

The Advantages of Oral Fluid for Workplace Drug Testing

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It is very important to understand how significant and numerous the benefits of oral fluid testing technologies are over conventional testing methods.

The benefits of oral fluid testing technologies are found on two levels.

First, there are the benefits that oral fluid has over conventional testing methods. These benefits are claimed by all oral fluid POCT (Point of Collection Test) devices.

Second, there are the specific benefits the OraPoint™ has over all other oral fluid POCT devices. For the purposes of this information package, oral fluid testing will be compared to traditional urine testing.

Urine testing is currently the most widely used specimen type for workplace drug & alcohol testing – although being rapidly overtaken by alternative specimen types. There are generally considered to be five specimen types: urine, oral fluid, hair, sweat & blood. They are all scientifically sound except for sweat, which to date still has some reported accuracy issues.

Blood is considered the ideal testing specimen for determining current drug use, but is very invasive and expensive, make it an impractical testing method for workplace testing. Hair is accurate, but requires roughly 2 weeks before drug classes can be detected, thus eliminating it as a practical testing method. *Table 1* provides an overview comparing specimen types.

TABLE 1: Specimen Type Comparison

	Urine (Laboratory)	Urine (On-Site)	Oral Fluid (Laboratory)	Oral Fluid (On-Site)	Hair (Laboratory)	Sweat (Laboratory)	Blood (Laboratory)
Ease of Use / Administration	LOW	MED	HIGH	HIGH	LOW	LOW	LOW
Adulteration / Substitution Risk	HIGH	HIGH	LOW	LOW	LOW	MED	LOW
Instant Results (5-12 minutes)	NO	YES	NO	YES	NO	NO	NO
GC/MS Lab Confirmation (Gas Chromatography / Mass Spectrometry)	YES	YES	YES	YES	YES	YES	YES
MRO Review (Medical Review Officer)	YES	YES	YES	YES	YES	YES	YES
Detection of "Recent Use" (within minutes of consumption)	NO (6-10 hrs)	NO (6-10 hrs)	YES	YES	NO (2 weeks)	NO (days)	YES
Detection up-to 2-3 Days	YES	YES	YES (except THC)	YES (except THC)	YES	YES	YES
Detection 30 Days +	NO (possibly THC)	NO (possibly THC)	NO	NO	YES	NO	NO
Individual Test Cost	MED	LOW	LOW	LOW	MED	MED	HIGH
Total Testing Cost (admin., downtime, employee travel, etc.)	HIGH	MED	LOW	LOW	MED	MED	HIGH
Dignified Collection	NO	NO	YES	YES	YES	MODERATE	YES
Technical Accuracy	YES	YES	YES	YES	YES	MODERATE	YES

The less invasive nature of oral fluid POCT sample collection creates obvious benefits such as convenience / ease-of-use, instant results and avoids any dignity or gender issues.

Beyond these obvious and convenient benefits, the most important benefits address serious problems and voids in traditional testing practices. Even though these benefits are claimed to be common to oral fluid POCT devices, individual oral fluid POCT device performance varies dramatically. The majority of oral fluid POCT devices, especially those not developed and manufactured in the U.S. are urine technology (urine test strips) applied to an oral fluid test device. However, the science and specimen handling techniques are fundamentally different between oral fluid and urine, and this practice accounts for the poor performance of many oral fluid POCT devices. In contrast, the OraPoint™ was developed and is produced by teams that have specialized in oral fluid technologies for nearly a decade, thus explaining the superior performance.

Detection of “Recent Use”

Oral Fluid Testing	Urine Testing
Detects “recent use”: from within minutes of consumption up to 2-3 days for opiates, cocaine, amphetamines / meth-amphetamines; and up to 24 hours for native THC (marijuana).	Detects historical use: 6-10 hours for the drug(s) to metabolize before detection and then up to 2-3 days for opiates, cocaine, amphetamines / methamphetamines; and up to 30+ days for THC metabolite (marijuana).

