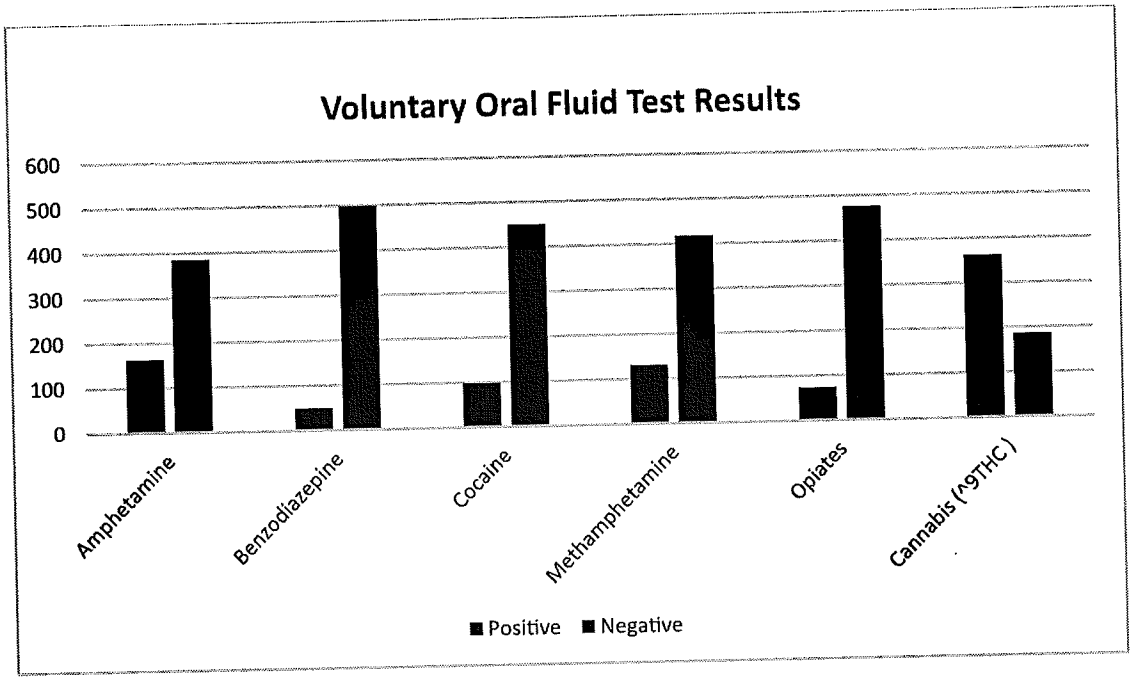
- Matrix analyzed
- Cut-off levels
- Limit of detection
- Limit of quantification
- Cross reactivity
- Confirmatory instrumentation
- Scope of analysis
- Incident time vs. sample collection time

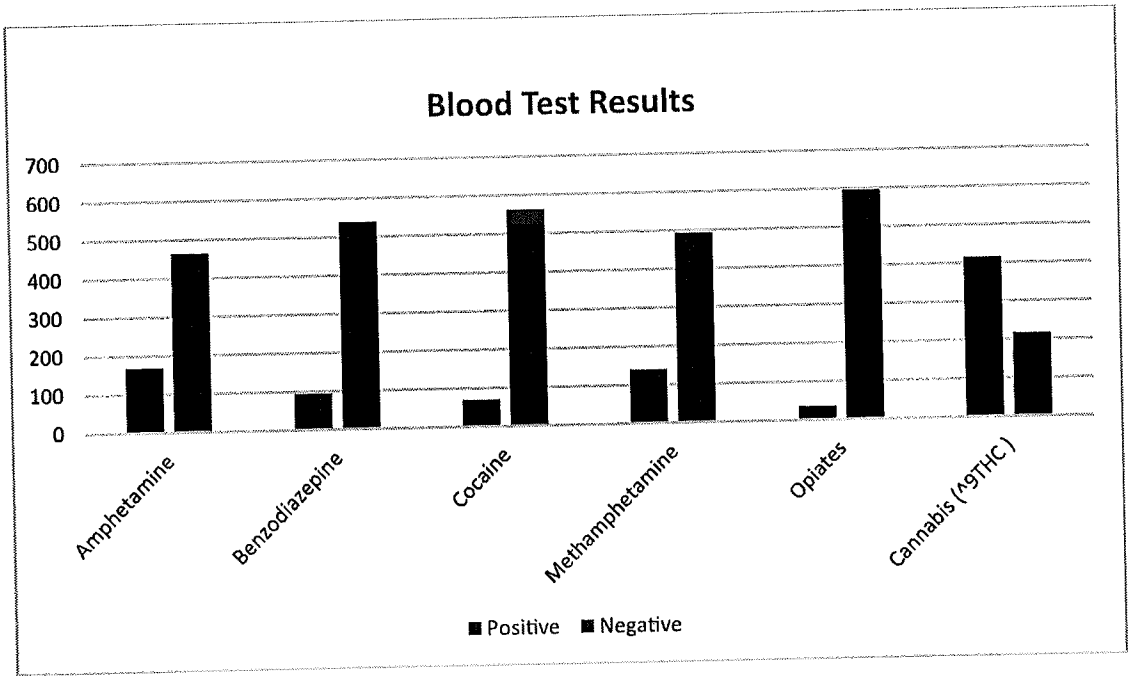
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

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.



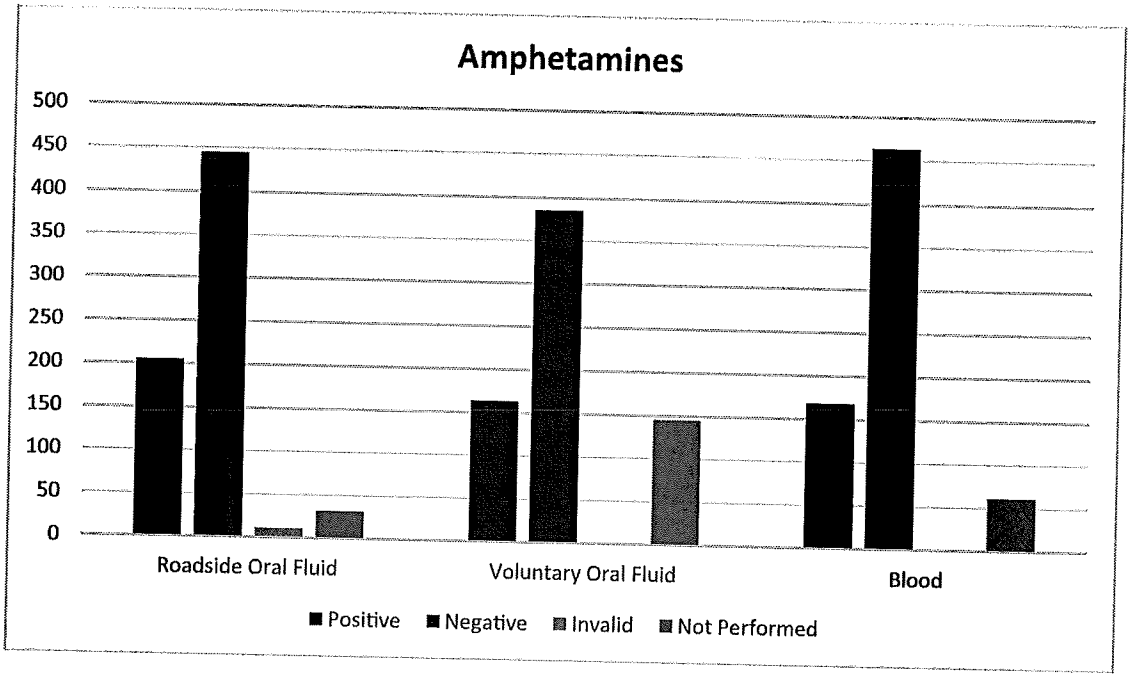
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

