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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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.

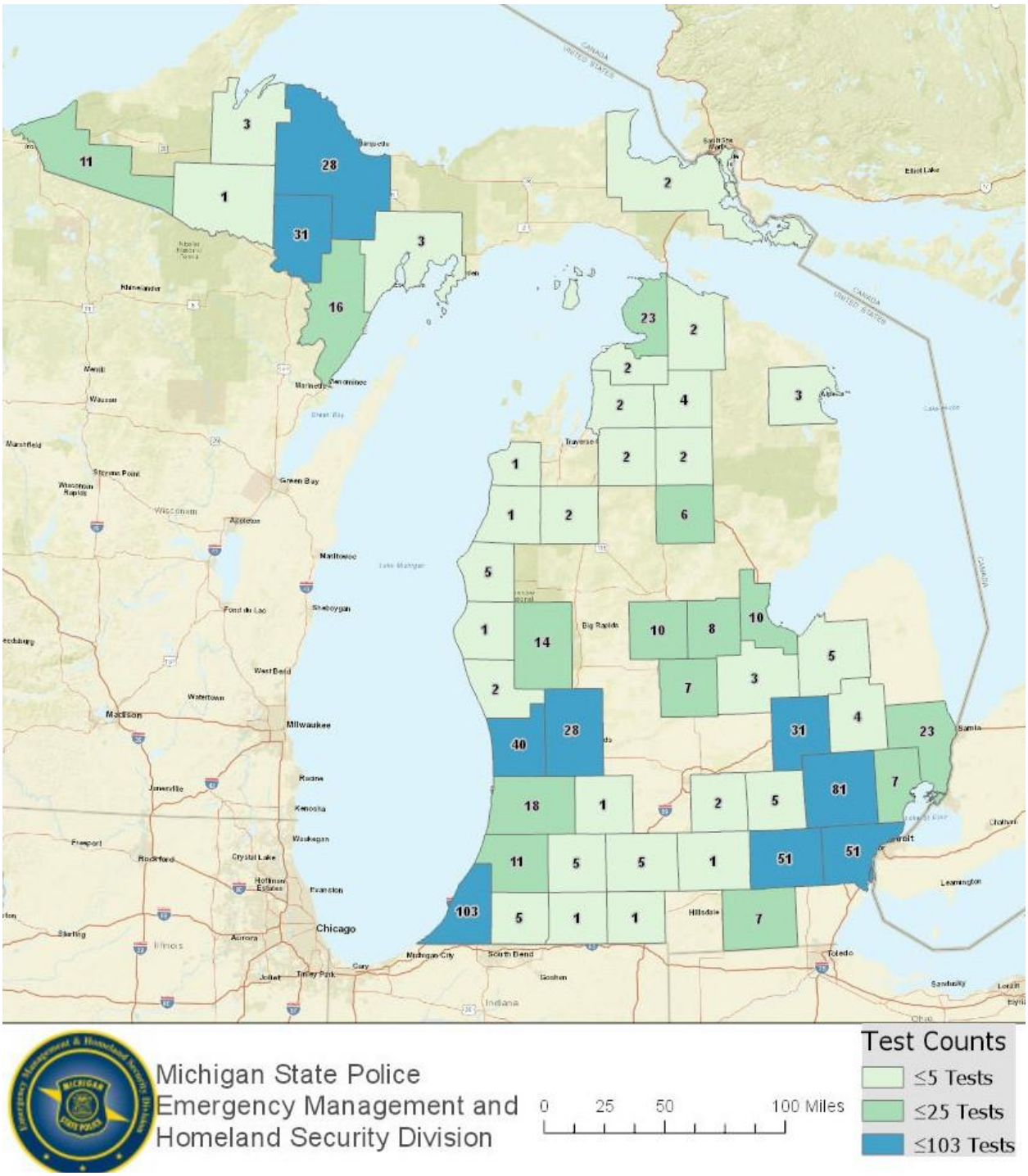
Prior to participation in the program, DREs attended a training session to include:

- 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.

