IACP DRE Conference
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Oral Fluid Testing Update: Oregon DRE Field Certifications and THC testing at an EDM Festival

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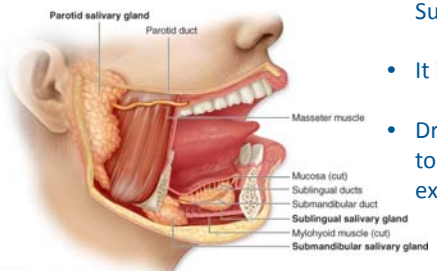
Oral Fluid



- Oral Fluid is a mixture of fluids excreted from the Parotid, Sublingual, and Submandibular glands.
- It is a plasma ultra-filtrate
- Drugs partition from blood to oral fluid by diffusion and extraction.

Why Oral Fluid?

- Timely Sample.
- Ease of Collection.
  - Observed, Gender Neutral Collection
  - Field Compatible
  - No Transport
  - No Phlebotomist
  - On-Site Options

Oregon DRE Field Certs

OR Assessment

- Dräger DT5000
- Robust, portable unit.
- Well validated.
- Automated operation.
- Easy to use.
- Electronic readout.
- Printout.
- Seven Drug Panel:
  - THC, Amp, Meth, Coc, Benzo, Opiates, Methadone

Introduction

- As part of the DRE training in Oregon, the State Police coordinate a training exercise for the students to gain experience evaluating individuals under the influence of various drug categories
  - Officers from agencies all over Oregon
  - Cannabis, stimulant, narcotics, etc.
  - Ethanol concentration (BrAC) must be below 0.08 or the effects of EtOH would mask other drug categories during evaluation

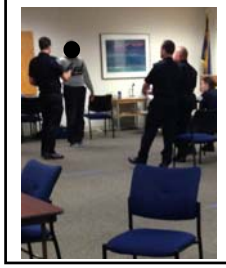
Introduction

- Why collect oral fluid as part of the DRE evaluations?
  - Oregon is a urine state, meaning after a DUI/DUID arrest the officers can only collect urine. Blood can only be collected in the instances of more severe crimes (i.e. homicide, etc.). This brings up issues of impairment and drug/metabolite presence in dealing with urine
  - Oral fluid was collected as part of a study to show that oral fluid could be used as an alternative to urine for DUI/DUID or other cases in the future

Volunteer Participation

- Volunteers signed a waiver form
  - Free to leave at anytime
  - Encouraged to use an alias
  - No information gathered during the evaluation could be used against them
  - Could refuse evaluation or sample collection
  - All evaluation results and sample collection results would be used for research purposes only
- Volunteers were patted down before entry
  - There were designated spots to store their belongings

DRE Evaluation



Evaluation and Sample Collection

- **57 Subjects**
- **DRE Evaluation**
  - About 45 minutes in length, done by the officers
- **Urine Collection**
  - To verify the volunteers were using drugs
  - Sent to local hospital, results were received next day
- **Drager Oral Fluid (OF) Screen**
  - Collection device and instrument for analysis
  - Immunoassay gives results in about 8 minutes
- **Quantisal™ Oral Fluid (OF) Collection**
  - Cotton applicator placed in the mouth with blue indicator
  - Applicator removed and stored in buffer/tube provided

Urine Testing

Sample Information

Specimen ID	15003	**Test Reason**	Random
Patient Name	, 15-003	**Type**	Urine
Lab Accession #	1203449	**Collected**	9/23/2015
DOB		**Received**	9/24/2015
SSN			

Sample Result **POSITIVE**

Tests Requested

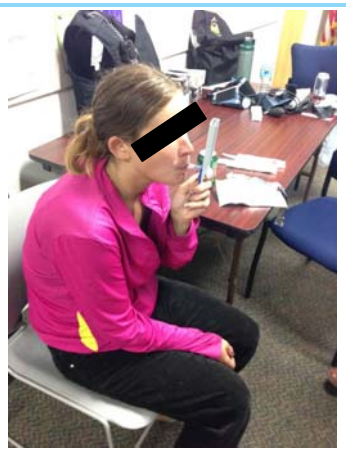
11USCRO D11 A/C/T2/O/E/Z/B/P/M/X/Q/6A

Test	Result	Quantitation	Screen Cutoff	Confirm Cutoff
AMPHETAMINES	POSITIVE		500 ng/mL	
COCAINE	Negative		150 ng/mL	
MARIJUANA	POSITIVE		20 ng/mL	
OPIATES	Negative		300 ng/mL	
ETHANOL	POSITIVE		10 mg/dL	
BENZODIAZEPINES	Negative		200 ng/mL	
BARBITURATES	Negative		200 ng/mL	
PCP	Negative		25 ng/mL	
METHADONE	Negative		300 ng/mL	
PROPOXYPHENE	Negative		300 ng/mL	
METHAQUALONE	Negative		300 ng/mL	
6- ACETYLMORPHINE	Negative		10 ng/mL	
VALIDITY CREATININE/SPGR	ACCEPTABLE			
VALIDITY OXIDANT	ACCEPTABLE			
VALIDITY pH	ACCEPTABLE			

