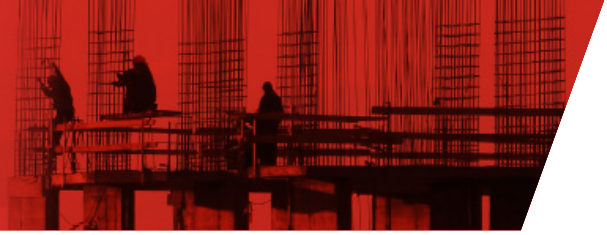

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THE TRUTH ABOUT INSTANT ORAL FLUID TESTING

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

IDEA IN BRIEF

In Canada, workplace drug testing programs are becoming a more common requirement for employers exercising due diligence in safety-sensitive operations. However, little guidance is available to inform employers on the basic characteristics of a trustworthy drug testing method and help them navigate the available choices with confidence. The purpose of this document is to clearly present the basic requirements of forensic drug testing and the current status of instant oral fluid testing.

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

Choosing the right technology requires a basic understanding of what makes a testing application trustworthy. A trustworthy test application produces fair and reliable results that can be acted upon with confidence. It must test to a defensible standard—specifically, that outlined by the Department of Health and Human Services (DHHS). This standard has been adopted by the Construction Owners Association of Alberta (COAA) and recognized as the only acceptable standard in regulated North American workplace drug testing programs.

The most important goal of workplace drug testing in Canada is to manage risk and improve safety.

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

Important technical questions remain unanswered about instant oral fluid devices. These relate to the time it takes to desorb the drugs for testing from the test pad, the sensitivity of the current technology, visual recognition of the result given the low detection cut-off limits and the possible effects of the device on the integrity of the sample. These questions can be explored once a device is available that 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.

The goal of this document is to give Canadian employers clear and reliable information on the current limitations of instant oral fluid testing devices in meeting the accepted performance standards of workplace drug testing in Canada.

FUNDAMENTAL REQUIREMENTS OF WORKPLACE TESTING

The main legal requirement of workplace drug testing in Canada is that the employer must establish a bona fide occupational reason to conduct testing[4]. 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[1]. The aim is to determine whether there was drug use before the test, as an indicator of immediate and ongoing risk.

It is difficult to demonstrate in a scientific experiment that substance use causes work-related injury[2]. It is, however, easy to demonstrate that an individual with a positive test working in a safety-sensitive position is too great a risk to personal and public safety to be left unmanaged. This con-

clusion is reasonably acceptable and well supported in the findings of related case law, where it forms the premise of the arguments[5][6][24][27],correlation studies[17][18][21], Canadian Labour Code[7], and criminal implications of failing to address a known hazard[13].

Employers performing drug testing in Canada need to be aware that there are standard program requirements for doing so successfully[1]:

- 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[8]

The bottom line is always the same: safety. Effective risk management is primarily limited by accurate risk identification. Actionable and accurate risk identification is the primary measure of testing methods. Secondary considerations include the speed of obtaining a result, availability in remote operating locations, and the 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 that the result must be forensic—in other words, legally defensible. Establishing legal defensibility is no small task; in fact, in the United States, where drug testing is federally regulated, there are over 140 pages of procedures to ensure that a result is defensible. These procedures are issued under the authority of the Department of Transportation and guidance of the DHHS and outlined in the Code of Federal Regulations 49 C.F.R. Part.40[25].They have been accepted by Canada and throughout North America as the only North American standard, as a consequence of the conditions set in the North American Free Trade Agreement, January 1, 1994.

The benefit of this standard is that it ensures a fair, accurate, and legally defensible testing program. If the standard is not followed, a test result could be disputed. This is why Canadian employers are strongly encouraged to use testing applications, processes, and specifications that conform with the standard as currently adopted by the COAA and described in the Canadian Model for Providing a Safe Workplace[9].

