



What's the Buzz

SAMHSA
EDITION



SAMHSA'S NEW
ORAL FLUID GUIDELINES:

WHAT DO THEY MEAN?



04 Frequently Asked
Questions Regarding
SAMHSA Guidelines

07 Oral Testing vs.
Urine: Pros and Cons

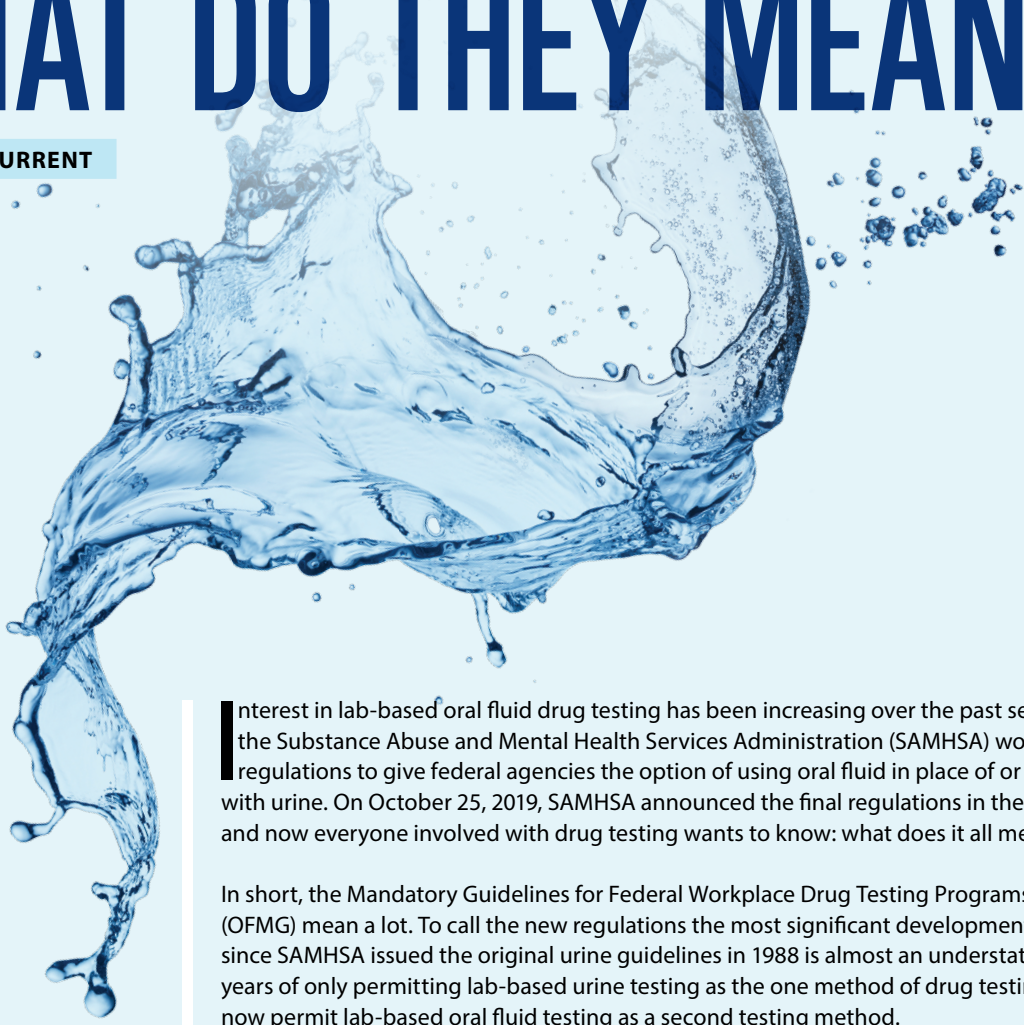
12 SAMHSA and State
Law Impacts

SAMHSA'S NEW ORAL FLUID GUIDELINES: WHAT DO THEY MEAN?

BY BILL CURRENT

The OMFG now permit lab-based oral fluid testing as a second testing method.

 [Click here to listen to our webinar](#)



Interest in lab-based oral fluid drug testing has been increasing over the past several years as the Substance Abuse and Mental Health Services Administration (SAMHSA) worked to finalize regulations to give federal agencies the option of using oral fluid in place of or in combination with urine. On October 25, 2019, SAMHSA announced the final regulations in the Federal Register, and now everyone involved with drug testing wants to know: what does it all mean?

In short, the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OMFG) mean a lot. To call the new regulations the most significant development in drug testing since SAMHSA issued the original urine guidelines in 1988 is almost an understatement. After 30 years of only permitting lab-based urine testing as the one method of drug testing, the OMFG now permit lab-based oral fluid testing as a second testing method.

Although initially the new guidelines will only apply to federal workplace drug testing programs, they will have a profound impact on every aspect of how drug testing is sold and bought, how testing is conducted, and how results are used to maintain safe and drug-free workplaces.

So, why did SAMHSA develop these new regulations? There are lots of reasons, and they are articulated in the Federal Register announcement. Ultimately, SAMHSA has endorsed lab-based oral fluid testing primarily because of the science. SAMHSA has stated:

“The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine... the OMFG provide the same scientific and forensic supportability of drug test results as the Urine Mandatory Guidelines for Federal Workplace Drug Testing Programs.”

