

ROSITA II Project: Evaluation of On-Site Saliva Drug Testing Devices in Washington State

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ABSTRACT

Washington State, as part of the collaborative ROSITA II project (please see group abstract), evaluated two oral fluid drug testing devices. Samples were collected from Washington State drivers who were under arrest for DUI. The devices were also evaluated using non-driving subjects (parole violators) under the influence of drugs and volunteered to be evaluated by officers completing their Drug Recognition Expert training. Washington's law currently has no provisions for the collection of an oral fluid specimen and for the purposes of this study, subjects were asked to provide a specimen voluntarily at the conclusion of the arrest and other testing procedures, with the understanding that the oral fluid test results would not be used in any criminal prosecution.

During Phase I of the project, which ran from January through August 2004, seventy samples were collected and tested using both the *SalivaScreen 5TM* (UltiMed Products) and *InterceptTM* (OraSure Technologies) devices. In Sixty-eight of these cases blood was also collected. Thirty-three of the seventy samples received failed to provide a valid reading, resulting in only thirty-seven samples that were able to be included in phase I of the study.

Phase II of the project began in May 2005 and was completed in September 2006. There were 332 subjects who volunteered for the study. In contrast to Phase I, the *DrugWipe5TM* (Securetec) drug test device was used, rather than the *SalivaScreen 5TM*. Due to either refusal of one or more tests, incomplete paperwork, or failure by the officer to submit all samples, only 264 subjects were included in the Phase II study.

Device Evaluation Summary, Phase I (Device: UltiMed Products, *SalivaScreen 5™*)

	Total	THC	Amph	Cocaine	Benzo	Opiates
Total assays conducted "n"	185	37	37	37	37	37
True Positives	28	6	7	9	2	4
True Negatives	132	17	28	25	32	30
False Positives	5	2	0	0	2	1
False Negatives	20	12	2	3	1	2
Sensitivity	58.33%	33.33%	77.78%	75.00%	66.67%	66.67%
Specificity	96.35%	89.47%	100.00%	100.00%	94.12%	96.77%
Positive predictive value	84.85%	75.00%	100.00%	100.00%	50.00%	80.00%
Negative predictive value	86.84%	58.62%	93.33%	89.29%	96.97%	93.75%
Prevalence	25.95%	48.65%	24.32%	32.43%	8.11%	16.22%
Accuracy	86.49%	62.16%	94.59%	91.89%	91.89%	91.89%

Device Evaluation Summary, Phase II (Device: Securetec *DrugWipe5™*)

	Total	Cannabinoids	Amphetamines	Cocaine	Opiates
Total assays conducted "n"	1056	264	264	264	264
True Positives	211	10	14	163	24
True Negatives	712	208	241	53	210
False Positives	14	5	1	5	3
False Negatives	119	41	8	43	27
Sensitivity	63.94%	19.61%	63.64%	79.13%	47.06%
Specificity	98.07%	97.65%	99.59%	91.38%	98.59%
Positive predictive value	93.78%	66.67%	93.33%	97.02%	88.89%
Negative predictive value	85.68%	83.53%	96.79%	55.21%	88.61%
Prevalence	31.25%	19.32%	8.33%	78.03%	19.32%
Accuracy	87.41%	82.58%	96.59%	81.82%	88.64%

Note: Data generated using the *Intercept™* device as the reference sample

Key Words: Oral Fluid, Point of Collection, DUID

Site Coordinators: Jayne E. Thatcher (2005-2006), Sgt. Carlos Rodriguez(2005-2006), Sgt. Steve Johnson (2003-2004), Dr. Dorota Schranz (2003-2004), Dr. Barry Logan (2003–2006)

Introduction

The Walsh Group in collaboration with Dr. Alain Verstraete [University of Ghent, Belgium] established a collaborative agreement to conduct a joint U.S./European international study to assess the prevalence of illegal drug use among drivers failing a standard field sobriety test and determine the feasibility of police use of saliva drug testing devices at the roadside to verify drug use by drivers. This project was conducted in major cities in the U.S. and Western Europe by teams composed of scientists working in collaboration with local police. Intent of the project was to build on the success and the lessons learned in the original European ROSITA project that evaluated drug testing devices in eight European nations. For this project, four teams were identified in the United States located in Washington State, Salt Lake City, Utah, Wisconsin State and Hillsborough County, Florida. This section reports on the results of the study from the various law enforcement agencies across the State of Washington.

