

Lab-Based vs. Instant Oral Fluid Drug Testing

Drug testing has proven to be a powerful weapon in the war on drugs. It is effective in identifying people who need help in deterring others from using drugs in the first place. When a donor tests positive, employers have several options available to help mitigate the negative impact of those individuals being at work under the influence, including referral to drug treatment or removal from duties that may impact the safety of others.

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There are several drug testing specimen types, including urine, hair, and oral fluid. Additionally, there are both laboratory-based testing and instant testing methods available. Each specimen type and testing method presents unique advantages. When done properly, all drug testing methods are sound and, as such, it's not a matter of choosing the best drug testing method, but rather the method or combination of methods that best fits a specific need.

When researching which drug testing method to choose, it's important to address three critical questions:

1. Does it accurately detect the drugs in question?
2. Is it legally permitted in the locations requiring drug testing?
3. Will it meet the unique business needs and circumstances of the testing program?

The first two questions are rather objective, while the third may be more subjective, based on the individual circumstances of each company. This white paper will apply these three questions to lab-based oral fluid testing and instant oral fluid testing and will identify the advantages and shortcomings of each testing method. Because both methods involve oral fluid testing, we will start by looking at the pros and cons of using oral fluid as a specimen when testing for drugs.

Oral Fluid Testing

Oral fluid drug testing has been around for many years, yet only in the past 10-15 years has it become a serious alternative to lab-based urine testing, which continues to be the most common drug testing method. While other drug testing specimen types like urine, hair, and blood have their advantages, the benefits of oral fluid testing are best presented in comparison to some of the challenges presented by these other testing methods.

It Is an Alternative to Urine

Despite a great number of advantages in favor of lab-based urine testing, some people do not like it. Yes, it's permitted in every state, legally defensible, and scientifically accurate when conducted properly. At the same time, it is by comparison more susceptible to a variety of cheating methods, more challenging to collect, and may be considered more invasive. Some employers conduct 24-hour shifts of workers in safety-sensitive environments or maintain workplaces in out-of-the-way, rural locations. The need for drug testing exists, but the practicality of sending a donor to a collection site for a urine collection can range from moderately inconvenient to nearly impossible and the cost of these collections can be prohibitive. Oral fluid testing matches up well when compared against these challenges associated with urine testing.

Collections are Easy to Administer

Oral fluid collections are relatively easy to administer. Because the collection process is minimally-invasive, the entire procedure can be conducted with both the donor and the test administrator in view of one another throughout the duration of the collection. Because collections can be administered in-house by trained employees, emergency or off-hours collections no longer result in expensive collection fees. And, of course, collections can occur in any work location.

Adulteration is Virtually Impossible

Oral fluid specimens are virtually impossible to adulterate. With the entire collection process taking place in full view of the test administrator, there is not opportunity for the donor to substitute or adulterate their sample which could occur in the privacy of a restroom. A trip to the Internet will reveal dozens of websites offering cheating methods for urine drug tests, but the best advice for a drug user who is about to be subjected to an oral fluid test is to avoid the test. Why? Because there is no reliable way to successfully cheat on an oral fluid drug test.

Recent Use

With urine drug testing, the window of detection takes 30-60 minutes to begin and with hair testing it can take several days. The window of detection with oral fluid begins almost immediately after the ingestion of a drug by the user. This makes oral fluid testing an excellent indicator of recent use, which is ideal for post-accident and reasonable suspicion testing programs. Though the window of detection closes sooner with oral fluid, its ability to detect drugs almost immediately after use, makes it possible to render positive results from recent use that may be missed by other drug testing methods.

Lab-based Oral Fluid Drug Testing

With the advantages of oral fluid testing in mind, it's now appropriate to compare the two methods of oral fluid testing against each other based upon the three critical questions outlined in the introduction. We will start with lab-based oral fluid drug testing – Is it accurate, legal, and practical?

Is it Accurate?

Regarding the issue of accuracy, there are several advantages to lab-based drug testing, and with few exceptions these advantages apply to oral fluid testing. There are many legal precedents in support of lab-based drug testing. Lab-based testing is the only method permitted by the federal government's Substance Abuse and Mental Health Services Administration (SAMHSA), the arm of the government that oversees and certifies laboratories for drug testing. It is also the only testing method permitted by the U.S. Department of Transportation (DOT). Why? Because lab-based testing conducted in accordance with guidelines issued by the government has passed the test of time. It has proven to be both scientifically and legally sound. (Note: These Federal programs only permit urine testing at this time.)

