Oral Fluid Screening Solutions

The Value of Oral Fluid Drug Testing in the Workplace
In a challenging economy, can employers really afford to continue drug testing employees and job applicants? That seems like an appropriate question to ask. But an even more pertinent question might be: can you afford NOT to conduct drug testing?
The challenges of today
Drug testing has become an important safety issue in the workplace for human resources and safety professionals, as approximately 75% of all drug abusers are employed either full or part time. As a result, the majority of companies surveyed today perform some form of drug testing in their establishments.

The purpose of drug testing is to lessen the impact from drug abuse in the workplace, including accidents, tardiness, absenteeism, turnover, attitude problems, theft, decreased productivity, and crime and violence. The U.S. Department of Labor estimates that drug use in the workplaces costs employers $75 to $100 billion annually in lost time, accidents, healthcare and workers' compensation costs. According to Texas Business Today, approximately 65% of all accidents on the job are related to drug or alcohol, with substance abusers impacting 80% of non-abusers. Finally, drug abusers account for 38% to 50% of healthcare benefits and are 5 times more likely to file workers' compensation claims than non-abusers.

Current testing modalities
Traditionally, urine collection has been the primary, long-standing sample type used, since it is less invasive and far less expensive than drawing blood which otherwise would be the optimal specimen type. While testing for drugs with hair is an option, this methodology will not detect drug use for the first 7-10 days and will report positive drug use for far too long to be effective in most workplace drug testing programs.

The act of voiding a urine specimen is generally viewed as humiliating. It is also generally believed that urine is dirty and can make a person cringe at having to handle even a sterile specimen cup when presented at the workplace. Shy bladder often occurs when a person is asked to produce a sample, further delaying the program. Shy bladder syndrome can be amplified when governing procedures dictate that the collection be witnessed. Witnessed collections add to the humiliation of the worker and can add stress. Urine testing has also been known to be easily adulterated, substituted, or diluted, leaving the door wide open to anyone who may have a predisposed want or need to cheat a test. Collecting and testing urine or sending an employee offsite to be tested has its drawbacks, but it has become a necessary deterrent to drug abuse in the workplace.
About 10 years ago, the science of drug testing took on a new face. Oral fluid drug testing had been making its way into the scientific community. The life insurance industry had already been using oral fluid to test for marker drugs, like cocaine and cotinine (the metabolite of nicotine), for over a decade. Seeing the necessity for a less invasive, accurate method for testing other drugs, OraSure Technologies pioneered and fine-tuned lab-based testing assays for the major drugs utilizing oral fluid. These tests have been used effectively in the workplace, drug treatment, and criminal justice industries.

Oral fluid collection overcomes all of the drawbacks of urine collection and has proven to be just as competent. Drug content in oral fluid closely mirrors that in blood and can be tested for parent drugs and metabolites, which cannot be done with urine. This allows oral fluid to be considered as an “under the influence” indicator as well. Collections can be done anywhere, anytime, without having to deal with the embarrassment of urine. Collections are easily observed without stress on either party. Some workplaces who have adopted oral fluid testing will even collect from an entire group using only a few observers, allowing more time for interviews and hiring decisions.

With its easily observed collection, sample substitution or sample adulteration is eliminated. Oral fluid tests are also impervious to dilution tactics or any of the currently available masking agents or washes. Although, many websites give advice and/or sell products to cheat drug tests, none have a proven method for cheating an oral fluid test. One of the many sites, www.wikihow.com/pass-a-drug-test, states:

“Try to avoid the test (oral fluid). If one is being tested and has used in the past 3 days you will need to overcome the saliva collection. To do this you will have to avoid submitting saliva and perform the steps requested of you by the instructor.”

Another offers this advice:

“To pass this (an oral fluid test) you should always know the detection time of the drug you have taken. Marijuana can be detected via saliva drug testing from an hour after ingestion up to 24 hours depending on use. Between these periods of time, you must avoid being screened or you will surely test positive.”

With more than a decade of scientific and legal scrutiny, oral fluid has grown considerably in usage as various industries have discovered the important benefits and utility of oral fluid collections.
But what are the cons of oral fluid testing? There has to be some give and take, right?