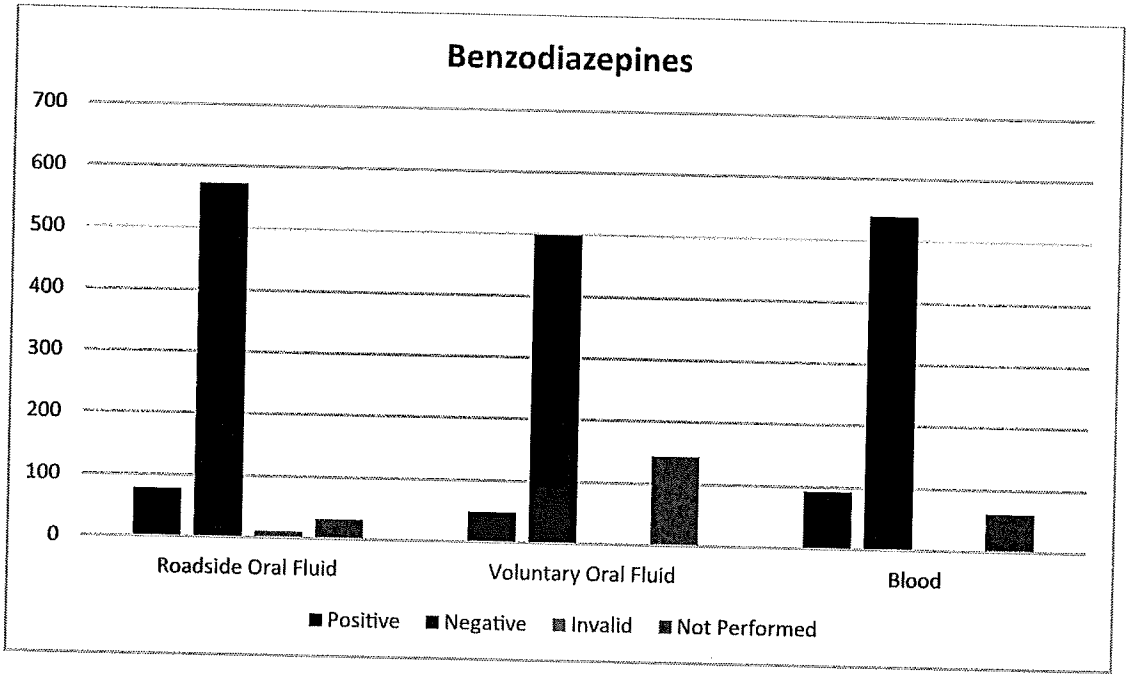




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

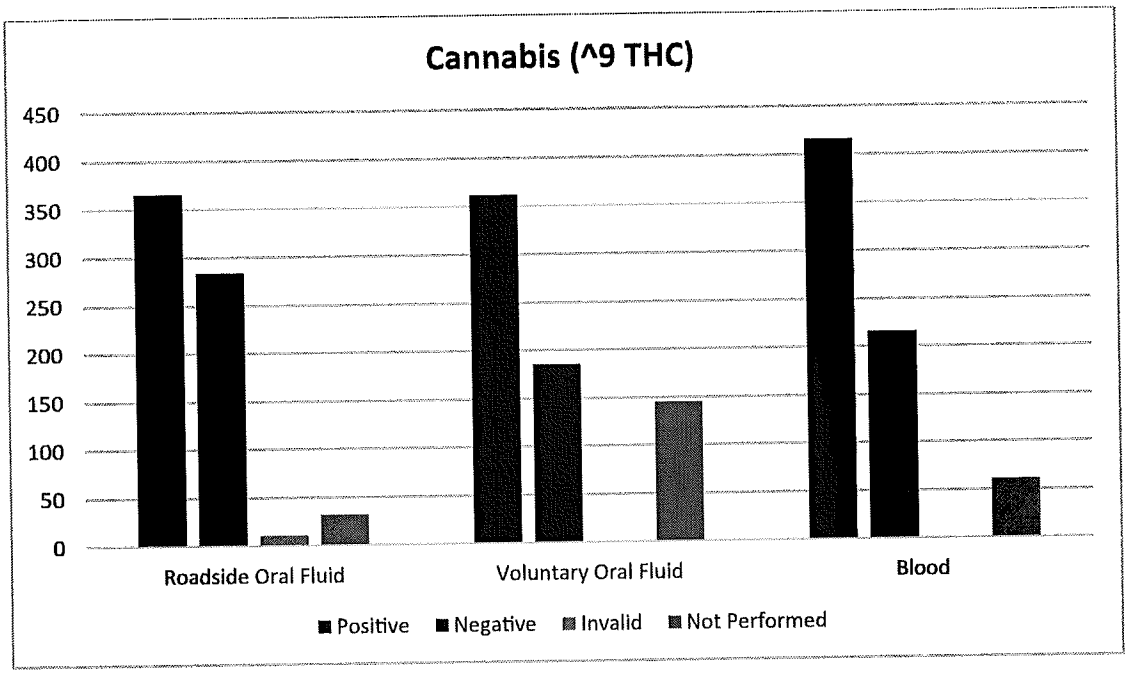
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

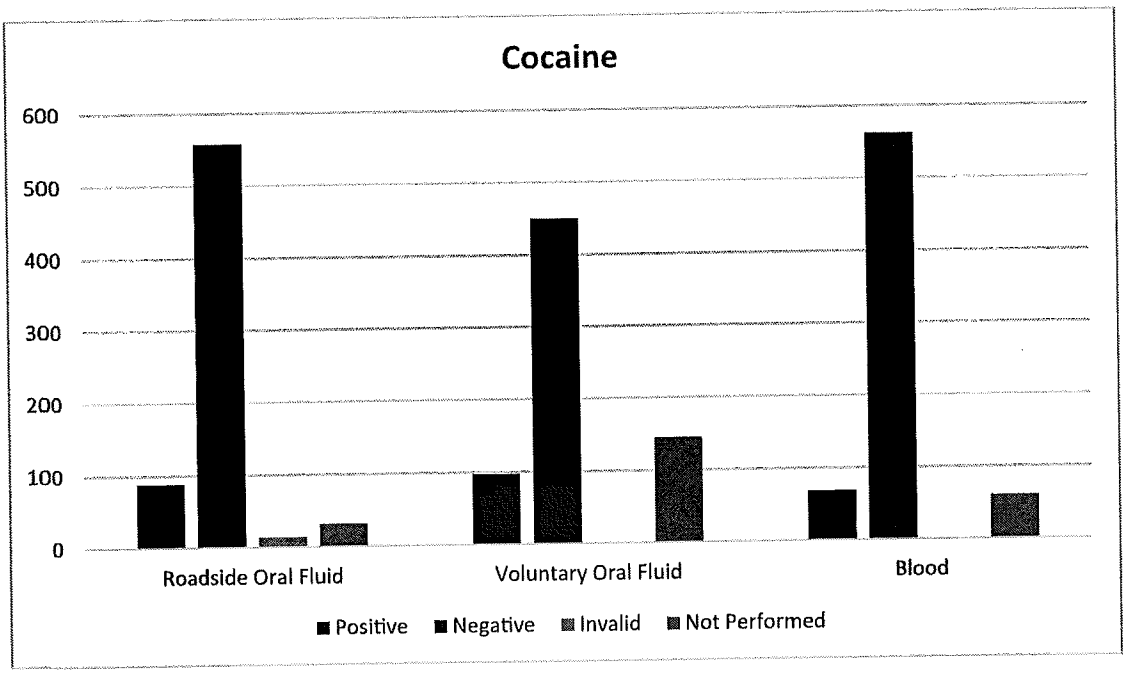




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

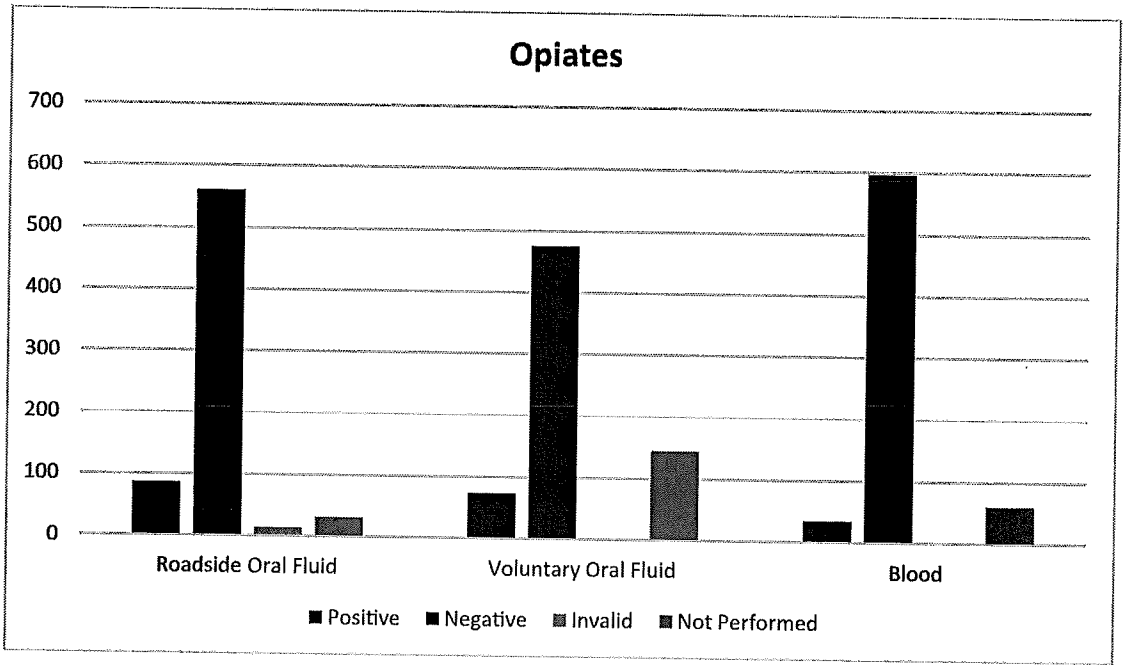
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

