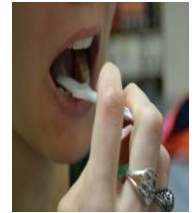


The 20th Annual Training Conference on Drugs, Alcohol and Impaired Driving

Using Oral Fluid in DUID Enforcement Cases: Experience with Field Studies

Barry K Logan PhD, D-ABFT

DUID Testing: Current Approaches



	Urine	Blood	Oral Fluid
Invasive	√√	√√√	√
Related to Recent Use	√	√√√	√√√
Correlated to Degree of effect	-	√√	√
On-Site Testing Capability	√	-	√√√
Can be collected at roadside	-	-	√√√
Volume available for testing	~50mL	~10mL	~1mL
Cost for sample collection	\$\$	\$\$\$\$	\$
Cost for confirmatory testing	\$\$	\$\$	\$\$

Why Oral Fluid?

- On-site Screening.
 - Immediate result
 - Portable
 - Handheld
 - Disposable
 - Optional printout
 - Electronic record
 - Deterrent
 - Investigative Tool
 - Probable Cause Tool
- Forensic Laboratory Confirmation.



Planning a Pilot Program

- Purpose:
 - Proof of Concept.
 - Data to change the law.
 - Demonstrate ease of use.
 - Evaluate for adoption in your agency.



Planning a Pilot Program

- Prerequisites:
 - Buy-in from management and DA.
 - Support from Highway Safety Office.
 - Dedicated team of DRE/DUI Squad.
 - Scheduled checkpoints and emphasis patrols.
 - Technology partner
 - Consistent laboratory test protocol
- Costs
 - Overtime detail for training.
 - Oral fluid testing.

So many choices...
























Testing Protocol

Device	Drugs Screened
Dräger	Amp, mAmp, Coc, Opi, THC, Benzos, MDN
Oratect	Amp, mAmp, Coc, Opi, THC, PCP
OraScreen	Amp, mAmp, Coc, Opi, THC
DrugWipe	Amp/mAmp, Coc, Opi, THC, Benzos
iScreen	Amp, mAmp, Coc, Opi, THC, PCP
OraLine	mAmp, Coc, Opi, THC
Oral Q	mAmp, Coc, Opi, THC, Oxy, Benzos
Oral Stat	Amp, mAmp/MDMA, Coc, Opi, THC, Benzos, MDN, PCP, Barbs, PPX
ToxSure	Amp, mAmp, Coc, Opi, THC, Benzos
Alere	Amp, mAmp, Coc, Opi, THC, Benzos
Saliva Scan	Amp, mAmp, Coc, Opi, THC, Benzos, MDN, Bup
Xalex	Amp, mAmp, Coc, Opi, THC, PCP


Testing Protocol

- Selected a total of 12 drugs that were spiked into a series of 9 blind controls.
- Open positive and negative controls.
- Testing protocol used was specific to the device, based on manufacturer's instructions
- Devices run in triplicate.
- Interpreted and scored by two independent observers.
- Devices scored on target, cut-off, sensitivity, specificity, accuracy, robustness, ease of use, readability, published performance.

Results

Device	Cut-Off	Performance	Readability/ Robustness
Dräger DT5000*			
DrugWipe*			
Alere DDS2*			
iScreen			
OraLine			
Oral Q			
Oratect			
OraScreen			
ToxSure			
Saliva Scan			
Xalex			

 Excellent

 Good

 Average

 Poor

 Unacceptable

So many choices...



...three viable options.



OF Screening Partners

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

Dräger



OF Screening Partners

- Alere DDS2
- Lateral Flow Immunoassay
- Robust, handheld unit.
- Relatively new to market
- Automated operation.
- Easy to use.
- Electronic readout.
- Printout.
- Six Drug Panel:
 - THC, Amp, Meth, Coc, Benzo, Opiates



OF Screening Partners

- SecureTec DrugWipe5®
- Lateral Flow Immunoassay
- Disposable device
- Proven technology
- Manual test
- Easy to use.
- Operator read
- No Printout.
- Five Drug Panel:
 - THC, Amp/Meth, Coc, Benzo, Opiates



DRUG IMPAIRED DRIVING/DRE TOXICOLOGY PANEL (QUALITATIVE), ORAL FLUID (FORENSIC) TEST (9005OF)

