ORAL FLUID IN DUID CASES

LIFESAVERS CONFERENCE
MARCH 17TH 2015
10.45AM – 12.15PM

- AMY MILES
- WISCONSIN STATE LABORATORY OF HYGIENE, WI
- amy.miles@slh.wisc.edu
- 608 224 6247

- CHRISTINE MOORE
- IMMUNALYSIS CORPORATION, CA
- cmoore@immunalysis.com
- 909 451 660

OVERVIEW

- *1. Impaired driving and utility of oral fluid*
- *2. North American roadside surveys*
- *3. California initiative*
- *4. Oral fluid in DRE training sessions*
- *5. DRE, drivers and drug test results (Oklahoma)*
- *6. Ongoing projects*

IMPAIRED DRIVING

- *Increasing awareness that drugs, as well as alcohol are responsible for, or at least a factor in traffic accidents*
- *Understand the scope of the problem*
  - *Measurement of drug prevalence in driving population*
- *Need for information related to traffic incidents*
- *Improved procedures for detecting drugs in biological specimens and wider test panels*
- *Rehabilitation of drivers using illegal drugs*
- *Education of drivers using legal prescription drugs in the wrong way*

WHY ORAL FLUID ?

- *Drugs accumulate in saliva by diffusion from the blood*
- *Drug properties determine how much is deposited into oral fluid*
- *Easy, rapid collection*
- *Can be taken proximate to the traffic stop*
- *Non-invasive & observed*
- *Identification of active compound may provide information on recent drug intake*
- *2007, 2013 large scale NHTSA Studies included collection of oral fluid and blood in Roadside Surveys*

NORTH AMERICA: ROADSIDE SURVEYS

MEASURING THE PROBLEM

- ***2007: National Roadside Survey***
  - ***Blood & oral fluid***
- *2008, 2010, 2012: Canadian Roadside Survey, British Columbia; (OF)*
- *2010, 2012: California Roadside Survey (Oral fluid)*
- *2013, 2014: National Roadside Survey (Blood & oral fluid)*
- *2014: Canadian Roadside Survey, Ontario; (Oral fluid)*
- *2014: Washington State Initiative (Blood & oral fluid)*

SAMPLE COLLECTION

BLOOD

- *Gray-topped tube*
  - *3,276 samples*
- *Samples shipped overnight to the laboratory for analysis*
- *Laboratory received blood and oral fluid samples separately*
- *Blinded to paired specimens*

ORAL FLUID

- *Quantisal™ collection device*
  - *1 mL of oral fluid collected (+-10%)*
  - *3 mL stabilization buffer*
  - *7,539 samples*

2007 RESULTS

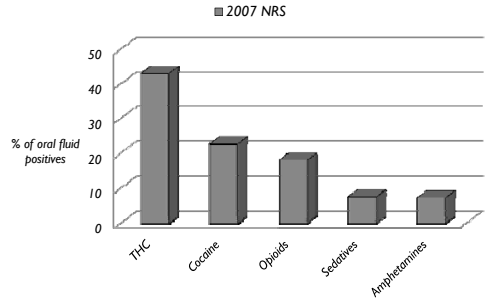
- *16.3% of drivers positive for drugs*
  - *Almost 50% for THC*
- *326 pairs: positive in both blood and oral fluid*
  - *75.7% were an exact drug match across all classes*
  - *21.4% had at least one drug class match*
  - ***97.1% correlation rate for paired specimens***

Data supports utility of oral fluid as a viable alternative to blood, providing similar information on drug intake

2007 DRUG TEST PANEL

- ***Cocaine***
- ***Marijuana***
- ***Opiates***
- ***Amphetamines***
- ***Benzodiazepines (8)***
- *Tramadol*
- *Methadone*
- *Fluoxetine*
- *Sertraline*
- *Phencyclidine*
- *Barbiturates*
- *TCA's (4)*
- *Zolpidem*
- *Carisoprodol*
- *Methylphenidate*
- *Oxycodone /Oxymorphone*
- *Meperidine*
- *Propoxyphene*
- *Dextromethorphan*
- *Ketamine*

