

Oral Fluid Screening Solutions

The Myths and Facts About Oral Fluid Drug Testing



OraSure Technologies

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There is no shortage of misinformation surrounding the science of drugs of abuse testing. Oral fluid drug testing, being one of the newer technologies, is no exception to this fact. The team of scientists working for OraSure Technologies has led the drug testing industry and the scientific community with the research and tools to pioneer this highly accurate and efficient method of testing for drugs of abuse. OraSure has been selling collection devices and laboratory detection kits since 1991, and continues to be valued as a reliable and trusted brand with many long-time customers. OraSure has banded its team of experts and a library of scientific articles to bring you the facts surrounding oral fluid and its plausibility in the detection of drugs in the body.

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MYTH: Oral fluid testing is not accurate.

FACT: The results of oral fluid testing may have greater relevance to understanding the effects of drug abuse and assessing an individual's behavior, job performance, and safety risk than the results from urine testing. The presence of drugs in oral fluid is usually related to the amount of drug in the bloodstream at the time of sample collection.¹

1. Oral fluid provides a "blood-equivalent" result because it measures molecules similar to those found in blood plasma.

2. When analyzing blood or oral fluid it is possible to actually test for the parent drug itself and not just a metabolite of that drug. This makes it possible to detect recent drug use more accurately than urine testing, which detects only metabolites.

3. Advances in oral fluid testing and collection technology are making it possible to more accurately quantify drug test results. This relates to both the collection device and laboratory test that are used to screen for drugs of abuse.

4. As with any alternative drug testing method, much depends on the quality of the actual device being used. There is a wide gap in terms of accuracy, reliability and ease-of-use between the best products available and the least expensive products on the market. In particular, with oral fluid testing devices you get what you pay for.

MYTH: The window of detection with oral fluid testing is too short to detect drugs.

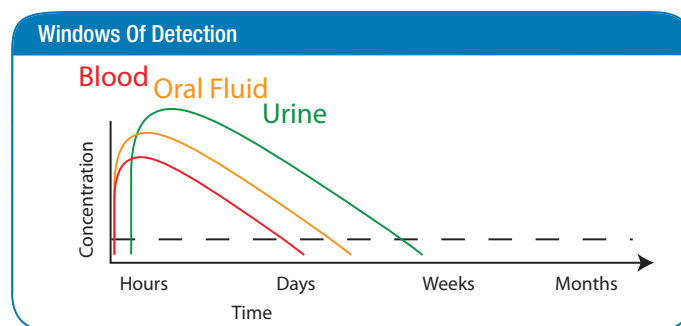
FACT: Drug transfer to oral fluid from blood occurs as long as the drug is in the bloodstream, thus detection times start within minutes of ingestion and continue for as long as the drug remains in the bloodstream. Drug detection by oral fluid testing is as effective as urine testing over a comparable time period.¹

1. Regardless of the type of test being conducted (urine, oral fluid, hair or blood) the window of detection will be affected by many factors including:

- Drug being detected
- Size of the dose
- Preparation and/or route of administration (IV, smoke, oral, etc.)
- Acute vs. chronic use
- Cut-off levels by drug
- pH and concentration of the fluid
- Personal differences and variations in metabolism

2. Every drug has its own unique window of detection regardless of the specimen being tested.

3. Each specimen type has its own unique ability to reveal the presence of a particular drug.



SAMHSA, Drug Testing Advisory Board (DTAB) Meeting 1/26/2011

4. While there are published windows of detection for each specimen and each drug, it is impossible to say precisely what the window of detection will be for a particular testing situation.

5. This much we know... the window of detection for oral fluid testing starts earlier than with urine and hair testing.^{6, 10} Typically, marijuana is detectable through oral fluid testing within an hour, if not immediately, of the use of the drug. With urine testing the window of detection for marijuana won't begin for at least 4-6 hours (and certainly not immediately) and with hair testing it won't begin for days or weeks after usage.

6. Generally, oral fluid and urine provide comparable positivity rates.¹ Oral fluid can pick up drugs early on which urine will miss; urine can sometimes pick up positive results longer which oral fluid will miss... but on balance we have developed cut-off levels for oral fluid that produce similar positive rates. Because both testing methods produce similar positivity rates than it really comes down to which testing method best meets a buyer's needs.