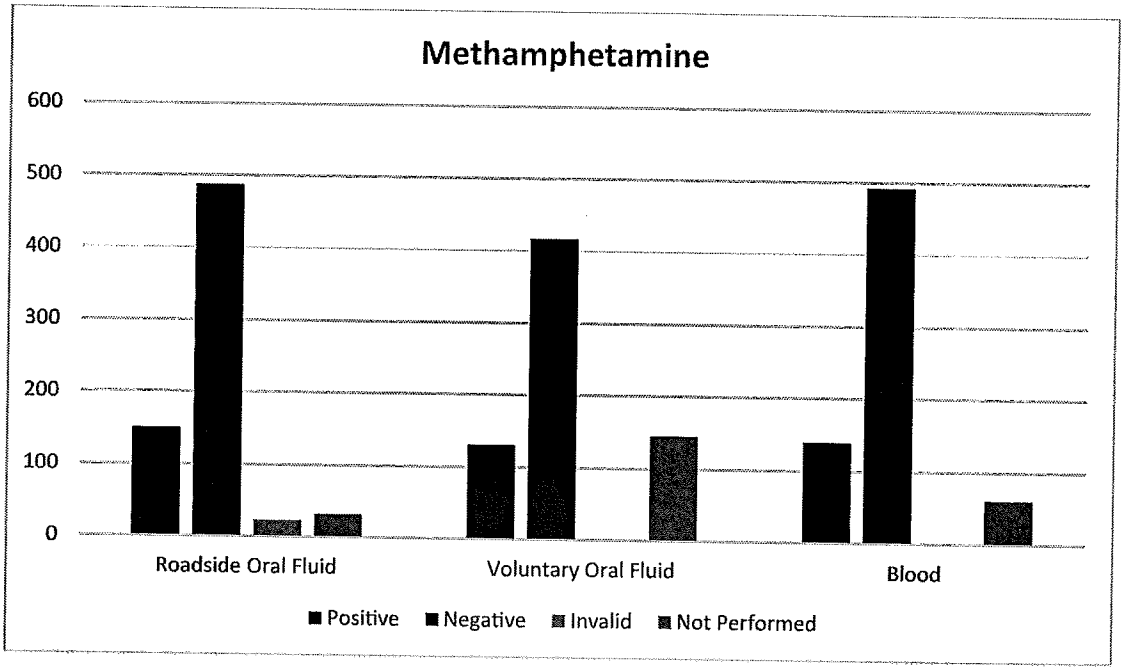




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

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.

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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%

MICHIGAN STATE POLICE ORAL FLUID PILOT STUDY
ANALYSES BY DHRUV B. SHARMA, Ph.D.

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.

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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).

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STATISTICS APPENDIX:

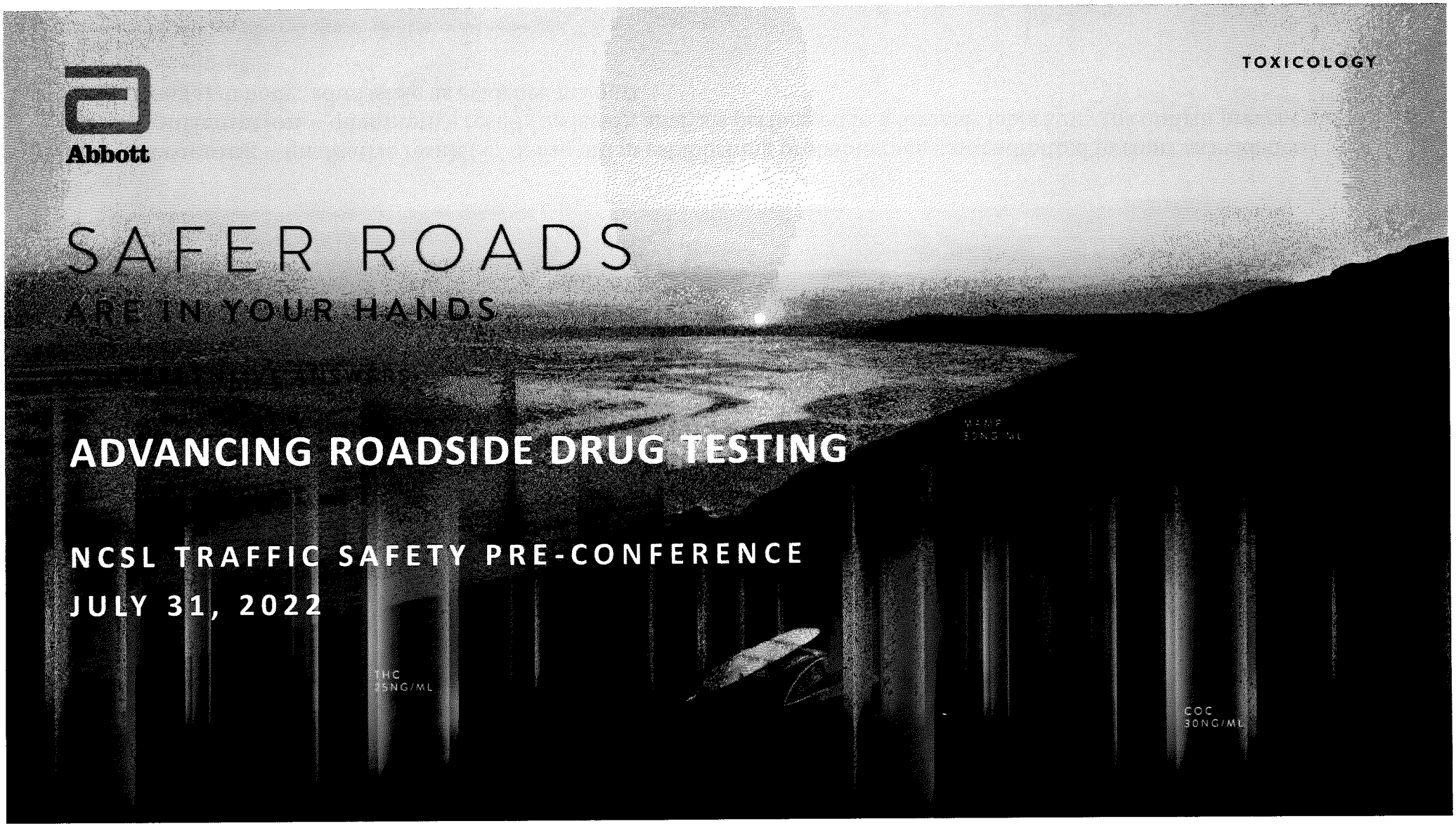
Inference for these percentages is reported using sample estimates of the performance measures and their 95% confidence interval of binomial proportions. To explain what we mean by 95% confidence interval, we note that the key goal in inferential statistics is to draw inferences about unknown population 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.

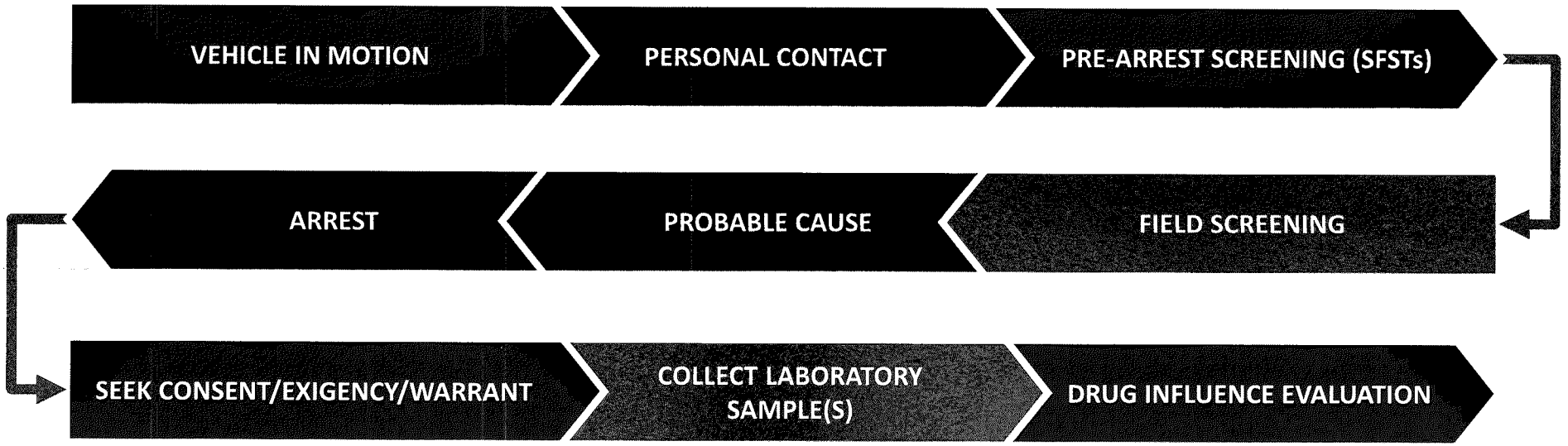
ORAL FLUID FORENSIC FLUIDS LABORATORIES LABORATORY METHOD:

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.