FIVE CLASSES COVER >90% OF POSITIVES



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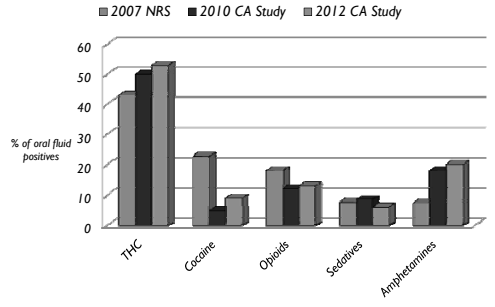
CALIFORNIA SURVEYS

Oral fluid:

- ***2010:***
- *14.4% of all drivers positive for drugs*
- *8.5% of all drivers positive for THC*

- ***2012:***
- *14% positive for drugs*
- *7.4% positive for THC*

>90% OF POSITIVES



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SAMPLE COLLECTION

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- *Gray-topped tube*
  - *4,686 samples*
- *Samples shipped overnight to the laboratory for analysis*
- *Laboratory received blood and oral fluid samples separately*
- *Blinded to paired specimens*

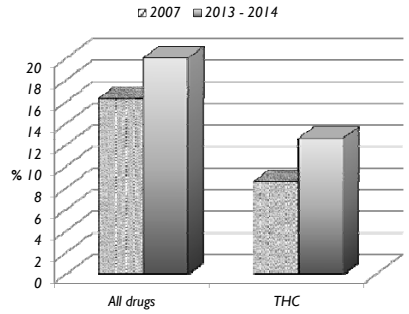
ORAL FLUID

- *Quantisal™ collection device*
  - *1 mL of oral fluid collected (+-10%)*
  - *3 mL stabilization buffer*
  - *7,881 samples*

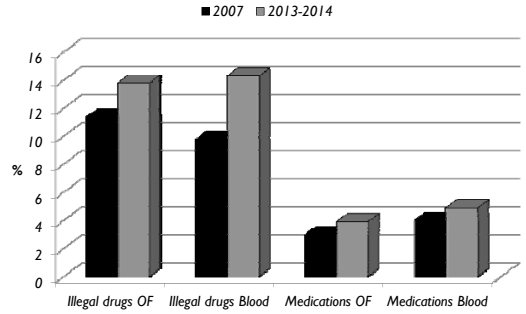
2013-2014 DRUG TEST PANEL

- *Cocaine*
- *Marijuana*
- *Opiates*
- *Amphetamines*
- *Benzodiazepines (15)*
- *Tramadol*
- *Methadone*
- *Fluoxetine*
- *Sertraline*
- *Phencyclidine*
- *Barbiturates*
- *Antidepressants (16)*
- *Zolpidem*
- *Carisoprodol*
- *Methylphenidate*
- *Oxycodone /Oxymorphone*
- *Meperidine*
- *Propoxyphene*
- *Dextromethorphan*
- *Ketamine*
- ***Diphenhydramine***
- ***Chlorpheniramine***
- ***Doxylamine***
- ***Fentanyl***
- ***Buprenorphine***

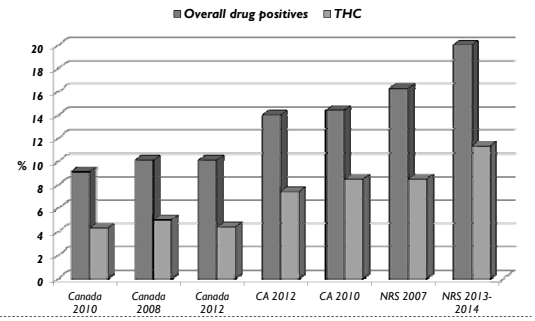
POSITIVITY RATE: NIGHT-TIME DRIVERS



RESULTS



ORAL FLUID ANALYSIS: NORTH AMERICAN SURVEYS



SUMMARY

- While overall drug positives in drivers were lower in Canada than the USA, the percentage of THC positives remains approximately 50%
- Drug positives for both medications and illegal drugs in US drivers has increased since 2007
- Overall drug prevalence (night-time drivers):
  - 2007: 16.3%
  - 2013-14: 20%
- The drug with the largest increase in weekend night time prevalence was THC
  - 2007: 8.6%
  - 2013-14: 12.6%