7. Lab-based oral fluid testing provides a longer window of detection than current POCT devices on the market, especially with respect to marijuana. This is due to the cut-offs for POCT devices being higher than lab-based oral fluid tests. Several studies show comparable results with marijuana positives in urine and oral fluid samples.⁵

NIDA-5 Drug Panel	Urine Analysis	INTERCEPT®	INTERCEPT® Cut Offs
Overall positive rate	4.46%	5.06%	
Marijuana	3.17%	3.22%	1 ng/mL
Cocaine	0.69%	1.12%	5 ng/mL
Amphetamines	0.29%	0.47%	see below*
Opiates	0.29%	0.23%	10 ng/mL
PCP	0.02%	0.03%	1 ng/mL

Journal of Analytical Toxicology, Vol. 26, December 2002.

**Intercept® amphetamine detection includes assays for amphetamine (100 ng/dL), methamphetamine (40 ng/dL) and also detects Ecstasy.*

8. A common myth regarding the detection of marijuana in urine is that it can be detected for up to 30 days. In reality, the window of detection is much shorter.⁶

MYTH: Oral fluid testing is not as efficient as urine testing.

FACT: Oral fluid testing is, perhaps, the most efficient drug testing method.

1. Oral fluid testing is one of the simplest methods of drug testing and for many employers, who consider urine testing to be “yucky,” it eliminates the need to collect and handle urine.

2. The collection process is less invasive, requires less complicated training for administrators, and is very easily and quickly conducted. A collection can take place wherever a private room can be found; a bathroom is not required. Because bathrooms are not needed there is no need to turn off running water, put blue dye in toilets, or perform temperature checks on specimens as is the case with urine testing.

3. Drug testing is never slowed down by claims of shy bladder.

4. There are many factors to consider when measuring the cost-effectiveness of a drug test besides the price of the test itself. For example, how much downtime is involved in collecting a specimen? Can a manager or supervisor administer the collection or will it require the services of a professional collector? Can the test take place at the worksite or will a collection facility be needed?

5. Oral fluid testing, in general, is very cost-effective when compared to all other drug testing methods. Because oral fluid collections are easily administered on-site, downtime is minimized because employees are only away from their duties for 10-15 minutes rather than an hour or longer.

6. Collection costs are eliminated entirely when managers and supervisors are trained to conduct oral fluid collections at the worksite.

MYTH: Oral fluid testing is just as susceptible to cheating as urine testing.

FACT: Oral fluid testing is virtually adulteration proof.

1. Drug test cheating is a major concern because urine testing is particularly susceptible to adulteration, tampering and substitution. Efforts to combat cheating such as validity testing, various precautionary measures such as putting blue dye in toilet water, management supervision, retests and observed collections add to the cost of drug testing and create a legitimate complaint that drug testing is an invasion of privacy.

2. A quick search on the Internet will reveal hundreds of websites that promise to help would-be cheaters successfully pass a drug test they have no business passing. Products and methods for cheating on urine drug tests, such as synthetic urine, have spawned a multi-million dollar industry.

3. A recent report from a drug testing laboratory in Hawaii showed that pre-employment positives for marijuana were up considerably during the fourth quarter of 2010... from 2.7% in 2009 to 3.5% in 2010. The laboratory also found that 2.3 percent of all applicants tested positive for "synthetic urine," a common way in which drug users attempt to cheat on drug tests.⁷

4. Oral fluid testing virtually eliminates concerns about drug test cheating. Every oral fluid collection can be "observed" making it impossible for someone to tamper with the specimen.

5. Substitute saliva is not readily available on the Internet as is the case with urine or synthetic urine.

MYTH: Oral fluid testing is illegal in most states.

FACT: Oral fluid testing is legal in almost every state.²

1. For workplace drug testing there are only two states and one U.S. territory that prohibit the use of oral fluid testing altogether:

- Hawaii
- Maine
- Puerto Rico

2. There are a handful of states that do not permit POCT and as a result do not permit POCT oral fluid testing. These states include:

- Kansas
- Minnesota
- Nevada
- New York (location where POCT is conducted must be licensed by state)
- Vermont

3. There are a number of states that have voluntary drug testing laws that may restrict how drug testing is conducted, including limiting testing to either lab-based testing only or urine testing only. The conditions of the voluntary laws only apply to those employers who qualify for and actually participate in the program. Outside of the voluntary laws in these states there may not be restrictions on oral fluid testing.