The science of lab-based oral fluid drug testing is sound, credible, legally defensible, and can practically be applied to a typical workplace drug testing program. However, the issuance of new federal regulations is bound to have a broad impact on a diverse and complicated field such as the drug testing industry. Let’s briefly review how the regulations will impact the four key players involved in a drug test: the buyer/employer, the collector, the laboratory and the Medical Review Officer (MRO).



COLLECT

INSERT

SEAL

The science of lab-based oral fluid drug testing is sound, credible, and legally defensible

What do the OFMG mean for employers/buyers?

Initially, the new regulations will only apply to federal workplaces. Eventually, it is anticipated that both the U.S. Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) will adopt lab-based oral fluid testing and, when they do, the OFMG will have a direct impact on covered employers. The stated goal is for the DOT to have their regulations for lab-based oral fluid testing in place by the time SAMHSA completes the 12-18-month implementation period.

The issuance of the OFMG will likely have a more immediate impact on non-government, non-mandated workplace drug testing. The OFMG serve as an official endorsement of lab-based oral fluid testing by the federal government, and the guidelines provide a new “gold” standard for how to best utilize the technology. This will give many employers a green light to begin implementing oral fluid testing either in place of, or in combination with, urine drug testing.

Additionally, while lab-based oral fluid testing has historically been legally permitted in 47 states, there are several states with general laws, industry-specific laws, or workers’ and/or unemployment compensation laws that

defer to the federal guidelines. This means that historically, employers covered by those state laws have only been permitted to utilize urine testing. Presumably, the OFMG now make lab-based oral fluid testing a viable option in some of those jurisdictions.

What do the OFMG mean for laboratories?

Laboratories that wish to offer oral fluid analysis must become certified before being able to do so in accordance with the OFMG. This is a rigorous process very similar to the one labs must go through in order to become certified to analyze urine specimens. Not all labs will choose to become certified for oral fluid testing. However, in the coming months and years, using a SAMHSA-certified laboratory will become the preferred way to conduct oral fluid testing, in much the same way that using a certified lab has been the preferred way to conduct urine testing for three decades.

What do the OFMG mean for collectors?

Just as is the current case with urine collections, the person who collects an oral fluid sample will be a key part of the drug testing process. The OFMG define a collector as someone “who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer’s procedures for the collection device.” Hence, an oral fluid

collector’s training will cover two key parts—the regulations and the specific collection device being used.

The OFMG contain specific collection device requirements. For example, collectors may only use an FDA-cleared collection device. Among the requirements for FDA clearance, a device must have a built-in volume indicator and be capable of collecting a least 1 mL of “undiluted (neat) oral fluid.”

Split specimen collections are required. The OFMG offers the following guidelines:

“The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ‘A’ (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ‘B’ (split) either simultaneously or serially (i.e., using two devices or using one device and subdividing the specimen)...”

With a trained person conducting the collection and using an FDA-cleared device, oral fluid split specimens will not be a complicated issue.

Continues on back cover...

This information is provided for educational purposes only. Reader retains full responsibility for the use of the information contained herein.

SAMHSA MANDATORY ORAL FLUID GUIDELINES

FAQs

The long-awaited release of the Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for lab-based oral fluid drug testing (OFMG) has finally arrived. The Federal Register announced the new regulations via the reading room on Thursday, October 24 and published the regulations the following day. Of course, with the release of these new regulations, there are many questions. What follows are some of the most frequently asked questions so far, with an emphasis on “so far.”

Q. When do the new regulations go into effect?

The OFMG effective date is January 1, 2020. A 12-18-month implementation period will follow, giving laboratories, device manufacturers, Medical Review Officers (MROs), and collectors the time necessary to comply with the new regulations.

Q. Do the new regulations apply to employers mandated to drug test by the DOT or the NRC?

Currently, the new regulations only apply to drug testing of federal employees. The Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) must engage in their own rulemaking activities before covered employers can use lab-based oral fluid testing in compliance with those regulations. However, adoption of lab-based oral fluid testing by these agencies is anticipated. When the DOT and/or the NRC officially permit lab-based oral fluid testing, SAMHSA's OFMG will be their guiding document.

Q. Do the new guidelines replace lab-based urine drug testing?

No. Federal agencies may choose between urine and oral fluid drug testing, or utilize both testing methods as part of the same program. Under the regulations, either testing method may be used to detect the same drugs under the same circumstances as before. The drugs that can be tested for are marijuana/THC, cocaine, heroin, amphetamines, PCP, oxycodone, hydrocodone, oxycodone, oxycodone, and hydromorphone. These drugs can be tested for under the following circumstances: pre-employment, reasonable suspicion, post-accident, random, return-to-duty, and follow-up.

Q. Do the guidelines allow for testing with rapid or point of care (POCT) oral fluid tests?

No. The OFMG only permit laboratory-based oral fluid drug testing.

Q. Do the OFMG permit on-site collections?

Yes. Per the OFMG, employers will have the option of using trained employees and/or professional collectors to conduct oral fluid collections. These collections may take place at the workplace, or in other locations that meet the OFMG requirements for a collection site. Acceptable collection sites must permit observed collections, collector control of the device(s) throughout the collection process, record storage, and protect donor privacy.