One of the most significant ongoing challenges in drug testing is continuing to ensure that the test is able to detect the drugs in question.

A lab result puts the final analysis in the hands of proven science. With lab testing, an employer's supervisors, managers, and collectors are not asked to make a determination about the positivity of a result as with an instant test device. With lab-based testing, if an initial screen is non-negative, the specimen is already on location where a confirmation test can be conducted. If the specimen is confirmed positive, it can follow the standard process of a lab-based urine sample as it is verified by a licensed Medical Review Officer (MRO). Of course, lab confirmation and MRO verification should also be applied to instant results that are non-negative, but it adds more steps to the process and some may be tempted to skip these essential steps which can call into question the integrity and accuracy of a test result.

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in question. Trends indicate that drug users are becoming more flexible about the drugs they use. A typical 5-panel drug test for marijuana, cocaine, opiates, amphetamines, and PCP makes it possible for some users to successfully pass a drug test without cheating simply by using drugs that are not part of a typical test, such as barbiturates, benzodiazepines, or prescription opiates like hydrocodone and oxycodone. To accurately detect a wide variety of drugs, the drug testing system must be capable of detecting both the parent drug and its metabolites.

The body continuously produces saliva. Therefore, drugs that are in the bloodstream can typically be detected in oral fluid. The sophisticated instruments employed in a laboratory make it possible to detect both the parent drug and its metabolite from virtually any type of drug. This is an important distinction and a valuable advantage of lab-based testing. Testing for an expanded panel of drugs with the necessary sensitivity (the ability to detect each drug) and specificity (the ability to detect the absence of different drugs) is best done with a lab-based test. As such, it's possible for a donor who would have tested positive in a lab test to produce a negative result in an instant test.

The oral fluid collection device manufacturer should be able to provide independent, empirical data to support the accuracy claims and information contained in the package insert. Another assurance of quality is clearance by the U.S. Food and Drug Administration (FDA) for both the collection device and for the drugs being tested. FDA clearance essentially means that the product can perform in a manner at least equal to other products currently available and used for the same purpose. It also means that the FDA has examined the product to ensure that existing data backs up the claims made by the manufacturer in the package insert. Unfortunately, if a device is not FDA-cleared, crucial, independent review of data may be lacking, including accuracy levels at the cutoffs being used. FDA clearance is a key indicator of quality and reliability, and as such this should be a minimum selection criterion.

Is it Legal?

On October 25, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, published the Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/ Fluid (OFMG) that established scientific and technical guidelines that allow for the inclusion of oral fluid specimens in federal executive branch agencies' drug testing programs.

OFMG establishes 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. The effective date is January 1, 2020.

These guidelines would serve as the basis for the technical requirements if the U.S. Department of Transportation (DOT) or Nuclear Regulatory Commission (NRC) wishes to incorporate oral fluid drug testing into their requirements. However, separate rulemaking would be required.

As it pertains to state laws, lab-based oral fluid testing presents a slightly more complicated issue. The good news is that lab-based oral fluid testing is legally permitted in most states. The less-than-good-news is that Hawaii, Maine, and Vermont are exceptions to this rule and thus employers should consult the statutes in these states for specific guidance.

Additionally, there are some states with “voluntary” laws that only permit urine testing. These states include: Alaska, Florida, Mississippi, Ohio, South Dakota, and Tennessee. These laws offer a workers’ compensation premium discount to employers who follow drug testing guidelines issued by the state. For employers who do not wish to participate in the program or who do not qualify, the requirements of the law do not apply to them. While there are some states that restrict testing to urine specimens for certain categories of employees, industries, and testing reasons, outside of the voluntary laws, there are few restrictions surrounding the utilization of lab-based oral fluid drug testing in non-DOT situations. In crafting their drug testing policies, employers should obtain additional information as appropriate from an attorney licensed to practice law in the relevant state. It is important to note that most state drug testing laws only apply to workplace drug testing. A state law that prohibits lab-based oral fluid testing in the workplace would not typically apply to schools, sports, criminal justice organizations such as probation and parole, community corrections, drug treatment facilities, and family court testing. However, in crafting their drug testing policies, employers should obtain additional information as appropriate from an attorney licensed to practice law in the relevant state.

Is it Practical?

