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COMPARISON OF LABORATORY BASED ORAL FLUID RESULTS WITH FIELD BASED SCREENING USING THE ALERE DDS2 AND DRÄGER DRUGTEST 5000

Mandi Mohr, M.S.

Oral Fluid Advantages

- Emerging biological matrix
 - Easily collected allowing for on-site samples
 - Proximate to time of driving
 - Uses non-invasive procedures
 - Does not require specially trained personnel
 - Minimal potential for adulteration
 - Diminished error associated with sample collection
 - Predominantly parent drug detected

Oral Fluid and DUID in the U.S.

- 2007 National Roadside Survey of Alcohol and Drug Use by Drivers
 - Oral fluid samples collected from 7,719 subjects
- Baker et. al. 2013 comparison of drug detecting in oral fluid and blood data
 - Concluded oral fluid is a reliable alternative matrix to blood for drug testing



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Comparing Drug Detection in Oral Fluid and Blood: Data From a National Sample of Nighttime Drivers

T. KELLEY-BAKER¹, C. MOORE², J. H. LACEY¹, and J. YAO¹

¹*Pacific Institute for Research and Evaluation, Calverton, Maryland*

²*Immalysis Corporation, Pomona, California*

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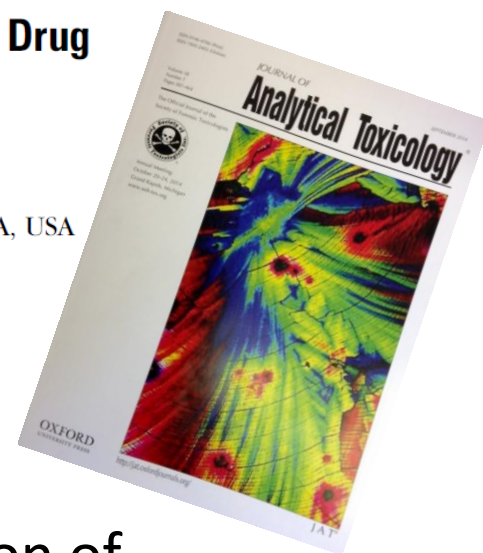
Pilot OF DUID Study

Detection and Prevalence of Drug Use in Arrested Drivers Using the Dräger Drug Test 5000 and Affnition DrugWipe Oral Fluid Drug Screening Devices

Barry K. Logan^{1,2*}, Amanda L. A. Mohr¹ and Stephen K. Talpins³

¹The Center for Forensic Science Research and Education, Willow Grove, PA, USA, ²NMS Labs, Willow Grove, PA, USA and ³Institute for Behavior and Health Inc., Rockville, MD, USA

- Miami Field Study
 - 92 total participants
 - Drivers who were pulled over for suspicion of impairment
 - Oral fluid samples tested roadside using the Dräger Drug Test 5000 and Securtec DrugWipe
 - Confirmatory specimen collected with the Immunalysis Quantisal



Device Performance Assessment

Detection and Prevalence of Drug Use in Arrested Drivers Using the Dräger Drug Test 5000 and Affiniton DrugWipe Oral Fluid Drug Screening Devices

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- Two valuable indicators of performance:
 - Sensitivity: proportion of subjects who subsequently test positive in a confirmatory assay whose positive status was correctly predicted by the field test
 - Positive Predictive Value (PPV): proportion of subjects whose field test correctly predicted they would test positive in the confirmatory test

Field Test Device Strengths

	Overall Accuracy	Overall Sensitivity	Overall PPV
DDT5000	96%	53%	93%
DrugWipe	91%	51%	67%

- Both devices were highly effective in generating confirmable positives
- Differences in PPV
 - 5 unverified field test positives for THC and 5 unverified field test positives for cocaine on the DrugWipe

Field Test Device Limitations

- Devices were less effective in detecting some drug categories
 - THC: 58% sensitivity on DDT500, 44% sensitivity on DrugWipe
 - Benzodiazepines: Both DDT5000 and DrugWipe failed to detect benzodiazepine use in the field on 6 cases
 - Four Alprazolam
 - Two Lorazepam