Q. What is included in SAMHSA's oral fluid guidelines?

The OFMG are the oral fluid version of the Urine Mandatory Guidelines. Quoting from the regulations:

“The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.”

Q. Is it really that simple?

Yes and no. Drug testing is a science and science can be complicated. One of the good things about the OFMG is they explain complicated issues in an easy-to-understand way. For example, the OFMG require oral fluid collection devices to be FDA-cleared. Among the requirements for FDA clearance is that a device must have a built-in volume indicator and be capable of collecting a least 1 mL of “undiluted (neat) oral fluid.” That sounds complicated, but, as an employer, if you use an FDA-cleared oral fluid collection device from a reputable company such as OraSure, for example, you'll be in compliance.

This information is provided for educational purposes only. Reader retains full responsibility for the use of the information contained herein.

Q. Will split specimens be required?

Yes, and the regulations make this requirement very easy to understand. Collections can be performed either simultaneously or serially, meaning a collector can use two devices, each of which must collect 1 mL of neat oral fluid, or the collector can use one device and subdivide the specimens into two, 1 mL samples. With a trained person conducting the collection, and with the use of an FDA-cleared device, oral fluid split specimens will not be a complicated issue.

Q. How do the OFMG affect state drug testing laws?

It is important to remember three key points relative to state drug testing laws:

1. If you are federally mandated to drug test, federal drug testing regulations always trump state drug testing laws. For example, regardless of what type of drug testing a state law may or may not permit, once the DOT approves lab-based oral fluid testing, covered employers will have the option of using both urine and oral fluid testing to comply with that agency's regulations.
2. Historically, only three states have prohibited lab-based oral fluid collections, although there is some impact based on the release of the OFMG. The other 47 states have historically permitted lab-based oral fluid to some extent, though some states have industry-specific regulations and/or workers' or unemployment compensation laws that specify how to conduct drug testing.
3. To an extent, some states require employers to follow the SAMHSA guidelines. We can assume that lab-based oral fluid testing will be permitted in these states once the 12–18-month implementation period is complete, if not sooner. The best advice is to always check local legal requirements to ensure compliance.

Q. Why did SAMHSA issue mandatory guidelines for lab-based oral fluid testing?

In the *Federal Register*, SAMHSA once again articulated the reasons why the agency decided to add lab-based oral fluid testing to the mandatory guidelines. These reasons include:

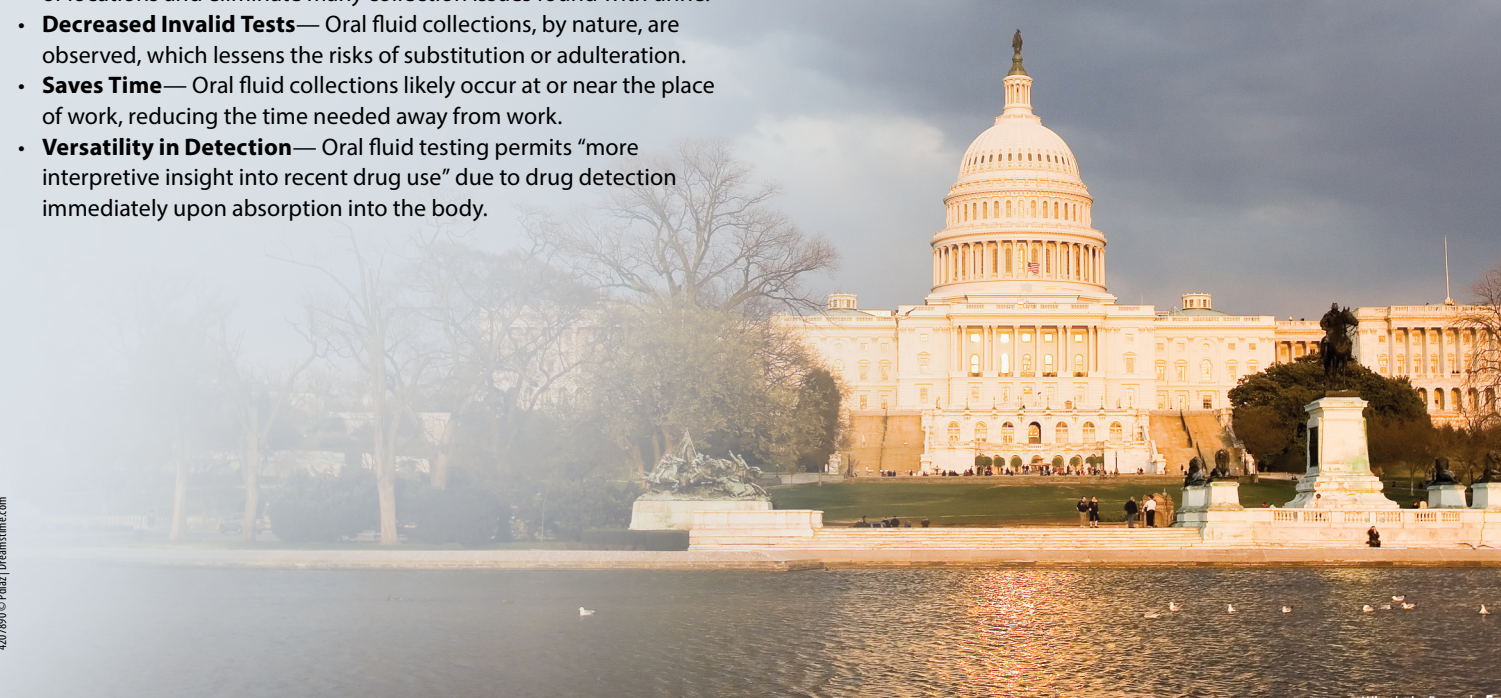
- **Enhanced Flexibility**— Oral fluid collections provide flexibility to address workplace drug testing needs by permitting the use of either urine or oral fluid, whichever specimen is best suited to the situation.
- **Enhanced Versatility**— Oral fluid collections can occur in a variety of locations and eliminate many collection issues found with urine.
- **Decreased Invalid Tests**— Oral fluid collections, by nature, are observed, which lessens the risks of substitution or adulteration.
- **Saves Time**— Oral fluid collections likely occur at or near the place of work, reducing the time needed away from work.
- **Versatility in Detection**— Oral fluid testing permits “more interpretive insight into recent drug use” due to drug detection immediately upon absorption into the body.