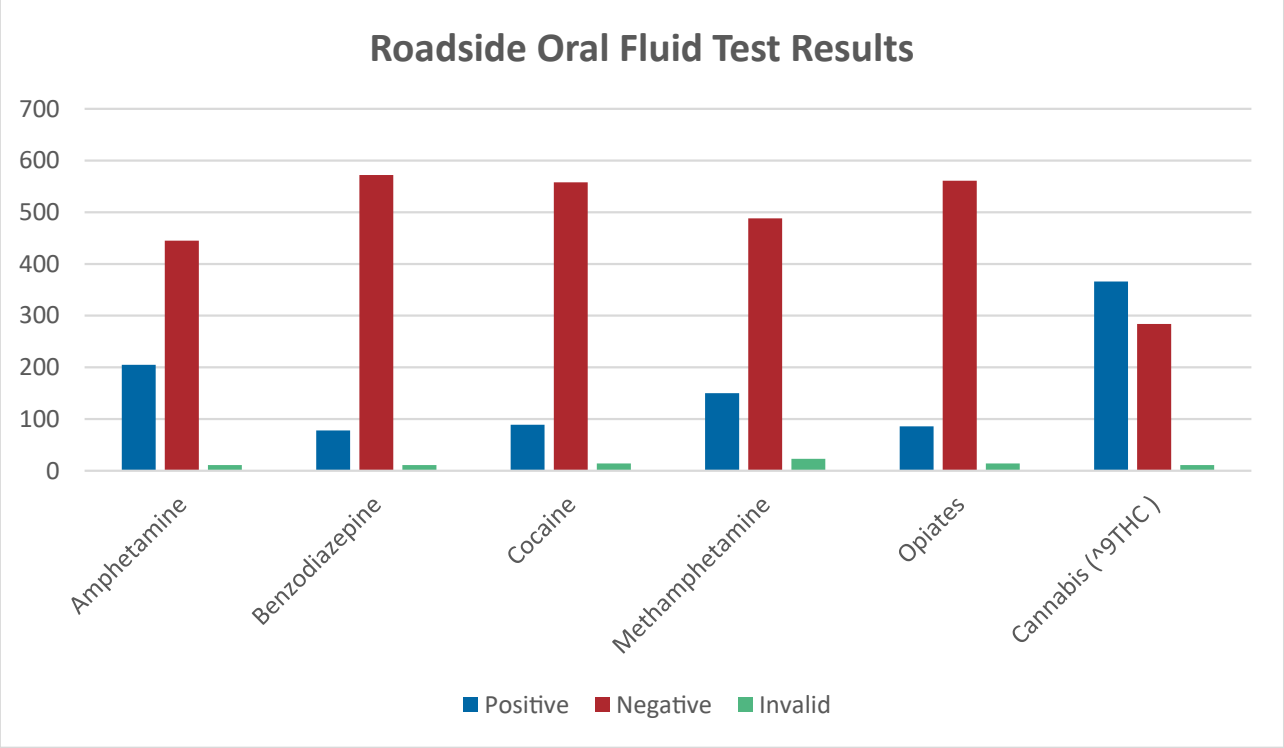
RESULT INTERPRETATION:

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

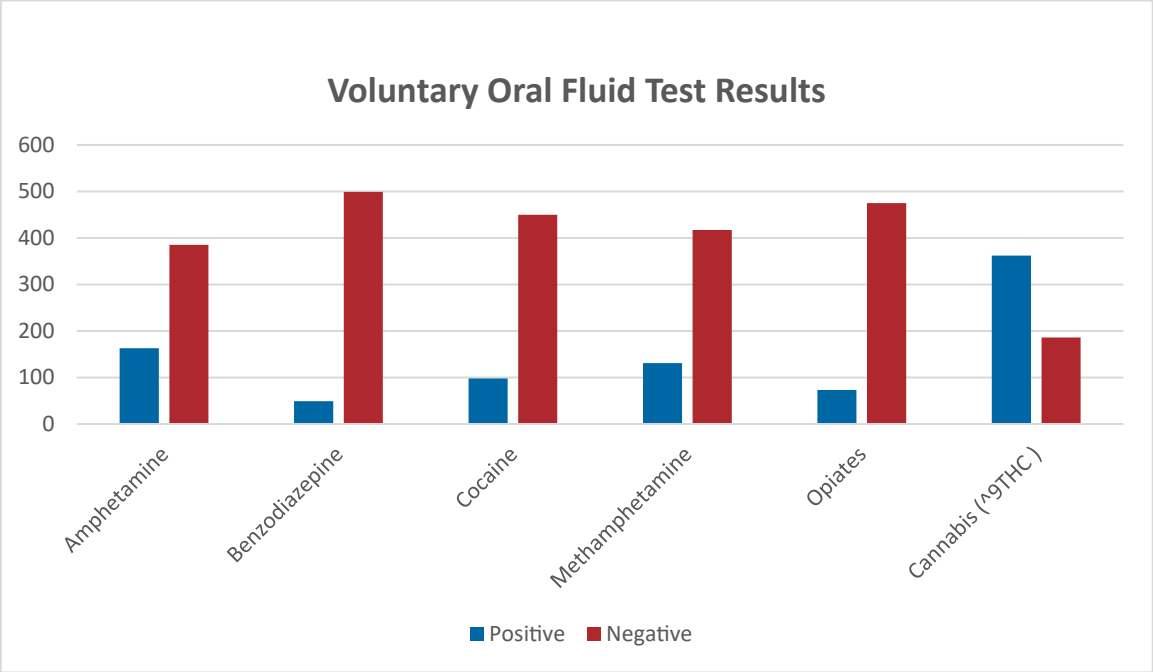
- Matrix analyzed
- Cut-off levels
- Limit of detection
- Limit of quantification
- Cross reactivity
- Confirmatory instrumentation
- Scope of analysis
- Incident time vs. sample collection time

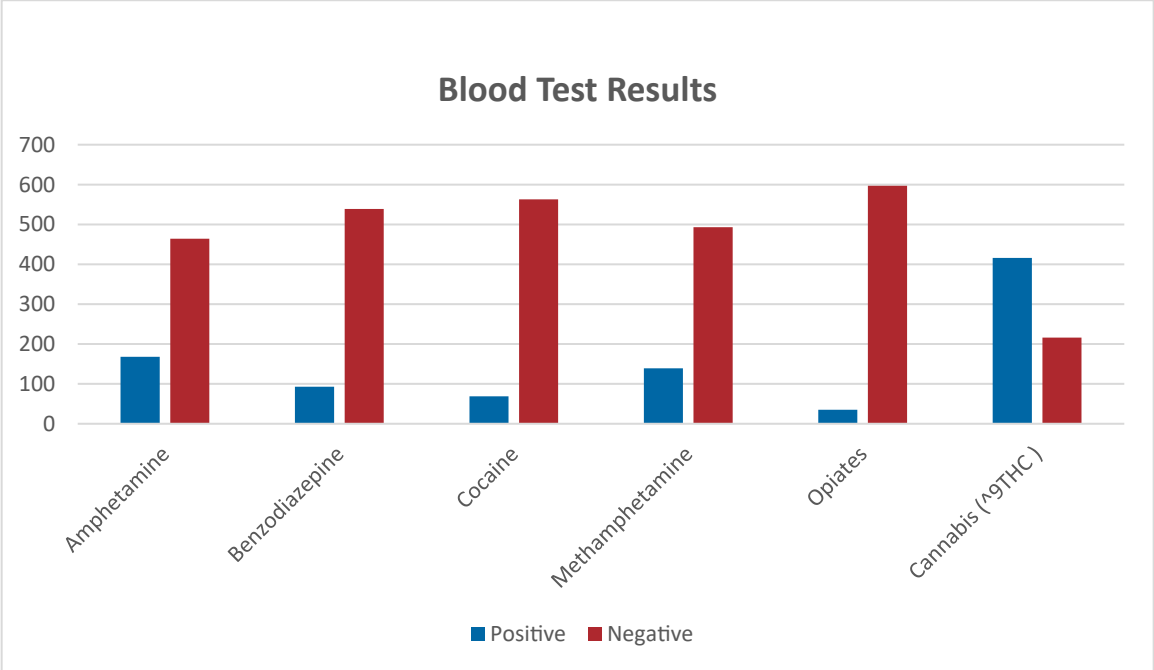
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

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.