Abbott
TOXICOLOGY
SAFER ROADS
ARE IN YOUR HANDS
ADVANCING ROADSIDE DRUG TESTING
NCSL TRAFFIC SAFETY PRE-CONFERENCE
JULY 31, 2022
THC
25NG/ML
COC
30NG/ML

SAFER ROADS ARE IN YOUR HANDS

Impaired driving investigation: Oral fluid screening



- **Screening** = qualitative result (+/-); can aid in establishing probable cause; not admitted in court as evidence
- **Confirmation** = quantitative result (ng level); analysis performed in a forensic laboratory to confirm presence of drug(s) in body; admissible as evidence in court

SOURCES

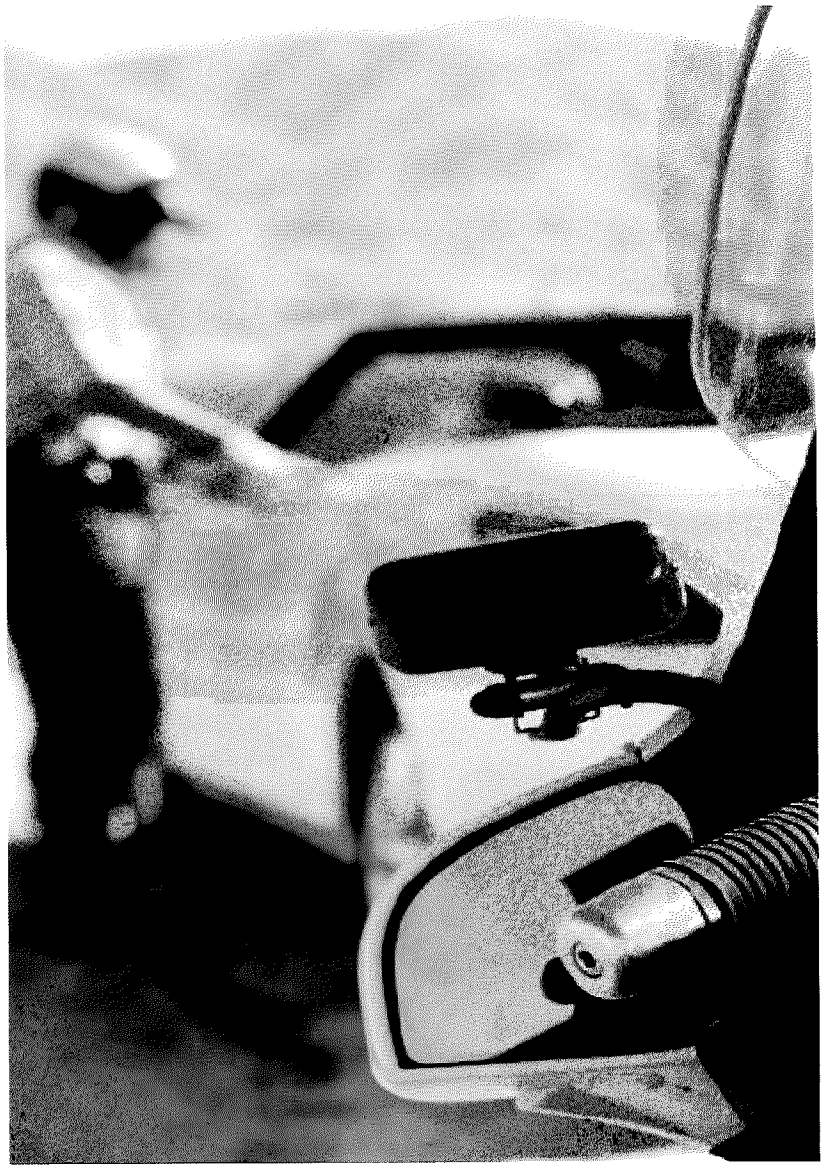
AAA Foundation for Traffic Safety (2020). Using Oral Fluid to Detect Drugs Handout. Available online.

SAFER ROADS ARE IN YOUR HANDS

Advantages of roadside drug testing

Roadside drug testing programs that utilize oral fluid screening have multiple benefits:

- Aid the investigative process (e.g., help establish probable cause)
- Enhance public safety
- Support strategic use/allocation of resources
- Create general deterrence



SAFER ROADS ARE IN YOUR HANDS

Oral fluid screening technology

- Analyzer devices use lateral flow immunoassay technology.
- Simple and quick collection process; subject performs oral fluid collection using swab.
- Cartridges inserted into instruments analyze oral fluid sample.
- Most devices test for common drugs of abuse (e.g., cannabis (THC), cocaine, amphetamines, methamphetamines, opioids, benzodiazepines).
- Devices use pre-set cut-off levels for each drug.
- Rapid screening results returned in minutes.
- Officers do not have to interpret results - analyzer provides qualitative result for each drug (objective measure).
- Ability to print results (e.g., to attach to arrest reports); technology can store test results (including date/time).
- Technology has built-in quality checks and procedures.

SAFER ROADS ARE IN YOUR HANDS

Benefits of oral fluid screening technology

- Easy and rapid sample collection
- Portability (ideal for roadside environment)
- Minimally invasive; comparable to a preliminary breath test
- Ability to collect sample proximal to the time of a traffic stop
- Active drug detection shows recent use
- Gender-neutral collections
- Medical personnel are not required for sample collection
- Real-time information to support decision-making
- Results can support search warrant requests for evidential samples (e.g., blood)
- Ability to identify polysubstance-impaired drivers
- Can lead to creation of ALS/ALR process for drug-impaired drivers

SoToxa: Drugs and cut-offs

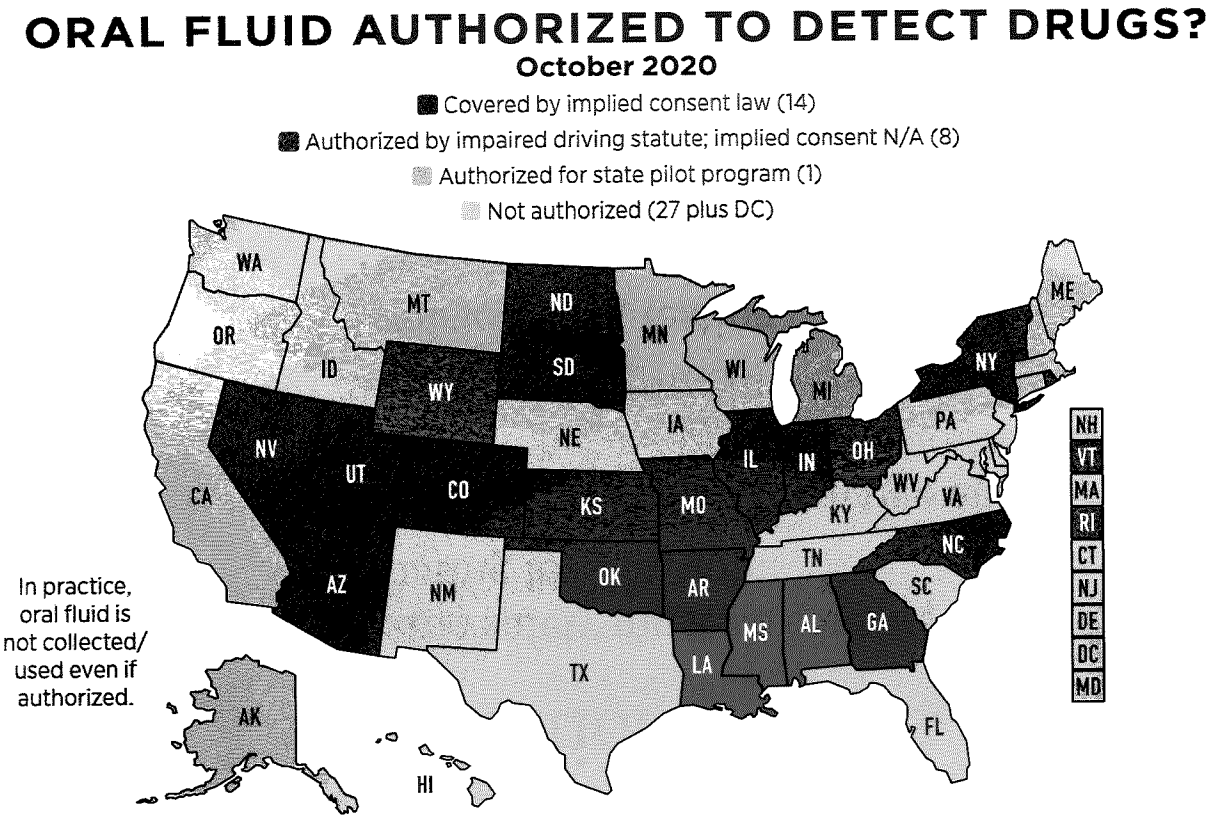
- Cut-off level - the decision point which differentiates a test result as being either positive or negative.
- The cut-off for a test is given as a defined drug concentration.
- For drug screening tests, a cut-off is chosen that will minimize the number of false positive results.

DRUG CUT-OFF LEVELS

DRUG GROUP	TARGET COMPOUND	CUT-OFF (ng/mL)
Amphetamine	(S) Amphetamine	50
Benzodiazepine	Temazepam	20
Cannabis	Delta-9-THC	25
Cocaine	Benzoylecgonine	30
Methamphetamine	(S) Methamphetamine	50
Opiates	Morphine	40

Current policy landscape: Oral fluid authorization

- Oral fluid can be authorized for screening, evidential testing, or both.
- 23 states authorize oral fluid testing in statute in some form (approaches include: implied consent, preliminary testing, pilot laws, etc.).
- Oral fluid pilots have been completed in numerous jurisdictions.
- Shift towards conducting feasibility studies and implementing permanent programs.



