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Oral Fluid Testing Devices -Validation of Selected Commercial Products for Future Roadside Screening for Drugs

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ORAL FLUID DRUG TESTING DEVICES

VALIDATION OF SELECTED COMMERCIAL PRODUCTS

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TABLE OF CONTENTS

ABSTRACT

The demand for a quick and simple roadside screening device for oral fluid is rapidly increasing. Commercially available oral fluid screening devices all operate similarly and are based on point of collection saliva testing combined with immunoassay detection of selected (illicit) drugs. Their applicability to roadside testing, however, requires consideration of a number of variables: ease of operation (sample collection, completion time and ease of result reading/interpretation), reliability, sensitivity, specificity and kit cost. Although the manufacturers test and provide abundant performance data, it is imperative that end-users conduct an objective validation of any device prior to implementing one or more into a standard operating procedure for roadside testing. Towards this goal, BCIT reviewed the currently available point-of-collection devices and chose three for validation under laboratory conditions (Oratec-II/III, OraLine-IV and Drugwipe-5/5+) based on the characteristics noted and proposed Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines. The five target drug classes tested were Cocaine, Amphetamines, Opiates, THC and Benzodiazepines. A low detection limit for THC was considered as a secondary selection criteria and eliminated many potential devices from the study. The devices were challenged with single drug formulations of known concentration by spiking into either pooled saliva or water prior to device testing. Overall, the testing of saliva-spiked samples performed less well compared to the water-spiked samples, although the latter precluded their additional testing on the Oraline-IV device. Each device showed instances of good and bad sensitivities and specificities depending on the medium and/or drug tested. The results of this project, taken in totality, do not point to a single point-of-collection device with superior performance characteristics but the technology in general holds promise for further testing and future roadside screening for drugs.

INTRODUCTION

BACKGROUND:

Section 253 of the Canadian Criminal Code, operating while impaired states:

> *"Every one commits an offence who operates a motor vehicle or vessel or operates or assists in the operation of an aircraft or of railway equipment or has the care or control of a motor vehicle, vessel, aircraft or railway equipment, whether it is in motion or not,*
>
> *a) while the person's ability to operate the vehicle , vessel, aircraft or railway equipment is impaired by alcohol or a drug; or*
>
> *b) having consumed alcohol in such a quantity that the concentration in the person's blood exceeds eighty milligrams of alcohol in one hundred milliliters of blood."*

The alcohol limit of 0.08 was established in Canada in 1969, the basis of which stems from influential research published in 1964 establishing the role of drinking drivers in traffic accidents via the alcohol-crash relative risk curve (1). Successful removal and prosecution of drunk drivers stems from enforceable legislation, accurate technology/testing and general acceptance of blood-alcohol levels consistent with impairment. Forty years later, current countermeasure strategies and Criminal Code penalties (Tables 1 and 2) successfully remove hundreds of alcohol impaired drivers from Canadian roads each year (2).

According to the results of a 2004 Canadian Addiction Survey (3), a comprehensive household survey of alcohol and drug consumption, 79% of Canadians aged 15 and older have consumed alcohol in the previous year. Although less prevalent, the reported usage of illicit drugs in the year prior to the survey was approximately 14%. Cannabis accounted for the vast majority of this usage with approximately 1% reporting having used an illicit drug other than cannabis in the this period. Comparison to the 1989 National Alcohol and Other Drugs Survey revealed significant findings with respect to cannabis, namely an approximate doubling of the reported rate of usage of this drug. More disconcerting is the doubling in the prevalence of driving while under the influence of cannabis in this same period (4). Not surprisingly, drug users are involved in motor vehicle accidents – research studies have estimated that approximately 2% of injuries and 4% of fatalities in motor vehicle accidents are due to drug impairment and a combination of

Table 1 - Provincial/Territorial Countermeasure Initiatives

Province/ Territory	Roadside Licence Action	BAC (mg%)	Young Driver BAC	Pre-Conviction Licence Action	Licence Suspension (months)			Vehicle Impound-ment (days)[i]	Ignition Interlock Program
					1st Offence	2nd Offence	3rd Offence		
NL	24 hrs	50	zero[a]	3 month suspension	12	36	60	30	Yes
PEI	24 hrs	50	zero	3 month suspension	12	36	60	30	No
NS	24 hrs	50	zero[a]	3 month suspension	12	36	indefinite[c]	90[d]	Yes
NB	24 hrs	50	zero[a]	-	12	36	60	-	No
QC	-	80	zero[a]	30 day suspension	12	36	60	30	Yes
ON	12 hrs	50	zero[a]	3 month suspension	12	36	lifetime[c]	45	Yes
MB	24 hrs	50	zero[a]	3 month suspension	12[e] 60[f]	60[e] 120[f]	120[g] lifetime[f]	30	Yes
SK	24 hrs	40	zero[a]	3 month suspension	12	36	60	30	Yes
AB	24 hrs	50	zero	3 month suspension	12	36	60	30	Yes
BC	24 hrs [j]	50	zero[a]	3 month prohibition	12	36	indefinite[c]	30[j]	Yes[h]
YT	24 hrs	80	zero[a]	3 month prohibition	12	36	indefinite	30	Yes
NT	12-24 hrs	50	-	[h]	12	24	36	-	No

a. Includes all novice drivers.
b. Licence action in this category exists for novice drivers only.
c. Reducible to 10 years.
d. Given Royal Assent December 3, 1998.
e. Category "A" offences only (driving while impaired, driving over .08, refusal to provide sample). Greater penalties exist in this category for Failure to Provide a Breath Sample.
f. Category "B" offences only (driving while impaired causing death or bodily harm).
g. Fourth offence = lifetime ban.
h. Pending.
i. Figures listed in this column represent only minimum penalties.
j. A 24-hour vehicle impoundment now accompinies the 24-hour roadside suspension.
* Countermeasure initiatives are subject to change without notice.