The voluntary state laws that restrict oral fluid testing include:

- Alabama (oral fluid testing is not permitted under the voluntary law)
- Alaska (oral fluid testing is not permitted under the voluntary law)
- Florida (oral fluid testing is not permitted under the voluntary law)
- Georgia (POCT oral fluid testing for pre-employment screening only)
- Mississippi (oral fluid testing is not permitted under the voluntary law)
- Ohio (oral fluid testing is not permitted under the voluntary law)
- Tennessee (oral fluid testing is not permitted under the voluntary law)

Two states with voluntary laws, Florida and Ohio, require certain state contractors to comply with the requirements of their otherwise voluntary laws.

4. There are a number of states that permit POCT but require that the device used is FDA cleared. Because there are no FDA cleared POCT oral fluid devices the use of such devices is prohibited in these states:

- Louisiana
- Maryland
- Montana
- Oklahoma

5. Workplace drug testing laws do not apply to other markets such as schools, criminal justice, treatment and athletics. Oral fluid testing is typically not restricted in these markets.

6. Oral fluid testing has been in use with many buyers in probation, parole, community corrections, drug courts, pre-trial services, diversion programs, and law enforcement at all levels (city, county, and state) and public and private drug treatment programs, and mental health agencies.

7. There are other restrictions that may apply to oral fluid testing. It is important to review all applicable state laws before implementing any type of drug testing policy to ensure complete compliance.

MYTH: The federal government does not permit the use of oral fluid testing.

FACT: Many agencies of the federal government use oral fluid testing.⁸

1. The SAMHSA guidelines do not include oral fluid testing as an approved drug testing method. However, the SAMHSA guidelines only apply to the testing of certain federal employees and certain drug testing programs regulated by the federal government.

2. For instance, oral fluid testing is not permitted in compliance with the DOT regulations. Likewise, POCT urine and hair testing are not permitted.

3. However, many federal agencies do permit oral fluid testing and some actually use oral fluid testing. For example, some departments within the Federal Probation Service currently use oral fluid test devices. Other agencies such as branches of military and the Bureau of Prisons may not restrict the use of oral fluid testing internally as well as by private-sector organizations that fall under their respective authority.

4. The Drug Testing Advisory Board has recently indicated that it will examine the benefits of lab-based oral fluid testing with the intent of modifying the SAMHSA guidelines to permit the use of the technology.

MYTH: Only oral fluid testing devices cleared by the U.S. Food & Drug Administration (FDA) can be legally used.

FACT: This is true of POCT... there are NO FDA cleared rapid oral fluid tests. The OraSure Intercept® device is the only FDA cleared lab-based testing system that can detect Amphetamine Specific, Methamphetamines, Cocaine, THC, Opiates, PCP, Methadone, Barbiturates and Benzodiazepines.¹³

1. Currently, the FDA has not cleared a POCT oral fluid device. Therefore, in those states that require the use of FDA cleared devices for rapid result testing oral fluid testing cannot be conducted. The only states with such restrictions include: Louisiana, Maryland, Montana, and Oklahoma.

2. It is important to understand what FDA clearance means. It means the FDA has examined a product to ensure it is “substantially equivalent” to a device that is already legally marketed for the same use.

3. Until the FDA clears a POCT oral fluid device, a buyer is well advised to either rely on lab-based oral fluid testing or, if they insist on using rapid testing, carefully research the manufacturer’s credibility and ask for independent studies to support the accuracy and reliability of the product.

4. In 2010, the FDA issued cease-and-desist orders to at least two manufacturers of POCT oral fluid testing devices (Branan Labs and American BioMedica). Both companies challenged the orders and continued selling their oral fluid testing devices in the workplace market. Varian (now Agilent) voluntarily pulled its product off the market, at least temporarily. Other providers continued to make their oral fluid devices available.

5. Lab-based oral fluid testing is not affected as long as the oral fluid testing system is FDA cleared.

MYTH: It is too complicated to switch from a urine testing program to a lab-based oral fluid testing program.

FACT: Actually, making the switch to lab-based oral fluid testing is easier than you think.

1. Oral fluid testing fits well with most existing drug-testing programs. Employees tend to support it because it is less invasive than urine, blood or hair. The collection process is easy to administer and the analysis itself is highly accurate. It can work in virtually any workplace setting, in any industry, under many different circumstances.

2. Switching from a urine testing program to oral fluids can best be accomplished with the following 7 steps:

Step 1: Identify drug testing objectives. Once a company understands what it hopes to achieve with oral fluid testing it will be easier to decide how to set up the program. Why a company tests determines how, whom and when to test.

Step 2: Update the policy. The company's policy should be revised based on the objectives that were identified. The testing procedures section, in particular, must now reflect oral fluid testing. The policy should explain how tests will be conducted, confirmation testing and MRO procedures as well as chain-of-custody protocols. How results will be reported should also be explained in the revised policy.