The detection of recent use versus historical use is the most important benefit of oral fluid over urine. Recent use is the ability to detect within minutes of consumption through the intermediate impact period (including impairment period). Urine testing requires the ingested drug class to be metabolized by the liver and metabolites deposited into urine before detection. This can take hours as demonstrated graphically below in *Chart 1*.

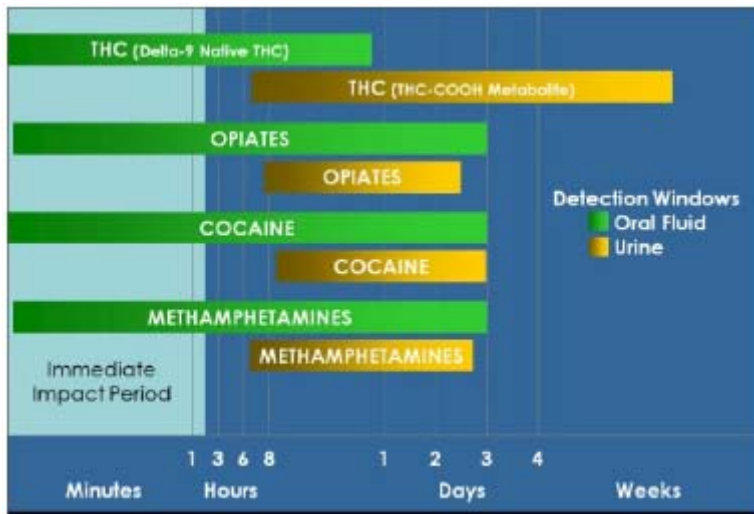


Chart 1: Oral vs. Urine Detection Periods

The ability to detect if an employee / subcontractor has recently improperly used a drug gives the employer or test administrator the ability to do everything “reasonable practicable”, as legislated by occupational health and safety regulations. Employers have OSHA responsibilities to ensure a safe workplace and ensure that workers are “fit for duty”. The ability to detect recent use means employers can detect usage in their immediate workplace and detect if workers are “fit for duty”. Oral fluid drug testing works like a qualitative breathalyser – detecting a MAYBE or NO for recent use. The goal is not determining drug impairment, as there are no established impairment limits for drugs as there is for alcohol (.08BAC), but to determine if the worker has recently used, or the presence of drugs. This is

the safety aspect that aligns oral fluid testing with an employer’s occupational, health & safety legislated responsibilities.

Oral Fluid Testing	Urine Testing
There are no known adulterates for oral fluid. Additionally, collection of the oral fluid samples witnessed by the test administrator, which in eliminates any possibility of sample substitution.	Adulteration & substitution are significant problems with current urine testing. In addition to not being a witnessed collection, there are many adulterates that mask drugs in urine. Laboratories actually test for the known adulterates but generally lag behind available adulterates or masking agents.

Oral fluid is replenished every 3-5 minutes in the oral cavity. Scientific studies have demonstrated a high correlation between results obtained in oral fluid vs. blood, and is believed that drugs pass from blood to oral fluid via a process called passive diffusion. If a donor is somehow able to alter oral fluid in their mouth before a test undetected (by rinsing their mouth out with a bleach or solvent for a prolonged period of time), oral fluid will reappear after time and testing will still detect the presence of drugs - as if the drug is present in their blood stream. Drinking a glass of water and waiting 5 minutes should overcome any adulteration attempt.

Cost Benefits

There is a substantial cost benefit to be realized by using oral fluid testing over traditional methods. There is an actual cost associated with drug abuse in the workplace. Federal studies (United States Department of Health and Human Services) show that on average 10% of the entire workforce abuses drugs. These studies looked at all workplace sectors including retail, insurance, government, hospitality, etc as well as traditional industrial sectors. The construction sector was broken out at nearly 24% workplace drug abuse. The US study expanded to include an associated dollar value of roughly \$10,000 per worker per year (see *Table 2*). There was no single line item for the entire cost, but combined was an overall productivity loss. For example, a company of 1000 workers using the conservative estimate of 10% drug abusers would realize a loss of \$1,000,000 annually. By implementing a workplace D&A policy, a reduction of drug abuse through deterrence and testing from 10% to even 5% would mean a savings of \$500,000 annually to the bottom line.

