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OCCUPATIONAL TESTING SERVICES

Instant Oral Fluid Testing

For workplace testing programs in Canada, instant oral fluid testing raises major concerns. We understand choosing a method for workplace testing can be overwhelming. We recommend asking a few questions, evaluating the options, and setting a standard high enough for it to be trusted now and in the future.

IDEA IN BRIEF

The purpose of this document is to clearly present the basic requirements of forensic drug testing and to provide clear and reliable information on the current status and limitations of instant oral fluid testing in meeting the accepted performance standards of workplace drug testing in Canada. With this information you will have an understanding of the basic characteristics of a trustworthy drug testing method, and will be able to navigate your available options with confidence.

The most important goal of workplace drug testing in Canada is to manage risk and improve safety, and achieving this requires testing technology that verifiably produces fair and reliable results for actionable and accurate risk identification.

What makes a testing application trustworthy?

- Produces fair and reliable results that can be acted upon with confidence;
- Tests to a defensible standard as outlined by the Department of Health and Human Services (DHHS);
    - This standard has been adopted by the Construction Owners Association of Alberta (COAA), and is recognized as the only acceptable standard in regulated North American workplace drug testing programs. Available instant oral fluid testing devices are not able to detect all the positive results that would be identified in a laboratory-based test using the standards set by the DHHS.

    Choosing an instant oral fluid testing device could potentially have a negative impact on workplace safety, and could result in non-compliance with the testing standards set in contractual obligations.

Important technical questions remain unanswered about instant oral fluid devices:

- How long does it take to desorb the drugs for testing from the test pad?
- How sensitive is the current technology?
- What sort of visual recognition is there of the result given?
- How low are detection cut-off limits?
- Are there possible effects of the device on the integrity of the sample?

These questions can be explored once a device is available which matches the industry standards and does not compromise safety for convenience.

Recommendations:

Drug testing is like any other safety tool. Looking for conformance with an established standard is as important when choosing testing options as it is when choosing personal protective equipment. Just as the Canadian Standards Association's green triangle on the steel-toe boots of your workforce confirms a class one toe cap and puncture-resistant sole, the DHHS is the proven standard in testing methods. Laboratory-based urine testing and laboratory-based oral fluid testing are the only test methods recognized under the current standards.

FUNDAMENTAL REQUIREMENTS OF WORKPLACE TESTING

As an employer, you must establish a bona fide occupational reason to conduct testing[6]. In most cases, testing programs must be limited to personnel working in safety-sensitive positions.

The aim of drug testing is not to determine impairment at the time of the test, as no existing testing technology can do so[2]. The aim is to determine whether there was drug use before the test, as an indicator of an immediate and ongoing risk.

It is difficult to demonstrate that substance use causes work-related injuries[2]. It is easy, however, to demonstrate that an individual with a positive test who works in a safety-sensitive position is too great a risk to personal and public safety to be left unmanaged. This conclusion is reasonably accepted and well supported in the findings of related case law, where it forms the premise of the arguments[4][5][31][25], correlation studies[14][20][22], Canadian Labour Code[17], and criminal implications of failing to address a known hazard[19].

The Fundamental Requirements of a Workplace Testing Program[2]:

- Establishing an occupation to be safety-sensitive, thereby legitimizing testing as a bona fide occupational requirement.
- Ensuring the written policy that guides all testing applications does not discriminate, as per Canadian human rights legislation.
- Providing professional training to supervisory staff responsible for the policy application.
- Ensuring that all testing produces fair and reliable results[18].

The Fundamental Measures of Workplace Testing Methods:

- Actionable and accurate risk identification.
- Speed of obtaining a result.
- Availability in remote operating locations.
- Ability to satisfy contractual obligations.

THE ONLY TRUSTED STANDARD IN WORKPLACE TESTING APPLICATIONS

For an employer to take action on a test result, the result needs to be reliable. For workplace testing, this means the result must be forensic, or legally defensible. Establishing legal defensibility is no small task:

In the United States (where drug testing is federally regulated), there are over 140 pages of procedure to ensure that a result is defensible. These procedures are issued: under the authority of the U.S. Department of Transportation in the Code of Federal Regulations 49 C.F.R. Part.40[32], and under the guidance of the DHHS, as a consequence of the North American Free Trade Agreenment in 1994.

- Following this standard ensures accurate, fair and legallay defensible testing which is able to properly identify risk.
- If the standard is not followed, a test result could be disputed in court, lead to other legal reprecussions, or worse, a serious incident could occur at the workplace[19].

Cut-Off Standards

All regulated laboratory-based testing applications must perform within legally defensible standards of sensitivity, specificity, and accuracy in drug metabolite detection at various concentrations in accordance with the acceptable cut-off levels: the exact concentration of a drug metabolite which separates the negative from positive results. The purpose of cut-off levels is to ensure passive exposure does not produce a positive laboratory result. This is critical in maintaining the integrity of the final result.

