

## Please Improve Montana Workplace Drug Testing Statute

Montana has a problem with injured workers. We need safer workplaces. Drug free workplace programs decrease injuries, save money for employers, and save lives. Let's give employers in Montana the ability to use drug testing to empower their drug free work place programs. A top executive of a major manufacturing business in my community said that drug testing was the most important safety program in the companv. Their human injury and accident rate decreased dramatically after implementing a drug testing policy. At Northwest Healthcare we decreased the percent of employees injured per year from 14% in 1999 to 2% in 2007 and even less since then. We saved \$3,000,000 in workers' compensation reserves in the last two years alone. Drug testing is a key component of our comprehensive injury prevention program.

Drug testing is a powerful tool: a powerful deterrent for occasional and weekend users to stay sober, a powerful incentive for chronic users to quit, and a powerful way to monitor compliance with a treatment program.

Drug testing saves money, decreases injuries, increases productivity, and protects the public.

### Problems with our current statute:

- 1) Oral fluid testing can't be done because there is no technology to collect a split specimen
- 2) Hair and blood testing are not included
- 3) Many impairing drugs are not included
- 4) Return to duty testing is not included

### Purpose of the proposed changes:

- The purpose of the bill is to allow oral fluid testing. The current statute states that you can use oral fluids, but then confusing language in the "process" requires a split specimen. It is difficult to produce enough oral fluid to for a split specimen, so there are no containers designed to collect a split for oral fluid. With the new wording we can screen with oral fluid, then obtain a second specimen to send for split confirmation.
- This technique will save a lot of time and money for employers. In collecting urine if the donor can't pee he or she has to stay at the collection site up to 3 hours--at the expense of the employer. Typical charge for urine lab testing is \$30-40--point of care oral fluid devices cost \$3-\$10. Training for urine collectors takes several hours--oral fluid is less than an hour.
- Oral fluid testing is much easier for the donor. Would you rather pee in a cup or put a swab between your cheek and gum?
- Oral fluid testing makes it more difficult for the donor to adulterate or substitute the specimen and virtually impossible to dilute the specimen. In other words, donors can't cheat as easily.
- Oral fluid testing more accurately reflects current impairment, making it better for post accident and reasonable suspicion situations.
- Our current statute defines "controlled substance" by reference to 49 CFR Part 40, which does NOT define "controlled substance." By using the definition from Montana statute an employer may choose which impairing substances to test for. This is especially important in health care settings where the impairing drugs of choice may not be on the SAMHSA list.

Drug Testing Myths:

- **Myth: Drug testing is invasive and demeaning.** Truth: Montana statute mandates that employers follow procedures to protect the privacy of the specimen donor. A urine donor goes into the bathroom alone. Oral fluid testing is even less invasive. A swab is placed between the gum and cheek.
- **Myth: Drug testing does not reflect current impairment.** Truth: For most drugs the detection periods are short, particularly with oral fluid testing. Marijuana metabolites may be detected for prolonged periods in urine. However, because marijuana's impairing effects are also so long lasting, the argument that the person is impaired by marijuana still has significant validity. To counter this concern we need the capability to test oral fluid or blood specimen.
- **Myth: Drug testing gives employers information about an employee's personal medical problems.** Truth: Montana statute requires that all non-negative test results be reported to a Medical Review Officer (MRO), a physician, who contacts the donor to ask for an explanation. If the donor has a medical condition and/or a legal prescription acceptable to the MRO, then the MRO will report the result to the employer as "negative." Montana statute specifically prohibits the MRO from releasing private medical information to the employer.
- **Myth: Drug testing is a violation of an employee's right to privacy.** Truth: An employer has a responsibility to provide a safe workplace and to protect employees from unsafe working conditions. An employer has a responsibility to protect the public from unsafe employee actions. A drug free workplace helps the employer meet those responsibilities. An employee does not have the right to be impaired at work.
- **Myth: Termination for positive drug test is unreasonable.** Truth: Montana statute requires an employer to have a rebuttal process. Montana statute mandates collection of a split specimen; the donor may request that the second specimen be tested by a different laboratory.