Table 2 - *Criminal Code* Penalties for Impaired Driving Offences*

Offence		Penalties		
		Prohibition from Driving (Mandatory)*	**Fine****	**Jail****
** Driving While Impaired BAC Over .08 (refusal to provide sample)	1st Offence: Summary	12 to 36 months	$600 to $2000	0 to 6 months
	1st Offence: Indictment	12 to 36 months	$600 no maximum	0 to 60 months
	2nd Offence: Summary	24 to 60 months	up to $2000	14 days to 6 months
	2nd Offence: Indictment	24 to 60 months	no maximum	14 days to 60 months
	3rd Offence: Summary	36 months to lifetime ban	up to $2000	90 days to 6 months
	3rd Offence: Indictment		no maximum	90 days to 60 months
Impaired Driving Causing Bodily Harm	Indictment	up to 10 years	no maximum	up to 10 years
Impaired Driving Causing Death	Indictment	up to lifetime	no maximum	up to life imprisonment

* The *Criminal Code's* driving prohibition is distinct from any driver licence suspension that a province/territory may impose. Under the *Criminal Code*, an offender may be authorized to drive during the remainder of the prohibition period, provided the offender is registered in a provincial/territorial ignition interlock device program. The start date may be set by a judge as follows:

- 1st offence - after at least 3 months of the driving prohibition has been served;
- 2nd offence - after at least 6 months of the driving prohibition has been served;
- 3rd offence - after at least 12 months of the driving prohibition has been served.

** Mandatory penalties in addition to prohibition from driving are as follows:

- 1st offence - $600 minimum fine;
- 2nd offence - minimum 14 days imprisonment;
- 3rd offence - minimum 90 days imprisonment.

drugs and alcohol more than doubles these estimates (5).

In response to the increasing risk to Canadians by drugged-drivers, the Canadian government tabled a Committee Report in the House of Commons in June of 2007. The Bill (C-32) is an act to amend sections of the Canadian Criminal Code pertaining to impaired driving by expanding drug enforcement capabilities of police (6). Although the Criminal Code currently makes driving under the influence an offence under section 253(a), there is a lack of legal options for police for enforcement. With proposed amendments, section 253(a) investigations would allow police to demand physical sobriety tests and bodily fluid samples (blood, saliva or urine). The Bill also increases penalties for drug and/or alcohol impaired driving and creates new offences for impaired driving causing death or bodily harm. Currently admission of evidence in the form of drug testing results is admissible only in circumstances where the driver participated voluntarily. Under Bill C-32 police officers are authorized to perform roadside Standardized Field Sobriety Testing (SFST) upon reasonable suspicion of drugged driving. SFST tests an individual's ability to multitask, so-called divided attention tests. Upon a driver failing this screening step an officer has reasonable grounds to believe an offence has been committed and is, therefore, authorized to escort the individual to the police station for the administering of the Drug Recognition Expert (DRE) evaluation and assessment. The DRE is an extensive test for drug impairment (or a combination of drug and alcohol impairment) conducted by a certified officer and is a multi-step process: breath test, interview (of arresting officer and subject), eye and vital sign examination and divided attention test. Failure of the DRE exam leads to bodily fluid collection for conformational toxicology testing.

The proposed legislation changes of Bill C-32 are not without its critics. As a case in point the authors point to the opinion paper released by The Canadian Centre on Substance Abuse (CCSA), a national non-government organization with a legislated mandate to provide evidence-informed analysis and advice on substance abuse (7). Although the CCSA supports the underlying premise and intentions of Bill C-32, they outline potential caveats and considerations. They argue that there is a relative lack of knowledge of the effects of drugs and driving compared to alcohol, the former arguably a far more

complex problem. Compounding this is a lack of comparable drug levels linked to impairment and no reliable drug testing devices for roadside screening akin to alcohol testing. The CCSA supports the ongoing commitment of government and police to support the SFST and DRE programs which (as of June 2007) have 2427 and 153 certified officers, respectively. A review of the scientific literature by CCSA supports the investment in DRE training because the result is a powerful investigative tool with an accuracy typically exceeding 85%, and relatively rare false positives (although false negatives were not uncommon).

It is within this context that stems the current interest by the Canadian Police Research Centre in point-of-collection (POC) drug devices as an expansion of the driving–under-the-influence (DUI) of alcohol programs as per Bill C-32. Any new roadside screening devices that can reliably and accurately detect recent drug consumption via presence in saliva represent a potentially powerful tool to assist in section 253(a) investigations. Several studies have already tested the validity of the commercial screening kits as a complement to the currently available laboratory testing methodologies (8-11). The ease of use of these non-invasive devices holds the promise of expanded testing programs not only in the aforementioned DUI investigations but also in the workplace, drug rehabilitation programs, schools and other medico-legal applications.

ROSITA (Roadside Testing Assessment):

Unlike alcohol intoxication studies, research linking drug use (and levels) to impairment is scant although this is perhaps not surprising given the obvious technical difficulties, safety and ethical concerns inherent to this type of research. Nonetheless, point-of-collection devices have been studied by many countries in preparation to combat drug impaired driving. Between 2003 and 2005, the European Union (EU) has completed a *Roadside Testing Assessment* (ROSITA) in which numerous countries carried out comprehensive validation of on-site drug testing devices (13). The stated objective of this study was to identify the requirements for roadside testing equipment, and to make an international comparative assessment of existing equipment or prototypes in order to assess the validity, equipment reliability,

practicality and costs. The extensiveness of the study is highlighted by the list of deliverables: 1. Drugs and medicines suspected of having a detrimental impact on road user performance; 2. Inventory of state-of-the-art roadside testing equipment; 3. Operational, user and legal requirements across EU member states for roadside drug testing equipment; 4. Evaluation of different roadside drug tests; and 5. General conclusions and recommendations.

The study involved police agencies analyzing urine and saliva (oral fluid) samples from participants at roadside check-stops and comparing these results to a confirmatory test like Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS). The study found that some devices performed better for certain drugs and poorly for others and no devices met their criteria fully. Selected findings from ROSITA include:

- A device failure rate from less than 5% to over 25%. The evaluators considered that a failure rate of a maximum of 5-10% was acceptable.
- **Amphetamines** and **methamphetamines** sensitivities between 40 and 83% and specificities between 80 and 100%.
- **Benzodiazepines** sensitivity of between 33 and 69% and specificity between 85 and 94%.
- **Cannabis** sensitivity between 0 and 74% and specificity between 70 and 100%.
- **Opiates** sensitivity between 51 and 100% and specificity between 86 and 100%.
- **Cocaine** sensitivity between 0 and 97% and specificity between 91 and 100%.
- No device met the proposed detection criteria for amphetamines, benzodiazepines and cannabis (sensitivity and specificity of greater than 90% and accuracy greater than 95%).

