Historically, impaired driving was most often linked to alcohol impairment. As such, governments and researchers devised roadside portable breath test (PBT) tools for police to use to identify intoxicated drivers. No such roadside test was possible or necessary for drivers suspected of drug impaired driving—at least until now. The reason for the push for roadside point of contact testing for drugs in 2014 is that drug-impaired driving has become a worldwide safety issue. The use of potentially impairing medication is widespread.
Indeed, many drivers operate their vehicles while accidentally under the influence of legally prescribed medication. Recognizing the need for better enforcement, police agencies everywhere are looking for new tools to combat drug-impaired driving. One such experimental tool is Oral Fluid Collection (OFC). It is a means for law enforcement to perform roadside testing of a suspected driver’s mixed saliva for drug impairment with an OFC device (OFCD). The United Kingdom was the first to sanction this type of testing on its driving population.

OFC is said to be able to identify the possible presence of a drug, whether legally prescribed or illegal. The roadside test may also be followed up with a confirmatory technique such as gas chromatography with mass spectrometry (GC-MS). And so, it is the purpose of this article to introduce OFC devices to the reader and describe how they work. We will then explain why we believe OFC devices will be coming to a roadside near you. Finally, we will discuss the application of Frye or Daubert challenges to the admissibility of OFC evidence.

**What Is Oral Fluid Collection?**

In the world of forensic science, Oral Fluid Collection (OFC) is technically referred to as Mixed Saliva Sampling (MSS). In the non-law enforcement world, however, it is known as Point of Collection Testing (POCT). POCT has been a feature of worksite testing for some time. Police proponents of this testing technique proclaim that it is faster, cheaper, just as accurate as blood or urine but less invasive. Notwithstanding these claims, as we will see with this promising technology, it is not wholly validated or acceptable for judicial use at this time.

**How OF-POCT Works**

Not all OFCDs work the same way. Each is unique depending on its manufacturer. There are, however, some similarities between the devices—one of which is that they will be used on the roadside just like PBTs are now used. For example, a citizen would have some automobile traffic contact with a law enforcement officer wherein there was some evidence of drug impairment observed and no evidence of alcohol consumption. It would be at this point that the officer would ask the suspect driver to consent to a short OFCD test on a device similar to the one above. However, it is crucial to note that just like the roadside PBTs, the OF-POCT requires a deprivation period. In its instructions and user guide, Drager says that operators must wait 10 minutes before using it.

Whatever device is used by the officer, it usually consists of a collector and a portable reader. The collection OFCD has some sort of tube consisting of an absorbent material at the end to collect saliva from the suspect. Depending on the device, a 1mL sample can be taken from the tongue, gums, inside the cheek, etc., and then placed in the oral screening device. Once the screening process is started, it takes from 2 to 10 minutes to develop a result. After the sample is analyzed, the reader displays whether or not the sample contains any of the drugs it was designed to detect. Some readers even have the ability to print out the results of the test for later use; others produce a number indicating the concentration of drugs found, similar to BrAC results; and others simply are displayed on the screen with no method of memorialization. If the results are positive, the suspect might be arrested for drugged driving. We believe that this initial result will likely be treated as presumptive test—as it certainly should, if scientific principles are followed. Later, the motorist would be asked to provide another saliva sample to be used for an evidentiary test. The sampling container would be then transferred to a laboratory where the OF/MSS would be extracted and subjected to either GC-MS or Liquid Chromatography with Mass Spectrometry (LC-MS) analysis, depending upon the laboratory’s analytical abilities.

**Example of Analysis Done by One of These Machines**
Although there are numerous devices on the market, each device uses a slightly different analysis. The Dräger DrugTest® 5000 is already in use in Los Angeles and seems poised to become one of the prevalent devices within the United States. Therefore, in order to gain a better understanding of the device and ways to challenge the use of the device, a description of how the Dräger DrugTest® 5000 works is necessary. Currently, the Dräger DrugTest® 5000 is the only device to gain federal approval through NHTSA.

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5000 is immunoassay. This analytical tool has been in use for over 30 years.*

Immunoassays begin with injecting a target analyte** into an animal such as a goat. The immune system of the animal will create an antibody? to this foreign substance. These antibodies are then harvested from the animal and used in the creation of immunoassay tests. It is only after these antibodies are acquired that the test can be designed and performed.

The antibodies are designed to target the analyte and cause the analyte to bind to the antibody. Think of this like a jigsaw puzzle, where the antibody is the puzzle that has a hole in it for a puzzle piece to fit, and the analyte is that piece of the puzzle. When the puzzle piece (the analyte) finds a spot in the puzzle (antibody) where it can fit perfectly, it will snap into place in (bind with) the puzzle.