Urine has been the gold standard in drug testing for 30+ years, and change is not easy for many organizations. There are many misconceptions that persist about oral fluid drug testing – most of them have been dispelled in scientific literature, but they still continue.

Although the window of detection for oral fluid is slightly shorter than that of urine, oral fluid testing can detect drugs sooner (within 1 hour of use), and all the published data suggests that the positivity rates are comparable.⁶
Another misconception that persists is that oral fluid tests do not adequately detect marijuana (THC). This applies to point-of-care tests (POCTs), not lab-based oral fluid tests (see chart above). Lab-based oral fluid tests such as the Intercept® device cross-reacts with the parent drug for THC at very low cutoff levels (1 ng/mL). Point-of-care or instant oral fluid tests cross-react at much higher levels (typically 50 ng/mL or higher), making the window of detection for THC much shorter than lab-based oral fluid tests. Based on data from Quest Diagnostics, most positive THC samples fall in the < 20 ng/mL range, which is below the detection range for instant oral fluid drug tests.7

The FDA has not cleared any rapid devices for testing, primarily due to the THC detection limitation. However, there are several FDA-cleared lab-based products on the market today, including the Intercept® test.

Consider the following when evaluating testing methodologies for an addition to or replacement in your testing toolbox:

1. Is the test accurate?
2. Is the test susceptible to cheating?
3. Is the dignity of the employee protected?
4. Is the test cost-effective to my drug testing program?
Accuracy

Start researching products by looking on the FDA's website to see which products have FDA clearance. Other web searches should uncover independent, empirical data from peer-reviewed publications. These articles always disclose the devices and manufacturer of the testing elements used in the study. A comparison of the product's package insert data to the independent studies data can be quite revealing.

Once research has been satisfied, a call or visit to the manufacturer's website can uncover a history of satisfaction with long-standing users. If this information is not readily available, ask for referrals. These references should be able to give guidance in knowing the company and individuals you are dealing with, how they interact with your laboratory, and how they can assist in any issues encountered.

Cheating

Drug testers are full of stories about people trying to cheat their drug test. Companies are are familiar to these sometimes absurd antics. It has been well documented that urine testing is suspect to cheating. Many laboratories have added adulterant or dilution tests to their standard drug-testing packages. (Note: These costs are an added cost factor from the laboratory and most times invisible during contract negotiations). Lab-based oral fluid tests are very difficult to adulterate due to ease of observation and the fact that other tactics have proved ineffective.

FDA-510K Cleared Assays*

<table>
<thead>
<tr>
<th>Assay Menu</th>
<th>Intercept*</th>
<th>Oral-Eze*</th>
<th>Quantisal™</th>
<th>Lin-Zhi International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Methamphetamine (Including Ecstasy)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓*</td>
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<tr>
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<tr>
<td>Opiates</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Marijuana (THC)</td>
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<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td>✓</td>
<td></td>
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<tr>
<td>Benzodiazepines</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>✓</td>
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*Not Approved for Ecstasy
Dignity
No urine, no bathroom … no collection fees, no scheduling inconveniences for collections, and, if managed onsite, no humiliating observed collections, no gender match-up issues, no threats of drug test cheating.

With oral fluid collection, the employee and administrator/employer observe the collection together, so the specimen never leaves the employee's sight alleviating legal challenges or the employer's sight removing adulteration attempts. Collections can be done anytime, anywhere, to maximize productivity and hiring timelines.

Cost-effectiveness
When comparing test costs from one brand or methodology to another, it requires more than just a direct assay-to-assay and/or collector-to-collector cost comparison. The invisible "soft" costs commonly overlooked should become part of the evaluation.

With urine testing, one “soft” cost is the amount of time away from work for collections, or the number of days it may take to make a hiring decision. Another overlooked cost is accounting for the number of tests rejected by the lab due to adulteration or dilution but for which the lab will still bill. It’s not uncommon that more than 5% of collected urine specimens are rejected based on dilution, adulteration or insufficient volume.9

In addition, “hidden” administrative costs include the need to have gender-specific personnel to manage a drug collection if performed onsite and/or any special costs associated with the collection facility (i.e. dedicated bathroom).