Under Washington Law a person can be found guilty of driving under the influence of any drug and is subject to punishment, if the person (1) was driving or was in actual physical control of a

vehicle in Washington, and (2) while driving or in actual physical control of a vehicle, the defendant was under the influence of, or was affected by any drug OR (3) the defendant was operating a vehicle in a negligent manner likely to endanger persons or property and while so operating the vehicle, exhibited the effects of having consumed a controlled substance or a prescription drug. Washington has an implied consent law for drugs which requires the suspect to provide a blood sample, and additionally a suspect may be compelled to provide a sample subject to a special evidence warning in the event that a person is killed or suffers a serious bodily injury as a result of a collision. Under these circumstances the person must be placed under arrest prior to the sample being taken. Washington law also permits a police officer to obtain a telephonic search warrant for blood based on probable cause of driving impairment and poor performance in sobriety tests. Washington's law currently has no provisions for the collection of an oral fluid specimen and for the purposes of this study, subjects were asked to provide a specimen voluntarily at the conclusion of the arrest and other testing procedures, with the understanding that the oral fluid test results would not be used in any criminal prosecution. Subjects signed a waiver to that effect.

Phase I

Methods

Overview:

During Phase I, training was offered to all certified Drug Recognition Expert (DRE) officers in Washington State. DRE officers receive specialized training in physiology, vital signs, and field sobriety testing in addition to the basic driving under the influence training that all officers in the state receive. This makes them better qualified to identify drug impaired drivers and categorize them into one or more of the seven classes of drugs, or to rule out possible medical or mental disorders that could have symptoms similar to drug intoxication. When a non-DRE officer contacts a subject who is suspected of driving under the influence of drugs, they will call out a DRE to evaluate the subject. This made DREs the ideal group of officers to train for this study, as they would encounter the most drug positive subjects. During Phase I, thirty-six DRE officers were trained. The training provided a brief history of the project, criteria for subject inclusion, and instructions on asking subjects if they would volunteer to participate, how to use the oral fluid collection devices assigned, and how to prepare the paper work for sample submission to the WSTL. Participating officers were made aware the goal for the project was 250 oral samples for Phase I.

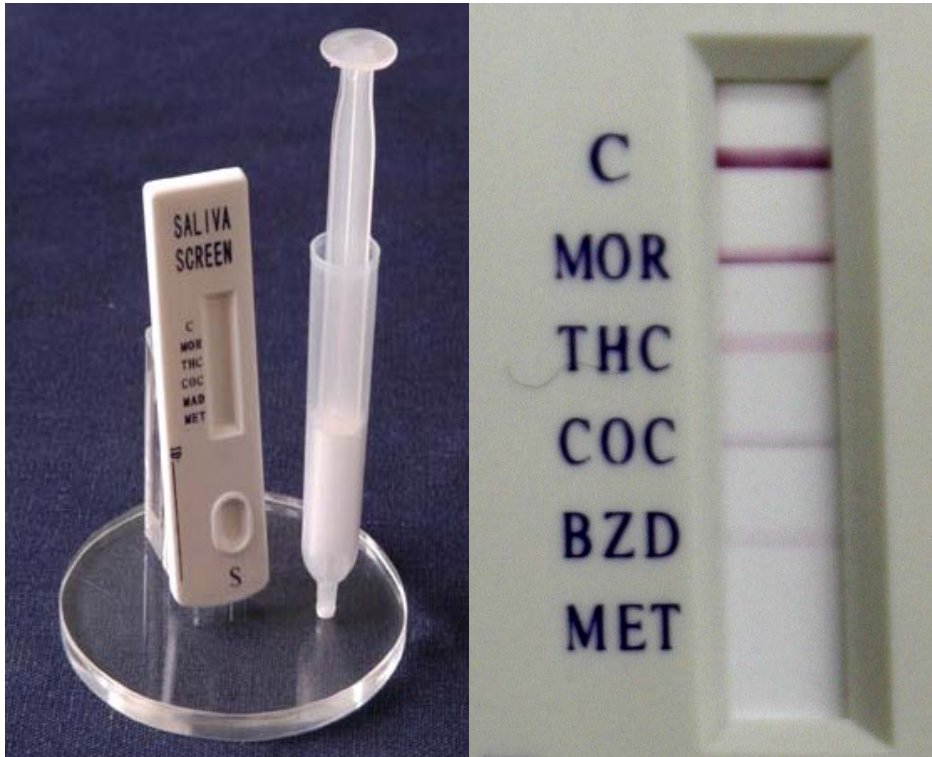
Specimens collected:

The WSTL collected two oral fluid specimens and blood. One oral fluid specimen was collected using the assigned experimental device. The second specimen was collected in the provided *Intercept*TM collection pad and forwarded in the transport vial to the University of Utah's Center for Human Toxicology (CHT) for laboratory confirmation. (See Appendix A for procedures involving collection of the *Intercept*TM specimen). A blood specimen was also collected as required by Washington State law for a DUID offense and was analyzed by the WSTL.

Device Assigned:

For Phase I, Washington State was assigned the *SalivaScreen 5TM* (UltiMed Products, Germany) drug test. This device is described in the following illustration.

UltiMed *SalivaScreen 5TM*



Matrix: Saliva, sweat

Available for: Methamphetamine, Opiates, Cocaine, Cannabinoids, and Benzodiazepines

Number of parameters per device: 5

Not FDA approved

Storage conditions: Room Temperature

Manipulations to obtain a result:

- 1) Collect the saliva sample with the collection swab.
- 2) Press the collection swab from top to bottom to expel 3-4 drops of collected saliva. Allow 2 minutes for dissolving of reagents and 10 minutes for the completion of the chromatography.
- 3) Test validity and results must be interpreted between 10 and 20 minutes after initiating the test.
- 4) Interpret the test validity.

Interpretation of the result: Visual [Although a reader device is available but not provided]

Save specimen for Confirmation: Possible in collection well

User friendliness: Good

Drugs to be tested:

The WSTL evaluation relied on the results of the laboratory saliva (*InterceptTM*) tests results and blood results to validate *SalivaScreen 5TM* drug testing system. The primary reference was the laboratory saliva (*InterceptTM*) test results. Each specimen collected was tested for a core set of drugs as follows:

Saliva Rapid Test: The *SalivaScreen 5TM* device tested oral fluid for cannabis, cocaine, opiates, methamphetamines, and benzodiazepines.

SalivaScreen 5TM test profile and cutoffs

THC	20 ng/mL
Cocaine	30 ng/mL
Opiates	30 ng/mL
Methamphetamine	50 ng/mL
Benzodiazepines	50 ng/mL

Saliva Laboratory Test: CHT screened the laboratory saliva (*InterceptTM*) specimen for cannabis, cocaine, amphetamines, methamphetamines, opiates, and benzodiazepines.

CHT Oral Fluid laboratory screening test profile

THC	2 ng/mL
Cocaine	5 ng/mL
Amp/meth	40 ng/mL
Opiates	10 ng/mL
Benzodiazepines	2 ng/mL

Blood Laboratory Test: At minimum, the WSTL screened all blood samples for cannabis, cocaine, amphetamines, methamphetamines, opiates, and benzodiazepines using Enzyme Multiplied Immunoassay Technique (EMIT). Positive cases were confirmed by GC-MS.

WSTL blood laboratory screening test profile

THC	10 ng/mL
Carboxy THC	10 ng/mL
Benzoyllecgonine	100 ng/mL
Methamphetamine	200 ng/mL*
Opiates	20 ng/mL
Benzodiazepines	100 ng/mL

* Samples that give an elevated reading, including those not above the cutoff, are confirmed by GC-MS.

Inclusion Criteria:

Before a driver was invited to participate in the study, they had to meet at least one of the following criteria:

- The driver’s appearance, behavior or odor indicated drugs may have been used
- The driver’s Breath Alcohol Concentration was less than 0.08 or inconsistent with the level of observed impairment
- The driver had illicit drugs or drug paraphernalia in the vehicle
- The driver admitted to using drugs

Procedures:

After subjects were placed under arrest and the officer took the subject to the hospital for a legal blood draw, subjects were invited to participate in the study. All volunteers signed a consent form before collection of the oral fluid samples.