Let’s take this one step further and be more specific to the DrugTest® 5000. The immunoassay technique used is a competitive immunoassay. An antibody is added to the test kit as well as a drug conjugate that has been manufactured by the company. The antibody is labeled so that when it binds with something it gives off a detectable color.
Inside the test collection device are strips of absorbent material. Both the antibody and the drug conjugate are placed on this test strip. The labeled antibody is placed towards one end of the strip. In the middle of the test strip the drug conjugate is embedded. This area, where the drug conjugate is embedded, is the detection zone and is where the color change is watched for and measured. The oral fluid sample is placed on the far end of the strip next to where the labeled antibody is.

Now it becomes a competition where any drug that may be present in the sample competes with the drug conjugate to bind with the antibody. Because the oral fluid sample will come into contact with the labeled antibody before the drug conjugate can, then any drug present in the sample will "win" the competition it is having with the drug conjugate and bind with the antibody first. If there is no drug present in the sample, then the labeled antibody cannot bind until it reaches the detection zone and binds with the drug conjugate. When the labeled antibody binds with the drug conjugate, it creates a detectable red line in the detection zone that is then measured with a LED light source and detector.
The detector will measure the amount of color given off by the reaction of the labeled antibody binding with the drug conjugate. The greater the response the more drug conjugate has bound with the antibody, meaning that there was lesser amount of drug, or no drug, in the sample. When a drug is in the sample, then there will be fewer antibodies available to bind with the drug conjugate in the detection zone (because most of the antibodies have already bound with the drug in the sample), and therefore there will be less detectable color. Therefore, the signal amount identified by the detector is inversely proportional to the amount of drug present in the sample: more drug equals less signal, less drug equals more signal (as depicted in Figure 3).

Problems arise with this technique when a substance that is NOT the analyte of interest has a structure similar enough to the antibody that this other substance can bind with it just as the analyte of interest does. When this occurs the immunoassay test will show a positive result for presence of the target analyte even though the target analyte is not in the sample. This is a false-positive result known as cross reactivity.

It is very important to understand that this type of testing is presumptive and subject to many false positives from cross-reactivity. Any results obtained from immunoassay testing must be confirmed by a confirmatory test such as Gas Chromatography Mass Spectrometry.

**Why Is Oral Fluid Collection Coming to a Road Near You?**

Well, it?s simple: As of January 2014, for 14 states it is already here. OF/MSS is specifically authorized by statute, and some states already have regulations that allow for it.4 In fact, Los Angeles made POCT part of its New Year?s Eve checkpoint effort. Along with PBTs, the officers were authorized to ask drivers if they would consent to a voluntary portable oral fluid test.5 After consent is obtained, the OF is placed into a portable machine: the machine being used was the Dräger DrugTest® 5000,6 which gives immediate results without the need for a blood test.7 Addressing the media and the use of this technology, Los Angeles City Attorney Mike Feuer stated: ?Traditionally, our office has focused on drunken driving cases. We?re expanding drug collection and aggressively enforcing all impaired-driving laws.8
Further illustrating the point, the federal government is stepping up focus on drugged driving and the use of POCT. The Office of National Drug Control Policy, along with the White House, the Department of Transportation, and other Federal Agencies, have taken steps to address drugged driving, and several studies have been published on the perceived problem. For example, *The National Roadside Survey of Alcohol and Drug Use by Drivers* found that in 2007, approximately one in eight weekend nighttime drivers tested positive for illicit drugs. *Drug Testing and Drug-involved Driving of Fatally Injured Drivers in the United States: 2005?2009*, found that roughly one in four of fatally injured drivers who tested positive for drugs were under the age of 25. In 2009, narcotics and cannabinoids accounted for almost half of all positive results. In that same year, 18 percent of all fatally injured drivers nationwide tested positive for drugs at the time of the crash. Finally, the Institute for Behavior and Health published *Drugged Driving Research: A White Paper*. That paper concluded that drugged driving was a significant domestic and international problem. Also, there are many drugs with potential impairing effects being prescribed at a rate higher than we have seen in the history of this country. Accordingly, drug-impaired driving has been thrust into the spotlight of law enforcement, media, awareness groups, and lobbyists.

Moreover, federal agencies under the name ?National Drug Control Strategy? announced their goal not only to reduce drugged driving by ten percent by the year 2015, but also to put the prevention of drugged driving on par with drunk driving prevention. Included in their strategy was to develop standard screening methodologies for drug-testing labs to use in detecting the presence of drugs.