HB 242 Revise Workforce Drug Testing Laws

49 CFR Part 40	Current Montana	HB 242	Comments
Drug testing using urine specimen only	Urine testing only. Oral fluid is included in section 39-2-206 (12), but section 39-2-207 (1) negates the use in drug testing by stating that procedure must be as stringent as 49 CFR Part 40 [technology does not exist to collect split oral fluid specimens].	Urine, oral fluid, hair, or blood	--Oral fluid and hair are less invasive to collect and harder to substitute or adulterate than urine. --Oral fluid and blood samples are more sensitive to current impairment. --Hair samples show a longer period of use. --Urine testing is still the least expensive and offers the widest range of drugs. The employer needs the ability to select the best specimen for the type of test and the individual being tested.
Drugs to be tested ARE NOT specified in 49 CFR Part 40	"Follow 49 CFR Part 40" AND excludes prescription drugs and drugs "used legally"	Controlled substances defined by current Montana statute	Allow employers to specify impairing drugs to be tested
Split specimen must be collected and sent off to laboratory for screening	"Follow 49 CFR Part 40"	Screening test may be done at the collection site	Split not required for screening test
Specimen must be sent to HHS approved laboratory for testing	"Follow 49 CFR Part 40"	Split specimen must be sent to laboratory for confirmation testing	May use Montana laboratory for confirmation testing
Require laboratory confirmation of non-negative tests using chromatography methodology	"Follow 49 CFR Part 40"	Require laboratory confirmation of non-negative tests using chromatography methodology	Montana laboratory must have capability to perform GCMS or LCMS test AND maintain specimen integrity (custody and control)
Alcohol testing using breath or oral fluid for screening	"Follow 49 CFR Part 40"	Same	Oral fluid testing is much easier and less expensive than breath testing
EBT (evidentiary breath alcohol tester) for confirmation testing	"Follow 49 CFR Part 40"	EBT, or blood for confirmation testing	Allows employer to use blood in areas or situations where breath testing may not be available.

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**JAN 26 2012**

TO: Administrator

FROM: Director, CSAP

SUBJECT: Recommendations from SAMHSA's Center for Substance Abuse Prevention  
Drug Testing Advisory Board - **ACTION**

ISSUE

Two recommendations from SAMHSA's Drug Testing Advisory Board (DTAB) to expand the federal workplace drug testing program as follows: (1) to evaluate the scientific sufficiency of oral fluid as a potential alternative specimen; and (2) to evaluate the scientific sufficiency of Schedule II prescription medications.

DISCUSSION

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) establish the scientific and technical guidelines for Federal Workplace Drug Testing Programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies, under authority of section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, and Executive Order (E.O.) 12564. SAMHSA publishes the Mandatory Guidelines as required by federal law. The Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970) and have since been revised numerous times, most recently on April 30, 2010 (75 FR 22809).

SAMHSA's DTAB is a scientific council that advises SAMHSA's Administrator and reviews SAMHSA's program for national laboratory certification for Federal workplace drug testing programs as required by Public Law 100-71 and as described in the Mandatory Guidelines. The DTAB recommends areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing recommendations, and reviews specific science areas on new drugs of abuse and the methods necessary to detect their presence.

On July 13, 2011, the DTAB considered, discussed, and voted on the following two recommendations in an open public session:

*Recommendation 1.*

Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

*Recommendation 2.*

DTAB recommends the inclusion of additional Schedule II prescription medications (e.g., oxycodone, oxymorphone, hydrocodone, and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

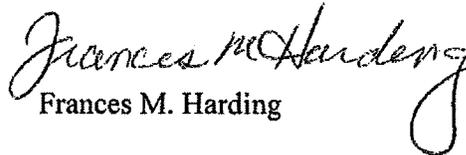
With these two recommendations, the DTAB supports the utilization of the best available science for Federal Workplace Drug Testing Programs, as required by statute. These recommendations also support SAMHSA's Strategic Initiative on the Prevention of Substance Abuse and Mental Illness.

The DTAB recommendations were reviewed by the Prescription Drug Subcommittee of HHS' Behavioral Health Coordinating Committee (BHCC) to ensure that U.S. Department of Health and Human Services' (HHS) Operating Divisions and Offices are in agreement with these recommendations. All questions raised by BHCC members were satisfactorily resolved and there are no outstanding concerns remaining. In addition, the Counselor to the Secretary of HHS has been briefed on these recommendations. Implementation of these recommendations will require revising and updating the Mandatory Guidelines to adopt the DTAB's two recommendations.