The impact of an employer acting on a result that is inaccurate, or not maintaining integrity of testing standards and procedures, can be substantial to both the employer and the employee. If an employee is falsely identified as having a positive result, the employer may face legal repercussions and the company's reputation could be damaged. Worse, if an employer chooses a testing application that fails to identify risk, a serious incident could result[13].

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. A cut-off level is the exact concentration of a drug metabolite that produces a negative rather than positive laboratory result. The main purpose of cut-off levels is to ensure that 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[25] for laboratory-based urine testing and the proposed cut-off levels for laboratory oral fluid testing[26] are the most current North American standards available for employment testing. The inability of instant oral fluid test devices to meet these standards is the greatest limitation of instant oral fluid testing technology.

The bottom line is always the same: safety

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

The cut-off level is never set at zero, because passive or unintentional exposure may occur and not pose a risk to safety. This cut-off level is key to maintaining the integrity of the laboratory test results and ensuring that risks are adequately identified. Raising the threshold too high allows risks to go undetected. Placing the threshold too low can jeopardize the integrity of your test results and undermine your entire program.

Instant oral fluid devices must contain a package insert outlining the performance characteristics as they relate to the listed test cut-offs. The first consideration with any instant device is whether or not it is designed to match the DHHS-recommended cut-off levels[26]. If the device is not testing at the recommended cut-off levels (See Fig 1.1 and Fig 1.2), then the test device will produce results that are not up to standard and should immediately be ruled out as a conforming and trustworthy test option.

DHHS-Recommended/COAA-Adopted[9][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
6-acetylmorphine	4	4
Phencyclidine	10	10
Amphetamines/Methamphetamines	50	
• Amphetamine		50
• Methamphetamines		50
MDMA	50	
• MDMA		50
• MDA		50
• MDEA		50

Table 1.1

The second consideration, assuming the first is satisfied, is how accurate the device is at producing results that correspond with the stated 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 the device results indicate a negative. A true non-negative result is produced when the concentration is above the cut-off level and the device results indicate a non-negative test.

The third consideration is the sensitivity of the device, defined as the degree to which testing is accurate as the drug metabolite concentration approaches or moves away from the cut-off level. The fourth consideration, specificity, 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.

The major concern with commercially available instant oral fluid devices is that they are designed to test for much higher concentrations of certain drugs and do not detect concentrations that fall between the industry standards and the device cut-off levels. As a result, they fail to identify some risks. For example, the average cut-off level for marijuana in the devices listed in Table 1.3 is approximately 16 times the recommended cut-off level. None of the instant oral fluid devices reviewed to date test at the industry standard cut-off levels for all of the drugs (see Table 1.2 and Table 1.3).

In addition to not testing to the recommended cut-off levels, instant oral fluid testing technology has not been able to test with 100% accuracy at concentrations 25% below or above the cut-off levels. Therefore, none of the instant oral fluid testing devices reviewed to date are FDA-approved. In contrast, the above standards are the very minimum requirement of DHHS compliance in laboratory urine testing[25].

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 that the information contained in the inserts is not misrepresented, we recommend that before using a device, employers obtain documentation from their third party administrator showing that the device has been FDA confirmed[14], that the cut-off levels match the standards in Table 1.1, and that the performance indicated on the inserts meets or exceeds the minimum acceptable parameters required at a DHHS laboratory[10][16][19][23][29].

FDA Approval Database:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

DHHS-Recommended/COAA-Adopted[9][26] Laboratory-Based Oral Fluid Cut-off Levels vs. Device Cut-off Level