[TEST CATALOG HOME](#)
[EDUCATION](#)
[INNOVATION](#)
[NEW TESTS](#)
[TEST UPDATES](#)
[SUGGEST A TEST](#)
[CLIENT PORTAL](#)
[SPECIAL REQUEST TESTING](#)
[TOX WIKI](#)
[SITE MAP](#)

Drug Impaired Driving/DRE Toxicology Panel (Qualitative), Oral Fluid (Forensic) Test (9005OF)

Analysis Code	9005OF
Test Name	Drug Impaired Driving/DRE Toxicology Panel (Qualitative), Oral Fluid (Forensic)
Test Includes	Amphetamines [ELISA]; Benzodiazepines [ELISA]; Cocaine / Metabolites [ELISA]; Delta-9 THC [ELISA]; Methadone [ELISA]; Opiates [ELISA]; Phencyclidine [ELISA]
Compound Synonym(s)	Angel Dust; PCP; Sherm
Purpose	Drug of Abuse Monitoring. This test is New York State approved.
Category	Narcotic Analgesic, Hallucinogen
Method(s)	Enzyme-Linked Immunosorbent Assay (ELISA)
Specimen Requirements	5 mL Oral Fluid
Transport Temperature	Refrigerated
Specimen Container	Oral Fluid collection device
Special Handling	Immunoanalysis Quantisal™ collection device is preferred. Other collection devices are acceptable; however they may affect the reporting limit of the assay. Pour-off containers from non- Immunoanalysis Quantisal™ collection devices are acceptable. Samples are stable up to 3 days at room temperature and should be refrigerated thereafter. DO NOT FREEZE the OraSure Intercept® or Immunoanalysis Quantisal™ collection devices.
Light Protection Required	Not Required

NMS LABS TEST CATALOG

Select by first letter or code number

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z
0 1 2 3 4 5 6 7 8 9



Enter your e-mail address if you would like NMS Labs to add this test to the selection of tests that can be purchased by using a credit card versus traditional ordering methods.



Sign me up for email updates

Planning a Pilot Program

- Full Day Orientation:
 - Field study Plan
 - Key Contacts
 - Data packet summary
 - Device test procedure
 - Quantisal Procedure
 - Process checklist
 - Data control
 - Sample logistics
 - Test Results...

Pennsylvania State Police Oral Fluid Study Protocol

Overall Protocol

At the conclusion of the arrest procedures, including the collection of the evidential urine, follow the following procedure.

1. Confirm:
 - a. The subject was NOT involved in a multi-vehicle accident
 - b. The subject is NOT a minor.
 - c. The subject can understand and sign the consent form.
 - d. Subject has not declined a DRE exam including blood collection.
2. Describe the study to the subject (follow the description on the consent form), and have them complete the sign the consent form.
3. Ensure that 10 minutes have passed during which the subject was under your control and had not eaten, smoked, or had anything to drink.
4. Perform the Drager DT5000 on-site drug test according to the attached protocol.
5. Perform the Quantisal oral fluid collection using the attached protocol.
6. Assemble the data packet immediately after releasing or transferring the subject.

General Guidance

Oral Fluid Drug test kits should be stored with temperatures between 41°-77°F

Do not perform tests in temperatures above 104° F

Do not store test kits in vehicle overnight. Bring remaining test kits back into the station at the conclusion of the shift.

When transporting test kits in hot temperatures, a cooler pack should be used.

Planning a Pilot Program

- Evening run-through.
 - Set up
 - On-site logistics
 - Troubleshooting
 - Post action review



Final Report

*Final Report
Summarizes:
Protocol.
Field Results.
Lab results.
Calculations of sensitivity,
specificity and accuracy.*

THE CENTER FOR
FORENSIC SCIENCE
RESEARCH & EDUCATION

Final Report: Lancaster Oral
Fluid Specimen Project

Amanda Arntson¹, Barry Logan^{1,2}, and Celeste Metzger²
¹The Center for Forensic Science Research and Education, ²NIMS Labs

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy
THC	6	0	0	10	100.0%	100.0%	100.0%
Cocaine	1	0	0	13	100.0%	100.0%	100.0%
Amphetamine	1	0	0	15	100.0%	100.0%	100.0%
Methamphetamine	0	0	0	15	N/A	100.0%	100.0%
Benzodiazapines	1	5	0	10	16.7%	100.0%	68.8%
Opiates	4	0	0	11	100.0%	100.0%	100.0%
Methadone	0	0	0	15	N/A	100.0%	100.0%
Overall	13	5	0	73	72.2%	100.0%	94.5%

Protocol I

- Test pursuant to stop.
- Collect oral fluid sample for field test.
- Perform field test (5-8 mins).
- Based on result collect Quantisal sample for confirmation testing (2mins).



