Canadian Society of Forensic Science
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Report on Drug Screening Equipment – Oral Fluid

Canadian Society of Forensic Sciences
Drugs and Driving Committee

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Introduction

This document provides general information about oral fluid drug screening. This discussion is specific to three target compounds: tetrahydrocannabinol (THC), cocaine and methamphetamine and to the Drugs and Driving Committee's (DDC) standards and evaluation procedures for drug-screening equipment – oral fluid[1] [drug screening equipment] which are formulated for the purposes of investigations under the Criminal Code of Canada. This document discusses drug screening equipment in general, without reference to any specific product or manufacturer. The information in this document is based upon a review of the relevant scientific literature.[2]

The technological basis for drug screening equipment – oral fluid

Currently, drug screening equipment employs immunoassay-based technology to identify target compounds in oral fluid. Immunoassay-based analyses are commonly used both in clinical and forensic settings as they are rapid, robust, amenable to use in portable/roadside/single use technologies, and commonly use a small sample volume. The general population may be familiar with the use of immunoassay technology in home pregnancy tests.

Immunoassay involves the ability of a specific antibody to bind to a target compound of interest, resulting in a measurable effect (e.g., colour change). The utility of a particular immunoassay is dependent upon the ability of that antibody both to bind the target compound of interest and to not bind other compounds.

Immunoassay-based analyses are commonly used as preliminary analyses, providing presumptive results. To confirm the presumptive results, more specific methods of analysis are performed. Whereas immunoassays are reliant upon a single marker for identification of a target compound (antibody binding), more specific methods of analysis commonly rely upon multiple means of identification for increased confidence (e.g., mass spectra). For Criminal Code investigations, drug screening equipment is recommended for use as a preliminary means of identification of specific target compounds (THC, cocaine, and/or methamphetamine).

The DDC's standards are designed so as to both maximize the specificity (identification of true negatives[3]) and the sensitivity (identification of true positives[4]) of drug screening equipment. In addition, by:

- setting suitable cut-off concentrations for the target compounds;
- specifying that the target compounds must be the drugs themselves, as opposed to other related compounds or metabolites; and

[1] https://www.csfs.ca/

[2] It should be noted that there are limited studies which examine the use of these drugs in "real life"/recreational situations due to inherent ethical considerations.

[3] True negatives are oral fluid samples for which the target compound is either not present or present below the oral fluid cut-off concentration.

[4] True positives are oral fluid samples for which the target compound is present at or above the oral fluid cut-off concentration.

- examining cross-reactivity results so that the potential for "false positives" caused by related compounds and metabolites is minimized;

the standards are designed to:

- maximize the likelihood at the time that an individual tests positive on drug screening equipment, they have those target compound(s) in their blood at or above any *per se*[5] levels; and
- minimize the likelihood of individuals testing negative on drug screening equipment who have these target compounds present in their blood at or above any *per se* levels.

Oral fluid

Oral fluid is commonly referred to as saliva, but is actually a mixture of saliva and other materials that may be present in the mouth. Advantages of oral fluid as a sample for roadside drug screening include the ease of collection, low health and safety risks, and minimal privacy issues associated with its collection. However, there are challenges that need to be considered and addressed with use of oral fluid as a sample for drug-impaired driving investigations.

Certain drugs, including THC, cocaine and methamphetamine, may decrease saliva production and make it difficult for individuals to provide sufficient oral fluid required for analysis. To address this challenge, manufacturers commonly minimize sample volumes required. DDC standards require drug screening equipment collect sufficient oral fluid for analysis within 4 minutes of the start of collection.

Drugs generally become detectable in oral fluid shortly after administration. They can be present as a result of drug excretion and partitioning into the oral fluid from the body as well as from residual drug deposits in the oral cavity. For example, following injection there may be a lag period of minutes between administration and detection in oral fluid due to the time needed for drug distribution throughout the body and excretion into oral fluid. In contrast, oral fluid may be positive immediately following smoking due to residual drug deposits.

Due to their specific chemical and pharmacokinetic properties, cocaine and methamphetamine are relatively well-excreted into oral fluid from the body in contrast to THC, which is weakly distributed into the oral fluid.

There is a risk that oral fluid may be contaminated by a drug as a result of passive exposure. However, the oral fluid cut-off for THC in the DDC's standards is higher than those concentrations reported from scientific studies of passive exposure, virtually negating the possibility of individuals testing positive on drug screening equipment by this means. While there is a paucity of research on passive exposure to cocaine and methamphetamine, given the typical means of consumption, patterns of use, and basic

[5] http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors148-eng.html

scientific principles, the potential for passive exposure and resultant contamination of oral fluid is unlikely.

As positive drug screening results generally occur as a result of consumption[6] (whether from excretion and/or residual drug deposits), and with cut-off concentrations selected so as to virtually negate the possibility of passive drug exposure, positive oral fluid results on drug screening equipment can be considered as a preliminary indication of the presence of that drug in the body.