Step 3: Determine a method for collection.

Because oral fluid testing collections are so easy, companies can eliminate the cost of using professional collectors in favor of using trained employees. This should also be included in the revised policy.

Step 4: Train supervisors. A company's management must understand how the new oral fluid testing program works. The company should review the revised policy with them and ensure that they understand the new collection procedures. If supervisors will administer collections themselves they should be properly trained (OraSure can help with this).

Step 5: Ensure that vendors are set up. Make sure the lab and MRO are aware of the switch to oral fluid testing. OraSure will help with this also.

Step 6: Set up confirmation testing. To ensure the integrity of the program all initial screen positive or non-negative results should be lab confirmed.

Step 7: Announce the program to all employees. Now that everything is set, the policy is revised, collection procedures are in place, the management team is trained, and confirmation testing protocols have been set up, the company is ready to begin testing. From start to finish a company should be able to convert from traditional lab-based urine testing to lab-based oral fluid testing in about three weeks. Much will depend on the internal approval processes at a company, which vary from one firm to another.

MYTH: Oral fluid testing is more expensive and not as cost-effective as urine testing.

FACT: Oral fluid testing is no more expensive, and could be less expensive than urine testing. Oral fluid testing can also be much more cost-effective.³

Consider the following when estimating the potential cost savings of oral fluid testing:

Collection

First, because collecting an oral fluid specimen is easy and virtually trouble-free an employer can easily administer the process internally and eliminate the cost of professional collector services. Collections administered by the company also significantly reduce the lost productivity associated with off-site collections, which typically take an hour or longer in many instances. It also represents greater flexibility in drug testing. No longer is the employer obligated to work around the availability of the collector... collections can take place any time, any day. This is particularly appealing to companies with 24-hour shifts or workplaces in out-of-the-way or rural locations.

Lab Analysis

While lab-based oral fluid testing still requires the sample to be shipped overnight to a laboratory for analysis the end result is a lab-based result provided by a licensed lab. Typically, negative results are easily available within 24 hours, positives within 48-72 hours.

MRO

Of course, non-negative or presumptive positive screen results should always be confirmed by a lab and verified by an MRO. Employers should also be aware that some state drug testing laws require that

non-negative screens be confirmed by a lab and that an MRO review all drug test results before any employment-related action can be taken.

Looking at Costs³

Let's break down the cost of a typical drug test. For demonstration purposes we will say that a typical lab-based urine test costs at least \$40 and here is how it breaks down:

Collection	\$15.00
Lab Analysis	\$18.00
MRO	\$5.00
Admin Fee	\$2.50 (includes data management, etc.)
TOTAL	\$40.50

With oral fluid testing, regardless of whether it involves a POCT device or lab analysis, the cost of the collection can be eliminated altogether. That saves at least \$15... because there is the "soft" dollar savings of not sending employees and supervisors to off-site collection facilities for an hour or more the cost savings is actually much higher.

The lab analysis remains the same because there is still a fee for the device, though the actual cost will depend on the price paid for the device.

Though using an MRO is always recommended some employers choose to utilize such services only when the initial screen is positive. For demonstration purposes we will leave MRO costs in cited example below. (Note: When employers utilize an MRO for positives only the cost per review is significantly higher than the \$5.00 estimated in this example.)

The seller may still charge some type of administration fee so let's assume that stays the same. Now, let's do the math for an oral fluid test.³

Collection	\$0.00
Lab analysis	\$18.00
Device	\$5.00
MRO	\$5.00
Admin Fee	\$2.50 (includes data management, etc.)
TOTAL	\$30.50

In this example the cost of a drug test has been cut significantly. Additionally, there are other cost savings worth noting. For example, how long does it typically take to send an employee to an off-site collection facility? An hour? Two or three hours? Let's split the difference and say it takes 90 minutes. Compare 90 minutes of lost productivity to approximately 15 minutes when collecting an oral fluid sample on site.

Reasonable suspicion testing is often time-consuming and costly. Typically, a supervisor escorts a suspected drug using employee to the collection facility. That's two people off site not doing their regular jobs. An on-site collection ensures that everyone is back to work faster, and oral fluid collections are easier to administer than urine collections.

When measuring the ROI of oral fluid testing there are many factors to consider; however, it is easy to see the potential savings under a variety of circumstances.

MYTH: Oral fluid testing is on the decline.

FACT: Use of oral fluid testing is growing each year.