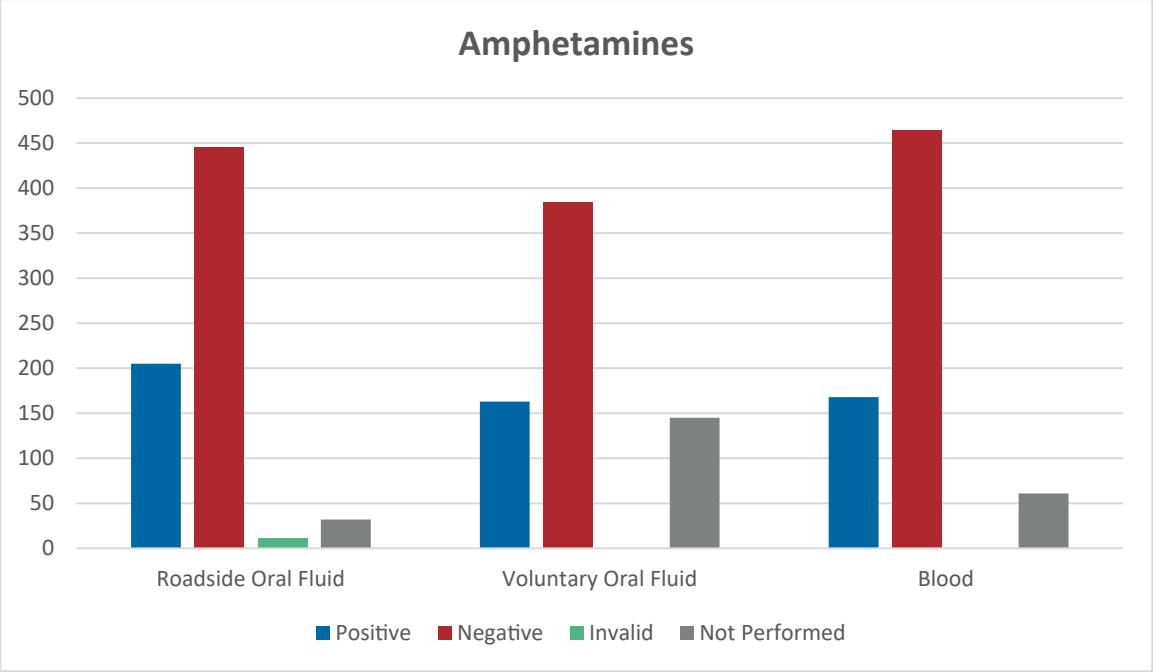
RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

