ORAL FLUID AS A CHEMICAL TEST FOR THE DRE PROGRAM: HISTORY, THE FUTURE, AND PRACTICAL CONSIDERATIONS

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NMS Labs and Dräger Safety Diagnostics have created a partnership to develop and market oral fluid tests for the DRE marketplace.
Current Options in Drug Testing
Drug Testing: Current Approaches

- **Urine**
  - Less invasive sample collection.
  - Some on-site testing capability.
  - Broad detection time window.
  - Targeting metabolites for detection.
  - No relationship to brain concentrations.
  - No relationship between urine concentration and effect.
  - Time delay for collection.
Drug Testing: Current Approaches

Blood

- Closest relationship to brain concentrations.
- Targeting parent drug for detection.
- Large literature for comparative interpretation.
- Somewhat invasive collection.
- Limited detection window.
- Time delay for collection.
- Lack of strict quantitative/qualitative effect relationship.
- No on-site testing capability.
Drug Testing: Current Approaches

**Oral Fluid**

- Least invasive collection.
- No time delay for collection.
- Targeting parent drug for detection.
- Potential for on-site testing capability.
- Limited relationship to blood concentrations.
- No relationship between OF concentration and effect.
- Limited detection window.
- Limited specimen volume.
- Workplace considerations.
Drugs in Oral Fluid
Oral Fluid

- Saliva 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.
Cocaine in Oral Fluid

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

Cocaine

Benzoylcegonine

Ecgonine methyl ester

(µg/L)

Hours

Courtesy, Marilyn Huestis, NIDA
THC in Oral Fluid

3.55% THC GC-MS

Oral Fluid
Plasma

ng/mL or ng/mg vs. Hours

Courtesy, Marilyn Huestis, NIDA
Methamphetamine in Oral Fluid

- Oral fluid (cutoffs 50 Meth/2.5 Amp)
- Urine (cutoffs 500Meth/200 Amp)

Courtesy, Marilyn Huestis, NIDA
History of OF Drug Testing
History of OF Drug Testing

- 2002  ROSITA II contract signed (www.rosita.org).
- 2004  Australian states begin random roadside oral fluid testing.
- 2005  ROSITA II report issued.
  - Not ready for forensic implementation
  - Limited sensitivity
  - Operator dependent
  - Poor QC in manufacturing
History of OF Drug Testing

- 2006   DRUID Project begins
- 2009 “ESTHER” report issued.
  - Evaluation of oral fluid Screening devices by TISPOL to Harmonise European police Requirements.
  - 16 Devices evaluated
  - Technology has improved and devices are being evaluated in roadside surveys through DRUID project.
DUID Oral Fluid Use

Belgium: saliva screening, blood/saliva confirmation

France: saliva screening, blood confirmation

UK: FST, blood sampling; no device being used

Switzerland: Approved for use

Germany: saliva/urine testing, blood confirmation

Australia: saliva screening (2x), saliva confirmation
Drug Testing Around the World

- **Australia** (THC, Meth, MDMA)
  - Almost 90,000 drivers tested in Victoria
    - small vehicles: Positive rate 1:65 (all 3 drugs)
    - large vehicles: Positive rate 1:47 (mainly meth.)
  - The rate has come down from 1:40 in the first 2 years.
  - This compares to alcohol positive rate of 1:100 for same driver cohort
  - False positive rate: 1% - very low since two screening devices are used
  - Aimed at deterrence, not impairment
Drug Testing Around the World

**Belgium** (THC, Amps, MDMA, Benzos, cocaine, opiates)

Since October 2010:
- Drivers stopped by the police (not randomly selected)
- Indication of recent drug use: oral fluid on-site screening test
- Screen Positive: blood sampling, later oral fluid sampling for confirmation analysis
- Faster procedure (no test battery, no doctor needed)
- Judicial authority: less false positives; therefore more cost effective
- OF sampling more user-friendly
DUID Oral Fluid Use

United States: OF Specifically Approved in:
- Alabama
- Arizona
- Colorado
- Indiana
- Kansas
- Louisiana
- Missouri
- New York
- North Carolina
- North Dakota
- Ohio
- Oregon
- South Dakota
- Utah

Canada: OF Approved in Federal Legislation

North Dakota

Utah
SAMHSA Proposes Oral Fluid Workplace Testing.

Federal Register Volume 76, Number 112

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• What analytes should be measured in oral fluid for the initial and confirmatory tests?

• What initial and confirmation cutoffs should be used for the oral fluid drug tests?

• Should the oral fluid drug testing panel be expanded to include schedule II prescription medications?

