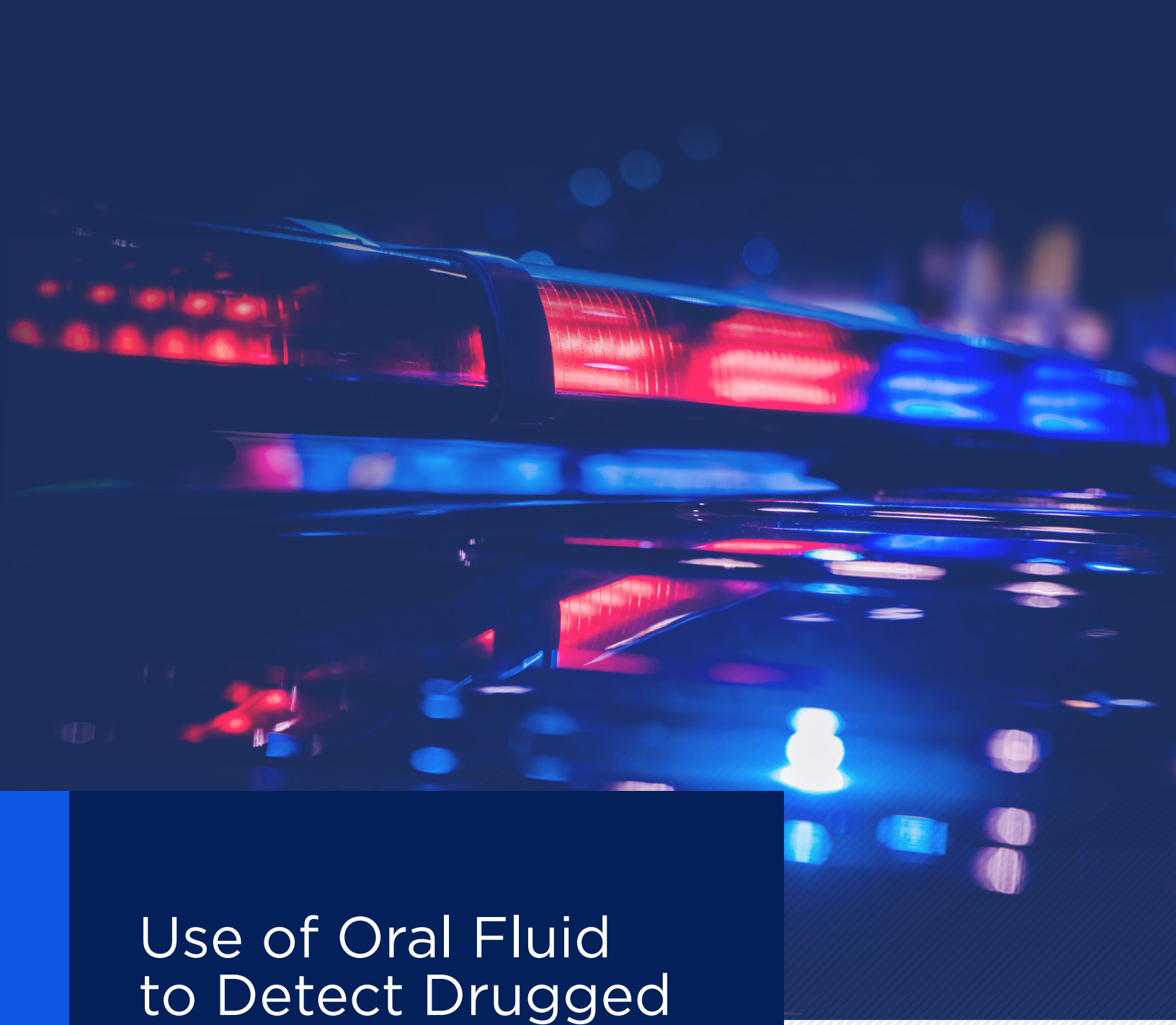

Use of Oral Fluid to Detect Drugged Drivers: A Toolkit

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Part I: Background

Scope of the Problem

Driving impaired by any drug, including alcohol, is illegal in all 50 states and the District of Columbia. This is true regardless of the legal status of a drug for use medically (e.g., prescription and over-the-counter medications, cannabis in some states) or recreationally (e.g., alcohol, cannabis in some states).

National data relative to drugged driving in the United States is incomplete making it difficult to accurately quantify the magnitude and scope of the problem. Presently, the best available data sources on drugged driving are outlined in the table below. Together, these data suggest that driving under the influence of drugs is an escalating public health and safety challenge in the U.S. that needs to be addressed. Results also suggest higher rates of drug use among drivers during the COVID-19 pandemic as compared to before it began.

Table 1. Data Sources on Drugged Driving

Data Source	Key Findings	Limitations
National Survey on Drug Use and Health **(Substance Abuse and Mental Health Services Administration)**	During 2018, approximately 12 million (4.7%) U.S. residents aged ≥16 years reported driving under the influence of marijuana and 2.3 million (0.9%) reported driving under the influence of other illicit drugs during the past 12 months (Azofeifa et al., 2019).	These are self-reported data and subject to several forms of bias, namely recall bias and response bias.
Fatality Analysis Reporting System **(Governors Highway Safety Association)**	Nearly 28% of drivers with known drug test results were drug-positive in 2006 as compared to nearly 44% in 2016 (Hedlund, 2018).	Note that only about half of fatally injured drivers have known drug test results captured in FARS. Further, not all states test drivers in fatal crashes at the same rate, nor do states use consistent testing methods or test for the same set of drugs. Results of data analyses using these data must be interpreted with caution.
National Roadside Study of Alcohol and Drug Use by Drivers **(National Highway Traffic Safety Administration)**	Total drug-positive nighttime driving increased significantly, from 16.3% in 2007 to 20.1% in 2013–2014. The prevalence of THC-positive drivers increased from 8.7% in 2007 to 12.7% in 2013–2014, an increase of 46% (Kelley-Baker et al., 2017).	This study estimated drug prevalence, not drug impairment, among a random sample of drivers on public roadways. Conclusions about impaired driving cannot be made from these data.
Data from Trauma Centers and Medical Examiner Offices **(National Highway Traffic Safety Administration)**	Drivers in serious or fatal accidents showed significantly higher overall drug prevalence during the public health emergency with nearly 65% of U.S. drivers testing positive for at least one active drug during the COVID-19 pandemic as compared to nearly 51% beforehand (Thomas et al., 2020).	These data represent a convenience sample only. Results cannot be generalized to reflect national trends.

Mitigation of drugged driving through state policies and law enforcement practices traditionally used to curb alcohol-impaired driving is a complex task. This is especially true given the inability to correlate degrees of impairment or crash risk with the presence or concentration of a particular drug, or drug combination. In short, the result of a roadside drug screen or laboratory drug test on its own cannot prove driver impairment to any degree.

Use of oral fluid to detect drugs among impaired driving suspects is an important topic because it offers a less invasive way to collect more accurate and timely evidence of recent drug use by individuals suspected of impaired driving. Despite the benefits of using oral fluid for this purpose, it is imperative that state policymakers and members of the criminal justice system gain a firm understanding of the strengths and limitations of using it for roadside screening versus laboratory testing, as well as the risks of its improper use. The purpose of this toolkit is to aid in well-informed decision making at state and local levels.

Audience

The implementation of an oral fluid drug screening or testing program should be a collaborative process involving multiple stakeholders within the administrative and criminal justice systems. This ensures that different perspectives are taken into account and important considerations of each system facet are addressed. An isolated approach limits success and has the potential to lead to unnecessary challenges or issues that could otherwise be easily resolved. This toolkit was designed with a collaborative approach in mind and provides guidance and key considerations to each of the primary stakeholder groups who must be consulted when exploring the possible initiation of an oral fluid program. These stakeholders include law enforcement, toxicologists, and prosecutors. In addition to this core group, we recommend that broader outreach and consultation involve a variety of stakeholders who are identified within the toolkit.

Law Enforcement

Law enforcement agencies and officers are the entities responsible for collecting oral fluid samples (both screening and confirmatory) and are frequently involved with the selection of instruments and overseeing the deployment of this technology in the field. For this audience, we include information about available tools, how to properly use them, and discuss limitations of the devices. Law enforcement can utilize these testing devices in a similar fashion as they would a Preliminary Breath Test (PBT) for alcohol. The field results, which are available in less than 10 minutes, can assist in the determination of probable cause for arrest during an impairment investigation and can be included as probable cause when applying for a search warrant to collect another oral fluid sample and blood sample to send to a laboratory for confirmatory testing.

A multitude of oral fluid field screening (OFFS) devices are available; therefore, law enforcement and laboratory personnel must take a variety of factors into consideration when determining which devices to approve and use in the field. These considerations are outlined in the toolkit and should serve as a starting point for discussion. As with other forms of technology, there is a range in device quality on the market. Agencies tasked with reviewing available options should ensure that devices selected for use in the field meet certain criteria and have high performance standards.

Over the past few years, various police departments, in conjunction with State Highway Safety Offices (SHSOs) and other stakeholders, have collaborated on projects involving screening oral fluid in the field. These pilot projects have been initiated for several purposes but have largely been conducted to collect data and evaluate whether the technology is reliable and accurate. Many agencies view oral fluid testing as an attractive option in drug-impaired driving investigations due to the ease of specimen collection proximate to the time of the traffic stop. The rapid metabolism and dissipation of specific drugs prior to blood collection is a significant challenge in impaired driving investigations. Pilot programs have been implemented to determine whether oral fluid technology can assist agencies in overcoming the known issues that arise with delays in collecting blood draws from suspected impaired drivers.

When considering what OFFS device to select, law enforcement commonly prioritizes the following:

- Speed of sample collection and analysis
- Drug classes included in the test panel
- Instrumented detection (as opposed to visually read tests; in other words, does the device contain an analyzer that reports the results of the test and eliminate subjectivity on the part of the law enforcement officer?)
- Ease of device operation and use
- Mechanism for retention of results

Other important considerations for law enforcement discussed within this toolkit include the following:

- Officer safety concerns
- Oral fluid sample collection procedures (i.e., timing and methods for sample collection)
- Format of displayed results
- Manufacturer's guidelines for the operation of certain devices and how these guidelines can affect results in field screening device cases

A final point of consideration—and possibly contention—is whether the results of oral fluid screening should be transmitted to the officer using the device and if so, when in the investigation or evaluation process these results should become available to these officers assuming they are not among the arresting officers.

Toxicologists

Scientists (namely forensic toxicologists) are another key stakeholder group who should be involved in oral fluid program discussions. Similar to law enforcement, laboratory scientists may play a role in selecting and/or approving devices for field and confirmation testing and must be well-versed in the technology and the interpretation of results. This toolkit provides information about the tools as well as proper techniques to use in the laboratory and in the courtroom. Not only are the results of testing important, but the interpretation of results also can be critical in an impaired driving case, so best practices are included. Importantly, this resource also includes guidance on how to utilize the "must know" oral fluid studies (i.e., what they say and how they are applicable to particular devices and/or procedures) for scientists, and prosecutors, who will be tasked with explaining both the technology and specific findings in court.

Prosecutors

The adjudication of impaired driving offenses is difficult due to the complex and scientific nature of these cases. Drug-impaired driving cases tend to be particularly challenging because state statutes vary considerably and the approaches commonly used in prosecuting DUIs (e.g., proving that a defendant had a blood alcohol concentration above the per se limit) are not always applicable. Furthermore, prosecutors who are assigned impaired driving cases are often early in their criminal law careers and lack experience. They also encounter highly specialized and skilled defense counsel who are well-versed in relevant studies, as well as effective challenges and arguments. This toolkit includes sections that will help prosecutors evaluate a drugged driving case, including how to determine the meaning of laboratory results, and facilitate fluency in discussing oral fluid collection and testing scenarios, which may happen in court. Data privacy issues are reviewed in the context of how legal rulings might impact the admission of oral fluid evidence. Ideas on how to respond to issues relative to chain of custody, reliability, and other grounds cited in motions to suppress are provided. In cases that involve oral fluid testing, witnesses may include law enforcement, manufacturer representatives, scientists, etc. The toolkit details what to expect from witnesses of various disciplines based on their qualifications. From pleading templates to predicate questions for fact and expert witnesses, this toolkit is designed to support all traffic safety partners throughout the entirety of a drugged driving case.

Policy Makers

Policy is another important area that is explored throughout this resource. It is preferable, and in most instances necessary, to have some form of statutory authorization to implement a permanent oral fluid screening and/or testing program (versus temporary pilot programs). Note that pilot programs do not require such authorization *if driver participation is on a voluntary basis*. The majority of oral fluid pilots that have been conducted in the United States have lacked supporting legislation and therefore, participation could not be compelled. In many instances, this has led to small sample sizes due to inability to require drivers to provide an oral fluid sample when asked. However, these efforts have produced a growing body of data and provided important lessons about how to design, implement, and evaluate oral fluid programs. The exception is Michigan's pilot, because this program was originally established by the state legislature as a five-county pilot that was subsequently expanded statewide following promising study results. The Michigan roadside drug screening program was also unique on account of the "teeth" that were included in the pilot's framework. The addition of penalties for refusing to submit to a request for an oral fluid sample transitions the pilot from voluntary to mandatory.

Statement of Purpose

While use of oral fluid to detect drugs is not new to the science arena, use of field screening technology by law enforcement at roadside is a newer concept prompted by the commercialization of cannabis and by the opioid epidemic. Programs have been in place internationally for many years; however, models are in their infancy within the United States. This limited experience has led to questions about how to structure, implement, and successfully administer roadside drug screening. Currently, state law makers are evaluating the merits of starting or expanding the use of oral fluid drug screening technology, foregoing OFFS in exchange for use of oral fluid confirmation testing in the laboratory, or pursuit of both. Since permanent programs are relatively new within the United States (though more commonplace internationally), guidance for the development and implementation of oral fluid roadside

screening and laboratory evidentiary testing programs is helpful for agencies interested in deploying this technology as a tool for use in impaired driving investigations. Lessons learned from jurisdictions that have piloted and/or currently utilize oral fluid drug screening or testing are instructive for jurisdictions that are exploring the viability of this approach.

The material in this resource is compiled from numerous scientific and legal sources and is continually updated with new scientific literature, legal decisions, and policy developments. With the expansion of roadside drug screening and laboratory testing programs in U.S. jurisdictions—at the local, county, agency, and/or state level—lessons learned regarding what works and how best to address common barriers and challenges can inform future efforts.

Comparison of Biological Specimens

There are advantages and disadvantages of different specimen types (i.e., blood, urine, oral fluid) for purposes of drugged driving investigation (Table 2); although the vast majority of states collect blood in suspected drugged driving cases. Therefore, the greatest volume of reference data available is for blood drug concentrations. Specimen choice considerations include degree of invasiveness, ease and cost of collection and analysis, state statute, and correlation to recency of use. It is important to note that there is not a direct correlation between concentration and the degree of impairment for drugs other than alcohol with any specimen type and it is ill-advised to predict impairment in a specific individual based on toxicology results alone. The totality of circumstances in a drugged driving case should also be considered when opining on impairment.

Table 2. Specimen Comparison: Applications, Advantages, Disadvantages

Specimen	Blood	Urine	Oral Fluid
Applications	DUI, Postmortem	DFC, Workplace	DUI, Workplace
Window of Detection*	Up to 24 hours	Days to weeks	Up to 24 hours (THC may be shorter)
Parent Drugs	Yes	Mostly metabolites	Yes
Subject to Adulteration	No	Yes	No
Invasiveness	High	Low	Moderate
Confirmation Specimen Collection Time	Often 2 hours post-arrest	Often 2 hours post-arrest	Ability to collect at roadside

**Window of detection is heavily influenced by cut-off selection or limit of detection, frequency, and history of drug use.*

Blood. Blood is considered, by most, to be the gold standard of biological samples in drug-impaired driving cases. It is blood that carries the drug throughout the body so that it can interact with receptors in the brain to cause effects. Therefore, it is an attractive specimen that contains pharmacologically active parent drug and often reflects recent drug use.

Due to the invasive nature of the search, drivers are afforded more legal protections than are present with other specimen types (e.g., breath, which may be taken as a search incident in order to arrest). Adulteration potential is extremely low but challenges with blood analysis include delay in collection time (e.g., ≥ 2 hours between arrest and blood draw in many states), requirement of specialized personnel for collection (e.g., nurse, phlebotomist), higher laboratory costs, and longer analysis time.

Urine. Urine typically contains high concentrations of drug metabolites while often lacking parent drugs (e.g., THC). Because THC is lipophilic, its metabolites may remain in the body for days or weeks after last use, especially in frequent users of cannabis. The window of detection for drugs in urine does not reflect recent use and lacks any correlation to impairment. Despite it being less expensive to perform qualitative testing in urine, agencies are discouraged from using this specimen type in DUID cases. However, it is recognized that some states collect urine for drugged driving cases because of per se laws and/or the ease of analyzing for drugs.

Oral Fluid. Despite its limited use in drugged driving investigations, oral fluid testing has been around for decades and is used today in workplace drug testing, pain management monitoring, criminal justice, and other applications. Oral fluid is the most practical specimen to be used by field screening devices (i.e., at the roadside) due to it being rapid, minimally invasive, and simple to collect a sample. Field devices may be used by law enforcement to establish probable cause in a drugged driving investigation. Observed collection minimizes the potential for adulteration and same gender observation is not required. The level of invasiveness is lower than for blood or urine collection and likely more akin to breath testing. Like blood, oral fluid usually contains the pharmacologically active parent drug, which likely represents recent drug use (Society of Forensic Toxicologists, 2018). Another significant advantage of oral fluid in a drugged driving investigations is the ability to collect the confirmation specimen closer to the time proximity of driving (e.g., at the roadside) than blood or urine. It is well known that some drugs (e.g., THC, cocaine) rapidly metabolize and dissipate from the body and timely collection increases the likelihood of detection.

Disadvantages may include smaller sample volume, difficulty providing a specimen (dry mouth) and the requirement for sensitive analysis. Further disadvantages related to field screening devices include the cost for the instrument and test cartridges, as well as limited scope of analysis, although most commercially available devices analyze for drugs that are most often seen in DUID cases (e.g., THC, benzodiazepines, opioids, cocaine).