Each year WFC & Associates, a drug testing consulting firm, conducts a survey of drug testing providers to identify trends in the industry. Some of the points made here are based on responses from the 2010 survey. The executive summary of the survey is available from WFC & Associates at billcurrent.com.⁹

1. Users of oral fluid drug testing in both the workplace and criminal justice markets have increased in the past three years. In a fairly short period of time it has become the testing method of choice for many organizations.^{9, 12}
2. While it will not meet the needs of every organization, because of its unique advantages oral fluid drug testing will appeal to many employers, treatment providers and criminal justice agencies whose circumstances make the collection of a urine sample impractical and/or too expensive.
3. Oral fluid testing will continue to grow in popularity in the United States as more people learn about it and more drug testing companies promote it.
4. Most of the major laboratories now offer both lab-based and POCT oral fluid testing, another indicator of its potential for growth.
5. Oral fluid testing is a popular choice in the criminal justice market where cost and convenience are key deciding factors in choosing a drug testing method.
6. Oral fluid testing is already more popular than urine testing in many foreign markets.¹⁰

MYTH: There are so many products on the market it's impossible to know which ones are worth using.

FACT: Actually, with a little bit of research it is very easy to know which product is right for you.

When choosing the testing device that is best for you look for these 7 things:

1. FDA clearance is a critical issue when considering any testing method that involves self-administering collections and especially analysis as in the case of POCT. There are no FDA cleared POCT devices as of January 2011. That's not to say the devices on the market today are not good or do not accurately detect drugs. However, some states require the use of FDA cleared devices. If a program or result is ever challenged it sure makes a company's defense a lot easier if the employer can substantiate the integrity of the device used with an FDA clearance. The OraSure Intercept® collection device and lab-based screening tests (assays) are the only lab-based oral fluid testing product line with a compliment of 9 assays cleared by the FDA¹³... that's quite a distinction.

2. A history of proven performance. New devices are coming on to the market regularly; unless they come from a manufacturer with a well known track record it may be best to let someone else be the guinea pig.

3. A user-friendly device. Not all devices operate the same; some are more difficult to use than others... the best advice here is to "try it before you buy it".

4. Legal support from the product manufacturer... not all state laws permit oral fluid testing though most do. Your supplier should be able to answer state and federal law questions for you.

5. Independent scientific data to back up accuracy claims. Not all manufacturers can provide such data; a buyer should insist on it.

6. Lengthy shelf life

7. Collector training is critical if the employer plans to have employees conduct collections.

The OraSure Difference

While this document should dispel many of the myths surrounding oral fluid drug testing, many more will arise as laws and societal changes occur. OraSure is committed to developing and delivering innovative diagnostic solutions to meet tomorrow's challenges. Our long established expertise in oral fluid drug testing delivers trusted and reliable value to our customers while working in partnership towards a common goal.

References / Resources

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Regulatory Reference:

13. The Intercept® oral fluid drug testing system is cleared by the FDA and filed with the following numbers:

FDA Clearance 510K Numbers	Intercept® Device/Assay
K011057	Oral Fluid Collection Device
K992918	Amphetamine Specific Microplate
K013882	Benzodiazepines Microplate
K001976	Barbiturates Microplate
K002375	Cannabinoids Microplate
K001197	Cocaine Microplate
K002010	Methadone Microplate
K993208	Methamphetamine Microplate
K000399	PCP Microplate

Government Resources:

Substance Abuse and Mental Health Services Administration (SAMHSA):

<http://www.samhsa.gov/>

National Survey on Drug Use & Health

<http://oas.samhsa.gov/nsduhLatest.htm>

Substance Abuse Screening

<http://store.samhsa.gov/facet/Treatment-Prevention-Recovery/term/Substance-Abuse-Screening?headerForList=>

Centers for Disease Control and Prevention (CDC): Illegal Drug Use

<http://www.cdc.gov/nchs/fastats/druguse.htm>

National Institute on Drug Abuse (NIDA):

<http://www.nida.nih.gov/nidahome.html>

Department of Labor (DOT):

Working Partners for an Alcohol and Drug-Free Workplace

<http://www.dol.gov/asp/programs/drugs/workingpartners/dfworkplace/dfwp.asp>

Procedures for Transportation Workplace Drug and Alcohol Testing Programs - DOT rule, 49 CFR part 40

http://www.dot.gov/ost/dapc/NEW_DOCS/part40.html

To learn more about OraSure's fine line
of oral fluid testing tools, go to
www.orasure.com or call
1-800-ORASURE.

The Value of a Reliable and Trusted Brand

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