1. One oral fluid specimen was tested by the DRE officer using the *SalivaScreen 5TM* on-site drug testing device and a second oral fluid specimen was collected using the *InterceptTM* saliva collector. The results of the *SalivaScreen 5TM* device were read by the police officer and recorded on the data sheet. The second *InterceptTM* specimen was annotated with the case number on the *InterceptTM* saliva transport vial and placed in a plastic envelope along with the data and consent sheets. This completed subject package was submitted with the blood tubes to the WSTL.
2. Upon arrival at the WSTL, blood specimens were handled in accordance with normal Washington State procedures. The paperwork specific to the study and the *InterceptTM* devices were transferred to the laboratory’s ROSITA coordinator, who then submitted the *InterceptTM* devices to CHT and then documented results of the testing.

Data Collection Form:

All data required for the project was written on the Data Collection Form as described below. A copy is attached as Appendix (B).

Case No. – A unique case number generally same as used for the arrest citation

Officer ID – Officer’s badge number or other officer identification

Date of Stop: (Month/day/year)

Time of Stop: Time of the stop (i.e. 9:45 pm)

Site Location – Preprinted on the form for each center

Reason for Drug Test – Checked box indicating the reason for the drug test

Reported BAC Test Results – Reported BAC level and time the BAC test was conducted

Oral Fluid Drug Test Device – The name of the assigned saliva rapid drug-testing device

Officer’s Test Results – Results indicating “+” or “-” for each drug tested

Specimen Collection Time – Time each of the specimen(s) were collected

Consent Form:

A copy of the standard U.S. site consent form is included as Appendix (C). Each subject included in the study was asked to sign a consent form prior to participating and prior to

collecting the specimen(s). Normally, this was completed after all evidentiary specimens and forms for the arrest were concluded by the police officer.

Results Summary

Subjects Summary Phase I	Phase I
Device Evaluated	UltiMed Products, <i>SalivaScreen 5TM</i>
Number of stops and subjects solicited	Unknown
Number of refusals	Unknown
Number of specimens collected/tested	70
Number of device failures	33
Number of OF specimens collected with complete data	37
Number of blood specimens collected	68

Device Evaluation Summary, Phase I (Device: UltiMed Products, *SalivaScreen 5TM*)

	Total	THC	Amph	Coc	Benzo	Opi
Total assays conducted "n"	185	37	37	37	37	37
True Positives	28	6	7	9	2	4
True Negatives	132	17	28	25	32	30
False Positives	5	2	0	0	2	1
False Negatives	20	12	2	3	1	2
Sensitivity	58.33%	33.33%	77.78%	75.00%	66.67%	66.67%
Specificity	96.35%	89.47%	100.00%	100.00%	94.12%	96.77%
Positive predictive value	84.85%	75.00%	100.00%	100.00%	50.00%	80.00%
Negative predictive value	86.84%	58.62%	93.33%	89.29%	96.97%	93.75%
Prevalence	25.95%	48.65%	24.32%	32.43%	8.11%	16.22%
Accuracy	86.49%	62.16%	94.59%	91.89%	91.89%	91.89%

Discussion

There were several difficulties encountered in collecting valid data during Phase I. One of the problems encountered was poor officer participation. Only twenty of the thirty-six officers trained submitted samples. Of those twenty who submitted samples, only half submitted more than one sample. The lack of participation may have been the result of an inadequate sample collection device. The test kits were required to be kept at room temperature. The eastern portion of Washington State has large seasonal variations in temperature and during the winter months the temperature is below the recommended storage temperature of 2°C. This prevents those officers from carrying the devices in their car. Additionally, the *SalivaScreen 5TM* device gave more invalid tests than it did valid. Twenty-one devices did not give readings (control bar did not appear). Other officers reported the result bands smearing or not enough saliva collected

by the device to give a reading. The lack of valid data may have discouraged officers from asking other subjects to volunteer. Feedback from officers also indicated that the device was not practical and needed to be simplified. Specifically, that it took two minutes to collect the sample, having to manually transfer saliva from collection device to reading device, and then waiting an additional ten minutes for the device to produce results.