SOURCES
AAA Foundation for Traffic Safety (2020). Using Oral Fluid to Detect Drugs Handout. Available online.

STRENGTHENING THE DUI/D SYSTEM

Legalization lessons

- Traffic safety must be considered when debating legalization.
- States should take a proactive and comprehensive approach to address drug and polysubstance-impaired driving.
- Roadside drug testing can provide better insight into the magnitude and characteristics of the DUID problem to inform decision-making.
- Canadian example - roadside oral fluid screening was authorized in advance of legalization to protect public safety and create general deterrence.

STRENGTHENING THE DUI/D SYSTEM

Roadside programs: Pathways to implementation

Established via legislation and funded by the **STATE LEGISLATURE.**

(e.g., Michigan)

Established and funded by a **STATE HIGHWAY SAFETY OFFICE** (program implemented by law enforcement agencies).

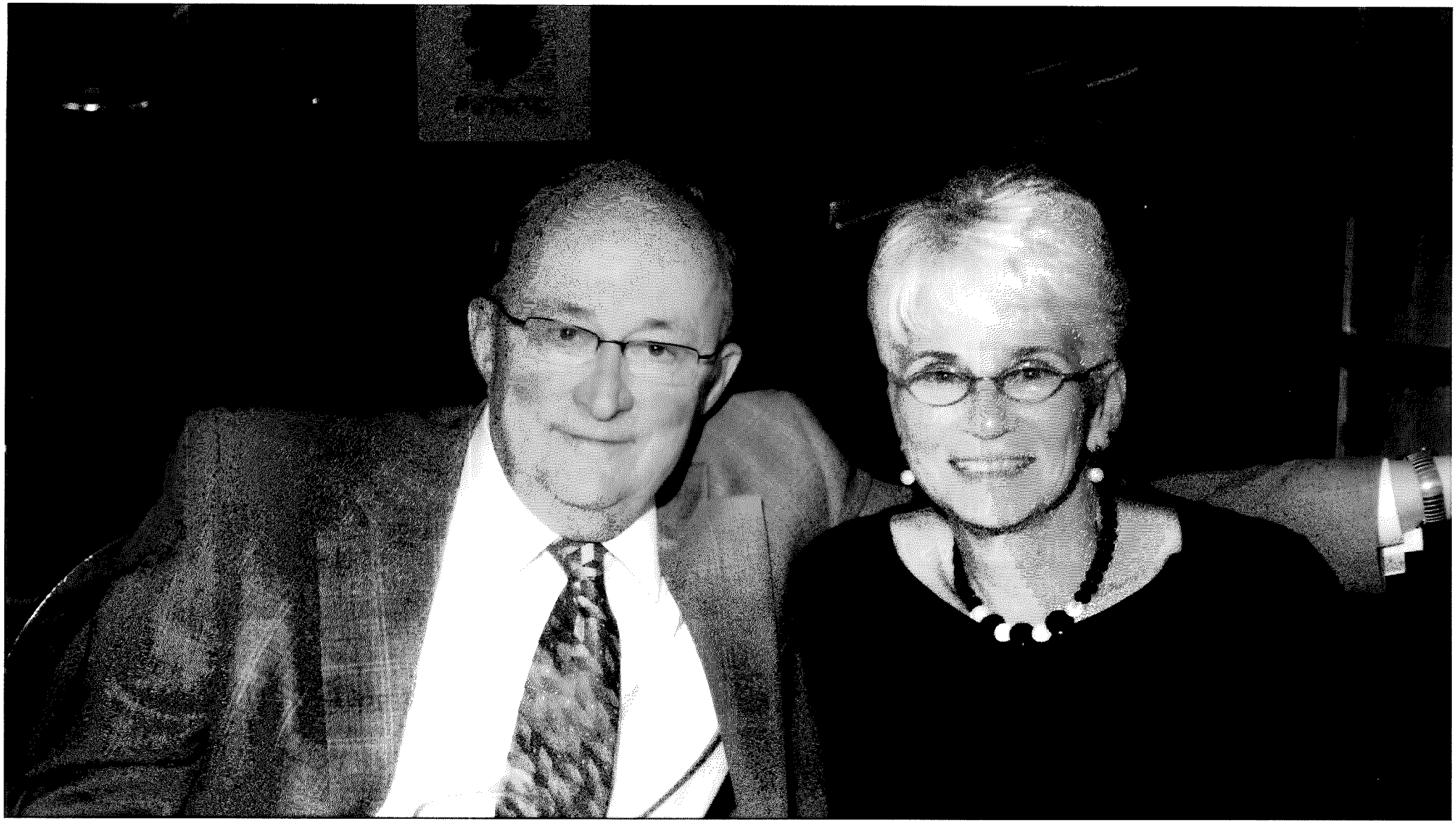
(e.g., Indiana)

Launched by a **LAW ENFORCEMENT AGENCY.**

(e.g., California, Illinois)

Established by a **STATE AGENCY** (e.g., forensic laboratory) in coordination with law enforcement agencies and other partners.

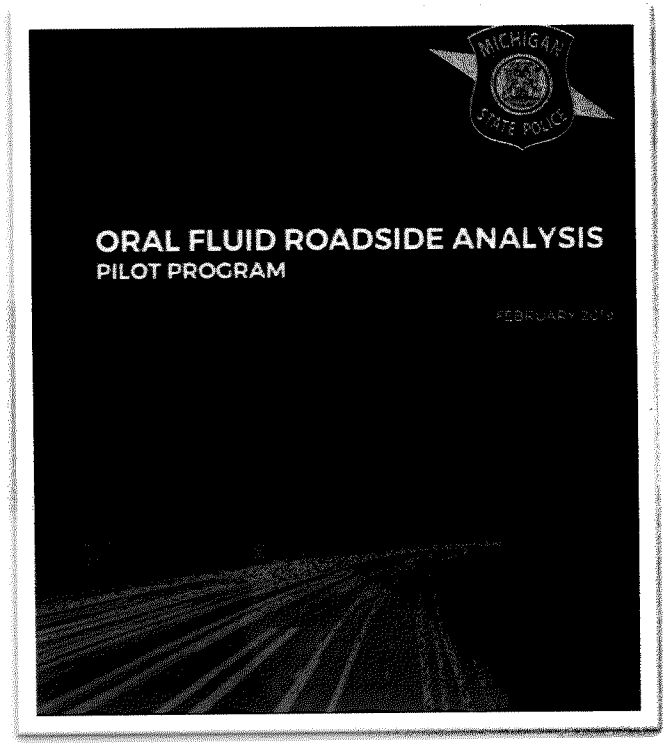
(e.g., Alabama)



ADVANCING PROGRESS

Michigan pilot findings

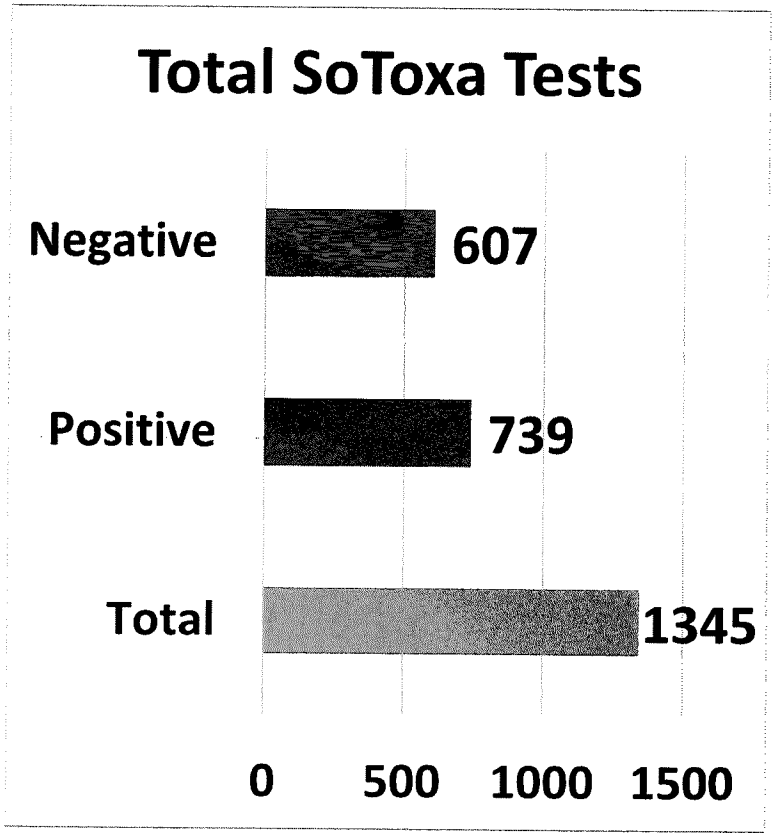
- Michigan State Police (MSP) pilot study concluded:
  - Oral fluid has been found to be ***accurate for purposes of preliminary roadside testing.***
  - It is one of many tools that officers can use during impaired driving investigations.
  - SoToxa is easy to use, requires minimum training, and provides a result within 5 minutes after collection of the sample.
- Legislation is pending that would authorize preliminary oral fluid screening in Michigan, establishing parity with preliminary breath testing.
- Michigan pilot data used to establish a permanent statewide program in Indiana.



