RAPID ORAL FLUID MOBILE DRUG TEST SYSTEM

Alere™ DDS®2

Overview and User Experience.

Better information. Better decisions.

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Recent roadside surveys

- 2007: Full scale National Roadside Survey
  - Biological specimens were collected for the first time
  - Blood and oral fluid
- 2010: Crash Risk Study (Blood and oral fluid)
- 2010: California Study -1 (Oral fluid)
- 2012: California Study -2 (Oral fluid)
- 2013: National Roadside Survey (Blood and oral fluid)
Drivers randomly stopped at different locations in the USA primarily during night-time hours

Not suspected of impaired driving

Asked to consent to:
- Survey / questionnaire
- Breath alcohol test
- Oral fluid sample collection and/or
- Blood sample collection

Why? Opportunity to compare oral fluid results to blood
Why oral fluid?

- Oral fluid concentrations reflect blood levels to some extent
- Easy, rapid, non-invasive, observed collection
- Collected proximate to traffic stop
- Difficult to adulterate
- Detection of parent drug (rather than metabolites) may indicate recent intake and the individual is likely to be feeling drug effects
Sample collection

Blood: Gray-topped tube
- 2007: 3,276 samples
- 2013: 4,841 samples

Oral fluid: Quantisal™ collection device:
- 1 mL of oral fluid collected (+-10%)
- 2007: 7,719 samples
- 2013: 8,031 samples

All specimens sent to laboratory for testing – NOT ROADSIDE TESTS
Results: paired specimens, 2007

3,276 pairs of samples
326 pairs: positive in both matrices

Of the 326 pairs:
- 75.7% exact drug match across all classes
- 21.4% had at least one drug class match
- 97.1% correlation rate for paired specimens

Conclusion:
- Oral fluid analysis provides similar information to blood regarding drug intake
2007 & 2013 drug testing profile

- Amphetamines
- Barbiturates (5)
- Benzodiazepines (14)
- Carisoprodol
- Cocaine
- Dextromethorphan
- Fluoxetine
- Ketamine
- Marijuana
- Meperidine
- Methadone
- Methylphenidate
- Opiates
- Oxycodone / Oxymorphone
- Phencyclidine
- Propoxyphene
- Sertraline
- TCA’s (19)
- Tramadol
- Zolpidem

Added in 2013:
- Buprenorphine
- Diphenhydramine
- Fentanyl
- Synthetic cannabinoids
- Additional antidepressants
- Muscle relaxants
Five classes account for >90% of positives

- THC
- COC
- Opioids
- Sedatives
- AMPS

2007 NRS
2010 CA Study
2012 CA Study
Overview

- Oral fluid gives similar information to blood regarding drug intake
- Problem of drugged driving is extensive but not overwhelming
- Vast majority of drugged driving is related to:
  - Cannabis
  - Cocaine
  - Pain medications (particularly opioids)
  - Sedatives (particularly benzodiazepines)
  - Amphetamines
So, to the future...

- Oral fluid is easily and rapidly collected proximate to traffic stop
- Time saving for officers
- But, laboratory based analysis – not a roadside test
- What about testing at the roadside?
- A drug result within a few minutes could be helpful
Alere DDS®2 mobile test system
Latest technology

- Handheld mobile drug testing device for oral fluid analysis
- Rapid results
- Assisting and empowering law enforcement
- Presumptive positives **must** be confirmed with a second specimen
  - Quantisal™ oral fluid collection device is preferred
## DDS2-403 – 6 Panel: OPI/COC/AMP/MAMP/THC/BZO

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Cut-off (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>50</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>20</td>
</tr>
<tr>
<td>Cannabis</td>
<td>25</td>
</tr>
<tr>
<td>Cocaine</td>
<td>20</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>50</td>
</tr>
<tr>
<td>Opiates</td>
<td>40</td>
</tr>
</tbody>
</table>

403 panel for roadside application
Running a test

When prompted by the analyser screen, insert the test cartridge.

The analyser will check that the cartridge is valid.

⚠️ Make sure to keep the analyser horizontal and still at all times.

