

Development and validation of the Cozart® DDS Oral Fluid Collection Device

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AIMS: Oral fluid testing for drugs of abuse is becoming commonplace in drug rehabilitation clinics, prisons, custody suites and in the workplace. Legislation exists in many countries for roadside testing of oral fluid for drugs of abuse. The main requirements for its implementation are a rapid sample collection time, collection of a known sample volume and recovery of drugs from the collection device. Many of the collectors currently used are based on timed collections (without an indicator) which result in highly variable collection volumes. Avoidance tactics, such as gripping the device between the teeth, also result in little or no oral fluid being collected. The recently developed Cozart® DDS oral fluid collector combines rapid and adequate collection of oral fluid (indicated by the sample presence indicator) with reliable recovery of drugs from the collection media. We report here the evaluation of this device in terms of speed and volume of oral fluid collected, and recovery of drugs.

METHODS: Oral fluid was collected from a number of volunteers, including drug users (n = 134) and drug-free individuals (n = 137), using the Cozart® DDS oral fluid collector. The time taken for collection and the volume of oral fluid collected were recorded. Recovery studies were also undertaken using drug-free oral fluid collected by expectoration and spiked at known concentrations of amphetamine, Δ^9 THC, cocaine, methadone, methamphetamine, morphine and temazepam. The DDS collectors were used to collect 0.35mL aliquots of spiked saliva. Drugs were extracted from the collector using the Cozart® DDS Buffer and drug recovery was determined by enzyme-linked immunosorbent assays.

RESULTS: The Cozart® DDS oral fluid collector is designed so that collection of 0.35mL (± 0.05 mL) of oral fluid would activate the sample presence indicator. The average time for the completion of collection (full colouration of the sample presence indicator) was 34 seconds for drug-free individuals and 44 seconds for drug users, the quickest collection time for both sample populations was 9 seconds and the longest took 104 seconds. No chemical stimulant (to induce salivation) was used to achieve the collection times observed in either the drug-free or the drug-taking sample populations. Studies showed that the recovery for amphetamine, cocaine, opiates and methamphetamine was 100%, Δ^9 THC was 94.5%, temazepam was 92.1% and was 91.1% for methadone.

CONCLUSIONS: The Cozart® DDS oral fluid collector provides a reliable mechanism for the collection of oral fluid at the roadside that achieves the rapid collection times required. The sample presence indicator accurately reflects the volume of sample collected and overcomes the problems associated with both timed collections (without an indicator) and avoidance tactics. Recovery studies show that a significant percentage of the drugs in a sample are eluted from the collector. This demonstrates the suitability of the collector for both on-site and laboratory analysis of oral fluid not only for drugs of abuse but also many other potential applications such as therapeutic drug monitoring, hormone analysis and testing for infectious diseases. Furthermore, the commonly reported problem of dry mouth syndrome, either drug induced or due to anxiety, was not experienced during sample collection even though a number of drug-taking volunteers described the symptoms before beginning the test.

KEYWORDS: *Drugs of abuse, Oral fluid, Roadside testing, Sample volume, Collection time, Drug recovery*

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