For additional insights into the differences among the various testing methods utilized in impaired driving investigations including advantages, disadvantages, and identified limitations, refer to Table 3. This comparison differentiates between oral fluid testing used for screening in the field and as a confirmation sample in a laboratory setting.

Table 3. Strengths and Limitations of Testing Methods in Impaired Driving Investigations

Testing Method	Purpose	Advantages and Strengths	Disadvantages and Limitations
Oral Fluid	Screening (field)	• Identifies recent drug use • Easy and fast collection (< 10 minutes) • Gender-neutral collections • Minimally invasive; similar to breath test • No warrant required for collection • Rapid results (<10 minutes) • Demonstrated accuracy, sensitivity, and specificity • Used in conjunction with other evidence to establish probable cause for arrest • Results may support search warrant requests for other biological samples • Ability to quickly identify drug and polysubstance-impaired drivers (including those with a BAC above .08) • Admissible in certain hearings (e.g., probable cause) • Creates option for administrative license suspension/revocation (ALS/ALR) for drug-impaired drivers	• Quality of technology and devices varies by manufacturer • Sensitivity concerns for certain drugs (e.g., benzodiazepines) • Tests for a limited number of drugs (often six or seven substances and/or drug classes) • Practitioners not as familiar with this method because it is a newer drug detection technology; requires training/education for criminal justice practitioners • Used in a screening capacity, not for evidential purposes • Negative results should not be taken to infer that an individual is not impaired; device results merely indicate whether an individual is positive or negative for certain drugs above set cut-off levels • Testing methods may be subject to admissibility hearings in some states
Oral Fluid	Confirmatory/ evidentiary (laboratory)	• Easy and fast collection (< 10 minutes) • Collection proximal to the time of traffic stop, which reduces time and expense and preserves chemical evidence that rapidly dissipates • Gender-neutral collections • Minimally invasive, easy to use (compared to blood and urine) • No warrant required • Conclusive, sensitive, specific • Low likelihood of specimen contamination/adulteration • Short window of detection likely captures recent drug use • Detects pharmacologically active (impairing) drugs (e.g., THC, cocaine) • Laboratories use validated and accepted analytical techniques and instruments	• Costly analysis • Few qualified laboratories due to need for specialized instrumentation • Testing methods may be subject to admissibility hearings

Testing Method	Purpose	Advantages and Strengths	Disadvantages and Limitations
Blood	Confirmatory/ evidentiary (laboratory)	• "Gold standard" • Reflects recent drug use and indicates drugs circulating in the body • Conclusive, sensitive, specific • Relatively short window of detection • Can test for an extensive number of substances • Low likelihood of specimen contamination/adulteration	• Expensive (especially when used for designer or novel psychoactive substances) • Intrusive procedure that requires law enforcement to handle biological samples • Requires trained/certified individual to conduct blood draw • Warrant required in DUI cases if suspect refuses to voluntarily provide a sample • Rapid metabolization of some drugs and delays in obtaining the blood draw can lead to loss of chemical evidence • Delay can be 1.5 to 2 hours between the time of the stop and sample collection; as drugs metabolize and dissipate over time, test results can make cases difficult to adjudicate, particularly in states with per se laws for drugs • Prosecutors have difficulty proving chain of custody, and labs might not be able to provide a witness for trial • Potential backlog in processing blood samples in DUID cases, which can lead to a case proceeding to trial without chemical evidence
Urine	Confirmatory/ evidentiary (laboratory)	• Conclusive, sensitive, specific	• Officers must observe driver providing the sample; same gender observation required for collection • Requires officers to handle biological samples • Can take hours to provide a sample • Long window of detection that identifies drug metabolites; problematic in DUI cases because it is more difficult to establish recent vs. historical use

Implementation of the Program

This toolkit is designed to aid law enforcement, toxicologists, criminal justice practitioners, highway safety professionals, and policy makers in the implementation of an oral fluid drug testing program. Agencies are encouraged to consider the following information before making a decision about deploying oral fluid technology that can be utilized in different ways. A program may include (a) roadside OFFS devices used by law enforcement to establish probable cause during drugged driving investigations and/or (b) oral fluid confirmation testing by a forensic toxicology laboratory. Immunoassay-based screening tests should be considered presumptive; laboratory-based confirmation analysis can be considered evidential.

The first step in the process is to identify all program stakeholders. Table 4 has a list of agencies and professionals whose involvement may strengthen the program planning process.

Table 4. Oral Fluid Program Stakeholders

Important Stakeholders	Examples/Considerations
Law Enforcement	• Collectors of oral fluid samples for screening and testing • Agency leadership representative • Agency legal representative • Drug Recognition Experts • Consider range of LE agencies (e.g., state patrol, state associations for chiefs of police and county sheriffs)
Toxicology Personnel	• Laboratory director(s) • Experts on field screening and confirmation collection devices being evaluated • Laboratory/consultant toxicologists (if applicable) • Consult SOFT Oral Fluid Committee (http://www.soft-tox.org/oral-fluid-committee) via oralfluid@soft-tox.org (general guidance)
Traffic Safety Resource Prosecutor(s)	• These are prosecutors who are funded entirely or in part by federal grants to train, consult, and advise on traffic safety issues • Local prosecutors without NHTSA funding also are important stakeholders to consider
State Standard Field Sobriety Test (SFST) Coordinator/Drug Evaluation & Classification Program (DECP) Coordinator	These roles could be held by the same or separate individuals
SHSO	Seek a SHSO representative with decision-making authority if possible
Legislators	Perhaps judiciary committee chair or member
Judiciary Representatives	• State court administrator • State public defender • Judicial outreach liaison(s) (peer-to-peer educators)
Device Manufacturers	Manufacturer representatives for device(s) under consideration
Local, State, and/or Regional Impaired Driving Groups	AAA, MADD, etc.
Researchers and/or Data Analysts	Ideally, an analyst from the existing state traffic records group would participate.
Probation Personnel	Probation or parole operations within a state may elect to use the same technology as law enforcement. Cross training and education are the potential benefits.
State Public Health Agency	• State agency director/executive director or their designee • Consider inviting someone with expertise in substance abuse education and treatment for offenders • Consider inviting someone with expertise in providing minors, adolescents, and juvenile offenders with substance abuse treatment and related services (if the representative above does not also bring this expertise).
Driver Licensing Officials	• Staff in a position to help develop rules and regulations for license sanctions related to forensic testing should be included for expertise on local practices.

Use of Oral Fluid to Detect Drugs in the Field

Once stakeholders are identified, jurisdictions that opt to move forward with establishing a program are strongly encouraged to identify and address potential barriers and challenges that commonly arise and use the content within this toolkit to assist in the planning and implementation process.

The material provided in this toolkit offers guidance for the creation of a program including important policy considerations that should be addressed at the outset, factors to consider in selecting testing devices, and how to utilize screening and confirmation results in the courtroom. This resource provides an objective assessment of the capabilities of oral fluid technology and considerations that agencies should navigate before making a decision to modify existing practices and protocols. The ultimate decision regarding whether the addition of oral fluid drug testing is feasible and/or necessary should be made by law enforcement agencies in consultation with relevant stakeholders in individual jurisdictions. The factors that law enforcement and laboratory personnel need to consider when determining which devices to approve and use in the field are discussed in this report. Several police departments, in conjunction with SHSOs, have already collaborated on projects involving OFFS pilot testing. Aspects to consider in selection of an OFFS device include speed of sample collection and analysis, drug classes included in the test panel, instrumented detection (as opposed to visually read devices), and a mechanism for retention of the result. The manufacturer's guidelines for certain devices are discussed, as well as how these guidelines can affect results in cases where an OFFS device was used. Officer safety concerns are addressed, including when law enforcement officers should collect samples. Implications of how results are displayed by devices are covered, as well as how results can be transmitted to DREs, if a DRE is utilized in an investigation.

When developing a rapid oral fluid screening program, policy considerations should be given to a state's applicable legislation or applicable case law relative to the collection, submission, and/or use of any bodily fluid, including oral fluid. Finally, careful consideration must be given to (a) which state agency will approve oral fluid devices, (b) how the approval process will be, managed in the absence of model specifications and a conforming devices list from NHTSA, and (c) how oral fluid devices will be distributed throughout each jurisdiction. This final point is important because a single agency within the state must be responsible for oversight of the oral fluid program. By establishing rigorous oversight, law enforcement agencies can be confident that devices are maintained according to regulations and/or requirements and that quality assurances protect the overall integrity of the program, which can lead to greater acceptance by the judiciary and others.

Law enforcement officers should revisit their agency's Standard Operating Procedures as they relate to DUI investigations and the collection of evidence. Each agency will need to conduct the requisite training on how to properly collect, maintain, and document oral fluid samples. Often, what occurs in the courtroom is a function of the reports produced by law enforcement during their investigations.

Use of Oral Fluid to Detect Drugs in the Laboratory

It is critical to gain support and collect advice from laboratory personnel within the jurisdiction prior to the implementation of any program. Laboratory personnel can provide insight about particular devices (i.e., reliability, validity, etc.), proper laboratory protocols, and pertinent

literature. This toolkit provides practitioners with resources to help in these areas, especially by providing specifications of instruments, suggested practices, recent peer-reviewed papers, and where to find must-have documentation such as SOFT/American Academy of Forensic Sciences Oral Fluid Committee's Oral Fluid Drug Testing Pilot Project Guidelines for DUID Investigations (updated September 2020). These guidelines are intended for use by groups interested in collecting data on drug prevalence in drivers from local jurisdictions by testing oral fluid and using rapid test devices in the field (available from the AAFS-SOFT DUID committee). Development of confirmation protocols for use in a toxicology laboratory are explained, as are topics such as proper storage and transportation of samples.

Additional Considerations

Building Program Support

Regardless of the approach taken to establish an oral fluid program, the initiation of an effort should begin with extensive planning. Before debating the specifics of program structure, interested parties must first discuss with program stakeholders (see Table 4) whether support exists to justify the use of oral fluid screening or testing. With numerous competing priorities and possible constraints, being able to identify the degree to which drug-impaired driving is a problem is important.

Oral Fluid Legislation and Policy Considerations

If buy-in and support for a program can be obtained, the next task is to determine whether legislative and/or policy changes are needed to move forward. Depending on existing resource allocations, legislative appropriations for program funding might be needed. If program authorization or appropriation legislation is required, this process of amending statutes or introducing policy can take significant time (e.g., months or years). This toolkit identifies states that currently have authorizing language in statutes in support of oral fluid testing.

About half the states have laws in place that authorize the use of oral fluid to detect drugs (see Figure 1). Few states have proactively amended their statutes to allow it specifically for use in impaired driving investigations. In practice, very few states that are currently authorized to use oral fluid for this purpose actually collect it. At present, only Alabama collects oral fluid for use in roadside drug screening *and* for laboratory confirmation testing.

As the use of oral fluid to detect drugs grabs the attention of state lawmakers interested in addressing the rapidly evolving issue of drugged driving, they may not be aware that an existing statute may already authorize the collection and use of oral fluid for this purpose. In these cases, new policy to fund and regulate oral fluid screening and/or testing programs would be required.

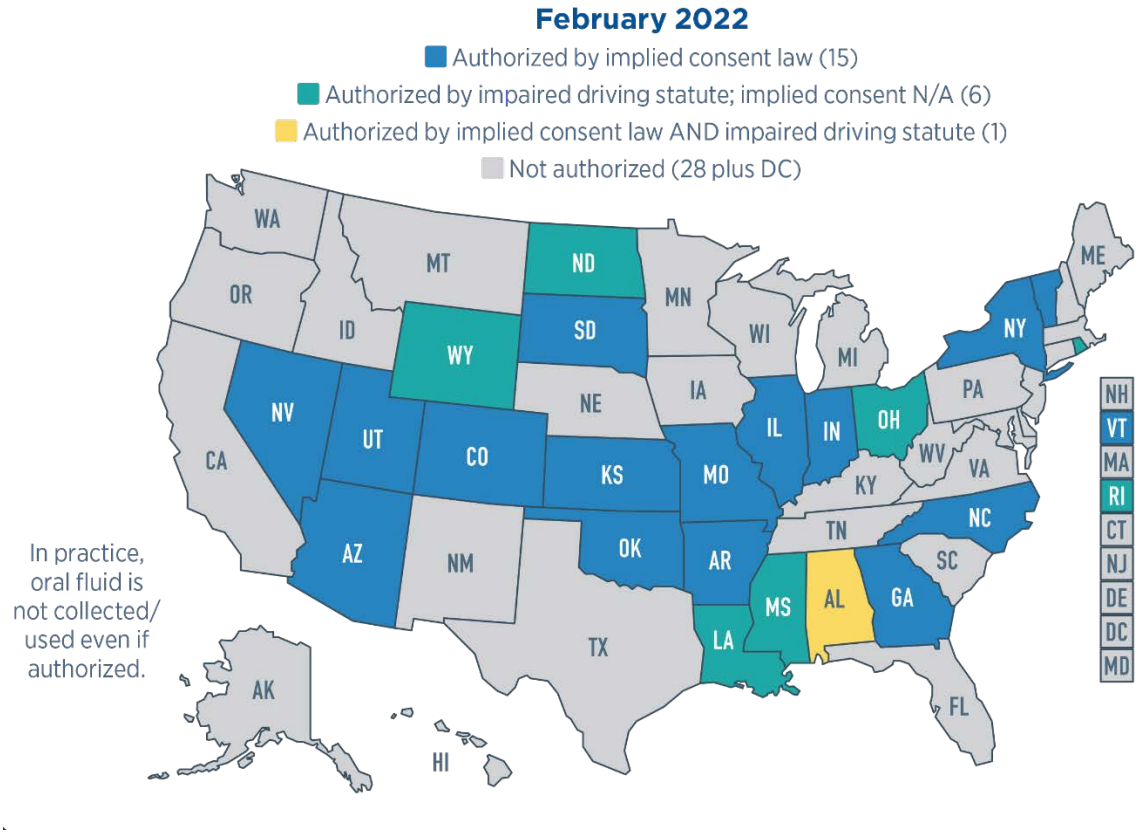
Summarized below are the current ways in which oral fluid screening and/or confirmation testing typically appears in legislation across the United States.

- **Pilot Programs Using Oral Fluid in Field Screening and/or Laboratory Confirmation Testing.** The creation of a pilot program via state legislation offers policymakers the opportunity to carefully craft and regulate program attributes that foster program success and minimize loopholes that could limit benefits of a program. Beyond specific statutory language to authorize use of oral fluid, examples of program attributes to carefully consider

include but are not limited to rules and processes for specific agencies, appropriations for program administration, penalties for chemical test refusal, and data reporting.
This approach was utilized in Michigan where Public Acts 242 and 243 (2016) gave authority to state police to develop an oral fluid field screening program initially in five counties. The pilot program was later expanded statewide for one year ending September 30, 2020.

- **Use of Oral Fluid to Detect Drugs is Authorized Within an Implied Consent Law.** By way of applying for a driver's license, state implied consent laws require that motorists give consent to field sobriety tests and chemical tests to help in determining impairment.
  - Terminology used in state statutes varies from one state to another. Typically, statutes include one of the following terms: saliva, oral fluid, other bodily substances, or other bodily fluids.
  - Commonly, the statute outlines circumstances under which a preliminary test (i.e., field screen) or confirmatory chemical test (i.e., laboratory analysis) can be performed (e.g., only DREs can collect samples, testing is limited to specific drugs, drug analysis is permitted only in serious injury or fatal crashes, etc.) and how the results can be utilized (e.g., to help establish probable cause versus for evidentiary purposes).
  - Where preliminary breath test laws are established, some states include language relative to preliminary oral fluid analysis (i.e., field screening) in the statute to establish parity. Meanwhile other states (e.g., New York) may have established policy relative to preliminary breath testing, yet remain silent on the use of oral fluid for field screening, but authorize the use of oral fluid for confirmatory chemical testing conducted in a laboratory.
- **Use of Oral Fluid to Detect Drugs is Authorized Within a Broader Testing Statute.** These statutes often include provisions that apply to numerous testing scenarios including but not limited to impaired driving investigations. Oral fluid field screening or chemical testing may not be applicable throughout a given state’s entire testing statute.

Figure 1. States Authorizing the Use of Oral Fluid Evidence



Other Potential Uses and Applications

There are many applications of OFFS and oral fluid testing with several being outside the scope of this document (e.g., workplace drug testing, pain management compliance, use in detention facilities, in court, pre-trial and/or post-sentence monitoring [such tools may help determine drug use while under supervision to help hold offenders accountable and help reduce recidivism], post-mortem drug testing, and surface drug detection). Other applications may not be bound by statutory and administrative guidelines that govern forensic testing for criminal justice purposes; however, users should refer to manufacturer guidelines for recommendations. State experts and prosecutors should consider the probative value of this evidence and how results may or may not be used in a courtroom setting before implementing these tools. OFFS devices may be used at roadblocks or checkpoints and while verifying drug use in volunteers during DRE field certifications (with permission of state coordinator) (*People v. Gonzales,* 2006).[1]

[1] In *People v. Gonzales,* April 20, 2006, SCI# 1092/06, New York Supreme Court [Unreported Decision]. S (see Appendix F a Varian Incorporated oral fluid swab used to detected drug use by probationer "has been accepted by the relevant scientific community and was properly performed" therefore was admissible as evidence of the defendant's violation of probation.

Program Costs

Roadside Screening Devices

The cost of roadside screening devices that include an analyzer as part of the instrument ($3,500–$5,000 per unit) and associated test cartridges ($15–$25 per test) could be cost prohibitive for some agencies. However, these prices are volume dependent and may change with market forces as oral fluid programs become more commonplace in the U.S. Other forms of roadside oral fluid screening devices are single-use and disposable, which can be less expensive than the instrumented devices described above.

Laboratory Confirmation Testing

While oral fluid screening can be costly, the cost of collecting an oral fluid sample for confirmation testing is generally more affordable ($2–$4 per sample). Actual cost is dependent on the manufacturer, volumes purchased, and market forces. Note that oral fluid testing is not currently common for most forensic laboratories and would require time, financial resources, and skilled personnel to method development and validate methods. However, the building of laboratory capacity has become an important priority for many within the traffic safety field. Additional funding for state laboratories to increase efficiency and reduce backlog in sample analyses could support more widespread adoption of oral fluid confirmation testing. Costs would be comparable to those for blood confirmation testing.