Protocol II

- Secure and seal Quantisal sample.
- Place in pre-labelled, pre-paid FedEx envelope.
- Complete COC and requisition.
- Schedule pick/up.
- Results in 3-5 days.
- Results available on-line.



Confirmation

Confirmation:

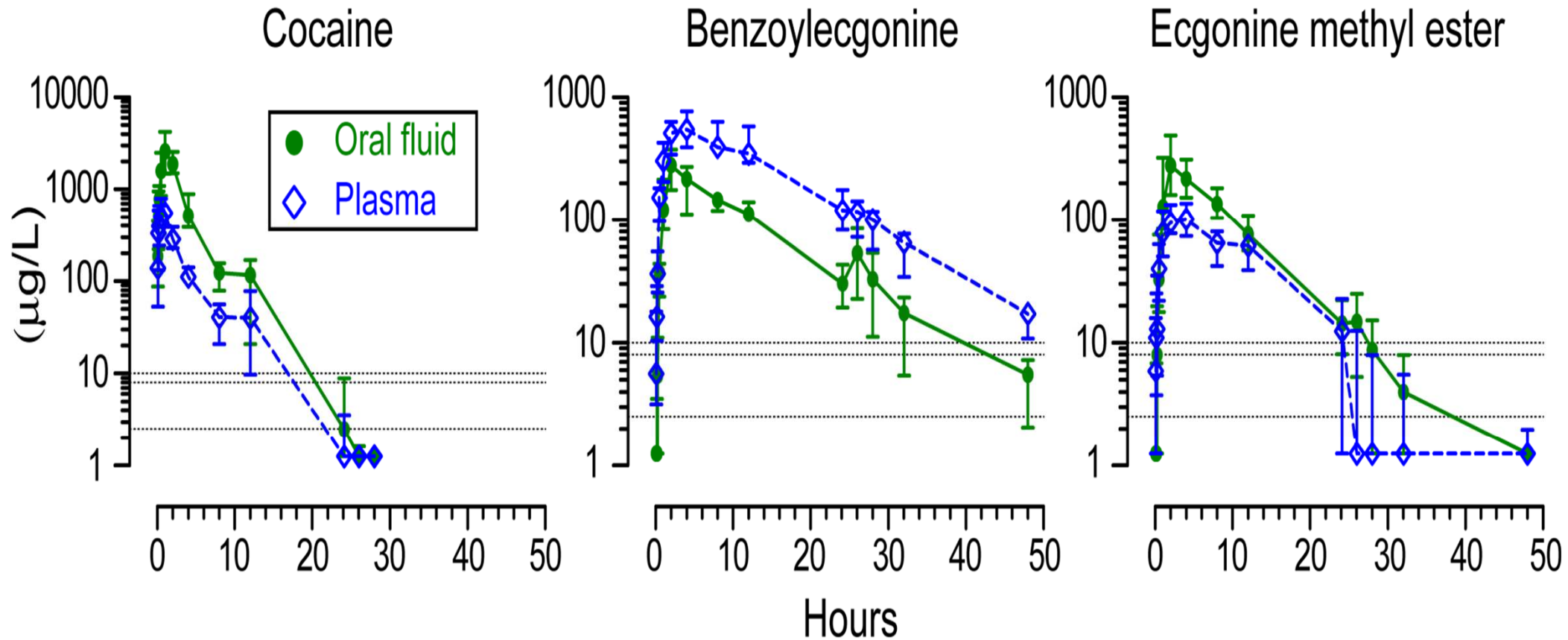
- Liquid Chromatography Tandem Mass Spectrometry.
- 3D Gas Chromatography Mass spectrometry