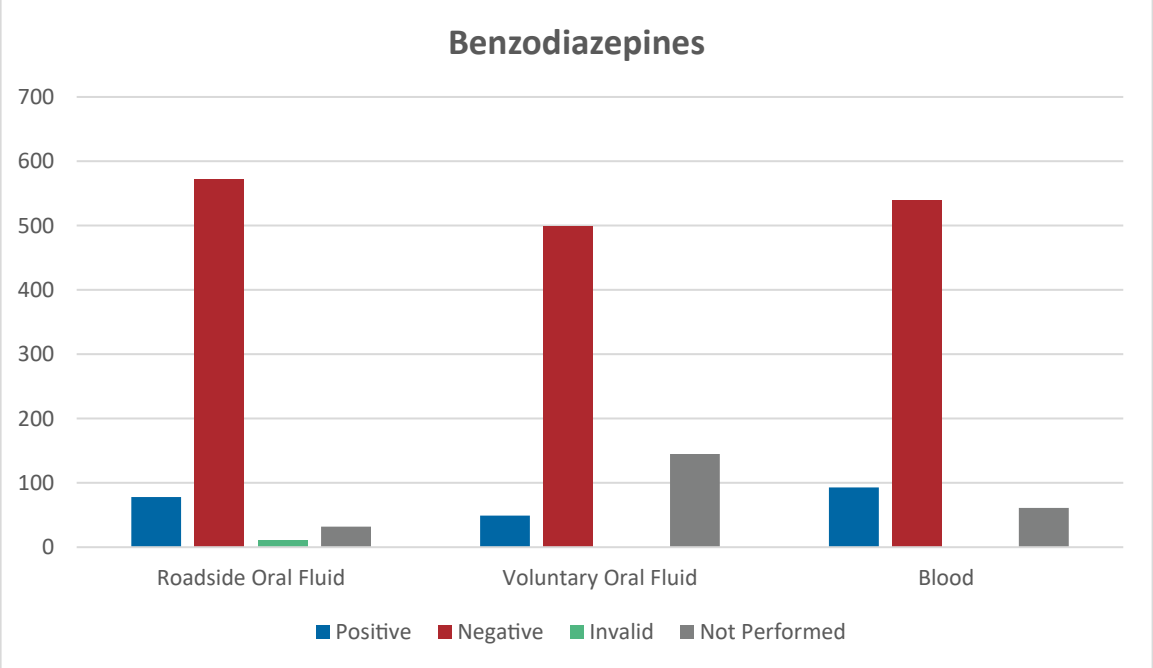




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

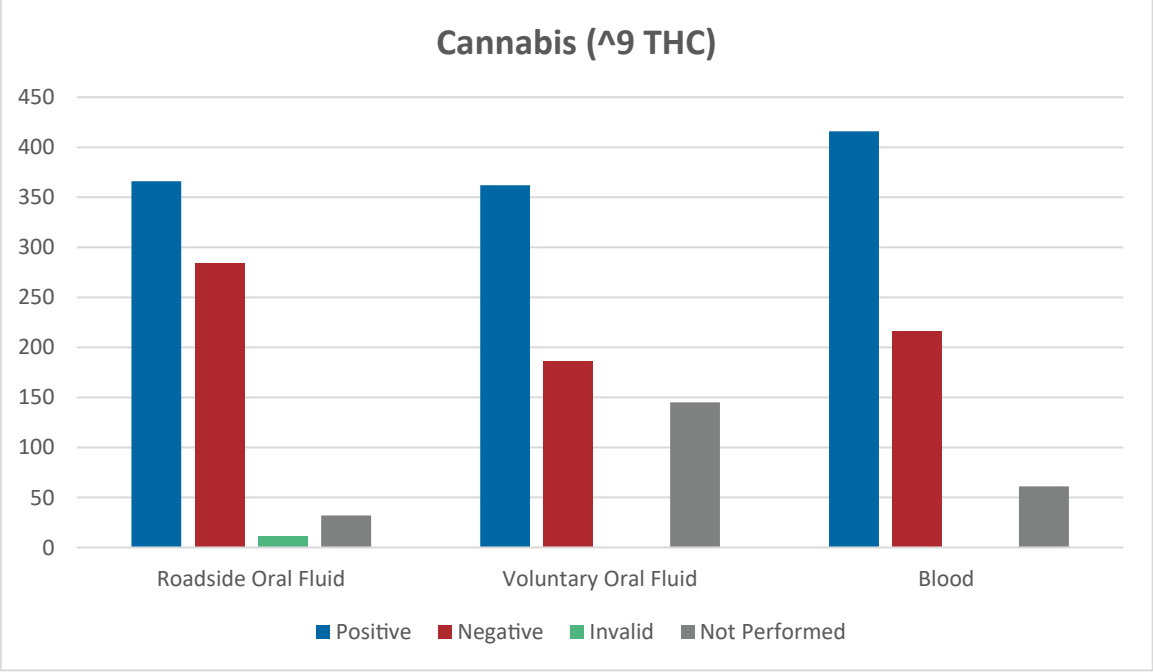
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

