

**Oral Fluid Drug Testing Pilot Project Guidelines for DUI/D Investigations
(Version 2 - 09/18/20)**

SOFT/AAFS Oral Fluid Committee

Statement of Purpose

The Oral Fluid (OF) Pilot Project guidelines are intended to provide guidance to law enforcement and forensic toxicology laboratories interested in establishing OF field screening and/or laboratory confirmation programs.

Audience: The following guidelines are intended for toxicologists, Drug Recognition Experts (DRE) and law enforcement personnel, and other stakeholders who are interested in implementing an OF drug testing program in their state, county, or city.

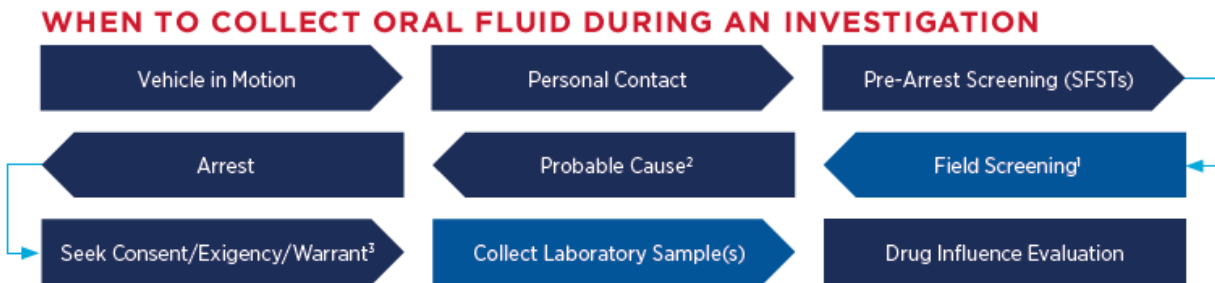
Objectives

1. To validate and implement an OF field screening device AND/OR
2. To validate and implement an OF laboratory confirmation program
3. If necessary, to provide data to facilitate legislation change to include the analysis of OF as a viable specimen for DUI/D investigations

Introduction

OF field screening and OF laboratory confirmation testing are two distinct entities. A program may choose to implement one or both aspects. The OF field screen should be conducted pre-arrest to establish probable cause and provide additional information to seek a search warrant for evidentiary sample collection (Figure 1). The OF field screen may not target all impairing substances present in a specific case, so it is important to follow the outlined steps in a DUI/D investigation and not rely solely on the OF field screen results.

Figure 1:



Reference: Using OF to Detect Drugs. AAA Infographics. 2020.

OF field screening device validation may be achieved via an in-house laboratory (i.e. must have validated OF confirmation methods) or through collaboration with a reference laboratory (e.g. Forensic Fluids, NMS Labs, Abbott). OF laboratory evidentiary confirmation testing is conducted post-arrest (Figure 1). Blood has historically been considered the “gold standard” for confirmation testing for the presence of alcohol and/or drugs in DUI/D cases. However, there is not a direct correlation between a blood drug

concentration and degree of impairment. In light of that, it is potentially beneficial to evaluate matrices, such as oral fluid, that require less invasive collection techniques and offer similar advantages to blood.

OF testing has several advantages for DUI/D cases including:

- Rapid, easy roadside collection and on-site analysis
- Detects recent drug use with a specimen collected proximate to the incident
- No medical personnel required for oral fluid collection
- Several major drug classes included in roadside test
- Portable, robust test systems
- No gender issues with observed collections

For more information on Frequently Asked Questions, please visit the SOFT Website at <https://www.soft-tox.org/oral-fluid-faq>.

For more information on the differences between roadside and confirmation testing, please see AAA OF Infographics document at <https://tinyurl.com/AAAOralFluidHandout>.

For more information on oral fluid testing status in different states, see SOFT OF survey results (e.g. states that allow OF testing per statute, saliva vs. OF in statutes).

It is recommended to involve the key stakeholders below when initiating a Pilot Project:

1. Toxicologist(s) (for scientific study design)
2. Laboratory Director
3. Traffic Safety Resource Prosecutors (TSRPs)
4. DRE Coordinator (and other DREs)
5. Law Enforcement Agency Representatives
6. District or Municipal Attorneys
7. State Impaired Driving Councils
8. Expert in the OF field screening device and confirmation collection device being evaluated (for training purposes)
9. Accredited Reference Toxicology Laboratory / Consultant toxicologists (if applicable)
10. Consult SOFT OF Committee (<http://www.soft-tox.org/oral-fluid-committee>)

Program Management

- A. Research state laws to determine if roadside and/or confirmation OF testing is permitted. (SOFT OF Annual survey, AAA OF Infographics document)
- B. Identify project coordinator in charge of collating results from the field and laboratory
- C. Determine scope of validation/project
 - a. OF field screening device validation only (must collaborate with Reference Toxicology lab to compare to OF confirmation testing)
 - b. OF field screening device and in-house laboratory OF confirmation
 - c. Make decision to validate single OF device or multiple devices
 - d. Establish inclusion/exclusion criteria for subject participation (e.g. presence or absence of ethanol)

