



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)



# Methodology

- 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

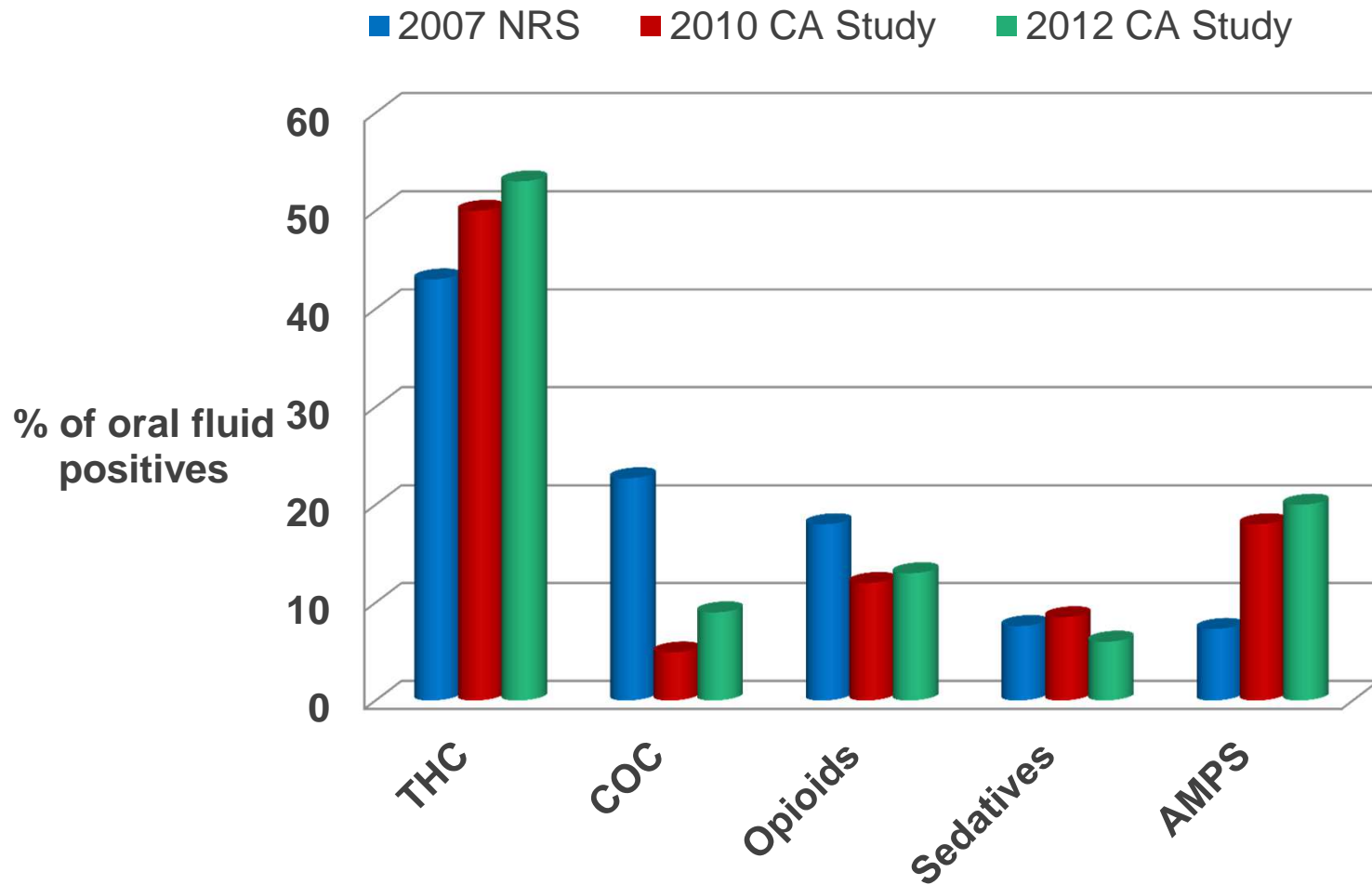


## 2007 & 2013 drug testing profile

- 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







# 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<sup>®</sup>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



# Test cartridges

DDS2-403 – 6 Panel: OPI/COC/AMP/MAMP/THC/BZO

Drug class	Cut-off (ng/mL)
Amphetamine	50
Benzodiazepines	20
Cannabis	25
Cocaine	20
Methamphetamine	50
Opiates	40