Q: How many drug tests will transition to lab-based oral fluid testing as a result of the OFMG?

SAMHSA estimates that about 7% of the roughly 150,000 annual drug tests of federal employees will transition to oral fluid in the first year, and about 25% after four years. SAMHSA also estimates the same transition rate for the 6 million DOT-mandated drug tests, or about 1.5 million eventually transitioning to oral fluid. If 25% of the nearly 40 million non-mandated workplace drug tests transition to oral fluid, that would be another 10 million or 16 million-plus when combined with the DOT drug tests.

However, according to drug testing industry experts who participated in a 2019 survey conducted by the Current Consulting Group and co-sponsored by OraSure Technologies, 53% of participants indicated that interest in lab-based oral fluid testing among their clients would increase once SAMHSA issued the OFMG. That was up from 38% in the 2018 survey.

Continues on page 6...



Federal agencies may choose between urine and oral fluid drug testing, or utilize both testing methods as part of the same program



Q: As an employer, what can I do to implement oral fluid testing?

If you are a non-regulated company that would like to begin conducting lab-based oral fluid testing now, speak with your OraSure representative to help with the following:

- Identify your drug-testing objectives
- Update your policy with specific lab-based oral fluid testing language
- Determine how you will collect oral fluid samples (on-site with trained employees and/or professional technicians or at off-site collection facility)
- Prepare supervisors/managers
- Ensure all vendors are ready to provide their services
- Announce the program to your employees

If you are a regulated company that would like to begin conducting lab-based oral fluid testing after the SAMHSA implementation period, speak with your OraSure representative to help with the following:

- Updating your SAMHSA drug testing policy to reflect the addition of lab-based oral fluid testing
- Training employees to conduct on-site oral fluid collections per the regulations, including securing the collection location, using the federal chain of custody form for oral fluid, collecting split specimens, and properly shipping specimens to a certified laboratory for analysis
- How to identify qualified professional collectors, certified laboratories, and trained medical review officers
- Note: SAMHSA- and DOT-covered employers may immediately begin utilizing lab-based oral fluid drug testing for their non-DOT or SAMHSA covered employees or in non-DOT or SAMHSA testing circumstances (OraSure can provide up-to-date state law information to help you comply with applicable legal requirements)

Have more questions? To learn more, contact us at (610)419-7657 or at chooseintercept@orasure.com

 [Click here to listen to our webinar](#)

©2010-2019 The Current Consulting Group, LLC – No portion of this article may be reproduced, retransmitted, posted on a website, or used in any manner without the written consent of the Current Consulting Group, LLC. When permission is granted to reproduce this article in any way, full attribution to the author and copyright holder are required.



URINE TESTING VS. ORAL FLUID: THE PROS AND CONS

BY YVETTE FARNSWORTH BAKER, ESQ.

CURRENT CONSULTING GROUP



The CONS of Urine Testing

Observed Collections and Cheating

One con to urine testing is the dilemma of the observed collection. Urinating is an extremely private matter, and no one wants to be watched while doing it. However, total privacy during the collection of a urine sample opens the door to drug test cheating. When an individual has complete privacy to submit a urine sample, they can dilute the sample, add substances to it, use synthetic urine, or use urine from another person. Collectors have methods to attempt to combat these tricks, but they are costly, time-consuming, and are not fool proof. Employers also feel much more secure when acting on a positive drug test rather than on a diluted or potentially tampered test.

Shy Bladder

There are some with a legitimate medical condition that makes it difficult for them to produce a urine sample on command. Often, individuals seeking to skirt a urine test will claim the inability to urinate. Handling such employee issues with respect is complicated, time-consuming, and costly.

When making decisions about workplace drug testing, one of the big choices is deciding what bodily fluid sample to test. One of the most longstanding test samples is the urine test. But, does longstanding always mean best? This article will explore the pros and cons of urine testing, and compare those to the pros and cons of oral fluid testing.