- D. Identify key stakeholders
- E. Organize a training meeting to cover project protocols:
 - a. Discuss differences between OF field screening and confirmation
 - i. Advantages, disadvantages, and limitations
 - b. Scope of testing for both OF field screening and confirmation testing
 - i. OF testing does not include alcohol, must use state-approved test (e.g. breath or blood) if alcohol is suspected
 - ii. Consider NSC recommendations (Tier 1 and 2 compounds) when selecting OF confirmation methods
 - c. Demonstration of device operation and/or OF confirmation sample collection
 - i. Instrumented devices will print and/or retain result
 - ii. Non-instrumented (i.e. visually read) devices must have a mechanism by which the result can be retained (e.g. photograph)
 - iii. Volume adequacy indicator
 - d. Outline proposed study design and seek input from stakeholders
- F. Ensure personnel administering test and volunteers understand the legal aspects of the project as well as specimen testing and collection
- G. Obtain appropriate participant consent, IRB approval, and/or ethics committee approval (if applicable)
- H. Discuss and decide how results from the OF field screening test and subsequent confirmatory procedure will be retained and evaluated
- I. Discuss and decide on dissemination of results and how data can be utilized to achieve objectives
- J. Schedule a final meeting to discuss study results with stakeholders

Oral Fluid Program Protocol (Option #1 - Collecting samples from DUI/D arrests)

- a. Driver is stopped by police officer
- b. Standard procedures followed for DUI/D investigation (Figure 1)
- c. If a DRE is available, the DRE evaluation is performed and the opinion is documented
- d. Consent form is explained and provided to subject (Appendix 1)
 - i. Consent form is completed and consent is granted prior to proceeding
- e. Oral fluid sample is collected for the on-site test
 - i. Officer completes necessary paperwork/documentation
 - ii. Officer performs test (typically 5 – 8 min)
- f. Oral fluid sample is collected for the confirmation test
 - i. Officer completes necessary paperwork/documentation (chain-of – custody/requisition form)
 - ii. Samples submitted to the laboratory for analysis per laboratory guidelines (e.g. common carrier, hand-delivery)

Oral Fluid Program Protocol (Option #2 - Collecting samples from volunteer drug users [e.g. during DRE class field evaluations, may not be driving related])

- a. Consent form is explained and provided to subject (Appendix 1)
 - i. Consent form is completed and consent is granted prior to proceeding

- b. If a DRE is available, the DRE evaluation is performed and the opinion is documented
- c. Oral fluid sample is collected for the on-site test
 - i. Officer completes necessary paperwork/documentation
 - ii. Officer performs test (typically 5 – 8 min)
- d. Oral fluid sample is collected for the confirmation test
 - i. Officer completes necessary paperwork/documentation (chain-of – custody/requisition form)
 - ii. Samples submitted to the laboratory for analysis per laboratory guidelines (e.g. common carrier, hand-delivery)

Validation Parameters and Considerations

Oral Fluid Field Screening Device Validation*

- a) Selection of device(s) [e.g. OF device, cannabis breath device]
- b) Level of portability (best practice = roadside application for probable cause)
- c) Robustness (e.g. temperature, etc.)
- d) Selection of number of subjects (e.g. n=50-100)
- e) Establish minimum number of subjects per drug target (e.g. n=10)
- f) Determine collection site and time frame (e.g. in the field or volunteers)
- g) Determine laboratory to test confirmation samples (i.e. in-house with validated methods, reference laboratory)
- h) Evaluate the following by comparing roadside OF results to confirmation specimen (preferable OF, but blood as second option)
 - i) Sensitivity = $(TP/(TP+FN))$
 - ii) Specificity = $(TN/(TN+FP))$
 - iii) Overall Accuracy = $((TP+TN)/(TP+FP+FN+TN))$
 - iv) PPV = $((TP/(TP+FP))$
 - v) NPV = $((TN/(TN+FN))$
 - vi) False Positives
 - vii) False Negatives
- i) State limitations of study (e.g. low number of subjects evaluated for specific device target)

* Alternatively, rely on data from published studies depending on specific device (see references)

Oral Fluid Confirmation Validation

- a) Selection of Confirmation OF Device
 - i) Instructions for officers
 - ii) Training for officers
- b) Target & Cutoff Selection (Tier I & II)
 - i) NSC Recommendations
- c) Refer to ASB Validation guidelines for qualitative method validation (ANSI/ASB Standard 036)
 - i) Precision, LODs, Interference (matrix, drugs), Ion Suppression
 - ii) Options: LC/MS/MS, Q-TOF screen, ELISA
 - iii) Considerations: Separate cannabinoids with its own extraction, select 80-95% of most prevalent drugs in relevant geographical area

References:

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2. Barry K. Logan, Amanda L. A. Mohr, Stephen K. Talpins. “Detection and prevalence of drug use in arrested drivers using the Dräger Drug Test 5000 and Affiniton DrugWipe oral fluid drug screening devices.” *Journal of analytical toxicology* vol. 38,7 (2014): 444-50.
3. Hallvalrd Gjerde, Linn Gjersing, Havard Furugaugen, Anne Line Bretteville-Jensen. Correspondence between Oral Fluid Drug Test Results and Self-Reported Illicit Drug Use among Music Festival Attendees. *Subst Use Misuse*. 2019;54(8):1337-1344.
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5. Lorraine D. Edwards, Katherine L. Smith, Theodore Savage. “Drugged Driving in Wisconsin: Oral Fluid Versus Blood.” *Journal of analytical toxicology* vol. 41,6 (2017): 523-529.
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7. Barry K. Logan, Amanda L. D’Orazio, Amanda L.A. Mohr, Jennifer F. Limoges, Amy K. Miles, Colleen E. Scarneo, Sarah Kerrigan, Laura J. Liddicoat, Karen S. Scott, Marilyn A. Huestis. “Recommendations for Toxicological Investigation of Drug-Impaired Driving and Motor Vehicle Fatalities—2017 Update” *Journal of analytical toxicology* vol 42,2 (2018): 63-68.
8. AAA Infographic. 1st Edition. Curt Harper, Jennifer Knudsen, Bill Lindsey, Christine Moore. “Using Oral Fluid to Detect Drugs” (2020). <http://tinyurl.com/AAAOralFluidHandout>
9. ANSI/ASB Standard 036 “Standard Practices for Method Validation in Forensic Toxicology” (2019).
10. SOFT Oral Fluid Committee. “Oral Fluid Frequently Asked Questions” (2018). <http://www.soft-tox.org/oral-fluid-faq>
11. SOFT Annual Conference Oral Fluid Annual Surveys, 2018-2020.

APPENDIX 1 - Consent Form Example #1:

CONSENT FORM: DUI/D ORAL FLUID STUDY

The _____ Police Department's Impaired Driving Task Force / Traffic Safety Squad is participating in a research study that will examine the prevalence and/or effects of drugs on impaired drivers.

You are being asked to participate in this study. PARTICIPATION IS ENTIRELY VOLUNTARY. Your participation will neither help nor hurt you with your case. If you decide to participate, you will be asked to provide two oral fluid samples.

THE RESULTS OF THESE TESTS WILL NOT BE USED AGAINST YOU IN A COURT OF LAW AND ARE BEING COLLECTED ENTIRELY FOR EMPIRICAL DATA FOR A RESEARCH STUDY.

_____ YES - I hereby consent to and authorize the collection of two oral fluid samples from me for analysis and use in a research study described above.

_____ NO - I do not wish to participate in this study.

If you agree to participate, you must read and acknowledge the information below by completing the required fields:

I indemnify and hold the researchers conducting this study and _____ its employees, agents and servants harmless for all liability, loss or damage due to my participation in this voluntary research study from any and all acts, including negligent acts or omissions of any officer, employee, agent of _____.

I further agree to waive all rights and claims for damages, legal or equitable, arising out of any negligent act or omission by any officer, employee, agent or servant of _____ and the researchers resulting directly or indirectly from my participation in this study.

Participant's Name

Witness Signature

Date

Participant's Signature

APPENDIX 2 - Consent Form Example #2:

CONSENT FORM

XXXXXX COUNTY ORAL FLUID PROJECT

The _____ (police agency) is participating in a pilot project that will examine the prevalence and/or effects of drugs on drivers. The purpose of this project is simply to collect information and provide data to assist in exploring potential changes in Wisconsin law to allow for analysis of oral fluid as viable evidence in OWI cases.

You are being asked to participate in this project. **PARTICIPATION IS ENTIRELY VOLUNTARILY.** Your participation will not help or hurt your case in any way. If you decide to participate, you will be asked to provide oral fluid samples.

THE RESULTS OF THESE TESTS CAN NOT BE USED AGAINST YOU IN COURT AND ARE BEING COLLECTED SOLELY FOR THE PURPOSE OF GATHERING EMPIRICAL DATA FOR A PILOT PROJECT.

_____ **YES** – I consent to and authorize the collection of oral fluid samples for analysis and use in a pilot as described above.

_____ **NO** – I do not wish to participate.

If you agree to participate, you must read the information below and sign your name in the space provided:

I indemnify and hold the individuals conducting this project and this law enforcement agency's employees, agents, and servants harmless for all liability, loss or damage due to my participation in this voluntary pilot project from any and all acts, including negligent acts or omissions of any officer, employee, and agent of this law enforcement agency.

I further agree to waive all rights and claims for damages, legal or equitable, arising out of any negligent act or omission by any officer, employee, agent or servant of this law enforcement agency and the individuals resulting directly or indirectly from my participation in this project.

Participant's Name

Witness Signature

Date

Participant's Signature

Date