California Study

- Objective was to collect evidential quality oral fluid results
 - Intent was to introduce the oral fluid evidence into court through a Kelly-Frye Evidential hearing
- Four counties participated in the study
 - Kern, Los Angeles, Orange, and Sacramento





Sacramento County
Sacramento
Alere DDS2

Kern County
Bakersfield
Dräger Drug Test
5000

Los Angeles County
Los Angeles
Dräger Drug Test 5000

Orange County
Fullerton
Alere DDS2

California Study Design

- Officers followed routine arrest procedures
 - Waiver: Participation was voluntary, but oral fluid results could be used in court
 - Arrestees additionally completed a field oral fluid test and submitted an oral fluid sample for confirmatory testing
- Confirmatory specimen collected with the Immunalysis Quantisal



Device Comparison

- Alere DDS2

- Lateral Flow Immunoassay
- **Handheld Unit**
- Automated Operation
- Electronic Readout
- Printout
- **Six Drug Panel**

- THC, Amp, Meth, Coc, Benzo, Opiates



- Dräger Drug Test 5000

- Lateral Flow Immunoassay
- **Portable Unit**
- Automated Operation
- Electronic Readout
- Printout
- **Seven Drug Panel**

- THC, Amp, Meth, Coc, Benzo, Opiates, Methadone



Field Test Device Cutoffs

Analyte	Alere DDS2 Cutoffs (ng/mL)	DDT500 Cutoffs (ng/mL)
Amphetamine	50 (Amp)	50 (Amp) 35 (mAmp)
Benzodiazepines	20 (Temazepam)	15 (Diazepam)
Cannabis	25 (THC)	5 (THC)
Cocaine	30 (BZE)	20 (Coc)
Methamphetamine	50 (mAmp)	Combined with Amp
Methadone	-	20 (Methadone)
Opiates	40 (Morphine)	20 (Morphine)

SAMPLE ANALYSIS

LC-MS/MS 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

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
- 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

Analyte	Reporting Limit
THC	0.5 ng/mL

Data Analysis

- Data was assessed using ROC analysis
 - Determined sensitivity, specificity, accuracy, PPV, and NPV
- True Positive: OF field test result corresponded to laboratory confirmation
- True Negative: both field test and laboratory test result were negative
- False Positive: OF field test result positive, but not confirmed in the laboratory test
- False Negative: OF field test result negative, analyte detected in confirmatory assay

RESULTS

Alere DDS2 Results

- Orange and Sacramento Counties
 - 122 subjects

Alere DDS2 vs. Oral Fluid

Drug	TP	FN	FP	TN	Sensitivity	Specificity	Accuracy	PPV	NPV
THC	32	1	1	88	97.0%	98.9%	98.4%	97.0%	98.9%
Cocaine	3	2	0	117	60.0%	100.0%	98.4%	100.0%	98.3%
Amphetamine	88	10	3	21	89.8%	87.5%	89.3%	96.7%	67.7%
Methamphetamine	100	1	1	20	99.0%	95.2%	98.4%	99.0%	95.2%
Benzodiazepines	1	0	0	121	100.0%	100.0%	100.0%	100.0%	100.0%
Opiates	19	3	0	100	86.4%	100.0%	97.5%	100.0%	97.1%
Overall	243	17	5	467	93.5%	98.9%	97.0%	98.0%	96.5%