At the end of ROSITA, no device was considered reliable enough to be recommended for roadside screening although this has not stopped some countries (i.e. Australia) from implementing their use. Regardless, the results from the ROSITA projects helped formulate a systematic way of evaluating devices for such a study in Canada.

PROJECT OBJECTIVES:

Newly introduced within the last several years, roadside drug screening devices have utilized oral fluid (saliva) to screen for recent usage of impairing-type drugs. Numerous commercial products are available, all of which have different characteristics and limitations. Such devices, should they be validated in the laboratory (by scientists) and in the field (by police officers), would have the potential to save significant police resources in terms of investigation and training time, both of which would save money in the prosecution of the drug-impaired driver. Studies in this area, including that proposed here, becomes part of the overall body of scientific evidence required by policy makers to enact driving under the influence of drugs legislation.

Point-of-collection applicability to roadside testing requires consideration of a number of variables: ease of operation, reliability, sensitivity, specificity, kit cost and test completion time. Although the manufacturers test and provide abundant performance data, it is imperative that end-users conduct an objective validation of any device prior to implementing one or more into a standard operating procedure. Towards this goal, this CPRC-funded project conducted at BCIT will form a foundation for future studies in this area. This phase of the project had the following objectives:

1. Review the currently available POC devices on the market, ROSITA and relevant literature.
2. Choose three commercial devices for validation under laboratory conditions.
3. Develop requisite LC/MS and/or GC/MS protocols for drugs of interest.
4. Assess single drug specificity and sensitivity levels for each device.
5. Report findings.

EXPERIMENTAL METHODS

Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed revisions to the mandatory guidelines for Federal Workplace Drug Testing Programs with respect to screening test cutoff concentrations for selected drugs in oral fluid (Appendix 1). Previous studies have utilized 0.5, 2 and 10x SAMHSA levels for testing and where possible were followed in this project (Table 3).

Table 3. Drug Concentrations (ng/mL)

Drug Class	**Amphetamines**		**Cocaine**	**Opiates**	**THC**	**Benzodiazepines**
Spiked Drug	Meth-amphetamine	MDMA	Cocaine	Heroin	Δ -9-THC	Temazepam
SAMHSA	50	50	20	40	4	5
Low	25	25	10	20	5	2.5
Medium	100	100	40	80	20	10
High	500	500	200	400	100	50

Certified reference standards were purchased from *Cerilliant* (Round Rock, TX). Pooled normal human saliva was purchased from *BioChemed Services* (Winchester, VA) in 200mL volumes, divided into 15-20mL aliquots and frozen (-20ºC). Oratect-II/III devices were purchased from *Branan Medical Corporation* (Irvine, CA). OraLine-IV devices were purchased from *Sun Biomedical Laboratories Inc.* (Blackwood, NJ). Drug Wipe-5/5+ devices were purchased from Securetec (Munich, Germany). All devices tested were utilized within their expiration times.

Each stock drug standard vial (1mg/mL) was cracked freshly at the beginning of testing and an initial dilution was made in solvent (acetonitrile or methanol), saliva or water to a concentration of (2ng/μL) as needed. All standard solutions were pipetted with Hamilton syringes and stocks prepared in clean volumetric flasks. All dilution series were diluted accordingly for device testing or instrumental analysis as above.

The laboratory (*in vitro*) device testing followed as closely as possible the manufacturer's recommended guidelines. Specific procedures used and common to each device:

1. Blank and drug-spiked solutions (saliva [Phase-1] or water [Phase 2]), containing a single drug, were prepared fresh each day from the 1mg/mL stock solution.
2. A negative control of blank solution (saliva or water) was first analyzed on each device prior to drug testing.
3. All devices were tested (5 replicates) for a given drug on a single day using the same standards.
4. After the appropriate period of time, all results were recorded by a single individual and the results photographed.

LC-MS, GC-MS analysis

The certified drug standards from *Cerilliant* were tested using GC/MS and LC/MS to ensure that the quality and concentration of the drug standards during testing of the oral fluid devices. The analytical testing was accomplished by performing single or multiply-point calibration curves utilizing internal standards comprised of the corresponding deuterium-labeled drug standards from *Cerilliant*. The GC/MS instrument utilized during the experiment was a Hewlett Packard HP6890 GC series/Mass Selective Detector 5973. The LC/MS instrument utilized during the experiment was an Agilent 1100 Series/Hewlett Packard MSD.

Drugwipe-5/5+ sample application and testing

In phase-1 of this testing (saliva-spiked standards), the supplied Drugwipe-5 kit required the user to fill a reservoir with water after saliva collection. Specifically, sample was applied to the collection testpad by direct rubbing/soaking in a clean plastic container followed by water reservoir application (15 seconds in upright position), removal of reservoir and a 10 minute wait time (horizontal position) prior to reading and photographing.

In phase-2 (water-spiked standards), a new version (Drugwipe-5+) was supplied that had a built in water reservoir. Based on the manufacturer's recommendation, the sample application procedure was also

changed. Specifically, 10µL of sample was applied directly to each testpad using a Hamilton syringe (Figure 1), the integrated ampoule of water snapped and a 10 minute wait time prior to interpreting and photographing. A valid test required the presence of two control lines, whereas a positive test required the presence of a test line within a defined region of the testing window.

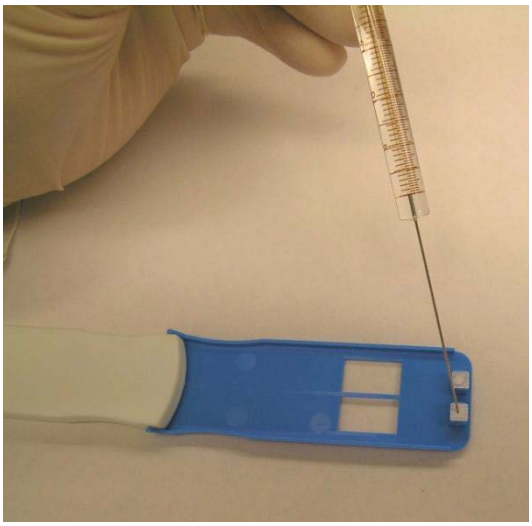


Figure 1: Example of sample application to the testpad region of a Drugwipe-5+ device.