ADVANCING PROGRESS

Indiana: Benchmark for success

- Program launched in November 2020 with phased rollout.
- Statewide implementation at local level; ARIDE-trained officers.
- Significant indicators of success:
  - Increase in identification of drug-impaired drivers including drivers under the influence of multiple drugs.
  - Increase in DRE drug evaluations.
  - Increase in drug submissions to forensic laboratory.
  - Increase in officer engagement with training (all-time high participation in ARIDE trainings).



ADVANCING PROGRESS

Indiana: Benchmark for success

- Significant increase in submissions to lab for drug analysis:
  - **61** of **92** (78%) of counties increased submissions by **15%** or more.
  - **42** of **92** (46%) of counties increased submissions by **50%** or more.
  - **71.1%** of submissions positive for one or more drugs (6,246 vs. 6,720).
  - THC positives increased from **40.4%** in 2019 to **53.4%** in 2021 (+13%).

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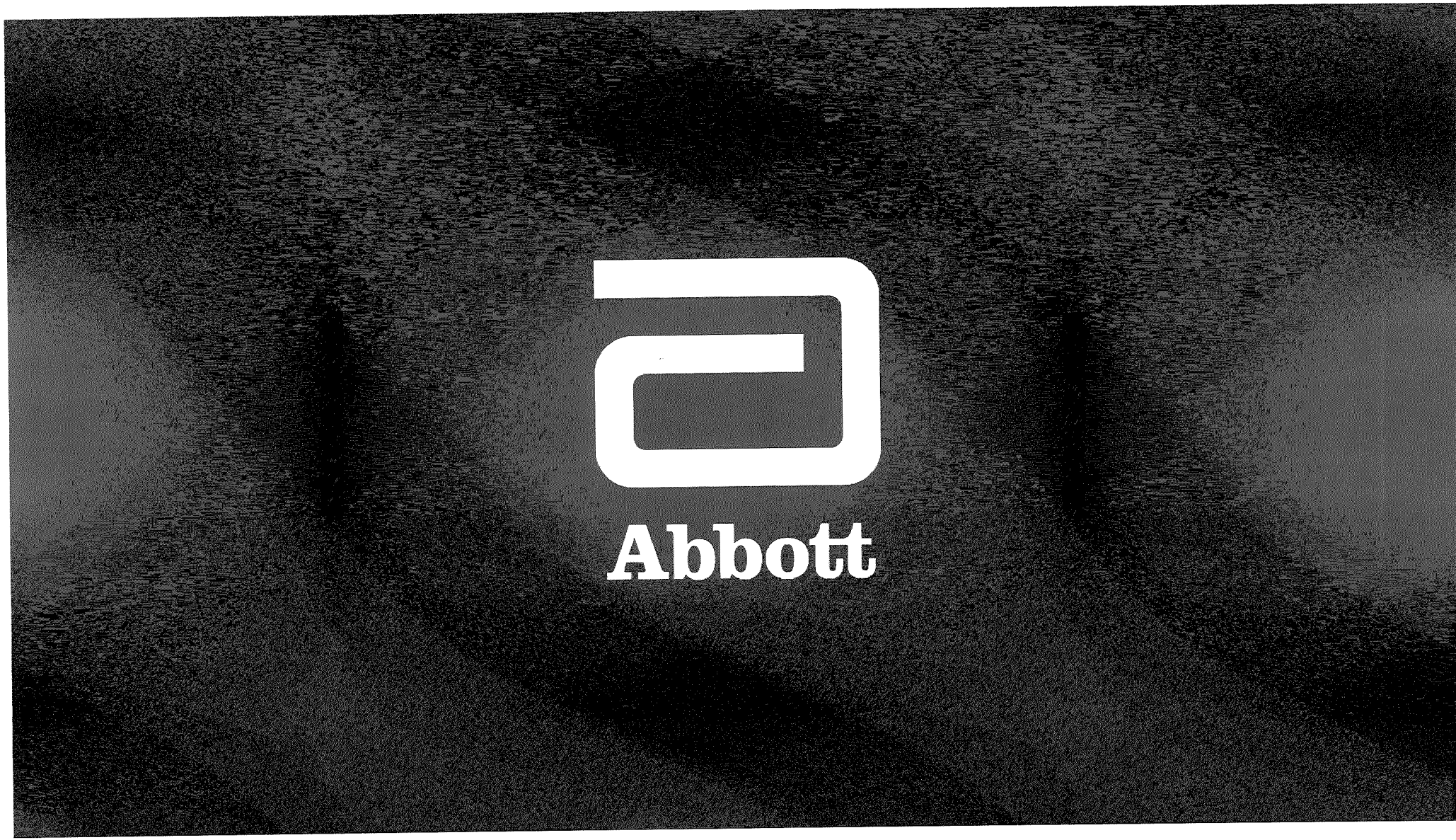

Abbott

Legislative Report

Minnesota oral fluid roadside testing report to the legislature

February 21, 2025

Minnesota Department of Public Safety
Office of Traffic Safety
dps.mn.gov/divisions/ots

Table of Contents

Introduction

Impaired driving, specifically multiple-substance impaired driving, continues to be a serious danger on Minnesota roads. Advances in technology have helped law enforcement officers identify and screen for impairing substances at roadside. Manufacturers have developed instruments that can screen drivers for the presence of controlled and intoxicating substances using an oral fluid sample. Samples can be collected and tested at roadside; the screening is non-invasive; and the observed collection process limits contamination and tampering concerns.

The collection and testing at roadside help determine probable cause to arrest and obtain a search warrant for evidentiary blood or urine samples. This proven technology has been successfully implemented in many U.S. states as well as around the globe. Minnesota law enforcement officers would like to use this technology to help remove impaired drivers from the roadways.

Whenever new technology is introduced, it must be done with great care to establish sound legal precedent. Preliminary breath testing (PBT) instruments in Minnesota underwent a rigorous certification program to gain approval for law enforcement use by the Minnesota Legislature and the Minnesota Department of Public Safety (DPS) commissioner. To ensure the longstanding use of new roadside oral fluid testing technology, Minnesota followed a similarly rigorous certification program for oral fluid screening.

Professionals from the DPS Office of Traffic Safety (OTS), DWI Task Force, law enforcement, criminal defense attorneys, prosecutors and DPS Bureau of Criminal Apprehension (BCA) laboratory supervisors teamed up to create a Roadside Oral Fluid Testing Pilot Project Committee. The committee's goals were to:

- Test roadside oral fluid testing instruments.
- Create a standardized law enforcement training program.
- Gain legislative support to approve a pilot project.
- Gather data and statistics to substantiate each instrument's accuracy and reliability.
- Authorize the instrument's permanent use in Minnesota's rules and statutes.

The Cannabis Legalization Act, Minnesota Session Laws 2023, Chapter 63, Article 4, Section 49 granted approval to OTS to design, plan and implement a pilot project to study oral fluid roadside testing instruments. The instruments determine the presence of a controlled or intoxicating substance in individuals stopped or arrested for driving while impaired offenses.

The pilot program began in January 2024 and concluded on Aug. 31, 2024. The legislation required the DPS commissioner to submit by Feb.1, 2025, a report to the chairs and ranking minority members of the legislative committees with jurisdiction over public safety on the results of the pilot project. The report must include, at minimum, information on:

- The accuracy of the instruments when tested against laboratory results.
- How often participants were found to have controlled substances or intoxicating substances in their systems.
- How often there was comingling of controlled substances or intoxicating substances with alcohol.
- The types of controlled substances or intoxicating substances found in participants' systems, which types were most common and the number of participants in the project.

In addition, the report was to assess the practicality and reliability of using instruments in the field and to make recommendations for the future.

Device selection

The intent of the pilot project was to purchase different models of oral fluid screening instruments that met the specifications listed below for an evaluation of the instruments' testing capabilities.

Device specifications

- Portable handheld instrument for ease of use in the field.
- Rechargeable and fully automated instrument.
- On-screen instructions.
- Results within 10 minutes or less.
- A large operating temperature range or an on-board heater to ensure tests run at optimal temperature.
- Battery life capable of running up to 50 tests.
- Printer included with the instrument.
- Collection device separate from test cartridge.
- Collection device has a volume adequacy indicator.
- Capacity to retain at least 500 test records.
- Test records have unique identifiers for data tracking.
- Test data can be downloaded.
- Buffer solution integrated with test cartridge.
- Positive and negative quality control (QC) cartridges included with an instrument to verify the instrument is interpreting the results correctly.
- Minimum test panel to include amphetamines, methamphetamines, opiates, cocaine, benzodiazepines and cannabinoids at appropriate cutoff concentrations.
- Minimum cutoff concentrations, which produce a positive result at or lower than the concentrations listed below:

Drug class	Cutoffs in ng/mL
Amphetamines	50
Methamphetamines	50
Opiates	40
Cocaine	30
Benzodiazepines	20
Cannabinoids	25

Based on these specifications, the Abbott SoToxa™ Oral Fluid Mobile Test System and the Dräger DrugTest 5000 were selected for use.