The draft proposed revisions to the Mandatory Guidelines will be published in the Federal Register for public comment and subsequently routed to other Federal agencies for their review and to HHS and the Office of Management and Budget for their approval.

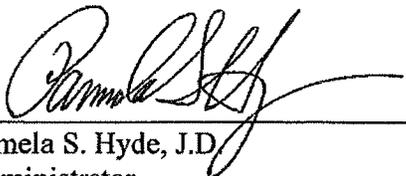
RECOMMENDATION

I recommend that you approve the DTAB's two recommendations and direct that SAMHSA implement the recommendations through revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

  
Frances M. Harding

DECISION

Approved  Disapproved  Date JAN 26 2012

  
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Pamela S. Hyde, J.D.  
Administrator  
Substance Abuse and Mental Health Services Administration



## Oral Fluid Drug Testing Fools Cheaters

By Edward J. Cone, Ph.D., FTCB  
Johns Hopkins School of Medicine, Baltimore, MD  
February 2011

The ingenuity of drug abusers to avoid detection has always been apparent but never as highly developed as today. Many drug abusers have become highly competent "cheaters" when it comes to urine drug testing. Drug abusers have detailed instructions available on the Internet on how to beat drug tests accompanied by a supporting industry of products such as synthetic urine, adulterants and devices designed to fool urine collectors and confound specimen analysis. An emerging

drug test that uses a few drops of oral fluid (primarily saliva) overcomes many of the problems of urine testing. With the advanced analytical technology available

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today, laboratory based oral fluid drug testing represents a new tool that is as accurate as urine tests and overcomes the problems associated with drug "cheaters".

### **Cheating on Urine Drug Tests**

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Although urine has been the predominant specimen of choice for conducting drug tests, it has clearly defined collection weaknesses that have been recognized since its first use. Not only is there embarrassment to both the donor and the collector when a urine specimen is collected, drug abusers find ways to foil the drug test in a variety of innovative ways. Prior to showing up for a drug test, drug abusers know that by

"water-loading" they may escape detection by providing a highly dilute specimen thereby lowering drug concentrations below detection thresholds<sup>1</sup>. A second dilution method is simply adding fluid to the specimen during collection. However, laboratories have become adept at detecting a "dilute" specimen; therefore, many drug abusers take additional precautions to improve their chances of escaping detection.

A variety of ways are available for beating a drug test. Adulterants (chemicals) can be purchased on the Internet and in health-food stores that, when added to urine specimens, either destroys the drug or interferes with the test method, the result being a false negative report. Adulterants are products designed to be easily concealable in clothing so they can be added to the collection cup before, during or after urination without the collector's knowledge. Detection of adulterants by laboratory analysis can be problematic; some laboratories have developed tests for specific adulterants, but new adulterants continually appear. The demand for new adulterants is such that laboratories simply cannot keep up with the expanding list of products nor can they continue to bear the associated costs of testing for each new adulterant.

Another method that has proved effective is substitution of "clean" urine in place of the individual's authentic specimen. Clean specimens can be obtained from another individual or purchased on the Internet either as freeze dried specimen (with instructions to add warm water),

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*Of course the additional testing costs necessary for adulterants and sample dilutions are passed along to the end user.*

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intact urine, or synthetic urine. Appliances, such as the Whizzinator and the Butt Wedge, can be purchased and loaded with fake urine. These urine delivery devices are difficult, if not impossible, to detect even during witnessed collection. Once a substituted specimen is collected, the laboratory cannot distinguish a substituted urine specimen from an authentic specimen.

In sum total, millions of dollars are spent yearly on these types of products designed to help drug abusers avoid drug detection; unfortunately no one really knows how frequently drug abusers attempt or are successful in beating their urine drug tests. With all the effort drug test cheaters expend, the laboratories have to stay diligent in order to catch them. Of course the additional testing costs necessary for adulterants and sample dilutions are passed along to the end user. These costs are further amplified by the "soft costs" to be considered in combating cheating attempts - keeping a bathroom secure for collections, turning off the water, bluing agents in the toilet, and mirrors; all add to the cost of urine collection.