Analyte	Reporting Limit
Amphetamine	2.5 ng/mL
Methamphetamine	2.5 ng/mL
MDA	2.5 ng/mL
MDMA	2.5 ng/mL
Diazepam	1.5 ng/mL
Nordiazepam	1.5 ng/mL
Oxazepam	2.25 ng/mL
Temazepam	1.5 ng/mL
Chlordiazepoxide	25 ng/mL
Lorazepam	1.5 ng/mL
Clonazepam	1.5 ng/mL
Alprazolam	1.5 ng/mL
Midazolam	2.25 ng/mL
Codeine	2.0 ng/mL
Morphine	2.0 ng/mL
Hydrocodone	2.0 ng/mL
6-MAM	2.0 ng/mL
Hydromorphone	2.0 ng/mL
Oxycodone	2.0 ng/mL
Oxymorphone	2.0 ng/mL
Dihydrocodeine	2.0 ng/mL
Cocaine	2.5 ng/mL
Benzoyllecgonine	1.25 ng/mL
Cocaethylene	1.25 ng/mL
Methadone	2.5 ng/mL
EDDP	2.5 ng/mL
PCP	1 ng/mL
Dextromethorphan	25 ng/mL

Cocaine in Oral Fluid

150 mg/70 kg sc cocaine, (N=14 oral fluid) (N=13 plasma)



Courtesy, Marilyn Huestis, NIDA

Field Studies

Miami FL Protocol (n=92):

Research Only

Complete Arrest Procedure

Collect DRE Urine

Administer informed consent

Perform testing:

Drager Drug Test 5000

Affiniton Drug Wipe 5

Quantisal Collection for Lab OF



Field Studies

Lancaster PA Protocol: Drager vs Lab OF (n=35)

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy
THC	14	5	0	16	73.7%	100.0%	85.7%
Cocaine	6	1	0	23	85.7%	100.0%	96.7%
Amphetamine	1	1	1	29	50.0%	96.7%	93.8%
Methamphetamine	0	0	0	31	N/A	N/A	N/A
Benzodiazapines	3	6	0	21	33.3%	100.0%	80.0%
Opiates	5	8	0	16	38.5%	100.0%	72.4%
Methadone	6	1	0	24	85.7%	100.0%	96.8%
Overall	35	22	1	129	61.4%	99.2%	87.7%

Field Studies

Lancaster PA Protocol: Drager vs Blood (n=16)

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy
THC	6	0	0	10	100.0%	100.0%	100.0%
Cocaine	1	0	0	13	100.0%	100.0%	100.0%
Amphetamine	1	0	0	15	100.0%	100.0%	100.0%
Methamphetamine	0	0	0	15	N/A	N/A	N/A
Benzodiazapines	1	5	0	10	16.7%	100.0%	68.8%
Opiates	4	0	0	11	100.0%	100.0%	100.0%
Methadone	0	0	0	15	N/A	N/A	N/A
Overall	13	5	0	73	72.2%	100.0%	94.5%

Field Studies

Los Angeles CA Protocol (n=20):

Enforcement Model

Complete Arrest Procedure

Collect DRE Blood

Request voluntary Oral Fluid Test

Perform testing:

Drager Drug Test 5000

Quantisal Collection for Lab OF



Field Studies

Los Angeles CA Protocol: Drager, n=20

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy
THC	19	0	0	1	100.0%	100.0%	100.0%
Cocaine	3	0	0	17	100.0%	100.0%	100.0%
Amphetamine	0	0	1	19	N/A	95.0%	95.0%
Methamphetamine	0	0	0	20	N/A	100.0%	100.0%
Benzodiazapines	0	1	0	19	N/A	100.0%	95.0%
Opiates	1	0	0	19	100.0%	100.0%	100.0%
Methadone	0	0	0	20	N/A	100.0%	100.0%
Overall	23	1	1	115	95.8%	99.1%	98.6%