Program Funding Sources

State highway safety grants may be a viable avenue to secure funding to purchase roadside screening devices and/or specimen collection kits for use in laboratory confirmation testing of oral fluid for drugs. The allocation of these grant funds is heavily influenced by strategic highway safety plans required of all states by the U.S. Congress. States typically form task forces to inform these plans; the membership of these advisory bodies often include many of the stakeholders listed in Table 3, which underscores the importance of involving these stakeholders very early in the process of planning a new program or expanding a pilot program.

Note that use of highway safety grant dollars comes with clear restrictions relative to the purchase of equipment and supplies. For example, only roadside screening devices manufactured in the U.S. may be eligible (see Table 7). Working closely with the SHSO will help to ensure that such restrictions are shared and followed as appropriate.

General funds within a state budget are another possible way to help offset program costs. Some states cover the costs associated with processing confirmatory blood testing for alcohol and other drugs. Individuals convicted of impaired driving in these states may have to pay restitution as part of their sentence, which may include payments to the state for the costs associated with the laboratory tests associated with their case.

Collection of Oral Fluid Specimens

Use of the same specimen for both roadside screening and confirmation testing is typically not The volume of the secondary specimen (typically 2–4mL) may restrict the number of confirmatory tests that can be performed. Laboratories performing qualitative analysis via liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) can do so with small

sample sizes (Moore et al., 2020) supported by available technology, with some exceptions, such as the Dräger DrugTest 5000, which is used in Australia. Therefore, to allow for confirmation testing, a second oral fluid confirmation sample should be collected and sent to a forensic toxicology laboratory.

It is important to note that cut-off concentrations for field screening devices and limits of detection/quantitation for confirmation techniques exist with any analytical test. The potential for false positive/false negative results and the determination of precision at the decision point (i.e., cut-off) should be evaluated during any device approval and method validation. The possibility of drug presence below the cut-off or level of detection always exists, which should be considered in conjunction with timing of sample collection when interpreting toxicology results.

Note: See other Potential Challenges.

Part II: The Tools for Oral Fluid Field Screening

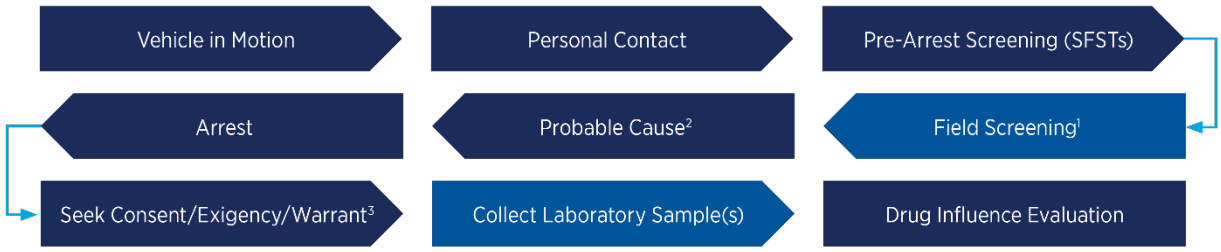
Timing of Field Screening and Evidentiary Oral Fluid Collection

Law enforcement officers are trained to follow standard steps when conducting an impaired driving investigation. With oral fluid field screening now available, a common question is when should the sample be collected? Figure 2 details the proper steps to follow in a drug-impaired driving investigation. Field screening—preliminary breath analysis or preliminary oral fluid analysis—should be conducted during the roadside stop after the law enforcement officer has made personal contact with the driver and administered the Standardized Field Sobriety Tests (SFSTs). The results of field screening in combination with all other observations and evidence collected during the investigation can be used to establish probable cause for an impaired driving arrest. An important point of clarification is that field screening is designed to supplement and enhance existing investigative procedures; decisions to arrest should be made based on the totality of circumstances, not only the results of a PBT or OFFS.

In addition to knowing when and how oral fluid field screening should be used, it is important to understand how this differs from the collection of an oral fluid confirmation specimen. Laboratory confirmation samples are collected later in the process and are subject to greater scrutiny and procedures, namely maintaining a documented chain of custody.

The inclusion of oral fluid testing in impaired driving investigations is discussed in further detail below.

Figure 2. Oral Fluid Collection During an Impaired Driving Investigation



[1] Oral fluid field screening (OFFS) and preliminary breath test, if applicable.

[2] Based on totality of investigation.

[3] First seek consent. If no consent, are there exigent circumstances? If none, can you apply for a warrant?

Law enforcement can use OFFS devices to identify drug use during a drugged driving investigation. Most of these devices screen for common drugs, such as marijuana, cocaine, methamphetamine, amphetamine, opioids, and benzodiazepines. Similar to PBTs for alcohol, OFFS devices should be used to establish probable cause. OFFS display results of either "positive" or "negative" and should be used to confirm suspicion of drug use, after the officer has concluded that the driver is impaired and unable to safely operate a vehicle using SFSTs. Roadside oral fluid screening is used to identify which drug class or classes are likely causing the impairment. This information can be used to assist with obtaining a search warrant to collect a confirmation specimen (i.e., blood and/or oral fluid). Field screening should not be used for evidentiary purposes; local law (Responsibility.org, n.d) will dictate if field screening results are admissible in court and under what circumstances.

Preferably, an oral fluid specimen will be collected, after any required advisement (e.g., implied consent, if applicable), as the evidentiary specimen as close as possible to the time of the suspected impairment (see Figure 2). Some drugs, such as THC and cocaine, metabolize and dissipate rapidly from the body. Because of this, drug concentrations in blood taken 2 hours or more after the arrest or crash often are low or not detected. Therefore, the analysis of the blood specimen and the blood concentration at the time of the traffic stop or crash may be significantly different. The delay in blood sample collection is particularly problematic in states that have established per se limits for drugs and can make it difficult to prosecute cases. For these reasons, oral fluid should be collected by the investigating officer at roadside as close to the time of the arrest or crash as possible. Roadside collection will increase the likelihood of detecting the impairing substance at the time of driving. For a more comprehensive picture of impairment and recency of use, both blood and oral fluid may be tested as confirmation specimens (the Alabama Department of Forensic Sciences utilizes this approach in its oral fluid drug testing program).

As with any DUI investigation, the investigation should consider all facets of the investigation, including the motion of the vehicle, personal contact, and SFST performance. The totality of circumstances should be reviewed in conjunction with the toxicological analysis (Moore et al., 2020).

Oral Fluid Screening Devices (OFFS)

A major advantage of oral fluid drug testing is the amenability to rapid point of collection (on-site) testing (e.g., roadside testing for drugged driving investigations). OFFS devices typically include an oral fluid collector (e.g., cartridge with pad) and an internal detection system based on a lateral flow immunoassay. The presence of a drug can be determined by an objective reading of the test strip by the device itself, typically in the form of an analyzer (e.g., Abbott SoToxa [formerly Alere DDS2], Dräger DrugTest 5000), or by visual inspection of an appearance or disappearance of a line (e.g., DrugWipe).

The National Highway Traffic Safety Administration (NHTSA) evaluated five OFFS devices in January 2017 (Buzby et al., 2021), *see Table 5*.

> The purpose of this evaluation was to explore the practical aspects of designing and performing tests on the latest generation of oral fluid devices to assess their accuracy, reliability and performance to specification. The following devices were included in the evaluation: the Dräger DrugTest 5000, Dräger DrugCheck 3000, Securetec DrugWipe S 5-Panel, the Alere DDS2 [now known as Abbott SoToxa] and the AquilaScan Oral Fluids Testing Detection System . . . An appropriate scope of testing and cut-off concentrations was based on two studies: the Roadside Testing Assessment (ROSITA), which recommended greater than 90% sensitivity and specificity and greater than 95[%] accuracy; and Driving Under the Influence of Drugs, Alcohol and Medicines (DRUID), which recommended greater than 80[%] sensitivity, specificity and accuracy. Based on the summation of all testing performed for each device, the DDT5000, the DDC3000, and each of their individual assays demonstrated performance consistent with the requirements of the ROSITA group. The DDS2 data, in aggregate, also met the performance requirements for ROSITA; however, the THC assay did not. None of the individual assays on the DrugWipe or the AquilaScan met the performance requirement of ROSITA, nor did the performance of either device in aggregate. The DDT5000, DDC3000 and DDS2 in aggregate also met the performance requirements for DRUID.

Table 5. Aggregate Performance Data for the Five Devices Evaluated Using the Described Protocol

Overall Device Test Results									
Device	**TP**	**FN**	**FP**	**TN**	**Sensitivity (%)**	**Specificity (%)**	**Accuracy (%)**	**PPV (%)**	**NPV (%)**
DDT5000	886	8	15	1766	99.1	99.2	99.1	98.3	99.5
DDC3000	589	17	0	929	97.2	100.0	98.9	100.0	98.2
Drug Wipe w/ Drug Read	289	213	3	489	57.6	99.4	78.3	99.0	69.7
Drug Wipe w/ Manual Evaluation	451	73	2	466	86.1	99.6	92.4	99.6	86.5
DDS2	635	62	4	1306	91.1	99.7	96.7	99.4	95.5
Aquilascan	161	581	5	988	21.7	99.5	66.2	97.0	63.0

Source: Buzby, D. et al (2021). *Evaluation of on-site oral fluid drug screening technology* (DOT HS 812 854). NHTSA.

A number of other evaluations were performed to assess device use and robustness. Interferent evaluations consisted of running a series of experiments of solutions of beverages (milk, beer, orange juice, soda), oral hygiene products, tobacco, and mint-flavored gum. Saliva was mixed with commonly encountered food, drinks, or orally ingested products (tobacco, gum, etc.). OFFS cassettes containing the physical testing strips for each device were subjected to extremes of heat and humidity in environmental test chambers, then returned to the laboratory for evaluation of performance in testing oral fluid samples.

What Do Oral Fluid Field Screening Results Mean?

Oral fluid, which is reflective of the quantity and type of free drug circulating in the blood, can be collected and analyzed with commercially available OFFS devices. The result can be shown within a few minutes, which is particularly useful for situations where quick determination of drug intake is required.

A field screening result represents a qualitative assessment (i.e., positive or negative). OFFS devices are usually immunoassay based. For forensic purposes, an independent confirmatory test is required as with any other immunoassay screening procedure. A specific drug (e.g., methamphetamine) or drug class (e.g., benzodiazepines) may be indicated by a positive field screening result for a specific drug (e.g., methamphetamine) or drug class (e.g., benzodiazepines) while an evidentiary confirmation will indicate the specific drug present in the oral fluid. For example, a benzodiazepine positive by a field screening device could be identified as alprazolam by evidentiary confirmation in the laboratory (Moore et al., 2020).

History and Current Status of Field Screening Devices

Small handheld instruments or visually read devices are typical of OFFS devices, but bench-top instruments operating in jails and hospital settings may also be considered field screening devices.

Several years ago, an assessment of field screening devices available for testing drivers noted that the devices did not reach adequate reliability paraments for implementation (Pehrsson et

al., 2011); however, improvements in sensitivity, technology, and instrumentation have greatly improved performance and there are now several commercially available devices that are valid for this purpose.

In 2000, Australia was the first country to implement OFFS, using a device for the identification of THC and methamphetamine (with cross-reactivity to MDMA); many other countries (e.g., Argentina, Austria, Belgium, Brazil, Canada, Chile, Columbia, France, Germany, Ireland, Italy, Netherlands, New Zealand, Poland, Portugal, South Africa, South Korea, Spain, Sweden, Turkey, United Kingdom, and Vietnam) have now introduced field screening with different drug panels and various devices. There is great variability in the size, scope, and structure of these international programs.

Oral Fluid Pilots and Programs in the United States. In the United States, police departments and researchers in Alabama, California, Colorado, Kansas (Rohrig et al., 2017), Massachusetts, Michigan, Oklahoma (Veitenheimer, 2017), Oregon, Utah, Vermont, and Wisconsin (Edwards et al., 2017) evaluated field screening devices and concluded, for the most part, that these devices were useful in assisting law enforcement in identifying drugged drivers. Law enforcement agencies in other states are in the process of planning and implementing programs in their respective jurisdictions. The passage of cannabis legislation and the expansion of Michigan's pilot from five counties to statewide has led other states to consider establishing their own initiatives.

In 2018, Alabama approved three oral fluid screening devices for use by law enforcement in the field: Dräger DrugTest 5000, Abbott SoToxa, and Randox Evidence MultiStat. The devices were evaluated, validated, and approved for use by the Alabama Department of Forensic Sciences. The State of Alabama rules for "Chemical Test for Intoxication" (Chapter 370-1-1) were updated accordingly. No statute change was required since §32-5A-194 Code of Alabama (1975) allows for "breath, blood, or other bodily substance" to be tested in DUI cases. At the time of this writing, approximately six agencies had purchased devices and the state of Alabama has the distinction of becoming the first U.S. state to establish a permanent oral fluid program.

Oklahoma has approved the Abbott SoToxa and Dräger DrugTest-5000 for use in the state.

Following a successful pilot study (Michigan State Police, 2019), Michigan expanded their program from the initial six counties to statewide implementation. In the second phase of the Michigan pilot, which ran for one year and concluded at the end of September 2020, DREs from more than 50 law enforcement agencies used OFFS as part of drug-impaired driving investigations. Unlike other jurisdictions, refusal to submit to an oral fluid request in Michigan leads to a civil infraction. The mandatory participation coupled with statewide coverage made Michigan's Phase II pilot the largest to date in the United States. After completion of the pilot, the Michigan State Police issued a report to the state legislature comparing OFFS results with confirmation testing. While the initial five-county pilot results were deemed promising, the number of samples collected (n = 92) was not large enough for the legislature to make the program permanent. Phase II collected data from 693 incidents and 661 roadside oral fluid tests. In Phase II, 131 DREs from 65 different law enforcement agencies participated. The expansion of the pilot included 69 counties in Michigan during Phase II. The report concluded that,

> Roadside Oral Fluid testing in the Phase II Pilot has been proven to be accurate to a certain degree as demonstrated in the data contained within this report. Each of the six drug classes demonstrated varied percentages of accuracy when compared to the "Gold

> Standard," which is a blood test. Oral fluid testing does not equal the "Gold Standard" but has been found to be accurate for purposes of preliminary roadside testing. (Michigan State Police, 2021)

Massachusetts, in their 2019 Legislative report, reviewed over a dozen reports and stated that oral fluid testing devices such as Dräger DrugTest 5000, Securetec DrugWipe 5, and Abbott SoToxa are as portable as a PBT. The report also recommends that Massachusetts offer the oral fluid test at roadside once probable cause is established and, in the event of a positive test, use as a preliminary drug test prior to a DRE. It also recommends that the state "adopt [a] statute making oral fluid testing admissible." (Massachusetts Cannabis Control Commission, 2019)

Overall, the researchers recommended expansion of test panels (currently up to six drug classes), as other common drugs may affect driving (e.g., fentanyl, tramadol, etc.). More importantly they recommend that the sensitivity for benzodiazepines be improved because of their impairing nature as well as poor incorporation into oral fluid due to strong binding to proteins and weak acidity. A recent paper indicated the odds of culpability in crashes associated with use of impairing drugs in injured drivers was highest with methamphetamine, followed by high levels of THC (in blood) and benzodiazepines (Drummer et al., 2020).

Because they are based on immunoassay technology, OFFS devices offer the same advantages as other immunoassays, as well as the drawbacks associated with cross-reactivity and antibody selection. Advantages include convenient sample collection, ease of use, rapid results, straightforward interpretation, and relatively low testing costs. In oral fluid, the predominant drugs are the parent compounds (e.g., THC and cocaine) so immunoassays must target the correct drug.

The most extensively evaluated devices by law enforcement and researchers in roadside settings are the Dräger DrugTest 5000, Securetec DrugWipe 5, and Abbott SoToxa (formerly Alere DDS2). Recently published evaluations have shown good overall performance in terms of sensitivity, specificity, and accuracy (Buzby et al., 2021; D'Orazio et al., 2021; Edwards et al., 2017; Rohrig et al., 2017; Veitenheimer et al., 2017).

Guidance for Implementing Oral Fluid Pilot Programs

Guidance documents for jurisdictions intending to perform evaluation studies of field screening instruments or pilot projects are available from the Society of Forensic Toxicologists (2020).

These guidelines are intended for law enforcement personnel and other stakeholders, who are interested in the implementation of a project based on an oral fluid testing protocol within their DUID program. These guidelines are intended for use in data collection projects regarding the utility of oral fluid in DUID situations only. In an authentic traffic stop, oral fluid should be collected as soon as possible in relation to the driving event. Preliminary tests should not be considered as evidentiary.

Accuracy and Reliability Studies. There are many commercially available OFFS devices (see Table 6), and there are significant differences in drug test panels, cut-off concentrations, and result interpretation and retention. Evaluation over the years has generally concluded that performance is variable: For some drugs, the tests are specific and reliable, and for others, predominantly marijuana and benzodiazepines, improvements in sensitivity are necessary.

Table 6. Examples of Commercially Available Oral Fluid Drug Screening Devices

Device	Drug Classes	Cut-off Concentrations (ng/mL)						
		THC	AMP/METH/MDMA	Morphine	Cocaine BZE	Benzodiazepines	Methadone	PCP
DrugTest 5000	7	5	50/35/100	20	20	diazepam 15	20	–
SoToxa	6	25	50/50/–	40	30	temazepam 20	–	–
DrugWipe 5	5	10	25/10/10	25	10	diazepam 10	–	–
MultiStat	–	10	50/50/–	10	20	20	4	–
OrAlert	7	100	50/50/–	40	20	oxazepam 10	–	10
Oral-AQ 6 and 7	6 or 7	25	50/50/35	25	20	oxazepam 5 or 10	–	10
Rapid STAT	6	15	25/25/–	25	12	oxazepam 25	–	–

Some manufacturers offer different cartridges with single or multiple drug classes, depending on the market requirements. For example, a roadside drug testing program in one jurisdiction might authorize screening for six drug classes, whereas another jurisdiction may only authorize screening for two drug classes. The cartridges utilized for the second jurisdiction would have to be different in order to align with the program regulations. Canada is an example of a jurisdiction that requires a smaller test panel. THC and cocaine are currently the only drugs that are screened as part of the country's roadside drug testing program; however, methamphetamine is being added.