Dräger Drug Test 5000 Results

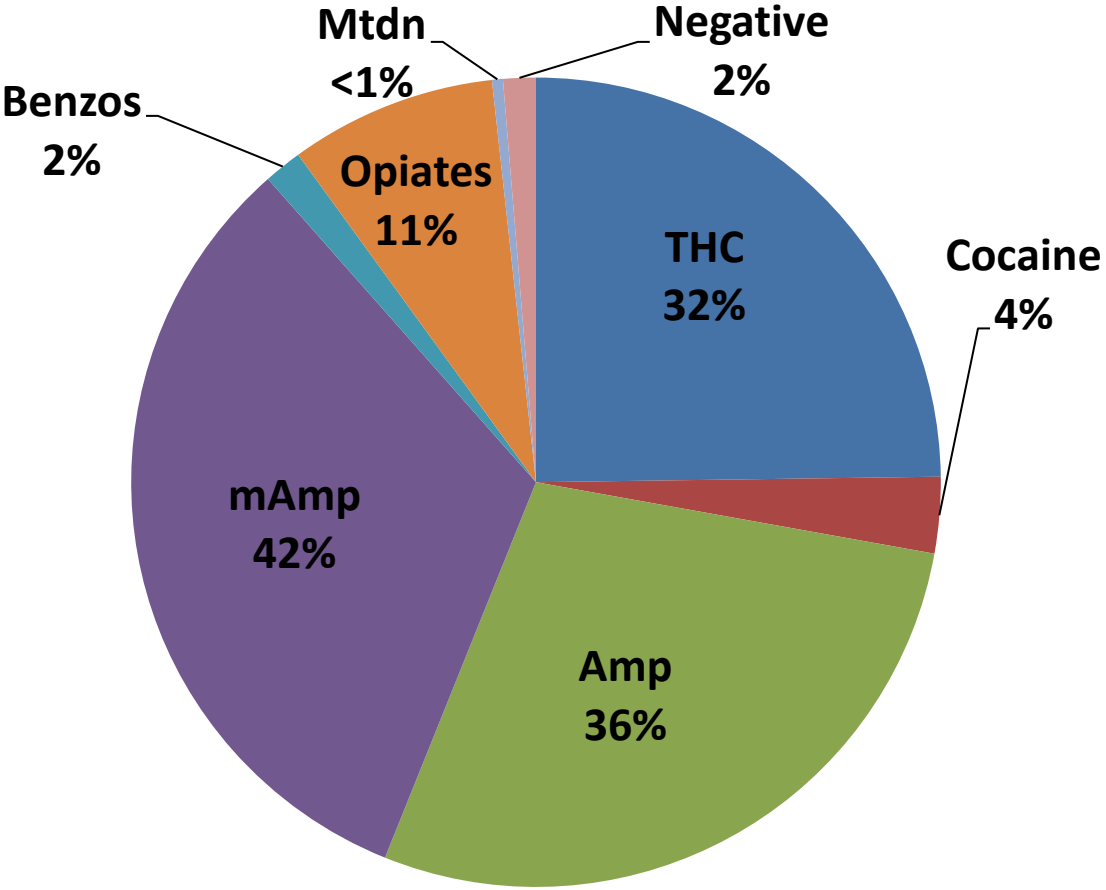
- Los Angeles and Kern Counties
 - 235 subjects

Dräger 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%	100.0%	99.1%	100.0%	99.1%
Amphetamine	42	7	2	184	85.7%	98.9%	96.2%	95.5%	96.3%
Methamphetamine	49	0	0	186	100.0%	100.0%	100.0%	100.0%	100.0%
Benzodiazepines	6	0	4	225	100.0%	98.3%	98.3%	60.0%	100.0%
Opiates	19	0	0	216	100.0%	100.0%	100.0%	100.0%	100.0%
Methadone	2	0	0	233	100.0%	100.0%	100.0%	0.0%	100.0%
Overall	211	10	8	1416	95.5%	99.4%	98.9%	96.3%	99.3%