CALIFORNIA INITIATIVE

CA OFFICE OF TRAFFIC SAFETY INITIATIVE

- *Followed 2010 and 2012 CA studies where drugs were detected in the oral fluid of1 out of 7 drivers*

- ***Objective:***
- *To reduce the incidence of DUID through increased enforcement*
- *LA City Attorneys obtained funding to begin OF testing of drivers*

- *Suspect / driver underwent DRE exam and blood collection*
- *Then, **voluntary** rapid OF test using either **DDS2 or Drug Test 5000** performed by officer*
- *Quantisal™ specimens obtained for confirmation*

CA-OTS INITIATIVE

- *CA does not specifically allow oral fluid analysis for DUID offenses*
- *Under this research project, drivers tested voluntarily*
- *2 year project, which ended September 2014*

- *Many choices for oral fluid roadside testing….*

- *So which oral fluid test devices were chosen for the project, and why ?*

IMPORTANT FEATURES

- *Easy, rapid collection at time of traffic incident*
- *Fast results (all devices run within 10 minutes)*
- ***Instrumented testing device preferred***
- ***Printed or stored test result***

- ***Outcome assists law enforcement in decision making regarding the driver's competence***

CA-OTS INITIATIVE

- Alere DDS2 and Draeger Drug Test 5000 chosen

DDS2

Drug Test 5000

Printed or retained results
Published field studies
Law enforcement / DRE involvement

CALIFORNIA INITIATIVE

58 Counties in California

CA-OTS SITES

- Kern County PD, LA County PD (Draeger Drug Test 5000)
- Sacramento PD, Fullerton PD (Alere DDS2®)

- **Fullerton PD:**
  - 92 subjects with complete test results
    - DDS2® oral fluid screening
    - Quantisal™ oral fluid confirmation (NMS Labs)
    - Blood analysis (Orange County Crime Laboratory)

- **Sacramento PD:**
  - 34 drivers with complete test results
    - DDS2® oral fluid screening
    - Quantisal™ oral fluid confirmation (NMS Labs) and/or crime laboratory blood analysis

SUMMARY: FULLERTON PD

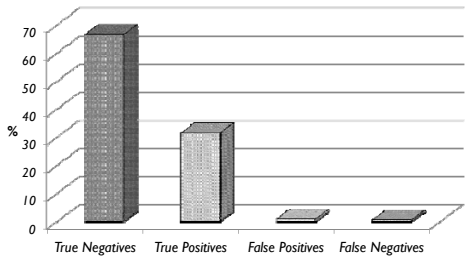
- *92 subjects completed OF rapid screening, OF confirmation, and blood analysis*
- *Excellent results*
- *DDS2®:*
  - *1 false positive METH - not confirmed in either matrix*
  - *3 false negative benzo not confirmed in OF; alprazolam in blood*
  - *3 false negative opiates not confirmed in OF; MOR in blood*
  - *3 false negative THC not confirmed in OF; present in blood*
  - *Sensitivity decreased when the metabolite THC-COOH included in blood confirmation*

SUMMARY: SACRAMENTO PD

- *34 drivers:*
  - *OF roadside screening, OF confirmation, and/or blood analysis*
- *DDS2:*
  - *THC and OPI: no false positives; no false negatives*
  - *COC: 1 false positive; no false negatives*
  - *AMP & METH: 3 false positives; no false negatives*
  - *Benzodiazepines: 3 false positives; 1 false negative*

COMBINED DATA: DDS2 .V. QUANTISAL™ (N = 126)

FULLERTON AND SACRAMENTO PD



CA STUDY
LOS ANGELES AND KERN COUNTIES (N = 235)

Draeger DDT 5000 vs Oral Fluid									
Drug	TP	FN	FP	TN	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)
THC	82	1	2	150	98.8	98.7	98.7	97.6	99.3
Cocaine	11	2	0	222	84.6	100	99.1	100	99.1
Amphetamine	42	7	2	184	85.7	98.9	96.2	95.5	96.3
Methamphetamine	49	0	0	186	100	100	100	100	100
Benzodiazepines	6	0	4	225	100	98.3	98.3	60	100
Opiates	19	0	0	216	100	100	100	100	100
Methadone	2	0	0	233	100	100	100	100	100
Overall	211	10	8	1416	95.5	99.4	98.9	96.3	99.3