Determination of a cut-off concentration (the concentration below which the result must be reported as negative) is challenging because research on oral fluid drug concentrations, while expanding, is much more limited than that on urine or blood. Recommended drug cut-offs for workplace drug testing, which is intended as a deterrence program, or clinical applications intended to determine concurrent drug use with prescribed medications may be different than for testing drivers suspected of being impaired, in which drug use should be more recent than in the other situations (i.e., if driving is affected; see Table 7).

Table 7. Comparison of Cut-Off Concentrations for Oral Fluid Drug Testing in Different Applications

	Screen Cut-Off Concentrations (ng/mL)		
Drug(s)	**National Safety Council (NSC)*—DUID**	**Canadian Society of Forensic Science Drugs and Driving Committee (DDC)**	**SAMHSA (Workplace Testing)****
THC	4	25	4
COC/BZE	15	50	15
MOR/COD	30	–	30
HYC/HYM	30	–	30
OXYC/OXYM	30	–	30
6-MAM	–	–	4
AMP/METH	20	50	50
MDMA/MDA	20	–	50
PCP	–	–	10
Methadone	20	–	–
Benzodiazepines	5	–	–

** (D'Orazio, 2021)*

*** (Department of Health and Human Services, 2019).*

Currently, there are no federally approved model specifications for field screening devices in the United States. However, any future development of such guidelines should consider engaging with manufacturers and subject matter experts.

Table 8 provides information on some of the devices available; this is not intended to be an endorsement of any product. The data in this table was located using open-source information. Data, to include accurate unit pricing, requires a quote from a salesperson (Criminal Justice Testing and Evaluation Consortium, 2020).

Table 8. Sample Comparison of OFFS Devices Specifications

					
Device	**Abbott SoToxa**	**Dräger DrugTest 5000**	**Mavand Rapid STAT**	**Randox MultiStat**	**Securetec DrugWipe**
Web Address	https://www.globalpointofcare.abbott/en/product-details/sotoxa-mobile-test-system-us.html	https://www.draeger.com/en-us_us/Products/DrugTest-5000	http://www.mavand.de/en/products/drug-tests/rapid-statr.html	https://www.randoxtoxicology.com/instrumentation/evidence-series/evidence-multistat/	https://www.securetec.net/en/products/saliva-drug-test-drugwipe/
Direct Read Kit			✓		✓
Instrument Cost	~ $3,500	~ $5,000	N/A	Not published, contact manufacturer	N/A
Collection Kit Cost	~ $25	~ $25	Not published, contact manufacturer	Not published, contact manufacturer	Not published, contact manufacturer
Country of Origin	Great Britain	Germany	Germany	Great Britain	Germany
Printer Available	✓	✓		✓	✓
Notes	Manufactured in China.		Optional light box for poor lighting conditions.	Randox claims to analyze 44 analytes from a sample of oral fluid, blood, or urine. Results are generated in 20 minutes. Some detection limits not published.	Small sample required, short collection time.

Device Performance. The identification of accurate and reliable oral fluid technology is one of the most important aspects of any roadside drug testing program. By initiating a pilot prior to establishing a permanent program, stakeholders can evaluate device performance and functionality. To instill confidence in the integrity of an oral fluid program, it is imperative that technology meet identified criteria (as set forth by the evaluating agency) and only device(s) that perform up to those standards be selected for use in the field.

The following device parameters should be evaluated: accuracy, specificity, sensitivity, positive predictive value, and negative predictive value. The equations to calculate these parameters are as follows:

- Sensitivity = TP/(TP+FN)
  - Ability to identify positive cases
- Specificity = TN/(TN+FP)
  - Ability to avoid false positives, identify negative cases
- Positive Predictive Value = TP/(TP+FP)
  - Ability to correctly label as positive
- Negative Predictive Value = TN/(TN+FN)
  - Ability to correctly label as negative
- Accuracy = (TP+TN)/(TP+FP+TN+FN)
  - Overall correctness

TP = True Positive, TN = True Negative, FP = False Positive, FN = False Negative

Performance at 80% or better is typically desired. In addition, false positive rate, false negative rate should be determined for each drug or drug class.

Device Operation. In addition to overall device performance, the functionality and reliability of devices should also be taken into consideration when determining the right fit for each agency. Ultimately, devices should be relatively simple to use and troubleshoot in the field, operate in different environments, and be designed in a way that takes into consideration officer safety. Law enforcement officers should have confidence in their equipment. Oral fluid field screening devices should serve their function without significantly adding to officer workload. Specific questions and considerations include the following:

- Is the device user-friendly in collection and operation?
- How much training is required to operate the device?
- Does the device have any self-checking capabilities?
- Does the device have sensors or other mechanisms to identify issues with sample analysis (e.g., tilt sensor)?
- Will error codes appear if there is an issue?
- Will the device prevent a result from being issued if it detects a possible problem?
- How easy is troubleshooting in the field?
- Can the device operate in extreme temperatures?

- How will the use be affected under different environmental conditions (e.g., how easy is it to operate and read any results in poor lighting)?
- Is there a color indicator on the collection device to indicate adequate volume has been collected?
- Does the sample collection process take officer safety into consideration? What is the officer's level of exposure to the driver's oral fluid?
- Is the device portable (e.g., able to be used at roadside; weight)?
- Does the device retain and/or print the result or is it a visually read device?
- Can the result be read visually in compromised lighting conditions?
- If the device is battery-operated/requires charging, how many tests can be administered in the field before another charging is required?
- How are test results displayed? Can this be customized to agency specifications?
- Can device be powered inside the police car or are additional batteries required to be carried?
- What additional equipment (if any) is needed is test is performed in a separate location (e.g., jail, hospital, etc.)?

For agencies considering oral fluid programs, comprehensive information about device performance and operation along with other critical information should be obtained during initial planning. Manufacturers should provide comprehensive device specifications. This information includes drug test panels, cutoff concentrations for each drug included in the test cartridge, cross-reactivity, and any interferents from commonly ingested substances (e.g., coffee, nicotine, toothpaste, etc.). Other information that should be reviewed and taken into consideration when making device selections includes the following:

- Device operation
- Standard operating procedures
- Potential interferents (e.g., mouthwash, chewing gum, etc.)
- Error codes and how to troubleshoot various problems
- Cartridge use and how to verify whether a cartridge is valid or expired
- Quality assurance protocols and so on

Note: Expired cartridges should not be used. In some cases, the device will not perform if an expired cartridge is used. However, if a test is performed, the accuracy of an immunoassay decreases as both antibodies and antigens can degrade over time so false results become more likely—this is particularly the case for THC and cocaine tests.

Portability. For roadside programs where the oral fluid device will be deployed in the field as opposed to a controlled environment, portability is an important consideration. Some common portability considerations include the following:

- Is the device battery operated?
- How often does any battery need to be charged?
- Is storage in a vehicle an issue?
- Does the device need to be on a level surface for operation?

Another recommendation for law enforcement agencies exploring pilot options is to conduct outreach with other agencies who have commenced or completed pilots. This affords project stakeholders an opportunity to ask questions about devices, first and foremost, but also identify potential issues or challenges. Being able to address problems proactively and learn from the

experiences of counterparts is extremely valuable and can help in shaping a strong pilot program.

Evidence Handling: Submission, Preservation, and Storage

Avoid prolonged exposure to heat/sunlight. Proper chain of custody should always be maintained.

The following factors impact the stability of drugs in oral fluid: chemistry of drug, collection device, elution buffer, and storage conditions. The timely analysis of an oral fluid sample is recommended due to instability of some target drugs (e.g., THC, cocaine). OFFS device manufacturers should provide specific storage instructions and stability data.

OFFS Devices. Listed are some common devices and their use and storage parameters:

- ***Dräger DrugTest 5000:*** The device must be used in an environment between 4°C and 40°C degrees Celsius (39.2°F and 104°F). The kits must be stored between 4°C and 30°C (39.2°F and 86°F).[2]
- ***Abbott SoToxa:*** The device must be used in an environment between 5°C and 35°C (41°F and 95°F). SoToxa is equipped with ambient temperature sensors to monitor during testing. An onboard heater will warm up the testing platform to allow the test cartridge to run at the optimum temperature.[3] The kits must be stored between 15°C and 25°C degrees Celsius (59°F and 77°F).[4]
- ***Securetec DrugWipe:*** The device must be used in an environment between 5°C and 25°C degrees Celsius (41°F and 104°F). The recommended operating temperatures for the WipeAlyser device are between 5°C and 40°C.[5] The kits must be stored between 2°C and 30°C (35.6°F and 86°F).

The majority of oral fluid test kits have similar storage requirements. The narrow temperature range of use and storage creates challenges. Test kits cannot be placed in a patrol car and forgotten. Summertime temperatures in an enclosed parked vehicle can easily soar to over 140°F and wintertime temperatures can easily dip below 0°F. Storing the test kits outside of the recommended range can severely compromise the accuracy or render the kit unusable.

Operation of Field Screening Devices. Officers shall use the device according to the manufacturer's operational procedure.

Four examples are provided:

- Dräger DrugTest 5000[6]
- Abbott SoToxa[7]
- Randox MultiStat[8]

[2] See https://www.draeger.com/Products/Content/drugtest_5000_testkit_pi_9046366_en.pdf
[3] See https://www.globalpointofcare.abbott/en/product-details/sotoxa-mobile-test-system-us.html
[4] See https://www.toxicology.abbott/en/index.html
[5] See http://drugwipeusa.com/drugwipe-s
[6] https://www.draeger.com/en-us_us/Products/DrugTest-5000#images-videos
[7] https://www.globalpointofcare.abbott/en/product-details/sotoxa-mobile-test-system.html
[8] https://www.randoxtoxicology.com/instrumentation/evidence-series/evidence-multistat/

- Securetec DrugWipe[9]

Many devices have on-screen instructions that guide the process, self-tests, and test cartridge expiration identification. Quality control (QC) tests and annual maintenance shall be conducted per manufacturer's operational procedure. The device is working properly if the QC test(s) pass. Device requirements for operating temperature and air humidity should be consulted prior to use. Some devices have criteria for delayed analysis (e.g., 4–8 hours after collection).

Once an adequate amount of oral fluid is collected, the sample interacts with the test membrane that is coated with antibodies and drug conjugates. If the sample is drug free, the antibodies can react freely with the drug conjugates, which triggers a signal on the test membrane. If the sample contains drugs, they bond to the membrane coated with antibodies, which weakens the generated signal. The signal is inversely proportional to the drug concentration in the sample.

A 10-minute deprivation period should start at the time of stop or initial contact. The subject should not eat, drink, or smoke 10 minutes prior to giving a sample. By the time SFSTs are finished, 10 minutes will have passed. Per the NHTSA report (Buzby et al., 2021), the incorporation of a 10-minute waiting/deprivation period as recommended by the manufacturers prior to testing eliminated all the effects of the potential interferents such as chewing tobacco, coffee, milk, cola, and wintergreen mints. The collection and analysis phases largely depend on how long it takes to generate enough oral fluid to collect a sufficient sample. This can typically be completed in 3 to 10 minutes. Analysis of the sample takes additional time (5 to 10 minutes). Similar to the field screening, collection of enough oral fluid for a confirmation or evidential sample will take 3 to 10 minutes. Overall, the process to collect and analyze oral fluid screening results and to collect a second oral fluid sample to be sent to a laboratory for confirmation testing lasts between 11 and 30 minutes. Dry mouth, or xerostomia, can occur as a result of smoking, opioid use, or other medical conditions such as diabetes; drivers with dry mouth may take longer to produce adequate oral fluid for testing.

How Do Devices Record, Display, Store, and/or Print Results?

Preference should be given to devices that adequately record, display, store, and print results. Officers should retain printed results or a photograph of the device results. Specific protocols may be dictated by local law enforcement agency policy. Alternately, a policy specific to roadside drug testing program data might be established along with other program requirements. Several devices will electronically store a specific number of test results that may be periodically uploaded and retained. In the future, the creation of manufacturer dashboards/portals or oral fluid program databases could be used to house test results and facilitate data analysis.

Consent and Search Warrants

Traffic stops vary in nature and purpose. A traffic stop is a seizure under the Fourth Amendment (*Whren v. U.S.*, 517 U.S. 806, 809-810 (1996). The seizure of a vehicle is a separate constitutional event from the search of a vehicle. This restraint on government conduct generally bars officers from undertaking a search or seizure absent individualized suspicion. A law enforcement officer only needs reasonable suspicion to comply with the requirements of the Fourth Amendment. *Heien v. North Carolina*, 574 U.S. 54, 60 (2014); *see also U.S. v.*

[9] https://www.securetec.net/wp-content/uploads/2018/08/s602g_instructions_70085-en-v05-2016-11-16.pdf

Singletary, 798 F.3d 55, 59 (2d Cir. 2015) (reasonable suspicion "demands specific and articulable facts which, taken together with rational inferences from those facts, provide detaining officers with a particularized and objective basis for suspecting legal wrongdoing").

In DUI cases, the ability to articulate reasonable suspicion is extremely important. The basis for reasonable suspicion may also be critical evidence of a DUI case. These traffic investigations commonly turn into probable cause needed to arrest an individual. Because of this, these traffic investigations must be conducted diligently, and without undue delay. *Rodriguez v. U.S.*, 575 U.S. 348, 357 (2015). The standard for review of these traffic stops is reasonableness and the courts must balance law enforcement's intrusion into an individual's Fourth Amendment interest against the promotion of a legitimate governmental interest. *Delaware v. Prouse,* 440 U.S. 648, 654 (1979). Courts have held that even a 50-minute traffic stop can be reasonable and in line with the requirements of the Fourth Amendment. *U.S. v. Hardy*, 855 F.2d 753, 758 (1988); *see also U.S. v. Sharpe*, 470 U.S. 675, 683 (1985) (a 20-minute stop is not unreasonable when the police have acted diligently and a suspect's actions contribute to the added delay about which he complains).

There are limited circumstances where courts have upheld searches conducted without particularized suspicion of individuals. These situations typically occur at sobriety checkpoints. "At a checkpoint the balance of the State's interest in preventing drunken driving [and] the degree of intrusion upon individual motorists who are briefly stopped, weighs in favor of the state program [and] it is consistent with the Fourth Amendment." *Michigan Dept. of State Police v. Sitz*, 496 U.S. 444, 455 (1990). Checkpoints are not a de minimus seizure, and require an examination of reasonableness analysis. For checkpoint seizures to be held reasonable, they must meet the balancing test outlined by the U. S. Supreme Court in *Brown v. Texas*, 443 U.S. 47, 51-52 (1979) and applicable state law. The same applies to administrative inspections. *See New York v. Burger*, 482 U.S. 691, 702 (1987). A similar test is used for Border Patrol checkpoints, as outlined in *U.S. v. Martinez-Fuerte,* 428 U.S. 543, 561-562 (1979). Typically, courts look at the duration of a stop at a border checkpoint, not at the set of questions asked by law enforcement. *U.S. v. Machuca-Barrera*, 261 F.3d 425, 433 (5th Cir. 2001).

DUI investigations take time and as long as officers are meticulous in their investigations, they will be in compliance with the Fourth Amendment. Asking any driver to submit to an OFFS only requires reasonable suspicion and should be done at the conclusion of SFSTs. The recommended observation period can coincide with the administration of SFSTs. Users must be mindful of constitutional and legal limitations on the reasonable duration of a traffic stop to avoid suppression of evidence. Judicial review of the reasonableness of a traffic stop includes the duration of the stop and the notion that all investigative activities conducted during a traffic stop are part of an ongoing seizure and therefore are subject to both subject-matter and durational limitations. Further, during a traffic stop, an officer is limited to investigatory inquiries that are reasonably related to the purpose and reason for the initial traffic stop; unrelated investigations may only be justified if the officer develops separate reasonable grounds or probable cause of other violations.

Time is of the essence in collecting biological samples in DUI cases. The longer the delay between the time of a traffic stop and the eventual collection of an evidential chemical sample, the greater the likelihood that concentrations of alcohol and/or drugs in the body will be considerably lower than at the time of vehicle operation. It is best practice to first seek consent for an evidential test meaning, have the impaired driving suspect voluntarily submit to the

requested form of testing. In cases where drug impairment is suspected, an evidential urine, blood, and/or oral fluid sample can be collected if legislation authorizes the testing method.

The majority of states rely on blood testing in drug-impaired driving cases and this has Fourth Amendment implications. If a driver refuses to voluntarily provide a sample, a search warrant is acquired to perform a forced blood draw, when lawful in the particular jurisdiction. In *Missouri v. McNeely*, 569 U.S. 141 (2013), and *Birchfield v. North Dakota*, 577 U.S. 1045 (2016), the Supreme Court indicates that technological advancements have created an environment where law enforcement should be able to obtain search warrants in a timely fashion. The Court in *McNeely* ruled that the natural dissipation of alcohol in blood did not create a per se exception to the Fourth Amendment's warrant requirement based on exigent circumstances. The *Birchfield* Court held that officers could compel blood samples from DUI suspects in three scenarios:

1. Probable cause to believe the individual operated a vehicle while impaired and a warrant to seize blood is obtained
2. The driver voluntarily provides a blood sample
3. Exigent circumstances

The invasive nature of drawing blood, which involves piercing the skin, was cited as justification for the search warrant requirement.

While it is true that a DUI search warrant can be quickly obtained in some jurisdictions, this is not a universal experience. Law enforcement officers in many jurisdictions, particularly those serving in rural counties, encounter significant delays in acquiring a warrant and transporting a suspect to have an authorized professional perform an evidential blood draw. Therefore, unless the jurisdiction where the DUI occurred allows for and has an expedited warrant system and short wait times, obtaining the confirmation sample can take in upward of 2 hours. Failure to expeditiously secure an evidential blood sample translates to loss of evidence as drugs rapidly metabolize and dissipate within the body. In states that have per se laws for drugs, these delays can negatively affect case outcomes.

To overcome some of these delays, more law enforcement agencies have begun to rely on electronic warrant systems that allow for expedient preparation, transmission, review, and approval of search warrants in impaired driving investigations. To learn more about e-warrants, refer to the Responsibility.org implementation guide and legislative checklist (Responsibility.org, 2018).