The authors believe that although the strategy calls for standard methodology in laboratories, it is not an inconceivable leap to standardized methodology for testing roadside. These federal agencies have money to fund research. Here, it must be noted that scientific meetings, such as the American Academy of Forensic Sciences as well as the American Chemical Society, are now including presentations and a considerable amount of discussion about this OFCD technology. Government money is pushing research which in turn is pushing innovation. Seizing the opportunity, various for-profit companies such as Dräger, National Medical Services, Cozart Bioscience Ltd., Varian, Branan Medical Corporation, and Innovacon have entered the market and already have viable devices in use. OFC tests that produce rapid and cheap results that can be read onsite by law enforcement officers who have little to no training seem to be an ideal product for supporters of the technology.

**Is OFCD Technology Ready for Court?**

Regrettably, all of these roadside devices have significant limitations—notably initial costs, limited scope, lack of sensitivity, and non-validation of the method used vis-à-vis unacceptably high rates of false positives. Clearly, these limitations underlie the need for improved technology and research.

The US lags significantly behind Europe and Australia in its investment in drugged driving research and in applying lesson learned to saving lives and reducing injuries. The evidence that drugged driving is a serious public health and safety problem in the US is strong, as is the evidence that current efforts to combat it are grossly inadequate . . . Improved testing technology also is needed with more sensitive rapid onsite oral fluid tests. . . .

The Office of National Drug Control Policy commitment to improving awareness, education, and fighting the ever-growing problem of drugged driving, plus its reliance on the reports discussed above, are evidence of our government?s renewed efforts to combat drugged driving. This will come, as the White Paper encourages, from OFCDs. The criminal defense bar needs to be prepared for these OFCDs. In this regard, it is not a matter of ?if we see them? but ?when will we see them?? Remember, for most of us, OFCDs will come, but for 14 states, they are already here.
How to Prepare Frye and Daubert Challenges to OFCD Evidence

In order to prepare to defend clients accused of drugged driving and testing by OFCDs, the primary scientific attack should be by Daubert or Frye challenges. We cannot allow the assumption of valid science to enter our courtrooms unchallenged, lest we have more revelations such as those that surround lead bullet analysis, fire science, pattern recognition, and hair and fiber analysis.

The Frye standard is well known:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.23

A Frye challenge to OFCD roadside evidence is proper at this point in time because as the White Paper stated, the United States lags significantly behind Europe in terms of drugged driving enforcement. Several European countries have addressed their concerns with drugged driving by approving and commissioning several studies regarding OFC. The below studies show that current OFC technology is not ready for widespread use and is certainly not generally accepted within its field.

From 2006?2008 Driving Under the Influence of Drugs, Alcohol, and Medicines commissioned a study entitled Analytical Evaluation of Oral Fluid Screening Devices and Preceding Selection Procedures.24 This European project focused on the improvement of road safety related to the problem of alcohol, drugs, and medicines. The objective was to give scientific support to the European Union?s transport policy by providing a basis to generate harmonized regulations for driving under the influence of alcohol, drugs, and medicine.

This study looked at eight devices: BIOSENS® Dynamic; Cozart® DDS 806; Drugwipe® 5+; Dräger
DrugTest® 5000; OraLab6; OrAlert; Oratect® III; and Rapid STAT®. All of the devices were tested with substance classes: amphetamines, methamphetamines, MDMA or Ecstasy, cannabis, cocaine, opiates, benzodiazepines, and PCP. The study revealed that OF screening tests have only been used in a few countries, but an increasing number are planning to introduce them in the coming years. It acknowledged the benefits that recent drug use is better detected in OFC and it is less invasive than many of the other tests currently on the market. The report, however, acknowledged that there were several issues with the devices. First, none of the tests reached the target value of 80 percent for sensitivity, specificity, and accuracy. The sensitivities for cannabis and cocaine were quite low in all the tests. This problem was further compounded as these two particular drugs are most prevalent in individuals suspected of drugged driving. The study concluded, “the time consuming process of onsite oral fluid screening, in combination with the quite high cost of the devices and the relatively low sensitive for cannabis, which in many countries is the most frequently used illegal drug, will probably prevent large scale testing in practice.”

Washington’s 2004-2006 ROSITA II Project was a study commissioned to roadside-test OFCDs. It tested two devices, the SalivaScreen® and the DrugWipe®, and concluded that the SalivaScreen® was not suitable for roadside use as it suffered a large number of failures and was not sensitive or accurate enough to detect marijuana. Rosetta II found that DrugWipe® fared better, stating that it made interpretation of the results easier and more reliable, that it was easier to use, and that it did not fail. Noticeably absent, however, was any mention of the sensitivity or accuracy to detect marijuana. A chief complaint in the report was the high cut-off rate for marijuana. The officers argued the cut-off rate has to be lower, as other than alcohol, marijuana is the most prevalent drug for DUI-D arrests. Ostensibly, higher sensitivity was not possible for the device.