Ask the donor to unwrap a new Alere™ DDS®2 Oral Fluid Collection Device from the packaging.

Ensure that they hold the collection device by the plastic stem, and then place it in the mouth.

The sample donor must actively swab the collection device around gums, tongue and inside the cheek.
Continue swabbing until the sample presence indicator turns completely blue.

Insert the **collection device** into the **test cartridge** (in the analyser). Gently push all the way into the cartridge to the **stop position**.

The analyser will now test the sample. The test time will be displayed on the screen. Make sure to keep the analyser **horizontal** and **still** at all times.
The results will be displayed on the analyser screen.
If it has been enabled, a donor questionnaire will begin after pressing 'OK'.

If required, the results can be printed.
Please ensure that the printer is connected to the analyser and has been switched on before printing.
To skip this step press 'NO'.

The test cartridge and collection device can now be removed from the analyser.*
Do not remove the test cartridge by pulling the collection device and do not attempt to remove the collection device from the test cartridge.
User experience

- 2012: Gardena, CA
- 2013: Tulsa, OK
- 2014:
  - Ultra-Fest, Miami, FL
  - DRE Training, Jacksonville, FL
  - Fullerton PD, CA
2012: Gardena, CA

- 50 drivers asked for additional oral fluid specimen
- Analyzed on-site using the DDS®2 mobile test system
- 5 minutes to run after sample collection
- No manufacturer representative present
- Laboratory blinded to on-site results until Quantisal™ confirmation had been reported
### Results

<table>
<thead>
<tr>
<th>DDS®2 result</th>
<th>Corresponding Quantisal™ confirmation result (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>32</td>
</tr>
<tr>
<td>Positive</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>6</td>
</tr>
<tr>
<td>THC</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>THC 5</td>
</tr>
<tr>
<td></td>
<td>THC 10</td>
</tr>
<tr>
<td></td>
<td>THC 10</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Amphetamine 86; Methamphetamine 2255</td>
</tr>
</tbody>
</table>

15.7% positivity rate for on-site rapid test
100% correlation with laboratory results
Caveats…

- Preliminary results only
- Fifty drivers agreed to donate oral fluid after the Quantisal™ collection
- Some flow errors due to specimen being collected after the subject had already supplied oral fluid
- Outcome:
  - **Barcode errors – resolved**
  - **New software iteration**
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)
New software for DDS®2 screen
Objective:
- To determine whether a roadside oral testing device can 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)
- DDS®2 oral fluid test:
  - non-evidentiary
- Blood and/or urine collected as per Tulsa protocol:
  - for evidential purposes
Outcome

DDS®2 results mostly correlated with DRE observations, laboratory screening and LC-MS/MS confirmatory tests

- Roadside test can serve as a preliminary screen to aid police officers in DUID evaluation

Oral fluid analysis provided reliable results

- Oral fluid is a valid specimen for collection and roadside testing

Results very encouraging
Urine, blood and oral fluid

- Quantisal™ and DDS®2 where possible

Specimens confirmed at NMS Labs, PA

- 146 DDS®2 results
- 36 positive cartridges
- 48 positive results
Positive screens: Ultra-Fest, Miami, FL
Device operation training provided

Practical feedback:

- “The 2 days went well and the devices functioned very well
- ..... ease of use was impressive to the officers who utilized them”
Fullerton PD

- Device operation training provided
- 64 DDS®2 results:
  - 59 positive for METH/AMP
  - 10 positive for Opiates
  - 9 positive for THC
  - 1 positive for COC
  - In all cases the officer suspected corresponding drug
- 2 negative results: Officer suspected THC
Summary

- Handheld drug testing device for analysis of oral fluid
- Easy sample collection
- Rapid results
- Controls included
- Presumptive positives must be confirmed with a second specimen
  - Quantisal™ oral fluid device is preferred
  - Blood is optional
- DDS®2 and Quantisal™ training programs can be provided
Drug testing as easy as A, B, C

Alere™ DDS®2

For additional information or assistance with this device email us at toxicology@alere.com

aleretoxicology.com

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