Location of Testing

Urine testing at the workplace is tricky, and more often than not is done at a collection site away from the workplace. While not impossible, organizing a location in the workplace where urine collection can be hygienic and free from tampering is complicated. Frequently, water sources are turned off, and dyes are used in toilets so that an employee cannot dilute their urine sample with outside water. Collectors need a place in close proximity to monitor for tampering and to collect the sample from the employee as quickly as possible.

At the same time, having employees travel to and from a collection site takes time and costs money, which can impact productivity.

Historical Drug Use

Another con to urine testing is that, for some drugs, historical drug use is captured much more reliably than recent use. Marijuana is an example of one such substance. Marijuana use can show up on a urine screen for as long as 30 days after use.¹ At the same time, urine screens can often miss marijuana that has been in the system for less than several hours. Due to the way that marijuana is metabolized, urine tests cannot accurately assess when a person last used marijuana. Thus, a positive marijuana test taken from a urine sample cannot tell an employer whether the individual used marijuana that morning, or three weeks earlier. Additionally, a urine-based test can miss the most significant marijuana use: that of someone who used thirty minutes ago.

The PROS of Urine Testing

Historical Use

While historical use can often be a con to urine testing, it can be a pro of this testing as well. If employers want to know if an individual has used drugs, no matter how long ago, urine is a great option. This is often the case with preemployment testing, when employers are less worried about impairment on the job and more interested in the individual's background.

Well-Known and Well-Understood

Another big pro to urine testing is that it is well-known and well-understood by the public. People feel secure in the testing results and are familiar with the procedures.



This information is provided for educational purposes only. Reader retains full responsibility for the use of the information contained herein.

Oral fluid can
often detect
substances only 15
minutes after use



The PROS of Oral Fluid Testing

Ease and Security of Collection

A big pro to oral fluid testing is how easy it is to collect. Oral fluid is collected by swabbing the inside of the mouth for a short amount of time. The privacy dilemma of urine collection is not an issue with oral fluid. Collectors do not need special accommodations to take samples on site as they do with urine collections, and employees do not need to travel to a special collection site. Additionally, because direct observation of the individual during the collection is simple and nonintrusive, it is nearly impossible to cheat an oral fluid test.

Short Detection Window

Another pro to oral fluid testing is that oral fluid testing has a quick detection window. Oral fluid can often detect substances only 15 minutes after use. In addition to this, oral fluid testing does not return a positive test for use that happened weeks before the test. Oral fluid testing will usually only return positive results 1–2 days after use.

This short detection window can be very important when it comes to marijuana testing. As marijuana use, both medical and recreational, becomes more widespread, employers are increasingly pressed to identify only recent use of marijuana and not historical use. Some states even require employers to have a good faith belief that an employee has used marijuana recently before imposing workplace discipline. Oral fluid testing not only captures some recent use that urine tests cannot capture, such as use that occurs less than an hour before testing, but also eliminates the possibility that use occurred many days in the past. Thus, oral fluid testing gives an employer more accurate information about a time frame for marijuana use than does a urine test.

**Concerned about drug use
in your workplace?**
Oral fluid testing catches twice as
many users than urine testing.



OraSure Technologies

Reference: Overall positive rate for general workforce testing, Quest Diagnostics Drug Testing Index 2019.

Overall Positivity Rates

Additionally, lab-based oral fluid testing returns high rates of positive drug screens. Almost without exception, lab-based oral fluid reported higher positivity rates than lab-based urine testing, according to Quest Diagnostic Drug Testing Index, 2018. Overall positivity rates in the general workforce are 10.2% for oral fluid, compared to 5.1% for urine.

The CONS of Oral Fluid Testing

Not Permitted in All States

Oral fluid testing has its own downsides as well. One con to oral fluid testing is that it is not currently permitted in all states. Maine, Vermont, and Hawaii historically have not allowed oral fluid samples to be used in workplace drug testing (though that has changed with the recent announcement of SAMHSA's oral fluid guidelines), which leads us into our second con to oral fluid testing.

Newer Methodology, Not Widely Understood

Oral fluid testing is a newer methodology and uses newer technology than urine testing. This means that some individuals are not familiar with it and do not understand the procedures and science. Often, people may choose to stay with what they know than they rather than adopting new systems.

Conclusion

Any sample choice for drug testing will have its strengths and its weaknesses. Where urine samples stumble, oral fluid samples find their strength. Employers should take time to evaluate, or reevaluate, the needs of their workplace when choosing a drug testing method. The safety and security of their business could depend on it.

Because direct observation of the individual during the collection is simple and nonintrusive, it is nearly impossible to cheat an oral fluid test

1. [1]Paul L. Cary M.S., *Marijuana Detection Window: Determining the Length of Time Cannabinoids Will Remain Detectable in Urine Following Smoking: A Critical Review of Relevant Research and Cannabinoid Detection Guidance for Drug Courts*, *Drug Court Review Volume 5 Issue 1*, 2005.



Oral fluid workplace drug testing: What the new federal guidelines mean for you

New guidelines issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) permit oral fluid (saliva) drug testing in federally regulated workplaces. This is the first time in nearly 30 years that SAMHSA is supporting an alternative to urine testing. Why is this exciting news for the industry? Read on to find out.