• Specimen Validity, Collection, Collection Devices, Technologies
2007 US National Roadside Survey

- Conducted in Fall 2007
- 7000 drivers at 63 sites
- 6000 Oral Fluid Samples
- 3000 Blood samples
- Tested for therapeutic and abused drugs
- Preliminary results July 2009
Sample Collection

- **Blood**: Gray-topped tube
  - Approximately 3,276 samples (all night-time)

- **Oral fluid**: Quantisal™ collection device:
  - 1 mL of oral fluid collected (+-10%)
  - 3 mL stabilization buffer
  - Day-time: 1,850
  - Night-time: 5,869
2007 US NRS Scope

- Cocaine
- Marijuana
- Opiates
  - Codeine, morphine, hydrocodone, hydromorphone, 6-AM, 6-AC
- Amphetamines
  - AMP, METH, MDMA, MDA, MDEA, phentermine, pseudoephedrine, phenylpropanolamine
- Benzodiazepines
  - oxazepam, nordiazepam,
  - lorazepam, bromazepam,
  - temazepam, diazepam,
  - alprazolam, triazolam,
  - chlordiazepoxide, nitrazepam,
  - nordiazepam, clonazepam,
  - flurazepam, flunitrazepam
- Tramadol
- Methadone
- Fluoxetine
- Sertraline
- Phencyclidine
- Barbiturates
- TCA’s
  - Amitriptyline, nortriptyline
  - imipramine, desipramine
- Zolpidem
- Carisoprodol
- Methylphenidate
- Oxycodone / Oxymorphone
- Meperidine
- Propoxyphene
- Dextromethorphan
- Ketamine
2007 National Roadside Survey

- 2.2% of randomly tested drivers positive for alcohol >0.08g/100mL
- 16.3% positive for drugs other than alcohol.
  - #1 Marijuana – 6.8%
  - #2 Cocaine – 3.9%
  - #3 OTC Drugs 3.9%
  - #4 Methamphetamine 1.3%
### 2007 National Roadside Survey

<table>
<thead>
<tr>
<th>Drug</th>
<th>Positivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>THC</td>
<td>8.65%</td>
</tr>
<tr>
<td>Cocaine</td>
<td>3.92%</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>0.68%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>0.82%</td>
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<tr>
<td>Alprazolam</td>
<td>0.64%</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>0.84%</td>
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<tr>
<td>Sertraline</td>
<td>0.50%</td>
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<tr>
<td>Propoxyphene</td>
<td>0.52%</td>
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<tr>
<td>Tramadol</td>
<td>0.46%</td>
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<tr>
<td>Diazepam</td>
<td>0.38%</td>
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<tr>
<td>Amphetamine</td>
<td>0.45%</td>
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<tr>
<td>Fluoxetine</td>
<td>0.37%</td>
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<tr>
<td>Phentermine</td>
<td>0.26%</td>
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<tr>
<td>Dextromethorphan</td>
<td>0.22%</td>
</tr>
<tr>
<td>Methadone</td>
<td>0.19%</td>
</tr>
</tbody>
</table>

### Nighttime Positivity – Blood and Oral Fluid

- 2.2% of randomly tested drivers positive for alcohol >0.08g/100mL
- 16.3% positive for drugs other than alcohol.
Agreement between paired samples:

- Overall, 5,869 oral fluid samples (OF) and 3,276 blood samples were collected from night-time drivers.
- Of the paired specimens, 559 pairs showed at least one matrix as drug positive; 326 pairs were positive in both matrices.
- In 129 cases, OF was negative with a corresponding positive blood.
- In 104 cases, the blood was negative with a corresponding positive OF.
- A breakdown shows blood to be superior to OF for sertraline, phentermine and benzodiazepine analysis;
- OF was superior for cocaine as well as several pain medications.
- THC was found in oral fluid but not blood in 72 cases (although 43 of the bloods had THC-COOH present).
Implementing OF Testing
Making OF Testing work for DRE

- Reliable Roadside/Portable Test
  - Targeted to DRE priority drugs
  - Robust
  - Rapid training curve
  - Sensitive
  - Non-subjective
  - Documentable
Making OF Testing work for DRE

- Sample Collection Storage and Shipping
  - QC of manufactured devices
  - Consistent volume
  - Capacity indicator
  - Stimulated vs non-stimulated
  - Differential blood to plasma ratios
  - Variability of Oral Fluid
  - Should be ambient temp. stable
Making OF Testing work for DRE

- Forensic Laboratory Confirmation
  - Integrated with screen wrt scope and sensitivity
  - Validated for collection devices
    - Recovery
    - Stability
    - Interference
    - Matrix matching
  - Works well with limited sample volume
  - Forensic chain of custody
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.
- Adoption requires management support and buy in from prosecutors.