All these costs can increase exponentially when dealing with employees and a drug testing program.

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The Value of Oral Fluid Drug Testing in the Workplace

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<table>
<thead>
<tr>
<th>Urine Collection Model</th>
<th>Travel</th>
<th>Deliver</th>
<th>Return</th>
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<tbody>
<tr>
<td>15 minutes</td>
<td>15 minutes</td>
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<table>
<thead>
<tr>
<th>Intercept® Oral Fluid Model</th>
<th>Travel</th>
<th>Deliver</th>
<th>Return</th>
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</thead>
<tbody>
<tr>
<td>None</td>
<td>5 minutes</td>
<td>5 minutes</td>
<td></td>
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</table>
One last question –
Will oral fluid work for my organization?

Objectively you must answer, “It depends.”
- It depends on your organization’s objectives.
- It depends on the circumstances under which testing is administered.
- It depends on where testing occurs.
- It depends on applicable state and federal laws.

Overall, the general answer would be YES.

Advantages of oral fluid testing:
1. Flexible – sample can be collected anytime, anywhere
2. Legally defensible as technology is widely considered reliable
3. Scientifically accurate
4. More accurate method in measuring “recent” use
5. Easy to administer and often preferred by those who administer tests
6. Minimal lost work time
7. Hiring faster process
8. Less embarrassing collection process for the donor
9. Fewer scheduling inconveniences and collection fees
10. Virtually adulteration proof

Facilitates Faster Hiring Decisions

<table>
<thead>
<tr>
<th>Urine Collection Model</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
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</thead>
<tbody>
<tr>
<td>Offer</td>
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<td></td>
<td></td>
<td></td>
<td>Result</td>
</tr>
<tr>
<td>Collection Site (48 hrs. to report)</td>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Intercept® Oral Fluid Model</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
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</thead>
<tbody>
<tr>
<td>Offer</td>
<td></td>
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<td></td>
<td></td>
<td>Result</td>
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</tbody>
</table>

The Value of Oral Fluid Drug Testing in the Workplace
The OraSure difference

As the innovators in oral fluid drug testing, OraSure Technologies has led the oral fluid drug testing industry and the scientific community with the research and tools that have pioneered this highly accurate and efficient method of testing for drugs of abuse.

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.

Our dedicated field-based consultants are available to answer any questions you may have, assist with your training efforts, and provide the necessary support and expertise for your drug testing programs and policies.

Partner with OraSure and the Intercept® brand for your Oral Fluid Drug Testing Needs...a Reliable and Trusted Brand for Over 10 Years.
References / Resources

4. NIDA. Strategic Planning for Workplace Abuse Programs, 2002.
8. The Intercept® oral fluid drug testing system is cleared by the FDA and filed with the following numbers:

<table>
<thead>
<tr>
<th>FDA Clearance 510K Numbers</th>
<th>Intercept® Device/Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>K011057</td>
<td>Oral Fluid Collection Device</td>
</tr>
<tr>
<td>K992918</td>
<td>Amphetamine Specific Microplate</td>
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<tr>
<td>K001976</td>
<td>Barbiturates Microplate</td>
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<td>K013862</td>
<td>Benzodiazepines Microplate</td>
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<td>K002375</td>
<td>Cannabinoids Microplate</td>
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<td>K002010</td>
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<td>K993208</td>
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<td>K981341</td>
<td>Opiates Microplate</td>
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<tr>
<td>K000399</td>
<td>PCP Microplate</td>
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Government Resources:

Substance Abuse and Mental Health Services Administration (SAMHSA): http://www.samhsa.gov/
National Survey on Drug Use & Health http://oas.samhsa.gov/nduflatest.htm
Substance Abuse Screening http://store.samhsa.gov/facet/Treatment-Prevention-Recovery/term/Substance-Abuse-Screening?headerForList=
Procedures for Transportation Workplace Drug and Alcohol Testing Programs - DOT rule, 49 DFR part 40 http://www.dot.gov/ost/dapc/NEW_DOCS/part40.htm
To learn more about Intercept® Oral Fluid Drug Testing, go to redplanttesting.com or call 1-610-509-0567.

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