Finally, the National Highway Traffic and Safety Administration conducted a study entitled State of Knowledge of Drug-Impaired Driving. That study discussed OFC testing and its problems. Some issues preclude meaningful use in the field. For example, some drugs inhibit salivary secretions (e.g., MDMA, opiates, and methamphetamine). Without sufficient sample size, the portable machines cannot achieve a valid result. Further complicating this problem, there appears little commutability among devices, with some reporting false positives or false negatives with the same sample. Another problem is that there is no consensus on cut-off levels for the operable portable devices. Almost universally and pandemic across the OFCDs is that their results are not accurate, reliable, or valid for cannabis. Further, there are no nationally established standard methods for oral fluid testing; nor are there any certification programs available. In addition to these problems, recent evaluations of available point of collection testing devices indicate that like the European and Washington studies, the specificity, sensitivity, and predictive values for drugs have been poor.

Additionally, the cut-off levels for the kits are set too low for many substances and will absolutely cause the false arrest of non-impaired drivers. For example, consider the oral fluid kit for the Drager device pictured following:
With an amphetamine cut-off level of 50 ng (AMP 50), a lot of people who are properly using therapeutic drugs such as Adderall will be caught by this unnecessary wide net.

Drugs that are taken orally, such as cannabis, or that get into the oral cavity can provide inaccurate results upon confirmatory testing, much like residual mouth alcohol can provide inaccurate BrAC results at roadside with a portable breath test. These over-reported results, based upon contamination, can totally skew the extrapolation of the OFC sample quantitative result by GC-MS to a pharmacodynamic effect. Finally, there are limited studies of insufficient value that translate the quantitative results of OF POCT to traditional blood levels in plasma, making opining as to pharmacodynamic effect nearly impossible.

These and other studies reach similar conclusions?i.e., 31 that the OFCD evidence should not survive a Frye challenge by competent and prepared defense attorneys with good experts.

Here, it must be remembered that these devices are not generally accepted within the scientific community. Although they do have their benefits, such as being less invasive than blood testing and cheaper in terms of collection costs, what they DO NOT have is the ability to give reliable, accurate, and valid results that are generally accepted within the relevant global scientific community.

What if you live in a Daubert state? The Daubert standard replaced the Frye standard in 1992 when the United States Supreme Court decided Daubert v. Merrell Dow Pharmaceuticals. This ?new? test abandoned the ?generally accepted? standard and instead employed a variety of factors to determine whether scientific evidence is reliable. The factors that were considered:

1. is the theory, technique, methodology, etc., testable and has it been tested;
2. has it been subject to peer review and publication;
3. what is its known error rate;
4. are there standards and controls maintained for the technique and methodology; and
5. has the theory, technique, methodology, etc., been generally accepted.

These factors, however, are not all inclusive, and subsequently courts have employed a number of other factors. Using the Daubert Court?s factors, a successful challenge can also be made against the OF POCT. The technique has been tested. This article discusses two of them, and the endnotes reference several more.
It has been subject to peer review and publication. The results of those tests, however, can be described as inconclusive at best, and at worst, demonstrate that the technique and the methodology used is not scientifically reliable for all of the reasons stated above. This is not only true for the roadside portable testing, but also in the confirmatory GC-MS and LC-MS testing due to the contamination. Of import here is that the error rate in these devices has been shown to be high. In fact, in the Washington study, the testing device was completely abandoned because of a constant error rate. The simple truth of the matter is that these devices are not yet ready to be used in everyday policing or prosecution. Although they show promise from a scientific and policing point of view, they are neither reliable nor scientifically proven to be scientifically acceptable.

Conclusion

Drugged driving enforcement is on the increase and will soon be on par with drunk driving. Law enforcement will be using OFCDs to combat it?even though the technology is not up to the task yet. That said, it is our job as constitutional defenders to constantly hold the government scientifically and legally accountable. To do so, we are obligated to learn and understand both the science and the law, meaning their processes, weaknesses, and strengths. Most importantly, we must always do so with dedication, honor and courage.

Notes

1. Interestingly, several of the devices look similar to an over-the-counter pregnancy test. For example, the Oratect® III test shows a blue line to indicate there is an adequate sample, and then a red line appears to indicate the presence of any drugs in the OF.