M. Mohr, NMS Labs, 2014 SOFT presentation

CONCLUSIONS

- *Two mobile systems for drug detection in oral fluid were tested under realistic conditions in California Police Departments during 2014*
- *Overall device performance was excellent when compared to either oral fluid or blood as the "gold standard"*
- *In Fullerton and Sacramento - 756 tests:*
  - *1% false positive results*
  - *0.67% false negative results*
- *Accuracy in Kern and LA Counties: 98.9%*

ACKNOWLEDGEMENTS

- *California Office of Traffic Safety: Julie Schilling*
- *LA City Attorneys: Janette Flintoft*
- *Kern County DA's office: Michael Yraceburn*
- *DRE Officers and Police Personnel*
  - *Sgt. Timothy Petropoulos, Capt. George Crum (Fullerton PD)*
  - *Sgt. Christian Prince (Sacramento PD)*
  - *Sgt. Bill Ware (Bakersfield PD)*
- *NMS Laboratory Staff:*
  - *Dr. Barry Logan*
  - *Amanda Mohr*
- *Orange County Crime Lab Staff:*
  - *Jennifer Harmon*
  - *Dana Mati*

DRE'S, DRIVERS & ORAL FLUID DRUG TEST RESULTS

TULSA PD: DRUGGED DRIVING

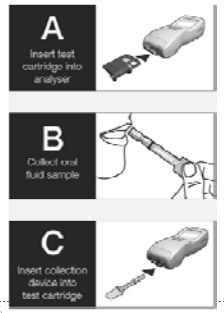
- *Can a roadside oral testing device serve as a preliminary screen to aid police officers in DUID detection ?*
- *Is oral fluid a reliable specimen for collection and roadside testing ?*
  - *Drivers stopped*
  - *DRE evaluation (includes SFST's)*
  - *DDS2 oral fluid test:*
    - *non-evidentiary*
  - *Blood and/or urine collected as per Tulsa protocol:*
    - *for evidential purposes*

DRUG DETECTION SYSTEM (DDS2)

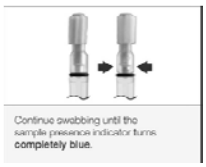
- *Rapid screening*
  - *Sample collection in ~ 1 min*
  - *Results in ~ 5 min*
- *Individual data can be stored in device*
- *Results can be printed*

Drug Class
Amphetamine
Benzodiazepines
Cocaine
Methamphetamine
Opiates
THC

How does it work?



- *Lateral flow device*



2013: Tulsa Police Department

- *Study designed with Drug Recognition Experts (DRE)*
- *DRE Training involves recognition of signs and symptoms caused by drugs falling into seven categories:*
  - *Cannabis*
  - *Narcotic analgesics (e.g. heroin, oxycodone)*
  - *CNS Stimulants (e.g. amphetamines, cocaine)*
  - *CNS depressants (e.g. benzodiazepines)*
  - *Hallucinogens (e.g. LSD)*
  - *Dissociative Anesthetics (e.g. PCP)*
  - *Inhalants (paint, gasoline)*

Software for DDS2 Screen

RESULTS

Subject	DRE observations	Intoxilyzer	DDS2	Quantisal™ (ng/mL)	Blood /Urine
1	Odor of burnt marijuana; Elevated blood pressure;		Error code	THC: 398	Urine: THC-COOH positive
2	No drivers license No insurance Improper tag display		THC METH AMP	THC: 44 METH: 7399 AMP: 864	
3	Parked vehicle, engine running Bloodshot eyes; slurred speech; Unsteady; alcohol odor	0.23%	Negative	Negative	

COMBINED RESULTS

Subject	DRE observations	Intoxilyzer	DDS2	Quantisal™ (ng/mL)	Blood /Urine
4	Driving erratically; HGN: no clues; Officer opinion: not impaired		COC	Negative	
5	Subject stated: taking Lortab (HYC), Xanax (alprazolam), marijuana, and cocaine	0.00%	COC AMP METH	COC: 147 AMP: 129 METH: 946 THC: 4 Alprazolam: 1.8 Nordiazepam: 4	
6	Passed out at light, vehicle running, foot on brake Stated taking one Xanax and smoking pot 5-6 hours prior to stop		THC Benzos	THC: 99 Alprazolam: 17	