What do the new guidelines say about oral fluid testing?

For years only urine testing was allowed under the SAMHSA/Department of Transportation (DOT)/Nuclear Regulatory Commission (NRC) guidelines. Laboratory-based oral fluid drug testing will become a viable option for SAMHSA regulated employees, once the implementation period is complete. This means federally regulated employers will soon be able to take advantage of the many benefits laboratory-based oral fluid drug testing has provided to non-regulated employers for nearly 20 years. It is important to note that the new oral fluid guidelines do not include the use of instant or rapid oral fluid drug testing products.

Why are these new guidelines so significant?

The rate of workforce drug positivity hit a 14-year high in 2018 (Quest Diagnostics, 2019). With the opioid epidemic plaguing many cities and towns—along with the legalization of marijuana in some states—reliable workplace drug testing is more essential than ever.

The inclusion of oral fluid drug testing in the SAMHSA guidelines presents employers with the ability to conveniently perform collections while maintaining the accuracy of a laboratory-based test. According to the 2019 Quest Index, overall positivity rates in the general workforce are 10.2% for oral fluid, compared to 5.1% for urine.

What is oral fluid drug testing?

Oral fluid drug testing involves collecting an oral fluid sample from an individual and analyzing it for the presence or absence of drugs. Collection is typically performed by placing an absorbent pad in a subject's mouth to collect an adequate quantity of sample for testing. The sample is placed into a vial containing a preservative, sealed under chain of custody protocol, and then sent to a laboratory for screening and confirmation testing of any non-negative samples.



“Oral fluid should substantially lessen the risk of specimen substitution and adulteration...”
SAMHSA



“Time savings from 1-3 hours per test”
SAMHSA



OraSure Technologies

The benefits of oral fluid testing vs. urine testing

The key advantages of oral fluid drug testing include:

- **Better recent-use detection** – deal with on the job risks and concerns related to marijuana more effectively.
- **Easy to administer** – collect samples anytime, anywhere reducing costs.
- **Faster processing** – improve productivity with less time away from work than with urine collection.
- **Virtually tamper-proof and cannot be diluted** – reduce risk of missing positives, increasing safety in the workplace.
- **Accurate and legally defensible** – have confidence in your results.
- **Eliminates privacy and gender issues** – improve attitudes about testing and streamlines collection.

How to make the switch

If you are a non-regulated employer, or have a portion of non-regulated employees, there is nothing to wait for—you can switch now. Simply consult with your provider on how to make laboratory-based oral fluid drug testing part of your policy/program. If your provider or laboratory does not currently offer oral fluid testing as a service, just let us know and we will help you.

If you are a regulated employer that follows SAMHSA guidelines, it is important to learn about these changes, what the implementation period will be and begin to explore the potential benefits to your business. This includes selection of oral fluid testing products and finding an oral fluid SAMHSA-certified laboratory.

OraSure can help with these steps and answer any questions you may have about the new oral fluid guidelines.

**To learn more, contact us at
1-610-419-7657 or chooseintercept@orasure.com.**



About OraSure

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. These products include oral fluid testing solutions for drugs of abuse testing, including Intercept® Oral Fluid Drug Testing System and Q.E.D.® Saliva Alcohol Test. www.orasure.com.

www.orasure.com

SAMHSA'S NEW ORAL FLUID GUIDELINES UPDATE MORE THAN JUST FEDERAL TESTING:

STATE LAW IMPACTS

KATHERINE MILLER

Employers in Kentucky, Maine, Puerto Rico, and Tennessee are all impacted by SAMHSA's recent changes

The addition of oral fluid as an approved specimen for the Substance Abuse and Mental Health Services Administration's (SAMHSA's) mandatory guidelines has changed more than the specimens that can be used in federal drug testing. While many states have drug and alcohol testing laws that are state-specific, some states require compliance with SAMHSA and/or Department of Transportation (DOT) regulations. While the DOT has not yet issued oral fluid guidelines, it is likely that they will, and that they will have an even further reaching impact on state laws than SAMHSA's oral fluid guidelines do.

What States are Impacted by SAMHSA's New Guidelines?

Although the number of states that do not require compliance with SAMHSA regulations far outweighs the number that do, it is still essential for employers to understand if they are impacted by the addition of oral fluid to SAMHSA's mandatory guidelines. Employers in Kentucky, Maine, Puerto Rico, and Tennessee are all impacted by SAMHSA's recent changes. So, what does this mean?

This information is provided for educational purposes only. Reader retains full responsibility for the use of the information contained herein.



Kentucky

Kentucky has a voluntary drug and alcohol testing law, meaning that employers can comply, but are not required to do so. Employers that choose to comply with the voluntary law are eligible for a 5% credit on their workers' compensation premium. Employers that choose not to comply with the voluntary law may have already used oral fluid in the past, however, employers that chose to comply with the law have historically been unable to do so.