Table 2

No Single P&L Line Item for Workplace Drug Abuse Costs	
On-the-job Accidents	50% +
Absenteeism	40 days vs. 4 days
Employee Turnover	30% + greater
Shrinkage / Employee Theft	36x higher
Workers Compensation	5x more claims
Health Care Benefit Utilization	300-400% More Utilization
Workplace Violence	2/3 arrestees test positive
Company of 1000 workers with 10% using illicit drugs = 1000 x 10% = 100 workers at \$10,000 each annually =	
\$1,000,000 in Loss Productivity	

This is the cost benefit of effective workplace drug testing. However, there are additional cost benefits by using oral fluid testing. First, the administration costs associated with using traditional urine-based drug testing companies (or Third Party Administrators – TPAs) can be eliminated altogether by taking the testing in-house. Designated company representatives in-house can be easily

trained to administer oral fluid POCT devices. TPAs charge anywhere from \$20-\$120+ administration fees to collect a single urine sample.

Furthermore the cost of sending employees, or even applicants to another, off-premise location to provide a urine specimen need to be also calculated. Consider the benefits of avoiding worker downtime for leaving location to be tested and a prolonged hiring process for pre-employment testing. For example, a large construction contractor took all pre-employment testing in-house with oral fluid. They conducted approximately 1000 pre-employment tests per year at a cost of \$100 per test by their TPA (~\$100,000 per year). Conducting in-house pre-employment testing will now cost them roughly \$25,000 (1000 x \$25 per test). They also saved \$120,000+ or 4000+ man-hours that were required employees to go to the TPA and be tested (1000+ tests ~4 hrs each).

Integral Laboratory Confirmation Process

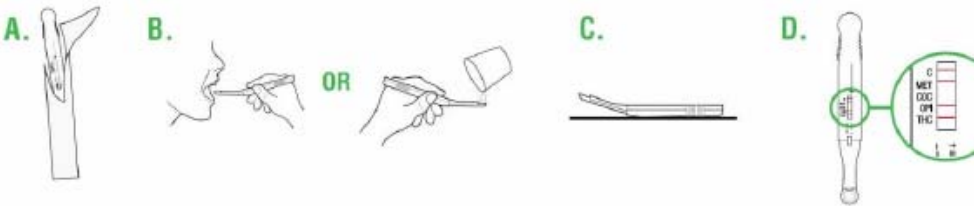
Both oral fluid and urine testing have the same integral laboratory confirmation process. When a POCT device (either oral fluid or urine) is “non-negative”, it is sent to a certified laboratory for confirmatory testing. This process uses a 5-part *Chain of Custody* for properly managing and controlling the sample being sent to and confirmed at the laboratory. The laboratory uses calibrated GC/MS or LC/MS/MS processes to analyze the samples. Quantitative results at or above pre-established levels are sent from the laboratory to an independent MRO (medical review officer) who verifies the information, contacts the specimen donor, and determines the final “positive” or “negative” result.

The OraPoint™

The OraPoint™ has all the benefits of oral fluid technologies outlined above. In addition, there are a few very important qualities that distinguish the OraPoint™ as the premium product on the market – both for performance and quality.

<p>Superior THC / Marijuana Detection</p>	<p>Detection of THC has been the Achilles heel for oral fluid POCT devices. Most oral fluid POCT devices on the market today do not detect THC consistently, or at low concentrations if at all. This is primarily due to the fact that they implement “urine” testing technologies into test devices that use saliva as the specimen type. Most of these manufactures are urine technology manufactures and have simply attempted to use the same technology in an oral fluid test.</p> <p>The developers of the OraPoint™ are a joint-venture of the two original manufactures that figured out how to properly use saliva as the medium to detect THC. Both manufactures specialize and only work with oral fluid. This process has taken a decade to develop and has resulted in the most accurate oral fluid POCT device for THC on the market today.</p> <p>Currently, the OraPoint™ detects THC at concentrations of 4ng/ml or higher (nanograms/millilitre). This concentration level is by far superior to other oral fluid POCT devices on the market.</p>
<p>Detection of “Popular” Drug Classes - Most Likely to be Found in Today’s Workplace Environment</p>	<p>Traditional urine testing is based on the SAMHSA (Substance Abuse Mental Health Services Administration) Panel-5 drug testing standard. Most oral fluid POCT devices have taken the same lead and detect the same drug classes. There are a number of problems with this standard however. First and foremost, it was developed over 20 years ago and does not reflect today’s drugs-of-abuse. The developers of the OraPoint™ designed the device to detect the drugs-of-abuse found in today’s workplace. Abuse of prescription painkillers is significantly on the rise. The OraPoint™ detects these expanded opiates which traditional tests do not. In addition, the OraPoint™ detects Ecstasy, which is also on the rise in both countries among younger age groups.</p>