Generally, practitioners understand the process, and barriers, to securing blood samples in DUI cases. But what about an evidential oral fluid sample? If a warrant is required for a blood draw (except in the instances outlined above), does the same requirement extend to evidential oral fluid testing? At this time, the answer is no. The use of oral fluid for confirmation testing in impaired driving cases is new in comparison to blood and its use is limited, translating to fewer court challenges. It stands to reason that oral fluid drug testing might be treated similarly to evidential breath testing as the processes are comparable. The latter is non-invasive and was classified by the U.S. Supreme Court as a search incident arrest. The collection of an oral fluid sample is more invasive than expulsion of air but is less invasive than venipuncture. While warrantless oral fluid confirmation testing will eventually be challenged, if courts determine that law enforcement officers can obtain these samples without needing a warrant, oral fluid testing will confer several advantages over blood draws in DUI cases including ease and speed of sample collection.

While these judicial matters will eventually be litigated in state and possibly federal court, another barrier to evidential oral fluid testing is legislative in nature. At present, of the states that authorize the collection of oral fluid to detect drugs, most include it as part of their implied consent laws.

It is best practice to first seek consent for an oral fluid and or blood confirmation specimen. Depending on state law, law enforcement may be able to seek a search warrant for the collection of oral fluid samples. An individual can revoke consent at any point until the sample is lawfully taken by authorities. A law enforcement officer who accepts such revocation should document the revocation in his or her report and alert the prosecutor as soon as possible.

What Should an Officer Do If the Field Oral Fluid Test Result Is Negative?

When a field oral fluid test result is negative and there is objective evidence of impairment, a toxicological sample (blood and/or oral fluid) should be collected and sent to the laboratory for comprehensive analysis. It is imperative that officers continue the drugged driving investigation independent of the field test results, since the absence of a positive result does not preclude the existence of another drug not tested by the device; an individual could be under the influence of a drug that is beyond the scope of the oral fluid field screen. A negative result produced by an oral fluid screen could also mean that an individual tested below the cut-off concentrations for the drugs included in the panel. An individual could have a drug in their system but still be below a cut-off, although impairment at these lower levels is less likely. Finally, a negative result on an oral fluid field screen does not take into account blood alcohol concentration or impairment resulting from a combination of alcohol (at any level) and other drugs. There are panel limitations with devices that may account for the negative result. See Special Considerations: Benzodiazepines.

What Should an Officer Do With the Field Screening Device/Cartridge After Use?

Oral fluid cartridges inserted in mobile test systems that include analyzers are usually disposable and do not have any future scientific value (i.e., cannot be tested again) once the result is produced. Disposable devices should be used for nearly immediate results and should only be stored and tested within the time frame provided by the manufacturer. For example, if oral fluid is collected at the roadside for probably cause purposes, one may not store the device after use or send to a laboratory for additional testing beyond the intent of the manufacturer. The only known exception is Australia's program where an expectorant sample is collected simultaneously with the Draeger DT5000 cartridge.

Figure 3. Dräger DT5000 With Simultaneous Confirmation Collection

Oral fluid samples collected for confirmation testing are different than those used for screening. Samples submitted to laboratories are analyzed using different methods and are subject to chain of custody and other policies/protocols related to use, storage, and retention.

Special Considerations for Law Enforcement

Officer Training

Manufacturers of oral fluid confirmation collection devices often offer online video instruction and/or in-person training for users. It is the responsibility of each law enforcement agency to maintain permanent records documenting the training of each officer in the use of approved field screening devices and the annual maintenance results on each device in use. Courts deciding the admission of results may look to see whether the person administering the test was properly trained and administered the test properly according to the manufacturer's recommendation.

Dräger provides an agency end-user class (4 hrs.) for up to ten officers and additionally, an agency train-the-trainer course (4 hrs.) that are both complimentary as part of the purchase of the equipment. Dräger also offers online training options. An example Dräger DrugTest 5000 certificate is provided in Appendix G.

Securetec DrugWipe offers in-person and online training. Online training may be provided via Zoom access for DrugWipe. An example training certificate is provided in Appendix H.

In most cases, onsite training is available with the SoToxa training program. SoToxa has an online training video that covers product storage, printer and system charging, and a list of dos and don'ts. The training is followed by a short exam and a certificate of completion can be printed if the officer passes the exam. An example training certificate is provided in Appendix I. Also, SoToxa has intuitive on-screen prompts that walk the user through the testing process, a

help button will bring the user back to the instructions screen. Testing consists of three simple steps**.**

Officer Safety

The arresting officer should engage in general officer safety practices at all times. Law enforcement should avoid direct contact with oral fluid. It is recommended that the officer wear gloves during the collection for hygienic reasons. For both officer and driver safety, collection of the specimen using a collection pad may be easier than attempting to expectorate, rinse the mouth, or spit into a tube. Most manufacturers of roadside and confirmation collection devices instruct the officer to direct the subject to place the collection device into his or her mouth and remove it upon completion. A sample cannot be forcibly collected upon subject refusal. Although collection of a confirmation specimen at the roadside is preferred, this may not be practical due to time constraints, subject behavior, location of traffic stop, or other factors. In these situations, the oral fluid confirmation specimen should be collected as soon as a safe environment is secured.

As an example, SoToxa supports officer safety since it is a truly handheld analyzer fitting comfortably in one hand while freeing up the other. The system is designed to mix the buffer, run the test, and interpret the results when ready. SoToxa can be put down once the testing begins should the officer choose to do so. The system will give an audible alert when test results are ready in 5 minutes, there will also be a visual on the screen that stays until the officer presses OK. This allows the officer at roadside to focus on the driver and surrounding environment.

Report Writing for Law Enforcement

Law enforcement should always include details about the use of any field screening device in the narrative and perhaps an impairment form (if there is space to report preliminary screening results). Possible facts of the case could be demeanor of the subject during testing, if the subject had difficulty giving a sample, and positive or negative result. An arrest decision cannot be solely based on the results of the OFFS test; however, results need to be included in the report as an element of the facts.

Drug Evaluation & Classification Program

A DRE is a specially trained law enforcement officer that can identify drivers who may be under the influence of a drug or driving in an impaired condition by checking for signs and symptoms of drug use as well as the presence of one or more of seven drug categories.

The DRE protocol is a standardized and systematic method of examining a suspect to determine the following: (a) whether or not the suspect is impaired; if so, (b) whether the impairment relates to drugs or a medical condition; and if drugs, (c) what category or combination of categories of drugs are the likely cause of the impairment. The DREs utilize a 12-step process to assess DUID suspects. The process is *systematic* because it is based on a complete set of observable signs and symptoms that are known to be reliable indicators of drug impairment. Based on the totality of the evaluation, the DRE forms an opinion as to whether or not the subject is impaired. If the DRE determines that the subject is impaired, the DRE will indicate what category or categories of drugs may have contributed to the subject’s impairment.

If a DRE follows the 12-step process, the knowledge of a field screen result should not influence the opinion.

Field oral fluid drug screening serves to complement the DRE program and does not provide a substitution for a DRE evaluation or comprehensive DUID investigation. Oral fluid drug testing is a test of drug use, not impairment; the result can be used to support the DRE officer's opinion about what drugs are responsible for the observed impairment. Oral fluid drug testing is a tool that assists a DRE investigation, providing real-time chemical test information that can be used by the officer in questioning the subject about their drug use. When a DRE officer is not available, officers should perform standardized field sobriety test battery, followed by the oral fluid field screen. A DRE or toxicologist can later give an opinion about whether the observations in the SFSTs are consistent with the drugs detected in the field.

To reduce the appearance of bias, a system may be established to withhold field screening results from the arresting officer and/or DRE if an evaluation will be included during the DUID investigation. This may include a policy where the arresting officer does not share the specific drug/drug class that screened positive in the field. Alternatively, the manufacturer of the field screening device may program the device to only display positive or negative as an overall result and hide the specific drug or drug class that screened positive.

Part III: Laboratory Oral Fluid Confirmation

Confirmatory Laboratory-Based Testing for Drugs in Oral Fluid

It is important to discern between a screening and confirmation test conducted at a forensic toxicology laboratory for evidentiary purposes. The recommendations for collection of a second oral fluid sample after the field screen is covered earlier in this report. All presumptively positive field screen results must be re-screened (e.g., by immunoassay) and/or directly confirmed with a laboratory-based analysis. An evidentiary confirmation aids in evaluating or monitoring false positives and negatives. While OFFS devices typically screen for 6 to 8 drugs or drug classes, evidentiary testing should expand the panel to include relevant Tier I and Tier II compounds as recommended by the NSC-ADID (D'Orazio et al., 2021) (see Table 9).

Table 9. 2021 NSC Cut-Off & Scope Tier I Recommendations

Drug(s)	Oral Fluid Cut-Off Concentrations (ng/mL)	
	Screen	Confirm
DRE Category: Cannabis		
Δ9-tetrahydrocannabinol (THC)	4	1
Carboxy-THC	-	-
11-hydroxy-THC	-	-
DRE Category: CNS Stimulants		
Methamphetamine	20	20
Amphetamine	20	20
MDMA*	20	20
MDA*	20	20
Cocaine	15**	8
Benzoylecgonine	15**	8
Cocaethylene	-	8
DRE Category: CNS Depressants		

Carisoprodol	500	500
Meprobamate*	-	500
Zolpidem	10	10
Low-Dose Benzodiazepines	5	-
Alprazolam	-	1
Alpha-Hydroxyalprazolam	-	-
Clonazepam	-	1
7-Aminoclonazepam	-	1
Lorazepam	-	1
High-Dose Benzodiazepines	5	-
Diazepam	-	1
Nordiazepam	-	1
Oxazepam	-	1
Temazepam	-	1
DRE Category: Narcotic Analgesics		
Codeine*	30	5
6-acetylmorphine	-	1
Buprenorphine	1	2
Norbuprenorphine	-	-
Fentanyl	1	0.5
Hydrocodone*	30	5
Hydromorphone*	30	5
Methadone	20	10
Morphine	30	5
Oxycodone*	30	5
Oxymorphone*	30	5
Tramadol	50	10
O-desmethyltramadol	-	-

**Must have ≥80% cross-reactivity if using immunoassay for blood and urine*

***Screening for either benzoylecgonine or cocaine in oral fluid is acceptable*

The gold standard for confirmation testing in forensic toxicology is mass spectrometry. Upon receipt of a specimen, analysis of oral fluid for drugs is a relatively straight-forward proposition because of improved sensitivity of available instrumentation. Oral fluid methods use similar analytical methods, instrumentation, and sample volume as blood and urine analyses. Manufacturers provide methods for the identification of a wide range of drugs in oral fluid (see https://www.agilent.com/search/?Ntt=Oral%20Fluid%20Analysis and Xie et al., 2016) and there are numerous publications for the analysis of the main drug classes in oral fluid (Cone et al., 2015; Coulter & Moore, 2019; Jang et al., 2013; Liu et al., 2015; Tuyay et al., 2012). Even though LC-MS/MS instruments are often the instruments of choice, gas chromatography/mass spectrometry (GC/MS) instruments can be used for adequate sensitivity to detect drugs in oral fluid. Generally, drugs should be efficiently extracted from transportation buffers to avoid injection of stabilizers and surfactants directly into instruments. An excellent review by Desrosiers and Huestis, references over 80 GC/MS or LC/MS published methods for oral fluid confirmation (Desrosiers & Huestis, 2019). Advances in technology have enabled the analysis of multiple drug classes in oral fluid using a single assay, especially if a qualitative approach is used. Such an approach can save valuable time, reduce analysis cost, and improve turnaround

times. Turnaround time depends on a variety of factors, including staffing, scope of analysis, instrumentation and methodology, caseload (submissions), and management of resources. With adequate staffing, instrumentation, and methodology, blood analysis turnaround times typically range from 15 to 75 days. Oral fluid (qualitative) analysis can be completed within a few weeks or less. Automation equipment and techniques can further reduce turnaround times.

Guidelines for Oral Fluid Collection as a Confirmatory Specimen

Oral fluid can be collected as an undiluted fluid via passive drool, expectoration into a tube, or using a cotton or synthetic fiber collection pad placed into a dry tube or into a diluent for shipment to a laboratory. All have strengths and weaknesses in convenience, stability of matrix and analytes, and other parameters. Confirmation specimens should be collected in appropriate tubes/devices with volume indicators and/or a mechanism for demonstrating when adequate volume has been collected (e.g., color change). The collection of neat oral fluid via spitting or expectoration may be problematic in terms of hygiene and achieving adequate volume for testing. THC is particularly unstable in oral fluid without stabilizing buffer.

It is best practice to collect an oral fluid confirmation specimen by passive means as opposed to a stimulated and/or expectorant collection (stimulated and expectorant collection may dilute the drug concentration in oral fluid). Smoking and drug use can affect the production of saliva, as well as time needed to collect an expectorated sample, which is often viscous will be longer than with a passive pad collection. Common examples of passive oral fluid collection devices include Quantisal, OralEze, NeoSal, Intercept I2, and Intercept I2he, which all include volume adequacy indication and sample stabilization buffers to provide drug recovery and assure stability of the sample during transport. Some pads are treated with additives (e.g., citric acid) to stimulate saliva production, which may affect the concentration of the drug in oral fluid.

The newly released Substance Abuse and Mental Health Services Administration (SAMHSA) mandatory guidelines for workplace drug testing state that a minimum of 1 mL ± 10% of neat oral fluid be collected regardless of device and 80% of the drug collected on the pad must be recovered. The guidelines also state that for the Federal workplace testing program every collection must provide a split sample (i.e., Tube A and Tube B). In oral fluid collection from drivers while this may not be a mandatory requirement, it would provide a second identical specimen reserved for any future testing requirements. In such cases, assessment of drug stability in collection devices under long-term storage conditions is essential.

Selection of a device for confirmatory testing is a critical decision. The device can affect the analytical result and therefore the reliability and accuracy of the data generated. As well as following the manufacturer's instructions (volume adequacy activation, pad residence time, transportation method, etc.), other post-collection and laboratory handling precautions should be assessed.

Example Protocol for Oral Fluid Collection

The Quantisal oral fluid collection device is one of the most commonly studied and used devices for evidentiary collection. The following are the manufacturer instructions, provided for illustration purposes:

- Check expiration date on Quantisal packaging and ensure the subject has refrained from consumption of food or beverage for 10 minutes prior to specimen collection.

- Instruct the subject to peel open package and remove collector.
- Have subject move tongue side to side to accumulate saliva in his or her mouth before starting to speed up the collection.
- Keep the tip of the device pointed down. Instruct subject to position collector under tongue and close mouth.
- Keep head down to allow gravity to help with saliva collection. Ensure subject does not chew on pad, talk, or remove collector from mouth until indicator turns blue, or until 10 minutes has elapsed.
- Instruct subject to hold transport tube in an upright position and uncap by pushing up with thumb(s). Do not stand tube on table. Do not spill or empty liquid from tube. Instruct subject to insert collector into the uncapped transport tube and replace the cap.
- Snap cap firmly for transport. Place center of specimen seal on top of tube and press down both sides.
- Complete paperwork and send sample to laboratory for testing.
- If the sample is not sent immediately, it should be refrigerated until transport to the test facility.
- Oral fluid should be collected by the investigating officer or by his or her representative as close to the arrest or crash as possible (e.g., at roadside). Collect the oral fluid confirmation sample in this order of preference: at roadside (after 10-minute observation period), prior to DRE evaluation (if applicable), after DRE evaluation (if applicable), at the same time as the blood draw. For more details, see Alabama Department of Forensic Sciences collection instructions (Antemortem Specimen Kit Instructions (Form DFS-670), ADFS).

Validation of Confirmation Methods

Confirmation of drugs and metabolites in oral fluid usually involves extraction of the analytes from the fluid itself or oral fluid/buffer mix from collection devices. Even with neat oral fluid there are still sample preparation steps remaining before injection into an instrument (e.g., centrifugation and precipitation). Dilution with buffer, supported liquid extraction (SLE), solid phase extraction (SPE) and liquid-liquid extraction (LLE) methods have also been reported. When collection devices with no buffer are used, the drugs are eluted from the pad or device using an organic solvent, which may be directly injected into the instrument. For quantitative analysis, the dilution factor from collection devices that incorporate transportation buffers must be taken into account for the calibrators and controls used in the assay.

Validation parameters for the determination of drugs in oral fluid are the same as those necessary for other analytical methods in toxicology and should include linearity, limits of detection and quantitation, precision, accuracy, and specificity. Additional parameters for LC-MS/MS assays include measurement of ion suppression, matrix effects, and process efficiency. Unique variables in the analysis of oral fluid are drug recovery from a collection device (if used) and drug stability in transportation buffers and during storage. Professional guidance is available on acceptable validation of methods for drug analysis in oral fluid. ANSI/ASB Standard Practices for Method Validation in Forensic Toxicology (American National Standards Institute & AAFS Standards Board, 2019).

Laboratories may elect to develop qualitative methods since there is a correlation between presence and absence of drug in oral fluid and blood, but not a direct correlation between concentrations in oral fluid and blood in most cases; this is due to a variety of factors (e.g., oral cavity contamination from recent use, unknown exact volume of confirmation oral fluid specimen, individual variability in pharmacokinetics and pharmacodynamics). For qualitative

methods, uncertainty of measurement, accuracy, and limit of quantitation assessments are not required. Quantitative measurement of drug concentrations for research purposes is essential to developing a better understanding of typical oral fluid drug concentrations in various populations, which in turn helps with the development of screening devices with the appropriate sensitivity. Furthermore, such research will assist with optimizing cut-offs for screening and confirmation methods as well as establishing blood-to-oral fluid ratios at different pharmacokinetic time points.

The Alabama Department of Forensic Sciences is the first state crime laboratory to implement a comprehensive oral fluid program to include field screening and laboratory confirmation testing. As part of the program, two confirmation methods were developed and validated including an 18-target drug of abuse extraction method using DpX (Dispersive Pipette Extraction) technology and a 6-target cannabinoid method using liquid-liquid extraction. Each assay required 500 µL of oral fluid sample for a total of 1 mL for both extractions. Methods were validated on a 6460 Agilent Triple Quadrupole LC-MS/MS instrument following Scientific Working Group for Forensic Toxicology (SWGTOX) Method Validation Guidelines. DUI biological specimen kits were redesigned to include two tubes for blood collection and one Quantisal oral fluid collection device. Officers are instructed to collect both blood and oral fluid. As of March 2021, approximately 600 oral fluid cases have been submitted to the laboratory for confirmation testing since inception of the program over the summer of 2018.