COMBINED RESULTS

Subject	DRE observations	Intoxilyzer	DDS2	Quantisal™ (ng/mL)	Blood /Urine
7	Subject passed out in driver's seat with vehicle running; slurred speech, staggered gait, droopy eyes, used vehicle to balance		THC Benzos	THC: 144 Alprazolam: 1.7	Blood: Screen positive: THCA; Benzos Confirmed: Sertraline Lamotrigine
8	Subject speeding; EtOH odor; bloodshot eyes, slurred speech	0.15%	COC	COC: 239	
9	Failed to maintain traffic lane; EtOH odor; Stated: beer 4 hours ago; Xanax night before	Error	THC	Refused collection	

OUTCOME

- *DDS2 results correlated with laboratory screening and LC-MS/MS confirmatory tests*
  - ***Yes, a roadside test can serve as a preliminary screen to aid police officers in DUID evaluation***
- *Oral fluid analysis provided reliable results, consistent between laboratories*
  - ***Yes, oral fluid is a reliable specimen for collection and roadside testing***
- *Results very encouraging*
- *2015: Project is on-going*

MOST FREQUENTLY ASKED QUESTIONS..

- *1. WHAT CONCENTRATION OF THC IN ORAL FLUID IS EQUIVALENT TO THC IN BLOOD ?*
- *2. WHAT CONCENTRATION OF THC IN ORAL FLUID CORRELATES WITH IMPAIRMENT ?*

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GJERDE ET AL. Estimation of equivalent cutoff thresholds in blood and oral fluid for drug prevalence studies. J. ANAL. TOXICOL. 2014; 38(2): 92 – 98 (TABLE II)

Substance	*Cut-off in blood (ng/mL)*	*Cut-off in OF (ng/mL) 95%CI*	*Correlation R^2*	*n*
Alprazolam	10	2.8 (1.8 – 4.2)	0.998	106
AMP	20	290 (84 – 680)	0.993	86
Clonazepam	10	1.2 (0.2 – 2)	0.962	57
Cocaine	10	190 (26 – 350)	0.932	112
Codeine	10	83 (50 – 130)	0.999	92
Diazepam	50	1.1 (0.3 – 3.6)	0.930	94
METH	20	630 (120 – 1800)	0.993	55
Morphine	10	100 (37 – 180)	0.902	76
Nordiazepam	50	2.2 (1.2 – 4.5)	0.997	130
Oxazepam	50	12 (4.4 – 34)	0.962	55
THC	***1***	***44 (27 – 90)***	***0.991***	***182***
Tramadol	50	490 (85 – 1500)	0.966	51

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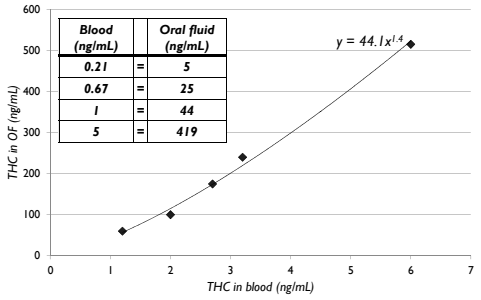
GJERDE ET AL. Estimation of equivalent cutoff thresholds in blood and oral fluid for drug prevalence studies. J. ANAL. TOXICOL. 2014; 38(2): 92 – 98 (FIGURE 1. THC)



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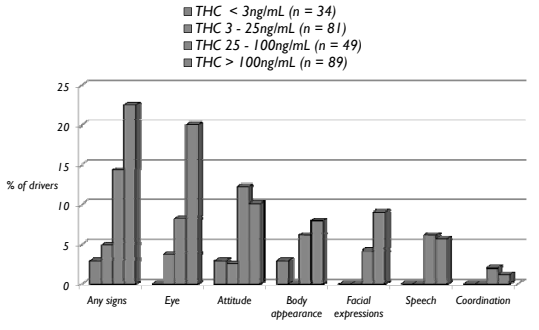
THC CONCENTRATION IN SALIVA & SIGNS OF IMPAIRMENT

- ***Fierro et al. The relationship between observed signs of impairment and THC concentration in oral fluid. Drug Alcohol Depend 2014; 144: 231- 238***
- *Spanish researchers investigated whether the judgment of a police officer regarding signs of impairment was related to the concentration of THC in oral fluid*
- *2632 drivers were investigated;*
  - *253 were positive in oral fluid for THC only*
- *Recorded 31 signs of impairment in 6 categories*

2014: FIERRO ET AL.