Drug	DHHS-Recommended Cut-Off Level (ng/mL)[9]	iScreen/Oral Device Cut-Off Level (ng/mL)[29]	VeroFit Cut-Off Level (ng/mL)[29]	Oralert Cut-Off Level (ng/mL)[10]	Clonal Technologies Cut-Off Level (ng/mL)[10]	DrugCheck SalivaScan Cut-Off Level (ng/mL)[16]
Marijuana metabolites (THC)	4	100* *Requires 25 times more of the drug to be detected	50	100*	25	50
Cocaine metabolites • Cocaine or benzoylecgonine	20	20	25	20	50* * Requires 2.5 times more of the drug to be detected	20
Opiates	40	40		40	50	40
• Codeine			10			
• Morphine			4			
6-acetylmorphine	4	25	4	25	400** **Requires 100 times more of the drug to be detected	25
Phencyclidine	10	10	Not included	10	10	10
Amphetamines/methamphetamines	50					
• Amphetamine		50	25	50	50	50
• Methamphetamines		50	25	50	50	50
MDMA	50	50	50	50	50	75
FDA-confirmed device performance	N/A	No	No	No	No	No

Table 1.2

Marijuana DHHS-Recommended Cut-off Levels[9][26] vs. Device Cut-off Levels

Drug	Marijuana Metabolites (THC)	Concerns
DHHS-recommended cut-off level (ng/mL)[9]	4	N/A
iScreen/oral device cut-off level (ng/mL)[18]	100	Requires 25 times more of the drug to detect
VeroFit cut-off level (ng/mL)[28]	50	Requires 12.5 times more of the drug to detect
Oralert cut-off level (ng/mL)[22]	100	Requires 25 times more of the drug to detect
Clonal Technologies cut-off level (ng/mL)[10]	25	Requires 6.25 times more of the drug to detect
DrugCheck SalivaScan cut-off level (ng/mL)[10]	50	Requires 12.5 times more of the drug to detect

Table 1.3

REMAINING QUESTIONS REGARDING INSTANT ORAL FLUID TECHNOLOGY

Once an oral fluid device becomes available that is designed to test at the current standard, a number of questions will remain to be answered.

- It can take a number of hours for the drugs absorbed in the oral fluid collection device to be extracted by the buffer so they are available for laboratory testing[15]. 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? According to a recent study, "Somewhat disturbingly, none of the devices in the study performed at above 80% for sensitivity, specificity and accuracy for all of the separate tests that they comprised."[3]
- 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?[22]
- 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 workplace testing programs in Canada, instant oral fluid testing raises two major concerns. The first is that many employers are unaware that the cut-off levels of instant test devices are currently far from recommended levels. The second is the need for further investigation into outstanding questions about the technology.

Laboratory-based oral fluid testing is easier to administer, has a shorter detection window[12][13][20] and is anecdotally more widely accepted by employees/unions as a preferred testing option over urine laboratory-based testing. Another benefit of the laboratory-based oral fluid testing is that 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.

We understand that choosing a method for workplace testing can be overwhelming. We recommend asking a few questions and to evaluate the options.

First, why does your drug and alcohol testing program exist? Evaluating your choices based on your objectives can provide all the direction you need. What are your current standards for workplace safety? What are your standards for production quality? What are your standards for safety of the public?

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 occurring?

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

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Mr. Demers has a strong academic background graduating with an Honours BSC and a minor in Biology at the University of Waterloo; performing with a dean's list average. Mr. Demers' academia has contributed to a detailed understanding of the laboratory processes, current technologies, and considerations in workplace testing and monitoring programs. With a special interest in statistics and critical thinking, Mr. Demers has consolidated and translated research findings into actionable information employers can not only understand but use. While Mr. Demers is managing the operations in the Occupational Health Department of CannAmm OTS, he is continuing to pursue new ways to educate industries on the best practices and criteria by which to assess information and options relating to their safety goals. Although Mr. Demers' background is science, his passion lies in providing actionable information that can form the foundation of attaining results in real world business operations.

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ABOUT CANNAMM

CannAmm Occupational Testing Services (CannAmm) helps our clients to develop safer work environments. We work closely with organizations to develop Drug-Free Workplace and Occupational Health programs that can be trusted to be both effective and legally defensible. Our extensive network of collectors ensures that we can provide timely service anywhere in Canada and the USA, and our IT systems enable 24/7 online results reporting and booking requests.