Evidence Handling: Submission, Preservation, and Storage

All evidence should also be properly sealed with tamper evident tape to prevent escape of evidence. Evidence labels should be filled out with relevant information to include subject's name, collector's name or initials, and date/time of collection. Store unused collectors at room temperature. Avoid prolonged exposure to heat/sunlight. Ship samples to laboratory as soon as possible. To enhance sample integrity and maximize stability oral fluid specimens collected for confirmation testing should transferred to a refrigerator and stored at 4°C. Proper chain of custody should always be maintained. A portion of the sample or a second sample should be maintained for a period between 12 and 24 months to allow the defense access for a secondary test.

The following factors impact the stability of drugs in oral fluid: chemistry of drug, collection device, elution buffer, and storage conditions. The timely analysis of an oral fluid sample is recommended due to instability of some target drugs (e.g., THC, cocaine). Manufacturers of oral fluid collection devices designed for laboratory testing should provide specific storage instructions and stability data.

Quantisal I Device (Table 10): THC shows significant loss at room temperature after 7 days; other drugs (i.e., Benzoylecgonine amphetamine, methamphetamine, morphine, oxycodone, PCP) remained stable. Higher concentrations demonstrate greatest instability but were minimized when refrigerated. Refrigerated specimens show minor degradation with THC losses minimized at low and high concentrations. Drugs are stable in Quantisal collection devices for 30 days at room temperature with the exception of THC, which shows significant loss after 7 days (25%–30%). All drugs, including THC, are stable in Quantisal for at least 30 days (<20% loss) in refrigerated conditions. No significant drug loss in transportation using standard shipping methods was observed.

Quantisal II Device (split specimens): Cocaine, benzoylecgonine, and THC are stable when collected with the Quantisal II device with less than 10% loss from original concentration for 5

days at 30°C and 30 days at 5°C and during routine transportation. Samples showed less than 20% loss at 3 months. PCP is stable when collected with the Quantisal II device with less than 10% loss from original concentration for 10 days at 30°C and 60 days at 5°C and during routine transportation. Samples showed less than 20% loss at 3 months. THC, cocaine, benzoylecgonine, PCP, methamphetamine, amphetamine, and methadone were still positive in refrigerated, unopened tubes after 1 year of storage (when compared to the original analysis). Some losses in THC and cocaine concentrations over time were observed. The differences in drug concentrations were ±15% between split specimens.

Therefore, it is recommended that laboratories complete confirmation testing in a timely manner; preferably within 2 weeks to 1 month of collection if possible.

Table 10. Stability of Drugs Collected With the Quantisal Collection Device

Stored at Room Temp. (23°C)	***Loss Percentage***				
Drug Class	**Day 0**	**Day 3**	**Day 7**	**Day 14**	**Day 30**
Benzoylecgonine	0	−2	7	24	13
Amphetamine	0	5	11	11	12
Methamphetamine	0	7	15	21	13
Morphine	0	1	4	1	2
Oxycodone	0	0	0	3	−7
Phencyclidine	0	0	7	7	0
Delta-9-tetrahydrocannabinol	0	−3	−25	−27	−30

Stored at Refrigerated Temp. (4°C)	***Loss Percentage***		
Drug Class	**Day 0**	**Day 14**	**Day 30**
Benzoylecgonine	0	20	17
Amphetamine	0	7	13
Methamphetamine	0	14	15
Morphine	0	1	9
Oxycodone	0	6	1
Phencyclidine	0	7	3
Delta-9-tetrahydrocannabinol	0	0	−2

Training and Qualification Requirements for Forensic Toxicologist

Adequate training in a formalized training program must be completed by a toxicologist prior to conducting oral fluid laboratory testing to include competency testing. Proficiency testing should be conducted regularly per accreditation guidelines to evaluate maintenance of skill and performance.

The Scientific Working Group for Forensic Toxicology (2015) Standard for Laboratory Personnel document delineates the minimum requirements for educational qualifications, training, and certification for a technician, analyst, and toxicologist. It reflects a minimum standard of practice and details the scope of duties per classification. A technician may perform basic analytical functions but does not evaluate data, reach conclusions, sign reports, or provide interpretive

opinions. An analyst may conduct, direct, or review analysis of forensic toxicology samples, evaluate data and reach conclusions, and sign reports, but does not provide interpretive opinions. A toxicologist may perform the duties above and provide interpretive opinions related to the results of toxicological tests. A toxicologist may opine on pharmacokinetics (i.e., absorption, distribution, metabolism, elimination) and pharmacodynamics (e.g., the effects of drugs on human behavior and driving performance) (Olson, 2019).

Interpretation of Oral Fluid Results

According to the Society of Forensic Toxicologists (2018), the onset of drug detection in oral fluid is dependent on the route of administration. Drugs that are smoked, inhaled, snorted, or taken as edibles appear rapidly and at high concentration in oral fluid because of buccal cavity exposure; intravenously administered drugs are also detected rapidly. Drugs that are administered orally in capsules (e.g., dronabinol) generally do not contaminate the oral mucosa, and may not be as readily detectable until an equilibrium has been reached between oral fluid and blood (Bakke, 2019).

Oral fluid and blood concentrations are not equivalent; the corresponding oral fluid drug concentration to a blood value depends on achieving a steady state between the two media.

Oral fluid and blood THC concentrations are not directly correlated immediately after intake; drugs require time to equilibrate within the body; initial oral fluid concentrations are elevated because of oromucosal deposition depending upon the route of administration. Oral cavity contribution (contamination) can be viewed as an advantage in identifying recent drug use.

For many drugs, particularly when smoked, vaped, or snorted, oral fluid drug concentrations do not predict concurrent blood drug concentrations; however, when prescription doses are taken as prescribed, equivalent drug quantitative ranges may be established for some drugs (Heiskanen et al., 2014).

However, at this time, it is not recommended to estimate drug concentrations in whole blood from oral fluid drug concentrations or vice versa. It is not possible to correlate a quantitative drug concentration in any bodily fluid directly to degree of impairment in a specific individual. Whereas significant research has been published on therapeutic plasma, serum, and blood concentrations, further research needs to be conducted with oral fluid.

Oral Fluid–Blood Pairs

In 2007, the National Highway Traffic Safety Administration (NHTSA) carried out the first national survey of drivers that included the testing of biological specimens (blood and oral fluid) for illegal, prescription, and over-the-counter drugs. More than 16% of drivers showed the presence of one or more of these compounds, with marijuana accounting for almost half of the positives. The results showed a 97% agreement between the two sample types, indicating that oral fluid is a viable alternative to blood for the detection of drugs in drivers (Kelley-Baker et al., 2014). The study was repeated in 2013–2014 with an increase to 20% in overall positives (8% to 12% for cannabis) (Kelley-Baker et al., 2017).

The agreement between the results in blood and oral fluid was largely due to the fact that they were collected virtually simultaneously. Typical windows of detection of drugs in oral fluid mirror blood when collected simultaneously: for most drugs 24 to 48 hours and for THC 12 to 24 hours depending on the route of administration, drug dose, drug formulation, history of use, sensitivity

of the analytical test method and cut-off concentration (Society of Forensic Toxicologists, 2018). In reality, the collection of blood samples may be a few hours after the traffic stop as a search warrant may be required and medical personnel must perform the collection, allowing drugs in blood to dissipate. Oral fluid, which is essentially a reflection of free drug in the blood, can be collected much more quickly following a traffic incident and is therefore a more reliable indicator of drugs present in the body at the time of the stop. Several researchers have attempted to establish correlation of drug results from simultaneously collected oral fluid–blood pairs but the studies have acknowledged weaknesses in study design such as uncontrolled conditions (Langel et al., 2014), unknown oral fluid collection volume, and poor or unknown drug recovery from oral fluid collection devices.

Specific Drug/Drug Class Information

Basic drugs: Amphetamines, phencyclidine, and cocaine diffuse into saliva from the blood relatively easily and accumulate in measurable concentrations. Any validated blood analysis procedures are easily adaptable for these drugs.

Cannabis: The main psychoactive component of cannabis is THC, which is easily detected in oral fluid collected by various extraction techniques using GC/MS and LC-MS/MS. THC is predominantly from buccal cavity exposure to cannabis smoke. Few differences have been observed between smoking and vaping, with THC peaking almost immediately; the time to maximum concentration of THC after oral consumption (edibles) is approximately 24 minutes (Swortwood et al., 2017).

Benzodiazepines: Benzodiazepines are an important group of prescription medications, which when over-used can cause driving impairment. Because of a high degree of protein binding and low saliva/plasma ratios they do not accumulate well in oral fluid, which makes detection challenging.

Opioids: Most of the commonly prescribed and illicit opioids (e.g., codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, buprenorphine, methadone, fentanyl, and tramadol) have oral fluid-to-plasma ratios greater than 1, so they accumulate well in oral fluid and can be easily detected via routine GC/MS and LC-MS/MS (Moore, 2015). Robust chromatography combined with multiple transition monitoring is essential to differentiate between structurally related compounds assays when compounds have the same molecular weight and potentially the same fragmentation patterns, and so are not separated chromatographically (Tuvay et al., 2012).

Part IV: Oral Fluid in Court

Legal Background

The use of OFFS and laboratory oral fluid testing have not been widely litigated in the criminal justice system. Nearly half the states authorize oral fluid drug testing (see Figure 1). Some state-implied consent laws extend to include the use of oral fluid for this purpose, while the balance of these states authorize the use of oral fluid elsewhere in state statute. In practice, the collection and use of oral fluid to detect drugs in the context of impaired driving case investigations is limited.

It is very important to know all applicable laws prior to starting any program and in case a related issue arises in an impaired driving case regardless of the law.

Asking for a biological sample(s) during a DUI investigation is considered a search. *Schmerber v. California*, 384 U.S. 757,766-722 (1966) (testing of the blood is a search under the Fourth Amendment requiring courts to determine whether the search was justified and whether the means used to get blood were reasonable), and is subject to constitutional scrutiny (the level of scrutiny differs depending on the type of sample).

Birchfield, supra, provides guidance on the legal analysis of these searches. This decision notes that there are far fewer privacy concerns with breath tests than blood tests. *Id.* at section VB1 (there is no piercing of the skin, the effort is comparable to blowing up a balloon, expelled air [breath] is not part of the body, breath test reveals only the amount of alcohol compared to other results that may come from testing blood, and so on). Breath tests do not give rise to significant privacy issues (including no embarrassing moments during collection) and only create minimal inconvenience for the test subject. “[T]he Fourth Amendment permits warrantless breath tests incident to arrests for drunk driving” but not blood tests. *Id*. at section VC3. Blood tests are significantly more intrusive, because getting blood is extracting a part of the person’s body by piercing skin and going into a vein and blood can be tested for things besides the alcohol content. *Id*. at section VB2. Thus, courts must weigh more privacy issues in cases involving blood.

The Court has not heard a case concerning oral fluid, but we can compare sample types using its analysis of breath and blood in *Birchfield*. The level of intrusiveness is somewhere between blood and breath. There is no piercing of the skin, but the collection involves taking something from the body that a person is not ordinarily disposing of frequently like breath when someone exhales. There is no piercing of the skin or veins involved, but the subject may have to keep a device in her mouth for several minutes (compared to seconds for breath testing instruments or blowing up a balloon). No embarrassing moments should occur during the collection. Oral fluid is almost always collected to test for drugs other than alcohol so it is more like blood in that the results are not just limited to the measurement of alcohol in the sample.

Another similarity between breath and oral fluid is that law enforcement may take two breath samples, one on the roadside (PBT) and one after arrest (using an approved instrument in a controlled environment). The PBT results may help a law enforcement officer establish probable cause to arrest and/or know whether further testing is required (i.e., if a person who appears to be greatly intoxicated blows 0.000% on PBT, then an officer should consider a test that can detect other drugs). This result should be used in pre-trial hearings or as allowed by law only. After probable cause has been established, the results from a second test may be used at trial.

The use of oral fluid testing can be conducted in a similar way. An OFFS device is also used by law enforcement to assist in establishing probable cause for the arrest and to apply for a search warrant for blood and/or confirmatory oral fluid sample. Any lab results from testing oral fluid are admissible in all legal proceedings, including trial (like blood results).

The collection of the oral fluid sample to send to a lab is similar to DNA collection. Oral fluid can be collected as an undiluted fluid via passive drool, expectoration into a tube, or using a cotton or synthetic fiber collection pad placed into a dry tube or into a diluent for shipment to a laboratory. The United States Supreme Court has already ruled those similar types of collection processes are far gentler than a blood draw and that the intrusion is negligible. *See Maryland v. King,* 569 U.S. 435, 446 (2013). The balance of privacy issues and law enforcement concerns will aid in determining the reasonableness of the search.

There is not a direct corollary with the evidentiary test results and impairment, but it will aid law enforcement and prosecutors in explaining the impairment and may give all parties a potential timeframe of when the individual last used the drug.

At least one trial court has had a hearing on the admissibility of an OFFS device result. The evidentiary hearing concerned the use of a Dräger DrugTest 5000, and the court found that "the correct scientific procedures were used . . . [t]he court further finds that there is sufficient reliable evidence of the drug screening test administered." *People v. Junior Salas*, Register of Actions Kern County, California Case Number BF15363A. November 30, 2015 (Appendix A) and Transcript of Excerpt of Jury Trial Testimony (402 Hearing) (Appendix B). While this unpublished ruling and documents created during the litigation of the case are resources we can look at in future cases, we encourage the use of OFFS for probable cause determinations only.

It is critical for practitioners to know the background of oral fluid testing programs, available tools, and confirmation testing previously discussed prior to stepping into the courtroom. We describe some best practices and provide information on applicable resources below.

Education for the Judiciary

Given the criminal justice system is generally less familiar with the science relative to the use of oral fluid to detect drugs, acceptance of oral fluid screening or testing results for probable cause or as admissible evidence in court, respectively, will vary from court to court. Unbiased, research-based education for the judiciary is one path to raising awareness of and building support for the use of oral fluid screening and testing in the context of impaired driving adjudication.

Viable methods for connecting judges to education on this topic include but are not limited to the following:

- Judicial Outreach Liaisons (JOLs). Developed through a cooperative agreement between the American Bar Association and the National Highway Traffic Safety Administration, JOLs provide peer-to-peer education, technical assistance, and evidence-based best practices to judges relative to a variety of traffic safety policy matters including impaired driving.
- National Association of State Judicial Educators (NASJE). Founded in 1975, this association strives to improve the justice system through judicial branch education. NASJE is a leader in defining the practice of judicial branch education and in gathering and sharing resources among educators.

- National Association of Drug Court Professionals (NADCP). Established in 1994, this 501(c)(3) organization has offered a variety of training to judges, attorneys, and clinical and other professionals interested in proven methods within the judicial system to help people with substance and mental health disorders that contribute to impaired driving, among other crimes.
- National Judicial College (NJC). Established at the recommendation of the U.S. Supreme Court in 1964, the National Judicial College is a nonprofit institution committed to the education of practicing judges across the country on wide range of topics.
- Traffic Safety Resource Prosecutors (TSRPs). Typically, current or former prosecutors, TSRPs are funded entirely or in part by federal grants available through the National Highway Traffic Safety Administration to provide training, education, and technical support to judges, traffic crimes prosecutors, and law enforcement personnel throughout their state. Traffic crimes and safety issues include but are not limited to alcohol and/or drug impaired driving.
- Drug Recognition Experts (DREs). These are specially trained police officers who can recognize impairment in drivers under the influence of drugs other than, or in addition to, alcohol. The International Association of Chiefs of Police coordinates the International Drug Evaluation and Classification (DEC) Program with support from the National Highway Traffic Safety Administration. The DEC Program educates judges, prosecutors, and toxicologists on the DRE process and the drug categories.
- Forensic Toxicologists. These scientists perform tests on samples collected by forensic pathologists during an autopsy, crime scene investigators, and law enforcement officers. Forensic toxicologists work to isolate and identify any substances in the body, like alcohol or other drugs, that may have contributed to a crime.

While these professionals are among the best vehicles for getting information to judges on the strengths and limitations of using oral fluid to detect drugs, very limited information is currently organized for use by the U.S. judiciary. This report, the many resources it promotes, and the publications cited within it may serve as the basis for judicial education on this topic.

Discovery

It is important to know any discovery obligations you may have for a particular event and for the introduction of experts. For instance, will the tribunal require a letter under Rule 16 with the expert's opinion and disclosure of what the expert relied on to form such opinion(s)?

There are guidelines for scientists to follow when writing these documents. Written opinions should be separate from analytical results. The expert toxicological opinion should be based on the case history, circumstances, observations, and other relevant information, not solely on analytical results. It should include case specific documents and records and be supported by references (ANSI/ASB 037, 2019).

Other things a prosecutor may have to provide during discovery under Rule 16 include the following:

- Photographs of the OFFS device showing results
- OFFS device printout with results
- All law enforcement reports
- Proof that the test was properly administered according to manufacturer's specifications and government rules and regulations

- Training certificates for law enforcement officers and/or lab personnel
- Curricula vitae for all experts
- Any certificates related to instruments used, which may include proof that the OFFS device is approved by the proper regulating body and proof of proper maintenance
- Proof that the OFFS device was in working order on date of offense
- Proof of laboratory accreditation
- Laboratory reports

Other materials like training manuals, device specifications, and more may also be requested; however, if such are not within the possession and control of the prosecution, counsel may need to ask the court for appropriate subpoenas to produce. Sometimes, similar material is available online so be sure to speak to witnesses and research prior to filing any pleadings.

A deficit in the discovery may cause additional litigation, especially if there are not documents to show a device was in proper condition on the date of offense. Thus, it's easier to make sure everything is in place at the beginning of a case rather than trying to make up for gaps later.

Case Evaluation

Always start the evaluation of any case by collecting all pertinent local law. For example, know the elements of each charge, the administrative rules that apply to the admission of the chemical test evidence (*see*, *e.g.*, Alabama's rules concerning OFFS devices and laboratory testing), and any applicable case law. The prosecutor should opine whether there was reasonable suspicion for the contact and probable cause for arrest, considering all oral fluid evidence as part of the totality of the circumstances.

An oral fluid DUI case evaluation starts like any other DUI case. The best practice is for the prosecutor to meet with all witnesses to review the evidence of the case. Special attention should be paid to why the officer believed an oral fluid test was needed (i.e., no smell of alcohol, statements by defendant, paraphernalia found, etc.). Prosecutors should note the time the defendant was driving, when an OFFS and/or a PBT was used, and when each biological sample was taken. Attorneys should also note any potential issues and/or follow-up questions and work that needs to be done.