Oratect-II/III sample application and testing

In both phases of this testing, sample application remained consistent throughout. The manufacturer upgraded the Oratec-II device in the middle of the study to Oratec-III device, however, both included a control line to ensure enough oral fluid was applied during sampling. For sample application to this device, 1mL of solution was placed in the clean plastic cup supplied and the collection pad soaked in the fluid until the requisite movement of the blue line was noted in both test windows (Figure 2). Results were read at the recommended 5 minute mark (and in some instances the 30 minute mark) prior to interpretation and photographing. A valid test required the presence of two control lines, whereas a positive test required the absence of a test line within a defined region of the testing window.

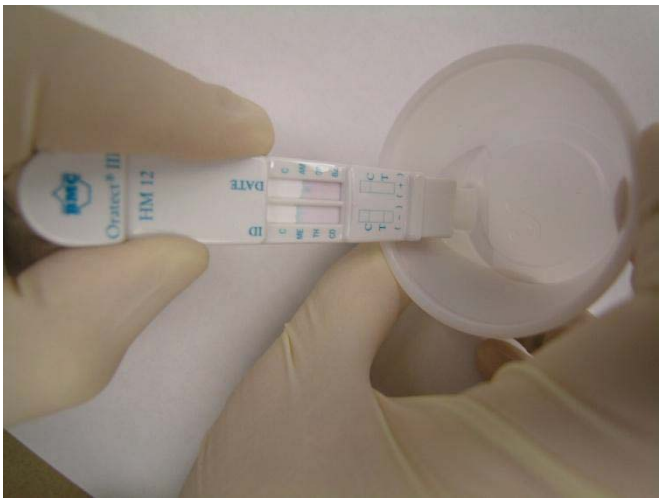


Figure 2: Example of sample application to the testpad region of an Oratec-II/III device.

OraLine-IV sample application and testing

In both phases of this testing sample application remained consistent throughout. For sample application to this device, 0.75 mL of solution was pipetted directly into the device collection spoon while the spoon was held horizontal (Figure 3). Once sample was visible in the test window the device was placed on a flat surface and results were read at the recommended 10 minute mark prior to interpretation and photographing. A valid test required the presence of a control line, whereas a positive test required the absence of a test line within a defined region of the testing window.

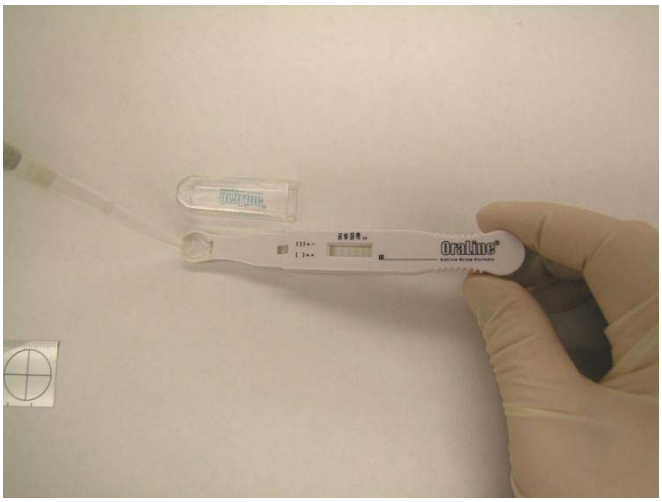


Figure 3: Example of sample application to the testpad region of an OraLine-IV device.

RESULTS AND DISCUSSION:

Sampling of saliva is a convenient and nonintrusive way of collecting a biological sample for testing recent drug use. Drug detection times of saliva are similar to blood, approximately 1-24 hours (8). Saliva, however, normally contains the parent drug rather than the metabolite such as in urine. The detection of drugs in saliva is dependent on the saliva-to-plasma ratio, which is often less than 1:1 depending on the drug (8). In a study by Magerl and Schulz (12), a certain pH value must be a prerequisite to the distribution between plasma and saliva. Substance concentrations in saliva is usually equivalent to the non-protein bound serum concentrations given the correct pH. The research of Magerl and Schuls identified three short comings of analyzing drugs in saliva:

1. The pH value of saliva is not constant and, therefore, influences the proportion between the distribution ratio of plasma and saliva.
2. Drugs taken orally can cause contamination causing high concentrations of drugs in saliva.
3. The saliva-to-plasma ratio concentration quotient increases in the absorption phase.

Despite these short comings saliva is the most convenient and non intrusive way for roadside testing of drug impairment.

Evaluation criteria were developed based on the criteria published in the ROSITA project (13) but with additional qualifiers to fit this study. Results were visually interpreted and recorded by the same analyst and all results photographed. This data was then evaluated based on the expected results (positive or negative) and tabulated. The results were categorized as True Positive (TP), True Negative (TN), False Positive (FP), False Negative (FN), False positive for Other Drug (FOD) or Invalid (IV). A true positive result was based on an expected positive result with respect to the device detection limit for a given (single) drug. A true negative result was an expected negative result based on a concentration that was below the device detection limit for a given (single) drug. A false positive was an expected negative result because the drug concentration was below the device detection limit, but an observed positive result was obtained. A false negative was an expected positive result because the drug concentration was above the device

detection limit but an observed negative result was obtained. A false positive for other drug was a positive result but for a different target drug. An invalid result was a device that had no control line(s) or that had leaked within the test time.