Relationship between drugs in oral fluid and in blood

There is not a direct correlation between drug concentrations in oral fluid and in blood. The oral fluid:blood ratio for a particular drug can vary both between individuals, and over time for a given individual following drug administration. There are numerous factors which affect both drug excretion into the oral fluid and overall oral fluid concentrations. There are also numerous factors that affect drug concentrations in the blood. These factors are separate from each other. For example, decreasing the acidity (increasing the pH) of the oral fluid will decrease the concentration of methamphetamine in the oral fluid, but will not affect its concentration in the blood. In addition, the presence and magnitude of residual methamphetamine deposits in the oral cavity can further complicate any attempt to correlate oral fluid and blood concentrations.

Cocaine and methamphetamine distribute well into both blood and oral fluid. While oral fluid concentrations of these drugs do not correlate directly with blood concentrations, in general the presence of cocaine and methamphetamine in the oral fluid indicates their presence in blood.

THC does not distribute well into either blood or oral fluid, and concentrations in both of these fluids can vary greatly dependent upon dose, route of administration and patterns of use. In general the presence of THC in the oral fluid indicates its presence in blood. It is more difficult to make this association for individuals immediately following oral THC consumption, prior to significant absorption into the body. The time frame for detection of THC in oral fluid varies, but may be much shorter than in blood. This is particularly applicable to frequent high-dose THC smokers who may have positive blood concentrations for several days since last use.

How long after drug use will an individual test positive on drug screening equipment?[7]

The time period for which an individual will test positive on drug screening equipment is dependent upon a number of factors: the drug in question, the time since last drug use, the drug dose and route of administration, the cut-off concentration of drug screening equipment, and the drug consumption history of the individual.

[6] Consumption includes all possible routes of drug administration, including oral ingestion, smoking, and intravenous use.

[7] Based on relevant scientific literature and the cut-offs required by the DDC standards for drug screening equipment.

The oral fluid cut-off concentration for cocaine required by the DDC's standards is 50 ng/mL. Cocaine is well excreted into oral fluid. Nevertheless, after cocaine use some individuals may not have oral fluid concentrations exceeding the cut-off; this is most likely after single low dose oral ingestion which is not a common route of administration for recreational cocaine use. While the time period for which individuals may test positive with the above-noted cut-off will vary, recreational users[8] would generally test negative on drug screening equipment within 4 to 6 hours after last use. Frequent high-dose cocaine users would be expected to test positive on drug screening equipment for the longest period of time, which could be a day since last use.

The oral fluid cut-off concentration for methamphetamine required by the DDC's standards is 50 ng/mL. Methamphetamine is well excreted into oral fluid. Nevertheless, after methamphetamine use some individuals may not have oral fluid concentrations exceeding the cut-off; this is most likely after single low dose oral ingestion. However, individuals in this population who do test positive, could do so for up to 4 to 6 hours since last use. While the time period for which individuals may test positive with the above-noted cut-off will vary, recreational users would generally test negative on drug screening equipment within 24 to 48 hours after last use. Frequent high-dose methamphetamine users would generally test positive on drug screening equipment for the longest period of time after last use, which could be 3 to 4 days.

The oral fluid cut-off concentration for THC required by the DDC's standards is 25 ng/mL. THC does not excrete well into oral fluid. However, as THC is commonly consumed via smoking or oral ingestion of edibles, individuals may have oral fluid concentrations exceeding the cut-off for short periods of time due to residual deposits in the oral cavity. In contrast, oral ingestion of THC-containing capsules would be less likely to result in residual deposits and oral fluid concentrations that exceed the cut-off. THC smokers (ranging from occasional smokers to frequent high-dose smokers) would generally test negative within 4 hours after smoking. Similarly, the available literature indicates that oral THC users would also generally test negative on drug screening equipment within 4 hours after ingestion. Thus, positive results on approved drug screening equipment can indicate recent THC use.

The relationship between a positive result on drug screening equipment and impairment[9]

Drug screening equipment does not measure drug impairment. Impairment is dependent upon the drug used, the dose, time since last use, route of administration, and is subject to inter-individual variability, among other factors. Nevertheless, depending on the drug involved, and the specifics of its use, a temporal association between a positive drug screening equipment result and impairment can be made.

Impairment from cocaine use is most pronounced within the first 1 to 2 hours following a single dose. Frequent high-dose cocaine use[10] prolongs the impairment and produces a subsequent crash phase[11],

[8] Individuals who occasionally use drugs primarily for the euphoric/high effects.
[9] Based on relevant scientific literature and the cut-offs required by the DDC standards for drug screening equipment.
[10] Includes "binge" use and common patterns of crack cocaine use
[11] A dysphoric phase commonly characterized by agitation, irritability, anxiety, depression, craving, and paranoia.

during which impairment is also present. Recreational cocaine users would generally test negative on drug screening equipment within 4 to 6 hours after last use; impairment would be expected to extend beyond this period. Thus, a temporal association between a positive drug screening equipment result for cocaine and impairment may be made for this population. Frequent high-dose cocaine users could test positive on drug screening equipment for a day since last use; impairment from this pattern of use would be expected to extend beyond this period. Thus, a temporal association between a positive drug screening equipment result for cocaine and impairment may be made for this population.