Selection of law enforcement agencies for pilot

A memorandum was sent to law enforcement agencies across Minnesota in July 2023 asking for participation in the pilot project. Strong consideration was given to agencies with one or more dedicated Drug Recognition Evaluator (DRE) officers.

Fifty-seven DREs from 41 law enforcement agencies participated across 36 Minnesota counties. Instruments were placed in various Minnesota Toward Zero Deaths (TZD) regions: 14 in Northeast, 14 in West Central, 24 in East Central, 12 in Southwest, six in Northwest, 50 in Metro, two in South Central and 16 in the Southeast for a total of 138 instruments. Of the 138, 69 were the Abbott SoToxa™ and 69 were the Dräger DrugTest 5000.

Pilot program implementation

OTS conducted a training session on Jan. 5, 2024, for all DREs from agencies that agreed to participate in the pilot for the SoToxa™ instrument and on Feb. 23, 2024, for the Dräger DrugTest 5000 instrument. Officers were instructed to perform the roadside oral fluid test on drivers suspected of using drugs as close to the traffic stop as possible to prevent the metabolization of drugs from the body, but after the standardized field sobriety tests (SFST) were completed.

Officers were instructed to explain the pilot project to the motorist and ask if they were willing to voluntarily provide an oral fluid sample for testing. If the motorist voluntarily consented, the officer provided the driver with an oral fluid collector (swab) and asked the motorist to swab their mouth as instructed.

The oral fluid collectors contain a colored indicator to notify the officer when enough oral fluid for testing is collected. The officer would not learn the test results until after the subject was arrested and the arrest process was completed. None of the information gathered by the oral fluid instruments was used to form probable cause to arrest or to obtain a search warrant for an evidentiary blood or urine test.

If the motorist declined to provide an oral fluid sample, no test was completed but the refusal was documented. The choice not to participate did not factor in the officer's decision to arrest, and it was not used in the formation of probable cause to apply for a search warrant for an evidentiary blood or urine test.

Officers were instructed to alternate between the SoToxa™ and Dräger instruments for each arrest, and where practical, to use both devices on each driver. Sixty-one subjects consented to be tested by both instruments (side by side). Post-arrest, blood or urine samples were also collected for testing at the BCA laboratory to compare those results with the oral fluid test results.

Pilot program results

During the pilot program, 329 oral fluid tests were conducted on 268 individuals, 61 of whom consented to take two tests. There were 59 motorists who refused further testing. Of the 329 tests, 214 were tested by the Abbott SoToxa™ instrument and 115 were tested by the Dräger DrugTest 5000 instrument. A delay in receiving the Dräger instruments led to fewer tests being conducted with that system.

Positive drug results were found in 191 of the 214 (89.3 percent) SoToxa™ tests while drug results were found in 96 of the 115 (83.5 percent) Dräger tests. This contributed to positive drug results in 287 of 329 or 87.2 percent of tests overall.

Instrument	Number of tests	Times drugs found	% Times drugs found	Times drugs not found	% Times drugs not found
Dräger	115	96	83.5%	19	16.5%
SoToxa	214	191	89.3%	23	10.7%
Total	329	287	87.2%	42	12.8%

A breakdown of the drugs identified, as well as the percentage of times each was identified, is listed in the chart below. During 214 tests, the SoToxa™ instrument, on average, identified 1.7 drugs per test. During 115 tests, the Dräger DrugTest identified 1.6 drugs per test. Drugs most frequently detected during the 329 total tests were cannabinoids with tetrahydrocannabinol (THC), methamphetamines and amphetamines.

Drug	SoToxa		Dräger		Total	
	Instance of drug	% Times found	Instance of drug	% Times found	Drug found	% Times found
Amphetamine	107	50.0%	53	46.1%	160	48.6%
Benzodiazepine	4	1.9%	3	2.6%	7	2.1%
Cannabinoid	117	54.7%	60	52.2%	177	53.8%
Cocaine	25	11.7%	7	6.1%	32	9.7%
Methamphetamine	111	51.9%	57	49.6%	168	51.15%
Opiates	6	2.8%	4	3.5%	10	3.0%
Totals	370		184		554	168.4%
Avg. # drugs found per test	1.7		1.6		1.7	

In the 61 individuals who consented to be tested by both instruments, the SoToxa™ identified more drugs than the Dräger instrument in 13 cases. See the table below.

	Drugs							Drug DRE categories				
Instrument	Amphetamine	Benzodiazepine	Cannabinoid	Cocaine	Methamphetamine	Opiates	# Oral fluid drugs	# Cannabis	# CNS Stimulants	# CNS Depressants	# Narcotic Analgesics	# Oral fluid drugs
SoToxa	28	2	30	2	27	1	90	30	57	2	1	90
Dräger	23	2	24	2	25	1	77	24	50	2	1	77
SoToxa finds more drugs	**5**	**0**	**6**	**0**	**2**	**0**	**13**	**6**	**7**	**0**	**0**	**13**

Oral fluid number of tests grouped by number of drugs found

Of the 329 oral fluid tests conducted, 42 tests detected no drugs; 110 tests found one drug, and 177 or 62 percent of tests detected more than one drug. Ninety-five tests found two drugs; 77 found three drugs; three found four drugs; one found five drugs, and one found six drugs.

Statistic	Quantity
Total tests with >1 substance	177
Avg. number of tests with >1 substance	62%

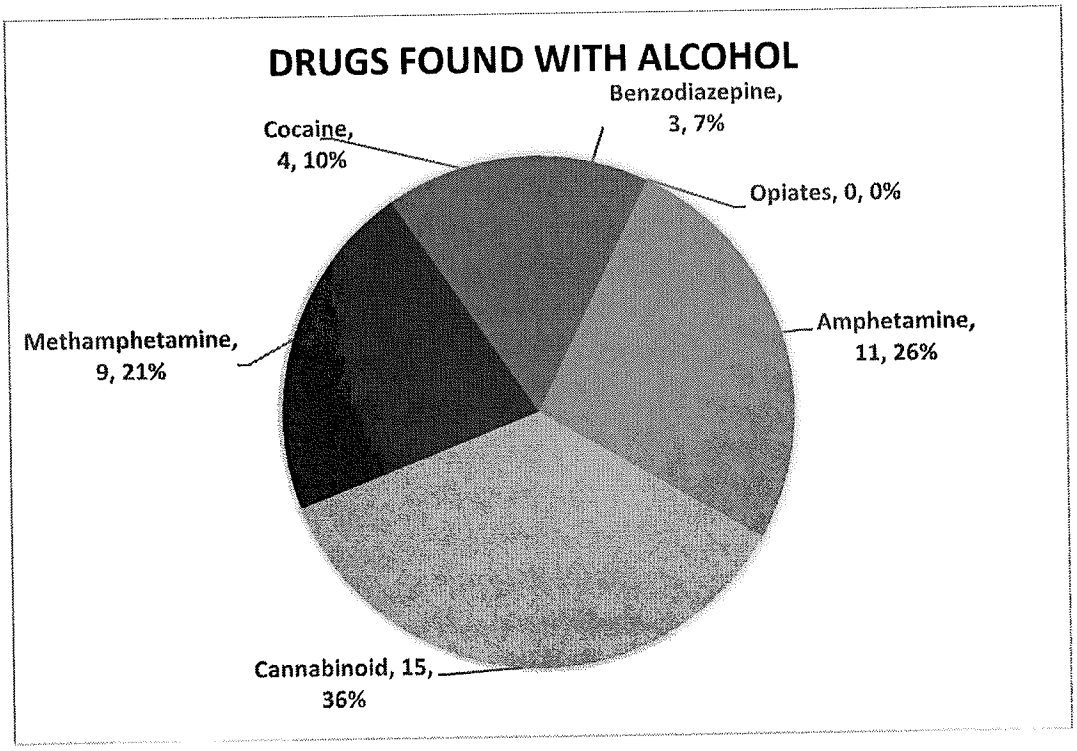
Instrument	Number of tests grouped by number of drugs found						Grand total
	1	2	3	4	5	6	
Dräger	34	36	26	0	0	0	96
SoToxa	76	59	51	3	1	1	191
Grand total	**110**	**95**	**77**	**3**	**1**	**1**	**287**
% test with	**38.3%**	**33.1%**	**26.8%**	**1.0%**	**0.3%**	**0.3%**	

Comingling of drugs with alcohol

During the pilot program, 244 individuals consented to a preliminary breath test (PBT). Alcohol was found in PBT testing 8.2 percent of the time. Drugs were also found 7.4 percent of the time when PBT tests were conducted.

There were 20 instances where drivers tested positive for alcohol, and of these 20 positive tests, 18 individuals also tested positive for drugs on the oral fluid instrument. When alcohol was detected, 90 percent of the time the driver also tested positive on an oral fluid instrument for one or more drugs.

The pie chart below shows the drugs that were detected in combination with alcohol. Some drivers tested positive for more than one drug.