- ***1. Eye signs:*** *Red eyes; Brusque movement; Nystagmus; Pupil dilation or constriction; Slow pupil reaction*
- ***2. Attitude:*** *Nervous; Euphoric; Provocative; Tearful; Sleepy; Scratching; No comprehension*
- ***3. Body appearance:*** *Trembling; Perspiration; Restlessness; Superficial breathing*
- ***4. Facial expressions:*** *Blinking; Red nose; Sniffing; Swallowing; Cannabis smell*
- ***5. Speech:*** *Talkative; Difficulty speaking; Low tone*
- ***6. Co-ordination:*** *Staggering; No co-ordinated movements; Legs trembling*

RESULTS



SUMMARY

- *A relationship was found between THC concentration in OF and some observed signs of impairment*
- *Eye signs were noticeable at OF THC >3ng/ml*
- *OF THC >2.5ng/ml was related to behavior, facial expression, and speech signs of impairment*
- *Alcohol and THC contributed to impairment independently and, when taken simultaneously, effects were comparable to the sum of the effects when consumed separately*
- *The observation of signs of impairment due to cannabis occurred in an OF concentration-related manner*
- *As a **clinical test**, OF had low sensitivity and specificity in a random roadside survey*

PLANNING A PROJECT

ORAL FLUID ANALYSIS AT THE ROADSIDE

PLANNING A PROJECT

- *Guidelines available for starting a pilot project*
  - *Intended for use in data collection projects regarding the utility of oral fluid in DUID situations*
  - *Preliminary tests should not be considered as evidentiary*
  - *Offered as a framework for the collection of information regarding drug use in drivers*

PLANNING A PROJECT

- *Define Objectives (examples):*
  - *To collect information on drug intake from stopped drivers*
  - *To identify drivers under the influence of drugs in a more efficient and effective manner*
  - *To use the information to potentially aid prosecution of DUID offenders, if allowable*
  - *To provide data to assist in changing the law to include OF analysis as a viable specimen for DUID cases, or to provide data to implement the use of oral fluid*
  - *To deter drug intake prior to driving by demonstrating reliable drug detection*

PLANNING A PROJECT

- *Co-operation from key stakeholders, for example:*
  - *Law Enforcement Agency Heads*
  - *DRE /DUID officers, traffic safety officers*
  - *District or City attorneys;TSRP's*
  - *State Highway Safety Office*
  - *Collection device and instrument providers*
  - *State or local toxicology testing laboratory personnel*
  - *Reference laboratory toxicologists*
  - *Consultant toxicologists*

MANAGE PROJECT

- *Organize a meeting to cover project protocol:*
  - *Oral fluid collection (screening and confirmation)*
  - *On-site test training and operation of devices*
    - *Instrumented devices will print and/or retain result*
  - *Requisition forms and paperwork for confirmation tests*
  - *Protocol for collection and submission of evidential specimen(s) to appropriate laboratory*

MANAGE PROJECT

- *Ensure personnel understand legal aspects of the project and specimen collection*
- *Have contact information readily available & identify individual in charge of collating results*
- *Discuss and decide how results will be retained, analyzed, disseminated and utilized*
- *Schedule a final meeting to discuss results with stakeholders*
- ***Decide whether the performance of oral fluid test devices warrants further expansion of the program, or whether the performance is not adequate for further evaluation***

SUMMARY

- *North American roadside surveys have established the validity and viability of oral fluid testing for in DUID*
- *Majority of drugs detected fall into 5 categories*
- *Recommended oral fluid drug concentrations for DUID are published*
- *Data from roadside/mobile oral fluid drug testing systems is increasingly published; preliminary results are encouraging*
- *Guidelines for the implementation of data collection projects are available*
- *More and more states interested in oral fluid roadside testing in conjunction with DRE's as marijuana legalization advances and concerns about drugged driving increase*