Certification

Certifying Scientist: J. Glode Date: 9/24/2015

Drager OF Collection



Drager OF Drug Screen

First name: John
Date of birth:
Address:

ID code: 15-003
Cause:
Location: OR DRE Field Certs
Comment:

COC	Negative
OPI	Negative
BZO	Negative
THC-5	Positive
AMP	Positive
MET	Positive
MTD	Negative

Drager OF Drug Screen

First name: John
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Quantisal OF Collection

Results

OR OF Drug Results

Drug*	Number of Positive Individuals
THC	37
Amphetamine	35
Methamphetamine	35
Morphine	19
6-Monoacetylmorphine†	17
Codeine	9
Methadone	3
Cocaine/Benzoylecgonine	2
Hydrocodone	1
Hydromorphone	1
Oxycodone	1

Table 4: Overall drug positivity in OF for the population included in the study
**Drug confirmation as per NMS Labs report*
† 6-Monoacetylmorphine is a metabolite of heroin

Device Performance Assessment

- Two valuable indicators of performance:
  - Sensitivity: Ability of field tests to detect drug use that can later be confirmed
  - Positive Predictive Value (PPV): Proportion of positive field test results that are confirmed as positive in the lab

OR OF Drug Results

DDT5000 Results relative to screening results in **Urine** by Legacy MetroLab

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
THC	37	14	0	6	72.5%	100.0%	75.4%	100.0%	30.0%
Cocaine*	1	4	2	49	20.0%	96.1%	89.3%	33.3%	92.5%
Amphetamines	33	3	5	16	91.7%	76.2%	86.0%	86.8%	84.2%
Benzodiazepines	0	0	0	57	N/A**	100.0%	100.0%	N/A**	100.0%
Opiates*	17	5	0	34	77.3%	100.0%	91.1%	100.0%	87.2%
Methadone	2	0	0	55	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	90	26	7	217	77.6%	96.9%	90.3%	92.8%	89.3%

**Note: 1 subject was invalid for cocaine and opiates*
***Note: No subjects were positive for benzodiazepines by field test or screening analysis*

OR OF Drug Results

DDT5000 Results relative to confirmation results in **OF** by NMS Labs

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
THC	37	0	0	20	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine*	2	0	1	53	100.0%	98.1%	98.2%	66.7%	100.0%
Amphetamine	23	7	2	25	76.7%	92.6%	84.2%	92.0%	78.1%
Methamphetamine	34	0	2	21	100.0%	91.3%	96.5%	94.4%	100.0%
Benzodiazepines	0	0	0	57	N/A**	100.0%	100.0%	N/A**	100.0%
Opiates*	17	0	0	39	100.0%	100.0%	100.0%	100.0%	100.0%
Methadone	2	0	0	55	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	115	7	5	270	94.3%	98.2%	97.0%	95.8%	97.5%

**Note: 1 subject was invalid for cocaine and opiates*
***Note: No subjects were positive for benzodiazepines by field test or confirmatory analysis*

OR OF Drug Results

Comparison of DDT5000 to OF and Urine

ROC Result	DDT5000 vs. OF	DDT5000 vs. Urine
Sensitivity	94.3%	77.6%
Specificity	98.2%	96.9%
Accuracy	97.0%	90.3%
PPV	95.8%	92.8%
NPV	97.5%	89.3%

OR OF Drug Results

Confirmation Rates of DRE opinion compared to Chemical Test

DRE Category	Number of Evaluation Opinions	DDT5000 % Confirmation of DRE opinion	Lab Urine % Confirmation of DRE opinion
Cannabis	**35**	89%	100%
CNS Stimulants	**28**	93%	82%
Narcotic Analgesics	**21**	81%	86%
CNS Depressants	**7**	0%	0%
Dissociatives	**1**	0%	0%
OVERALL	**95**	**80%**	**83%**