Device selection was based on a number of criteria: ease of operation (sample collection, completion time and ease of result reading/interpretation), reliability, sensitivity, specificity and kit cost. Particular importance was given to the drugs detected (and detection limits) and the time to acquire results. The investigators were cognizant of the practical requirements of road-side testing that require the holding of drivers while an officer performs the test. As such a time limit of 5-10 minutes was deemed reasonable and three multi-drug devices were chosen: (Oratec-II/III, OraLine-IV and Drugwipe-5/5+). Note a single drug device (Drugwipe-II) for benzodiazepines was also tested in phase-1 (saliva) only. Each device (Figure 4) uses immunoassay technology for the qualitative detection of multiple classes of drugs (Table 4) in human oral fluid including (at a minimum): THC, Cocaine, methamphetamines and opiates. The Drugwipe-5/5+ and Oratect II/III devices also detect amphetamines and depending on the choice of product the Oratect-II/III devices also detect benzodiazepines (HM12) or phencyclidine (HM11).

PHASE-1 (Drug-spiked saliva):

At the outset of this testing it was the investigators' intention to design an *in vitro* study that modeled as closely as possible a realistic scenario. The ultimate goal of roadside screening of drugged-drivers is an efficient screening of saliva. As such, the initial design of this phase was to spike known amounts of single drugs into human saliva. Given the large amounts of saliva required to complete the testing and maintain intra- and inter-device consistency it was decided that pooled human saliva would be purchased. Saliva is a complex biological fluid consisting of an aqueous solution of electrolytes, mucous, enzymes and cells. Therefore, care was taken to store the saliva at low temperature and minimize free-thaw cycles. Nonetheless, it was not possible to prevent denaturation and precipitation. It was noted that previous studies (9) performed multiple freeze-thaw cycles and centrifugation to "clarify" the saliva prior to testing.

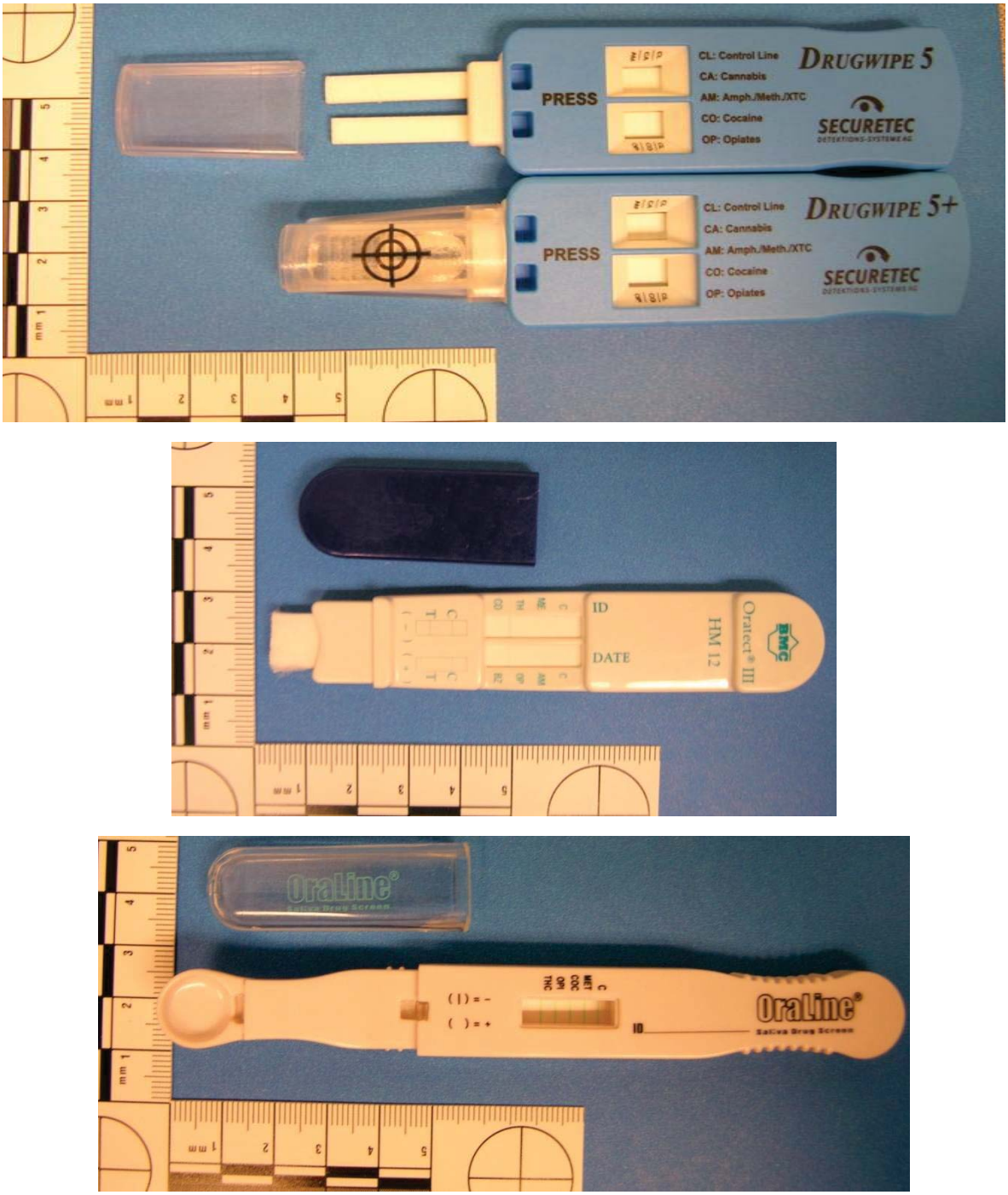


Figure 4: Top- Drugwipe-5 (old version) and Drugwipe 5+ (new version illustrating the addition of the integrated water ampoule). Middle – Oratect-III device with the collection pad exposed. Bottom – OraLine-IV with the collection spoon exposed.

Table 4: Device Sensitivity

Drug	Device ID	Device (Brand)	Detection Limit (ng/mL)
Δ-9-THC	CA	Drugwipe-5/5+	30
Amphetamine	AM	Drugwipe-5/5+	50
Methamphetamine/MDMA	AM	Drugwipe-5/5+	25
Cocaine	CO	Drugwipe-5/5+	15
Heroin	OP	Drugwipe-5/5+	10
Temazepam	Benzodiazepines	Drugwipe-II[1.]	10
Methamphetamine/MDMA	ME	Oratect-II/III	25
Cocaine	CO	Oratect-II/III	20
Heroin	OP	Oratect-II/III	15
Δ-9-THC	TH	Oratect-II/III	40
Temazepam	BZ	Oratect-II/III	5
Methamphetamine/MDMA	MET	Oraline-IV	50
Cocaine	COC	Oraline-IV	25
Heroin	OPI	Oraline-IV	40
Δ-9-THC	THC	Oraline-IV	4

1. Drugwipe-II is a single-drug device (tested in phase-1 only)

It is arguable, however, how closely this modified solution models human saliva. Tables 5a-c summarize the phase-1 (saliva) results for each device.