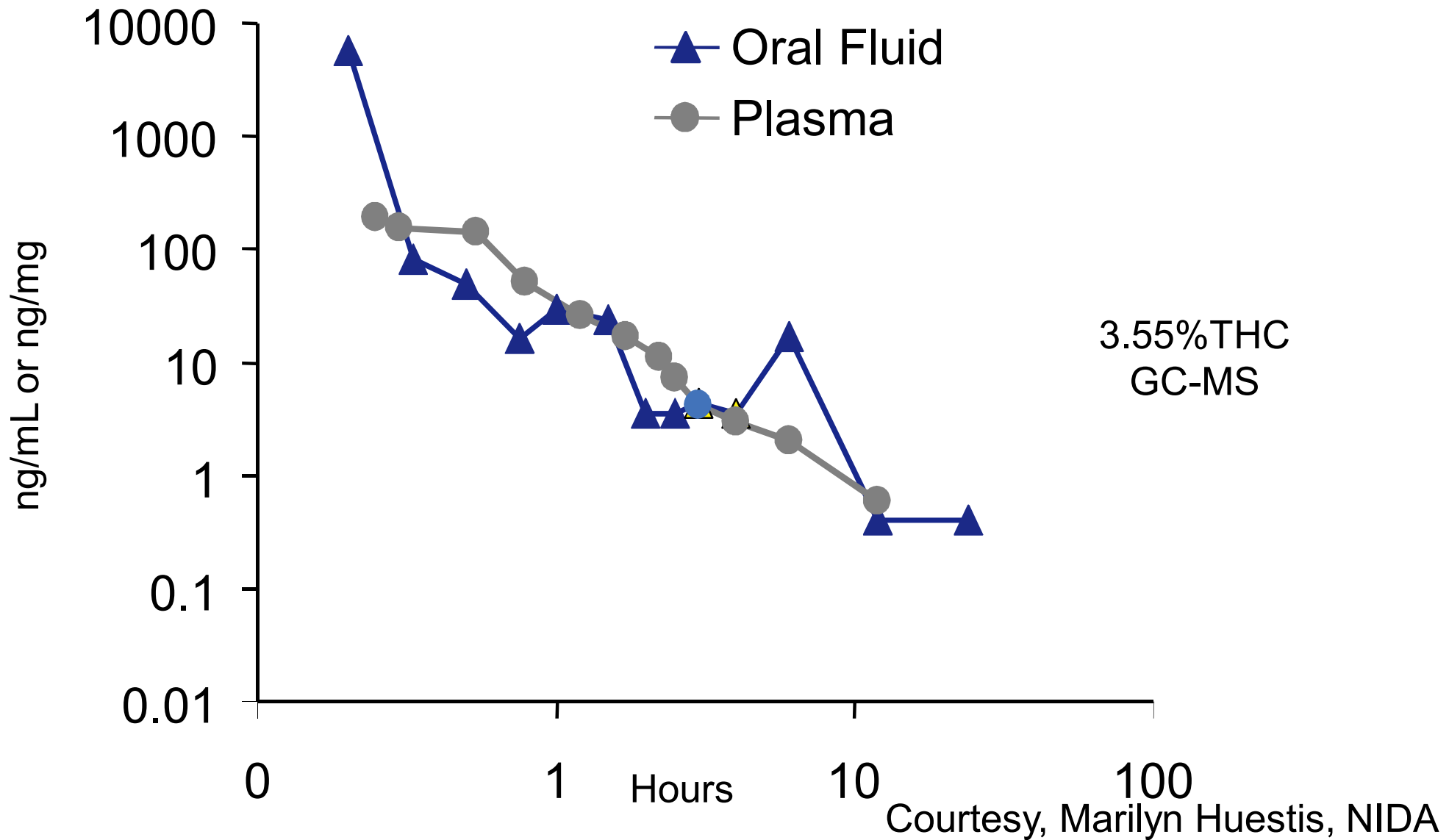
Los Angeles Protocol

Overall Observations:

- *Excellent Sensitivity and Specificity*
- *Results support DRE opinions*
- *High number of high THC cases dominate.*
- *Other studies:*
 - *Sensitivity for therapeutic benzodiazepines is poor.*
 - *Some opiates can be missed.*

Thank you for Attending
Questions and Discussion

THC in Oral Fluid



OF DRUG TESTING TECHNOLOGY

Testing Protocol

Device	Drugs Screened
Dräger	Amp, mAmp, Coc, Opi, THC, Benzos, MDN
Oratect	Amp, mAmp, Coc, Opi, THC, PCP
OraScreen	Amp, mAmp, Coc, Opi, THC
DrugWipe	Amp/mAmp, Coc, Opi, THC, Benzos
iScreen	Amp, mAmp, Coc, Opi, THC, PCP
OraLine	mAmp, Coc, Opi, THC
Oral Q	mAmp, Coc, Opi, THC, Oxy, Benzos
Oral Stat	Amp, mAmp/MDMA, Coc, Opi, THC, Benzos, MDN, PCP, Barbs, PPX
ToxSure	Amp, mAmp, Coc, Opi, THC, Benzos
Alere	Amp, mAmp, Coc, Opi, THC, Benzos
Saliva Scan	Amp, mAmp, Coc, Opi, THC, Benzos, MDN, Bup
Xalex	Amp, mAmp, Coc, Opi, THC, PCP