Kentucky's law states:

"Drug test' or 'test' means a chemical, biological, or physical instrumental analysis administered by a qualified laboratory, for the purpose of determining the presence or absence of a drug or its metabolites or alcohol **pursuant to standards, procedures, and protocols established by the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA).**" (emphasis added) 803 KAR 25:280(1)(5)

Kentucky's law goes on to state that urine is the appropriate testing specimen for drugs, and breath is the appropriate specimen for alcohol. The addition of oral fluid to SAMHSA's mandatory guidelines, in theory, would permit employers in Kentucky to test via oral fluid and still comply with the voluntary law. However, it is likely that legislators will need to update the law to state either that urine and oral fluid are permitted for drug testing, or that SAMHSA-approved specimens are permitted before employers can comfortably use oral fluid testing in the workplace and comply with the voluntary law.

While some employers may choose to oral fluid test under the voluntary law following the SAMHSA changes, employers that choose to do so must accept a certain level of liability.



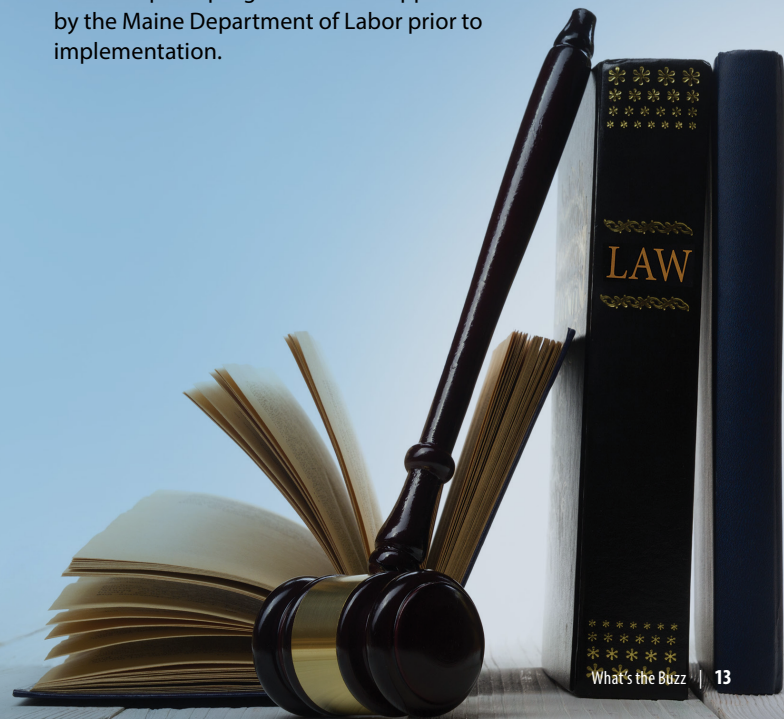
Maine

Compliance with Maine's mandatory law is required for all private employers in the state. Historically, Maine has only permitted oral fluid when used as a non-instrumented, rapid result/instant test. The addition of oral fluid to SAMHSA's mandatory guidelines has changed this.

Maine's law states:

"Screening test' means an initial substance use test performed through the use of immunoassay technology or a **federally recognized substance use test**, or a test technology of similar or greater accuracy and reliability approved by the Department of Health and Human Services..." (emphasis added) Maine Rev. Stat. 26-7-3A-682 7 A

As a subsidiary of the Department of Health and Human Services (HHS), SAMHSA's addition of oral fluid effectively permits lab-based oral fluid testing for employers in the state. Maine's laws contain extremely specific cut-off levels, and, as such, employers should review the law carefully prior to implementing an oral fluid testing program. Additionally, each drug-free workplace program must be approved by the Maine Department of Labor prior to implementation.





Puerto Rico

Puerto Rico’s mandatory law must be followed by all private employers in the territory. The law requires compliance with SAMHSA regulations in terms of specimens, however, the law is very specific when it comes to when alternative testing specimens can be used.

The law states:

“The drug tests shall be made through an urine sample, **except for those circumstances in which it is not possible** to take the same and shall be administered in accordance with scientifically accepted analytical and sample custody chain procedures, so that the privacy of the employee may be protected to the maximum, and **pursuant to the Mandatory Guidelines for Federal Workplace Drug Testing Program.**” (emphasis added) Laws of Puerto Rico 29-8-161b(b) (8)(d)

Although compliance with SAMHSA guidelines is required, which would technically permit the use of oral fluid as an approved testing specimen, the law specifically states that urine is the preferred specimen for drug tests. In fact, employers should not use oral fluid unless the donor is unable to provide a urine sample. In such cases, a SAMHSA-approved alternative specimen, such as oral fluid, can be used, but not outside of such cases.



Tennessee

Employers that choose to comply with Tennessee’s voluntary law qualify for a 5% discount on their workers’ compensation premiums. Under the voluntary law, employers are required to comply with SAMHSA’s mandatory guidelines, meaning that employers in the state are impacted by this update.

Tennessee’s law states:

“If an employee is unable to provide a urine specimen when requested, the United States **Department of Health and Human Services mandatory guidelines on fluid administration and for alternative oral specimen collection shall be followed.**” (emphasis added) Tenn. Comp. Rules & Reg. 0800-02-12-.06(4)

Although oral fluid is now permitted under SAMHSA regulations, employers that choose to comply with the mandatory law are only permitted to use oral fluid when a donor is unable to provide a urine sample. Oral fluid should not be used with all collections taken under the voluntary law.