403 panel for roadside application



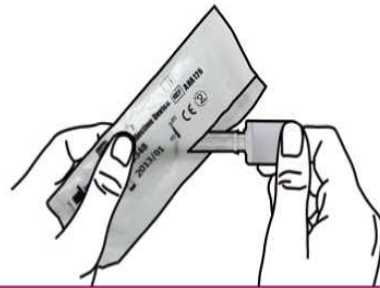
## Running a test



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

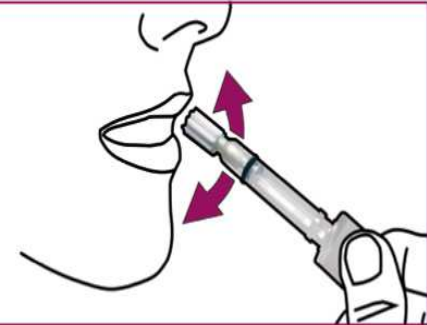
The analyser will check that the cartridge is valid.

 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.

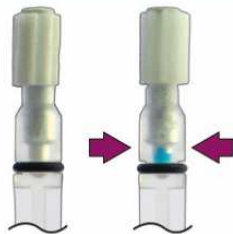
Ensure that they hold the collection device by the plastic stem, and then place it in the mouth.



The sample donor must actively swab the collection device around **gums**, **tongue** and **inside the cheek**.



## Running a test *(continued)*



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.

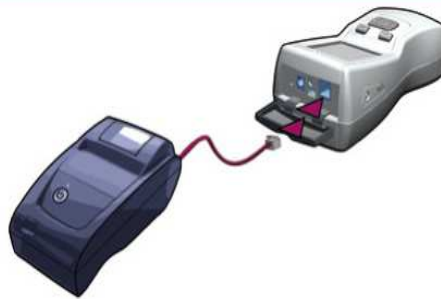


## Running a test *(continued)*

OPI	NEGATIVE
COC	POSITIVE
AMP	NEGATIVE
MAMP	NEGATIVE
THC	NEGATIVE

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<sup>®</sup>2 mobile test system
- 5 minutes to run after sample collection
- No manufacturer representative present
- Laboratory blinded to on-site results until Quantisal<sup>™</sup> confirmation had been reported



# Results

	DDS <sup>®</sup> 2 result	Corresponding Quantisal <sup>™</sup> confirmation result (ng/mL)
Negative	32	32
Positive	6	6
THC	5	THC 5
		THC 10
		THC 10
		THC 33
		THC 288
Methamphetamine	1	Amphetamine 86; Methamphetamine 2255

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**

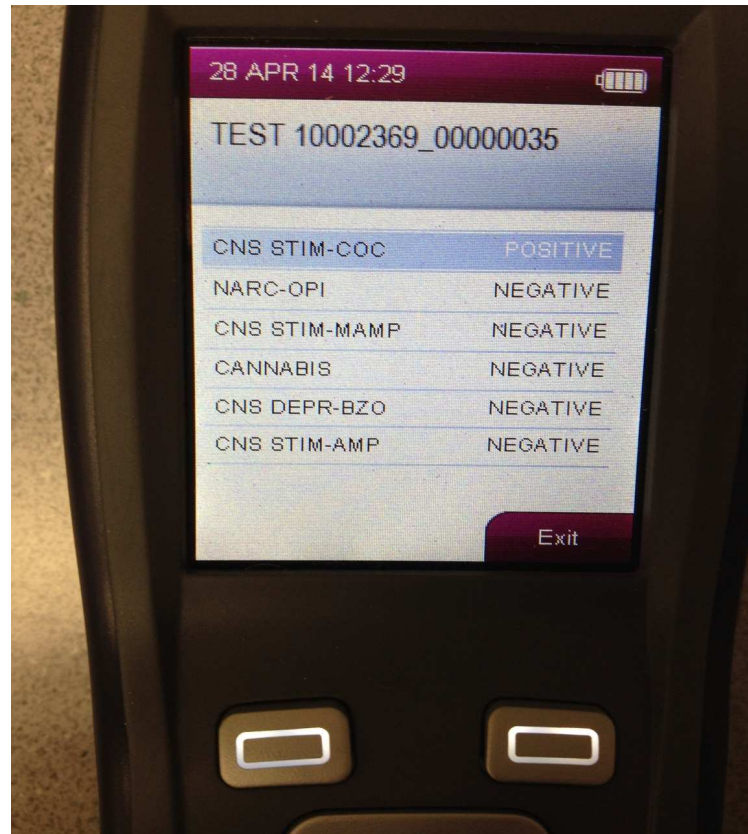


## Tulsa police department

- 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<sup>®</sup>2 screen





# Tulsa PD: drugged driving

## **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<sup>®</sup>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**