Methamphetamine has wide variations in the patterns of use, and resultant variability in its detection time periods in oral fluid. It has been suggested that low dose methamphetamine may improve performance; however, the dose and pattern of use are not typical of recreational methamphetamine use, and do not apply to drug abuse situations. Individuals who test positive on drug screening equipment following a single low dose oral ingestion could do so for up to 4 to 6 hours. As such, it is difficult to associate a positive result for methamphetamine on drug screening equipment with impairment for this population.

Impairment following recreational methamphetamine use extends beyond the initial euphoria or "high". With increased dose and frequency of use, a user becomes more likely to experience a subsequent "crash" phase, during which impairment persists. Recreational methamphetamine users would generally test negative on drug screening equipment within 24 to 48 hours after last use, while frequent high-dose methamphetamine users would generally test negative within 3 to 4 days. Despite an extended impairment period for these populations, individuals may test positive for methamphetamine on drug screening equipment beyond the time period for which impairment would be expected. Thus, it is difficult to make a temporal association between a positive drug screening equipment result for methamphetamine and impairment.

One of the strongest factors that correlates with THC impairment is the time since last use. Occasional THC smoking causes impairment which begins almost immediately and generally resolves within 4 to 6 hours following last use. THC enters the body more slowly following oral consumption, delaying the onset of action and extending the impairment period. In addition to acute impairment, frequent high-dose THC users may experience extended periods of performance deficits.

Individuals who test positive on drug screening equipment following THC use could do so for up to 4 hours. In general, a temporal association can be made between a positive drug screening equipment result for THC and impairment. It is more difficult to make this association for individuals who test positive on drug screening equipment immediately following oral THC consumption.

Potential for "false positive" results on drug screening equipment

Theoretically, false positive results are possible in any single analysis. Specific to drug screening equipment, false positive results fall into two general categories, but do not necessarily represent an instrument error or malfunction:

1. A positive result when that drug is either present below the cut-off concentration, or not present, in the oral fluid of the individual.
2. A positive result that is not confirmed in a subsequent blood sample (blood result is either negative or below *per se* levels).

While there is the theoretical possibility of the first category inherent in immunoassay-based technology, the specific DDC standards and evaluation procedures minimize the potential for this situation in drug screening equipment.

The second category could occur in a variety of theoretical and/or potential situations:

- Drug contamination of oral fluid or oral fluid collection systems in the absence of drug consumption. As previously noted, oral fluid cut-offs for THC in the DDC's standards are higher than those concentrations reported from scientific studies of passive exposure, virtually negating the possibility of individuals testing positive on drug screening equipment by this means. The potential for this situation is also minimized by sample collection procedures that avoid the risk of environmental contamination.

- Drug presence in oral fluid beyond the period for which it is present in the blood of that individual. The specific drug cut-off concentrations required by DDC standards minimize the potential for this situation to occur.

- Decreasing blood concentrations in the body during the period between oral fluid testing and blood collection from the individual. The likelihood of this situation increases with increasing delay between oral fluid testing and blood collection, for drugs which are rapidly eliminated or removed from blood, and for drugs which were present in blood at concentrations at or near their analytical limits of detection at the time of oral fluid testing. THC and cocaine are particularly susceptible to this situation.

- Drug degradation or loss from the blood sample between the time of collection and the time of analysis. Cocaine is particularly susceptible to this situation. The potential for this is minimized by reducing the delay between collection and analysis and by use of standard forensic laboratory practices.

- Oral cavity contamination following recent THC ingestion. Blood concentrations could be either negative or below *per se* levels due to the delay in THC absorption into the blood following oral ingestion, and typically low blood concentrations which result from oral consumption.

Potential for "false negative" results on drug screening equipment

Theoretically, false negative results are possible in any single analysis. Specific to drug screening equipment, false negative results fall into two general categories, but do not necessarily represent an instrument error or malfunction:

1. A negative result when that drug is present above its cut-off concentration in the oral fluid of the individual.

2. A negative result despite that drug's presence in the individual's blood at or above a *per se* level.

While there is the theoretical possibility of the first category inherent in immunoassay-based technology, the specific DDC standards and evaluation procedures minimize the potential for this situation in drug screening equipment.

The second category is a possibility, dependent upon the drug in question and the specifics of its use. This is reflective of the lack of direct correlation between drug concentrations in oral fluid and blood, as previously outlined.

Conclusions:

Drug screening equipment is a useful addition to the tools available for law enforcement in Criminal Code drug-impaired driving investigations, but should not be expected to address all situations. Confirmatory analyses of positive results are recommended given the nature of immunoassay-based technology. Given the complex and diverse nature of impairing drugs, a single tool cannot be expected to provide all information necessary to an impaired driving investigation. However, it can provide additional relevant information to law enforcement.

Representative peer-reviewed scientific literature

This is a list of representative articles which may be helpful to further educate readers on the topic. It is not an exhaustive list of the scientific literature available on this topic or which was considered by this committee in formulating its opinions.

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