For example, the administration of the OFFS test should only take place after SFSTs have been completed. If the test appeared somewhere else in the timeline of the investigation, the prosecutor should ask why and be prepared to combat any argument of bias on behalf of the officer who administered the test and knew of the screening results prior to arrest.

Ideally, the prosecutor is provided with observations from all three phases of the DUI investigation, an OFFS sample, and confirmatory samples of both oral fluid and blood. However, in most states this is not the current practice. It will be common for parties to have to litigate the use and admissibility of oral fluid evidence until it is more widely accepted across the country. For OFFS, the results should be used as support for the probable cause determination and/or for purposes other than guilt (e.g., the decision to ask the driver to supply a biological sample for confirmation testing). Knowing this limitation, prosecutors should be prepared with any challenges they may face if a screen does not match a laboratory confirmation, for example.

The Drug Toxicology for Prosecutors monograph (Kerrigan, 2004) has a section on case preparation and the toxicologist as Expert Witness Drug Toxicology for Prosecutors (p. 43). The

DWI Prosecutor's Handbook (National Traffic Law Center et al., 2008) has tips on effective case evaluation as well.

If it is determined that the case will go to court, careful consideration on whom to call and/or have available to testify is necessary. Witnesses have different levels of knowledge, skills, education, field experience, and training so it's best practice to get a curriculum vitae (CV) from each, especially any witnesses that you anticipate testifying as an expert and with whom you work on a regular basis so you understand how these people can assist you. Some prosecutor's offices maintain banks of CVs for their expert witnesses. In hearings about whether the evidence will be admissible at trial, especially, having the right expert witness cadre will be essential. Start planning early.

Potential Challenges

The National Traffic Law Center has monographs to assist attorneys in the prosecution of impaired driving cases. For example, in Overcoming Impaired Driving Defenses (American Prosecutors Research Institute, 2013), attorneys can get ideas about how to combat general defenses in these cases. In Challenges and Defenses II (National Traffic Law Center et al., 2013), authors provide advice on how to litigate cases with prescription drugs, defense arguments that the quantitative levels of the drug are below the therapeutic dose and therefore not capable of causing impairment, and uncertainty of measurement. Drug Toxicology for Prosecutors (Kerrigan, 2004) is another useful publication that covers topics like basic pharmacology, considerations related to interpretation of results, and testing methods.

The following are examples of more specific challenges that may occur in a case involving oral fluid evidence.

Motions to Suppress OFFS Device Results

The OFFS Device Used is Not Certified. The driver may argue that when there is not a formal regulation or certification process for a particular instrument that the accuracy (or reliability) is haphazard, because the device was not properly maintained and/or was overused.

Device is Not Approved by Government. Usually, a law will predicate use of a screening device to say something similar to the Colorado statue:

> Following the lawful contact with a person who has been driving a vehicle, and when a law enforcement officer reasonably suspects that a person was driving a vehicle while under the influence of or while impaired by alcohol, the law enforcement officer may conduct a preliminary screening test using a device approved by the executive director of the department of public health and environment after first advising the driver that the driver may either refuse or agree to provide a sample. The results of this preliminary screening test may be used by a law enforcement officer in determining whether probable cause exists to believe such person was driving a vehicle in violation of [law] and whether to administer a test pursuant to Implied/Expressed Consent laws.

Colo. Rev. Stat. § 42-4-1301(6)(i)(1).

Violation of Administrative Rules and/or Regulations

Lack of Foundation. Counsel will argue that discovery was not provided to prove the test was reliable; therefore, the prosecution should not be able to use the results. Admission of inaccurate or unreliable screening tests are substantially more prejudicial than probative. Admission would then be a violation of the driver's right to receive a fair and impartial hearing and/or trial (i.e., due process).

Template Language for Response to Motion to Suppress

1. [Law] allows the results of a preliminary screening device may be used by an officer in determining whether probable cause exists to believe a person was driving under the influence in violation of [law] and whether to collect a biological sample for confirmatory testing by a laboratory.
2. Under [law], neither the results of the preliminary screening test nor the fact that someone refused the test shall be used in any court action except a hearing outside the presence of a jury, when such a hearing is held to determine if a police officer had probable cause to believe a driver committed a violation of [impaired driving law].
3. The People intend on using the results of the field screening device at the suppression hearing to help show the officer had probable cause to arrest the defendant. The People do not intend on using these results at trial so this is not at issue.

Environmental Contamination

Officers are encouraged to wear gloves during collection for hygienic purposes. The officer and subject should avoid touching the oral fluid collection pad for both field screening and confirmation specimen collection. This will minimize drug contribution from the environment (e.g., residue in a vehicle or home) or skin (e.g., recent handling of drug and/or paraphernalia). Following proper collection instructions will minimize environmental drug contamination and reduce the likelihood of false positives. See Alabama Department of Forensic Sciences (2020) instructions as an example.

Passive Exposure

THC detection in oral fluid is possible following passive exposure to cannabis. In recent studies exposed individuals felt effects of marijuana smoke even though they did not partake.

Extreme exposure of nonsmokers could lead to positive drug tests and drug-induced behavioral changes not unlike those produced by active cannabis smoking.

It seems very unlikely that exposure under less extreme conditions, such as casual encounters with cannabis smoke and in situations where an individual was not aware of smoke exposure, would result in positive tests and behavioral changes. Further, in the federal guidelines for oral fluid testing, passive exposure to cannabis is not considered an acceptable excuse for a positive THC result (Cone et al., 2015).

Several studies showed THC to be present in the oral fluid of individuals passively exposed to environments with high levels of cannabis smoke. Most scenarios involved small confined spaces with low ventilation. Oral fluid THC concentrations typically were not detectable when specimens were analyzed at an initial screen concentration cut-off of 4 ng/mL and confirmed at

2 ng/mL. A comprehensive assessment of performance and/or impairment was not performed in these individuals. The presence of a metabolite in oral fluid or a drug in blood would be evidence against passive exposure (Moore et al., 2011).

Five studies on the passive inhalation of cannabis smoke monitored THC concentrations in oral fluid specimens. THC C_{max} was observed until 20 minutes after exposure to cannabis smoke (Berthet et al., 2016). THC concentrations were then seen to decrease rapidly until 60 minutes and until no longer detected.

To avoid direct contamination, oral fluid specimens must be collected outside the contaminated place or room and sampling devices should be protected from cannabis smoke.

Another element to consider as potential contamination is THC accumulation in the mucosa of the upper respiratory tract following active or passive smoking, even though cannabinoids are very poorly excreted in saliva. This phenomenon is more accurately described as THC coating or contribution. Active use contribution may last for 6 to 8 hours and can be detected using an adequately sensitive test (Berthet et al., 2016).

Reliable testing for THC requires an efficient test system (i.e., collection device, screening procedure, or confirmation assay). Among the most important issues are (a) the potential environmental contamination of the collection devices, (b) the stability of THC and its absorption to the polystyrene surfaces of collection devices, (c) the variability in the design of collection devices, and (d) the potential for false-positive test results following passive exposure, particularly if low cut-offs are used.

Recency of Use

The intent of establishing oral fluid cut-offs is to establish a window of use or duration of action relevant to driving. Typically, that would entail within 8 hours or less since last use. The intended detection time of federal workplace oral fluid drug testing may be substantially longer than DUID oral fluid testing because low cut-off concentrations are employed especially for THC.

Typical windows of detection of drugs in oral fluid mirror blood: for most drugs and/or metabolites, 24 to 48 hours depending on the route of administration, drug dose, drug formulation, history and frequency of use, sensitivity of the analytical test method, and cut-off concentration (Arnold et al., 2019). While it has been reported in a small number of subjects that THC can be detected up to 24 hours after use with a rapid test device, oral fluid typically detects THC for 6 to 8 hours at standard laboratory cut-off concentrations in most users. Even following edible intake and positive rapid test results, when using a confirmatory oral fluid cut-off of 5 ng/mL, the detection rates reported with both Dräger DrugTest 5000 and Abbott SoToxa were similar at each timepoint, with no THC true positives observed in either device 8 hours after intake. Cut-offs may need to be administratively set above the instrumental limit of detection to meet recommended cut-offs and ensure an appropriate window of detection (Logan et al., 2018).

The presence of THC in the oral fluid indicates it is still active in the body and therefore has potential to impair driving and other tasks; it is additional information to be taken into account for totality of the evidence. The presence of the pharmacologically active drug in the oral fluid provides an opportunity to partition and establish equilibrium with the blood, circulate throughout the body, and interact with receptors in the brain. If a pharmacologically active substance is present in the body, there is a potential for an effect on that person. The magnitude of effect will

depend on history of use and tolerance. In all cases, the totality of circumstances should be considered: driving performance, behavior, performance on SFSTs, and toxicology findings. Signs and symptoms of drug use and poor performance on SFSTs are evidence against the development of sufficient tolerance.

Interferences

Experiments were run to evaluate the potential for other substances that may be present in the subject's mouth to cause interferences with the various assay platforms. These consisted of running a series of experiments of solutions of beverages (milk, beer, orange juice, soda), oral hygiene products, tobacco, and mint-flavored gum. Saliva was mixed with commonly encountered food, drinks, or orally ingested products (tobacco, gum, etc.) (Buzby et al., 2021).

Chewing tobacco produced frequent false positive and false negative results across all five devices. Coffee, milk, cola, and wintergreen mints produced intermittent and inconsistent false positives or false negatives on one device or another, but there was no consistent pattern of interference. However, incorporation of a 10-minute waiting/deprivation period as recommended by manufacturers prior to testing eliminated all the effects of the potential interferents (Buzby et al., 2021).

Oral Cavity Contamination Contribution

Recent use of drugs (e.g., smoking, snorting, oral) may result in high oral fluid drug concentrations often >100 ng/mL or in some cases >1000 ng/mL. Terminology such as oral fluid cavity contamination or contribution has been used to characterize this phenomenon. Oral fluid cavity contribution (i.e., high oral fluid concentrations) is likely an indication of recent use. Therefore, this may be viewed as an advantage in identifying recent users. The assertion that oral fluid cavity contamination (i.e., residue drug) is present without a pharmacological effect is unlikely.

Scope of Analysis, Panel Limitations, and Cross-Reactivities

Field screening devices typically screen for > 80% of the most prevalent drugs detected in driving cases. However, the most significant scope limitations include fentanyl, buprenorphine, methadone, zolpidem, tramadol, carisoprodol, novel psychoactive substances, inhalants, anticonvulsants, muscle relaxants, antidepressants, and antipsychotics. Confirmation testing at forensic toxicological laboratories will also have some gaps in scope of analysis; nonetheless, manufacturers are encouraged to expand panels to include additional targets in the future.

Cross-reactivity can impact scope of analysis within this drug class (and others). Immunoassay kit inserts that provide details on cross-reactivity and interferents associated with each drug class should be studied carefully to understand any limitations.

Per the NHTSA device evaluation report, none of the nontargeted drugs, which included caffeine, nicotine, nonsteroidal anti-inflammatory drugs (NSAIDs), over-the-counter analgesics, selective serotonin/noradrenaline reuptake inhibitors (SSRIs/SNRIs), zolpidem, dextromethorphan, lidocaine, or PCP, produced false positives on any of the test platforms at concentrations of 1000 ng/mL. Other members of the drug classes to which the devices are targeted showed variable cross-reactivity (Buzby et al., 2021).

Special Considerations: Benzodiazepines

Benzodiazepines have low sensitivity due to protein binding and oral fluid-to-blood partition ratios <1. However, detection of benzodiazepine misuse is likely to exceed common cut-off levels employed. The route of administration such as snorting or crashing pills prior to oral ingestion can lead to high oral fluid concentrations of benzodiazepines (Society of Forensic Toxicologists, 2018 [#2]).

Courtroom Preparation

Adequate preparation for the courtroom in cases involving oral fluid test results goes above and beyond other cases for many reasons, but especially because many of the issues have not been widely litigated yet. After general preparation tips (e.g., developing a witness list, how to prepare witnesses, and what questions to ask each person), this toolkit includes guidance on how to best utilize many of the studies discussed earlier. Prosecutors and scientists are strongly encouraged to review the Society of Forensic Toxicologists (2018) Frequently Asked Questions prior to court.

Getting Started

Before any hearing, prosecutors should be organized and know what must be presented. Figure 4 is a template one may use (adding or amending depending on local practice and type of case):

Figure 4. Trial Preparation Template

Defendant's Name_____ **Case #** _____

L

O

V

I

D

S

Witnesses:

	Sub'd/waiver
#1:	**ps:** ☐
purpose:	**wr:** ☐
#2:	**ps:** ☐
purpose:	**wr:** ☐
#3:	**ps:** ☐
purpose:	**wr:** ☐
#4:	**ps:** ☐
purpose:	**wr:** ☐
#5:	**ps:** ☐
purpose:	**wr:** ☐
#6:	**ps:** ☐
purpose:	**wr:** ☐

Facts:

Speedy date:

Offer:

Physical evidence:

Motions filed and outcome:

Defense attorney:

Defense theories:

Issues/Problems/Reminders:

Checklist

- ☐ 911 call(s)
- ☐ Charging documents with appropriate charges, if not, move to amend or add counts
- ☐ List of witnesses and criminal histories for each
- ☐ Witness statements
- ☐ Affidavit in support of warrantless arrest, if the defendant was arrested
- ☐ Sobriety examination or equivalent report
- ☐ Crash report (if applicable)
- ☐ Miranda advisement and waiver form
- ☐ Expressed/Implied consent form
- ☐ Test(s) Report
  - Preliminary screening test results,
  - Maintenance history for all instruments, and
  - Certificates for all instruments.
- ☐ Warrant for biological sample
- ☐ Biological sample consent, chain of custody, the box label (i.e., the label showing where the sample was mailed or dropped off), the certificate showing that the lab used to test the sample was accredited on the date of offense, and results form (may have more than one of each)
- ☐ Drug Recognition Expert Face Sheet
- ☐ Defendant's driving record
- ☐ Defendant's criminal history
- ☐ Narrative reports
- ☐ Photos (including booking photo)
- ☐ Videos (bodycam and/or in-car camera)
- ☐ Documents and/or audio recording of radio traffic
- ☐ Expert reports and curricula vitae
- ☐ Certified bail bond conditions

Legend	
L – Location	Sub'd: subpoenaed
O – Elements of offense	ps: personal service
V – Venue	wr: waiver of service
I – Identification of defendant	
D – Date and time of offense	
S – Defendant's statement	

Witnesses

Witnesses may include scientists and various personnel typically found in a lab. It is important to identify what each person can cover when testifying based on their qualifications.

To determine whom to call as a witness, ask the following:

- What is the issue?
- What is the applicable law?
- What are the pertinent facts concerning the issue?
- Who knows the facts (firsthand is best)?

Most jurisdictions will have specific rules related to the timing and format of the disclosure of witnesses and/or notice about what the witness's testimony may involve.

Be sure to subpoena all first responders related to the collection of oral fluid, including any who offered the testing to the driver.

For a hearing on the reliability of oral fluid testing, consider endorsing the scientist(s) who conducted the testing, a chief toxicologist, and/or a representative who works for the device manufacturer. It is very important to know what your witness can testify to and any limitations. You may need more than one person from the lab and/or scientists from outside a local lab, depending on the circumstances. It is critical to discuss this with local lab personnel prior to sending subpoenas.

Review each witness's CV for an idea of where the person fits in your case. You may need people outside of those listed on the witness list in your case. Local TSRPs are good resources when looking for experts (Whitcomb et al., 2007). For example, some jurisdictions require a pharmacologist to testify about the interpretation of any results so you would need to verify your witness(es) meet the necessary legal requirements prior to court. For a discussion of types of witnesses from a laboratory, see below for Qualification of the Witness.

If you are provided with a witness list from the defense, be sure to research the background of each witness and go over the list with your experts well in advance of court. Research the defense expert online, look on the New York Prosecutors Training Institute's Prosecutors' Encyclopedia (https://login.nypti.org/),[10] reach out to local experts, contact your TSRP, and/or consider a technical assistance request to the National Traffic Law Center.

Witness Availability Issues. Due to personnel constraints, sometimes an analyst may not be available to testify. Prosecutors should know applicable case law when confronting such issues. Defense counsel may cite *Crawford v. Washington*, 541 U.S. 36 (2004) (testimonial out-of-court-statements are not admissible under the Confrontation Clause), which bars evidence in a criminal case where the prosecution offers testimonial evidence when a witness is unavailable (without prior opportunity to cross-examine). Also be aware of *Melendez-Diaz v. Mass.*, 557 U.S. 305 (2009) (forensic laboratory report stating that a suspected substance was cocaine was testimonial for purposes of the Sixth Amendment's Confrontation Clause; therefore, the prosecution may not introduce such a report without offering a live witness competent to testify to the truth of the statements made in the report) and *Bullcoming v. New Mexico*, 564 U.S. 647 (2011). In *Bullcoming*, the analyst who tested the blood was unavailable for trial and an expert

[10] Any prosecutor may sign up (no cost) for an account.

from the lab who had neither observed nor reviewed the testing testified. The Court found that Bullcoming's right to confront witnesses was violated by the introduction of a testimonial document where he did not have the current or prior opportunity to cross-examine the maker of the document. Local law may provide specific guidance to courts, which allow supervisors of lab staff to testify after a review of laboratory data. Have copies of such rulings available when going to court to be ready to address the issue immediately should it come up.

Expert Opinions

A prosecutor must know what the expert can and cannot say prior to court. Scientists follow commonly accepted guidelines when forming and articulating an opinion and testimony. For example, "[a] toxicologist should not opine as to a specific individual's degree of impairment based solely on a quantitative result." See American National Standards Institute & AAFS Standards Board (2019) Section 5.3(c). The initial draft document was developed by the toxicology subcommittee of the Organization of Scientific Area Committees (OSAC).

A lay opinion is based on facts from everyday life. Most jurisdictions look to some variation of rule of evidence (ROE) 701 where the opinion is based on perception, helpful for the determination of a fact at issue, and so on. Case law in each jurisdiction will interpret the local rule on particular issues. For example, in many jurisdictions case law says lay witnesses may opine on whether someone appeared intoxicated (maybe by a particular drug).