Conclusions

At the end of Phase I only thirty-seven valid specimens were collected. Due to the problems encountered with the *SalivaScreen 5TM* device, Washington State switched devices after Phase I.

Phase II

Methods

Overview:

During Phase II, Washington State changed the selection criteria for who would receive training. This time, the ROSITA training was offered to both DRE officers and non-DRE officers that specialize in the area of DUI enforcement or narcotics enforcement, and were willing to participate in the ROSITA project. Thirty-three officers received training.

In an effort to increase the number of samples received, during the sixth month of Phase II it was decided to ask subjects that were participants in DRE field certifications to volunteer specimens. During field certifications students training to become DREs examine subjects that may be under the influence of a drug. These subjects are usually parole violators that have volunteered to be examined. After the students completed their examination, the volunteers were asked to participate in the ROSITA project.

Specimens collected:

Specimens collected in Phase II were similar to Phase I, with the exception of the assigned device. Again, the WSTL collected two oral fluid specimens and blood. One oral fluid specimen was collected using the assigned experimental device. The second specimen was collected in the provided *InterceptTM* collection pad and forwarded in the transport vial to the University of Utah's Center for Human Toxicology (CHT) for laboratory confirmation. A blood specimen was also collected as required by Washington State law for a DUID offense and was analyzed by the WSTL.

Device Assigned:

For Phase II, Washington State was assigned the Securetec *DrugWipe5TM* drug test. This device is described in the following illustration.

Securetec DrugWipe5™



Matrix: Saliva, sweat, wipe

Available for: Amphetamines, Opiates, Cocaine, and Cannabinoids

Number of parameters per device: 4

Not FDA approved

Storage conditions: Room temperature

Manipulations to obtain a result:

- 1) Disconnect wiping section from the device
- 2) Wipe the surface of the tongue for approximately 10 seconds
- 3) Reassemble the device and dip the absorbent pad into water for 15 seconds
- 4) Read the result after approximately 10 minutes

Interpretation of the result: Visual

Save specimen for Confirmation: Possible

User friendliness: Good

Drugs to be tested:

In Phase II the WSTL evaluation again relied on the results of the laboratory saliva (*Intercept™*) tests results and blood results to validate the *DrugWipe5™* forensic drug testing system. The primary reference was again the laboratory saliva (*Intercept™*) test results. Each specimen collected was tested for a core set of drugs as follows:

Saliva rapid Test: The *DrugWipe5TM* device tested oral fluid for cannabis, cocaine, opiates, and amphetamines.

DrugWipe5TM test profile and cutoffs

THC	30 ng/mL
Cocaine	50 ng/mL
Opiates	20 ng/mL
Methamphetamine	100 ng/mL

Laboratory saliva Test (*InterceptTM*): CHT screened the laboratory saliva (*InterceptTM*) specimen for cannabis, cocaine, amphetamines, methamphetamines, and opiates.

CHT Oral Fluid laboratory screening test profile

THC	2 ng/mL
Cocaine	5 ng/mL
Amp/meth	40 ng/mL
Opiates	10 ng/mL
Benzodiazepines	2 ng/mL

Blood laboratory Test: At minimum, the WSTL screened all blood samples for cannabis, cocaine, amphetamines, methamphetamines, and opiates using Enzyme Multiplied Immunoassay Technique (EMIT). Positive cases were confirmed by GC-MS.

WSTL blood laboratory screening test profile

THC	10 ng/mL
Carboxy THC	10 ng/mL
Benzoylcegonine	100 ng/mL
Methamphetamine	200 ng/mL*
Opiates	20 ng/mL

* Samples that give an elevated reading, including those not above the cutoff, are confirmed by GC-MS.

Inclusion Criteria:

All drivers contacted and placed under arrest for DUID were eligible to participate in the study. Additionally, drivers who were under arrest for DUI and provided high breath alcohol samples but showed signs of drug impairment were also invited to participate. Finally, any parole violator that participated in the DRE Field Certifications was eligible. All of the subjects that participated were volunteers and signed a consent form.

Procedures:

For drivers, who met the inclusion criteria, specimens were collected and handled the same as they were for Phase I. For volunteers recruited from the DRE Field Certifications, a phlebotomist was on site to collect voluntary blood samples in addition to the oral fluids collected by the officers. These samples were forwarded to the WSTL in a similar manner to the legal blood draws.