It was apparent at the conclusion of phase-1 that working with aged saliva was highly problematic and potentially misleading when used to make conclusions of overall device performance. Of particular concern in this type of screening is the potential for false positive results. Such a finding in a real-life (road-side) scenario would unnecessarily expose civilians to follow-up investigation and additional sampling for confirmatory testing. Two of the three devices in this phase showed false positives (FP and FOD) with OraLine-IV and Drugwipe-5 having false positive rates of 19% and 20%, respectively. The false detection (FOD) of THC was a particular problem. Note, confirmatory GC/MS testing of the blank commercial (pooled) saliva was conducted to confirm the absence of THC present in this product (data not shown). In addition, the OraLine-IV device was prone to failure due to leakage resulting in an unacceptable level of invalid results (16% of devices tested). Additional sensitivity and specificity calculations were performed for this phase (Table 8) and are discussed with the phase-2 results below.

To assess the effects of aged, pooled saliva on device reliability and specificity an additional test was conducted whereby two drug-free donors (investigators within this project) voluntarily provided samples exactly as per the manufacturers' protocols. The testing was conducted as it would be in a road-side test, namely a donor inserting the device into the mouth directly. Each donor was tested 4-5 times per device. The results are summarized in Table 6. The results did show unexpected, false positives for THC for Drugwipe-5 and Oratect-III, however, these were extremely weak and in the case of the latter device converted to a true negative result after approximately 15 minutes. Note this additional time (Oratect devices can be read up to 30 minutes post-collection) may not be feasible for road-side testing. No false positives or invalid results (leakage) were seen for the OraLine-IV device and suggests that the poor phase-1 results observed were likely due to compositional changes inherent to using commercial (pooled) saliva.

Table 5a: Drugwipe-5 Phase-1 (Saliva) Results

Methamphetamine (DL = 25 ng/mL)[1.]	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	25	+	2	0	0	1	2	0
SAMHSA	50	+	4	0	0	0	1	0
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

MDMA (DL = 25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	25	+	1	0	0	4	0	0
SAMHSA	50	+	5	0	0	0	0	0
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

Cocaine (DL = 15 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	10	-	0	4	0	0	1	0
SAMHSA	20	+	-	-	-	-	-	-
Medium 1	40	+	0	0	0	2	3	0
Medium 2	50	+	0	0	0	3	2	0
High	200	+	0	0	0	0	5	0

Heroin (DL = 10 ng/mL**)**	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	20	+	0	0	0	5	0	0
SAMHSA	40	+	1	0	0	4	0	0
Medium	80	+	0	0	0	5	0	0
High	400	+	2	0	0	0	3	0

THC (DL = 30 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	1	0
Low	2	-	0	5	0	0	0	0
SAMHSA	4	-	0	5	0	0	0	0
Medium	20	-	0	2	3	0	0	0
High	100	+	1	0	0	2	2	0

Temazepam (DL = 10 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	2.5	-	0	5	0	0	0	0
SAMHSA	5	-	0	3	2	0	0	0
Medium	10	+	2	0	0	3	0	0
High	50	+	5	0	0	0	0	0

1. Drug detection limits (DL). Source: *Securetec Volume Sensitivities and Cross Reactivities (Confidential Document; version_02_2007*)

Table 5b: Oratec-II Phase-1 (Saliva) Results

Methamphetamine (DL = 25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	25	+	0	0	0	5	0	0
SAMHSA	50	+	0	0	0	5	0	0
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

MDMA (DL = 25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	25	+	0	0	0	5	0	0
SAMHSA	50	+	0	0	0	4	0	1
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

Cocaine (DL = 20 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	10	-	0	5	0	0	0	0
SAMHSA	20	+	0	0	0	5	0	0
Medium	40	+	5	0	0	0	0	0
High	200	+	5	0	0	0	0	0

Heroin (DL = 15 ng/mL**)**	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low-1	10	-	0	5	0	0	0	0
Low-2	20	+	5	0	0	0	0	0
SAMHSA	40	+	5	0	0	0	0	0
Medium	80	+	5	0	0	0	0	0
High	400	+	5	0	0	0	0	0

THC (DL = 40 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	2	0	0	0	0
Low	2	-	0	5	0	0	0	0
SAMHSA	4	-	0	5	0	0	0	0
Medium	20	-	0	5	0	0	0	0
High	100	+	0	0	0	5	0	0

Temazepam (DL = 5 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	0
Low	2.5	-	0	5	0	0	0	0
SAMHSA	5	+	2	0	0	3	0	0
Medium	10	+	1	0	0	4	0	0
High	50	+	5	0	0	0	0	0

Table 5c: OraLine-IV Phase-1 (Saliva) Results

Methamphetamine (DL = 50 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	2	0	0	0	1
Low	25	-	0	2	2	0	0	1
SAMHSA	50	+	4	0	0	0	1	0
Medium	100	+	3	0	0	0	0	2
High	500	+	4	0	0	0	0	1

MDMA (DL = 50 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	1	0	0	0	1
Low	25	-	0	1	4	0	0	0
SAMHSA	50	+	5	0	0	0	0	0
Medium	100	+	4	0	0	0	0	1
High	500	+	4	0	0	0	0	1

Cocaine (DL = 25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	10	-	0	5	0	0	0	0
SAMHSA	20	-	-	-	-	-	-	-
Detection Limit	25	+	0	0	0	4	0	1
Medium	40	+	5	0	0	0	0	0
High	200	+	5	0	0	0	0	0

Heroin (DL = 40 ng/mL**)**	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	0	0	0	1	0
Low	20	-	0	0	0	0	4	1
SAMHSA	40	+	0	0	0	0	2	3
Medium	80	+	1	0	0	1	0	3
High	400	+	5	0	0	0	0	0