The answer to this question will differ from organization to organization. When a company considers the advantages of oral fluid testing compared to other testing methods, it’s important to understand and balance the advantages and disadvantages of each testing method. For instance, is drug test cheating a concern? Is sending donors to a collection site a challenge? Is post-accident testing a significant reason for testing? If the answer to any of these questions is yes, oral fluid testing may be worth considering. Oral fluid testing is more difficult to cheat, collections are typically performed on-site, and the detection window could produce more positive post-accident test results.

Remember, it’s not a matter of declaring one testing method to be the best. It’s a matter of determining which testing method is best for a particular need or situation. For some employers, the reliability of a lab-based test result is the most important factor. Other employers may be looking for something entirely different from their drug testing program.

Instant Oral Fluid Drug Testing

Instant testing gets its name from the fact that a result is available almost immediately after the collection. Other commonly used terms for this type of testing include rapid testing, rapid-result testing, on-site testing, and point-of-collection testing (POCT).



Cutoff/Levels Case Study Marijuana is the most commonly detected illicit drug. The Quest Diagnostics Oral-Eze® lab-based oral fluid test has a marijuana confirmation cutoff of 1.5 ng/mL, while most instant oral fluid cut-offs range from 40-50 ng/mL. This means that it takes significantly more of the drug to trigger a positive result in an instant test as compared to a lab-based test. This study does an excellent job of quantifying the difference.

- Over a 3-year (36-month) period, more than 420,000 lab-based Oral-Eze THC confirmation tests had a concentration at or above the standard cutoff of 1.5 ng/mL.
- Upon examination during the confirmation process:
 - more than 50% had a concentration less than 20 ng/mL;
 - nearly 70% had a concentration less than 40 ng/mL; and
 - nearly 75% had a concentration less than 50 ng/mL.
- Simply stated, the increased sensitivity provided by the lab-based test allowed for the detection of more than 420,000 marijuana positives (at standard cutoffs), more than 3x as many as would have been detected with an instant test (cutoff at 40 ng/mL). In other words, two-thirds (67%), or more than 280,000 of the marijuana positives would have gone undetected with an instant test (cutoff at 40 ng/mL).

Is it Accurate?

There are many different instant testing devices available from a number of different sources. They can be purchased directly from the manufacturer or via a laboratory, third-party administrator, distributor, or simply over the Internet. In terms of the accuracy of these devices, the old adage ‘you get what you pay for’ may apply. There has traditionally been a notable difference in quality between the best instant oral fluid devices on the market and all the rest.

Generally speaking, instant oral fluid testing may not be as sensitive as lab-based oral fluid testing in its ability to detect drugs. There are instant oral fluid devices available that can

detect the drugs for which companies typically test, but not with the same sensitivity as lab-based testing. For this reason it is important to understand what a particular instant device is capable of doing, especially as it compares to lab-based testing.

Though many of the advantages of oral fluid testing apply equally to lab-based and instant testing, the technology behind each method is unique and this can have a significant effect on accuracy. In most cases, an instant device's ability to detect a drug will not be the same as a lab-based oral fluid test. As such, it is important to apply the same level of scrutiny to the selection of an instant device as would be applied to a lab-based test. Ask sellers for independent, empirical data to back up all accuracy and sensitivity claims. Put the package insert to the test by asking for a small sample of devices and then use them in real-life situations. And be sure to ask for references.

Remember, FDA clearance is the most reliable standard to look for with any drug testing device. This is particularly true in the case of an instant device.

Another key consideration is the cut-off levels used for each drug. Remember, an instant test is only a screen, not a confirmation test. Compare the cut-off levels for each drug you plan to test for with a particular instant device with the cut-off levels used in a lab for the same drugs.

Sensitivity and specificity ratings are usually different as well. While an instant testing device may be able to accurately detect the presence of marijuana, for example, the device may not be designed to do so at the same cut-off level or with the same specificity as a lab-based test. This information will be stated on the package insert.

Some employers may be confused about the marijuana issue given the growing number of states that have legalized the drug for medicinal and/or recreational purposes. However, there should be no confusion about the number of studies showing that workers under the influence of marijuana are less safe, less reliable, and less productive than their non-using counterparts. A testing method that accurately detects marijuana should be a priority for every company that conducts drug testing. For this reason, depending on a company's drug testing objectives and workplace situation, the commitment to get a reliable result for marijuana may be worth the slightly longer wait associated with lab-based testing.