## Ultra-Fest, Miami, FL

### **Urine, blood and oral fluid**

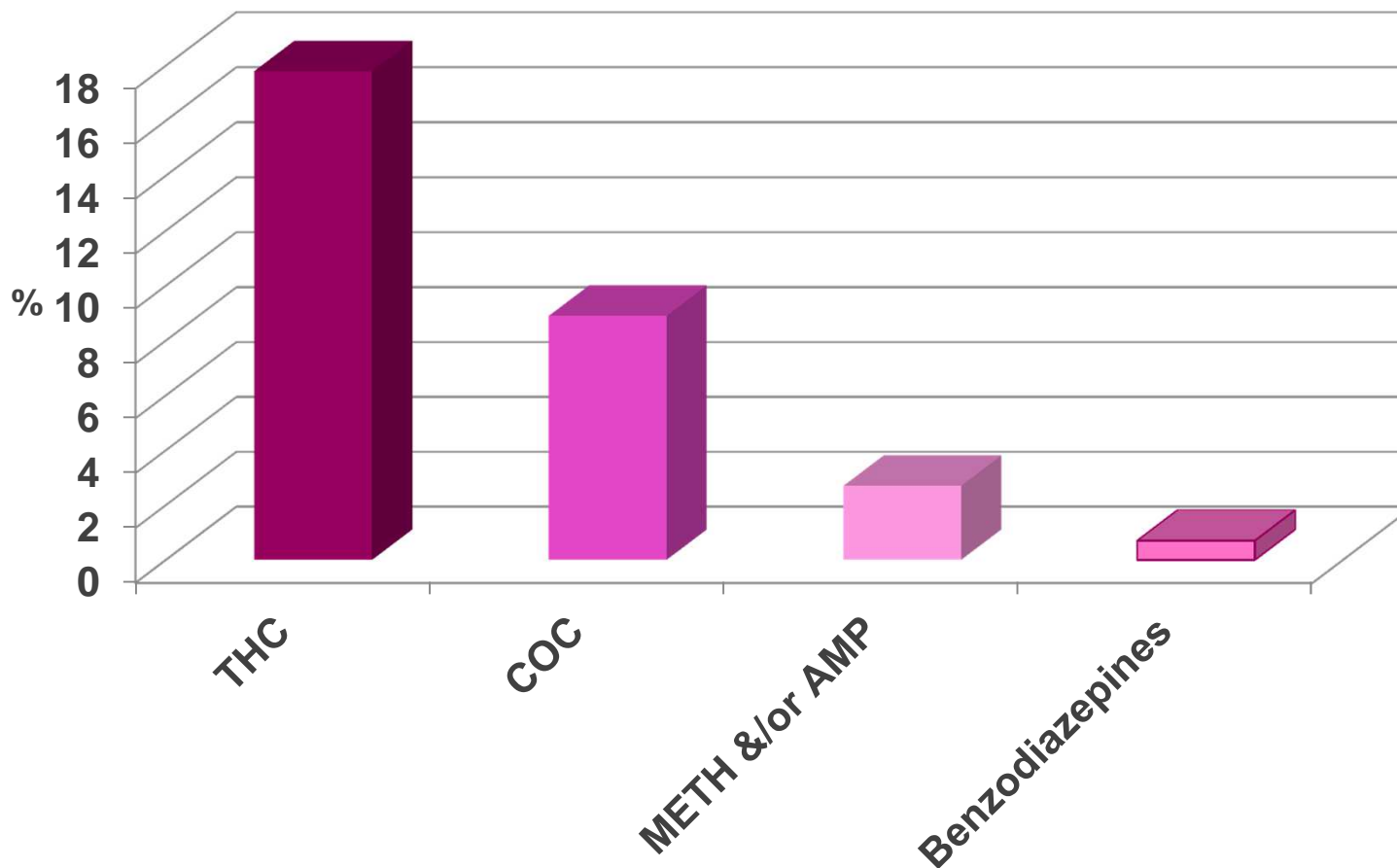
- Quantisal™ and DDS®2 where possible

### **Specimens confirmed at NMS Labs, PA**

- 146 DDS®2 results
- 36 positive cartridges
- 48 positive results



# Positive screens: Ultra-Fest, Miami, FL





# DRE training, Jacksonville, 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”



## CA OTS grants

### Fullerton PD

- Device operation training provided
- 64 DDS<sup>®</sup>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](mailto:toxicology@alere.com)



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