Testing Protocol

- Selected a total of 12 drugs that were spiked into a series of 9 blind controls.
- Open positive and negative controls.
- Testing protocol used was specific to the device, based on manufacturer's instructions
- Devices run in triplicate.
- Interpreted and scored by two independent observers.
- **Devices scored on target, cut-off, sensitivity, specificity, accuracy, robustness, ease of use, readability, published performance.**

...Three Viable Options



OF Screening Technology

- 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

Dräger



OF Screening Technology

- Alere DDS2
- Robust, handheld unit.
- Relatively new to market
- Automated operation.
- Easy to use.
- Electronic readout.
- Printout.
- Six Drug Panel:
 - THC, Amp, Meth, Coc, Benzo, Opiates



THE VERMONT FIELD STUDY

Field Studies

Study Protocol

Complete Arrest Procedure

Collect DRE/Legal Blood

Request voluntary Oral Fluid Test

Advisement of rights

Perform testing:

- *Field Oral Fluid Test*
- *Quantisal Oral Fluid Collection for confirmatory Lab test using forensically accepted methodologies*



Sample Collection

- *Oral fluid: Quantisal™ collection device:*
 - *1 mL of oral fluid collected (+-10%)*
 - *3 mL stabilization buffer*



LCMSMS Confirmation

Confirmation:

- Waters TQD API Tandem Mass Spectrometer/Waters Acuity UPLC
- Waters BEH C18 2.1 mm x 100 mm, particle size 1.7 micron
- Ammonium Formate (pH4)/ Ammonium Hydroxide in MeOH
- 9 minute run time



Analyte	Reporting Limit
Amphetamine	2.5 ng/mL
Methamphetamine	2.5 ng/mL
MDA	2.5 ng/mL
MDMA	2.5 ng/mL
Diazepam	1.5 ng/mL
Nordiazepam	1.5 ng/mL
Oxazepam	2.25 ng/mL
Temazepam	1.5 ng/mL
Chlordiazepoxide	25 ng/mL
Lorazepam	1.5 ng/mL
Clonazepam	1.5 ng/mL
Alprazolam	1.5 ng/mL
Midazolam	2.25 ng/mL
Codeine	2.0 ng/mL
Morphine	2.0 ng/mL
Hydrocodone	2.0 ng/mL
6-MAM	2.0 ng/mL
Hydromorphone	2.0 ng/mL
Oxycodone	2.0 ng/mL
Oxymorphone	2.0 ng/mL
Dihydrocodeine	2.0 ng/mL
Cocaine	2.5 ng/mL
Benzoylcegonine	1.25 ng/mL
Cocaethylene	1.25 ng/mL
Methadone	2.5 ng/mL
EDDP	2.5 ng/mL
PCP	1 ng/mL
Dextromethorphan	25 ng/mL

GC³MS Confirmation

Confirmation:

Agilent 7890A & 5975C

Column 1 (GC Oven) DB5MS (5m x 0.25 x 0.25)

Column 2 (LTM) DB17MS (15m x 0.25 x 0.25)

Column 3 (LTM) DB1MS (15m x 0.25 x 0.25)