Specifically regarding instant testing, there are states that prohibit instant testing regardless of the specimen type. In these states, oral fluid testing is permitted but only via lab-based testing. There are also states that limit the circumstances in which instant testing devices may be used (pre-employment screening) or the type of instant device that can be used (FDA-cleared devices only). Employers are well advised to carefully review all applicable state laws, and to consult with an attorney, before implementing an instant oral fluid testing program.

While the U.S. Department of Transportation does not permit the use of instant testing devices, regardless of the specimen

Is Instant Oral Fluid Drug Testing Legal?

- SAMHSA published Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid (OFMG) in 2019
- Hawaii, Maine and Vermont do not permit oral fluid testing
- Alaska, Florida, Mississippi, Ohio, South Dakota and Tennessee – do not permit the use of oral fluid testing as part of their voluntary workplace testing programs
- Some states require the use of FDA-cleared testing devices

type, there are other federal non-workplace uses, such as by the Federal Bureau of Prisons, various parole and probation departments, and other criminal justice entities that utilize or permit the use of instant testing.

Is it Practical?

Depending on the need or circumstances of a particular company, instant drug testing can be a practical solution that solves a number of challenges associated with lab-based drug testing. Of course, if an instant result is a high priority, a company can consider instant urine testing. The accuracy of many FDA-cleared instant urine testing devices is more comparable with that of lab-based urine testing, than instant oral fluid is with lab-based oral fluid testing. That said, some employers may consider instant oral fluid testing to be easier to administer than urine testing, especially regarding the collection procedures. For instance, urine collections require certain safeguards to be in place (secured bathroom stalls, water turned off, bluing agent in the toilet water, etc.) that are not needed with oral fluid collections. Furthermore, an observed urine collection is more invasive and requires the collector be the same gender as the donor (some state laws actually prohibit observed collections). Instant oral fluid testing eliminates these complications as every sample collection is completely observable without concern for invasiveness or gender matching.

With collections performed on-site by trained employees, the added expense of third-party collectors and the associated downtime is reduced with oral fluid testing. In turn, this lowers the direct (collection fees) and indirect (donor productivity) costs of each drug test.

Of course, there are challenges inherent in any drug testing method conducted on-site by employees. Foremost is the fact that employees need to make the determination of the result of a test rather than having the result determined in a controlled laboratory setting. While an employee collector can work fine, a company has to be prepared for the occasional challenge, which might call into question qualifications, interpretation, or device quality. Another potential complication with instant



oral fluid testing is that oftentimes a second laboratory-based urine or oral fluid collection must be performed to confirm a presumptive positive screening result as the instant screening device may not have a process to accurately quantify the concentration of the drug/metabolite that was in the original oral fluid specimen.

Like lab-testing, instant drug testing requires that certain practices be in place to ensure the integrity of the overall testing program. Chain of custody protocols that create a paper trail showing who handled the specimen at various stages should be followed. Instant test device results that indicate the presence of drugs should be confirmed at a laboratory and confirmed results should be verified by a licensed MRO. These are critical practices if a company is to secure the legal defensibility of its drug testing program.

Additionally, some state laws contain specific regulations as to how drug test results must be reported, including the method and timing of the communication. Of course, some states regulate what actions employers can take based on a confirmed and verified drug test result, which would apply to both instant and lab-based testing. When a company chooses to use instant testing, it must comply with all applicable legal requirements. However, all too often, employers are tempted to short-cut that

process by skipping confirmation testing and MRO verification, choosing instead to act solely on the instant test result. Of course, this is illegal in many states and can expose the company to increased exposure to liability.

Summary

When evaluating the variety of drug testing options, criteria like accuracy, legality, and practicality are critical considerations. While urine testing continues to be the most widely used, permitted, and accepted drug testing method, oral fluid testing presents a number of unique advantages including increased flexibility, simple collections, barriers to tampering, and the ability to detect recent use especially marijuana, that make it a viable alternative. While instant oral fluid testing provides additional flexibility, it comes with some accuracy and legality tradeoffs that employers should seriously consider.

In the end, when choosing a drug testing method, make sure the testing device of choice is FDA-cleared, in legal compliance with all applicable federal and state laws, and that lab-based confirmation testing and MRO verification are included as part of the testing process. Drug testing, regardless of the testing method, is a good decision when it's carefully thought out and properly implemented.

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