Drug / Drug Class	The OraPoint™	Urine Testing & Most Oral Fluid POCT Devices
Amphetamines / Methamphetamines	Detects amphetamines at a higher concentration level to avoid false-positives for regular stimulants (cold medicines); detects additional meth-amphetamines including Ecstasy.	Detects amphetamines at lower concentrations which causes higher false-positives for regular stimulants (cold medicine); and does not detect Ecstasy.
Cocaine	Same	Same
Marijuana	Same	Same
Opiates	Detects morphine and codeine, but also detects oxycodone (Oxycontin®, Percoset®), oxymorphone, and hydromorphone (Vicodin®).	Only detects morphine and codeine at a concentration level to high to detect most morphine and codeine abuse (2000 ng/ml).
PCP (Phencyclidine)	Does not detect PCP as “Angle Dust” is no longer a drug of choice.	Detects PCP.

<p>Ease of Use</p>	<p>Even though all oral fluid POCT devices are relatively easy-to-use, the OraPoint™ is by far the easiest to administer. Most oral fluid POCT devices require the administrator to “rub” the test around the oral cavity, handle the sample, or use a collection sponge or swab. This generally takes a number of minutes and can be uncomfortable or awkward for the donor. The OraPoint™, as illustrated below, takes seconds to administer.</p> <p>Accurate Results. Right Now. Open. Collect. Wait and Read.</p>  <p>A. Remove test from sealed pouch just prior to use. B. Collect saliva sample (directly from mouth or via sample cup). C. Place test device on flat surface. D. Read results in 10 to 12 minutes.</p>
<p>Training</p>	<p>Training for the OraPoint™ is simple and fast. Training is available online and requires administrators to go through a 20 minute tutorial and online quiz. Successful administrators are then sent a certificate of competency. Supplemental training at the request of the customer is provided by Integrated OH&S. This can be in the form of additional documentation, webinars or in person training. All OraPoint™ tests sent out to customers also include complete <i>Directions of Use</i>. This training process is the most comprehensive of all available oral fluid POCT devices on the market.</p>
<p>Technical Support</p>	<p>Integrated OH&S has ready access to PHD chemists that specialize in oral fluid testing technologies. It was a critical aspect that we aligned with a manufacture that could provide the technical support for not only the product itself, but for the technology beyond our expertise.</p>

On-site Oral Fluid Alcohol Tests

Oral fluid on-site alcohol screening is to the OraPoint™ device. Qualitative instant alcohol screen are also extremely easy to administer.

Notes

1. Actual detection periods fluctuate with each individual donor. Detection periods are a function of multiple factors, including but not limited to; gender, weight, etc., and the type, purity, quantity, and ingestion method of drug(s) consumed.
2. Federal and Corporate Study Data included, but is not limited to United States Department of Health and Human Service - National Institute on Drug Abuse (NIDA) & Substance Abuse and Health Services Administration (SAMHSA) ; Quest Diagnostics Annual Drug Index Survey; and the National Institute of Health (NIH).
3. POCT devices are generally considered to be *screens*. Screen results are either “negative” or “non-negative”. Only laboratory confirmatory test results, as verified by a MRO (medical review officer), can be determined as “positive”.4.
4. GC/MS refers to Gas Chromatography / Mass Spectrometry). LC/MS/MS refers to Liquid Chromatography / Mass Spectrometry.