# Drugs found with alcohol	# Oral fluid tests that found this # of drugs	Total # drugs across 20 alcohol cases
0	2	0
1	6	6
2	7	14
3	4	12
5	1	5
Grand total	**20**	**37**

Oral fluid results compared to blood or urine laboratory tests

In addition to oral fluid instrument testing, blood or urine samples were also collected from drivers. The BCA laboratory analyzed the samples using Immunoassay and Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) screening techniques. Twenty-one individuals refused to provide a blood or urine sample while 363 individuals complied with blood or urine testing.

One or more drugs were detected 808 times in blood or urine samples tested at the lab, while drugs were detected 554 times when using the oral fluid instruments. The reasons for this difference will vary. Some drugs, such as benzodiazepines, do not separate well into oral fluid but will be detected in blood or urine evidentiary testing. Another reason for this variance is that urine and blood testing will also detect more non-active drug metabolites. Finally, the BCA lab uses a much larger testing panel and will frequently detect drugs that the oral fluid instruments are not designed to detect.

The table below highlights these differences.

Drugs found by tester	Dräger	SoToxa	Grand total	Dräger lab match %	SoToxa lab match %	Oral fluid match %
Amphetamine – Oral Fluid	53	107	160	85.5%	102.9%	96.4%
Amphetamine - Lab	62	104	166			
Benzodiazepine – Oral Fluid	3	4	7	21.4%	23.5%	22.6%
Benzodiazepine - Lab	14	17	29			
Cannabinoid – Oral Fluid	60	117	177	75.9%	83.0%	80.5%
Cannabinoid - Lab	79	141	215			
Cocaine – Oral Fluid	7	25	32	87.5%	92.6%	91.4%
Cocaine - Lab	8	27	35			
Methamphetamine - Oral Fluid	57	111	168	100.0%	108.8%	107.0%
Methamphetamine - Lab	57	102	159			
Opiates – Oral Fluid	4	6	10	57.1%	85.7%	83.3%
Opiates - Lab	7	7	14			
Average				71.3%	82.8%	80.8%
Other drugs found by the lab but not found by SoToxa or Dräger instruments						
Barbiturates - Lab	0	0	0			
Buprenorphine - Lab	1	1	2			
Cyclobenzaprine - Lab	0	2	2			
Dextromethorphan -Lab	1	1	2			
Diphenhydramine - Lab	3	3	6			
Fentanyl - Lab	25	44	69			
Methadone - Lab	2	5	7			
Psilocin - Lab	0	1	1			

Oxycodone - Lab	0	0	0			
Trazodone - Lab	0	1	1			

Accuracy of oral fluid tests compared to blood or urine laboratory tests

The above table shows the number of times the listed drugs were found in the SoToxa™ and Dräger DrugTest 5000 instruments compared to the number of times these drugs were found in the BCA lab in blood or urine. There are instances when the lab found the drug and the oral fluid instruments did not detect them, and there are multiple reasons for the differences in results:

- The BCA lab may be picking up the inactive drug metabolite, whereas the oral fluid instruments are programmed primarily to detect the active drug compound.
- Differences can also be explained when the driver consented to the oral fluid test but refused the blood or urine test.
- Instances of false positives on the oral fluid test are possible where the instrument picks up a drug (such as a medication) that is cross-reacting and showing positive for amphetamine or methamphetamine. This would explain the lab match percentages that exceed a 100-percentage match.

Overall, the match rates all exceeded 82 percent except for benzodiazepines, which are known to not separate well in oral fluid and so are difficult to detect. In addition, there are many benzodiazepine drugs, and the oral fluid instruments are designed to only test for the most common benzodiazepines. The BCA lab panels are much broader and test for more drugs.

Accuracy of Drug Recognition Evaluator assessments compared to oral fluid tests

During the pilot program, DREs completed 229 evaluations on drivers in which the driver also consented to an oral fluid test. In 17 cases (eight Dräger, nine SoToxa™), the DRE did not detect impairment, but the oral fluid instruments detected one or more drugs. This can be explained by the instrument accurately detecting the drug(s) in the subject, but the drugs were not causing visible impairment at the time of testing.

This is to be expected because a positive oral fluid test is not an indicator of impairment, but rather an indication of recent drug use. A DRE evaluation is required to articulate the signs and symptoms of impairment.

Likewise, a negative oral fluid test is not evidence of non-impairment. The motorist may have ingested a drug or drugs that are not tested for by the oral fluid testing instrument, or the subject tested below the cutoff levels on the instrument yet still exhibited signs and symptoms of impairment. This was evidenced in the pilot program where 178 (67 Dräger, 111 SoToxa™) times the DRE detected impairment when the oral fluid result was negative. The table below reflects these results.

Values	Dräger	SoToxa	Grand total	Dräger match %	SoToxa match %	Oral fluid total match %
# Cannabis - DRE	39	70	109	153.8%	167.1%	162.4%
# Cannabis - Oral Fluid	60	117	177			
# CNS Stimulant - DRE	25	70	95	468.0%	347.1%	378.9%
# CNS Stimulant - Oral Fluid	117	243	360			
# CNS Depressant - DRE	1	6	7	300%	66.7%	100.0%
# CNS Depressant - Oral Fluid	3	4	7			
# Narcotic Analgesic - DRE	5	9	14	80.0%	66.7%	71.4%
# Narcotic Analgesic - Oral Fluid	4	6	10			

Practicality and reliability of oral fluid instruments

Thirty of the 57 participating DREs completed a user survey sent by DPS asking them to rate their experience with each oral fluid instrument during the pilot program. A scale of 1 to 5 or yes-no was used to assess responses, and we asked the same questions about each instrument.

1. When asked to rate their overall experience with the instrument:
   SoToxa™ — 79 percent rated their experience as either a 4 or 5.

   Dräger — 39 percent rated their experience as either a 4 or 5.

2. When asked to rate the size and portability of the instrument:
   SoToxa™ — 94 percent rated their experience as either a 4 or 5.

   Dräger — 3 percent rated their experience as either a 4 or 5.

3. When asked if the DRE considers the size and portability of the instrument to be acceptable:
   SoToxa™ — 93 percent said yes.

   Dräger — 7 percent said yes.

4. When asked if the DRE considers the storage of the instrument to be acceptable:
   SoToxa™ — 90 percent said yes.

   Dräger — 30 percent said yes.

5. When asked to rate the timeliness of sample collection:
   SoToxa™ — 64 percent rated their experience as either a 4 or 5.

   Dräger — 56 percent rated their experience as either a 4 or 5.

6. When asked to rate the timeliness of the analysis process:
   SoToxa™ — 70 percent rated their experience as either a 4 or 5.

   Dräger — 56 percent rated their experience as either a 4 or 5.

7. When asked which of the two instruments the DRE prefers:
   SoToxa™ — 83 percent

   Dräger — 17 percent

Summary

DPS thanks the Minnesota Legislature for providing resources to plan, implement and review the results of a pilot project to study oral fluid field screening instruments to determine the presence of controlled or intoxicating substances in individuals stopped or arrested for DWI offenses.

More than 50 percent of DREs from 41 agencies across 36 counties and all Toward Zero Deaths regions completed a survey on the practicality and reliability of the two instruments. Responses were mostly positive concerning the timeliness of the sample collection and analysis. In terms of practicality, respondents preferred the practicality of the Abbott SoToxa™ instrument to the Dräger DrugTest 5000 instrument.

Concerning accuracy, positive drug results were found in 287 of 329 (87.2 percent) oral fluid tests with the SoToxa™ instrument, detecting an average of 1.7 drugs per test. The Dräger DrugTest 5000 detected an average of 1.6 drugs per test. In the 61 individuals who consented to be tested by both devices, the SoToxa™ found more drugs than Dräger in 13 cases.

The most common drugs detected across all tests were cannabinoids (THC), methamphetamines and amphetamines. An alarming 62 percent of tests detected more than one drug in a single subject, confirming the dangers of multiple drug use on our roadways. Regarding the comingling of alcohol with drugs, 90 percent of those who tested positive for alcohol also tested positive for one or more drugs.

When comparing the oral fluid test results to the BCA blood or urine tests, the oral fluid instruments accurately detected the same substances that were found in the lab. Most match rates exceeded 82 percent. As expected, the BCA did detect more substances than the oral fluid instruments, due to the lab's expanded testing panels and lower cutoff thresholds.

Conclusion

The pilot test of advanced drug-detecting technology confirmed that a multiple-substance impaired driving crisis is occurring on Minnesota roadways. The pilot makes clear that we must adequately equip our law enforcement officers with every tool possible to assist them in removing dangerous drivers from our roadways.

Minnesota has taken great strides to train law enforcement officers in Standardized Field Sobriety Testing (SFST), Advanced Roadside Impaired Driving Enforcement (ARIDE), and Drug Recognition Evaluator (DRE) training. We need to provide our officers with additional tools to detect drug use that, when combined with their observations, allow them to develop probable cause to make proper arrests for impaired driving.

The pilot testing program revealed that while most officers preferred the SoToxa™ Mobile Testing System, both the SoToxa™ and the Dräger DrugTest 5000 instruments met stated requirements in their ease of use, reliability, accuracy and practicality.

Based on the pilot project results, we recommend legislators should approve both instruments as preliminary screening devices to assist officers in establishing probable cause for arrests in drug-impaired driving cases.