The cut-off levels mandated by the DHHS[32] for laboratory-based urine testing and the proposed cut-off levels for laboratory oral fluid testing[26] are the most current North American standards; the inability of instant oral fluid devices to meet these is the greatest limitation of instant oral fluid testing technology.

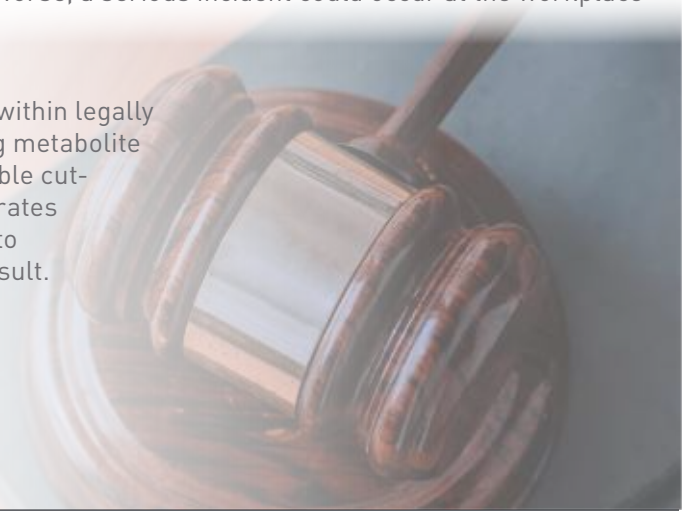

Table 1.1:
DHHS-Recommended/COAA-Adopted[10][26] Laboratory-Based Oral Fluid Cut-Off Levels

Drugs or Classes of Drugs	Screening Concentration Equal to or in Excess of ng/mL	Confirmation Concentration Equal to or in Excess of ng/mL
Marijuana metabolites (THC)	4	2
Cocaine metabolites	20	—
Cocaine or benzoylecgonine	—	8
Opiates	40	—
Codeine	—	40
Morphine	—	40
Hydrocodone	—	40
Hydromorphone	—	40
Oxycodone	—	40
Oxymorphone	—	40
6-acetylmorphine	4	4
Phencyclidine	10	10
Amphetamines/Methamphetamines	50	—
Amphetamine	—	50
Methamphetamines	—	50
MDMA	50	—
MDMA	—	50
MDA	—	50
MDEA	—	50

Instant oral fluid devices must contain a package insert outlining their performance characteristics, so you will want to make a few considerations upon reading this:

Does it match the DHHS-recommended cut-off levels[26]? If the device does not test at the recommended cut-off levels (See Table 1), then the test device will produce results not up to standard, and should immediately be ruled out as a trustworthy test option.

How accurate is the device in producing results which correspond with the package insert cut-off levels? Accuracy is defined as the likelihood of identifying a true negative or true non-negative[3] test result. A true negative test result is produced when the concentration is below the cut-off level, and a true non-negative result is produced when the concentration is above the cut-off level.

How sensitive is the device? This refers to the degree to which testing is accurate as the drug metabolite concentration approaches or moves away from the cut-off level.

How specific is the device? This relates to overall accuracy and sensitivity performance levels, and takes into account all the metabolic by-products of a drug that the device is designed to detect.

ERROR BY DESIGN: INSTANT DEVICES ARE NOT DESIGNED TO MATCH THE STANDARDS

The major concern with commercially available instant oral fluid devices is they are designed to test for much higher concentrations of certain drugs; as a result, they fail to identify some risks. None of the instant oral fluid devices reviewed to date test at the industry standard cut-off levels for all of the drugs (Table 1.2; Table 1.3).

In addition to not testing to the recommended cut-off levels, instant oral fluid technology has not been able to test with 100% accuracy at concentrations 25% below or above the cut-off levels. In contrast, the above standards (Table 1.1) are the very minimum requirement of DHHS compliance in laboratory urine testing[32].

Device package inserts show precision by indicating how many negative and non-negative results show up for each substance at various concentrations. Typically, precision is shown for the following levels: complete absence of the drug, 50% below the cut-off, 25% below the cut-off, exactly at the cut-off, 25% above the cut-off, and 50% above the cut-off. These results are only meaningful if the cut-offs for the devices match those outlined in Table 1.1.

To remain objective and to ensure the information contained in the inserts is not misrepresented, we recommend that before using a device, you obtain documentation from your third party administrator, showing the device has been FDA confirmed[28], the cut-off levels match the standards in Table 1.1, and the performance indicated on the inserts meets or exceeds the acceptable parameters required at a DHHS laboratory[7][13][29][30][29].