Data Collection Form:

All data required for the project was written on the Data Collection Form as described in Phase I.

Consent Form:

Forms and procedures used for Phase II were the same as those used for Phase I.

Results Summary

Subjects Summary Phase II	Phase II
Device Evaluated	Securetec, <i>DrugWipe5TM</i>
Number of stops and subjects solicited	Unknown
Number of refusals	Unknown
Number of specimens collected/tested	328
Number of device failures	0*
Number of OF specimens collected with complete data	264
*This is for the <i>DrugWipe5TM</i> only. One <i>InterceptTM</i> device failed to collect enough sample to allow for testing. In three cases officers noted that the device gave “faint lines”	

Device Evaluation Summary, Phase II (Device: Securetec *DrugWipe5TM*)

	Total	Cannabinoids	Amphetamines	Cocaine	Opiates
Total assays conducted "n"	1056	264	264	264	264
True Positives	211	10	14	163	24
True Negatives	712	208	241	53	210
False Positives	14	5	1	5	3
False Negatives	119	41	8	43	27
Sensitivity	63.94%	19.61%	63.64%	79.13%	47.06%
Specificity	98.07%	97.65%	99.59%	91.38%	98.59%
Positive predictive value	93.78%	66.67%	93.33%	97.02%	88.89%
Negative predictive value	85.68%	83.53%	96.79%	55.21%	88.61%
Prevalence	31.25%	19.32%	8.33%	78.03%	19.32%
Accuracy	87.41%	82.58%	96.59%	81.82%	88.64%

Note: Data generated using the *InterceptTM* device as the reference sample

Discussion

The device failure rate was much lower for Phase II. To date, none of the *DrugWipe5TM* devices has failed to give a reading. However, one of the *InterceptTM* reference collection devices did not collect enough fluid to provide valid results.

We have experienced greater officer participation during Phase II. This is due in part to the inclusion of DRE Certification Subjects being allowed to volunteer for the study. Unfortunately, during one of the certification trainings, a set of the *InterceptTM* devices were discarded before submission to the WSTL. Another problem encountered during the collections at the training was running out of the *DrugWipe5TM* kits.

Overall, feedback from officers that use the device is positive. They report the device is easy to handle, the oral fluids are gathered quickly and it is not very intrusive. There have not yet been complaints of the water packets freezing (*DrugWipe5TM* test kits are required to be kept at room temperature) but with the cold weather recently experienced, this is a potential cause for concern.

The primary complaint received is the high cut-off rate for THC. In Washington State, marijuana is the most frequently detected drug, other than ethanol, detected in arrests made for impaired driving. Therefore a sensitivity of less than 20% is not acceptable.

Conclusions

The *SalivaScreen 5TM* used in Phase I was not suitable for roadside testing for two primary reasons:

- The device suffered a large number of failures (they failed to run to completion) that discouraged the police from using them.
- The device was not sensitive and accurate enough to detect the marijuana, which is the most frequently encountered drug (other than ethanol) in Washington State.

As a result, Washington switched devices during Phase II, and began using the *DrugWipe5TM*

The *DrugWipe5TM* used in Phase II is superior to the *SalivaScreenTM* for several reasons:

- The *DrugWipe5TM* did not have lines that smeared, making interpretation of the results *DrugWipe5TM* results easier and more reliable.
- The *DrugWipe5TM* was easier for officers to use. Results were able to be read within ten minutes, and they did not have to manually extract saliva out of the device.
- The *DrugWipe5TM* reliably gave control lines, indicating that the device had worked.

Acknowledgements: The Washington State Toxicology Laboratory, Denny Crouch and the Center for Human Toxicology, Washington State Patrol, County Sheriffs, and City Police across the state, Ann Marie Gordon, Lt. Robin Reichert, Leo Cangianelli, J. Michael Walsh, Ph.D, and The Walsh Group.

APPENDIX A
Intercept Oral Fluid Collection Procedures



Step 1
Inspect the expiration date on the Intercept® collection device packaging and open the outer packaging containing the collection pad and the specimen vial. Place the specimen vial on a flat surface in view of the donor. Instruct the donor to remove the handle and remove the collection device from the packaging sleeve.