### Tips for Controlling Urine Tampering

- Use Random Donor Selection Procedures
- Minimize Donor Access to Water Sources During Collection
- Place Blueing Agent in Toilet
- Request Donor Photo ID
- Request Removal of Outer Clothing (coats, hats, backpacks)
- Have Donor Empty Pockets
- Have Donor Wash Hand Prior to Collection
- Witness Sample Collection
- Check Sample Temperature (90 - 100 degrees F)
- Perform Creatinine Testing (to identify dilute samples)

# ORAL FLUID DRUG TESTING FOILS CHEATERS

## Oral Fluid Tests are Always Observed

Oral fluid is primarily saliva<sup>1</sup> and is easily collected with an absorptive device placed in the mouth. Collection takes only a few minutes and the collector observes the entire process from start to finish, thus eliminating attempts by the donor to cheat the test. Oral fluid testing preserves individual privacy while allowing for direct observation without embarrassment<sup>2</sup>. If an



additional specimen is desired, either simultaneous collection or sequential collection can be part of the routine procedure. Oral fluid collections eliminate gender collection problems and “shy bladder” issues associated with urine collection, however, insufficient specimen volume can be an occasional problem for oral fluid collection if the collection time is too short or the individual suffers from “dry mouth”.

## How Oral Fluid Tests Work

Salivary glands on the cheek and under the tongue supply the major fluid component to oral fluid. These glands have high blood flow; consequently drugs like cocaine migrate rapidly from blood to salivary glands and appear in saliva within minutes of drug administration<sup>3</sup>. For many of the major drugs of abuse, clinical studies have demonstrated parallel drug/metabolite relationships between oral fluid and blood. Thus,

oral fluid serves as a “window” into the body for most drugs. Detection times for drugs in oral fluid tend to be similar or longer than detection times in blood but generally shorter than in urine. Verstraete<sup>4</sup>, in a review of detection times of drugs of abuse in blood, urine and oral fluid, concluded that drugs can be detected for 5 to 48 hours in oral fluid as compared to 1.5 to 4 days in urine following a single drug dose and for a week or longer following chronic drug use.

Cannabis is different from most other drugs in the way it enters oral fluid primarily because of the “stickiness” of its key component, tetrahydrocannabinol (THC), the active ingredient of cannabis. During smoking or oral consumption, THC is deposited directly into mouth tissue and can be detected directly in oral fluid. Fortunately, the residence time of THC in the oral cavity is sufficient for detection over a similar time course as its presence in blood. Indeed, detection rates by oral fluid testing for marijuana and other drugs appear to be similar to or better than those seen in urine testing<sup>5</sup>. Figure 1 illustrates a study of private sector workplace tests with oral fluid compared with private sector workplace tests with urine. The overall positive prevalence rate (% positive tests in each population) for oral fluid was 5.1% and for urine was 4.5%. Data reported from Quest Diagnostics in a 5 year study ending in 2009 of over 4 million oral fluid samples, further substantiates these rates.

Following oral fluid collection, the specimen is typically placed in a sample vial containing a stabilizing buffer, sealed, and transported to a testing laboratory. From this point on, testing procedures are similar to those used in urine testing. Laboratory testing initially begins with a screening assay that eliminates negative specimens. Specimens that test presumptively positive are retested with a confirmation test that can accurately determine drug content. The specific drug or metabolite present is measured and, if the amount is sufficient to meet reporting criteria, the result is reported as positive. Both negative and positive results are sent to the authorizing agent, usually within 24-48 hours.