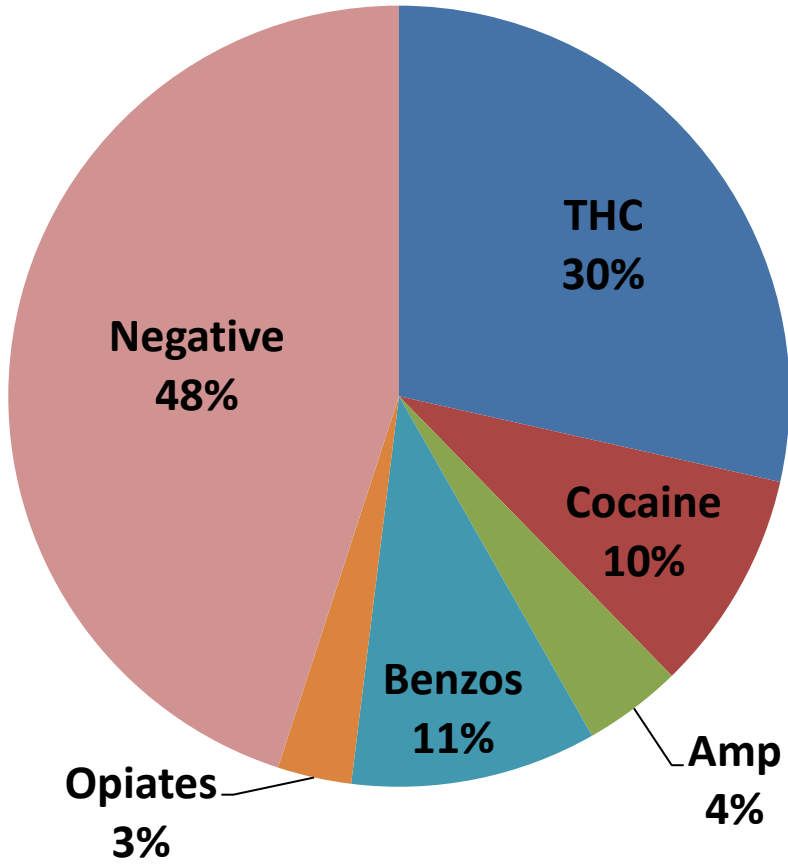
Positivity Rates

- A total of 357 subjects participated in the study
 - 351 of the 357 subjects were confirmed positive for one or more analytes within the scope of the confirmatory method
 - 98% of subjects were positive for at least one drug
 - Does not include results for alcohol

Population Distribution of Analytical Findings



California (n=357)



Miami (n=92)

Sensitivity Comparison

- **Sensitivity** – proportion of subjects who subsequently test positive in a confirmatory test whose positive status was correctly predicted by the field test

THC Sensitivity

	Prevalence	DDT5000	AlereDDS2	DrugWipe
Miami	30.0%	58.3%	----	43.6%
California	32.0%	98.8%	97.0%	-----

Cocaine Sensitivity

	Prevalence	DDT5000	AlereDDS2	DrugWipe
Miami	10.0%	88.9%	----	90.0%
California	5.0%	84.6%	60.0%	----

Positive Predictive Value Comparison

- **Positive Predictive Value** – proportion of subjects whose field test correctly predicted they would test positive in the confirmatory test

THC PPV

	Prevalence	DDT5000	AlereDDS2	DrugWipe
Miami	30.0%	93.3%	----	66.7%
California	32.0%	97.0%	97.6%	-----

Cocaine PPV

	Prevalence	DDT5000	AlereDDS2	DrugWipe
Miami	10%	100%	----	64.3%
California	5.0%	100%	100%	----

Benzodiazepines

- Miami: 6 subjects failed to test positive in the field, but were confirmed in the laboratory
 - 4 Alprazolam and 2 Lorazepam
- California: both the Alere DDS2 and DDT5000 successfully detected benzodiazepines in the field
 - DDT5000: 6 subjects positive in the field
 - Confirmatory Results: 5 Alprazolam cases, 1 Lorazepam
 - 4 false positive results
 - Alere DDS2: 1 subject positive in the field
 - Confirmatory Results: Alprazolam and Lorazepam

Conclusions

- Excellent sensitivity, specificity, and accuracy
 - Met DRUID guidelines ($\geq 90\%$ sensitivity and specificity and $\geq 95\%$ accuracy)
- Regional differences in drug detection
 - LA: THC
 - Kern, Orange, and Sacramento: Amp/mAmp
- Single drug vs. Poly drug use
- Using oral fluid in prosecution
 - All cases have pled out

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Questions?

mmohr@frfoundation.org