THC (DL = 4 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	0	2	0	0	1
Low	2	-	0	0	5	0	0	0
SAMHSA	4	+	5	0	0	0	0	0
Medium	20	+	4	0	0	0	0	1
High	100	+	2	0	0	3	0	0

Table 6: Device testing on drug-free donors (combined data)

Device	**Exp.**	**TN**	**FP**	**IV**	**Specificity(%)[1]**
Drugwipe-5	-	6	3*	0	67
Oratect-III	-	9	1**	0	90
OraLine-IV	-	10	0	0	100

1. Specificity =TN/TN+FP

* false positive for THC (very faint line at THC present at 10 minutes)

** false positive for THC at 5 minutes but developing a very faint line (i.e. TN) after ~15 minutes.

PHASE-2 (Drug-spiked water):

Based on the spurious results with aged saliva and recommendations from one of the manufacturers (14), the testing procedures were modified. Rather than spike pooled human saliva, it was decided to spike water (distilled and filtered). Selected drugs were chosen for retesting and various concentrations made as previously. Early on in this phase it was discovered that the OraLine-IV device was not amenable to the application of aqueous solutions. The application of these samples produced invalid test results on every attempt. The investigators also tested fresh saliva that had been freeze-thawed and clarified by centrifugation as outlined above. The process resulted in the removal of a large quantity of precipitate (Figure 5). Testing of this supernatant blank (in triplicate) produced invalid readings and leakage. Testing of this device was, therefore, discontinued. Tables 7a-b summarize the phase-2 test results for the remaining two devices.

Figure 5: "Clarification" of huma saliva prior to testing. After freezing and thawing, precipitate is removed by centrifugation and supernatant decanted for device testing

Table 7a: Drugwipe-5+ Phase-2 (Water) Results

Amphetamine (DL=50 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	50	+	5	0	0	0	0	0
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

Methamphetamine (DL=25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	25	+	5	0	0	0	0	0
Medium	50	+	5	0	0	0	0	0
High	250	+	5	0	0	0	0	0

Cocaine (DL=15 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low-1	15	+	5	0	0	0	0	0
Low-2	50	+	5	0	0	0	0	0
Medium	100	+	5	0	0	0	0	0
High	500	+	5	0	0	0	0	0

Heroin (DL=10 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	10	+	3	0	0	2	0	0
Medium	20	+	4	0	0	1	0	0
High	100	+	5	0	0	0	0	0

THC (DL=30 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	30	+	1	0	0	4	0	0
Medium	60	+	5	0	0	0	0	0
High	300	+	5	0	0	0	0	0

Table 7b: Oratec-III Phase-2 (Water) Results

Amphetamine (DL=25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	25	+	0	0	0	5	0	0
Medium	50	+	3	0	0	2	0	0
High	250	+	5	0	0	0	0	0

Methamphetamine (DL=25 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	25	+	2	0	0	1	2	0
Medium	50	+	4	0	0	1	0	0
High	250	+	4	0	0	1	0	0

Cocaine (DL=20 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	20	+	1	0	0	3	1	0
Medium	40	+	4	0	0	1	0	0
High	200	+	5	0	0	0	0	0

Heroin (DL=15 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	15	+	5	0	0	0	0	0
Medium	30	+	4	0	0	0	1	0
High	150	+	5	0	0	0	0	0

THC (DL=40 ng/mL)	**Conc.** (ng/mL)	**Exp**	**TP**	**TN**	**FP**	**FN**	**FOD**	**IV**
Negative	0	-	0	3	0	0	0	0
Low	40	+	1	0	0	4	0	0
Medium	80	+	3	0	0	2	0	0
High	400	+	5	0	0	0	0	0

Device Comparisons:

Table 8 summarizes the sensitivity and specificity calculations for each device/drug combination tested within both phases. Generally speaking, *in vitro* testing improved when aqueous media was used rather than saliva, although it precluded the OraLine-IV testing. The majority of all phase-1 and 2

Table 8: Sensitivity[1] and Specificity[2] Values (%)

Phase-1 (Saliva)						
	Drugwipe		Oratec		OraLine	
Drug	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Methamphetamine	94	100	50	100	100	67
MDMA	76	100	53	100	100	33
Cocaine	0	100	67	100	71	100
Heroin	18	100	100	100	86	0
THC	33	81	0	100	79	0
Temazepam	70	82	53	100	N/A	N/A
Phase-2 (Water)						
Drug	Drugwipe		Oratec			
	Sensitivity	Specificity	Sensitivity	Specificity		
Amphetamine	100	100	53	100		
Methamphetamine	100	100	77	100		
Cocaine	100	100	71	100		
Heroin	80	100	100	100		
THC	73	100	60	100		

1. Sensitivity values calculated from "Exp +" (expected positive) samples (Sensitivity = TP/TP+FN)
2. Specificity values calculated from "Exp -" (expected negative) samples (Specificity = TN/TN+FP)

sensitivities and specificities fell within the ranges reported in ROSITA with the exception of the following phase-1 results: Drugwipe-5 sensitivities for cocaine and heroin; Drugwipe-5 specificity for Temazepam (although the difference of 2% was not significant); and the OraLine-IV specificities for methamphetamine, heroin and THC.