2. Examples of some of the most common and prevalent devices on the market include: Drugwipe® by Securetec (Ottobrunn, Germany); ORALscreen® by Avitar (Canton, MA); Cozart RapiScan Oral Fluid; Drug Testing System by Cozart Bioscience, Ltd. (Oxfordshire, U.K.); BIOSENS® Dynamic by Biosensor Applications (Solna, Stockholm); Oratect® III by Branan Medical Corporation (Irvine, CA); and SalivaScreen 5® by Medimpex United Inc. (Bensalem, PA). This is by no means an exhaustive list but is intended to just give an example of the variety of devices available to the public.

3. For those readers who wish to see a video sample of how the devices work, please visit the Dräger DrugTest® 5000?s YouTube page [13]http://www.youtube.com/watch?v=SJ4tm6PCwF0.

4. Fourteen States currently have laws or regulations allowing for onsite oral fluid testing: Alabama, Arizona, Colorado, Indiana, Kansas, Louisiana, Missouri, New York, North Carolina, North Dakota, Ohio, Oregon, South Dakota, and Utah. See StopDUID, [14]http://www.stopduid.org/ (last visited July 9, 2013) (?Our goal is to provide the most recent information on drugged driving policies in the United States. This website tracks research and legislative activity to strengthen DUID laws in all 50 states.?).


8. Id.
9. Drugged Driving, supra note 2 (?Americans are all too familiar with the terrible consequences of drunk driving. Working with the Department of Transportation and other Federal agencies, the Office of National Drug Control Policy is taking steps to highlight the growing problem of drugged driving.?).

10. Id.


12. Id.

13. Id.


15. Id.

16. Id.

17. Id.

18. Id. at 7 (the strategy also calls for encouraging states to adopt per se drug impairment laws; collecting further data on drugged driving; enhancing prevention of drugged driving by education communities and professionals; and providing increased training for law enforcement on identifying drugged drivers).

19. Id. at 18.

20. Id. at 24.

21. Id. at 48.


25. Id.


27. There is also a study done in Missouri. The Missouri study looked exclusively at the Dräger DrugTest® 5000. The results of that study are available at [21]http://www.ucmo.edu/safetycenter/documents/DragerStudy.pdf.

30. Id.

31. See Olaf H. Drummer, Drug Testing in Oral Fluid, 27 Clinical Biochemist Rev. 147 (2006) (concluding more research is needed to further the detection of drugs present in [OF] which should allow improved reliability of detection of drugs. Similarly, future technological developments of on-site devices should allow more sensitive and reliable detection of a number of drugs.); K. Wolff et al., Driving Under the Influence of Drugs: Report from the Expert Panel on Drug Driving, Gov.uk (March 2013), [23] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/... (Currently, oral fluid tests cannot be used to give a precise prediction of the concentration of a drug in blood (or plasma or serum) for confirmation testing and therefore prediction of possible drug effects.); Wendy M. Bosker & Marilyn A. Huestis, Oral Fluid Testing for Drugs of Abuse, 55 Clinical Chemistry 1910 (2009) (?The promise of worldwide OF testing spurred commercial research and development of POCT devices, and commercial devices were rushed to market before much of the basic science of drug excretion into OF was known . . . The major problems with early generation OF POCT included inadequate limits of detection, specificity, and efficiency. Additional research has led to some improved products. However, additional research is critically needed to characterize potential problems with OF collection devices and immunological and chromatographic assays.); Marilyn A. Huestis, Oral Fluid Testing: Promises and Pitfalls, 57 Clinical Chemistry 805 (2011) (?OF limitations include difficulty of collection following recent drug use and the potential for passive contamination; the following technical issues with OF must be resolved: inconsistent oral fluid and elution buffer volume, variable drug recoveries, inadequate oral fluid immunoassay sensitivity and specificity, and lack of homogeneous immunoassays for automated analyzers; there could be inadequate specimen for multiple drug confirmations); F. M. Wylie et al., Drugs in Oral Fluid: Part II Investigation of Drugs in Drivers, 150 Forensic Sci. Int.? 199 (2005) (At present, no OF device has the sensitivity or specificity to successfully detect an extensive range of drugs).

Footnotes:

*Dräger DrugTest® 5000 is a registered trademark of Drager Safety AD & CO. KGAA Corporation.


**Analyte?The substance being analyzed in an analytical procedure. In this case it would be a drug such as marijuana, a benzodiazepine, cocaine, etc.

?Antibody?Proteins in the body that are designed to target and attack foreign substances that are harmful to the body, substances such as bacteria or viruses.

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