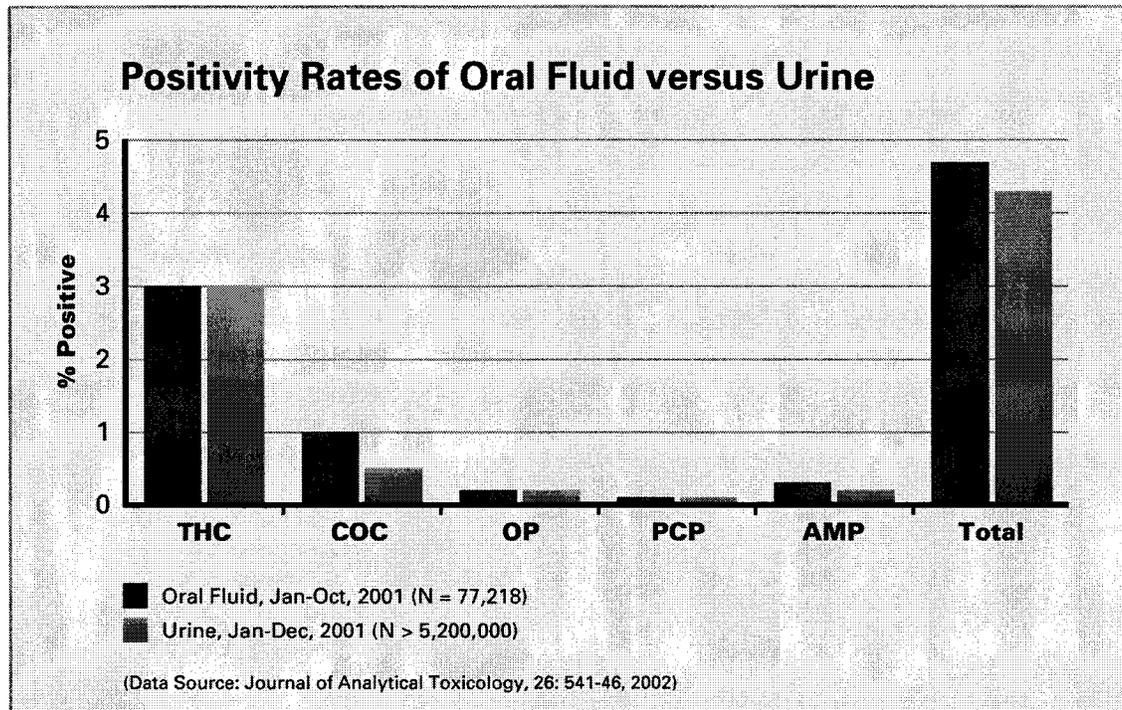


Figure 1. Prevalence rate of positive tests by oral fluid and urine in the private sector workplace.

## Accuracy of Oral Fluid Laboratory Tests Versus POCTs

Although point-of-collection tests (POCTs) have the advantage of rapid results, their allure is diminished if the test is not sensitive enough or accurate. Unfortunately, POCT technology for oral fluid drug tests has not reached acceptable levels of sensitivity for each of the five primary classes of drug. For example, authors of a recent 2010 evaluation of eight oral fluid POCTs report that "In particular, it is evident that the cannabis and cocaine tests of the devices still lack sensitivity..."<sup>6</sup>. Most laboratories engaged in urine and oral fluid testing utilize instrumented immunoassay tests for drugs which meet FDA requirements for commercial distribution, thereby insuring the product has been thoroughly evaluated for accuracy and sensitivity

and has a clearly defined threshold cutoff. Oral fluid collection devices are also regulated. Currently, there are only a limited number of FDA-cleared oral fluid collection devices and associated screening assays. The most recognized oral fluid testing system is OraSure's Intercept products. According to a 2010 survey of 26 drug testing providers, OraSure (Intercept<sup>®</sup>) was

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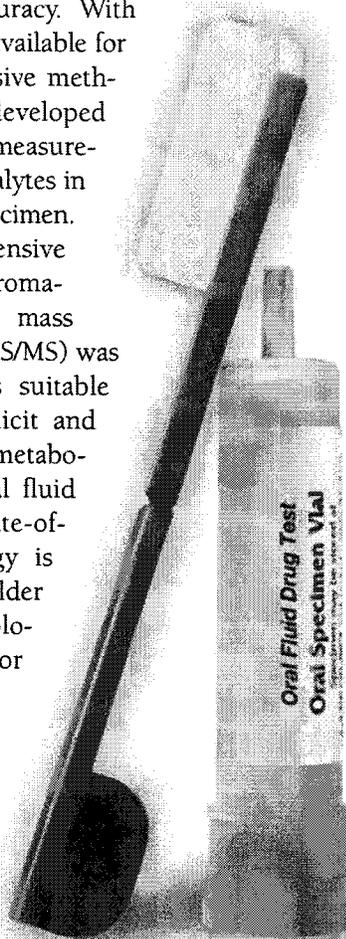
named by the vast majority of participants as the most recognized oral fluid testing brand name<sup>7</sup>. These laboratory-based tests are screened at the lab and negative results are reported within 24 hours - positive confirmations take up to 72.