Initial Temp 100°C Maximum Temp 350°C

Initial Time 0.50 min Equilibration Time 0.75 min

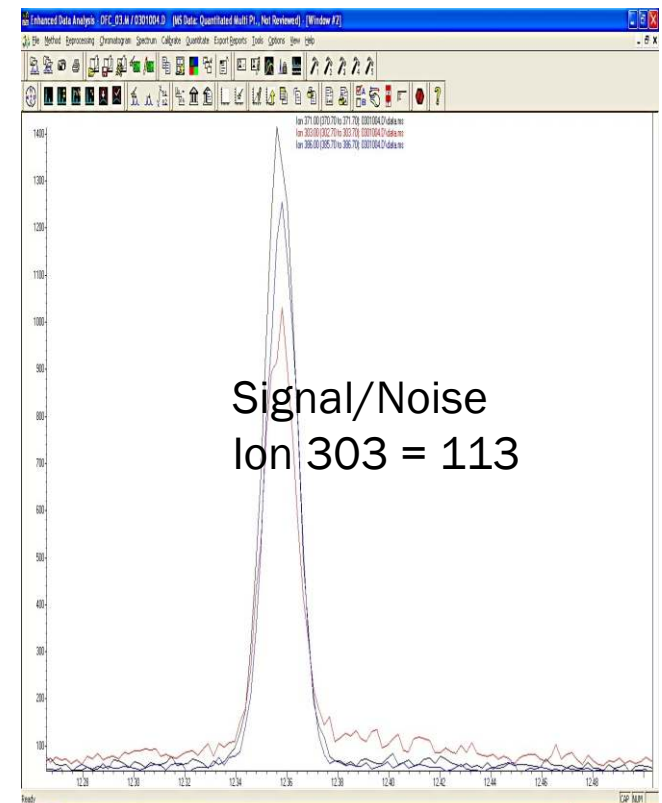
Rate 1 50°C/min Rate 2 30°C/min

Final Temp 1 210°C Final Temp 2 300°C

Run Time 14.2 min Post Run Time 0.75 min



Analyte	Reporting Limit
THC	0.5ng/mL



Assay Validation

- Matrix matching
- Within run/between run precision
- Recovery
- Matrix stability
- Autosampler stability
- Prep stability
- Dilution stability
- Interference
- Freeze/thaw
- Carryover



PRELIMINARY CALIFORNIA STUDY DATA

CA Study – In Progress

Fullerton and Sacramento Data (n=22)

Alere vs. Oral Fluid									
Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
THC	9	0	0	13	100.0%	100.0%	100.0%	100.0%	100.0%
Cocaine	0	0	0	22	-	100.0%	100.0%	#DIV/0!	100.0%
Amphetamine	17	2	0	3	89.5%	100.0%	90.9%	100.0%	60.0%
Methamphetamine	19	0	0	3	100.0%	100.0%	100.0%	100.0%	100.0%
Benzodiazepines	0	0	0	22	-	100.0%	100.0%	-	100.0%
Opiates	3	0	0	19	100.0%	100.0%	100.0%	100.0%	100.0%
Overall	48	2	0	82	96.0%	100.0%	98.5%	100.0%	97.6%

CA Study – In Progress

LA and Bakersfield Data (n=143)

Drager vs. Oral Fluid									
Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
THC	81	1	1	60	98.8%	98.4%	98.6%	98.8%	98.4%
Cocaine	11	2	0	130	84.6%	100.0%	98.6%	100.0%	98.5%
Amphetamine	42	6	2	93	87.5%	97.9%	94.4%	95.5%	93.9%
Methamphetamine	49	0	0	94	100.0%	100.0%	100.0%	100.0%	100.0%
Benzodiazepines	6	2	4	131	75.0%	97.0%	95.8%	60.0%	98.5%
Opiates	18	0	0	125	100.0%	100.0%	100.0%	100.0%	100.0%
Methadone	2	0	0	141	100.0%	100.0%	100.0%	0.0%	100.0%
Overall	209	11	7	774	95.0%	99.1%	98.2%	96.8%	98.6%

PRELIMINARY CALIFORNIA STUDY DATA

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Amphetamine	17	2	0	3	89.5%	100.0%	90.9%	100.0%	60.0%
Methamphetamine	19	0	0	3	100.0%	100.0%	100.0%	100.0%	100.0%
Benzodiazepines	0	0	0	22	-	100.0%	100.0%	-	100.0%
Opiates	3	0	0	19	100.0%	100.0%	100.0%	100.0%	100.0%
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Methadone	2	0	0	141	100.0%	100.0%	100.0%	0.0%	100.0%
Overall	209	11	7	774	95.0%	99.1%	98.2%	96.8%	98.6%

Summary

- *Oral Fluid testing for Law Enforcement purposes is a proven strategy.*
- *Advantages center around ease of collection.*
- *Oral Fluid ≠ Blood.*
- *Screen, collection and confirmation phases must be carefully planned and validated.*
- *Successful implementation requires management support and buy in from prosecutors.*



CNS Depressant Drugs

- Used for a variety of therapeutic purposes
 - Sedation
 - Anxiety
 - Depression
 - Seizure control
 - Muscle relaxation
 - Sleep
 - Allergies

Questions?

barry.logan@nmslabs.com