Table 1.2:

Recommended[9][26] Lab-Based Oral Fluid Cut-off Levels vs. Device Cut-off Levels

Drugs/Classes	Reccommended by COAA/DHHS (ng/mL)[10][26]	iScreen OFD® Oral Fluid Test Kit (ng/mL)[29]	Oralert (ng/mL) [30]	Clonal Technologies (ng/mL)[7]	DrugCheck® SalivaScan (ng/mL)[13]	Dräger DrugTest® System[30]	Abbot SoToxa™[1]
Marijuana metabolites (THC)	4	12	100*	25	50	5	25
Cocaine metabolites *Cocaine or benzoylecgonine*	20	20	20	50**	20	20	30
Opiates *Codeine* *Morphine*	40	40	40	50	40	20	40
6-acetylmorphine	4	40	25	400***	Not Included	Not Included	Not Included
Phencyclidine	10	10	10	10	10	Not Included	Not Included
Amphetamines/ Methamphetamines *Amphetamine* *Methamphetamines*	50	50	50	50	50	50 35	50
MDMA	50	Not Included	50	50	50	35	Not Included
FDA-Approved[14]	N/A	No	No	No	No	No	No

*Requires 25 times more of the drug than is recommended by DHHS/COAA[10][26] in order to be detected.

**Requires 2.5 times more of the drug than is recommended by DHHS/COAA[10][26] in order to be detected.

***Requires 100 times more of the drug than is recommended by DHHS/COAA[10][26] in order to be detected.

Table 1.3:
DHHS-Recommended[10][26] Cannabis Cut-off Levels vs. Device Cut-off Levels

Device	THC	Concerns
DHHS-Recommended (ng/mL)[10]	4	N/A
iScreen OFD® Oral Fluid Test Kit (ng/mL)[29]	12	Requires 3 times of of the drug to detect it.
Oralert (ng/mL) [30]	100	Requires 25 times more of the drug to detect it.
Clonal Technologies (ng/mL)[7]	20	Requires 5 times more of the drug to detect it.
DrugCheck® SalivaScan (ng/mL)[13]	50	Requires 12.5 times more of the drug to detect it.
Dräger DrugTest® System[30]	5	25% higher than DHHS-Recommended levels.

Approved Equipment

The devices listed that are currently accepted for Canadian Law Enforcement as roadside screening devices are limited to screening for the presence of a drug in a person's body, and the abovementioned issues remain unsatisfactory met for applications in a workplace safety program. There are, and will continue to be, vast differences between the thresholds of criminal culpability and the thresholds for a workplace safety violation.

For the purpose of the definition of *approved drug screening equipment* in section 320. 11 of the *Criminal Code,* the following equipment that is designed to ascertain the presence of a drug in a person's body are approved[19]:

Dräger DrugTest® 5000 and a Dräger DrugTest® 5000 STK-CA, when used together[15].

SoToxa™, an Abbot SoToxa™ Test Cartridge and an Abbott SoToxa™ Oral Fluid Collection Device, when used together[16].

REMAINING QUESTIONS REGARDING INSTANT ORAL FLUID TECHNOLOGY

Once an instant oral fluid device becomes available and is designed to test at the current standard, a number of questions will remain unanswered:

- It can take a number of hours for the drugs absorbed in the oral fluid collection device to be extracted by the buffer for laboratory testing[11]. How will this delay be overcome in an instant device to ensure the complete sample is tested in the minutes following the collection?
- Will instant testing be sensitive enough to accurately test at the recommended cut-off level?
- If the testing is sensitive enough, is the binding technology (colloidal gold enzyme) responsive enough at the required low concentrations to produce a visual result indicator that is clear enough to be accurately interpreted?[23]
- Does the wicking of the oral fluid up the test strip change the concentration of the sample when it reaches the enzyme binding sites?
- When a sample requires confirmatory testing, what can be done to demonstrate that the sample being sent has not been affected by the instant testing process (diluted, concentrated, contaminated, etc.)?

These are the types of question a lawyer or scientist would demand answers to in a legal grievance or arbitration setting—so they should be answered before using an instant testing device.

CONCLUSION AND RECOMMENDATIONS

For Canadian workplace testing programs, instant oral fluid testing raises two major concerns:

- Many employers are unaware that the cut-off levels of instant test devices are far from recommended levels.
- The need for further investigation into outstanding questions about the technology.

However, the technology has a few benefits when it is laboratory-based rather than instant:

- Easier to administer as a shorter detection window[9][19][21]
- Is anecdotally more widely accepted by employees/unions as a preferred testing option (opposed to urine-to-lab). Collections are performed under direct observation.

The **type of sample collected**, urine or oral fluid, should not be confused with the **testing application**, laboratory-based versus instant technologies.

Questions to ask yourself as an employer:

- Why does your drug and alcohol testing program exist?
- What are your current standards for workplace safety?
- What are your standards for production quality?
- What are your standards for public safety?

We recommend setting a standard high enough that it can be trusted now and in the future. We understand that this can sometimes be challenging operationally, but using a superior testing option mitigates the safety risk and liability that a false negative result poses on the job. Laboratory-based urine and oral testing at the recommended cut-offs is the most accepted and defensible standard.

Think of your testing application as any other safety tool:

- How do you currently evaluate personal protective equipment?
- What standards do you have for the reliability and quality of fall protection equipment?
- Would you accept equipment or processes that were less safe in the name of getting the job done?
- What lengths do you go to now to prevent a critical incident from occuring?

Laboratory-based urine and oral testing at the recommended cut-off levels is the most accepted and defensible standard.

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