Moving Forward

Generally speaking, the DOT follows SAMHSA, so it is likely that we will see more updates to state laws in the coming months as the DOT releases oral fluid guidelines for DOT-regulated employees and those states that require compliance with DOT regulations. For the moment, however, four states are impacted by the updates to SAMHSA’s mandatory guidelines, and each state is impacted differently. While Maine, for example, now permits oral fluid across the board, the other three states place restrictions on when oral fluid testing can take place. Consult state laws carefully to ensure that your policy is in compliance.






©2010-2019 The Current Consulting Group, LLC – No portion of this article may be reproduced, retransmitted, posted on a website, or used in any manner without the written consent of the Current Consulting Group, LLC. When permission is granted to reproduce this article in any way, full attribution to the author and copyright holder are required.

It is likely that we will see more updates to state laws in the coming months

ORAL FLUID INITIAL AND CONFIRMATORY TEST REQUIREMENTS

With the addition of lab-based oral fluid to federal workplace drug testing comes a new era for the industry. Although SAMHSA has aligned as much of the oral fluid guidelines as possible with the pre-existing urine guidelines, some things must change, such as initial and confirmatory test requirements.

The below information details initial and confirmatory test requirements for lab-based oral fluid only.

	Initial Test Analyte	Initial Test Cutoff	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration
	Marijuana (THC)	4 ng/mL	THC	2 ng/mL
	Cocaine/ Benzoyllecgonine	15 ng/mL	Cocaine Benzoyllecgonine	8 ng/mL
	Codeine/ Morphine	30 ng/mL	Codeine Morphine	15 ng/mL
	Hydrocodone/ Hydromorphone	30 ng/mL	Hydrocodone Hydromorphone	15 ng/mL
	Oxycodone/ Oxymorphone	30 ng/mL	Oxycodone Oxymorphone	15 ng/mL
	6-Acetylmorphine	4 ng/mL	6-Acetylmorphine	2 ng/mL
	Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL
	Amphetamine/ Methamphetamine	50 ng/mL	Amphetamine Methamphetamine	25 ng/mL
	MDMA/MDA	50 ng/mL	MDMA MDA	25 ng/mL

This information is provided for educational purposes only. Reader retains full responsibility for the use of the information contained herein.

©2010-2019 The Current Consulting Group, LLC – No portion of this article may be reproduced, retransmitted, posted on a website, or used in any manner without the written consent of the Current Consulting Group, LLC. When permission is granted to reproduce this article in any way, full attribution to the author and copyright holder are required.

25-30% of all federal employee drug tests...will be conducted using lab-based oral fluid in four years

Regarding collection sites, the OFMG dictate that collection sites can be permanent or temporary facilities located either at a work site or a remote location. SAMHSA anticipates that many employers will choose to collect oral fluid samples at the work site in order to save time and boost productivity. Collectors must ensure that work site being used for collections meets all the requirements of an approved collection site.

What do the OFMG mean for MROs?

The OFMG require that oral fluid test results be reported to a qualified MRO for interpretation and final reporting to the federal agency or employer. MRO requirements and procedures parallel those in place for federal urine drug testing programs; however, the federal MRO handbook will be revised and updated in the upcoming months.


Conclusion

SAMHSA projects that approximately 25-30% of all federal employee drug tests, and eventually 25-30% of all DOT- and NRC-mandated drug tests, will be conducted using lab-based oral fluid in four years.¹ If the same transition estimate is applied to the nearly 40 million non-mandated workplace drug tests conducted annually, it is easy to see how lab-based oral fluid testing will become a major force in the drug testing industry.

For the professionals who ensure the integrity of each drug test, such as collectors, labs, and MROs, the OFMG will become the "bible" for oral fluid drug testing. For employers, the OFMG will serve as the gold standard for lab-based oral fluid drug testing. For both groups, service providers and end users of their services, now is the time to prepare, so that when the 12-18-month implementation period is complete, all groups will be ready to take advantage of this exciting new development.

1. <https://www.federalregister.gov/documents/2019/10/25/2019-22684/mandatory-guidelines-for-federal-workplace-drug-testing-programs-oralfluid>

©2010-2019 The Current Consulting Group, LLC – No portion of this article may be reproduced, retransmitted, posted on a website, or used in any manner without the written consent of the Current Consulting Group, LLC. When permission is granted to reproduce this article in any way, full attribution to the author and copyright holder are required.



OraSure Technologies

Join us

for a free webinar

UPCOMING EVENTS

Why Multiple Testing Methodologies Are Better Than One Webinar
featuring *Nina M. French*
Dec. 3, 2019 | 2 p.m. Eastern

What is Oral Fluid Testing? Webinar
Jan. 28, 2020 | 2 p.m. Eastern



OraSure Technologies

220 East First Street, Bethlehem, PA 18015

800-ORASURE • chooseintercept@orasure.com

This information is provided for educational purposes only. This is not offered as legal advice, but is instead offered for informational purposes. Reader retains full responsibility for the use of the information contained herein. No portion of this newsletter may be reproduced, retransmitted, posted on a website, or used in any manner without the written consent of the copyright holder. When permission is granted to reproduce this article in any way, full attribution to the author and copyright holder are required.