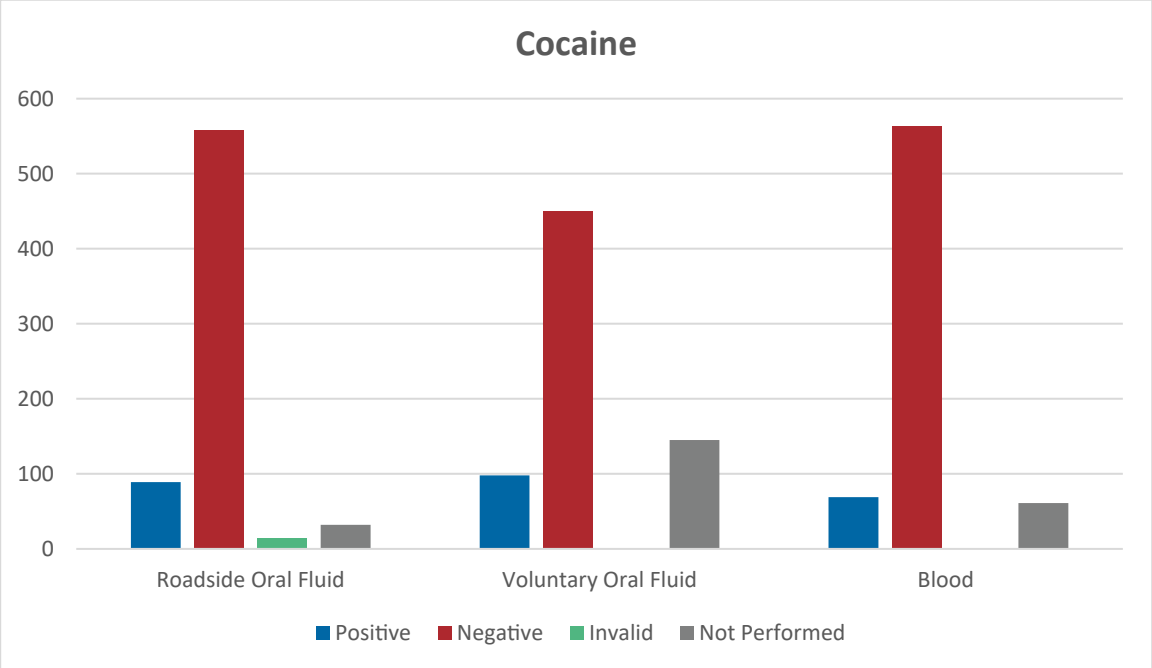




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

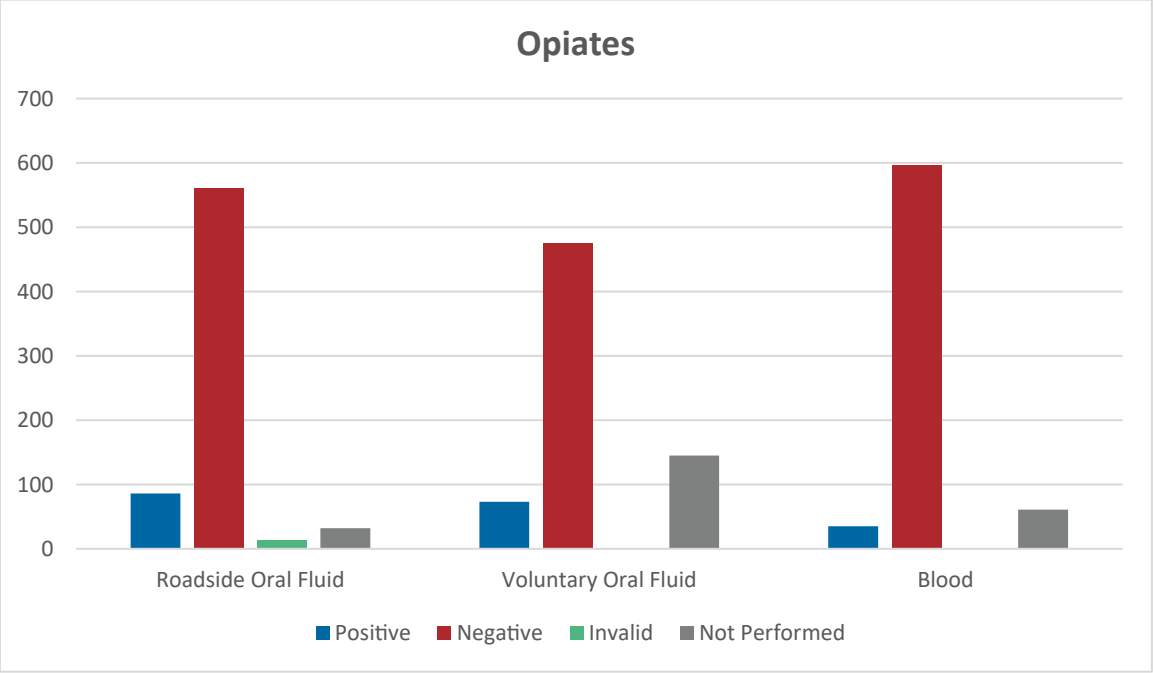
COMPARISON BETWEEN TEST INSTRUMENT, INDEPENDENT LAB, AND BLOOD TEST:

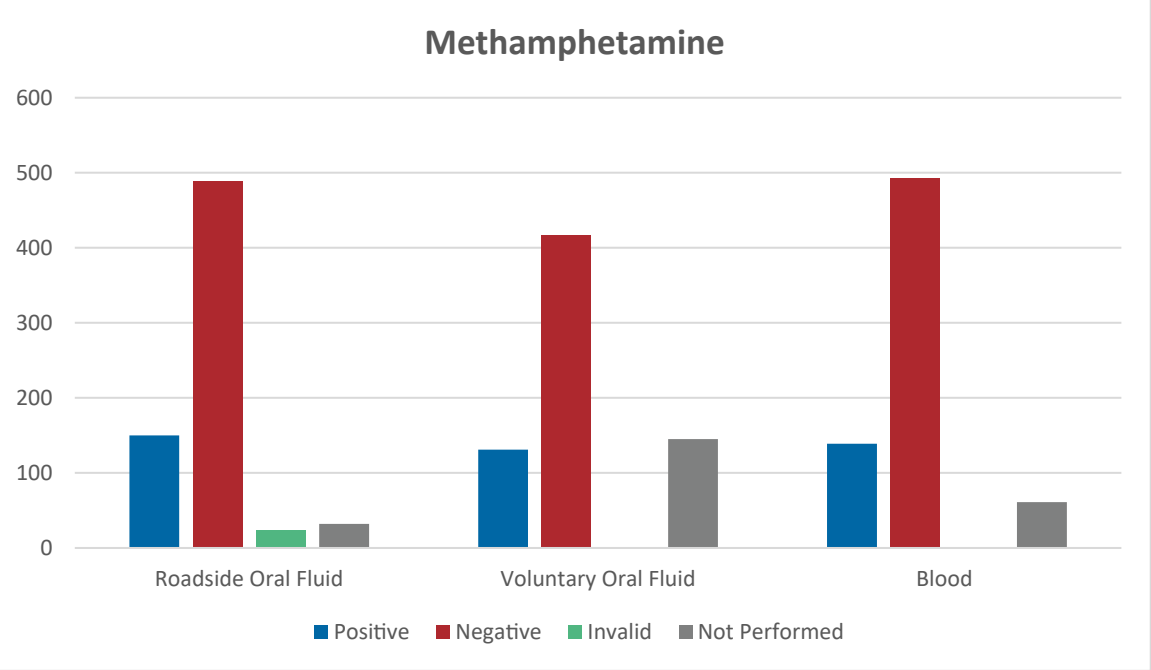




RESULTS FROM THE ORAL FLUID ROADSIDE ANALYSIS PILOT PROGRAM - PHASE II

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.

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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.