With respect to functionality, the devices varied in terms of ease of operation. The older version of Securetec's Drugwipe-5, which required the user to fill a water reservoir, had a distinct disadvantage compared to the Oratect and OraLine devices. This was remedied, however, in the Drugwipe-5+ version with the addition of the built in water ampoule. The sample application procedure of the Drugwipe-5/5+ device proved superior to the other two devices given the small amount of sample required. A user need only wipe the collection pad(s) across the tongue, collecting approximately 10 μL of saliva per pad. The Oratec-II/III device required the most sample for the *in vitro* and *in vivo* testing. It required a significant

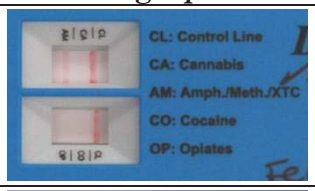
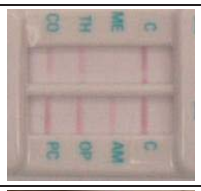
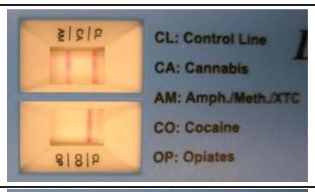
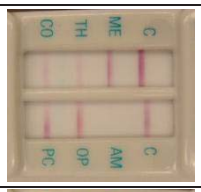
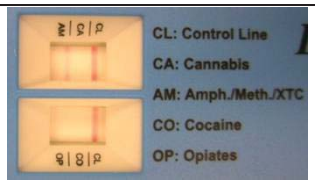
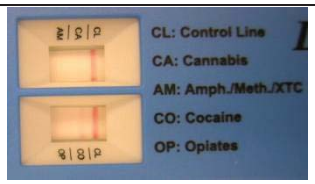
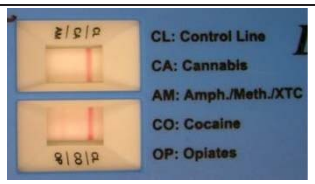
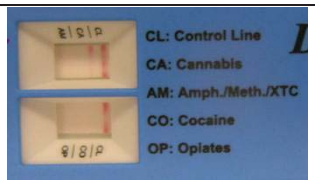
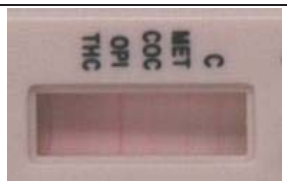
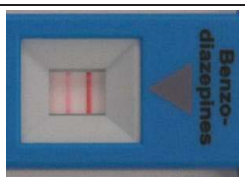
amount of time in the mouth to collect enough sample and the collection filter had a taste that might be objectionable to some individuals. The Oraline-IV collection was faster and required somewhat less sample compared to Oratect, but occasionally it proved messy if the subject attempted to the fill the spoon directly from the mouth. It did, however, come with a small plastic cup meant to facilitate saliva transfer.

The manufacturers' recommended wait periods varied: Drugwipe-5/5+ (3-10 minutes); OraTect-II/III (5-30 minutes; "..read results in 5 minutes after removing the device from the mouth. Do not read results after 30 minutes"); and OraLine-IV (10-12 minutes). Although the Drugwipe-5/5+ may be read as soon as 3 minutes post-sampling, results for THC may not develop this quickly given the solubility characteristics of this drug. Although Oratect-II/III results often develop within 5 minutes, on occasion the results became clearer if a longer wait time was used. This, however, may not be practical for roadside testing.

Table 9 provides an overview of "typical" true positive results for the high concentration samples for each drug and device. The investigators in this project found the Oratect-II/III device to have the easiest results window to read due to test region surface area and results line thickness. This was followed by Drugwipe-5/5+ and finally OraLine-IV. Although the OraLine-IV has a larger test region surface area, the result lines are thinner than Drugwipe-5/5+ and, therefore, harder to read. These properties would undoubtedly affect roadside testing usability and is worth noting here.

Device cost also varied considerably which may also impact end-user choice: Oraline-IV ($9.50 USD per device); Drugwipe-5/5+ ($19.50 USD per device in boxes of 25 units); and Oratect-II/III ($25 CDN per device in boxes of 25 units). Admittedly, however, device cost for large scale programs would likely be different.

Table 9: Selected high concentration True Positive (TP) results for illustration

Drug	Drugwipe[1.]	Oratec[2.]	Oraline[3.]
MDMA			
Amphetamine			N/A
Methamphetamine			
Cocaine			
Heroin			
THC			
Temazepam[4.]			N/A

1. MDMA (Phase-1; DW5) results shown. Amp., Meth., Coc., Her., THC (Phase-2, DW5+) results shown.
2. Phase-2 results shown.
3. Phase-1 results shown.
4. Drugwipe-II device (Phase-1) result shown.

CONCLUSIONS

The results of this project, taken in totality, do not point to a single point-of-collection device with superior performance characteristics; results which do not appear to contradict the general findings from ROSITA. Each device showed instances of good and bad sensitivities and specificities depending on the medium and/or drug. Based on the phase 2 (water) testing, however, the Drugwipe-5+ performed better than the Oratect-III. The investigators recommend further testing of all three devices in future *in vivo* tests and include OraLine-IV based on its high specificity in the drug-free donor tests. Generally speaking the technology holds promise for roadside screening for drugs and is worth pursuing with further studies and recommendations for manufacturer improvements where the technology allows. Such technology, should it be proven reliable enough, could augment the DRE evaluations, a power and recognized investigative tool but one that is lacking in certified officers despite the need.

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APPENDIX 1
SAMHSA Guidelines

Proposed Revisions to the Mandatory Guidelines for Federal
Workplace Drug Testing Programs

Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services

Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004 / Notices

SCREENING TEST CUTOFF CONCENTRATION FOR ORAL FLUIDS

THC Parent drug and metabolite ……4		(ng/mL)
Cocaine metabolites.....	20	
Opiate metabolites 1	40	
Phencyclidine.....	10	
Amphetamines 2	50	
MDMA	50	

1 Labs are permitted to initially test all specimens for 6-AM using a 4 ng/mL cutoff.

2 Methamphetamine is the target analyte.

CONFIRMATORY TEST CUTOFF CONCENTRATION FOR ORAL FLUIDS

THC Parent drug	2	(ng/mL)
Cocaine 1	8	
Opiates:		
Morphine	40	
Codeine.....	40	
6-Acetylmorphine	4	
Phencyclidine.....	10	
Amphetamines:		
Amphetamine	50	
Methamphetamine 2 50		
MDMA	50	
MDA	50	
MDEA	50	

APPENDIX 2
Manufacturer Information

Device Name	**Manufacturer/Website**	**Analytes**
Drugwipe-5/5+	Securetec www.securetec.net	Amp/Meth/MDMA, Coc. Opi. THC BENZO in single
Oraline-IV	Sun Biomedical Laboratories www.sunbiomed.com	Amp/Meth/MDMA, Coc. Opi. THC
Oratec-II/III	Branan Medical Corp. http://brananmedical.com	AMP/Meth/MDMA, Coc. Opi. THC, BENZO or PCB