OR OF Drug Results

- **Caveats**:
- Not all drugs in all drug classes were tested for:
  - ***Cannabis:***
    - Synthetic cannabinoids
  - ***Narcotic Analgesics***
    - Dilaudid (Hydromorphone)
    - New Synthetics, e.g. fentanyls, AH7921, U47700
  - ***CNS Depressants***
    - Aripiprazole (Abilify)
    - Zyprexa (Olanzapine)
    - Gabapentin (Neurontin)
    - Carisoprodol (Soma)

OR OF Drug Results

- For this study, the PPV was very high for all drugs and drug classes, excluding cocaine (small n).
- Greater than 92% of positive tests on the DDT5000 were subsequently confirmed in some other toxicological test
- DRE opinion was confirmed in 80% of cases with the DDT5000 compared to 83% with urine.
- False positive rates on the DDT5000 were less than 4%
- Results compare favorably to other studies in California and Florida.

Miami EDM THC Testing

Alere™ DDS®2 Mobile Test System

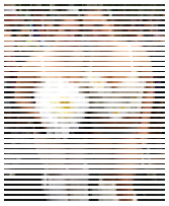
- Hand-held electronic portable device with digital screen for easy feedback of results
  - Lightweight
  - Easy to use
  - Results in 5 minutes
- Collection device
- Test cartridge

Device Cut-off Concentrations

Analyte	Cut-off (ng/mL)
Amphetamine	50
Methamphetamine	50
Cocaine	30
Cannabis	25
Benzodiazepines	20
Opiates	40
Methadone	15

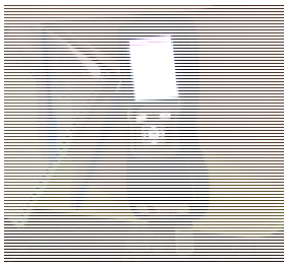
Project Overview

- Blood, urine, and oral fluid samples collected at an electronic dance music (EDM) festival
  - Ultra Music Festival in Miami, FL
  - IRB-approved research study
  - High frequency of recreational drug use


Project Overview

- Contemporaneous oral fluid (OF) samples collected and analyzed on-site using the Alere™ DDS®2 Mobile Test System

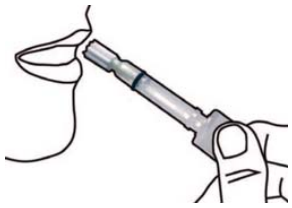


Quantisal™ OF Collection

- 384 participants provided OF samples using the Quantisal™ Oral Fluid Collection Device

DDS®2 OF Collection

- 122 participants provided OF samples for in-the-field testing using the Alere™ DDS®2
  - Immediate digital read out of results
  - Results recorded for later interpretation and comparison
- Drugs tested for:
  - Amphetamines, Cocaine, **Cannabis (THC)**, Opiates, and Benzodiazepines



Results

Sample Results

- 384 participants provided Quantisal™ OF
  - 152 subjects tested positive for THC
    - Mean: 56.0ng/mL
    - Median: 13.7ng/mL
    - Range: 1-857ng/mL
- 122 participants provided DDS®2 OF
  - 27 subjects tested positive for THC
  - 92 subjects were negative, 3 tests were invalid

Positive DDS®2 Results by Confirmation Cut-off

- All 27 positive OF samples were confirmed by LC-MS/MS

Confirmation Cut-off Concentration (ng/mL)	Number of Samples Positive for THC
> 5	27
> 10	23
> 15	21
> 25	18

- *DDS®2 Cut-off for Cannabis (THC): 25ng/mL*

Negative DDS®2 Results

- 92 samples were negative when tested in the field using the DDS®2
  - 89 of those samples were confirmed negative below the cut-off concentration of the device

Confirmation Cut-off Concentration (ng/mL)	Number of Samples Negative for THC
< 1	65
< 5	79
< 10	85
< 25	89

- *LC-MS/MS Limit of Detection for THC: 1ng/mL*

Negative DDS®2 Results

- 3 samples were determined to be false negatives following LC-MS/MS confirmation
  - Negative during field testing by DDS®2
  - Positive for THC (>25ng/mL) by LC-MS/MS

Concentration (ng/mL)
25.4
26.6
42.3

Results of Device Compared to Cut-off

	25ng/mL Cut-off	1ng/mL Cut-off
Sensitivity	90	50
Specificity	100	100
Positive Predictive Value	100	100
Accuracy	97.5	77.3

Discussion of Results

- Based on the performance of the device around the specified cut-off concentration of 25ng/mL, the DDS®2 met acceptable criteria surrounding sensitivity, specificity, positive predictive value, and accuracy

	25ng/mL Cut-off
Sensitivity	90
Specificity	100
Positive Predictive Value	100
Accuracy	97.5

Questions?

Barry K Logan PhD, F-ABFT