An expert opinion is based on facts from specialized training, experience, skill, knowledge, or education. This usually means the expert can testify to why, what, where, when, and/or experience or education. Most jurisdictions have some form of ROE 702, which governs expert testimony, that looks something like the federal rule:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

You will likely have to qualify (or apply law that allows the court to avoid any formal qualification procedures) any witness who makes an opinion based on fact (e.g., perceptions, observations, experiences, and so on) and specialized training, experience, skill, knowledge, or education. A good question to ask yourself is whether an average citizen (any person off the sidewalk) would know what it takes to get to a certain conclusion. For example, would an average citizen know what a marijuana edible is (i.e., what part of the plant is used might be expert testimony, but testimony about certain products like pot brownies might be lay testimony)? Jurisdictional requirements differ, so do research prior to court to decide whether expert testimony is necessary.

Considerations for Admissibility of Novel Scientific, Technical, or Other Specialized Knowledge. Oral fluid testing is not novel. An attorney must first articulate this argument using the information above.

Generally, the law governing admissibility of expert testimony looks to the reliability and relevance of the evidence. It is critical to understand the jurisdictional requirements of any pre-trial hearing. For example, you may not need a hearing on the reliability of any particular evidence; however, you may have a hearing where you must give the court enough information to make specific findings about the reliability of scientific principles involved and the expert's qualification to testify to such matters.

Things a court *may* consider include but are not limited to ROE 702 factors (previously mentioned) and the following:

Reliability. Reliability of the following:

- Scientific principles and methods (totality of circumstances in each case)
- Application of principles and methods (totality of circumstances in each case)
- Devices
- General acceptance by the particular community related to the principles and/or methods

It is important to ask the following:

- What has to be accepted?
- Who is the relevant community?
- How much agreement is necessary?
- What law applies?

Qualification of the Witness to Opine on Such Matters. The witness may have to testify to the following:

- Whether the technique can and has been tested
- Whether the theory or technique has been subjected to peer review and publication
- The scientific technique's known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation
- Whether the technique has been generally accepted
- The relationship of the proffered technique to more established modes of scientific analysis
- The existence of specialized literature dealing with the technique
- The nonjudicial uses to which the technique is put
- The frequency and type of error generated by the technique
- Whether such evidence has been offered in previous cases to support or dispute the merits of a particular scientific procedure

Relevancy. The relevancy of testimony will need to be established.

- Usefulness of the testimony to the jury
- Does the probative value substantially outweigh the danger of unfair prejudice, confusion of the issues, misleading the jury, considerations of undue delay, waste of time, or needless presentation of cumulative evidence (i.e., grounds for exclusion of relevant evidence under ROE 403)?

Case law may exist which sets forth how to determine the reliability of certain evidence, so know whether you need to litigate the issues prior to court (i.e., file a written response encouraging the court to let the fact finder decide the issues based on a determination of weight not admissibility) or if a hearing is necessary. *See*, *e.g.*, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (rules of evidence apply instead of the general acceptance rule when the court is determining the admissibility of scientific evidence; further, the trial court must ensure expert testimony is reliable and relevant); *Frye v. U.S.*, F. 1013, 1014 (1923) (polygraph results deemed inadmissible because scientific method must be generally accepted in the field to which it belongs as reliable before an expert may opine about it); and *U.S. v. Downing*, 753 F.2d 1224 (1985) (case about whether eyewitness testimony is helpful under ROE 702 and reviews the standard for admissibility of novel scientific evidence). In some hearings (say the case goes to trial), the proponent of the evidence may be able to ask the court to take judicial notice of reliability instead of offering testimony and other evidence.

Qualification. Prosecutors will lay a foundation through the witness of his or her knowledge, skill, experience, training, or education (see Appendices C–E). This information is contained within the witness's CV; local rules/procedures may require disclosure prior to court. Once a proper foundation is laid, the attorney should ask the court something like "We request that the Court qualify the witness as an expert in (the applicable field)." The defense attorney may object; state, "No objection;" or ask the court to subject the witness to voir dire (ask questions about the foundation for the witness to be qualified as an expert as offered).

If the expert is the only expert testifying and tactically the prosecutor wants to reduce the amount of testimony, the attorney may introduce the expert's CV. If the defense has experts to oppose any expert, ask more questions as part of the qualification process. Do not agree to stipulate to a DRE's qualifications or any other expert if the defendant has an opposing expert(s).

Hearing Not Required. A court does not need to hold an evidentiary hearing on matters within the court's discretion. How has opposing counsel worded the request for a hearing? Is the ultimate issue something within the court's discretion, for the jury to decide, subject to cross examination, addressed with carefully drafted instructions, and so on?

Is the request for a hearing on something that will not be an issue at trial? If so, tell the court the hearing is unnecessary.

Bases of Opinion Proponent. ROE 703 is a significant tool in this arena. The federal rule reads (emphasis added):

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, *they need not be admissible for the opinion to be admitted*. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Bases may be perceived before hearing, at a hearing, made known before hearing, or made known at a hearing. Investigate which tactic is best under the circumstances, and prepare accordingly prior to court.

Bases of Opinion Opponent. Prosecutors should be aware of ROE 705 as well, which reads (emphasis added):

> Unless the court orders otherwise, an expert may state an opinion—and give the reasons for it—without first testifying to the underlying facts or data. But *the expert may be required to disclose those facts or data on cross-examination*.

If the issue is litigated vigorously, argue that the standard of admissibility (under rule 702) is reliability and relevance NOT certainty. You should not have to litigate accuracy of any particular method as well. Such concerns may be addressed on cross examination and through carefully drafted instruction (if case is before a jury).

The best practice is to prepare your case as if the testimony is expert, provide appropriate discovery, and argue in the alternative (when you are not sure).

Scientific and Experience-Based Expert Testimony. It is critical to consider whether the evidence is scientific or experience based to prepare properly. Ask, is opposing counsel objecting to science or the specialized knowledge of your witness?

For experience-based expertise be ready to argue the following:

1. What experience and/or knowledge the expert has
2. Testimony will help the jury
3. The factors under the balancing test under ROE 403

Here, if the attack is about the method(s) used to test oral fluid, the evidence is scientific. If the attack is about the DRE's ability to make an opinion about impairment, the evidence is experience based.

Preparing the Witness. The first priorities in preparing the witness are as follows:

- Know the standard of proof and the burden of proof
- Know the facts and how each witness's testimony gets to each issue(s)
- Choose the best tactics depending on local practice so you can explain to the witness how you are ready for possible challenges

You need to tell the witness the following:

- ALWAYS TELL THE TRUTH
- Do not guess
- Do not testify to things the witness does not have personal knowledge about
- Consider word choice (e.g., use crash or collision instead of accident)
- Explain the law to the witness
- The factual and legal aspects of the issue
- How the witness's testimony fits with other witnesses' testimony
- Whether local practice or any anticipated issues related to such might impact the witness's testimony

Review all evidence (e.g., CVs, documents, statements, etc.) with the witness.

Have the witness practice explaining the foundation for any lay and expert opinion. Discuss direct examination, and if time allows, do a mock direct where you ask open-ended questions

then follow up with leading questions. Discuss possible lines of cross examination, and have another attorney do a mock examination.

Remember, after meeting with a witness, you must disclose facts that are exculpatory, impeaching, and/or mitigating that were not previously discovered.

Predicate Questions

Always use predicate questions for a starting point. Do not rely on a list without reviewing with each witness prior to court, and always listen to answers in court before automatically asking the next question. The following is a list of potential topics to cover with specific types of witnesses.

Law Enforcement (OFFS Use). Law enforcement may provide testimony related to training received by a device manufacturer and/or other entities, proper maintenance of device, time of analysis quality control check (if applicable), intended use of results, purpose of oral fluid field screen, operation of device, instructions for use, and collection (i.e., field screen and confirmation collection). Law enforcement should be familiar with the approval or validation of the field screening device. For detailed testimony regarding device validation and approval, a toxicologist may be required. See Appendix C for example predicate questions.

Analyst (Fact Testimony). An analyst can provide fact testimony to cover generally accepted methodology within the field (e.g., extraction processes, instrumentation), parameters evaluated during confirmation method validation, use of oral fluid as a specimen, chain of custody, and the results on the toxicological analysis report and how they were derived. For more details, review the SWGTOX Standard for Laboratory Personnel (Scientific Working Group for Forensic Toxicology, 2015) and ANSI/ASB Guidelines for Opinions and Testimony in Forensic Toxicology (American National Standards Institute & AAFS Standards Board, 2019). See Appendix D for example predicate questions.

Toxicologist (Expert Witness Testimony). An adequately trained toxicologist with relevant experience can provide interpretation-based opinions on the analytical results, effects of drugs on behavior and driving (i.e., pharmacodynamics), duration of drug effects, pharmacokinetic topics (e.g., absorption, metabolism, drug half-lives, and elimination), and applications of different specimens (e.g., blood, oral fluid, urine for more details, review the SWGTOX Standard for Laboratory Personnel (Scientific Working Group for Forensic Toxicology, 2015) and ANSI/ASB Guidelines for Opinions and Testimony in Forensic Toxicology (American National Standards Institute & AAFS Standards Board, 2019).

Using Studies

Is using studies even permissible?

- CRE Rule 803(18) – Learned Treatises. Exception to hearsay rule when relied on by expert in direct or to cross-examine an expert.
- CRE Rule 703 – Basis of Expert Opinion. Otherwise, inadmissible facts or data may be disclosed to aid the jury in evaluating expert testimony.
- You will almost certainly be required to make a copy of the study available to the defense per C.R.Crim.P. Rule 16, Part I(d)(3).

Most Important Thing: Be Prepared

- Read and understand the study.
- Be sure your witness has read and understands the study.
- Discuss the testimony in advance with the witness so that you are both on the same page.
- What are the possible biases of the study?
- Who funded it?
- Was it peer reviewed?
- Was the sample size too small?
- Was the sample representative enough?
- Do the possible biases invalidate the findings?
- What is the scope of the study?
- What are the findings of the study?
- What do these findings mean for your case?
- What information is outside the scope of the study?
- Does (or how does) this out-of-scope information affect the study's findings?
- How recent is the study? Does this matter?

Using the Study on Direct

- Bolster the prosecution expert's opinion.
- Show that the expert is an expert.
- Give hard data to support each opinion.
- Educate the jury.
- Teach the jury about the science behind police practices.
- Be prepared to address other studies and the extent to which they support or contradict the one(s) you are using.

Using the Study on Cross

- Get in, get out.
- Use the defense expert to bolster yours.
- Get the defense to agree that your study is good.
- Attack the defense expert's opinion.
- Show that expert does not know the material.
- Undermine the defense's studies by showing that yours is/are better.
- Make sure you know what the defense is going to say, if possible.
- Discretionary disclosure of defense expert material. C.R.Crim.P. Rule 16, Part II(b).
- Be prepared with a rebuttal expert.
- Probably better if it is not your officer.
- Do you need to disclose this witness to defense? *See*, *e.g.*, *People v. Avila*, 944 P.2d 673, 675-76 (Colo. App. 1997) (e.g., neither Colorado rules nor statutory law require the prosecution to endorse rebuttal witnesses).

Conclusion

We depend on law enforcement and prosecutors to promote the usefulness of oral fluid drug screening technology, while not overstating how such results can be used during the

adjudication of a DUID suspect. This toolkit leverages learnings from the oral fluid project in Alabama (and other states) combined with the expertise of the attorneys and scientists involved in these studies. This toolkit provides useful guidance relative to oral fluid field screening at roadside and oral fluid confirmation testing in the laboratory. By providing guidance, it is our hope that law enforcement, laboratory personnel, and prosecutors are able to utilize oral fluid testing technology and results in criminal cases.

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Acronyms And Abbreviations

Acronym	Definition
µL	microliter
6-AM	6-acetylmorphine
AAFS	American Academy of Forensic Sciences
ADFS	Alabama Department of Forensic Sciences
AMP	amphetamine
ANSI	American National Standards Institute
ASB	American Academy of Forensic Sciences Standards Board
BSKit	biological specimen kit
BZE	benzodiazepines
COC	cocaine
COD	codeine
CSFS	Canadian Society of Forensic Science
CV	curriculum vitae
DDC	Drugs and Driving Committee [CSFS]
DNA	deoxyribonucleic acid
DpX	dispersive pipette extraction
DFC	drug facilitated crimes
DRE	drug recognition expert
DUID	driving under the influence of drugs
GC/MS	gas chromatography mass spectrometry
HYC	hydrocodone
HYM	hydromorphone
IACP	International Association of Chiefs of Police
LC/MS/MS	liquid chromatography with tandem mass spectrometry
LOD	limit of detection
LOQ	limit of quantitation
MDA	3,4-methylenedioxy-amphetamine
MDMA	3,4-methylenedioxy-methamphetamine
METH	methamphetamine
mL	milliliter
MOR	morphine
ng	nanogram
ng/mL	nanogram/milliliter
NHTSA	National Highway Traffic Safety Administration
NSC	National Safety Council
NTLC	National Traffic Law Center
NTSB	National Transportations Safety Board
OF	oral fluid

Acronym	Definition
OFFS	oral fluid field screening
OSAC	Organization of Scientific Area Committees
OXYC	oxycodone
OXYM	oxymorphone
PBT	preliminary breath test
PC	probable cause
PCP	phencyclidine
QC	quality control
SAMHSA	Substance Abuse and Mental Health Services Administration
SFSTs	standardized field sobriety tests
SHSO	state highway safety office
SOFT	Society of Forensic Toxicologists
SWGTOX	Scientific Working Group for Forensic Toxicology
THC	delta-9-tetrahydrocannabinol
TSRP	Traffic Safety Resource Prosecutor

Appendices

Appendix A: *People v. Salas* (2015) Register of Actions

Appendix B: Transcript Excerpt of July Trial Testimony (402 hearing)

Appendix C: Predicate Questions for Operator of OFFS Device

Appendix D: Predicate Questions: OF Laboratory Analyst (Fact Witness)

Appendix E: Predicate Questions: Interpretation of OF Results (Expert Witness)

Appendix F: *People v. Gonzales,* April 20, 2006, SCI# 1092/06, New York Supreme Court [Unreported Decision] Decision and Order

Appendix G: Dräger DrugTest 5000 Training Certificate

Appendix H: DrugWipe Training Certificate

Appendix I: SoToxa Product Training Certificate

Definitions

Alcohol: For the purpose of this tool kit, use of this term shall refer to ethanol (drinking alcohol) unless otherwise specified.

Approved training: Training by the manufacturer of a device and/or an authorized agency.

C_{max}: The maximum or peak drug concentration in the blood after a dose has been administered.

Confirmatory testing: A test resulting in a definitive result that verifies the presence of a specific drug; typically using mass spectrometry techniques.

Cut-off: The defined concentration of an analyte in a drug test specimen at or above which is called positive.

Drug: Any substance, when taken into the human body, which can impair the ability of a person to operate a vehicle safely.

Drug Recognition Expert (DRE): A law enforcement officer trained to identify people whose driving is impaired by drugs by following a 12-step drug influence evaluation.

Evidentiary specimen: For the purpose of this tool kit, use of this term shall refer a specimen tested by the laboratory via confirmatory testing.

False negative: A screen result that is negative and the corresponding confirmation test is positive potentially due to a variety of factors (e.g., cut-off differences between screen and confirmation methods, poor cross-reactivity).

False positive: A screen result that is positive and the corresponding confirmation test is negative potentially due to a variety of factors (e.g., interference).

Immunoassay screen: A screening procedure for detecting a drug, drug metabolites, or drug class through the interaction of antigens and antibodies.

Limit of detection (LOD): Lowest quantity of a drug that can be identified.

Limit of quantitation (LOQ): Lowest amount of a drug in a sample that can be quantitatively determined.

Metabolite: Any substance produced in the body during metabolism either synthesized or broken down from a parent drug (e.g., THC to carboxy-THC, cocaine to benzoylecgonine).

Method: An orderly and systematic approach to analyze a biological sample for the presence of drugs.

Negative or none detected: A negative or none detected result indicates the sample is drug-free for the tested targets or below the cut-off level of the test.

Observation: The operator of a device must watch the subject for at ≥ 10 minutes prior to the administration of the screening device in accordance with manufacturer's guidelines.

Opinion or expert toxicological opinion: A coherent, scientifically sound statement or statements regarding the meaning of analytical findings in a forensic case that is formulated from a consideration of the synthesis of analytical data, pre-analytical factors, case history, and other relevant information.

Oral fluid (OF): A clear, tasteless fluid comprised of saliva produced by multiple salivary glands and other constituents inside the mouth.

Oral fluid field screen (OFFS): A qualitative oral fluid drug screen, often performed roadside during a DUI investigation to establish probable cause of drug use.

Parent drug: A drug administered in its original form that is typically pharmacologically active (e.g., THC, cocaine).

Per se law: Statutory assignment of a specific drug and/or drug metabolite concentration in a biological sample at or above which, it is an offense to drive.

Pharmacodynamics: A branch of pharmacology concerned with what the drug does to the body (i.e., the effects of drugs, mechanism of their action).

Pharmacokinetics: A branch of pharmacology concerned with what the body does to the drug (i.e., absorption, distribution, metabolism, elimination).

Pharmacology: The study of drugs including both pharmacodynamics and pharmacokinetics.

Presumptive positive result: A qualitative positive result that indicates the presence of the drug, its metabolite, or a cross-reacting substance but does not indicate level of intoxication, route of administration, or concentration.

Qualitative: A result reported as Positive, Present, Negative, or None Detected (ND).

Quantitative: A result reported as a concentration (e.g., 1000 ng/mL) indicating how much of a drug is present.

Saliva: A clear, tasteless fluid produced by multiple salivary glands (see oral fluid).

Screening: A qualitative analysis to determine the presence of a drug or drug class typically by immunoassay-based techniques. All positive findings are presumptive until confirmed by a more specific technique (e.g., mass spectrometry).

Standardized Field Sobriety Tests (SFSTs): A battery of validated and systematically administered tests (i.e., horizontal gaze nystagmus (HGN), the Walk and Turn, and the One Leg Stand) performed during a traffic stop to determine if a driver is impaired.

Tolerance: The reduction in effectiveness or effects of a drug after repeated and/or long-term use.

Uncertainty of measurement: Inherent variation associated with any analytical measurement denoting a best estimate of how far a quantity might be from the true value.