# ORAL FLUID DRUG TESTING FOILS CHEATERS

## Ultra-sensitive Technologies Used in Oral Fluid Laboratory Tests

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The growing popularity of oral fluid testing over the last two decades has been made possible through improvements in screening and confirmation technologies. Oral fluid specimens typically contain drugs and metabolites at considerably lower concentrations than in urine and are limited in volume generally to one milliliter or less. Thresholds, or "cutoffs" for oral fluid are at least ten-fold lower than urine and methods must be validated to enable reliable detection of recent drug use for the numerous classes of abused drugs<sup>8,9</sup>. Analytical methods for measuring multiple drugs and metabolites in oral fluid require high sensitivity, specificity and accuracy. With the limited volume available for testing, comprehensive methodology had to be developed for simultaneous measurement of multiple analytes in a small volume of specimen. A recent comprehensive assay by liquid chromatography tandem mass spectrometry (LC/MS/MS) was described that was suitable for measuring 21 licit and illicit drugs and metabolites in a single oral fluid sample<sup>10</sup>. This state-of-the-art methodology is rapidly replacing older confirmation technologies in current use for urine testing.



## An Enormous Scientific Literature Base Supports Oral Fluid Tests

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The development of oral fluid tests for drugs of abuse has engendered the publication of a significant body of scientific literature on a variety of aspects of oral fluid testing. Several reviews document aspects of oral fluid testing including drug disposition<sup>9,11,12</sup>, detection times<sup>4</sup>, diagnostics<sup>13</sup>, legal issues<sup>14</sup>, application of state-of-the-art technologies<sup>15-20</sup> and interpretation of results<sup>21</sup>.

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*Oral fluid (lab-based) tests offer an effective solution to persistent problems inherent in urine testing, including the dilution and adulteration tactics used by those who want to cheat a drug test.*

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## Oral Fluid Instead of Urine?

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Clearly, the growing and continually evolving problems of drug abuse demands novel strategies that reliably and reproducibly detect signs of abuse. The scientific community has endorsed oral fluid testing as a reliable methodology. Oral fluid tests offer an effective solution to persistent problems inherent in urine testing, including the dilution and adulteration tactics used by those who want to cheat a drug test. This established technology overcomes many of the problems of older methods by utilizing collection methods and technology that greatly surpasses older methods of drug detection. Oral fluid testing is changing the face of drug testing programs, improving ease of collection and reliability, while offering the same accuracy and precision across a broader spectrum of drugs of abuse as traditional drug testing methods. With all these advancements and the proven science, oral fluid drug testing would make a valuable addition to the tool box of methods utilized by Drug Court professionals.

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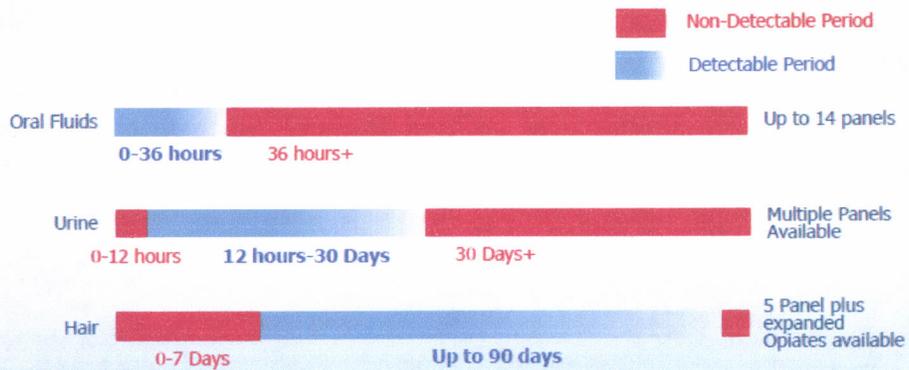
**Author Disclosure:** Dr. Cone is a consultant to OraSure Technologies and Aegis Sciences Corporation.



A-CHECK

## Drug Screening Detection Windows

Comparison: Oral Fluids vs. Urine vs. Hair



Urine testing is the most widely-used screening method. Saliva testing is gaining popularity due to its lower cost and high reliability for current use detection.

INSTANT ACCESS TO A WORLD OF INFORMATION