Step 2
Instruct the donor to place the collection pad between the lower cheek and gums and gently rub the pad back and forth along the gum line until the pad is moist.



Step 3
Once moist, leave collection pad between cheek and gums for a full two (2) minutes.



Step 4*
After 2 minutes, have the donor open the specimen vial in an upright position, with the tip pointed downward, by gently rocking the cap back and forth to avoid spilling the contents. Instruct the donor to push the collection pad into the specimen vial as far as it will go.



Step 5*
Instruct the donor to snap the collection wand at the scored line against the side of the vial. Instruct the donor to not tilt the vial or spill the fluid inside.



Step 6*
Instruct the donor to place the cap onto the vial until it snaps, ensuring a secure fit.



Step 7*
Instruct donor to place tamper evident seal across the top of the specimen vial and down the sides, date and initial.

*At some sites Steps 4 through 7 were accomplished by the collector.

APPENDIX B

CASE NO: _____

OFFICER ID: _____

ROSITA2 DATA COLLECTION FORM

POLICE OFFICER INFORMATION

Date of Stop: _____

Time of Stop: _____

Site Location: Washington

Reason For Drug Test:

- Unusual appearance, behavior, or odor indicating drug use
- Failed SFST and BAC level < 0.08
- Had drug / drug paraphernalia in vehicle
- BAC level inconsistent with impairment
- Driver admits to using drugs. Which drug(s)? _____

Reported BAC Test Results:

BAC Level	Time

Saliva Rapid Drug Test Device: DrugWipe 5

Indicate Positive Result with (+) and Negative with (-) for each drug

	CA	AM	CO	OP
Test Results				

Specimen Collection Date/Time: Oral Fluid: _____ Urine: _____
Collection Time Collection Time

Officers Comments: _____

FOR LABORATORY USE ONLY

Lab Accession Number: _____

Indicate Positive with (+) and Negative with (-) and quantitative concentration (ng/mL)

Drug	Confirmation Analyte	Oral Fluid		Urine	
		Screen (+) or (-)	Confirm ng/mL	Screen (+) or (-)	Confirm ng/mL
AMP	AMP / METH				
	Amphetamine				
METH	Methamphetamine				
	MDMA (Ecstasy)				
	MDEA				
COC	MDA				
	COC				
THC	Cocaine				
	Benzoyllecgonine				
	THC				
OPI	9THC (parent)				
	THCCOOH (metab.)				
	OPI				
	Morphine				
BDP	Codeine				
	Hydromorphone				
	Oxycodone				
	Hydrocodone				
PCP	BDP				
	Diazepam				
ETOH	Oxazepam				
	PCP				
	(If Determined)				

Comments: _____

APPENDIX C

Case Number: _____

Site Location: _____

TITLE OF STUDY: ROSITA 2 – Evaluation of Oral Fluid (Saliva) Drug Detection Devices

You are being asked to be in a research study to test new drug detection devices that use saliva. To be in the study, all you need to do is sign this consent form and provide saliva specimens.

CONSENT TO BE IN THE RESEARCH STUDY

If I choose to consent and provide saliva specimens:

- ✓ All information that might tie my name to the results will be removed after all testing is completed. Therefore, after that is done my name cannot be connected to the results
- ✓ The specimens will be used for research purposes only
- ✓ The results will be kept completely confidential
- ✓ There are no known risks to my being in the study
- ✓ The saliva collection devices are sterile and the person collecting the saliva has been trained to do so in a manner that is safe
- ✓ The results of my saliva tests cannot be used against me in court
- ✓ My being in the study is completely voluntary
- ✓ Nothing will happen to me if I choose not to be in this study
- ✓ I may stop and quit the study at any time

Knowing all this, I agree to be in this study and give you permission to collect saliva specimens from me for research purposes.

Research Subject – Sign Here:

Witness – Sign Here:

This project is being funded by the Office of National Drug Control Policy (ONDCP), The National Institute on Drug Abuse (NIDA), and The National Highway Traffic Safety Administration (NHTSA) under the direction of The Walsh Group, P.A. and in cooperation with this police agency.

If you have any questions about the research project, the risks involved, and/or your rights as a participant, you may contact us at the following number / address:

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Bethesda, MD 20817
Telephone: 1-800-985-1225